平成１９年度　特許庁産業財産権制度問題調査研究報告書

研究で用いる特許権の取扱に関する
調査研究報告書

平成２０年３月

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要　約

１．目的

ライフサイエンス分野においては、発明から事業化まで長い期間と大きな投資を必要とするため、イノベーションにつなげる上で、特許は非常に重要な役割を果たしている。

特に、遺伝子改変マウス等のモデル動物、実験装置・機器、スクリーニング方法等の方法、データベースやソフトウェア等、研究を行うための道具として使用される物又は方法に関する特許である「リサーチツール特許」には、汎用性が高く研究の推進に資するものが多い一方で、代替性が低いものも多い。結果として、リサーチツール特許において、特許による研究の差止めを求めて訴訟に至った事例も生じている。

こうした状況に対して、国内外では近年各種取組が行われてきている。先進国間では、「遺伝子関連発明のライセンス供与に関する OECD ガイドライン」が 2006 年 2 月に OECD（経済協力開発機構）により策定され、また、米国では NIH（米国国立衛生研究所）が、リサーチツールの取得及び普及に関する NIH 研究資金受給者のためのガイドラインを示すとともに、NIH 等が保有する情報を公開するなどの取組を進めている。

さらに、欧州においては、「EC バイオ指令」が 1998 年に策定され、欧州各国においても、研究で用いられる特許権の使用に関する議論がなされている。

一方、我が国においても、総合科学技術会議にて、「大学等における政府資金を原資とする研究開発から生じた知的財産権についての研究ライセンス指針」が 2006 年 5 月に、また 2007 年 3 月に「ライフサイエンス分野におけるリサーチツール特許の使用の円滑化に関する指針」が、特許制度による保護と活用のバランスのとれた特許の使用に係る運用の指針として、それぞれ策定されている。

さらに、2007 年 5 月に策定された「知的財産推進計画 2007」においても、大学等や民間企業の試験・研究で用いられる特許権の特許法上の取扱について、国際的な議論の動向や各国の対応等を踏まえて検討することが求められ

ている。

これら最近の国内外の動向やニーズを鑑み、研究で用いる特許権の取扱に関する検討のための基礎資料に資するため、本調査研究を行った。

２．調査研究の方法

ライフサイエンス分野のリサーチツール特許を中心に、試験･研究の例外、裁定（強制）実施権、発明の特許性、（公的資金を原資とする）知的財産権の保護と特許使用の円滑化（パテントプール等を含む）等について、法令・規則、判例、基準、指針（ガイドライン)・指令、及び、学説・関連議論、及び指針・法令に至った経緯･背景や動向を国際機関、地域、国毎に調査研究を実施した。

調査研究対象の国際機関として（OECD(Organisation for Economic Co-operation and Development；経済協力開発機構)）、地域としてEU(European Union;欧州連合)、国としては、日本、米国、英国、ドイツ、フランス、ベルギー、スイスとした。調査研究は、対象国の大学･関係機関等の研究者等へ委託するとともに、文献調査を行った。更に、これらの調査の結果を機関・地域･国の間での類似･相違点の比較分析、機関・地域･国それぞれの経緯と機関・地域･国間での相関の２視点よりまとめを行った。

３．調査の結果・まとめ

（１）比較分析：機関・地域・国の間での類似・相違点

日本、OECD、米国、EU、英国、ドイツ、フランス、ベルギー、スイスにおいて、ライフサイエンス分野のリサーチツール特許を中心に、特許権者の利益を図りつつ、研究を推進しイノベーションを促進するための調整についてどのような議論がなされているか又はどのような方策が講じられているのかについて明らかにした。

検討を行うにあたり、権利の保護と利用のバランスをとる調整手法として複数のものが抽出され得る。具体的には、法的な調整手法として、（ｉ）試験・研究の例外、(ii) 強制実施、があげられる。その他の調整手法として、

（iii）ガイドライン／ポリシーの策定及び普及、（iv）パテントプールの形成等があげられる。

これらの各手法ごとに検討を行うこととする。

（ｉ）試験・研究の例外

特許権の行使における試験・研究の例外については、これまで多くの研究がなされている。

特許権の効力に一定の制限を課すこととなる試験・研究の例外を検討するにあたり、まずは、世界各国の多くの特許法の共通の枠組みの一つである「知的所有権の貿易関連の側面に関する協定（TRIPS 協定）」の第 30 条が、まずは参照され得る。

第 30 条（与えられる権利の例外）

加盟国は、第三者の正当な権利を考慮し、特許により与えられる排他的権利について限定的な例外を定めることができる。ただし、特許の通常の実施を不当に妨げず、かつ、特許権者の正当な利益を不当に害さないことを条件とする。

上記規定は、世界各国の多くの特許法において定められている試験・研究の例外等を考慮したものである。

日本の特許法では第 69 条第 1 項に「特許権の効力は、試験又は研究のためにする特許発明の実施には、及ばない。」と記載されている。また欧州各国、例えば英国（特許法第 60 条第 5 項(b)）、ドイツ（特許法第 11 条(b)）、フランス（特許法第 613 条 5(b)）、ベルギー（特許法第 28 条(1)(b)）、スイス（2007 年 6 月 22 日に議会に承認された改正特許法第 9 条(1)b）等の特許法においても、試験・研究の例外について規定されている。

しかし試験・研究の例外の規定は、各国で少しずつ異なり、またその適用範囲は明確に限定されているわけではない（明確に限定されるように規定することは至難であろう）。さらに各国の判例をみると、試験・研究の例外の適用範囲は、一見よく似た条文の内容であっても、少しずつ異なって解釈されている。例えば、ドイツでは臨床試験について広く例外を認めているが、英国では非常に狭くしか試験・研究の例外を適用していない。フランスでも

判例上、厳格に解釈されている。

ベルギーでは、2005 年 4 月 28 日に公布された改正特許法の第 28 条(1)(b)において、「特許所有者の権利は、発明の主題に関する(on)又は発明の主題を用いて(with)、科学的目的のためになされる行為には及ばない」と規定され、例外の範囲が拡大された。これにより研究の自由度が拡大することになるが、一方で特許権の効力が制限されることになる。本条項の導入により、特許の保護と利用のバランスがどのように変化するのか、その効果はまだ不明であり、今後の状況の推移を注視する必要があるだろう。

またスイスでは、特許法の改正が 2007 年 6 月 22 日に議会で承認され、第 9 条(1)で試験・研究の例外について規定されている。除外されるケースを各々列挙して記載するといったスイス特許法での規定ぶりは、英国のガワーズ報告において、より明確に除外を規定した好例として取り上げられ、当該規定ぶりに沿って研究例外を規定することは、権利者の利益に損害を与えることなしに、研究を促進することになるだろう、と述べられている。しかし、当該改正によりどのような効果が実際に得られるのかはこれからの研究が待たれるところである。

一方、米国特許法では試験・研究の例外については規定されておらず、コモン・ローによる除外を与えるのみで、その範囲は狭く解釈されている。ただし、1984 年のボーラー判決を受けて、FDA 承認申請に必要な行為については特許権行使の免除対象とする、いわゆるボーラー条項を導入した。このボーラー条項による法定除外の範囲は、2005 年のメルク事件における最高裁判決以降、広く解釈される傾向がみられる。

以上のとおり、試験・研究の例外について、日本や欧州諸国のように特許法上に規定されている場合であれ、米国のようにコモン・ローによる免除であれ、またその限界範囲は各国で異なっていて、かつ明確であるとは言えないものの、特許権の効力に対して一定の制限を課して、第三者との調整を図っていることは、各国共通である。しかし試験・研究の例外の範囲は特許権者と特許を利用する者とのバランスを考慮して調整されるべきものであることから、おのずと限定的にならざるを得ない。どんなに試験・研究の例外の範囲を拡大し、又は明確にしたとしても、試験・研究の例外の適用のみで、

特許権者の利益を考慮しつつ、第三者による特許権の権利の使用を円滑にして、イノベーションにつながる研究開発を促進することは不可能であろう。

（ⅱ）強制実施

強制実施についても、これまで多くの研究がなされている。

特許法における強制実施の規定は、日本や英国、ドイツ、フランス、ベルギー、スイス等の欧州諸国では導入されている。

一方、米国では過去に何度か特許法への導入が検討されたものの、産業界や特許権者における反対が強硬であり、現在のところ、例えば大気清浄法において汚染制御装置の特許の強制実施を規定するといった、非常に限定された形での強制実施が規定されている以外には、特許法において強制実施の規定を導入するような動きはみられない。

実際のところ、強制実施権が付与されたことは日本（ただし裁定実施権）ではこれまでなく、欧州各国でも非常に稀である。

特許権の権利者の利益と第三者による権利へのアクセスの改善を調整する手段として強制実施は可能性としてはあるが、実際にはこれまでほぼ機能していない。

（ⅲ）ガイドライン／ポリシーの策定と普及

権利の保護と活用のバランスをとる方法として、法的な調整手法以外の手法も検討され得るし、また実際的である。

米国ではNIH（National Institutes of Health：国立衛生研究所）が、NIH資金が投入されて行われた研究から生まれたリサーチツールが広く利用されることを推進するため、1999年にリサーチツール・ガイドラインを作成した。米国の大学の間では、NIHのリサーチツール・ガイドラインをベースにライセンス実務が行われているケースもあり、当該ガイドラインが米国内で広く受け入れられつつあると思われる。

OECDでは2002年頃から検討を重ね、2006年2月に「遺伝子関連発明のライセンス供与に関するOECDガイドライン」を策定し、「研究目的等のための遺伝子関連発明の広範なライセンス供与等の考え方」を示した。当該OECDガイドラインについて、OECD加盟国における普及を展開中である。

これに続いて、日本では、2006年5月23日に総合科学技術会議が「大学

等における政府資金を原資とする研究開発から生じた知的財産権についての研究ライセンスに関する指針」を、続いて翌年の 2007 年 3 月 1 日に同会議が「ライフサイエンス分野におけるリサーチツール特許の使用の円滑化に関する指針」をとりまとめた。後者のリサーチツール特許の指針は、「特許制度による保護と活用のバランスのとれた実務運用が重要との認識の下、ライフサイエンス分野におけるリサーチツール特許について、大学等や民間企業が研究において使用する場合の基本的な考え方を示すことにより、その使用の円滑化を図るものである。」とされている。本指針は上記 OECD ガイドラインと軌を一にしており、OECD ガイドラインと同様に国内外に広く周知されることが重要である。またリサーチツール特許の円滑な使用を促進するために、「大学等や民間企業が所有し供与可能なリサーチツール特許や特許に係る有体物等について、・・・その使用促進につながる情報を公開し、一括して検索を可能とする統合データベースを構築する。」こととされており、リサーチツール特許の指針が真に受け入れられるためには上記統合データベースが重要な役割を果たすものとして期待される。

（iv）パテントプールの形成

パテントプールは、「複数の権利者が有する二以上の特許権を一括して実施を希望する者（ライセンシ）にライセンスし、ライセンシはプール特許の対価を支払う一方、特許権者には当該対価を一定のルールに従って配分する方式をいう」。パテントプールは電機・通信分野では実際に形成され運用されているが、ライフサイエンスの分野ではパテントプールによる権利の活用はまだ行われておらず、またライフサイエンスの分野ではパテントプールは機能しにくいとの指摘がなされている。しかし一方で、欧米ではライフサイエンス分野におけるパテントプールの形成について議論されており、またパテントプールを実際に形成し運用する試みも始まっている。例えば米国の PIPLA や 2007 年 10 月に発足した英国の SC4SM 等の取組がどのように進展していくのか期待され得る。またパテントプールは独占禁止法との関係から、より排他性の少ないクリアリング・ハウスやパテント・コンソーシアムの形式に展開することも検討されているが、両者を合わせてパテントプールと呼ぶことも多い。この場合、電機・通信分野で行われているようなパテントプールの管理や運用の形態には拘束されない。

現在、世界が注目しているiPS細胞研究においても、包括的な研究組織を形成すると共に、知的財産権のライセンスの一括管理等、知的財産権の戦略的取組がオール・ジャパンとして検討されており、今後の進展が期待される。

（２）経緯分析：機関・地域・国それぞれの経緯と機関・地域・国間での相関

ライフサイエンス分野のリサーチツール特許に関連して、1980年のチャクラバティ判決、1988年のハーバード・マウスの特許等、1980年代からバイオテクノロジー分野の特許について、米国のプロパテントの流れに後押しされて、その重要度を増してきた。

一方、20世紀の終わりには、特許と科学研究、特にライフサイエンス分野における研究との関係において、例えばアンチコモンズの悲劇のようなプロパテントに内在する問題が指摘されるようになった。

これを背景に、特許権者と権利を利用する第三者とのバランスを調整することが必要ではないかということが議論されるようになり、特に、ライフサイエンス分野のリサーチツール特許については、それが基本的なものであり、かつ当該特許を回避することは非常に困難であるとの認識から、21世紀に入って議論が盛んになってきた。またちょうどその頃、遺伝子配列の解読が競争して行われ、その成果が特許化されるようになった。特にMyriad社のライセンス方針、すなわちある特定の遺伝子について特許を取得し、その権利をライセンスせずに自己実施するという方針をとったため、他の企業での開発のみならず、大学等の研究機関における研究にも支障を引き起こし、ベルギーに至っては特許法の改正までされる事態となった。実際には、その影響は話題にされる程には大きくないとの指摘もされている。

こうした状況の中、OECDでは2003年頃から遺伝子関連発明へのアクセスの容易化についての議論を促し、ついてはガイドラインの策定に集大成された。OECDでの議論はスイス特許法の改正の際にも参考とされている。

OECDガイドラインは各国でその取込が期待されるところ、日本では、ライフサイエンス分野のリサーチツール特許について、その円滑利用が課題としてあげられたため、OECDガイドライン等を参考にしつつ、指針がまとめられたところである。

このOECDにおける動きに対して、米国では必ずしもOECDの動向に同期しているようには表面上はみえないし、またライフサイエンス分野におけるパテントプールの形成について議論や試行がなされる等、独自の動きをみせているが、OECDの方向性と大きく異なるものではない。むしろパテントプールにおける議論や取組に象徴されるように、民間主導で議論や取組が進んでいるというべきであろう。

一方、欧州は、ライフサイエンス分野のリサーチツール特許について訴訟等の大きな問題はほとんど見られないものの、ベルギーやスイスに見られるように特許法の改正を行う等により、実務上での対応や議論を行い解決策を見出すというよりも政府が主導して法制上での足固めを行う動きがみられ、米国とは異なる対応をとろうとしているように思われる。

日本でも現在のところ、リサーチツール特許について大きな問題が発生しているわけではないが、リサーチツール特許の指針を普及する等により、特許権の円滑利用を促進するための取組や議論が今後もなされていくものと思われる。

はじめに

ライフサイエンス分野においては、研究成果から事業化・製品化に至るまで長い期間と大きな投資を必要とするため、イノベーションにつなげる上で、特許は非常に重要な役割を果たしている。特に、遺伝子改変マウス等のモデル動物、実験装置・機器、スクリーニング方法等の方法、データベースやソフトウェア等、研究を行うための道具として使用される物又は方法に関する特許である「リサーチツール特許」には、汎用性が高く研究の推進に資するものが多い一方で、代替性が低いものも多い。

このため、米国、欧州諸国をはじめとして先進国間で、リサーチツール特許を含めた研究で用いる特許権の取扱に関する検討がなされ、具体的な指針策定や法改正が先進国間で急速に実施されてきている。

このような状況に対し、本調査研究では、ライフサイエンス分野におけるリサーチツール特許を中心に、研究で用いる特許権について、様々な観点から、国際機関(例えば OECD)や日本、米国、欧州諸国での法令・規則、判例、基準、指針（ガイドライン）・指令、及び、学説・関連議論の現状とそれら指針・法令等に至った経緯・背景や動向に関して調査研究を行う。

学界の有識者からなる委員会を構成し、調査研究方針を取りまとめた上で、国内外文献等の調査を実施するとともに、米国、欧州諸国の機関・大学等の有識者に各国の調査研究を委託し、調査研究を実施した。

本調査研究報告書は、上記委員会での議論や海外調査、国内外文献等調査の結果をまとめたものである。本報告書が研究で用いる特許権の取扱に関する検討のための一助になれば幸いである。

最後に、本調査研究の遂行に当たり、委員として御指導・御協力いただいた政策研究大学院大学　隅藏康一准教授、ならびに同　鈴木潤教授に対しまして、この場を借りて深く感謝する次第である。

平成２０年３月

財団法人 未来工学研究所

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Ⅰ．調査研究の目的と概要

１．目的

ライフサイエンス分野においては、発明から事業化まで長い期間と大きな投資を必要とするため、イノベーションにつなげる上で、特許は非常に重要な役割を果たしている。

特に、遺伝子改変マウス等のモデル動物、実験装置・機器、スクリーニング方法等の方法、データベースやソフトウェア等、研究を行うための道具として使用される物又は方法に関する特許である「リサーチツール特許」には、汎用性が高く研究の推進に資するものが多い一方で、代替性が低いものも多い。結果として、リサーチツール特許において、特許による研究の差止めを求めて訴訟に至った事例も生じている。

こうした状況に対して、国内外では近年各種取組が行われてきている。先進国間では、「遺伝子関連発明のライセンス供与に関する OECD ガイドライン」[1]が 2006 年 2 月に OECD（経済協力開発機構）により策定され、また、米国では NIH（米国国立衛生研究所）が、リサーチツールの取得及び普及に関する NIH 研究資金受給者のためのガイドライン[2]を示すとともに、ＮＩＨ等が保有する情報を公開するなどの取組を進めている。

さらに、欧州においては、「EC バイオ指令」が 1998 年に策定され、欧州各国においても、研究で用いられる特許権の使用に関する議論がなされている。

一方、我が国においても、内閣総理大臣の下、科学技術政策の推進のための総合的かつ基本的な政策の企画立案及び総合調整を行っている総合科学技術会議から、「大学等における政府資金を原資とする研究開発から生じた知的財産権についての研究ライセンス指針」[3]が 2006 年 5 月に、また 2007 年 3 月に「ライフサイエンス分野におけるリサーチツール特許の使用の円滑化に関する指針」[4]が、特許制度による保護と活用のバランスのとれた特許

1 http://www.oecd.org/dataoecd/39/38/36198812.pdf
2 http://ott.od.nih.gov/NewPages/64FR72090.pdf
3 http://www8.cao.go.jp/cstp/output/iken060523_2.pdf
4 http://www8.cao.go.jp/cstp/output/iken070301.pdf

の使用に係る運用の指針として、それぞれ策定されている。

さらに、2007 年 5 月に策定された「知的財産推進計画 2007」[5]においても、大学等や民間企業の試験・研究で用いられる特許権の特許法上の取扱について、国際的な議論の動向や各国の対応等を踏まえて検討することが求められている。

これら最近の国内外の動向やニーズを鑑み、研究で用いる特許権の取扱に関する検討のための基礎資料に資するため、本調査研究を行うこととする。

5 http://www.kantei.go.jp/jp/singi/titeki2/kettei/070531keikaku.pdf

2．調査研究の概要

（1）調査研究の枠組み

図 2.1　調査研究の枠組み。

調査研究内容の項目は、大別して

－その１（縦欄）：指針・法令に至った経緯･背景や動向、法令・規則、判例、基準、指針（ガイドライン）･指令、及び、学説・関連議論

－その２（横欄）：試験･研究の例外、裁定（強制）実施権、発明の特許性、（公的資金を原資とする）知的財産権の保護と特許使用の円滑化（パテントプール等を含む）、その他

とした。具体的には、例えば、「試験･研究の例外」に関してそれに関する「指針・法令に至った経緯･背景や動向」を調査研究した。

調査は、機関・地域･国毎に実施した。機関・地域･国は具体的には、

－日本

－国際機関（OECD(Organisation for Economic Co-operation and Development；経済協力開発機構））

ただし、TRIPS 協定（Agreement on Trade-Related Aspects of

Intellectual Property Rights;知的所有権の貿易関連の側面に関する協定）についての調査もここに含めることとする。

－米国

－EU(European Union;欧州連合)

－英国

－ドイツ

－フランス

－ベルギー

－スイス

である。

また、調査は、

－海外調査：海外の大学･関係機関等の研究者等への委託調査

－国内外文献調査：文献等による調査

を実施し、これらの調査研究結果を調査研究項目－その２－に関して、機関・地域・国を横断的に比較対照すること等により、調査研究結果のまとめを行った。

具体的な、調査研究の方法について、以下に述べる。

（２）調査研究の方法

（ｉ）調査

① 海外調査

海外調査は表 2.1 に示す、関係分野での研究者に調査研究を委託した。

機関 国	氏 名	所 属
米国	Prof.Joshua D. Sarnoff	Washington College of Law American Univ.
英国	Prof.Jeremy Phillips	IP Consultant of Olswang Editor of Oxford Journal of Intellectual Property Law & Practice
ドイツ	Dr. Prinz zu Waldeck und Pyrmont	Program Director, Munich Intellectual Property Law Center Member of the Research Staff, Max Planck Institute for Intellectual Property, Competition and Tax Law
フランス	Mr. Alain Gallochat	Former Adviser to the government Consultant
スイス	Dr. Lucas Bu"hler	Swiss Federal Institute of Intellectual Property
ベルギー	Prof. Dr. Geertrui Van Overwalle	Katholieke Universiteit Leuven
ＯＥＣＤ	Ms. Christina Sampogna	Administrator Biotechnology Division

表 2.1 海外調査の委託先

なお、OECD については結局、調査への具体的な協力が得られなかった。

② 国内外文献調査

各機関・地域・国やその関係機関、学会等が公表している文献を図 2.1 の調査研究の枠組みに従って調査した。

（ⅱ）調査結果のまとめ

以上の調査結果を以下の視点により、機関・地域・国を横断的に調査研究結果のまとめを行った。調査研究結果のまとめの視点は以下のようである。

－比較分析：機関・地域･国の間での類似･相違点

－経緯分析：機関・地域･国それぞれの経緯と機関・地域･国間での相関

（３）報告書の構成

調査結果は「Ⅱ．調査」に、また調査結果のまとめは「Ⅲ．調査結果のまとめ」に記載する。

なお、海外調査の委託先の報告書は資料編として別冊に掲載する。資料編に掲載した海外調査の報告書は米国、ベルギー等、非常に詳細にまとめられていることから、「Ⅱ．２．調査の結果」の各（ⅱ）海外調査については、資料編（別冊）の原文の報告書の記載を必ず確認されることが望ましい。

Ⅱ．調査

１．調査の設計

（１）海外調査

表 2.1 に示した海外調査の委託先へ表 2.2 の調査研究項目を提示し、調査研究を行った。なお、表 2.2 の調査研究項目は図 2.1 調査研究の枠組みに示した調査研究項目に準拠した。

なお、委託先の国により、調査研究項目の主点に差異を設けた。例えば、近年、法改正等の大きな動きがあったベルギーやスイスに対しては、法令改正等に至った経緯･背景に主点を置いた調査を委託した。

表 2.2 海外調査の委託先への調査研究項目

	Item	Object	Description(analysis includes evaluation)
1	Settled law suites and its regal analysis	* Settled law suites	* Analysis of law suites including judgment, process of argument, its effect on the following law suites, movement of the government, research activity etc. * Theoretical analysis * Summary of information in academic paper and journals etc
2	Law suites pending in court and incidents and troubles	* Unsettled law suites * Unsettled troubles and incidents (outside court)	Analysis of law suites, incidents and troubles including the forecast of judgment, process of argument, its effect on the following law suites, movement of the government, research activity etc. * Summary of information in academic paper and journals etc
3	The trend of law and regulation	* The trend of discussion and activities among governmental, political, bureaucratic, business, and academic circles and general public	* Analysis * Summary of information in academic journals etc
4	4. The discussion upon law and regulation,and its social back ground	* The discussion upon law and regulation, and its social back ground among governmental, political, bureaucratic, business, and academic circles * The discussion upon law and regulation, and its social back ground and of general public	* Analysis * Summary of information listed in right columns

5	Altering process and background of the altering law (ex. Belgium)	* The history of of altering, including political and social process * The action and reaction of political circle * The action and reaction of academia * The action and reaction of business circle * The social background of altering law	* Analysis * Summary of information in publication
6	The process and background to start, the process to alter the law (ex. UK, Swiss)	* The history of of altering, including political and social process * The action and reaction of political, academic and business people * The social background of altering law	* Analysis * Summary of information in academic journals etc
7	The guideline to protect and use research tool patents	* Guidelines of government and private sector	* Analysis * Summary of information in report from government, business and academic sector.
8	The status quo of using the guideline	* Working mechanism in academic and business research. * The opinion of academic and business circle	* Analysis * Summary of information in academic journals etc
9	Other information(technological field, bibliographic item, price to license etc)	* Major items not included above items	* Analysis * Summary of information in academic journals etc
10	OECD guideline	* Working mechanism of the guideline Status quo of using	* Analysis * Summary of information in academic journals etc
11	NIH guideline	* Working mechanism of the guideline * Status quo of using	* Analysis * Summary of information in academic journals etc

（２）国内外文献調査

既に述べたように、各機関・地域・国やその関係機関、学会等が公表している文献を図 2.1 の調査研究の枠組みに従って調査した。

特に、海外調査との補完性を重視し、初期的な調査を行うことにより、調査研究の枠組みを構築し、文献調査を実施するとともに、文献調査では得られ難い調査項目を海外調査に反映させた。

２．調査の結果

（１）日本

（ｉ）概要

知的財産制度は保護と利用のバランスにより適切に運用されることが重要であり、研究活動に携わる者であっても、他者の知的財産権を尊重し、適正な配慮のもとに知的財産権を活用することが求められる。

大学等は、知的財産を創造する権利者であると同時に、研究活動において他者の権利を使用する者でもある。大学等における研究活動においても、特許権の効力が及ぶことが想定される状況においては、大学等は、両者の立場から知的財産権の管理や活用を図ることが必要となっている。

特許権の効力と試験・研究の関係については、特許法第 69 条第 1 項に、いわゆる試験又は研究の例外として規定されている。その場合の「試験又は研究」の範囲については、特許発明それ自体を対象とし、改良・発展を目的とする試験に限定されているとの解釈が示されている。また実施者が企業であるか大学であるかの相違によって特許権の効力の及ぶ範囲が異なるものではない。これについては産業構造審議会　知的財産政策部会　特許制度小委員会　特許戦略計画関連問題ワーキンググループ報告書「特許発明の円滑な使用に係る諸問題について」（2004 年 11 月）にて検討されている。

この解釈を前提とすれば、非営利目的の研究であっても特許権の侵害を問われることになる。一方、大学等の試験・研究に対し特許権が及ぶか否

かの判決は出ていない。

このため 2006 年 5 月 23 日、総合科学技術会議は「大学等における政府資金を原資とする研究開発から生じた知的財産権についての研究ライセンスに関する指針」をとりまとめた。本指針は、政府資金を原資として得られた研究開発の成果に基づく大学等の知的財産権について、他の大学等が非営利目的の研究においてそれを使用する場合の基本的な考え方を示すものであり、これにより大学等の研究における知的財産権の使用の円滑化を図ることを目的とする。

しかしながら、医薬やバイオテクノロジーの分野において、特に遺伝子改変動植物やスクリーニング方法のように研究を行うための道具となるリサーチツール特許は、汎用性が高く広範に使用されて研究の推進に資するものが多いが、同時に代替性が低いものも多い。こうしたリサーチツール特許が研究において円滑に使用されない場合、研究開発に支障が生じる可能性があり、現に、権利者と使用者のライセンス条件に乖離があり交渉が難航する場合も多く、特許による研究の差止めを求めて訴訟に至った事例も生じている。

そこで総合科学技術会議は 2007 年 3 月 1 日に「ライフサイエンス分野におけるリサーチツール特許の使用の円滑化に関する指針」を公表した。指針では、リサーチツール特許を所有又は使用する大学等や民間企業が、そのライセンスを授受する際の基本的な考え方が示されている。またリサーチツール特許の使用を促進するために、リサーチツールの種類、特許番号、使用条件等を含め、その使用促進につながる情報を公開し、一括して検索を可能とする統合データベースを構築し、リサーチツール特許の使用を促進することが重要であると述べられている。本指針は OECD や NIH の取組とも軌を一にするものである。

（ii）国内外文献調査

資料番号										
対象国･機関	日本		分類	背景等	法令規則	判例	基準	指針指令	学説	その他
名称	研究ライセンス指針									
書誌的事項	2006.5.23		「大学等における政府資金を原資とする研究開発から生じた知的財産権についての研究ライセンスに関する指針」総合科学技術会議 http://www8.cao.go.jp/cstp/output/iken060523_2.pdf							

調査結果

概要

１．基本認識

「知的財産制度は保護と利用のバランスにより適切に運用され、さらなる知的財産の創造活動を活性化することが重要であり、事業活動においてはもとより、研究活動に携わる者であっても、他者の知的財産権を尊重し、適正な配慮のもとに知的財産権を活用することが求められる。」（指針 1.(2)から抜粋）

２．本指針の目的

「本指針は、政府資金を原資として得られた研究開発の成果に基づく大学等の知的財産権について、他の大学等が非営利目的の研究においてそれを使用する場合の基本的な考え方を示すことにより、大学等の研究における知的財産権の使用の円滑化を図るものである。」（指針 2.(1)から抜粋）

３．研究ライセンスの基本的な考え方

○研究ライセンスの供与

「大学等の知的財産権者は、他の大学等から、非営利目的の研究のための知的財産権の非排他的な実施許諾（以下、「研究ライセンス」という。）を求められた場合、当該研究を差し止めることなく、その求めに応じて研究ライセンスを供与するものとする。」

○研究ライセンスの対価

「研究ライセンスに対する対価については、原則としてロイヤリティ・フリー又は合理的なロイヤリティとする。」

○簡便で迅速な手続

「大学等は、研究ライセンスが、簡便で迅速な手続きにより行われるよう努めるものとする。この場合、研究ライセンスのための簡便な書式を活用することや、大学等の間での相互の包括的な研究ライセンスの方式を活用することが望ましい。」（指針 3.から抜粋）

資料番号										
対象国・機関	日本		分類	背景等	法令規則	判例	基準	指針指令	学説	その他
名称										
書誌的事項	2007.3.1		「ライフサイエンス分野におけるリサーチツール特許の使用の円滑化に関する指針」 総合科学技術会議 http://www8.cao.go.jp/cstp/output/iken070301.pdf							

調査結果

概要

１．はじめに

「（１）医薬やバイオテクノロジーの分野においては、一つの基本特許により製品や方法を独占できる場合が多く、また、発明から事業化まで長い期間とリスクの高い大きな投資を必要とするため、特許は研究開発や製品開発を促進し、その成果をイノベーションにつなげるうえで重要な役割を果たしている。

（２）とりわけ、遺伝子改変動植物やスクリーニング方法のように研究を行うための道具となるリサーチツール特許には、汎用性が高く広範に使用されて研究の推進に資するものが多いが、同時に代替性が低いものも多い。こうしたリサーチツール特許が研究において円滑に使用されない場合、研究開発に支障が生じる可能性があり、現に、権利者と使用者のライセンス条件に乖離があり交渉が難航する場合も多く、特許による研究の差止めを求めて訴訟に至った事例も生じている。

（３）こうした問題は我が国のみならず他の先進国でも生じており、ＯＥＣＤが策定した「遺伝子関連発明のライセンス供与に関するＯＥＣＤガイドライン」（２００６年２月）においても、研究目的等のための遺伝子関連発明の広範なライセンス供与等の考え方が示されている。

（４）また、米国では、国立衛生研究所（ＮＩＨ）が、政府資金を原資とする研究開発により得られたリサーチツールを研究において円滑に使用するためのガイドラインを示すとともに、ＮＩＨ等が有するリサーチツールに関する情報を公開し、使用の促進を図っている。

（５）我が国においても、大学等や民間企業はリサーチツール特許を所有しているが、これらを研究において円滑に使用するという共通の理解は形成されておらず、また、これらリサーチツール特許やそのライセンス条件等の情報は研究者が利用しやすい形で公開はされていない。

（６）リサーチツール特許の使用の円滑化は、ライフサイエンス分野における研究開発を促進し、その成果をイノベーションにつなげるとともに、我が国の国際競争力を向上していくうえで重要な課題であり、大学等や民間企業を含め、国全体として認識共有を進める必要がある。」

（指針1.から抜粋）

２．本指針の目的

「（１）本指針は、こうした状況に鑑み、特許制度による保護と活用のバランスのとれた実務運用が重要との認識の下、ライフサイエンス分野におけるリサーチツール特

許について、大学等や民間企業が研究において使用する場合の基本的な考え方を示すことにより、その使用の円滑化を図るものである。
（２）大学等や民間企業は、本指針に沿った実務運用を確立することに努め、リサーチツール特許に関する紛争を未然に回避し、研究におけるリサーチツール特許の使用を相互に円滑化することが望まれる。
（３）なお、本指針に沿った実務運用を行うにあたっては、本指針が、我が国の特許法に基づき、日本特許の効力が及びうる国内での研究活動を対象として、ライセンス等の基本的な考え方を示すものであることに留意する必要がある。」
（指針2.から抜粋）

３．基本的な考え方
○「リサーチツール特許を所有又は使用する大学等や民間企業は、そのライセンスの授受にあたり、以下の基本的な考え方に基づき対応するものとする。ただし、リサーチツール特許のうち、商品化され市場において一般に提供されている物又は方法については、この限りでない。なお、リサーチツールに関する特許出願中の発明についても、本指針に準じた取扱いとする。」
（１）ライセンスの供与
「リサーチツール特許の権利者は、他者から研究段階において特許を使用するための許諾を求められた場合、事業戦略上の支障がある場合を除き、その求めに応じて非排他的なライセンスを供与するなど、円滑な使用に配慮するものとする。」
（２）ライセンスの対価及び条件
「リサーチツール特許に対する非排他的なライセンスの対価は、当該特許を使用する研究の性格、当該特許が政府資金を原資とする研究開発によるものか否か等を考慮に入れた合理的な対価とし、その円滑な使用を阻害することのないよう十分配慮するものとする。特に、大学等の間でのライセンス供与の場合は、大学等の学術振興の観点から、無償（有体物提供等に伴う実費を除く）とすることが望ましい。」
（３）簡便で迅速な手続
「リサーチツール特許に関するライセンスの当事者は、ライセンスが簡便で迅速な手続きにより行われるよう努めるものとする。」
（４）有体物の提供
「研究の場においてリサーチツール特許が円滑に使用されるためには、特許のライセンス供与に加えて、その特許に係る有体物の円滑な提供が不可欠である。これら有体物の所有者は、合理的な条件と簡便で迅速な手続による有体物の提供に努めるものとする。」
（本指針3.から抜粋）

４．統合データベースによる情報の公開
○「リサーチツール特許の使用を促進するためには、大学等や民間企業が所有するリサーチツール特許及びそのライセンス条件等に関する情報が広く公開され、活用される必要がある。」
○統合データベースの構築
「関係府省は、大学等や民間企業が所有し供与可能なリサーチツール特許や特許に係る有体物等について、リサーチツールの種類、特許番号、使用条件、ライセンス期間、ライセンス対価（参考となる過去の対価実績）、支払条件、交渉のための連絡先等を含め、その使用促進につながる情報を公開し、一括して検索を可能とする統合データベースを構築する。」
（本指針4.から抜粋）

５．本指針の周知
「関係府省は、本指針を大学等や民間企業に対し広く周知し、研究の場において適切な実務運用が行われるよう、その普及に努めるものとする。」
（本指針 5.から抜粋）

資料番号										
対象国・機関	日本		分類	背景等	法令規則	判例	基準	**指針指令**	学説	その他
名称	特許発明の円滑な使用に係る諸問題について									
書誌的事項	2004.11		産業構造審議会 知的財産政策部会特許制度小委員会 特許戦略計画関連問題ワーキンググループ http://www.jpo.go.jp/shiryou/toushin/shingikai/pdf/strategy_wg_prob/00.pdf							

調査結果

概要

○検討の背景
・大学・公的研究機関の研究活動について、他者の特許発明が円滑に使用できないと自由な研究活動を阻害するのではないかという懸念がある。
・また、汎用性が高く代替性の低い上流技術（特にライフサイエンス分野における遺伝子関連 技術やリサーチツール等）については、特許が取得され、特許発明の利用が制限されると、当該分野における後続又は下流領域の研究開発活動に大きな影響を及ぼす可能性があるとの懸念が示されている。
・このような懸念を受け、円滑な研究活動と知的財産保護の両立を図るという観点、又は知的財産の円滑な利用を促進するという観点から、特許法第69条第1項に定める特許権の効力が及ばない「試験又は研究」の範囲の明確化が求められている。
・さらに、前記リサーチツール等の上流技術については前記特許法第69 条とともに裁定実施権による対応可能性の検討も求められている。
・また、技術標準に資するパテントプールを支援するという観点から、技術標準に必須となる特許を有する権利者がパテントプールに参加しない場合の対処の困難さが指摘され、それに対して裁定実施権による対応の検討が求められている。

試験･研究の例外

○特許権の効力が及ばない「試験又は研究」の例外について
・リサーチツール等についての問題及び大学等での研究活動についての問題という2つの観点から、特許法第69条第1項に規定される特許権が及ばないとされる「試験又は研究」について、諸外国も含め判例や学説等の事実関係を調査した結果を提示することにより、本規定に関する従来からの一般的な解釈を改めて整理し、検討した。
・本規定の解釈に言及している判決としては、後発医薬品の臨床試験に関する最高裁判決が存在するものの、これは、実質的な特許権存続期間の延長により特許権者に特許法が想定するところを超える利益を与えるのは適当でないとされた特殊な事例であって、この判決により特許法第69条第1項の一般的な解釈が定まったものではない。つまり、一般的に「試験又は研究」をどう解釈するかについては十分な判例の蓄積がない。
・一方、従来から通説とされている学説によれば、例外に当たる「試験又は研究」の範囲をその対象及び目的により区分し、対象については特許発明それ自体に限定するとともに、目的についても「技術の進歩」を目的とする行為（特許性調査、機能調査、改良・発展を目的とする試験）に限定すべきとされている。この通説については、こ

れまで特段の異論は唱えられておらず、特許法の解説書等においてもこの通説を引用して説明されているのが一般的である。
・他方、諸外国における類似の規定や判例、学説等についても調査したが、我が国において通説とされている試験又は研究の例外の範囲についての解釈は、諸外国における解釈と比較しても特に限定的なものではない。
・具体的にみてみると、欧州主要国においては、特許権の効力が及ばない「試験」について、対象を「特許発明の主題」に限定する明文規定を置いており、その目的についても我が国における上記通説とほぼ同様の範囲に限定する判決が存在する。
・米国においては、試験又は研究の例外に係る明文の規定は無いが、判例において、特許権の侵害とされないのは単に哲学的試験を目的とした行為等に限られるとして、その範囲は諸外国と比較して非常に限定的に解釈されている。また、アジア諸国においては、試験又は研究の例外に係る判例や通説と言える学説が存在しない国が多いが、わずかに判例が存在する中国においても、特許侵害とならないのは特許発明それ自体に関する研究や試験でなければならないと解されている。
・以上のような調査結果を基にすると、我が国特許法第69条第1項に規定される特許権が及ばないとされる試験又は研究の例外の範囲については、上記通説の考え方に特段の問題はないと考えられる。
・よって、上記通説の解釈にしたがえば、リサーチツール等の問題については、多くは特許発明それ自体を研究対象とする場合（例えば遺伝子特許について特許明細書に記載された機能を確認する場合等）に当たらないため、第69条第1項の適用は否定されると考えられる。
・また、大学等での研究活動については、我が国の特許法が営利又は非営利目的により他者の特許発明の実施に区別を設けていないことにかんがみると、実施者が企業（営利機関）か大学等（非営利機関）であるかの相違によって特許権の効力が及ぶ範囲が異なるものではない。これまでは非営利機関である大学等を訴える利益に乏しかったこと等の様々な配慮により、実際に大学等が特許侵害により訴えられることはほとんど無かったが、今後産学官連携が進み活発化していけば、大学等が訴訟当事者となる場合も想定されることから、第 69 条第 1 項についての正しい認識が求められる。

裁定実施権

○裁定実施権による対応の可能性について
・代替性の低い上流技術に係る特許及び技術標準に必須な特許が円滑に利用されないために産業の発展及び技術の進歩が阻害されているのではないかという指摘を踏まえ、これらの問題について、裁定実施権制度による対応可能性を検討した。
・指摘のあったそれぞれの問題点については、何らかの対応が必要となっている重要な問題であるとの認識は得られた。
・しかし、検討した結果、代替性の低い上流技術に係る特許及び技術標準に必須な特許に係る問題を裁定実施権制度により解決するということについては、TRIPS協定をベースとした諸外国との良好な国際協調の維持及び我が国の知的財産政策等の観点から、慎重に検討すべきとの意見が多く出された。
・また、現時点において、これらの問題の解決のために裁定実施権制度を用いることについては、我が国の産業界においてもコンセンサスの醸成は十分とは言い難い状況にある。加えて、国際的に見ても、諸外国の動向や議論の方向性が定まっているとは言えない。
・よって、このような現状においては、裁定実施権の制度の改正又はその運用の見直しについては慎重に精査・検討する必要があり、早急な結論は出すべきではないとの結論に至った。

（２）国際機関

（ｉ）概要

①OECD

（指針策定に至った）経緯・背景、動向

世界 30 ヶ国が加盟している OECD は、2006 年、遺伝子関連発明のライセンス供与に関する OECD ガイドライン(GUIDELINES FOR THE LICENSING OF GENETIC INVENTIONS)を公表した。

本ガイドラインは、「OECD 加盟国及び非加盟国政府が遺伝子関連発明のライセンス供与及び移転における適切な行動を推奨する国家政策を整備する一助となることを狙っている。ガイドラインは全体として、OECD 加盟国及び非加盟国の両方におけるヘルスケアニーズにより効果的・効率的に対応するために、治療や診断など、遺伝子関連発明にもとづく製品やサービスの開発及び市場導入を促進することを意図している。」[6]

また本ガイドラインでは、「イノベーションの商業化やイノベーションへのアクセスを促進するのみならず、権利者が望む場合には、投資収益を回収する」[7]バランスのとれた知的財産制度が期待されている。

指針（ガイドライン）の内容

OECD ガイドラインは、

－ライセンス供与一般

－ヘルスケア及び遺伝子関連発明

－研究の自由

－商業的開発

－競争

について指針の原則とベストプラクティスを示している。

②TRIPS

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6 「遺伝子関連発明のライセンス供与に関する OECD ガイドライン（JBA 訳）」前文 1. http://www.jba.or.jp/top/top%20data/oecdguideline060323.pdf

7 同ガイドライン　前文 7.

TRIPS 協定（Agreement on Trade-Related Aspects of Intellectual Property Rights;知的所有権の貿易関連の側面に関する協定）は、第 30 条で与えられる権利の例外について、また第 31 条で強制実施について規定している。

第 30 条　与えられる権利の例外

加盟国は，第三者の正当な利益を考慮し，特許により与えられる排他的権利について限定的な例外を定めることができる。ただし，特許の通常の実施を不当に妨げず，かつ，特許権者の正当な利益を不当に害さないことを条件とする。

第 31 条　特許権者の許諾を得ていない他の使用

加盟国の国内法令により，特許権者の許諾を得ていない特許の対象の他の使用(政府による使用又は政府により許諾された第三者による使用を含む。)を認める場合には，次の規定を尊重する。

(a) 他の使用は，その個々の当否に基づいて許諾を検討する。
(b) 他の使用は，他の使用に先立ち，使用者となろうとする者が合理的な商業上の条件の下で特許権者から許諾を得る努力を行って，合理的な期間内にその努力が成功しなかった場合に限り，認めることができる。加盟国は，国家緊急事態その他の極度の緊急事態の場合又は公的な非商業的使用の場合には，そのような要件を免除することができる。ただし，国家緊急事態その他の極度の緊急事態を理由として免除する場合には，特許権者は，合理的に実行可能な限り速やかに通知を受ける。公的な非商業的使用を理由として免除する場合において，政府又は契約者が，特許の調査を行うことなく，政府により又は政府のために有効な特許が使用されていること又は使用されるであろうことを知っており又は知ることができる明らかな理由を有するときは，特許権者は，速やかに通知を受ける。
(c) 他の使用の範囲及び期間は，許諾された目的に対応して限定される。半導体技術に係る特許については，他の使用は，公的な非商業的目的のため又は司法上若しくは行政上の手続の結果反競争的と決定された行為を是正する目的のために限られる。
(d) 他の使用は，非排他的なものとする。
(e) 他の使用は，当該他の使用を享受する企業又は営業の一部と共に譲渡する場合を除くほか，譲渡することができない。
(f) 他の使用は，主として当該他の使用を許諾する加盟国の国内市場への供給のために許諾される。
(g) 他の使用の許諾は，その許諾をもたらした状況が存在しなくなり，かつ，その状況が再発しそうにない場合には，当該他の使用の許諾を得た者の正当な利益を適切に保護することを条件として，取り消

すことができるものとする。権限のある当局は，理由のある申立てに基づき，その状況が継続して存在するかしないかについて検討する権限を有する。

(h) 許諾の経済的価値を考慮し，特許権者は，個々の場合における状況に応じ適当な報酬を受ける。

(i) 他の使用の許諾に関する決定の法的な有効性は，加盟国において司法上の審査又は他の独立の審査(別個の上級機関によるものに限る。)に服する。

(j) 他の使用について提供される報酬に関する決定は，加盟国において司法上の審査又は他の独立の審査(別個の上級機関によるものに限る。)に服する。

(k) 加盟国は，司法上又は行政上の手続の結果反競争的と決定された行為を是正する目的のために他の使用が許諾される場合には，(b)及び(f)に定める条件を適用する義務を負わない。この場合には，報酬額の決定に当たり，反競争的な行為を是正する必要性を考慮することができる。権限のある当局は，その許諾をもたらした状況が再発するおそれがある場合には，許諾の取消しを拒絶する権限を有する。

(l) 他の特許(次の(i)から(iii)までの規定において「第 1 特許」という。)を侵害することなしには実施することができない特許(これらの規定において「第 2 特許」という。)の実施を可能にするために他の使用が許諾される場合には，次の追加的条件を適用する。

(i) 第 2 特許に係る発明には，第 1 特許に係る発明との関係において相当の経済的重要性を有する重要な技術の進歩を含む。

(ii) 第 1 特許権者は，合理的な条件で第 2 特許に係る発明を使用する相互実施許諾を得る権利を有する。

(iii) 第 1 特許について許諾された使用は，第 2 特許と共に譲渡する場合を除くほか，譲渡することができない。

（ii）国内外文献調査

資料番号										
対象国･機関	OECD		分類	背景等	法令規則	判例	基準	指針指令	学説	その他
名称	GUIDELINES FOR THE LICENSING OF GENETIC INVENTIONS									
書誌的事項	2006.2		出典：下記の備考を参照							

調査結果

概要

・ヘルスケアに使用される遺伝子関連発明のライセンス供与に関する原則とベストプラクティスについてのガイドライン。

・遺伝子関連発明にもとづく製品やサービスの開発及び市場導入を促進することを意図している。

原則　１．ライセンス供与一般

・ライセンス実務は、人のヘルスケアに係わる新しい遺伝子関連発明を開発する上でのイノベーションを促進し、かつそのような発明を駆使した治療や診断、またその他製品及びサービスが合理的に利用できるように保証すべきである。

・ライセンス実務は、遺伝子関連発明に関する情報の迅速な普及を奨励すべきである。

・ライセンス実務は、ライセンサー及びライセンシー双方が遺伝子関連発明に関連する投資から収益を得る機会を提供すべきである。

・ライセンシー及びライセンサーは、遺伝子関連発明に関する自らの権利とその制限事項について、合理的な確実性を持たせるべきである。

原則　２．ヘルスケア及び遺伝子関連発明

・ライセンス実務は、新製品やサービスの提供、ヘルスケアニーズ、ならびに経済的収益還元の間で、バランスが取れるようにすべきである。

・ライセンス実務は、患者にとって、当該国又は遺伝子発明を利用するサービス提供者の所属する国の法律に従って実現することができる、最も高水準のプライバシー、安全性、ならびに研究方法を享受できるようにすべきである。

・ライセンス実務は、患者やそのヘルスケア・サービス提供者が他の製品やサービスを選ぶことを制限するために利用されるべきではない。

・ライセンス実務は、OECD 加盟国と非加盟国の双方で、未対応で緊急のヘルスニーズに対処するために、遺伝子関連発明への適切なアクセス及びその利用を促進すべきである。

原則　３．研究の自由

・ ライセンス実務は、研究目的の遺伝子関連発明へのアクセスを減少させるのではなく、むしろ増大させるべきである。

・ 公共の研究活動において商業化を考慮する場合、研究者の学術的な自由を不当に妨げるべきではない。

・ 公共の研究活動において商業化を考慮する場合、特にこれらの活動から生まれてくる発明について特許保護を求める機会を損なわないようにする必要がある場合でも、研究の成果をタイムリーに発表する裁量を不当に制限すべきではない。

・ 公共の研究活動において商業化を考慮する場合、学生の教育研修を不当に制限すべきではない。

原則　４．商業的開発

・ 基礎的遺伝子関連発明は、広汎にアクセスできるようにライセンスされるべきである。

・ ライセンス実務は、遺伝子関連発明から生じる新しい製品やサービスの開発を通じて、ライセンサー及びライセンシー双方が価値を創造できる効果的手段として使用

されるべきである。
・ ライセンス実務は、多数の遺伝子関連発明にアクセスする必要がある場合、そこから生じる調整の問題を克服するよう努めるべきである。

原則　５．競争

・ 遺伝子関連発明に係わるライセンス実務は、適用される競争法を遵守しつつ、イノベーションと実質的競争を通じて、経済成長を助長すべきである。
・ ライセンス実務は、関連する知的財産権の範囲を超えて、独占的権利の広さを拡大するために用いるべきではない。

備考

原　文　　http://www.oecd.org/dataoecd/39/38/36198812.pdf
日本語（JBA 仮訳）
　　http://www.jba.or.jp/top/top%20data/oecdguideline060323.pdf

資料番号										
対象国・機関	TRIPS		分類	背景等	法令規則	判例	基準	指針指令	学説	その他
名称	TRIPS 協定									
書誌的事項	1998		TRIPS 協定（Agreement on Trade-Related Aspects of Intellectual Property Rights;知的所有権の貿易関連の側面に関する協定） 出典：詳細は下記の文中を参照							

調査結果

概要

・加盟国が「実施許諾などにおける行為または条件であって、関連市場における競争に悪影響を及ぼすような知的所有権の濫用となることのあるもの」を規制できるとし、強制的な一括実施許諾を認めている。

与えられる権利の例外（試験･研究の例外）

・第 30 条　与えられる権利の例外
加盟国は，第三者の正当な利益を考慮し，特許により与えられる排他的権利について限定的な例外を定めることができる。ただし，特許の通常の実施を不当に妨げず，かつ，特許権者の正当な利益を不当に害さないことを条件とする。

Article 30　Exceptions to Rights Conferred

Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

※英文
http://www.wto.org/english/tratop_e/trips_e/t_agm0_e.htm
※日本語文は日本国特許庁の仮訳
http://www.jpo.go.jp/shiryou/s_sonota/fips/trips/ta/mokuji.htm

上記条項は「多くの国の特許法において設けられている①試験・研究の目的のために特許発明の実施を行う行為、②医師による調剤行為等を考慮したものである。」※
※吉藤幸朔著、熊谷健一補訂『特許法概説　第 12 版』第 773 頁（株式会社有斐閣、1997 年）

強制実施

TRIPS では強制実施について、条件を詳細に設定することで、「強制実施権の適切な設定が行われる」※ように規定されている。
※吉藤幸朔著、熊谷健一補訂『特許法概説　第 12 版』第 773 頁（株式会社有斐閣、1997 年）

第 31 条　特許権者の許諾を得ていない他の使用
加盟国の国内法令により，特許権者の許諾を得ていない特許の対象の他の使用(政府

による使用又は政府により許諾された第三者による使用を含む。)を認める場合には，次の規定を尊重する。
(a) 他の使用は，その個々の当否に基づいて許諾を検討する。
(b) 他の使用は，他の使用に先立ち，使用者となろうとする者が合理的な商業上の条件の下で特許権者から許諾を得る努力を行って，合理的な期間内にその努力が成功しなかった場合に限り，認めることができる。加盟国は，国家緊急事態その他の極度の緊急事態の場合又は公的な非商業的使用の場合には，そのような要件を免除することができる。ただし，国家緊急事態その他の極度の緊急事態を理由として免除する場合には，特許権者は，合理的に実行可能な限り速やかに通知を受ける。公的な非商業的使用を理由として免除する場合において，政府又は契約者が，特許の調査を行うことなく，政府により又は政府のために有効な特許が使用されていること又は使用されるであろうことを知っており又は知ることができる明らかな理由を有するときは，特許権者は，速やかに通知を受ける。
(c) 他の使用の範囲及び期間は，許諾された目的に対応して限定される。半導体技術に係る特許については，他の使用は，公的な非商業的目的のため又は司法上若しくは行政上の手続の結果反競争的と決定された行為を是正する目的のために限られる。
(d) 他の使用は，非排他的なものとする。
(e) 他の使用は，当該他の使用を享受する企業又は営業の一部と共に譲渡する場合を除くほか，譲渡することができない。
(f) 他の使用は，主として当該他の使用を許諾する加盟国の国内市場への供給のために許諾される。
(g) 他の使用の許諾は，その許諾をもたらした状況が存在しなくなり，かつ，その状況が再発しそうにない場合には，当該他の使用の許諾を得た者の正当な利益を適切に保護することを条件として，取り消すことができるものとする。権限のある当局は，理由のある申立てに基づき，その状況が継続して存在するかしないかについて検討する権限を有する。
(h) 許諾の経済的価値を考慮し，特許権者は，個々の場合における状況に応じ適当な報酬を受ける。
(i) 他の使用の許諾に関する決定の法的な有効性は，加盟国において司法上の審査又は他の独立の審査(別個の上級機関によるものに限る。)に服する。
(j) 他の使用について提供される報酬に関する決定は，加盟国において司法上の審査又は他の独立の審査(別個の上級機関によるものに限る。)に服する。
(k) 加盟国は，司法上又は行政上の手続の結果反競争的と決定された行為を是正する目的のために他の使用が許諾される場合には，(b)及び(f)に定める条件を適用する義務を負わない。この場合には，報酬額の決定に当たり，反競争的な行為を是正する必要性を考慮することができる。権限のある当局は，その許諾をもたらした状況が再発するおそれがある場合には，許諾の取消しを拒絶する権限を有する。
(l) 他の特許(次の(i)から(iii)までの規定において「第 1 特許」という。)を侵害することなしには実施することができない特許(これらの規定において「第 2 特許」という。)の実施を可能にするために他の使用が許諾される場合には，次の追加的条件を適用する。
(i) 第 2 特許に係る発明には，第 1 特許に係る発明との関係において相当の経済的重要性を有する重要な技術の進歩を含む。
(ii) 第 1 特許権者は，合理的な条件で第 2 特許に係る発明を使用する相互実施許諾を得る権利を有する。

(iii) 第 1 特許について許諾された使用は，第 2 特許と共に譲渡する場合を除くほか，譲渡することができない。

Article 31 Other Use Without Authorization of the Right Holder

Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:

(a) authorization of such use shall be considered on its individual merits;

(b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;

(c) the scope and duration of such use shall be limited to the purpose for which it was authorized, and in the case of semi-conductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive;

(d) such use shall be non-exclusive;

(e) such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;

(f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;

(g) authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances;

(h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;

(i) the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

(j) any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

(k) Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur;

(l) where such use is authorized to permit the exploitation of a patent (“the second patent”) which cannot be exploited without infringing another patent (“the first patent”), the following additional conditions shall apply:

(i) the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;

(ii) the owner of the first patent shall be entitled to a cross-licence on reasonable terms to use the invention claimed in the second patent; and

(iii) the use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent.

※英文
http://www.wto.org/english/tratop_e/trips_e/t_agm0_e.htm
※日本語文は日本国特許庁の仮訳
http://www.jpo.go.jp/shiryou/s_sonota/fips/trips/ta/mokuji.htm

（３）米国

（ｉ）概要

Sarnoff 教授[8]及び Holman 教授[9]による今回の海外調査報告“ Recent Developments in the United States Regarding the Law and Practical Application of Patents on Research Tool Inventions ”では、米国特許法の下での最近の進展を総括すると共に、いわゆる“ リサーチツール ”発明の扱いについて、大学、産業界、政府機関の実務についていくつかの識見が提示されている。

「何年にもわたって、リサーチツールを発明し、開示するインセンティブとして排他的な特許権を与える必要があること－その排他権が特許されたリサーチツールのすべての使用とすべての使用者に適用されようと、リサーチツールのすべての使用者が引き続きおこる発明を過度に思いとどまることを妨げる排他権であろうと－について、活発な議論がなされてきた。発明を引き続き研究で使用することに関する特許権の適切な範囲についての懸念は長い歴史があるが、世紀の変わり目以降、司法判断に照らして詳細な調査が増えてきている。リサーチツールの使用とリサーチツール特許を行使する努力についての新しい研究は二つの判決、すなわち、Madey v. Duke University 事件で特許侵害に対する“ 実験での使用の除外 ”の限定的な解釈を与える 2002 年の CAFC 判決、及び Merck, KGaA v. Integra LifeSciences I Ltd.事件における成文化された“ 法定除外 ”の拡張解釈を与える 2005 年の最高裁判決に照らして行われてきた。

特許とリサーチツール発明に関する法律は 2000 年以降より明確になってきた。CAFC の 2002 年の Madey 判決は、実験での使用の除外に関する法律の状態を表しているとして、特に、最高裁も議会も CAFC のアプローチを修正するために介在することを選択しなかったとして、だんだん認識されてきた。したがって、特許されたリサーチツールの使用は、大学での基礎研究にとっても、今や、排他的特許権の起訴可能な侵害と考えられている。法定除外の場合のみ、特許されたリサーチツールの使用が起訴可能な侵害を構成するかということについて、非常に不確かなままである。その意味で Merck 事件における最高裁の解釈、それに続く CAFC の差し戻し判決、及びその他最近の事件の広い言い回しは、除外が、少な

[8] Joshua D. Sarnoff, Practitioner-in-Residence & Assistant Director, Glushko-Samuelson Intellectual Property Law Clinic, Washington College of Law, American University

[9] Christopher M. Holman, Associate Professor of Law, University of Missouri, Kansas City School

くともいくつかの、法定除外の目的に非常に関連した発明の、リサーチツールの使用に適用されるかもしれないということを暗示している。

それと同時に、社会的な実務はもっと複雑になってきている。最近の研究では、大学の研究者も民間の研究者も実際の法律の状態を無視して、特許発明を特許権者の許可なく日常的に使用している、と説明している。このアプローチは、多くのリサーチツール特許権者は研究を制限するために特許を行使することはないだろうということを説明する他の研究に照らして正当化されているようにみえる。しかし研究は過度に制限され、法律上の権利の日常的な無視は安定した地位ではないかもしれない。診断や幹細胞の発明といったある状況では、リサーチツール特許の積極的な行使は公衆の批判を引き出し、大学や政府の新しいガイドラインは、リーズナブルな条件でリサーチツールを広くライセンスすることが進展してきた。」[10]

「特許侵害に対する実験での使用(experimental use)の除外及び法定除外(regulatory approval exception)に関する法律は長年にわたって変化してきた。最近、実験での使用の除外の範囲はCAFCによって狭く解釈されていて、大学又は民間の科学研究において使用される特許されたリサーチツールへの適用はほとんど妨げられている。一方、最高裁及びCAFCは法定除外を広く解釈していて、地裁は少なくともいくつかのリサーチツールについて除外を適用する判決を下しており、いずれはリサーチツールを使用するための販売への除外適用を認める判決がなされるかもしれない。

これらの司法上の進展は、大学や民間の科学者に実務上の対応の変化を引き起こしている。特許された技術へのアクセスや科学的な研究開発についての進展の効果は不確かなものであるが、かなりの割合の不利な効果は、これまでアクセス制限に対する現在機能している複数の解決策の適用によって避けられてきた。この解決策は広く認知された侵害行為とそれに伴う特許権者による特許行使からの自制(forbearance)を含んでいる。しかし、書籍上の法律と実務上の法律との間の不連続性は、もっと重大なアクセスの問題が現れるかもしれないという懸念を提出し続けている。

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[10] “I. Executive Summary”から抜粋

さらに、現在機能している解決策の安定性は、特に、様々な特許法の理論及び政府、大学、産業界におけるライセンス実務に起こっている重大な変化のに照らしてみると、不確かである。これらの変化に対する実際の実務の感度も不確かである。したがって、特許化の行動、発明への資金供与、及び特許権者のライセンス行動についてのこれらの変化及び引き続きおこるであろう又は外的な変化が、特許発明を研究で使用することに関するアクセスの問題を緩和するか又はさらに悪化するか、を予想することは難しい。確かなことは、実験での使用の除外又は法定除外の範囲の問題、そのリサーチツールへの適用、実際の反応、法律と実務の社会的な帰結、及び研究で使用するための特許発明のアクセスを保証するための法律上及び実務上の手段が、懸念事項であり続けるだろうし、注意深い調査と経験的かつ理論的な分析を保証し続けるだろうということである。」[11]

[11] “VIII　Conclusions”から抜粋

（ii）海外調査

資料番号										
対象国・機関	米国		分類	背景等	法令規則	判例	基準	指針指令	学説	その他
名称	海外調査結果の概要									
書誌的事項		Prof. Sarnoff, Prof. Holman								
		‘Recent Development in the United States Regarding the Law and Practical Application of Patents on Research Tool Inventions’								

調査結果　※詳細は資料編の海外調査結果の資料１を参照のこと。

概　要

本報告書では、リサーチツール及びリサーチツール特許について基本的な定義を提供し、実験での使用の除外(experimental use exception)及び法定除外(regulatory approval exception)の歴史及びそれらのリサーチツールへの適用について紹介し、判例における最近の進展、研究者及び特許権者の最近の実務(practice)についての研究、リサーチツールに関するライセンス・ポリシーの最近の変化について総括する。また広い「実験での使用の除外」の代替手段についての議論も簡単に紹介し、関連する学術論文も紹介する。

１．イントロダクション（定義）

本章では、本報告書におけるリサーチツール及びリサーチツール特許の基本的な定義を提供する。報告書の焦点は、研究で用いられる技術の発展のために特許権により与えられる財政的なインセンティブというよりも、潜在的な特許の義務(potential patent liability)及びそのような義務の科学研究における効果に関する動向であるので、広い定義が採用される。

“リサーチツール”は多くの定義があり、また非常に広い範囲の技術を包含するだろう。例えば、細胞株、遺伝子配列、分析方法、ソフトウェア、顕微鏡やレーザといった機器などの特許発明はすべてリサーチツールとして参照される。リサーチツールは科学研究では、特許の応用分野で開示されるように、しばしば使用目的によって定義される。広範囲に議論するためには、研究のためだけ又は主に研究のために開示された目的で特許された発明よりも、リサーチツールの定義をより広く考えなくてはならない。

より広義の“リサーチツール”は特許発明がおかれるであろう使用に焦点が当てられる。最近の連邦巡回裁判所（CAFC）の事件※1ではリサーチツールを以下のように定義した。

「科学者が研究室で使うツールであり、それは次のものを含む－細胞株、モノクロナル抗体、試剤、モデル動物、成長因子、コンビナトリアルケミストリー、DNA ライブラリー、クローン、（PCR※2の様な）クローニングンツール、方法、実験設備・器具。」

本報告では、より広い定義、すなわち、「リサーチツールとは、研究を実施す

る際に使われる特許技術であり、研究時にその技術自体が目的ではないもの。」を用いる。

※1 Integra LifeSciences I Ltd. V. Merck KGaA, 331 F.3d 860, 872 n.4(Fed.Cir.2003)
※2 polymerase chain reaction（ポリメラーゼ連鎖反応）

2．実験での使用の除外及び法定除外

（1）実験での使用の除外の最初及び初期の解釈
米国における実験での使用の除外は、19 世紀初頭、最高裁の Story 判示による2件の判決により初めて明瞭に表現された。

①Whittemore v. Cutter※3
1813年の本事件において、Story判示は以下のように述べている。
「このような機械を、ただ単に物理実験に使うためや、あるいは、記述された効果が達成できるか確かめるために作った人を罰することが立法者の意図ではない。」

※3 29F.Cas.1120(C.C.D.Mass.1813)(No.17,600)

当時の特許法は、特許発明を“生産し、改造し、行使し、販売する”いかなる人に対して義務を与えていて、行使せずに作ること(making without use)は排他権の侵害を構成することを明確にするために法令の言葉は修正されていた。
そこで、Whittemore判決は2つのどちらかで理解され得る、すなわち、特許により与えられた特定の権利の限界についての法的解釈か、あるいは、その当時のより広範な司法のコモン・ローを作る力と首尾一貫した、付与された権利に対して法的に課された例外であるか、である。その区別は本質的にもまた手続的にも重要である。最初のアプローチは、当初与えられた所有権の限界を定義し、2番目のアプローチは、所有権の行使に制限を課する。
どちらのアプローチが正しいかについての論争はまだ決着していないが、義務からの「コモン・ローによる」免除として、例外が非常に頻繁に言及されている。

Whittmore 判決は、特許侵害の例外についての二つの異なる理由にも明瞭に述べている。一つは哲学的(Philosophical)実験であること、もう一つは開示された利用法について特許発明が充足しているかを確かめるためである。例外についてのこれら二枝の範囲は、その後の2世紀において広範囲に渡る論争及び数多くの裁判事件の論題となってきた。

②Sawin v. Guild※4
Sawin v. Guild 事件において Story判示は、次のように、例外の範囲をさらに明らかにしようとした。
「作ることは特許の権利を侵害する意図があること、また権利者の発見に対する法律上の報酬を奪う意図があることである。」

※4 21 F.Cas.554(C.C.D.Mass.1813)(No.12,391)

1852年から1950年における数多くの裁判事件において、「法律上の利益を奪う意図」と言う基準の範囲を探る判決がなされた。この間、大学における科学的研究に関する事件は、たった1件だけである（Ruth v. Stearns-Roger Manufacturing Co.)。その事件では、特許された機械は単に実験室で実験的に使用され、その後切断され交換されたものであって、使用された部品の交換をすることによって侵害に当たることにはならないと判断された。

1950年に議会は、実験での使用の除外、すなわち、販売のためではなく“単に研究又は実験のために特許発明を生産し又は使用すること”を侵害から除外することを、明示的に成文化しようとする法律を提案した。
しかし、1952年、議会は明示的な実験での使用の除外を規定せず、271(a)条で生産し、使用し、販売する排他的権利及び侵害について現行の司法の基準を成文化しただけの修正特許法を制定した。

Section271　特許侵害
(a) 本法に別段の定めがある場合を除き，特許の存続期間中に，権限を有することなく，特許発明を合衆国において生産，使用，販売の申出若しくは販売する者，又は特許発明を合衆国に輸入する者は特許を侵害する。

（２）ボーラー判決
1984年にCAFCはRoche Products Inc. v. Bolar Pharmaceuticals Co. 事件で、ジェネリック薬のFDA認可のための特許使用を試験・研究のための免除に当たらないと判決した。FDA認可申請は明らかに商業的目的であるために免除されないと述べている。議会はそれに対し、立法措置※５により法的規制のための認可申請を特許権行使の免除対象として、発明者とジェネリック薬メーカーのバランスを取った。

※5　Section271(e)(1)、いわゆるボーラー条項の創設

Section271　特許侵害
(e)(1) 特許発明(動物用新規医薬品又は獣医学上の生物学的製品(当該用語は,連邦食品医薬品化粧品法及び1913年3月4日の法律における使用法に従う。)であって，主として組換えDNA，組換えRNA，ハイブリドーマ技術又は位置特定遺伝子操作技術を含む他の方法を使用して製造されたものを除く。)を，医薬品又は獣医学上の生物学的製品の製造，使用又は販売を規制する連邦法に基づく開発及び情報提出に合理的に関連する使用のみを目的として，合衆国内において生産，使用，販売の申出若しくは販売すること又は合衆国に輸入することは，侵害行為とはしないものとする。

（３）その後のCAFCの狭い解釈
1984年に議会が271条を修正してから、CAFCは実験での使用の除外と271(e)(1)条の法定除外の両方を狭く解釈している(2000年のEmbrex Inc. v. Service Engineering Corp.)。

2002年、Madey v. Duke University事件で、CAFCは初めて実験での使用の除外が大学で行われる科学的研究に適用されるかもしれないと判決した。CAFCは地裁判決を取消し、判例は“司法上作り出された実験での使用という

抗弁は、しかしながら、非常に限定された形態において”認識されるべき義務を負わせると判決した。

Madey 事件以降、実験での使用の除外を扱った地裁事件はほとんど報告されていない。扱った事件についても、除外の狭い範囲について反復して述べるか、拘束力のある判例として Madey 事件に言及するのみである。

（４） 実験での使用のより広い除外を成文化する法律の提案

Bolar 判決以降、議会は、実験での使用のより広い除外を成文化するために提案された法律を導入する機会が何度かあったが、これらの努力は法律の変更を採用するに至っていない。

例えば、1990 年、「研究又は実験の目的」であれば、免除対象にする法案が提出された。2002 年には遺伝子配列特許の研究での使用は製造や販売でなければ免除される法案を提出した。2007 年にはヌクレオチド配列等の特許化を禁止する法案を提出した。リサーチツールに関連するこのような法案は、バイオ産業界その他の強い反対により成立の見込みは立っていない。

学会では、試験・研究のための免除が広範囲に行使されることの必要性について長年議論されてきていて、大学・非営利の研究者による特許された技術の使用は広く免除されるようにすることを唱える者がいる一方、広い試験・研究のための免除により新しいリサーチツールを開発するインセンティブが削がれることを危惧する者もいる。多くの意見では、制限された試験・研究の免除、強制ライセンス、その他の手段を組み合わせたハイブリッドな制度が提案されている。

（５）メルク対インテグラ事件 －271(e)(1)条の裁判所の解釈

2003 年、Integra Lifesciences I Ltd. v. Merck KGaA 事件において、CAFC は 271(e)(1)条の法定除外を狭く解釈した。臨床前実験は、“FDA の安全性及び有効性を承認する手続きのための開発や情報の提供に合理的に関係した使用のみ”ではないとされた。

2005 年、Merck KGaA v. Integra Lifesciences I Ltd.事件で、最高裁判所は、271(e)(1)条の法定除外における CAFC の狭い解釈を覆した。最高裁は、除外は安全性や有効性のデータを発生させるテストに限定されず、FDA に提出されるデータを発生させるかもしれない、（生物学上の仕組みに関する基礎研究を含めて）いかなるテストも含むと判決した。

しかし最高裁は、特許されたリサーチツールに法定除外が適用されることを扱うことを明示的に断り、実験での使用の除外について扱わなかった。

（６）2005 年のメルク事件における最高裁判決以降の法定除外を解釈する判決

2005 年のメルク事件における最高裁判決以降の裁判事件では、271(e)(1)条の法定除外を広く解釈する傾向が生じているだけでなく、リサーチツールの免除を明確に拡張してきている。

- 2005 年の Classen Immunotherapies, Inc. v. Biogen IDEC 事件における地裁判決
- 2006 年の Genentech, Inc. v. Insmed Inc.事件の地裁判決
- 2006 年の Amgen, Inc, v. F. Hoffman-LaRoche Ltd.事件の地裁判決
- 2006 年の Classen Immunotherapies, Inc. v. King Pharmaceuticals, Inc.事件の地裁判決

・ 2007年の、最高裁からの差し戻し事件である Integra Lifesciences I Ltd. v. Merck KGaA事件の CAFCの多数意見
・ 2007年の Forest Laboratories, Inc. v. Ivax Pharmaceuticals, Inc. 事件の CAFC判決

2008年には、CAFCは Proveris Scientific Corp. v. Innovasystems, Inc. 事件（No. 07-1428）で取り扱うかもしれない（口頭弁論を行ってきた)。本事件は271(e)(1)条の免除の範囲を解決する可能性がある。

総括すると、CAFCは試験・研究の免除の範囲を狭く、それと同時に明確化してきて、その範囲の元ではほとんどの科学的研究は、大学の研究であれ、非営利の基礎研究であれ、免除が与えられない。一方、最高裁は、271(e)(1)条の法定除外の範囲を拡張し、それは広範囲の実験に適用されるだろうが、法定除外の範囲は不明瞭のままである。

（７）最近の議論と実務

Madey 判決後、当該判決の効果を評価するために、特に、リサーチツールとしての機能を意図する発明に関する特許が基礎的な科学的研究を妨げる又は遅らせるかについて、多くの研究がなされてきた。これらの懸念は、“アンチコモンズ”又は複数の特許のライセンスが必要とされる特許の藪－これによって、より高いコスト、遅延、そして重要な科学的研究（特にバイオメディカル及び遺伝子関連研究について）が放棄されるかもしれないということになる－の進展の可能性に関する初期の理論的研究を反映している。またこれらの懸念は、遺伝子発明が基礎的で、それゆえ遺伝子配列の特許は迂回し得ないということも反映している。

これらの研究の結果は、特許の（特に大学研究者の）義務の拡大された法律上の可能性が原因で、現在重大な問題を引き起こしているということはほとんどないことを示している。しかし、この結果の理由は、特許保有者が積極的に自らの特許を行使しておらず、また科学的研究者がそのような特許を（Madey判決に照らすと）侵害するやり方で行動しているからかもしれない。また、警告状や特許侵害を思いとどまらせるための大学における内部努力は増えているものの、研究者の行動に重大な効果はまだない、という研究結果も示されている。言い換えると、書籍上の法律と実務の間には大きなギャップがあり、現在の状況の安定性は重大な関心事であり続けるということである。

３．特許化及びライセンスポリシー及び実務の最近の変化

相当の割合のリサーチツール特許、特に遺伝子及びバイオメディカルの研究に関するものは政府資金による研究や大学での研究から起こっている。それゆえ、リサーチツール特許は研究やイノベーションを妨げるかもしれないという懸念を処理する一つのアプローチは、これらの機関が、特許されたリサーチツールへの広く非差別的な利用を奨励する特許化及びライセンス実務を取り入れることを促進することである。

米国におけるバイオメディカル研究への資金配分の主要源である NIHを含む、政府資金配分機関は、内部ポリシーや外部への資金配分実務を行っており、ガイドラインを公表している。これらの実務やガイドラインは、いくつかの発明を特許化することを思いとどまらせることや、バイオメディカルの

リサーチツールを普及し利用することを推進するライセンスポリシーを促進することに向けられている。
大学も、リサーチツール特許の逆効果の可能性についての懸念を処理することに向けられた特許化やライセンス実務を取り入れてきた。

例えば、1999 年、NIH は、NIH 資金のリサーチツールが広く利用されることを推進する実務をグラント受託者が採用することを推奨する、リサーチツール・ガイドラインを発行した。

2005 年、NIH は、“遺伝子発明のライセンスのベストプラクティス”の最終通知を発表した。この“遺伝子ベストプラクティス”は、リサーチツール・ガイドラインと大概のところ首尾一貫しているが、法律的に縛られない規則としてベストプラクティスの推奨を表すことをもっと明示的に明らかにしている。

DNA 特許を最も多く取得した３０の米国の大学研究機関についての最近の調査では、ライセンス実務は NIH のリサーチツール・ガイドラインと遺伝子ベストプラクティスに大部分が一致していることを研究者は認めている。

いくつかの最も有名な米国大学のある連合は、最近、リサーチツール発明の広い普及と利用を奨励する技術ライセンスのガイドラインを採用することを確認し推奨する文書“九点文書※６”を公表した。

※6　In the Public Interest: Nine Points to Consider in Licensing University Technology (2007)

また、ウィスコンシン大学の技術ライセンス機関である WARF※７は、2007 年１月 23 日、大学及び非営利の研究者の利用条件を改善する、ライセンスポリシーの変更を公表した。

※7　Wisconsin Alumni Research Foundation

特許されたリサーチツールに関する産業界のライセンス実務の研究は、一般には入手できていないが、商業機関が保有しリサーチツールとして使用される特許に関する現在のライセンス環境にもっとまとまった評価を与えるためには必要とされる。

これらの新しい特許化及びライセンスポリシーの効果はまだ評価されていない。しかし、これらのポリシーは、進展する科学的研究で使用される特許された技術を利用することの制限をある程度改善しそうだ。

４．侵害に対する実験での使用の除外及び法定除外の代行手段

（１）強制実施(Compulsory Licensing)
強制実施は、侵害に対する実験の使用の除外及び法定除外の研究や製品開発における代行手段として有効な手段として取り上げられている。

経緯

強制実施の規定は、米国特許法の 1952 年改正で導入の可能性が検討されたが、最終法案が提出される前に法案草稿から削除された。

その後 2005 年に、ヘルスケアの非常時に関するある特許発明の強制実施を提供するであろう法案が議会提出されたが、法案は成立しなかった。

現在議会で検討中の特許改正法案は強制実施の規定を含んでいない。特許制度についての 2004 年の NAS※10 の報告書で述べられているように、産業界において、また特許権者の間には、強制実施のいかなる形態に対して敵意がある。

現状

米国法は特許された技術の強制実施をある限定された形で与えており、例えば大気清浄法（Clean Air Act）は、法律で強制された汚染制御基準に合う代替物を使用できない者に対して汚染制御装置の特許の強制実施を与える。

しかしながら、現在ある強制実施の規定は特許されたリサーチツール、特にバイオメディカル研究の文脈で用いられるリサーチツールの使用に、もしあったとしてもほとんど関連がない。

※10　National Academy of Science

（２）リーチスルー・ライセンス契約

リーチスルー契約は研究により得られた最終製品に対しても特許権を及ぼす契約であり、反トラスト法、特許法に違反する可能性を持っている。また、アンチコモンズの問題を大きくすると言うものもいる。

（３）パテントプール

米国のバイオテクノロジーの業界団体である BIO※８は、自発的なパテントプールは“特許が重なり合うことについての懸念に対する最も重要かつ可能性を秘めた解決策の一つ”であると述べている。同様に、米国特許商標庁は、パテントプール白書※９を出して、特許されたリサーチツールの利用を促進する方法としてパテントプールの利用を議論している。特許制度に関する 2003 年のＦＴＣ報告では、パテントプールに必然的に伴う集中管理は、ロイヤルティーの積み上がりの問題を避けることに役立つかもしれないと述べられている。

※ 8　Biotechnology Industry Organization

※ 9　Patent Pools: A Solution to the Problem of Access and Biotechnology Patents?

しかしながら、高い取引コストは遺伝子発明においてパテントプールを形成し利用する能力を実質的に制限するかもしれないと疑問を示す意見がある。これらの技術は、標準と内部操作性(interoperability)が重要であるためにパテントプールがより頻繁に用いられているエレクトロニクス分野とは基本的に異なっていると述べられている。さらに、バイオテクノロジー発明の予測可能性がより乏しいこと、またバイオテクノロジー企業がライセンス収入を最大化することにより大きく頼っているかもしれないことが、個々の特許権者がパテントプールの標準的なライセンス条件に参加し又は賛同するインセンティブを減らしているかもしれない。

しかし具体的なリサーチツールのパテントプールを作り出すための様々な提案がなされている。例えば、DNA マイクロアレイの先進企業であるAffymetrix は、遺伝子のパテントプールを作ることを提唱している。欧州の学者のあるグループは、診断テストの利用のために遺伝子技術の利用を促進するためにパテントプールを利用する可能性について議論する雑誌をシリーズで刊行している。カリフォルニア再生医学研究所及びその他の幹細胞研究の資金提供者のためのパテントプールも提案されている。

同様のアプローチはバイオメディカルのリサーチツールに有用であることが証明されるかもしれない。しかし、これまでのところパテントプールはバイオテクノロジー分野において重要な役割は果たしていない。バイオテクノロジーのパテントプールで最もよく知られた事例は、おそらく、“ゴールデン・ライス”を生産するための運営の自由を与えるべく、急いで作り上げまとめられた特許権の収集である。ゴールデン・ライスは商業的には適切な作物とは考えられておらず、プールの元でのライセンスは、本質的に人道的理由で、対価なしで与えられていた。SARS の研究に関連した特許のプールを作る試みもなされたが、この試みが完成したという報告はまだなされていない。

（iii）国内外文献調査

資料番号										
対象国・機関	米国		分類	背景等	法令規則	判例	基準	指針指令	学説	その他
名称	米国特許法									
書誌的事項			合衆国法典第 35 巻 (35 U.S.C. Title 35 of the United States Code) 出典：下記文末を参照							

試験・研究の例外

米国特許法では、いわゆる「試験・研究の例外」に関する明文の規定はない。
ただし、FDA※承認との関係における権利の効力の除外について、271 条(e)(1)において以下のとおり規定されている。

第271 条　特許侵害
(e)(1) 特許発明(動物用新規医薬品又は獣医学上の生物学的製品(当該用語は，連邦食品医薬品化粧品法及び1913 年3 月4 日の法律における使用法に従う。)であって，主として組換えDNA，組換えRNA，ハイブリドーマ技術又は位置特定遺伝子操作技術を含む他の方法を使用して製造されたものを除く。)を，医薬品又は獣医学上の生物学的製品の製造，使用又は販売を規制する連邦法に基づく開発及び情報提出に合理的に関連する使用のみを目的として，合衆国内において生産，使用，販売の申出若しくは販売すること又は合衆国に輸入することは，侵害行為とはしないものとする。

35 U.S.C. 271Infringement of patent
(e)(1) It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

※ Food and Drug Administration

出典：
英文
http://www.uspto.gov/web/offices/pac/mpep/documents/appxl_35_U_S_C_271.htm
日本語文（日本国特許庁の仮訳）
http://www.jpo.go.jp/shiryou/s_sonota/fips/pdf/mokuji/us_tokkyo1.pdf

資料番号										
対象国・機関	米国　NIH		分類	背景等	法令規則	判例	基準	指針指令	学説	その他
名称	NIH ガイドライン									
書誌的事項	1999.2		Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources: Final Notice http://ott.od.nih.gov/policy/rt_guide_final.html							

調査結果

概要

ガイドラインの基本的な目的と理念
(1)Reasonable terms and conditions for making NIH-funded research resources available to scientists in other institutions in the public and private sectors (disseminating research tools)
(2) restrictions to accept as a condition of receiving access to research tools for use in NIH-funded research (acquiring research tools)

（公的資金を原資とする）知的財産権の保護と特許使用の円滑化

○バイドール法の履行(2.Appropriate Implementation of the Bayh-Dole Act)
リサーチツールへの広範なアクセスをするため、Bayh-Dole 法の履行(公的助成で行なった研究成果について商業的開発を奨励する）が必要であるとしている。

○ リサーチツールの普及
(Dissemination of Research Resources Developed with NIH Funds)

使用を認める対象となるリサーチツール
研究成果が下記に該当する場合（ひとつ以上）には、他機関等での異なる使用方法、製品での使用を認めること。
(1)リソースの主な用途が FDA の承認対象物ではなく、研究のためのツールである
(2)リソースは限られた用途ではなく、多数の研究者にとって汎用性があり、発明を促進するために有用である。
(3)ツールとして、直ぐに使用・普及できること（更なる開発不要)。

Simple Letter Agreement の使用
-非営利団体への移転は UBMTA(Uniform Biological Materials Transfer Agreement) 以上に制限しない。
-特許化されていないツールの、他の NIH 資金提供プロジェクトへの移転は、Simple Letter Agreement 等の使用が望ましい。
-特許化された、または排他的にライセンスされたツールでは他の Agreement の使用が適切と思われるが、商業化オプション、リーチ・スルー・ロイヤリティ、最終成果物のアサインバック・グラントバックは不適切である。
-営利団体の internal use では障害が起こらないように移転する。

考察、備考等

開発されたツールの普及のための奨励事項

NIH の資金により開発されたツールの普及のための奨励事項などが記載され、普及に力が入れられている。

(4) EU(European Union;欧州連合)

（ｉ）概要

経緯・背景、動向

CPC(Community Patent Convention：共同体特許条約)は未発効であるが、構成国の国内法に取り入れられ、構成国間のハーモナイゼーションに寄与している。特許発明の主題に関し実験目的でなされる行為に対する特許効力の除外、強制実施権について規定されている。

法令･規則

EPC(European Patent Convention;欧州特許条約）では、欧州特許付与後の特許権は各国法の下で扱われ、侵害も各国法の定めに依拠しているため、必然的に特許権の侵害に対する免責である「試験・研究の例外」に関する規定はない。また、強制実施権に関する規定もない。

CPC の第 27 条（b）において、特許発明の主題に関し実験目的でなされる行為には、共同体特許に基づく権利は及ばないと規定されている。

CPC では、第 45-47 条に強制ライセンス(compulsory licences)について規定されている。

指針（ガイドライン）･指令と運用・利用状況

EC バイオ指令では、バイオ関連発明の特許の保護対象としての適格性、特許権者に基づく排他的権利及びその制限に関する条文を有し、「試験・研究の例外」を視野に入れている。構成国におけるバイオ関連発明に関する「試験・研究の例外」の導入が意図されている。

（ii）国内外文献調査

資料番号										
対象国・機関	EU		分類	背景等	法令規則	判例	基準	指針指令	学説	その他
名称	欧州（及び共同体）での特許条約									
書誌的事項	1977 年発効 1989 年及び 2000 年改正		EPC(European Patent Convention;欧州特許条約) http://www.epo.org/patents/law/legal-texts/html/epc/2000/e/ma1.html 日本語訳（日本国特許庁の仮訳） http://www.jpo.go.jp/shiryou/s_sonota/fips/epo/pc/mokuji.htm							
	1989 年 (未発効)		CPC(Community Patent Convention：共同体特許条約) http://legis.obi.gr/ESPACEDVD/legal_texts/LAWS_E/eu_cvn04.htm							

調査結果

概要

共同体特許条約（CPC）は未発効であるが、構成国の国内法に取り入れられ、構成国間のハーモナイゼーションに寄与している。

試験・研究の例外については発明の主題に関する実験目的の免責が、強制実施権については不実施と利用関係の場合が規定されている。

試験･研究の例外

EPC

・欧州特許付与後の特許権は各国法の下で扱われ、侵害も各国法の定めに依拠しているため、必然的に特許権の侵害に対する免責である「試験・研究の例外」に関する規定はない。

EPC の附属議定書

・2001 年に、EPO(European Patent Office; 欧州特許庁) 当事国はパリ政府間協議において、共同体内で統一的な司法制度を実現させるために、EPC の附属議定書の起草を決定し、作業部会を設置した。

・公表された欧州特許裁判所の規程の草案では侵害及び間接侵害行為等の実体規定は、CPC のものを原則踏襲したとされており、第 35 条の(b)は、CPC の第 27 条(b)と同様である。

CPC

・第 27 条（b）において、特許発明の主題に関し実験目的でなされる行為には、共同体特許に基づく権利は及ばない、と規定されている。

Article 27
Limitation of the effects of the Community patent

The rights conferred by a Community patent shall not extend to:
(a) acts done privately and for non-commercial purposes;
(b) acts done for experimental purposes relating to the subject-matter of the patented invention;

裁定（強制）実施権

EPC

・強制実施権に関する規定はない。

CPC

・第 45-47 条に強制実施権(compulsory licences)が規定されている。

「①強制実施権（CPC 第45 条）
・共同体特許について付与された強制実施権の範囲及び効果は、関連する領域に限定される。
・各CPC 締約国は、少なくとも強制実施権に対する補償について、司法裁判所への上告に関する規定を設けなければならない。
・実務当局は、共同体特許に強制実施権が設定された時には欧州特許庁に対してその事実を知らせなければならない。
・共同体特許条約の目的にかんがみ、「強制実施権」という言葉には、公的なライセンスや公共の利益のための特許発明の使用に関する権利も含まれるものと解釈される。
②不実施の場合（CPC 第46 条）
・あるCPC 締約国で製造された特許製品が、他のCPC 締約国の市場での需要を満たす十分な量が供給されていれば、当該共同体特許に対し強制実施権は設定されない。
③利用関係の場合（CPC 第47 条）
・利用関係については、当該特許権が共同体特許と国内特許との関係や共同体特許同士の関係に当たる場合についても適用される。」

（出典）産業構造審議会 知的財産政策部会特許制度小委員会 特許戦略計画関連問題ワーキンググループ「特許発明の円滑な使用に係る諸問題について」2004 年 11 月　第 67 頁
http://www.jpo.go.jp/shiryou/toushin/shingikai/pdf/strategy_wg_prob/00.pdf

Article 45
Compulsory licences

1. Any provision in the law of a Contracting State for the grant of compulsory licences in respect of national patents shall be applicable to Community patents. The extent and effect of compulsory licences granted in respect of Community patents shall be restricted to the territory of the State concerned. Article 28 shall not apply.

2. Each Contracting State shall, at least in respect of compensation under a compulsory licence, provide for a final appeal to a court of law.

3. As far as practicable national authorities shall notify the European Patent Office of the grant of any compulsory licence in respect of a Community patent.

4. For the purposes of this Convention, the term 'compulsory licences' shall be construed as including official licences and any right to use patented inventions in the public interest.

Article 46
Compulsory licences for lack or insufficiency of exploitation

A compulsory licence may not be granted in respect of a Community patent on the ground of lack or insufficiency of exploitation if the product covered by the patent, which is manufactured in a Contracting State, is put on the market in the territory of any other Contracting State, for which such a licence has been requested, in sufficient quantity to satisfy needs in the territory of that other Contracting State. This provision shall not apply to compulsory licences granted in the public interest.

Article 47
Compulsory licences in respect of dependent patents

Any provisions in the law of a Contracting State for the grant of compulsory licences in respect of earlier patents in favour of subsequent dependent patents shall be applicable to the relationship between Community patents and national patents and to the relationship between Community patents themselves.

考察、備考等

試験･研究の例外

・EU 法上で、大学等における「試験・研究」行為の特許権侵害の懸念について、特にあてた法的文書はない。
・（未発効であるが）CPC はドイツ他の一部構成国の国内法に取り入れられ、構成国間のハーモナイゼーションに寄与している。

裁定（強制）実施権

・EU 法に基づく共同体レベルの強制実施権の付与については、現在のところ事例がない。
・EU レベルにおいて、ブロッキング特許及びリサーチツール特許の問題の解決に関して強制実施権制度に言及した例はない。

資料番号										
対象国・機関	ＥＵ		分類	背景等	法令規則	判例	基準	指針指令	学説	その他
名称	EC バイオ指令									
書誌的事項	1998		EC バイオ指令 注：出典は下記文末を参照							

調査結果

概要

発明の特許の保護対象としての適格性、排他的権利及びその制限に関する条文を有し、構成国におけるバイオ関連発明に関する「試験・研究の例外」の導入が意図されている。

（出典）
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:1998:213:0013:0021:EN:PDF

試験･研究の例外

・直接触れた条文はない。
・バイオ関連発明の特許の保護対象としての適格性、特許権者に基づく排他的権利及びその制限に関する条文を有し、「試験・研究の例外」を視野に入れている。
・構成国におけるバイオ関連発明に関する「試験・研究の例外」の導入が意図されている。

資料番号											
対象国・機関	ＥＵ			分類	背景等	法令規則	判例	基準	指針指令	学説	その他
名称	「公的資金による研究機関における知財管理」報告書										
書誌的事項	2004			Expert group report ‘Management of intellectual property in Publicly-funded research organisations: Towards European Guidelines’, European Commission 注：下記出典を参照							

調査結果

概要

・欧州委員会(EC)の研究部門(Research DG)により、“公的資金による研究における知的財産の問題”に関する専門家グループが組織された。外部専門家のグループが招聘され、本論題について議論し、公的資金による研究機関における知財管理に関する一連の勧告がなされ、欧州のガイドラインの進展の基礎として提供され得る。本報告書には背景、問題の領域、現状のレビューが含まれ、公的研究機関（大学含む)、産業界、公共機関による行動の選択の調査がなされている。

・報告書の 2.6 項「知財ポートフォリオの専門的管理」では、知的財産保護、第三者の知的財産権の尊重、研究免除(Research Exemption)、材料移転契約(MTA)、機密情報について述べられている。

試験･研究の例外

・公的研究機関の研究に対し適正評価(due diligence)を実施する際に、特定の知的財産権と研究上の実務の関係に注意することが重要と指摘している。

裁定（強制）実施権

・言及なし

発明の特許性

・言及なし

（公的資金を原資とする）知的財産権の保護と特許使用の円滑化

・公的機関は非営利団体であるために、特許侵害その他の問題によって影響を受ける機会は稀であると認めつつ、これら機関が第三者の知的財産権に対する脅威に映る場面が増える可能性があると指摘している。

その他

・「オープン・サイエンス」モデルや「イノベーション・モデル」についても言及されている。

（出典）
http://ec.europa.eu/research/era/pdf/iprmanagementguidelines-report.pdf

（５）英国

（ｉ）概要

経緯・背景、動向

1977 年特許法で EPC との調和が取られ、その後 EC バイオ指令が 2000 年から 2002 年にかけて 3 段階を経て導入された。2004 年改定は主に EPC2000 への整合がはかられた。

EPC との調和が図られ、一般的な試験・研究の例外や、強制実施権が規定されている。大学等に特定した試験・研究の例外条項や、後発医薬品の臨床試験に関する例外条項は無い。また強制実施権については、1999 年改正以降の現行制度の下で付与された事例はない。

法令･規則

第 60 条［侵害］の第 5 項に試験・研究の例外に関し、(a)私的かつ非商業的な目的／(b)対象に関する試験的目的が規定されている。

強制実施権に関しては、第 55 条から第 59 条に規定があり、特許庁長官は、 (a)ライセンスの条件の取消し又は修正等／(b)及び／又は、ライセンス・オブ・ライト(同法第 46 条及び第 49 条)としての強制的な登録を命じることができる。

判例

－Smith Kline, French Laboratories v Evans 裁判（1988 Patents Court)：Smith Kline(SK&F)の医薬の３特許（A、B、C）に関する侵害訴訟で、裁判所は、「最終的に商業目的であっても、クレームされた発明に直接的に関連するものでなければならない、被告は原告の特許 C の異議申立のために特許 B を使っており、試験・研究の例外には該当しない」とした。

－McDonald v Graham 裁判（1993 Court of Appeal)：原告が特許を持つ印刷物シートを、原告のコンサルタントだった被告が入手し第三者に配布した事件で、控訴審は「被告は自身のビジネスのために保有し使っており、明らかに商業目的であって試験・研究の例外には該当しない」とした。

－Thomas Ralph Auchinloss 他 v Agricultural & Veterinary Supplies 他裁判（1998 Reports of Patent Cases 397)：被告の殺生物剤化合物が

原告特許に抵触するか否かが争われた裁判の中で、被告は農水省への提出試料に試験・研究の例外を求めたが、控訴審は、「農水省への提供は認可が目的あって、未知のものの発見や仮設の検証でもなく、試験・研究の例外に該当しない」とした。

（ii）海外調査

資料番号										
対象国・機関	英国		分類	背景等	法令規則	判例	基準	指針指令	学説	その他
名称	海外調査結果の概要									
書誌的事項		Prof.Jeremy Phillips								

調査結果　※詳細は資料編の海外調査結果の資料 2 を参照のこと。

概要

・判例を中心とした調査研究である。

試験･研究の例外

法令

・判例

① Monsanto Co v Stauffer Chemical Co and another
[1985]Reports of Patent Cases 515.31 July 1984(Patents Court),
11 June 1985 (Court of Appeal)

除草剤の差止め仮処分に対する試験・研究の例外適用を求めた訴えに対し、一審は、

・試験・研究の例外はその発明に対してのものであり、その商業化は該当しない
・私的でなければならず、第三者への提供はできない
・小規模であり、その発明に対して新たな知見を得るものでなければならない

とした。控訴審ではほぼ一審を支持しながら、更に

・試験・研究の例外が適用される試験は、通常の英語“experiment”の意味であり、商業目的であっても該当する。

とした。この決定に対して、不明確との指摘がある。

② Smith Kline & French Laboratories Limited v Evans Medical Limited
[1989]Fleet Street Reports 513, 10 November 1988(Patents Court)

Smith Kline(SK&F)のシメチジン薬の三件の特許（A、B、C）に関する侵害訴訟で、裁判所は、

・最終的に商業目的であってもよいが、クレームされた発明に真に直接的に関連するものでなければならない。
・被告は原告の特許 C の異議申立のために特許 B を使っており、試験・研究の例外には該当しない

とした。

③ McDonald and another v Graham
[1994]Reports of Patent Cases 407, 16 December 1993(Court of Appeal)

原告が特許を持つ印刷物シートを、原告のコンサルタントだった被告が入手し第三者に配布した事件で、被告は試験・研究の例外を求めたが、控訴審は、

・被告は自身のビジネスのために保有し使っており、明らかに商業目的であって試験・研究の例外には該当しない、

とした。

④ Thomas Ralph Auchinloss and Antec International Ltd v Agricultural & Veterinary Supplies Ltd., Vincent Rooney, South Western Chics Ltd and South Western Chicks (Warren) Ltd
[1999] Reports of Patent Cases 397, 29 October 1998.
[1998]EWCA(Civ.)1642

被告の殺生物剤化合物が原告特許に抵触するか否かが争われた裁判の中で、被告は農水省（MAFF, Ministry of Agriculture, Fisheries and Food）への提出試料に試験・研究の例外を求めたが、控訴審は、MAFFへの提供は認可が目的あって、未知のものの発見や仮設の検証でもなく、試験・研究の例外に該当しないとした。

国内・政界・法曹界・学会の動向

・特許を使う立場にもなりまた使われる立場にもなること、試験や研究での特許使用が特許権者に見つかりにくいことから、何か対策すべきか否かやどのようにすべきかについて殆ど総意は得られていない。
・ガワース報告（Gowers Review of Intellectual Property (December 2006)）は、1977年特許法第60条(5)(b)の下で現在規定されているものより明確かつより広い研究除外(research exception)に有利な法律の制定を労働党政府に代わって示している。報告では次のように述べられている：

“4.11　実験での使用の除外(experimental use exception)は研究者が発明を調査し、習得し、改善することができるように、明確にされなければならない。最近変更されたスイスの研究除外はより明確な除外の好例となっている。
4.12　スイスの線に沿って研究除外を明確にすることは、権利者の利益を損なうことなく研究を促進するだろう、と本報告は信じている。”

・現行法に対する司法界からの意見表明の機会はなく、認知できる法曹界の動向はない。
・学会では、特許権者と調和しながらも試験・研究の例外は最大限認められるべきというのが支配的で、特に著作権法に関して強く表明されている。

（iii）国内外文献調査

資料番号										
対象国・機関	英国		分類	背景等	法令規則	判例	基準	指針指令	学説	その他
名称	特許法									
書誌的事項	1977/2004(改定)		特許法							
			出典：下記考察･備考等の欄を参照							

調査結果

概要

・1977 年特許法で EPC との調和が取られ、その後 EC バイオ指令が 2000 年から 2002 年にかけて 3 段階を経て導入された。2004 年改正は主に EPC2000 への整合。

・EPC との調和がとられ、一般的な試験・研究の例外や、強制実施権が規定されている。大学等に特定した試験・研究の例外条項や、後発医薬品の臨床試験に関する例外条項は無い。また強制実施権については、1999 年改正以降の現行制度の下で付与された事例はない。
EC バイオ指令はそのままの形で導入されているが、特に審査段階で産業応用性（有用性）など特許要件の厳格な適用で対応しているとされている。

試験･研究の例外

・第 60 条［侵害］の第 5 項に以下が規定されている。

第 60 条　侵害の意味
(5) 本項がなかったならば発明の特許の侵害を構成する筈である行為は，次の何れかに該当するときは，その特許の侵害を構成しない。
(a) それが私的に，かつ，商業以外の目的で実行されること
(b) それがその発明の内容に係わる実験目的で実行されること

Meaning of infringement
60.(5)An act which, apart from this subsection, would constitute an infringement of a patent for an invention shall not do so if-
(a) it is done privately and for purposes which are not commercial;
(b) it is done for experimental purposes relating to the subject-matter of the invention;

裁定（強制）実施権

・強制ライセンス(compulsory licenses)について第 48 条から第 54 条に規定。

･また第 55 条から第 59 条に“国の業務のためにする特許発明の実施(Use of patented inventions for services of the Crown)”が規定されている。

・付与の根拠は以下である。
(1)不実施／不十分実施の場合

(2)合理的ライセンスの拒絶で、利用関係後発発明の実施、商業上産業上の活動の確立又は発展が不当に阻害される場合
(3)ライセンス条件により、特許権の保護を受けていない材料の生産、使用等や商業・産業活動の確立・発展が不当に阻害される場合

・付与の条件は以下である。
(1)特許付与の日から3年経過後/(2)国家事業のため/(3)特許権者の損失に見合う額を補償

・特許庁長官は、以下を命じることができる。
(1)ライセンスの条件の取消し又は修正等
(2)及び／又は、ライセンス・オブ・ライト(同法第 46 条及び第 49 条)としての強制的な登録

発明の特許性

・英国は EC バイオ指令をそのまま導入している。

考察、備考等

試験・研究の例外

・2005 年 2 月時点で成文法の改正は企図されていない。
・大学等の試験・研究の例外条項／後発医薬品の臨床試験に関する例外条項は無い。

裁定（強制）実施権

・主として英国内の市場への供給を目的とする。
・1997 年 5 月現在、1977 年特許法の下で 2 件付与されたことがあるが、1996 年 1 月 1 日時点ですべて失効している。
・現行制度（1999 年改正以降）の下で強制実施権が付与された事例なし

発明の特許性

・バイオ関連発明に対しては、特に産業応用性（有用性）など特許要件の厳格な適用で対応しているが、判例や EPO 決定がまだない状況なのでそれが支持されるかは不確定である。
・バイオ関連発明のリーチスルークレームに関して法には特に記述はないが、英国特許庁は米国連邦裁判所判断（ロチェスター大事件）と同様に記載不十分として拒絶する立場をとる。

（出典）英国特許法
英語：http://www.opsi.gov.uk/acts/acts2004/ukpga_20040016_en_1
日本語（特許庁仮訳）
http://www.jpo.go.jp/shiryou/s_sonota/fips/pdf/england/tokkyo.pdf

資料番号										
対象国・機関	英国			分類	背景等	法令規則	判例	基準	指針指令	学説	その他
名称	研究コンソーシアム SC4SM の特許ポリシー									
書誌的事項	2007			Intellectual Property Rights (IPR) Policy http://www.sc4sm.org/wp-content/uploads/2007/10/_2007-09-sc4sm-ip-policy-final-draft.pdf						

調査結果

概要

・ 幹細胞を使った新薬候補の毒性試験技術開発の官民コンソーシアム SC4SM(2007 年 10 月発足)の知財権取扱ポリシー

・幹細胞を使った新薬候補の毒性試験技術開発の官民コンソーシアム SC4SM では、参加者(社)との間で契約を締結し、プロジェクトの成果特許およびそれに関連する各社独自の特許について、非排他的ライセンスされるように規定している。

・バックグラウンド IPR の扱いなど、きちんとした特許対策を取ることを明記している。

試験･研究の例外

・試験・研究の例外の適用については全く言及しておらず、むしろバックグラウンド IPR の扱いなど、きちんとした特許対策を取ることを明記している。

（公的資金を原資とする）知的財産権の保護と特許使用の円滑化

・研究開発の推進のため、IPR の利用を容易にする仕組みを作っている。

・フォアグラウンド特許（プロジェクトの成果特許）の扱い
－成果特許は SC4SM に帰属することとし、その旨 Project Agreement に明記する。
－SC4SM はメンバーに対し、メンバーであった期間の成果 IPR について研究目的に限った非排他的／無期限／無償／全世界対象のライセンスを与える。
－SC4SM はプロジェクト参加者（社）に対し、プロジェクト成果 IPR について研究目的に限った非排他的／無期限／無償／全世界対象のライセンスを与える
－SC4SM は第３者からの申し入れに対し、役員会の承認の下、研究目的に限って個別の条件で非排他的ライセンスを与える。
－SC4SM はメンバー／プロジェクト参加者（社）／第３者からの商業的実施の申し入れに対し、役員会の承認の下、個別の条件で非排他的ライセンスを与える。

・バックグラウンド特許（プロジェクトの成果でないが関連する特許）の扱い
－メンバーおよび参加者（社）は、各自のバックグラウンド特許を適切･合理的条件で SC4SM や他者（社）にライセンスすることを期待。
－プロジェクト開始時には、バックグラウンド特許を選定し Project Agreement で明確化。
－プロジェクト実施時にメンバーは SC4SM に対し、バックグラウンド IPR の非排他的／無期限／無償／全世界対象／再実施許諾可能ライセンスを与え、他者（社）がプロジェクト中に使えるようにする。
－プロジェクト実施時、参加者（社）および SC4SM は他参加者（社）に対し、プロジェクト実施に必要なバックグラウンド IPR の非排他的／無償／全世界対象のライセンスを与える。
－成果 IPR のライセンスに際し、成果 IPR の遂行に必要なバックグラウンド IPR に

ついても SC4SM が再実施許諾可能なものはその目的に限定してライセンスを行う。

考察、備考等

研究コンソーシアム SC4SM について

・政府関係機関から 5 組織（各£15 万出資)、および民間から 3 社（各£10 万出資)をメンバーとして非営利の「Stem Cells for Safer Medicines Ltd.」（£105 万）を 2007 年に設立しており、更に新たなメンバーを募っている。
  ・政府系機関：保健省（Dept. of Health)、イノベーション・大学・職業技能省（Dept. for Innovation, Universoties and skills)、スコットランド政府（Scottish Government)、医学研究評議会（Medical Research Counsil)、バイオテクノロジー・生物科学研究評議会（Biotechnology and Biological Sciences Research Council)
  ・民間会社：アストラゼネカ（AstraZeneca 英)、グラクソ・スミスクライン（GlaxoSmithKline 英)、ロシュ（Hoffman-La Roche スイス)
・新薬開発の早期段階で毒性スクリーニングに使える幹細胞の、オープンな標準、手順の研究開発推進を目指しており、治療での使用の研究は対象としていない。
・知財権の扱いの原則を示しており、資金提供する研究プロジェクト実施に際しては参加者（社）との間で個別に具体的な Project Agreement を締結する。Project Agreement は基本的には IPR ポリシーに準じるが、役員会の承認の下に柔軟な対応も可能。

SC4SM：http://www.sc4sm.org/

資料番号									
対象国・機関	英国	**分類**	背景等	法令規則	判例	基準	指針指令	学説	その他
名称	Nuffield 報告書								
書誌的事項	July 2002	“The ethics of patenting DNA”, Nuffield Council on Bioethics http://www.nuffieldbioethics.org/fileLibrary/pdf/theethicsofpatentingdna.pdf							

調査結果
概要
・生命倫理に関する非営利の独立法人であるナフィールド委員会（Nuffield Council on Bioethics）が 2 年間にわたって検討し、問題の明確化と更なる議論のために提言としてまとめた。 ・試験・研究の例外の範囲の明確化を提言し、また公的研究機関（私企業もできる限り）はリサーチツールとしての DNA 配列の特許は排他的ライセンスをしないよう提言している。強制実施権については、公衆の利益に適合しない特定のケースに限定すべきとする。DNA 配列を用いた特定の診断試験の特許は有用だが、DNA 配列自体の特許は審査基準を厳格に適用すべきであり、特にリサーチツールとしての DNA 配列の特許は認めるべきでなく、米国の有用性ガイドラインは好ましい。
試験･研究の例外
・欧州では多くの国で試験・研究の例外が法制化されているがその範囲は明確ではなく、また米国では法制化されておらず慣習法的にも限定されている。米国での法制化と欧州での明確化を提言する ・産業界も、協力して、研究に使われる DNA 配列に試験・研究の例外の概念を広げていくことを提言
裁定（強制）実施権
・強制実施権はむやみに適用すべきでなく、診断試験に用いる DNA 配列特許が独占的で公衆の利益に適合しない特定のケースに限って認めるべき
発明の特許性
・DNA 配列に関する成立済み特許で正当性が疑われるものが多くある ・診断試験に用いる DNA 配列特許（product patent）は、特に発明性（進歩性）に関する審査基準を厳格に適用すべき ・DNA 配列を用いた特定の診断試験の特許（use patent）は、発明者に報いるためにも代替方法の開発のためにも効果的 ・リサーチツールとしての DNA 配列の特許を認めることはやめるべき。ルーチン的に見出された配列で明確な用途を示せないものは特許要件に適合しない。米国の有用性ガイドラインは好ましい ・病気に関連した遺伝子が分かれば遺伝子組み換え治療に使えるのは自明であり、そのような配列特許（product patent）は認めるべきではない ・新薬・治療用タンパク質を作るための DNA 配列の特許は許容できるが、記述されたタンパク質に限るよう狭く限定すべき。

（公的資金を原資とする）知的財産権の保護と特許使用の円滑化

・公的研究機関はたとえ短期的に回収が減ったとしても、また私企業もできる限り同様に、リサーチツールとしての DNA 配列の特許は排他的ライセンスをしないよう提言。

その他

・具体例として５例を紹介し検証

(1)BRCA1：乳がんに関連する遺伝子配列を用いた診断・スクリーニングの特許で、2001 年に Myriad Genetics 社の欧州特許が成立し、独占支配的で影響が大きいため、フランス、ベルギー、デンマーク無効を申し立て中（報告書当時）

(2)CCR5：米国 HGS 社（Human Genome Genetics Inc）が 2000 年に USP を取得。出願時は不明だったが、あとで HIV に関連することが判明。HGS は大学等がライセンスなしに研究するのを阻止しようとはしていない模様（報告書当時）

(3)C 型肝炎診断：米国 Chiron 社が出願し、広範な UK 特許（ウィルス成分・診断)、核酸プローブと PCR 物質に限定した欧州特許など、20 カ国以上で 100 件以上の特許が成立している。ワクチンは特許範囲ではないが、関連する DNA 配列は特許になっているため議論は残る。

(4)B 型肝炎診断：米国 Biogen 社が遺伝子組み換えによる抗原開発を 1978 年に UK 出願。異なる遺伝子組換え方法を使った他社を権利侵害として訴えたが、英国上院（最高裁に相当）は Biogen 社クレームは広すぎで、組み換えによる抗原作成すべてに及ぶのではないとした。

(5)マラリア（MSP-1)：国際慈善機関 PATH はマラリアワクチン開発支援のため、マラリア原虫が作る抗原たんぱく MSP-1 の特許状況を調査したが、多くの類似特許が錯綜していたため、それぞれの特許権者との交渉に多大な時間と労力を要した

考察、備考等

その他

・ Nuffield Council on Bioethics は、Medical Reseach Council、Nuffield Foundation、Wellcome Trust とが共同で設立

資料番号										
対象国・機関	英国			分類	背景等	法令規則	判例	基準	指針指令	学説	その他
名称	IPI 調査報告書									
書誌的事項	May 2004			“Patents for Genetic Sequences: the competitiveness of current UK Law and Practice - A study by the Intellectual Property Institute (IPI) on behalf of the DTI” http://www.berr.gov.uk/files/file10475.pdf						

調査結果

概要

・英産業省(DTI; Department of Trade and Industry)の委託により、特に遺伝子配列特許に関して大手民間企業、大学、研究機関等をインタビュー、および WEB アンケート調査した。

・EC バイオ指令に応じた 2000 年改正以来、重大な問題は殆ど無く、総体的に遺伝子配列に関する英国法令、実務は、産業分野と公的機関の双方のニーズを満たしていて大きな変更の必要性は無い。公的機関の研究について、時として高額であってもライセンスはされており、支障は認められない。ただし EPO の特許が付与されるまでの時間がかかりすぎて不利となっている面などあり、EU 内および全世界との一層のハーモナイズが重要である。

試験･研究の例外

・更なる改善として、小企業や公的機関で、法や利用に関する理解を深める必要がある。特に試験・研究の例外に関して不明確となっている

発明の特許性

・バイオ技術の EU 指令に応じた 2000 年改正以来、そのインパクトは良い方向であり、以前の事例調査でも重大な問題は殆ど無い

・総体的に、遺伝子配列に関する英国法令、実務は、産業分野と公的機関の双方ともニーズを満たしており、大きな変更の必要性は無い

・遺伝子配列の特許で、産業部門を過度に利しているという証拠は無く、また公的機関による研究に支障がでているとする証拠もない。patent thicket の証拠もない。時として費用が高すぎることはあるが、一般にライセンスは得られている。

・EPO など特に特許権利化までの時間がかかっており、EU 指令が全世界にいきわたってない状況でかなり不利となっている。EU 内および全世界との一層のハーモナイズは重要である

資料番号										
対象国・機関	英国			分類	背景等	法令規則	判例	基準	指針指令	学説	その他
名称	ガワーズ報告									
書誌的事項	Dec 2006			“Gowers Review of Intellectual Property”, U.K. HM Treasury http://www.hm-treasury.gov.uk/media/6/E/pbr06_gowers_report_755.pdf						

調査結果

概要

・英大蔵省（HM Treasury）の委託により、特にデジタル化の進展の中で英国知財制度の状況を調査報告。

・試験・研究の例外に該当するか否かについては判例も殆ど無く、明確でない。そのものに対する研究かそうでないかは、遺伝子関係技術では差はあいまいであり、権利侵害訴訟を危惧している研究グループもいる。特許法の条項をスイス特許法のように修正して明確化することを提言。

試験･研究の例外

・試験・研究の例外に該当するか否かが明確でない。そのものに対する研究かそうでないかで異なるが、遺伝子関係などの技術では両方にあてはまる可能性がある。

・判例も殆ど無く、DTI 報告（2004）によると、多くが、明確化が必要と考えており、また権利侵害訴訟を危惧している研究グループもいる。

・米国では知財権のために 1/6 の研究プロジェクトが停止したとされ（Murray, Stern 2004)、また知財権導入を拒絶された学術機関が 19%あるという報告（Walsh et.al. 2005)もある。

・植物育種の EC バイオ指令に関しては、独仏が盛り込んだのに対し、英国法では十分でなく、試験・研究例外規定ではカバーできていない。

・1977 年特許法の 60 条(5)項を修正して、experimentation、innovation、education に便宜を与えるよう試験・研究の例外を明確化することを提言。

・スイスの方向で明確化すれば、権利者の利益を損なうことなく研究を育成できる。

その他

・現行制度はほぼ十分であるが、改善が必要な点として以下の点を指摘
－模造品･海賊品対策として権利行使の強化
－IP 取得･維持費用の低廉化
－バランスの良く弾力的な知財権

資料番号											
対象国・機関	英国			分類	背景等	法令規則	判例	基準	指針指令	学説	その他
名称	OECD　STI　報告「特許された知識の研究使用」										
書誌的事項	Feb. 2006			“Research Use of Patented Knowledge: A Review”, STI Working Paper, (OECD Directorate for Science, Technology and Industry) http://www.oecd.org/dataoecd/15/16/36311146.pdf							

調査結果

概要

・本ワーキング・ペーパーは、特に研究免除（又は実験での使用の例外）の役割に焦点を当てて、特許された発明への研究アクセスに関する問題をレビューする。
・将来の政策策定のためのベースとして、OECD 国の試験と研究の例外の経済的・法的状況を調査・報告している。
・ほとんどの EU 国（英国を含む）は CPC（Community Patent Convention）第 27(b)項の規定、試験・研究の例外、を取り入れているが、いくつかの国では裁判所が法解釈を出しており、試験・研究の例外の範囲の差を生みだしてきた。いくつかの EU 国は更に公的認証取得の例外（特に医薬）も有する（英国は除く）。

試験･研究の例外

・殆どの EU 国は CPC（Community Patent Convention）の 27(b)項の規定、試験・研究の例外、を取り入れている。
・いくつかの国では裁判所が法解釈を出しており、試験・研究の例外の範囲の差を生みだしてきた。
・一般的な試験・研究の例外の法規定を持つ国は、さらに限定的に公的認証取得の例外（特に医薬）を有する傾向にあり、いくつかの EU 国はそのような規定を有する。

資料番号											
対象国・機関	英国			分類	背景等	法令規則	判例	基準	指針指令	学説	その他
名称	ACIP 討議報告「特許と実験使用」										
書誌的事項	Feb. 2004			“Patents and Experimental Use - ISSUES PAPER”, ACIP (Advisory Council on Intellectual Property) http://www.acip.gov.au/library/patentsexpuse.PDF							

調査結果　※「ドイツ」の ACPI 討議報告も参照のこと。

概要

・ACIP がオーストラリア産業・技術・観光省政務官の要請により、試験・研究の例外に関する国民的論議を促進するためにまとめており、各国状況についても紹介している

・英国を含む多くの EU 国は現行ドイツ特許法（1981）の試験・研究の例外の条項と同様の条項を有するが、ドイツの裁判所は試験・研究の例外に非常にリベラルな立場をとっているのに対し、英国を含む多くの EU 国は臨床試験は権利侵害としている。しかし、欧州では試験・研究の例外についてその他の技術分野でも判例法上の問題は生じておらず、本質的な問題は見られない。

試験・研究の例外

・ほとんどの EU 国は現行ドイツ特許法（1981）の試験・研究の例外の条項と同様の条項を有する。

・英国を含む多くの EU 国が臨床試験は権利侵害としているのに対し、ドイツの裁判所は試験・研究の例外に非常にリベラルな立場をとっている。

・Goddar の報告を紹介し、欧州では試験・研究の例外についてその他の技術分野でも判例法上の問題は生じておらず、本質的な問題は見られない、としている

考察、備考等

ACIP：Advisory Council on Intellectual Property
　　オーストラリア大臣、オーストラリア知的財産局に助言する独立機関

資料番号										
対象国・機関	英国		分類	背景等	法令規則	判例	基準	指針指令	学説	その他
名称	ESHG 報告「遺伝子検査に関する特許化及びライセンス」									
書誌的事項	June 2007		“Patenting and licensing in genetic testing - Ethical, Legal and Social Issues“ (final draft) ESHG (European Society of Human Genetics) 出典：下記考察･備考欄を参照							

調査結果

概要

・欧州委員会の専門部会が、公衆により役立つよう、状況を把握し特許システムの改善をはかるため議論を進めるベースとして報告をまとめた最終ドラフト。

・試験・研究の例外の境は明確でなく、欧州内でも各国で異なる法制化、解釈がされている。強制実施権はほとんど使われたことがないため実績や判例を欠いており、また数年間実施されない後でしか要求できないため、難しい。遺伝子リサーチツールは機能が明確でなく有用性の審査基準を満たさないが、研究用と診断用との差は小さく、問題は残る。

試験･研究の例外

・試験・研究の例外の境は明確でなく、欧州内でも各国で異なる法制化、解釈がされている。

裁定（強制）実施権

・強制実施権はほとんど使われたことがないため実績や判例を欠いており、また多くの国では数年間実施されない後でしか要求できない。

・英、独、仏などは特許権者が合理的条件でライセンスすることを宣言するしくみ、Licenses of Right があり、非排他的ライセンスが得られる一方、特許権者は特許維持費用を半減できる。

発明の特許性

・Nuffield 報告書の主張“用途限定した特定の診断試験の特許（use patent）は効果的”というのは誤解を招く。実際 Myriad 特許の用途クレームは DNA 自体のクレームと同様に迂回困難である。

・仏、独は権利範囲をクレームに書かれた用途に限定することで EC バイオ指令を取り込んだ。欧州委員会は 2005 年にこのような異なる各国対応の正当性について見解を示していない。

その他

・具体例として 4 例を紹介

(1)BRCA1/2：90 年代に国際協力研究がおこなわれていたが Myriad Genetics 社がいち早く特許化した。同社は他社へライセンスせず全て自社で検査する政策をとり、迂回ができず独占的支配力を有するため混乱を生じた。その後特許は無効ないし権利範囲の限定などされている。

(2)嚢胞性線維症（CF）：トロント小児病院とミシガン大が関連する遺伝子 CFTR を見

出して特許化し、商用テストキットと商業的検査機関からロイヤリティをとったが、CFTR へのアクセスは解放した。このため多くのテストキットの開発が進み合理的価格で広く実施されるようになっており、そのライセンスモデルへの大きな異議は生じていない。

(3)遺伝性ヘモクロマトーシス(HFE)：鉄が過剰となる常染色体劣性疾患の関連遺伝子を米国 Bio-Rad 社がクローン化し特許化。同社は高額のライセンス料を要求したため、他社はテストキット開発をできなかった。迂回ができないため BRCA1 と同様に独占的支配力を有する。

(4)カナバン病：治療法開発のために尽力した患者両親に無断で診断法を特許化し、高額料金で商用化。患者両親は無料開放を目指して訴訟を起こし、半額とすることで和解した。

・OECD 調査（2002）から、リサーチツール特許は通常それ用いて開発した製品のクレームを含んでいないが、ロイヤリティを要求していく傾向がみられる、と紹介。

・遺伝子リサーチツールは機能が明確でなく有用性の審査基準を満たさないが、研究用と診断用との差は小さい。

考察、備考等

その他

・ESHG (European Society of Human Genetics)は 1967 年に設立された学術団体で、EU 委員会などとも連絡を取っている

出典：
http://www.eshg.org/PatentingandLicensingDraftBackgrPaper07062007.pdf

（６）ドイツ

（ｉ）概要

経緯・背景、動向

リサーチツール特許に関する、試験・研究の免除（例外）、及び、強制実施権はドイツ特許法の規定は存在しない。また、現在、このような規定を法律化するかなどの議論はなく、特許の関係者や学会にもその必要性を訴える動きはない。

法令･規則

1998 年の TRIPS 協定に基づく見直しにより、２種類の強制使用が法制化された：

－公衆衛生のための強制使用

－利用特許の強制使用（特許交渉が不調に終わった場合）

試験・研究の例外は、第 11 条(a)～(f)項に以下が規定されている。

－私的かつ非商業的目的

－対象である発明に関する試験的目的

判例

Clinical Traial Ⅰ－試験･研究の例外に関する判例－

試験・研究の例外を商業目的にも拡大した。すなわち、例外の目的は特許権者の利益を最大限に守ることと、技術のさらなる向上のバランスを取ることにあり、試験の目的如何を問わない。

Polyferon 事件　-裁定（強制）実施権に関連する判例-

－ドイツ連邦特許裁判所は Polyferon がインターフェロンγ を含む唯一の医薬品であることを重視し、公共の福祉があるとして、ドイツ国内に限定した強制実施権を付与

－最高裁は「公共の福祉」については変化するものであり、また、他のほぼ同等の代替製品により公共の福祉が満たされる場合には、医薬品に関する強制実施権は認められないとした。

学説・関連議論

「試験・研究の例外」に対しては、ドイツの法令、判例、学説のいずれ

も、試験・研究行為の主体の性格、さらに、試験・研究行為の結果の利用目的も、「試験・研究の例外」の判断基準としていない。

また、商業的、非商業的性質という区分も放棄しており、大学等研究機関という行為主体の性格に基づく区分は用いられていない。

（ii）海外調査

資料番号										
対象国・機関	ドイツ		分類	背景等	法令規則	判例	基準	指針指令	学説	その他
名称	海外調査結果の概要									
書誌的事項		Dr. Prinz zu Waldeck und Pyrmont								
		‘The Permissibility of Using Patented Research Tools Under German Patent Law								

調査結果　　※詳細は資料編の海外調査結果の資料 3 を参照のこと。

概要

・本調査は、特許されたリサーチツールへの許されるアクセス、特に特許権の免除の範囲及び強制ライセンスの規定の可能性のある適用について、ドイツ特許法下における法的な状況を分析する。
・リサーチツール特許に関する、試験・研究の免除（例外）、及び、強制実施権はドイツ特許法の規定は存在しない。また、現在、このような規定を法律化するかなどの議論はなく、特許の関係者や学会にもその必要性を訴える動きはない。
・したがって、リサーチツールの試験・研究のための使用が認められるか、また、どの様に使えるかを現行の規定に照らして分析する。

試験･研究の例外

(ア)　特許法によれば
① 実験の場合
② 特許自体に関する場合
情報を得る目的に依らず、情報を獲得する実験が対象になる。ただし、特許技術が単に実験の手段の場合は免除の対象にはならない。

(イ)　医薬などの許認可の場合
特許法は公開の基準があり、発明を特許期間中に検証すること、及び、その検証に基づき技術の開発を行うことを認めている。認可取得試験はこの範囲に含まれるため免除の対象になる。
ただし、二つの医薬の同定は新たな知識を増やすわけでないため免除対象外

(ウ)　商業的目的か否か
商業的目的であることは適用に影響を及ぼさない。また、大学及び公益研究所の研究も私企業の研究より広い基準が用いられることはない。

(エ)　判例
Clinical Trial I
試験・研究の例外を商業目的にも拡大した。すなわち、除外の目的は特許権者の利益を最大限に守ることと、技術のさらなる向上のバランスを取ることにあり、試験の目的如何を問わない。

裁定（強制）実施権

1998 年の TRIPS 協定に基づく見直しにより、二種の強制使用が法制化された。
① 公衆衛生のための強制使用
特許交渉が不調に終わり、公衆衛生上重要な場合は強制使用可能。例えば、重要な医薬品など。
② 利用特許の強制使用
ある特許を使用することを含む特許において、特許交渉が不調に終わった場合。

（公的資金を原資とする）知的財産権の保護と特許使用の円滑化

・パテントプールはドイツのバイオ業界においては主要な役割を担っていない。

・Straus らによる得られる唯一の経験的な研究によると、クロスライセンス及びパテントプールは人気がなく、調査を行った企業のうちわずか三社がそれらの手段を用いていた。それらは非効率的と思われ、貢献と利益の不均衡のおそれから、ライセンス費用が増加した。

（iii）国内外文献調査

資料番号										
対象国・機関	ドイツ		分類	背景等	法令規則	判例	基準	指針指令	学説	その他
名称	特許法									
書誌的事項	2005(改正)		1981 年ドイツ特許法 出典：下記考察･備考欄参照							

調査結果

概要

・CPC 批准に伴い、1981 年ドイツ特許法により一般的な試験・研究の例外が設けられているが、大学等研究機関を特定した区分はない。強制実施権では公共の利益の観点が求められ、実際に適用された例はない。2005 年改正では EC バイオ指令に対応したが、そのままの形ではなく、人遺伝子配列の場合には、果たす役割をクレーム中に記載が必要として、権利範囲に制限をかけており、これに対して欧州産業界から、限定的解釈で却って EU 国内の不調和が拡大、と批判が出ている。

試験･研究の例外

・第 11 条(a)～(f)項に以下が規定されている。

第11 条
特許権の効力は次のものには波及しない。
(1) 非商業的目的のために行われる私的な行為
(2) 特許発明の対象に関係する行為であっても，実験目的のための行為
(2a) 新種植物の栽培、発見及び開発を目的とした生物学的物質の使用
(3) 医師の処方に基づいてなされる薬局内における医薬の即座の個々の調合，又は，このようにして調合された医薬に関する行為
(4) 産業財産の保護に関するパリ条約の他の締約国の船舶が一時的に又は偶発的に本法の効力が及ぶ水域に入った場合において，当該船舶の船上若しくは船内，又は当該船舶に搭載されている機械，索具，装置若しくはその他の付属物における特許発明の対象の使用であって，この対象が専ら当該船舶の必要のためにのみ使用されるという条件を満たすもの
(5) 産業財産の保護に関するパリ条約の他の締約国の航空機若しくは車両が一時的に若しくは偶発的に本法の施行領域に入った場合において，その航空機若しくは車両又はこれらの付属物を建造するにあたってなされる，若しくはこれらを運転するためになされる特許発明の対象の使用
(6) 1944年12月7日の国際民間航空に関する条約第27条に定められている行為であって、かかる行為が、同条の規定が適用される他国の航空機に関係しているときのもの

・大学研究機関の試験・研究に関する例外条項は無い。
・EC バイオ指令に応じて(2a)が追加された。

裁定（強制）実施権

・TRIPS 協定に整合(1998/7/16)、EC バイオ指令に整合(2005/1/21)

・付与のための一般的要件(第 1 項)（以下の AND）
・合理的な条件を提示して努力したがライセンスを得られなかった
・公共の利益の観点から必要
その他の要件
・利用関係（第 2 項)：先願と比較して、商業的重要性を有する重要な技術進歩を含むこと
・不実施（第 9 項)：特許権者が特許発明を実施しない、又はドイツ国内でほとんど実施しない場合（輸入は実施とみなす）
・手続き等
・強制実施権の付与、取下等の手続は、連邦特許裁判所無効部に訴えを提起
・強制実施権の付与においては、範囲、期間、目的などにつき制限又は条件を課すことができる
・特許権者は、強制実施権を付与された者から実施料を受け取る権利を有する
・実施権付与の前提となった状況が消滅し、かつ今後再び発生することが予測されない場合、特許権者は強制実施権の撤回を請求できる
・ドイツ連邦政府による特許発明の使用は、特許法第 13 条で規定

発明の特許性

・2005 年、EC バイオ指令に対応し、以下が規定されている。
・生物素材に特許を付与（第 1 条)。但し人遺伝子の塩基配列の権利範囲を厳密化（第 1a 条）
・単なる発見は不可（第 1a 条(1))、単離や技術的に獲得なら可（第 1a 条(2)）
・産業上の利用可能性として、遺伝子配列の果たす役割の具体的説明が必要（第 1a 条(3)）
・人遺伝子配列の場合には、果たす役割をクレーム中に記載が必要（第 1a 条(4)）
・「発明の主題が、人体の天然の遺伝子の配列又は部分的配列の構造と構造を同じくする遺伝子の配列又は部分的配列を持つならば、前項の産業上の利用可能性についての具体的な説明の行われた使用について、特許クレームに記載しなければならない。」
・特に科学者コミュニティで最も大きく議論された事項であり、連邦議会（下院）本会議での採択前の最終局面で挿入された

その他

・後発医薬品の臨床試験に関する例外条項は無い

考察、備考等

試験･研究の例外

・ドイツの法令、判例、学説のいずれも、試験・研究行為の主体の性格、さらに、試験・研究行為の結果の利用目的も、「試験又は研究」の例外の判断基準としていない。
・また、商業的、非商業的性質という区分も放棄しており、大学等研究機関という行為主体の性格に基づく区分は、用いられていない

裁定（強制）実施権

・1961 年に特許裁判所が設立されて以降に、12 件の申請があり、そのうち 1 件につき強制実施権が付与されたが、後に最高裁判所で取り消された（Polyferon 事件）
・その他の事例の多くは、「公共の利益」が存在することを立証できなかったことにより申請を却下されている。
・強制実施権制度が特許権者による自発的なライセンスにおける現実的なインセンティブになった事例は、近年も見られる

特許性に関して	
・ EuropaBio（ヨーロッパバイオテクノロジー産業連合）は、限定的解釈として批判（2005年） ・「ドイツ、フランスの履行したことは指令の文言上からくる幅ではなく、趣旨が異なっている。指令の主目的はＥＵ各構成国の特許法を調和させることなのに不調和が拡大している」	
	ドイツ語 http://www.jetro.de/j/patent/2005Jan_Feb/%93%c6%83o%83C%83I%97%9a%8ds%96@%8c%b4%95%b6%83e%83L%83X%83g.pdf
	日本語 ○欧州知的財産ニュース（2005年1・2 月号）： http://www.jetro.de/j/patent/2005Jan_Feb/%93%c6%83o%83C%83I%8ew%97%df%97%9a%8ds%96@%89%bc%96%f3.pdf ○日本特許庁仮訳（1998 年 http://www.jpo.go.jp/shiryou/s_sonota/fips/germany/pl/mokuji.htm

資料番号										
対象国・機関	ドイツ		分類	背景等	法令規則	判例	基準	指針指令	学説	その他
名称	ドイツ国家倫理委員会見解書「ヒト由来の生物物質の使用を伴うバイオテクノロジー発明の特許化」									
書誌的事項	Oct. 2004		“The patenting of biotechnological inventions involving the use of biological material of human origin”OPINION, Nationaler Ethikrat (German National Ethics Council) 出典：下記考察･備考欄を参照							

調査結果

概要

・EC バイオ指令が未履行前に、バイオ発明に特許性を認めた場合の倫理上、学術上、法律上の問題点を 25 名の専門委員が整理、分析し、見解をまとめた。

・研究の自由について、EU 指令や法案で規定されていないが、一般的な試験・研究の例外が適用できるので特に規定を設ける必要はない。強制ライセンスは特に診断学や治療法に関わる場合には狙いを定めて認めるべき。政府の EC バイオ指令導入案は妥当だが、さらに人 DNA 配列特許は技術的応用を請求項に記述して限定することを提言した。この限定は実際にドイツ特許法に取り入れられている。

試験･研究の例外

・研究の自由確保については、植物種に関する規定を除き、EC 指令や法案の枠内で特に定められていないが、特許法第 11 条第 2 号が研究の特権を一般的に定めていて、これがバイオ発明にも当て嵌まるため、特に規定を設ける必要はない。

裁定（強制）実施権

・特に診断学や治療法に関わる場合、強制ライセンスは重要な意味を持ってくる。ここでは狙いを定めて強制ライセンスを認めるべき。

発明の特許性

・ドイツ連邦政府の国内履行法案を妥当と評価。

・今後遺伝子の調製が新発明と見なされるケースが限定されて広範囲の成分特許が廃止され、TRIPS 協定と衝突するだろうが、実践の場での対処に任せることで十分。

・現時点で可能な独自のアプローチ手段や自由裁量幅を規定に活かすべき。

・人体から採取された DNA 配列は、詳細説明及び請求項の中で提示されている機能の技術的応用に限定すべきであり、1a 条第 3 項の文言は具体性の面から物足りない。

・どういう時に「発明」が成立するのか、明確で拘束力のある形で提示するのは困難なため、「発明」の前提条件や限界に関する EU レベルでの定義規定が欠落している限り、できるだけ狭義に解釈すべきであり、その旨、法案解説の中で明確に言及しておくべきである。

その他

・実際に 2004 年の EC バイオ指令履行法では、技術的応用をクレーム中に入れることが盛り込まれた。

（出典）
http://www.ethikrat.org/_english/publications/Opinion_patenting-of-biotechnological-inventions.pdf

資料番号											
対象国・機関	ドイツ			分類	背景等	法令規則	判例	基準	指針指令	学説	その他
名称	ESHG 報告 － 遺伝子検査に関する特許・ライセンスの問題										
書誌的事項	June 2007			“Patenting and licensing in genetic testing - Ethical, legal and social issues”, Draft Appendix A 出典：最下欄を参照							

調査結果

概要

Appendix A, Legal Framework 6.”National Legislation and Recommendations of National Councils”の”Germany”を参照のこと。

・ドイツの EC バイオ指令の導入は、特に DNA 配列の物質特許の扱いの点で発明者の利益と社会の利益とのバランスを欠いているとして物議をかもした。オランダが欧州司法裁判所に提訴した EU 指令無効化が却下されたことで、最終的に 2005 年に発効したが、フランスやルクセンブルクと同様に遺伝子配列の具体的な産業応用をクレーム中に記述することが盛り込まれている。

発明の特許性

・ドイツの EC バイオ指令の導入は、特に DNA 配列の物質特許の扱いの点で発明者の利益と社会の利益とのバランスを欠いているとして物議をかもした。
・ヒト遺伝子や細胞の物質特許は人の尊厳を冒すとみられ、またヒト遺伝子の数が当初予想よりかなり少ないこと、ほとんどの病気は多因性であること、などわかってきた。国民意識は 2000 年に成立したエディンバラ特許には反対であった。
・オランダが欧州司法裁判所に提訴した EU 指令無効化の結果を待っていたが、それが却下されたことで導入に向かった。
・最終的に 2005 年に発効したが、フランスやルクセンブルクと同様に遺伝子配列の具体的な産業応用をクレーム中に記述することが盛り込まれている。
・説明としてヒト胚保護法の規定が優先することが声明され、胚細胞や幹細胞の特許化は排除された。

（出典）
http://www.eshg.org/PatentingandLicensingDraftBackgrPaper07062007AppendixA.pdf

資料番号										
対象国・機関	ドイツ			分類	背景等	法令規則	判例	基準	指針指令	学説	その他
名称	ACPI 討議報告 － 試験・研究の例外-									
書誌的事項	Feb. 2004			“Patents and Experimental Use ISSUES PAPER”, ACIP (Advisory Council on Intellectual Property) 出典：最下欄を参照						

調査結果　※「英国」の ACPI 討議報告も参照のこと。

概要

・ ACIP がオーストラリア産業・技術・観光省政務官の要請により、試験・研究の例外に関する国民的論議を促進するためにまとめており、各国状況についても紹介している。
・ 英国を含む多くの EU 国は現行ドイツ特許法（1981）の試験・研究の例外の条項と同様の条項を有するが、ドイツの裁判所は試験・研究の例外に非常にリベラルな立場をとっているのに対し、英国を含む多くの EU 国は臨床試験は権利侵害としている。しかし、欧州では試験・研究の例外についてその他の技術分野でも判例法上の問題は生じておらず、本質的な問題は見られない。

試験･研究の例外

・ ほとんどの EU 国は現行ドイツ特許法（1981）の試験・研究の例外の条項と同様の条項を有する。
・ 英国を含む多くの EU 国が臨床試験は権利侵害としているのに対し、ドイツの裁判所は試験・研究の例外に非常にリベラルな立場をとっている。
・ 最高裁の Klinische Versuche ⅠとⅡでは、特許の対象に向かっての試験・研究である限り、クレームされた特性の試験でもクレームされていない方向を探る試験でも、許容されるとしており、憲法裁判所でも支持されている。
・ Goddar の報告を紹介し、欧州では試験・研究の例外についてその他の技術分野でも判例法上の問題は生じておらず、本質的な問題は見られない、としている。

※ACIP：Advisory Council on Intellectual Property
　　オーストラリア大臣、オーストラリア知的財産局に助言する独立機関

（出典）
ISSUES PAPER;
http://www.acip.gov.au/library/patentsexpuse.PDF
OPTIONS PAPER;
http://www.acip.gov.au/library/Experimental%20Use%20Options%20Paper%20A.pdf

（７）フランス

（ｉ）概要

経緯・背景、動向

法令はEU指令へ対応（整合）することにより改正されてきている。例えば、当初、医薬品の認可のための試験はこの特許権免除の対象にならないと考えられていたが、法律の改正で「特許権は医薬品の認可、および、認可に必要な行為などには及ばない。」とされた。

リサーチツール特許に関する特別な規定はなく通常の特許と同様に考えられ、試験・研究の免除範囲内での使用と商業的使用では全く異なる扱いを受ける。このことにより、問題も生じており、例えば、PCR特許で、特許権者は営利企業に許諾しない方針（あるいは高額な使用量を要求）であったため、血液検査センターはPRC特許の使用を中止した。

法令･規則

特許によって付与される権利は、次の各号には及ばない：

－私的に非商業的目的でなされる行為

－特許発明の主題に関し試験目的でなされる行為

司法機関による強制実施権の付与と行政機関の職権による実施権（裁定実施権）の付与が規定されている。

判例

試験・研究の例外に関する主たる判例は以下のとおり：

－Babolat/Boschian裁判（1992、PIBD 1992,n 525. Ⅲ.363)：製品の展示会への出品は、商業的な価値を探ることが目的である。

－Parienti Automobiles Peugeot 裁判（2002、 PIBD 2002)：全国紙へのプロトタイプの発表は実験の範囲を超えている。

－Agrosol Sodifag裁判（2005、 PIBD 2005 n.819. Ⅲ. 685)：プロトタイプを顧客となる者に示すことは商業的な目的である。

－Science Union Servier Corbiere 裁判（1984 、PIBD 1985,N,366, Ⅲ.118)：認可申請は製品の製造が商業目的を持っていることを示しており、特許侵害に当たる。

－Wellcome Parexel 裁判（1999、 PIBD 2001,n 729.Ⅲ.530)：(判例を

覆し）将来の販売を含む最終的な目標に関わらず、予備試験は試験・研究のための免除の対象であり、認可のための使用は特許侵害に当らない。

（ii）海外調査

資料番号										
対象国・機関	フランス		分類	背景等	法令規則	判例	基準	指針指令	学説	その他
名称	海外調査結果の概要									
書誌的事項		Mr. Alain Gallochat								
		“French Survey”								

調査結果　※詳細は資料編の海外調査結果の資料 4 を参照のこと。

概要

・法令は EC 指令へ対応（整合）することにより改正されてきている。例えば、当初、医薬品の認可のための試験はこの特許権免除の対象にならないと考えられていたが、「特許権は医薬品の認可、および、認可に必要な行為などには及ばない。」とされた。
・リサーチツール特許に関する特別な規定はなく通常の特許と同様に考えられる。すなわち、試験・研究の免除範囲内での使用と商業的使用では全く異なる扱いを受ける。
このことにより、問題も生じており、例えば、PCR 特許で、特許権者は営利企業に許諾しない方針（あるいは高額な使用料を要求）であったため、血液検査センターは PRC 特許の使用を中止した。
・フランスにおいては国家機関が正式に関係するパテントプールはない。研究組織や大学はパテントプールに関する論議を先導しようとする動きがあるが、現在のところ、その議論からは具体的な成果は出ていない。

試験・研究の例外

法令

・特許法は次の規定を設けている。
①特許権は特許を対象とした関連試験に及ばない。
・判例はこの規定が厳格（狭く：訳者注）に解釈されることを示している。また、次の二つが明確に区別される様に制限されている。
①発明の技術的利点を確認する試験、ないし一般知識を増進するための開発は該当
②商業目的の行為は非該当
(PIBD 1992,n 525.Ⅲ.363 PIBD 2002, PIBD 2005,n 819.Ⅲ.685)
・例示判決が示すように、顧客（となる可能性を持った）に提示された場合、特許権免除の対象とならない。このことはフランスの公共保健に対し深刻な影響を与え、実質的にフランスの判例に変化を与えた。
・当初、医薬品の認可のための試験はこの特許権免除の対象にならないと考えられた。(PIBD 1985,n 366.Ⅲ.118)
・しかし、認可試験は法律の改正で解決された。EC 指令 2004/27/CE がフランス法(Law n2007-248 of Feb. 27,2007)にとりいれられた。
①特許権は医薬品の認可、および、認可に必要な行為などには及ばない。また、医薬品には特許法の規定によりある範囲のバイオ製品が含まれる。
・判例
①Babolat/Boschian 裁判（1992、PIBD 1992,n 525. Ⅲ.363）：製品の展示会への出品は、特許の技術的有用性の確認や、その範囲、発展などの要求にそ

うものではなく、一般人の意見を聞くことで商業的な価値を探ることが目的である。

②Parienti Automobiles Peugeot 裁判（2002、 PIBD 2002)：全国紙に集中してコメントするというプロトタイプの発表は単に、実験の範囲を超えている。

③Agrosol Sodifag 裁判（2005、 PIBD 2005 n.819. Ⅲ. 685)：プロトタイプを顧客となる人の前に示すことは実験とは言えず、商業的な目的である。

④Science Union Servier Corbiere 裁判（1984 、PIBD 1985,N,366,Ⅲ.118)：認可申請は製品の製造が商業目的を持っていることを示している。従って、試験・研究のための免除の対象とならず、特許侵害に当たる。
のための実証試験は侵害には当たらない。

⑤Wellcome Parexel 裁判（1999、 PIBD 2001,n 729.Ⅲ.530)：(判例を覆し）将来の販売を含む最終的な目標がどうであれ、予備の試験は試験・研究のための免除の対象であり、認可のための使用は特許侵害に当らない。[TGI of Paris (1st instance Court) Feb. 20, 2001]
後の行為だけが商業的目的と考えられる。

リサーチツール特許の扱い

・フランスにおいて、リサーチツールに関して専門家の間で話し合われていないし、法律改正の予想もない。
・フランスではリサーチツール特許に関する特別な規定はなく通常の特許と同様に考えられる。すなわち、試験・研究の免除範囲内での使用と商業的使用では全く異なる扱いを受ける。
・その顕著な例として PCR 特許を取り上げる。
  ・PCR 特許は DNA 連鎖を複製する技術で少量の資料を検査可能な量まで複製し増加させる。
  ・ある試験機関は人の病気の試験セットを開発するためにこの特許を使っていたが、この場合は試験・研究のための免除に当たり、特許使用料の支払いは不要である。
  ・一方、血液検査センターで PCR 特許を使用し、患者に使用料を請求する場合、許諾契約を結び、使用料の支払いが必要である。
  ・結局特許権者は営利企業に許諾しない方針（あるいは高額な使用料を要求）であったため、血液検査センターは PRC 特許の使用を中止した。
・リサーチツールの問題は、その他にもある。物質スクリーニング特許（有用な物質かどうか検査する特許）の場合、特許権者はスクリーニングによって得られた分子を含む医薬品等の最終成果物の売上に対する特許料を請求する(リーチスルー特許請求の項目)。しかし、通常その様な特許請求の項目は仕様により規定する事が難しいため特許とならない。さらに、特許使用者はその様な計算を認めない。結局、その様なリサーチツール特許の売り方は普通の化学反応物としてうるしかなく、価格の決め方が難しい。

裁定（強制）実施権

法令

・フランスにおける強制使用はいくつかに分類できるがいずれも、非排他的でライセンス料が必要である。

（公的資金を原資とする）知的財産権の保護と特許使用の円滑化

パテントプール

・フランスにおいては国家機関が正式に関係するパテントプールはない。

・パテントプールは、様々な特許権者が有する複数の特許が必要な場合に適切な条件を潜在的に備えている。しかしながら、現時点において、パテントプールシステムは存在しない。
・いくつかの、研究組織や大学ではパテントプールに関する論議を先導しようとする動きがあるが、現在のところ、その議論からは具体的な成果は出ていない。
・“クリアリング・ハウス”による管理。

（iii）国内外文献調査

資料番号											
対象国・機関	フランス			分類	背景等	法令規則	判例	基準	指針指令	学説	その他
名称	知的財産法										
書誌的事項			知的財産法 出典：最下欄を参照								

調査結果

概要

・EU 国で一般的、試験・研究の例外が規定されている。強制実施権についても、付与から３年不実施、利用関係、など規定されている。

試験･研究の例外

第L613 条5
特許によって付与される権利は，次の行為には及ばない。
(a) 私的かつ非商業目的でなされる行為
(b) 特許発明の内容に関し実験の目的でなされる行為
(c) 医師の処方に従って薬局においてなされる個々の症例のための即座の調剤，
又はそのように調剤された医薬に関する行為

強制実施(compulsory license)

・司法機関による強制実施権の付与と行政機関の職権による実施権（裁定実施権）の付与が規定されている。

(1)司法機関による強制実施権の付与（第 L613 条 11-14）
-不実施の場合　付与から 3 年　出願から 4 年
-利用関係の場合　先行特許の権利者は改良特許の実施権を付与
-半導体の場合　争的な場合

(2)行政機関による実施権の付与（第 L613 条 16-17）
-公衆衛生上必要な場合　第 613-16 条
-量的・質的に不足する場合　異常に高い値段の場合
-経済上必要な場合　第 613-18 条
-防衛上必要な場合
審議はすべて非公開である。

（出典）
日本語（日本国特許庁の仮訳）：
http://www.jpo.go.jp/shiryou/s_sonota/fips/pdf/france/chiteki_zaisan.pdf

資料番号										
対象国・機関	フランス		分類	背景等	法令規則	判例	基準	指針指令	学説	その他
名称	「大学等における試験・研究をめぐる紛争事例」									
書誌的事項			産業構造審議会知的財産部会特許制度小委員会特許戦略計画関連問題ワーキンググループ「特許発明の円滑な使用に係る諸問題について」(2004 年 11 月)　第 25 頁 http://www.jpo.go.jp/shiryou/toushin/shingikai/pdf/strategy_wg11/file3.pdf							

調査結果
概要
「現在のところ、フランスにおいて、大学等の研究活動に関して、当該大学等以外の他者が有する特許発明の実施が権利侵害に当たるか否かが裁判で争われた事例は見あたらない。」

（８）ベルギー

（ｉ）概要

（法改正等に至った）経緯・背景、動向

法改正の過程中で、試験・研究の権利行使免除の範囲拡大のきっかけとなったのは、Myriad 社の乳ガン診断特許である。リサーチツールとして有用な遺伝子特許が独占的に権利主張された場合、病気に関連する遺伝子研究が滞る事が広く認識された。

試験･研究の例外に関しては、「免除は研究者と特許権者の微妙なバランスの上で成り立つが今回の法律はその点が不十分」と産業界からは法成立阻止の動きがあった。また、公衆衛生に対する強制ライセンスについての産業界の反応は、「小規模なベルギーの企業はより大規模な会社や外国企業と比較して深刻な影響を受ける」という懸念であった。

最終的法案は公共保健に関して幅広い試験・研究の権利行使免除と強制ライセンスを主体とし EC 指令が求める法を上回る法案となり、2005 年 4 月に公布された。

法令･規則

改正法ではバイオ分野に起きる特許権の行使に関して二つの追加措置が導入された。これらの措置は、バイオテクノロジー特許が公衆衛生に与える悪影響を制限することを目的としている。

－28 条(1)(b):研究目的における使用の例外の大幅な拡大

－31 条 2:公衆衛生上の理由に基づく強制ライセンス制度の導入

指令と運用・利用状況

法制当局は、98/44/EC 指令を特許法に反映させる作業を進め、主務大臣の承認を得て 2001 年 6 月に国会へ提出されたが議題として取り上げられず、指令への対応が遅延した。法制化遅延に対して EU 裁判所は義務違反と警告し、違反金を課す事にした。EC 指令の欧州域での位置づけが分かる経緯である。

学説・関連議論

調査報告者の Overwalle 教授は、拡大された試験・研究の免除は将来性を大きく期待されている。ただし、この拡大が問題の解決、試験・研究実施上の自由、バイオ技術の研究に対する刺激となるかは見守っていかなけ

ればならない。」と述べている。

(ii)海外調査

資料番号										
対象国・機関	ベルギー									
名称	海外調査結果の概要									
書誌的事項		Prof. dr.Geertrui Van Overwalle								
		“Research Tools in the R&D Phase”								

調査結果　※詳細は資料編の海外調査結果の資料 5 を参照のこと。

概要

・特許法改正の中で、試験・研究の権利行使免除の範囲拡大のきっかけとなったのは、Myriad 社の乳ガン診断特許である。このことにより、リサーチツールとして有用な遺伝子特許が独占的に権利主張された場合、病気に関連する遺伝子研究が滞る事が広く認識された。
・試験･研究の例外に関しては、「免除は研究者と特許権者の微妙なバランスの上で成り立つが今回の法律はその点が不十分」と産業界からは法成立阻止の動きがあった。
・公衆衛生に関する強制ライセンスについての産業界の反応は、「小規模なベルギーの企業はより大規模な会社や外国企業と比較して深刻な影響を受ける」という懸念であった。
・最終的（二番目）法案は公衆衛生に関して幅広い試験・研究の権利行使免除と強制ライセンスを主体とし EC 指令が求める法を上回る法案となり、2005 年 4 月に公布された。

試験･研究の例外

１．産業界の動き
以下の疑問が生じている。
(1)「科学的な目的」についてであり、知識の進歩に寄与することが必要であるが、その様な研究は民間企業でも行われている一方、商業目的の研究は大学や公的機関においても行われている。商業的研究と非商業的研究の解釈はかなり幅広くできる上、他の表現を使ってもそれも解決にはならない。

(2)用語の問題であり、この用語では特許による保護の範囲が狭く解釈される。その結果、発明は公開されず、トレードシークレット化される。免除は通常範囲を厳しく解釈される。現在は大学の研究では企業は特許権の行使について口出しせず、勝手にやらせている。

(3)製造法に関する場合である。現在製造法の特許は免除対象になっていないが、バイオ技術の研究においては、製造法が重要である。
　フランダースのバイオ技術協会は現在の形では成立阻止を働きかける。このままの状態であると、事前に予想しなかった、悪影響が発生するかもしれないためである。免除は研究者と特許権者の微妙なバランスの上で成り立つが今回の法律はその点が不十分なためである。

２．学会の動き
・法律学者の中には拡大された研究免除についていくつかの懸念を提起するものがいる。Overwalle 教授は、“拡大された研究免除は将来性を大きく期待されるが、この拡大が問題の解決、試験・研究実施上の自由、バイオ技術の研究に

対する刺激となるかは見守っていかなければならない”と述べている。日常的な研究現場で、科学的な目的と商業的な目的の両面を持った研究を展開する場合の線引きは非常に難しい。また、この法律により産業界がリサーチツール特許の開発意欲を失う結果とならないかと指摘している。

・EPC は医療の方法は特許としない。例えば、研究の方法は特許にならない。しかし、研究に使うために製品を売ることは特許化できる。このように法律により、研究者が研究室で特許を無断使用したと指摘されたり、企業が研究用の機材を特許に守られ作ることが出来る。したがって、研究の自由と発明の奨励を両立できる。

３．法改正の背景

ベルギー特許法における研究免除(research exemption)を修正する法案は、最終的に 2005 年 3 月 10 日に下院議会を通過し、2005 年 4 月 14 日に上院を通過した。法案は 2005 年 4 月 28 日に公布され、2005 年 5 月 13 日にベルギー官報に掲載された。

ベルギー特許法改正の中で、試験・研究の権利行使免除の範囲拡大のきっかけとなったのは、保健衛生分野の強制使用と同様に、Myriad 社の乳ガン診断特許である。この特許は、ライセンス条件が一方的であるのと共に、非常に高価であった。このことから、リサーチツールとして有用な遺伝子特許が独占的に権利主張された場合、病気に関連する遺伝子研究が滞る事が、誰の目にも明らかだったからである。

４．法改正の経緯

(1)1998 年 7 月 6 日欧州議会がバイオ技術に関する 98/44/EC 指令を採用した。法制当局はベルギー特許に反映させる作業を進めたが、選挙があり時間がかかる一方、内容やその範囲に関しての議論は白熱した。

(2)最初の法案は 1998 年 10 月 29 日に完成したが不採用となった。二番目の法案は 2000 年 8 月 8 日に発表され、一連の諮問機関から多くの意見が出された後、法案は大幅に修正された。主務大臣の承認を得て国会に 2001 年 6 月 21 日提出されたが、ほとんど議論されなかった。

(3)このようなベルギーの法制化遅延に対してＥＵ裁判所は義務違反と警告した。ベルギー政府は法制化に必要な手続きを進めていると反論したが、裁判所は 欧州委員会が定めた日程違反であるとこれを認めなかった。ベルギー政府が必要な手段を講じない場合、ＥＵ裁判所は違反金を課す事にした。

(4)事態の深刻化と、政府の変化があり新しい法案が整備された。法案は 2004 年 4 月 23 日国会に提出された。国会の委員会の議論やその他の法制化手続きをへて、2005 年 5 月 13 日に公布された。委員会での議論の過程で様々な修正が提案されたが、そのほとんど全てが採用されなかった。これは、2004 年 4 月 23 日の諮問委員会(council of Minister)で各方面の団体との合意があり、修正の余地がほとんど残っていなかったためである。

(5)2002 年 6 月 21 日の最初の法案はＥＣ指令からかなり距離のあるものであった。人遺伝子の特許化を避ける、また、道徳的な観点での除外を広く解釈でき

る、などである。最初の法案は賛成派と反対派の意見の妥協から生まれた。

(6)二番目の法案は様々な点で最初の法案と似ていたが、用語や解釈を工夫してよりＥＣ指令に近くなっている。この法案では反対派との妥協を主眼としたものでなく、公共保健に関して幅広い試験・研究の権利行使免除と強制使用を主体とし EC 指令が求める法を上回る案となっている。

(7)二番目の法案は 2005 年 4 月 28 日に公布された。

５．特許法の概要

(1)ベルギー特許法の新条項第 28 条(1)(b)は、特許所有者の権利は、発明の主題に関する(on)又は発明の主題を用いて(with)、科学的目的のためになされる行為には及ばない、と規定している。
　二つの主な疑問が、この新しい、拡大された研究免除についての議論を支配した。第一の疑問は、一対の概念である‘on and/or with’はどの様に理解されるのか、ということであった。第二の疑問は、‘科学的目的(scientific purposes)’という概念に関してであった。大臣は議会におけるある特別の演説の中で両問題を明らかにした。

(2)On/with 両方を含むことにより、研究の自由度を大幅に拡大する。また、科学的な発見、究明が主体で有れば免除されるが、商業的目的が主体の場合は免除されない。ただし、その境界がどの様な物であるかは今後の推移を見守ることが必要である。

(3)ジェネリック薬品の許認可にかかる使用は試験・研究の免除の範囲外であると解釈される。ただし、米国のボーラー条項に相当する欧州指令により、侵害をとわれない。

○公衆衛生(public health)のための強制ライセンス(compulsory license)

１．産業界の動き及び反応
(1)産業界の反応は、最初の提案(DOC50 1886/001 21 June 02)に対するバイオ工業界ほかからあった。それは小規模なベルギーの企業はより大規模な会社や外国企業と比較して、異なったより深刻な影響を及ぼすことを懸念している。また、EU 国間で異なる法律になる方法を使うことに賛同していない。二番目の提案に関しては、公衆衛生の分野だけでなくより広い分野への適用が広がると特許法が過剰に、また、不必要に効力や意義を失うことを懸念している。その結果、大学や研究所の研究が意欲をなくしてしまう。非合理な高額ライセンスを要求するミリヤッド社の乳ガン検査特許はその代表的な例である。その特許は結局一部を除き拒絶された。強制ライセンスは広い範囲に適用される：
　①医療
　②医療を行うための工程
　③人間と動物の診断

(2)これ以上の特許法の例外措置は国内技術に対する投資に対する意欲を奪うことになる。その結果国内の有力な医療関連企業の研究はヨーロッパの他の国に移される可能性がある。ほかの国、たとえばフランスでは公共保健に関する強制ライセンスは、それ以外の分野でも同じ法律で定めている。そのほかのヨーロッパの国でも同様に公衆衛生分野を特別に定めてはおらず、同様の強制ライセンスの項目は既存のベルギー特許法にすでにある。

(3)二番目の反対理由は誰でも強制ライセンスを求めることができる（これは正確な理解ではないが)、また、事前に特許権者と交渉することは求められない、時間的な尺度がかけるというものであるそのほかに、当事者の意見陳述が規定されておらず、明らかに被申立人の基本的権利が侵されている。取り扱う委員会は倫理面での判断を行うだけで、経済面の判断がかけており、委員に産業界の医薬、生命科学関係者が含まれていない。

(4)Myriad 社に対しては直接名指しはしないものの、産業界から非常に厳しい意見が出された。特許は産業の発展を加速し、持続させるシステムからすぐに且つ莫大な利益を生むシステムに変わった。このシステムは特許がただ単に最大の利益を生む財として扱うことでのみ実現できる。特許がこのように扱われた場合、医療診断の分野では特に、さらなる批判にさらされる。このような独占は診断を必要としている患者を犠牲にすることになる。

(5) 主要紙新聞(De Standaard and De Morgen)は、Myriad 社の BRCA 特許に対する異議の手続を大々的にかつ批判的に報道してきた－2000 年から 2007 年までの Myriad 事件についての一連の報道記事がその証拠である。

(6)バイオテクノロジー技術特許事務所の見解：「2005 年法には強制ライセンスについて多くの規定が盛り込まれているが。新条項の第 31 条によってベルギー政府に、公衆衛生に問題がある場合は強制ライセンスを付与することができる。強制実施が認められると、ライセンサーとライセンシーの間の関係は通常の契約ライセンスとみなされる。公衆衛生の強制ライセンスは、特許権者が並行輸入を止めることができるかに影響をあたえるのではないか、という懸念が生じるが、これは通常、強制ライセンスは特許権者の同意を必要としないと考えられるためである。」※
※Linklaters Brussels, Intellectual Property News, November 2005

２．学会の動き
(1)法律関係の研究者は新強制ライセンスを支持しているがいくつかの関心を示している。 また、Overwalle 教授はこの法律を革命的ととらえている。

(2)この法律により、ベルギーを特許権者と公共（患者）の利益のバランスを図り公共の健康に関心払う国として国際社会の中でとらえられる。しかし、効果はまだ不明であり、企業が利用するかどうかで決まってくる。

(3)ある学者は主務大臣がリーダーシップを発揮しなかったことを残念がっている。またある学者は意志決定に長い期間を要したことで強制実施権が法律を作

り上げるシンボルとしての意味を持ち得なかったのではないかと思っている。

(4)しかしながら、強制ライセンス権がライセンスに協力的ではない特許権者を公正で適切な交渉の場に引き出す効果を間接的に持つことを理解するべきである。

３．法改正の経緯

上記「試験・研究の例外」の３.「法改正の経緯」を参照のこと。

４．特許法の概要
(1)強制ライセンスは公衆衛生に関して適用される。
(2)適用される技術は、医薬品、医療機器、診断に使用する器具またはそれから派生する製品または組み合わせ。

（iii）国内外文献調査

資料番号										
対象国・機関	ベルギー		分類	背景等	法令規則	判例	基準	指針指令	学説	その他
名称	“－ベルギー特許法改正－研究目的における使用の例外の改正と公衆衛生上の理由による強制実施権制度の導入”									
書誌的事項			Prof. Geertrui Van Overwalle, Ms. Esther van Zimmeren, 知財研フォーラム Vol.64 p.42-49							

調査結果

概要

特許権者の利益と特許権へのアクセスを円滑化することのバランスをとることは非常に重要であり、そのための一つの手段となり得るものとして強制実施が考えられる。複数の国で強制実施が特許法に導入されているが、強制実施は特許権の効力を弱めるものであるから、強制実施に対しては慎重さが求められるであろう。

ベルギーでは特許法の改正により導入された強制実施に期待がよせられているが、どこまで効力を発揮するかについてはまだ不透明であり、「今後の展開を見守るしかない」、と Overwalle らは指摘する。

一方、強制実施はいずれの国でも一度も発動されたことがないか、あったとしても非常に少なく、いわゆる伝家の宝刀であるが、「非協力的な特許権者を公正かつ合理的なライセンス交渉の席に着かせるための間接的な「脅し」効果」があるとの指摘もなされている。

資料番号										
対象国・機関	ベルギー		分類	背景等	法令規則	判例	基準	指針指令	学説	その他
名称	“Patent pools and diagnostic testing”									
書誌的事項		Birgit Verbeure, Esther van Zimmeren, Gert Matthijs, Geertrui Van Overwalle, TRENDS in Biotechnology, Vol.24 No.3 (2006) p.115-120 出典：最下欄を参照								

調査結果

概要

IT の分野ではパテントプールがうまく機能しているが、バイオテクノロジー分野におけるパテントプールの取り組みも少しずつ出てきている。

Verbeure らは、バイオテクノロジー分野のパテントプールの例として、ゴールデンライス、SARS のパテントプール、HNPCC のパテントプールの三ケースを紹介しており、特にゴールデンライスは開発途上国への技術移転が目的である点で注目される。

http://www.epip.eu/conferences/epip02/lectures/Verbeureetal-2006-TIB-Publication.pdf

（９）スイス

（ｉ）概要

法改正に至った経緯・背景、動向

バイオ･医薬産業が重要な産業であるスイスの特許法は、バイオテクノロジー分野における発明の適切かつ効果的な特許保護を確保するために改正された（2007 年 6 月 22 日)。

改正の契機は、スイスは欧州共同体のメンバー国ではないものの、バイオ指令 98/44/EC に適合させることであった。

2000 年に特許法改正案が作成され､その後､公衆協議 (public consultation) にかけられた。意見収集の際にあがってきた問題（バイオテクノロジー発明の特許が基礎／応用研究または経済に与える影響）についてさらに詳細に分析することとなった。スイス特許庁は 2003 年に国内のバイオテクノロジー業界に調査を行ったところ、私的使用の抗弁の問題が提出された。

一方、OECD はバイオテクノロジーに関する調査を 2002 年、2004 年と二回にわたって行い、実験での使用(experimental use)の問題に関していくつかの勧告を行った。これはスイスの特許法改正にも影響を与えた。

そして 2007 年 6 月 22 日にスイス特許法の修正が議会で承認された。

法令

2007 年 6 月 22 日にスイス議会により承認された修正スイス特許法は第 9 条において特許の効果が及ばないものとして以下を列挙している；

(a)非商業的目的での私的範囲において行われた行為
(b)利用可能性を含む発明の目的についての知識を得るための実験及び研究を目的として行われた行為；特に、発明の目的に関するすべての科学的研究は認められる
(c)治療用製品に関する 2000 年 12 月 15 日の法律の規定に従って医薬品の販売許可を得るために必要な行為
(d)教育機関における教育目的のための発明の使用
(e)植物品種の選択又は発見及び育成を目的とした生物材料の使用
(f)偶然によるか、又は、技術的に不可避な、農業分野において得られた生物材料

また、特許の強制使用として以下の新条項第 40b 条が規定された；

第 40b 条

Ｆ．研究道具

特許されたバイオテクノロジー発明を、研究において道具又は手段として使用したいと思う者は、非排他的ライセンスの権利を与えられる。

ただし、本条項は競争者に製造や供給をライセンスするものではない。

また、第 40b 条は研究や技術革新が不合理な制約で悪影響される状況を防ぐことが意図されている。研究と技術知識の普及を保証し促進するため、本規定は技術知識を生み出した者と利用する者との間のバランスをとっている。

（ii）海外調査

資料番号										
対象国・機関	スイス		分類	背景等	法令規則	判例	基準	指針指令	学説	その他
名称	海外調査結果の概要 “Switzerland – Experimental use defence (research exemption) and research tools”									

調査結果　　※詳細は資料編の海外調査結果の資料6を参照のこと。

概　要

2007年6月22日にスイス議会に承認されたスイス特許法の修正は、過去数年間の技術進歩と国際的な進展に適合させるものである。その主なねらいは、バイオテクノロジー分野における発明の適切かつ効果的な特許保護を確保することである。変更点は公衆又は道徳の理由による特許性の排除を明らかにすること、バイオテクノロジー特許の保護の範囲を明らかにすること、研究免除及びボーラー免除(research and Bolar-exemption)の法制化、そして遺伝子源及び伝統的知識の出所開示義務の導入を含んでいる。しかし、スイス法に、TRIPS協定のドーハ宣言のパラ6の履行に関する2003年8月30日付けWTO決定を置き換えることや、PLRの批准、模倣品対策の有効な手段の導入といった、他の重要な司法の目標を含んでいる。

調査結果の報告では以下の項目について述べられている；

1．スイス特許法の改正を起こす主要な出来事
2．スイス特許法の改正の議論が始まった頃の、イノベーションと特許の関係（特に研究免除）
3．研究免除の範囲／商業使用と非商業使用／研究目的
4．特許の強制使用（Compulsory uses）
5．スイス特許法改正の主なパブリック・コメント

法改正の経緯

1998.7

・バイオテクノロジー発明の法的保護に関する欧州議会及び欧州委員会の98/44/EC指令（1988年7月6日)、いわゆるバイオ指令の採択が、スイス特許法改正の出発点となった。
・スイスは欧州共同体（EC）又は欧州経済領域（EEA）のメンバーではない（欧州特許条約（EPC）のメンバーではある)、したがってスイス特許法上記バイオ指令に合わせる義務はない。しかしスイスは自国の知財法を欧州共同体の法律とできる限り揃えようとしてきた国である。
・さらに、スイスの産業界は、バイオテクノロジー発明の特許化において、欧州で共通かつ明確な法律上のルールが必要であることを表明した。

1999.4

・1999年4月20日、スイス議会は、欧州議会の98/44/EC指令にスイス特許法を適合させることを可決した。

2000

・2000 年にスイス特許法を改正するための法案が作成された。
・この法案について公衆協議(public consultation)の手続が 2001／2002 に採られた。この協議はスイスにおけるバイオテクノロジー発明の特許化について、最初の公衆での議論となった。
・公共協議は、本トピックス（著者注：バイオテクノロジー発明の特許化）について経験的な証拠の欠如があることを明らかにした。それゆえ上院はスイス特許庁に、意見収集の際にあがってきたいくつかの問題をもっと詳細に分析することを求めた。
・詳細に調査された二つの領域は、以下のとおり；
　－基礎及び応用研究に与えるバイオテクノロジー発明の特許（特に遺伝子特許）の影響
　－経済に与えるバイオテクノロジー発明の特許（特に遺伝子特許）の影響

2003
・スイス特許庁は 2003 年、スイスのバイオテクノロジー業界の調査を行った（“Research and Patenting in Biotechnology – A servey in Switzerland”）。
・協議の手続の中で、またスイスのバイオテクノロジー業界の調査の中で、私的使用の抗弁の問題が提出された。

2002/2004
・そのころ OECD は、バイオテクノロジーの広範囲な研究の部分として実験での使用の抗弁の問題の調査を始めた。
・最初の調査は 2002 年に行われ、結果は“Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies”として公表された。
・この公表に続いて、2 番目の OECD の報告書”Patents and Innovations: Trends and Policy Challenge“が 2004 年に公表された。この報告書は実験での使用の問題に関していくつかの勧告を行った。国際レベルでの実験での使用の抗弁の議論はスイスの改正にも影響を与えた。

2007.6
・2007 年 6 月 22 日にスイス議会に承認されたスイス特許法の修正は、過去数年間の技術進歩と国際的な進展に適合させるものである。
・その主なねらいは、バイオテクノロジー分野における発明の適切かつ効果的な特許保護を確保することである。変更点は公衆又は道徳の理由による特許性の排除を明らかにすること、バイオテクノロジー特許の保護の範囲を明らかにすること、研究免除及びボーラー免除(research and Bolar-exemption)の法制化、そして遺伝子源及び伝統的知識の出所開示義務の導入を含んでいる。しかし、スイス法に、TRIPS 協定のドーハ宣言のパラ 6 の履行に関する 2003 年 8 月 30 日付け WTO 決定を置き換えることや、PLR の批准、模倣品対策の有効な手段の導入といった、他の重要な司法の目標を含んでいる。

試験・研究の例外

○スイス特許法の改正の議論が始まった頃の、イノベーションと特許の関係（特に研究免除）

1．法改正時の議論
・経済理論によると、特許は知識の普及とイノベーションの促進力であり、経済成長の重要な要素である、といわれている。しかし、最近の研究では、過度の特許化は研究、開発、イノベーションを妨げるのではないかということがわかった。

・研究のインセンティブと特許された研究へのアクセスを与えることを同時にバランスをとることは難しいことがわかっている。
・研究開発に対する影響という点では、特許権の保護は試験・研究の例外およびリサーチツールへの適応の問題を生じさせる。
・調査結果に関して、次の事実的要素に留意すべきである
－研究環境はここ何年かで変化した：今日の大学は私企業部門からの委託研究に積極的に関与している。欧州のほとんどの大学は、知的財産を取得し、管理し、ライセンスし、行使するために、技術移転機関（TLO: Technology Licensing Organization）を内部に又は会社を設立している。商業的研究と非商業的研究の境界線は消滅した。
－多くの欧州諸国の国内法をと異なり、スイス特許法は、発明の主題に関連して、私的及び非商業的使用のための、又は実験目的での使用のための法的抗弁を与えていない。しかしそのような抗弁は実際には考慮されているものの、この免除の正確な範囲はあまり明確ではない。
・法的抗弁の欠如と抗弁の不明確な範囲は、（公的資金を得ている研究機関及び私企業の）研究者の間に法的な不確実さを引き起こした。さらに PCR 技術の例に関して、調査の回答者は、バイオテクノロジー発明はイノベーションの過程では比較的初期段階に関係していて複製され得ないことから、科学者は重要なリサーチツールを使用することを制限されているかもしれないという懸念を述べた。そのため、2003 年のスイスのバイオテクノロジー業界の調査における回答者は、バイオテクノロジーにおける取引コストを減らす最も有効な治療法として、“広範な研究免除”をあげていて、報告書は“他の治療法と比較すると、広範な研究免除の導入は相対的に有益であると思われる”と結論づけた。こうした背景に基づきスイスでは、法的な実験での使用の抗弁の導入は、研究における特許のマイナスとなり得る効果を排除する方法として議論された。

2．改正特許法の内容

2007 年 6 月 22 日にスイス議会により承認された修正スイス特許法は次のような抗弁を規定している。

第 9 条
特許の効果は、次のものには及ばない：
(a)非商業的目的での私的範囲において行われた行為
(b)利用可能性を含む発明の目的についての知識を得るための実験及び研究を目的として行われた行為；特に、発明の目的に関するすべての科学的研究は認められる
(c)治療用製品に関する 2000 年 12 月 15 日の法律の規定に従って医薬品の販売許可を得るために必要な行為
(d)教育機関における教育目的のための発明の使用
(e)植物品種の選択又は発見及び育成を目的とした生物材料の使用
(f)偶然によるか、又は、技術的に不可避な、農業分野において得られた生物材料

新条項の第 9 条(1)(a)と(b)は 2004 年の共同体特許規則(Community Patent Regulation)のドラフトの第 9 条にみられる特許権者の権利の制限に対応している。これらの規定は私的かつ非商業的使用のための、または発明の主題に関する実験目的での使用の法定の抗弁を規定している。

第 9 条(1)(b)には最終的に商業目的を見込んだ試験も含まれるが、特許権者の

市場化努力を妨げる目的のために行われる試験には及ばない。

また、第 9 条(1)(c)は欧州諸国に導入された認証試験の例外（“ボーラー免除“)に対応するが、国の認証機関のみへの適用に制限されない。

新条項の第 9 条(1)(d)である“教育での使用“は、他の欧州国の特許法にはない。

3．特許の強制使用

2007 年 6 月 22 日にスイス議会により承認された修正スイス特許法は次のような強制ライセンスを規定している。

第 40b 条

F. 研究道具

特許されたバイオテクノロジー発明を、研究において道具又は手段として使用したいと思う者は、非排他的ライセンスの権利を与えられる。

第 40b 条はバイオテクノロジー発明のみに関連しているので、“研究のための道具と手段”は、研究室の装置や機械、データベース、コンピュータ・ソフトウエアは含まない。

第 40b 条は、第 9 条(1)(b)の試験・研究の例外に該当しないバイオ関連リサーチツール特許の非排他的強制使用を規定しているが、ただし、競争者に製造や供給をライセンスするものではない。

第 40b 条は、研究や技術革新が不合理な制約で悪影響される状況を防ぐことが意図されている。研究と技術知識の普及を保証し促進するため、本規定は技術知識を生み出した者と利用する者との間のバランスをとっている。

4．スイス特許法の改正についての主なパブリック・コメント

スイス特許法の第 9 条と第 40b 条はスイスのバイオテクノロジー及び医薬品産業（多国籍企業、中小企業、大学、研究機関を含む)、さらにはスイス経済を代表する機関によって協議され、賛同されている。

（iii）国内外文献調査

資料番号										
対象国・機関	スイス			分類	背景等	法令規則	判例	基準	指針指令	学説	その他
名称	”Blocking Patents and their Effects on Scientific Research: Evidence from the Biotechnology Industy”									
書誌的事項	2005			Nikolaus Thumm, IP & RTD: Articles No.23, IPR Helpdesk 出典：最下欄を参照						

調査結果

概要

世紀の変わる頃から、プロパテントの行き過ぎによるアンチコモンズがそこかしこで囁かれているが、アンチコモンズといったことが実際にどの程度社会で大きな問題となっているのかについては、曖昧である。

2004 年に Thumm により行われたスイス・サーベイ(Nikolaus Thumm, “Research and Patenting in Biotechnology – A Survey in Switzerland”)によると、「バイオテクノロジー発明にとって現在の特許制度の組織的な悪用は見あたらなかったし、乱用レベルの戦略的な特許化は見出せなかった。」

そのため、さらに権利の円滑利用を進めるためには、Thumm が提示するように、パテントプール、クロスライセンス、パテントコンソーシアムといった取り組みが注目される。

http://ipr-helpdesk.org/newsletter/23/html/EN/IPRTDarticleN1025F.html

Ⅲ．調査結果のまとめ

１．機関・地域・国の間でのまとめ

（１）比較分析：機関・地域・国の間での類似・相違点

「II．調査」の章では、日本、OECD、米国、EU、英国、ドイツ、フランス、ベルギー、スイスにおいて、ライフサイエンス分野のリサーチツール特許を中心に、特許権者の利益を図りつつ、研究を推進しイノベーションを促進するための調整についてどのような議論がなされているか又はどのような方策が講じられているのかについて明らかにした。

本項では、国際的な機関、地域、国の各々で取り組まれている又は検討されている調整手法について、どのような類似点又は相違点があるのかについて検討を行う。

検討を行うにあたり、「II．調査」の章で明らかになったとおり、権利の保護と利用のバランスをとる調整手法として複数のものが抽出され得る。具体的には、法的な調整手法として、（ｉ）試験・研究の例外、（ii）強制実施、があげられる。その他の調整手法として、（iii）ガイドライン／ポリシーの策定及び普及、（iv）パテントプールの形成等があげられる。

これらの各手法ごとに検討を行うこととする。

（ｉ）試験・研究の例外

特許権の行使における試験・研究の例外については、これまで多くの研究がなされている[12]。

特許権の効力に一定の制限を課すこととなる試験・研究の例外を検討するにあたり、まずは、世界各国の多くの特許法の共通の枠組みの一つである「知的所有権の貿易関連の側面に関する協定（TRIPS 協定）」の第 30 条が、まずは参照され得る。

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[12] 例えば、産業構造審議会 知的財産政策部会特許制度小委員会 特許戦略計画関連問題ワーキンググループ「特許発明の円滑な使用に係る諸問題について」2004 年 11 月（以下、「産構審 WG 報告書」という。）；財団法人知的財産研究所「平成 17 年度 特許庁産業財産権制度問題調査研究報告書　特許発明の円滑な利用のための方策に関する調査研究報告書」平成 18 年 3 月；E. Richard Gold, Yann Joly, Timothy Caulfield, ‘Genetic research tool, the research exception and open science’ Vol.3 No.2 p.1-13 (2005)

第 30 条（与えられる権利の例外）

加盟国は、第三者の正当な権利を考慮し、特許により与えられる排他的権利について限定的な例外を定めることができる。ただし、特許の通常の実施を不当に妨げず、かつ、特許権者の正当な利益を不当に害さないことを条件とする。[13]

上記規定は、世界各国の多くの特許法において定められている試験・研究の例外等を考慮したものである[14]。

日本の特許法では第 69 条第 1 項に「特許権の効力は、試験又は研究のためにする特許発明の実施には、及ばない。」と記載されている。また欧州各国、例えば英国（特許法第 60 条第 5 項(b)）、ドイツ（特許法第 11 条(b)）、フランス（特許法第 613 条 5(b)）、ベルギー（特許法第 28 条(1)(b)）、スイス（2007 年 6 月 22 日に議会に承認された改正特許法第 9 条(1)b）等の特許法においても、試験・研究の例外について規定されている。

しかし試験・研究の例外の規定は、各国で少しずつ異なり、またその適用範囲は明確に限定されているわけではない（明確に限定されるように規定することは至難であろう）。さらに各国の判例をみると、試験・研究の例外の適用範囲は、一見よく似た条文の内容であっても、少しずつ異なって解釈されている。例えば、ドイツでは臨床試験について広く例外を認めているが、英国では非常に狭くしか試験・研究の例外を適用していない[15]。フランスでも判例上、厳格に解釈されている[16]。

ベルギーでは、2005 年 4 月 28 日に公布された改正特許法の第 28 条(1)(b)において、「特許所有者の権利は、発明の主題に関する(on)又は発明の主題を用いて(with)、科学的目的のためになされる行為には及ばない」と規定され、例外の範囲が拡大された。これにより研究の自由度が拡大することになるが、一方で特許権の効力が制限されることになる。本条項の導入により、特許の保護と利用のバランスがどのように変化するのか、その効果はまだ不

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13 産構審 WG 報告書第 16 頁
14 吉藤幸朔著、熊谷健一補訂『特許法概説　第 12 版』第 773 頁（株式会社有斐閣、1997 年）
15 'The Bolar provision: a safe harbour in Europe for biosimilars' EURALex Issue No.172 p.19 (2006)
16 本報告書資料編の「フランス」を参照のこと。

明であり、今後の状況の推移を注視する必要があるだろう[17]。

またスイスでは、特許法の改正が 2007 年 6 月 22 日に議会で承認され、第 9 条(1)で試験・研究の例外について規定されている。除外されるケースを各々列挙して記載するといったスイス特許法での規定ぶりは、英国のガワーズ報告[18]において、より明確に除外を規定した好例として取り上げられ、当該規定ぶりに沿って研究例外を規定することは、権利者の利益に損害を与えることなしに、研究を促進することになるだろう、と述べられている。しかし、当該改正によりどのような効果が実際に得られるのかはこれからの研究が待たれるところである。

一方、米国特許法では試験・研究の例外については規定されておらず、コモン・ローによる除外を与えるのみで、その範囲は狭く解釈されている。ただし、1984 年のボーラー判決を受けて、FDA 承認申請に必要な行為については特許権行使の免除対象とする、いわゆるボーラー条項を導入した。このボーラー条項による法定除外の範囲は、2005 年のメルク事件における最高裁判決以降、広く解釈される傾向がみられる[19]。

以上のとおり、試験・研究の例外について、日本や欧州諸国のように特許法上に規定されている場合であれ、米国のようにコモン・ローによる免除であれ、またその限界範囲は各国で異なっていて、かつ明確であるとは言えないものの、特許権の効力に対して一定の制限を課して、第三者との調整を図っていることは、各国共通である。しかし試験・研究の例外の範囲は特許権者と特許を利用する者とのバランスを考慮して調整されるべきものであることから、おのずと限定的にならざるを得ない。どんなに試験・研究の例外の範囲を拡大し、又は明確にしたとしても、試験・研究の例外の適用のみで、特許権者の利益を考慮しつつ、第三者による特許権の権利の使用を円滑にして、イノベーションにつながる研究開発を促進することは不可能であろう。

（ii）強制実施

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[17] Geertrui Van Overwalle, Esther van Zimmeren, ‘ベルギー特許法改正－研究目的における使用の例外の改正と公衆衛生上の理由による強制実施権制度の導入’知財研フォーラム Vol.64　p.42-49

[18] ‘Gowers Review of Intellectual Property’ (2006) 4.11-4.12
http://www.hm-treasury.gov.uk/media/6/E/pbr06_gowers_report_755.pdf

強制実施についても、これまで多くの研究がなされている[20]。

特許法における強制実施の規定は、日本や英国、ドイツ、フランス、ベルギー、スイス等の欧州諸国では導入されている。

一方、米国では過去に何度か特許法への導入が検討されたものの、産業界や特許権者における反対が強硬であり、現在のところ、例えば大気清浄法において汚染制御装置の特許の強制実施を規定するといった、非常に限定された形での強制実施が規定されている以外には、特許法において強制実施の規定を導入するような動きはみられない。

実際のところ、強制実施権が付与されたことは日本（ただし裁定実施権）ではこれまでなく[21]、欧州各国でも非常に稀である。

特許権の権利者の利益と第三者による権利へのアクセスの改善を調整する手段として強制実施は可能性としてはあるが、実際にはこれまでほぼ機能していない[22]。

（iii）ガイドライン／ポリシーの策定と普及

権利の保護と活用のバランスをとる方法として、法的な調整手法以外の手法も検討され得るし、また実際的である。

米国ではNIH（National Institutes of Health：国立衛生研究所）が、NIH資金が投入されて行われた研究から生まれたリサーチツールが広く利用されることを推進するため、1999年にリサーチツール・ガイドラインを作成した。米国の大学の間では、NIHのリサーチツール・ガイドラインをベースにライセンス実務が行われているケースもあり、当該ガイドラインが米国内で広く受け入れられつつあると思われる。

OECDでは2002年頃から検討を重ね[23]、2006年2月に「遺伝子関連発明のライセンス供与に関するOECDガイドライン」を策定し、「研究目的等のため

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19 本報告書資料編の「米国」を参照のこと。

20 例えば、産業構造審議会 知的財産政策部会特許制度小委員会 特許戦略計画関連問題ワーキンググループ「特許発明の円滑な使用に係る諸問題について」2004年11月

21 中山信弘『工業所有権法（上）特許法　第2版増補版』第456-467頁（株式会社弘文堂、2000年）

22 ライフサイエンス分野のリサーチツール特許等に対する強制実施の適用については、竹田和彦著『特許の知識　第8版』第474頁（ダイヤモンド社、2006年）。

23 隅蔵康一、藪崎義康、石川浩‘遺伝子関連発明のライセンスに関する問題：OECDガイドラインをめぐって’知財管理　Vol.57 No.3 p.377-393 (2007)

の遺伝子関連発明の広範なライセンス供与等の考え方」[24]を示した。当該OECDガイドラインについて、OECD加盟国における普及を展開中である[25]。

これに続いて、日本では、2006年5月23日に総合科学技術会議が「大学等における政府資金を原資とする研究開発から生じた知的財産権についての研究ライセンスに関する指針」を、続いて翌年の2007年3月1日に同会議が「ライフサイエンス分野におけるリサーチツール特許の使用の円滑化に関する指針」をとりまとめた。後者のリサーチツール特許の指針は、「特許制度による保護と活用のバランスのとれた実務運用が重要との認識の下、ライフサイエンス分野におけるリサーチツール特許について、大学等や民間企業が研究において使用する場合の基本的な考え方を示すことにより、その使用の円滑化を図るものである。」[26]とされている。本指針は上記OECDガイドラインと軌を一にしており、OECDガイドラインと同様に国内外に広く周知されることが重要である。またリサーチツール特許の円滑な使用を促進するために、「大学等や民間企業が所有し供与可能なリサーチツール特許や特許に係る有体物等について、・・・その使用促進につながる情報を公開し、一括して検索を可能とする統合データベースを構築する。」[27]こととされており、リサーチツール特許の指針が真に受け入れられるためには上記統合データベースが重要な役割を果たすものとして期待される[28]。

（iv）パテントプールの形成

パテントプールは、「複数の権利者が有する二以上の特許権を一括して実施を希望する者（ライセンシー）にライセンスし、ライセンシーはプール特許の対価を支払う一方、特許権者には当該対価を一定のルールに従って配分する方式をいう」[29]。パテントプールは電機・通信分野では実際に形成され運用されているが、ライフサイエンスの分野ではパテントプールによる権利

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24 「ライフサイエンス分野におけるリサーチツール特許の使用の円滑化に関する指針」1.(3)
25 例えば、セミナー：知財戦略「生命科学分野のイノベーションに向けて：リサーチツールと知的財産権」in BioJapan2007（2007年9月21日）
26 上記指針2.(1)
27 上記指針4.(1)
28 隅蔵康一「ライフサイエンス分野におけるライセンス・データベースの展望－総合科学技術会議の指針を受けて－」知財プリズム Vol.6 No.63 p.9-18（2007年12月）
29 加藤恒『パテントプール概説－技術標準と知的財産問題の解決策を中心として』第2頁（社団法人発明協会、初版、2006年11月30日）

の活用はまだ行われておらず、またライフサイエンスの分野ではパテントプールは機能しにくいとの指摘がなされている[30]。しかし一方で、欧米ではライフサイエンス分野におけるパテントプールの形成について議論[31]されており、またパテントプールを実際に形成し運用する試み[32]も始まっている。例えば米国の PIPLA[33]や 2007 年 10 月に発足した英国の SC4SM[34]等の取組がどのように進展していくのか期待され得る。またパテントプールは独占禁止法との関係から、より排他性の少ないクリアリング・ハウスやパテント・コンソーシアムの形式[35]に展開することも検討されているが、両者を合わせてパテントプールと呼ぶことも多い。この場合、電機・通信分野で行われているようなパテントプールの管理や運用の形態には拘束されない。

現在、世界が注目している iPS 細胞研究においても、包括的な研究組織を形成すると共に、知的財産権のライセンスの一括管理等、知的財産権の戦略的取組がオール・ジャパンとして検討されており[36]、今後の進展が期待される。

（２）経緯分析：機関・地域･国それぞれの経緯と機関・地域･国間での相関

ライフサイエンス分野のリサーチツール特許に関連して、1980 年のチャクラバティ判決、1988 年のハーバード・マウスの特許等、1980 年代からバイオテクノロジー分野の特許[37]について、米国のプロパテントの流れに後押しされて、その重要度を増してきた。

一方、20 世紀の終わりには、特許と科学研究、特にライフサイエンス分野における研究との関係において、例えばアンチコモンズの悲劇[38]のような

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30 小田切宏之『バイオテクノロジーの経済』第 134-140 頁（東洋経済新聞社、2006 年 7 月 20 日）
31 例えば、Birgit Verbeure, Esther van Zimmeren, Gert Matthijs, Geertrui Van Overwalle, 'Patent pools and diagnostic testing' TRENDS in Biotechnology Vol.24 No.3 p.115-120 (2006)
32 森岡一、' バイオ関連特許活用についての一考察－フリーライセンスあるいはパテントプールの可能性について ' 知財研フォーラム Vol.64 p.32-41
33 Public Intellectual Property Resource of Agriculture http://www.pipra.org/
34 http://www.sc4sm.org/
35 隅蔵康一、' ライセンス・ガイドラインと知的財産権の集合的管理 ' ,『知的財産政策とマネジメント』（株式会社白桃書房、2008）
36 http://www8.cao.go.jp/cstp/project/ips/haihu3/ips-m.pdf
37小田切宏之『バイオテクノロジーの経済』第 122-127 頁（東洋経済新聞社、2006 年 7 月 20 日）
38 Michael A. Heller, Rebecca S. Eisenberg, 'Can Patents Deter Innovation? The Anticommons in Biomedical Research' Science Vol.280 p.698-701 (1998)

プロパテントに内在する問題が指摘されるようになった。

これを背景に、特許権者と権利を利用する第三者とのバランスを調整することが必要ではないかということが議論されるようになり、特に、ライフサイエンス分野のリサーチツール特許については、それが基本的なものであり、かつ当該特許を回避することは非常に困難であるとの認識から、21 世紀に入って議論が盛んになってきた。またちょうどその頃、遺伝子配列の解読が競争して行われ、その成果が特許化されるようになった。特に Myriad 社のライセンス方針、すなわちある特定の遺伝子について特許を取得し、その権利をライセンスせずに自己実施するという方針をとったため、他の企業での開発のみならず、大学等の研究機関における研究にも支障を引き起こし、ベルギーに至っては特許法の改正までされる事態となった。実際には、その影響は話題にされる程には大きくないとの指摘もされている[39]。

こうした状況の中、OECD では 2003 年頃から遺伝子関連発明へのアクセスの容易化についての議論を促し、ついてはガイドラインの策定に集大成された。OECD での議論はスイス特許法の改正の際にも参考とされている[40]。

OECD ガイドラインは各国でその取込が期待されるところ、日本では、ライフサイエンス分野のリサーチツール特許について、その円滑利用が課題としてあげられたため、OECD ガイドライン等を参考にしつつ、指針がをまとめられたところである。

この OECD における動きに対して、米国では必ずしも OECD の動向に同期しているようには表面上はみえないし、またライフサイエンス分野におけるパテントプールの形成について議論や試行がなされる等、独自の動きをみせているが、OECD の方向性と大きく異なるものではない。むしろパテントプールにおける議論や取組に象徴されるように、民間主導で議論や取組が進んでいるというべきであろう。

一方、欧州は、ライフサイエンス分野のリサーチツール特許について訴訟等の大きな問題はほとんど見られないものの、ベルギーやスイスに見られるように特許法の改正を行う等により、実務上での対応や議論を行い解決策を

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[39] Timothy Caulfield, Robert M Cook-Deegan, F Scott Kieff, John P Walsh, 'Evidence and anecdotes: an analysis of human gene patenting controversies' Nature Biotechnology Vol.24 No.9 p.1091-1094 (2006)

[40]本報告書資料編の「スイス」を参照のこと。

見出すというよりも政府が主導して法制上での足固めを行う動きがみられ、米国とは異なる対応をとろうとしているように思われる。

日本でも現在のところ、リサーチツール特許について大きな問題が発生しているわけではないが、リサーチツール特許の指針を普及する等により、特許権の円滑利用を促進するための取組や議論が今後もなされていくものと思われる。

平成１９年度　特許庁産業財産権制度問題調査研究報告書

研究で用いる特許権の取扱に関する調査研究
調査研究報告書

平成２０年３月

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資料１　米国

Recent Developments in the United States Regarding the Law and Practical Application of Patents on Research Tool Inventions

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I. Executive Summary

This report summarizes recent developments under U.S. patent laws and provides some insights into the practices of various academic sciences, industries, and government agencies regarding the treatment of so-called "research tool" inventions. For many years a vigorous discussion has existed about the need to provide exclusive patent rights as incentives to invent and to disclose research tools, whether such exclusive rights should apply to all uses and users of patented research tools, and whether exclusive rights to prohibit all uses of research tools would unduly discourage sequential invention. Concerns over the proper scope of patent rights in regard to subsequent research uses of inventions have a long history, but have received increased scrutiny in light of judicial decisions since the turn of the century. New studies of uses of research tools and efforts to assert research tool patents have been performed in light of the decision of the U.S. Court of Appeals for the Federal Circuit (Federal Circuit) in 2002 providing a restrictive interpretation of the "experimental use exception" to patent infringement in *Madey v. Duke University*,[1] and the decision of the U.S. Supreme Court in 2005 providing an expansive interpretation of the codified "regulatory approval exception"[2] in *Merck, KGaA v. Integra LifeSciences I Ltd.*[3] This report seeks to describe the broad parameters of these developments.

In general terms, the law regarding patents and research tool inventions has become clearer since 2000. The Federal Circuit's 2002 *Madey* decision has increasingly been recognized as expressing the state of the law regarding the experimental use exception, particularly as neither the U.S. Supreme Court nor the U.S. Congress have chosen to intervene to revise the Federal Circuit's approach. Thus, uses of patented research tools in almost all contexts, even for university-based basic research, must for now be considered an actionable infringement of exclusive patent rights. Only in the context of the regulatory approval exception does significant uncertainty remain regarding whether uses of patented research tools constitute actionable

[1] 307 F.3d 1351 (Fed. Cir. 2002).
[2] 35 U.S.C. § 271(e)(1) (2008).
[3] 545 U.S. 193 (2005).

infringements. In that context, the broad language of the Supreme Court's interpretation in the *Merck* case, the subsequent decision of the Federal Circuit on remand,[4] and other recent cases suggest that the exception may apply to at least some research tool uses of inventions closely related to the target of the regulatory approval decision.

At the same time, social practices have become more complex. Recent studies demonstrate that both academic and commercial researchers ignore the actual state of the law and routinely use patented inventions without the authorization of patent holders. This approach appears justified in light of other studies that demonstrate that many research tool patent holders will not assert their patents to restrict research. However, research may nevertheless be unduly restricted by fears of potential liability, and routine disregard of legal rights (even if unlikely to be asserted) may not be a stable position. In some contexts, such as diagnostic and stem-cell inventions, aggressive assertion of research tool patents has led to public criticism, and new academic and government guidelines have developed to assure broad licensing of research tools on reasonable terms.

This report provides basic definitions, briefly describes the history of the experimental use and regulatory approval exceptions and their application to research tools, and then summarizes recent developments in the case law, studies of recent practices of researchers and patent holders, and recent changes to licensing policies in regard to research tools. It also provides a brief discussion of alternatives to a broad experimental use exception and throughout contains references to relevant academic articles.

[4] 496 F.3d 1334 (Fed. Cir. 2007).

II. Introduction

This section provides a basic definition of research tools and research tool patents addressed in this report. A broad definition is adopted, because the focus of the report is on trends regarding potential patent liability and the effects of such liability on scientific research, rather than on financial incentives provided by patent rights for the development of technologies intended for use in research.

"Research tools" may have many definitions, and may include a very wide range of technologies. For example, patented inventions covering the following are all sometimes referred to as research tools: cell lines, genetic sequences, assay methods, software, and instruments such as microscopes and lasers. Research tools are often defined by their intended uses in scientific research, as disclosed in patent applications.[5] However, it is common to use technologies for research that is not contemplated by the patent holder, and the right to exclude others from using patented inventions is not limited in the United States to the disclosed and claimed uses.[6] Another approach that focuses only on liability for the research market would define research tools as patented technologies used only to produce products that do not incorporate the tool (and thus do not trigger liability when the products are commercialized).[7] For purposes of discussing the full scope of potential liability, one must consider a broader definition of research tools than inventions that are patented with a disclosed purpose solely or principally for research. (Nevertheless, such patents are often the subject of greatest concern regarding the need for patent protection, given that the anticipated market for any commercial value for the patent is for research.)

More expansive definitions of "research tools" focus on the uses to which patented inventions may be put. Thus, a recent Federal Circuit case defined research tools as "tools that scientists use in the laboratory, including cell lines, monoclonal antibodies, reagents, animal models, growth factors, combinatorial chemistry and DNA libraries, clones and cloning tools (such as PCR), methods, laboratory equipment and machines."[8] Similarly, analysts and academics have defined research tools broadly as "any . . . input into the process of discovering" products[9] and as "the technological developments that enable particular lines of research to be pursued."[10] We rely on these more expansive definitions below, *i.e.*, patented technologies used in conducting research that are not themselves the object of the research inquiry at that time.

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[5] *See, e.g.,* Philippe Ducor, *Research Tool Patents and the Experimental Use Exception – a No-Win Situation?*, 17 NATURE BIOTECH. 1027, 1027-28 (1999); Thomas D. Mays, *Sharing Biomedical Research Resources: Principles and Guidelines for Recipients of NIH Research Grants and Contracts: Race Horse or Trojan Horse?*, 2 BIO-SCI. L. REV. 56, 61 (1999-2000).

[6] *See* 35 U.S.C. § 271(a) (2008).

[7] *See, e.g.,* Janice M. Mueller, *No "Dilettante Affair": Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools*, 76 WASH. L. REV. 1, 14-15 (2001); Esther Pfaff, *"Bolar" Exemptions – A Threat to the Research Tool Industry in the U.S. and the EU?*, 38 INT'L REV. OF INTELL. PROP. & COPYRIGHT L. 258, 262-63 (2007).

[8] Integra LifeSciences I Ltd. v. Merck KGaA, 331 F.3d 860, 872 n.4 (Fed. Cir. 2003) (Newman, J., dissenting) (quoting National Institutes of Health, Sharing Resources: Principles and Guidelines for Recipients of NIH Research Grants and Contracts, 64 Fed.Reg. 72090, 72092 n. 1 (Dec. 23, 1999)).

[9] John Walsh, Ashish Arora & Wesley Cohen, *Effects of Research Tool Patents and Licensing on Biomedical Innovation*, *in* PATENTS IN THE KNOWLEDGE BASED ECONOMY 287 (Wesley M. Cohen & Stephen A. Merrill eds. 2003) [hereinafter "NRC Report"].

[10] Dianne Nicol, *Cooperative Intellectual Property in Biotechnology*, 4 SCRIPT-ED 136, 137 (2007), *available at* http://www.law.ed.ac.uk/ahrc/script-ed/vol4-1/nicol.asp (last visited Feb. 1, 2008).

However, it bears repeating that the expansive definition applies to many types of patented technologies having different intended markets than the research at issue.

III. Brief History of the Experimental Use and Regulatory Approval Exceptions

The following section summarizes the origins and history of judicial interpretations of the experimental use and regulatory approval exceptions in the United States. The summary is largely based on a forthcoming article co-authored by one of the authors of this report (Sarnoff), which provides additional details and a comparison to European law.[11] The summary identifies significant changes over time to the scope of the experimental use exception, as well as unresolved questions regarding its basic nature and regarding the nature, scope, and application of the regulatory approval exception.

1. Origins and Early Interpretations of the Experimental Use Exception

The experimental use exception in the United States was first articulated by Supreme Court Justice Story in two cases in the early Nineteenth Century. As Justice Story stated in 1813 in *Whittemore v. Cutter,*[12] "it could never have been the intention of the legislature to punish a man, who constructed such a machine merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects."[13] The patent statute at the time provided liability for any person who shall "make, devise, use, or sell" the patented invention, and the statutory language had been amended earlier to make clear that making without use constituted an infringement of the exclusive right.[14] Thus, the language of the *Whittemore* decision may be understood in one of two ways – either as a statutory interpretation of the limits of the specific rights granted by a patent, or as a judicially imposed exception to the rights granted, consistent with the more extensive judicial common lawmaking powers of the time. The distinction is significant, both substantively and procedurally, as the first approach would define the limits of property initially granted and the second approach would impose restrictions (in the nature of an affirmative defense to liability) on the use of that property.[15] The dispute over which approach is correct has not yet been settled, but the exception is most frequently referred to as a "common law" exemption from liability.[16]

The *Whittemore* decision also articulated two different grounds for an exception to patent infringement. The first was for "philosophical experiments," and the second was to "ascertain… sufficiency" of the patented invention for the disclosed uses. At the time, "philosophical experiments" was understood to mean scientific research,

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[11] See Henrik Holzapfel & Joshua D. Sarnoff, A Cross-Atlantic Dialog on Experimental Use and Research Tools, 48 IDEA (forthcoming 2008), draft *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1005269. *See also* Sean O'Connor, Enabling Research or Unfair Competition? De Jure and De Facto Research Use Exceptions in Major Technological Countries, in COMPARATIVE PATENT LAW: A HANDBOOK OF CONTEMPORARY RESEARCH (Toshiko Takenaka & Rainer Moufang, eds., forthcoming 2008).

[12] 29 F. Cas. 1120 (C.C.D. Mass. 1813) (No. 17,600).

[13] *Id.* at 1121.

[14] Act of Apr. 17, 1800, ch. 25, § 1, 2 Stat. 37-38 (1800) (current version at 35 U.S.C. § 271(a) (2008)). *See* Act of Feb. 21, 1793, ch. 11, § 5, 1 Stat. 318, 321 (1793) ("shall make, devise, and use or sell").

[15] *See* O'Conner, *supra* note 11, at 3, 7 (discussing alternative treatment of the doctrine as an exception or as an exemption).

[16] *See, e.g.*, Integra LifeSciences I, Ltd. v. Merck KGaA, 331 F.3d 860, 863 n.2 (Fed. Cir. 2003).

particularly in physics.[17] The scope of these two prongs of the exception has been the subject of extensive dispute and numerous cases over the course of the next two centuries.

In *Sawin v. Guild,*[18] Justice Story sought to clarify further the scope of the exception as follows:

> [T]he making of a patented machine to be an offence within the purview of it, must be the making with an intent to use for profit, and not for the mere purpose of philosophical experiment, or to ascertain the verity and exactness of the specification. In other words, that the making must be with an intent to infringe the patent-right, and deprive the owner of the lawful rewards of his discovery.[19]

Unfortunately, the decision did not clearly define what constituted "lawful rewards," although it seemed to suggest a distinction between non-commercial experiments and testing validity of the claimed invention on the one hand, and commercial benefits on the other. This distinction was made more explicitly by Justice Curtis in 1852 in *Byam v. Bullard,*[20] where he noted that scientific research and competitive evaluation do not cause injury to the exclusive patent right and are not performed "with [an] intent to deprive the patentees of some lawful profit."[21]

Numerous cases were decided between 1852 and 1950 that explored the limits of the "intent to deprive … of some lawful profit" standard. Commentators differ regarding the nature of the standard that the courts actually applied, but generally agree that a finding of infringement required the user of the patented technology either to have a commercial intent to make a profit through the use of the patented invention or to derive some actual commercial benefit from the use of the invention (such as sales or reduced costs of production).[22] During this period, only one case,

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[17] *See, e.g.,* II THE COMPACT EDITION OF THE OXFORD ENGLISH DICTIONARY 2154 (Oxford Univ. Press 1971) ("[p]ertaining to, or used in the study of, natural philosophy, or some branch of physical science").

[18] 21 F. Cas. 554 (C.C.D. Mass. 1813) (No. 12,391).

[19] *Id.* at 555.

[20] 4 F. Cas. 934 (C.C.D. Mass. 1852) (No. 2,262).

[21] *Id.* at 935.

[22] *See, e.g.,* Ronald D. Hantman, Letter to the Editor, *Re: The Experimental Use Defense*, 87 J. PAT. & TRADEMARK OFF. SOC'Y 348, 348–49 (2005) (noting that the historic case law for the exception required both experimentation and the absence of an intent to use for profit, i.e., where "the infringer makes or attempts to make a monetary profit while infringing the patent"); Ronald D. Hantman, *Experimental Use as an Exception to Patent Infringement*, 67 J. PAT. & TRADEMARK OFF. SOC'Y 617, 625 (1985) (distinguishing "use for profit" from cases in which "the experimenter neither made money nor tried to make money while infringing the patented invention."); N. Scott Pierce, *A New Day Yesterday: Benefit as the Foundation and Limit of Exclusive Rights in Patent Law*, 6 J. MARSHALL REV. INTELL. PROP. L. 373, 384-412 (2007) (discussing cases finding infringement that focused on the benefit of the invention gained by use, rather than profits obtained, and later cases focusing on commercial intent); Andrew S. Baluch, Note, *Relating the Two Experimental Uses in Patent Law: Inventor's Negation and Infringer's Defense*, 87 B.U. L. REV. 213, 250–53 (2007) (discussing factors to distinguish experimental from commercial use derived from experimental use cases relating to the public use bar of 35 U.S.C. § 102(b)). *Cf.* Richard E. Bee, *Experimental Use as an Act of Patent Infringement*, 39 J. PAT. OFF. SOC'Y 357, 367-68 (1957) (noting the failure of courts to impose reasonably royalty damages for non-commercial uses, arguing that courts generally treated the experimental use exception very narrowly and found it to apply only when the experiment was performed to gratify a philosophical taste, curiosity, or for amusement).

Ruth v. Stearns-Roger Manufacturing Co.,[23] addressed scientific research in a university setting. In that case, the court found that the defendant was not liable for contributing to infringement by supplying replacement parts used at a mining school, given that the patented machines were used only experimentally in a laboratory and subsequently were cut up and changed.[24]

In 1950, Congress proposed legislation that would have explicitly codified the experimental use exception, excluding from infringement "making or using of a patented invention solely for the purpose of research or experiment" and not for sale [25] However, in 1952, Congress enacted a revised patent law that did not provide an express exception for experimental use, but rather merely codified in Section 271(a) the exclusive rights to make, use, and sell and the existing judicial standards for infringement.[26]

2. The 1984 *Bolar* Decision and Legislative Adoption of the Regulatory Approval Exception

Between 1952 and 1984, relatively few experimental use cases were decided, and none involved scientific research.[27] In 1984, however, the Federal Circuit decided *Roche Products Inc. v. Bolar Pharmaceuticals Co.*[28] In *Bolar*, the court held that the experimental use exception did not apply to scientific tests using a patented pharmaceutical compound for the purpose of obtaining generic product marketing approval from the Food and Drug Administration (FDA).[29] Specifically, the court construed the experimental use exception to be narrow (limited to "amusement, to satisfy idle curiosity, or for strictly philosophical inquiry") and held that the defendant's tests were "solely for business reasons."[30]

Congress responded to the *Bolar* decision by codifying a regulatory approval exception to patent infringement, as part of broader legislation balancing the rights of pioneering and generic pharmaceutical manufacturers.[31] The principal concerns expressed by Congress when adopting this exception were that the *Bolar* decision had been wrongly decided, and that patent holders should not be able to dominate research and development during the patent term in a manner that would result in the improper effective extension of the right to exclude beyond the patent term (due to the need to obtain regulatory approval).[32] Specifically, Congress created new Section 271(e)(1), which excepted from infringement under Section 271(a) any making, using, or selling of a "patented invention" "solely for uses reasonably related to the development and submission of information under a Federal law which regulates . . . drugs."[33]

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[23] 13 F. Supp. 697 (D. Colo. 1935), *rev'd on other grounds*, 87 F.2d 35 (10th Cir. 1936).
[24] *See id.* at 703, 713.
[25] STAFF OF H. COMM. ON THE JUDICIARY, 81ST CONG., PROPOSED REVISION AND AMENDMENT OF THE PATENT LAWS, PRELIMINARY DRAFT WITH NOTES 59 (Comm. Print 1950) (proposed Section 73).
[26] *See* 35 U.S.C. § 271(a) (2008); S. REP. NO. 82-1979 (1952), *reprinted in* 1952 U.S.C.C.A.N. 2394, 2402 (noting that proposed § 271(a) was merely declaratory of what constitutes infringement).
[27] *See* Hantman, *supra* note 22, 67 J. PAT. & TRADEMARK OFF. SOC'Y at 630-39 (discussing the cases).
[28] 733 F.2d 858 (Fed. Cir. 1984).
[29] *See id.* at 862–63.
[30] *Id.* at 863.
[31] *See* 35 U.S.C. §§ 155, 155A, 156, 271(e) (2008).
[32] *See, e.g.*, H.R. REP. NO. 98-857, pt. 2, at 61 (1984); H.R. REP. NO. 98-857, pt. 1, at 46 (1984).
[33] *See* Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, § 202,

In Section 271(e)(1), Congress codified broad, categorical language that implicitly rejected the narrow *Bolar* construction of the experimental use exception in the particular context of human drug development.[34] Section 271(e)(1) differs from the historic scope of the experimental use exception by excepting from infringement sales for the specified experimental uses. Further, the language of Section 271(e)(1) encompasses experiments performed by commercial entities with the intent subsequently to market products, and does not clearly distinguish among types of patented inventions or among their roles in regard to experiments designed to obtain regulatory approval. This language was subsequently interpreted by the Supreme Court in *Eli Lilly & Co. v. Medtronic, Inc.*[35] to apply not only to patented inventions used in human drug development but also to inventions used in developing information for all products requiring pre-market approval by the FDA and subject to the patent term extension provisions of the U.S. patent law.[36]

3. Subsequent Federal Circuit Interpretations Narrowly Construing the Experimental Use Exception

Since Congress revised Section 271 in 1984, the Federal Circuit has construed narrowly both the experimental use exception and the regulatory approval exception of Section 271(e)(1). In 2000, in *Embrex, Inc. v. Service Engineering Corp.*,[37] the Federal Circuit reiterated language from *Bolar* that the experimental use exception does not apply when the experiments have "'definite, cognizable, and not insubstantial commercial purposes.'"[38] The court upheld a jury verdict of infringement of a patent for a method of injecting eggs based on injection tests performed by scientists, who were employed by a company that unsuccessfully sought to demonstrate a commercial vaccination machine for use as an alternative to the patented method. Specifically, the court held that the tests did not qualify as de minimis infringement or as experimental use, given that the tests were performed "expressly for commercial purposes."[39]

In 2002, in *Madey v. Duke University*,[40] the Federal Circuit held for the first time that the experimental use exception may apply to university-based scientific research. The District Court had granted summary judgment of non-infringement to Duke for constructing and using (in ways that allegedly were not authorized under a federal government contract, as Duke would have no liability if the used was so authorized[41]) certain free electron lasers and microwave guns that embodied the claims of two patents. The Federal Circuit reversed, holding that its precedents obligated it to

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98 Stat. 1585, 1603 (1984) (codified as amended at 35 U.S.C. § 271(e)(1)). Congress later extended the exception to offers to sell and imports and to approval of veterinary biological products. *See* Generic Animal Drug and Patent Term Restoration Act, Pub. L. No. 100-670, § 201, 102 Stat. 3971, 3988 (1988); Uruguay Round Agreements Act, Pub. L. No. 103-465, § 533, 108 Stat. 4809, 4988 (1994).

34 *See* Eli Lilly & Co. v. Medtronic, Inc., 872 F.2d 402, 406 (Fed. Cir. 1989) (citing 35 U.S.C. § 271(a), (e)(1)).

35 496 U.S. 661 (1990).

36 *See id.* at 669–78; 35 U.S.C. § 156 (2007).

37 216 F.3d 1343 (Fed. Cir. 2000).

38 *Id.* at 1349 (quoting Roche Products Inc. v. Bolar Pharmaceuticals Co., 733 F.2d 858, 863 (Fed. Cir. 1984)).

39 *Id.*

40 307 F.3d 1351 (Fed. Cir. 2002).

41 *See* 28 U.S.C. § 1498.

recognize a "judicially created experimental use defense, however, in a very limited form."[42] That exception "does not immunize use that is in any way commercial in nature…. [or] that is in keeping with the alleged infringer's legitimate business, regardless of commercial implications."[43]

With regard to universities, the court in *Madey* noted that scientific research "projects unmistakably further the institution's legitimate business objectives, including educating and enlightening students and faculty participating in these projects. These projects also serve, for example, to increase the status of the institution and lure lucrative research grants, students and faculty."[44] The court thus remanded for further evaluation of "the legitimate business Duke is involved in and whether or not the use was solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry."[45] On remand, the District Court found that Duke had presented no evidence to suggest that its experiments were not "in keeping with its legitimate business as an educational institution" and thus denied Duke's motion for summary judgment but left the issue open for proof at trial.[46]

Few reported district court cases have addressed the experimental use exception since the *Madey* decision. Those cases that do so either have reiterated the narrow scope of the exception or have simply referred to *Madey* as binding precedent.[47] In the 2003 Federal Circuit decision in *Integra Lifesciences I Ltd. v. Merck KGaA*[48] – discussed in detail below in regard to the regulatory approval exception – the majority opinion suggested in dicta that the experimental use exception not only is narrow but also is based on the concept of *de minimis* damages rather than the lack of infringement.[49] In contrast, a dissenting opinion suggested that the exception is significantly broader – *i.e.,* that the "subject matter of patents may be studied in order to understand it, or to improve upon it, or to find a new use for it, or to modify or 'design around' it."[50]

4. Proposals for Legislation to Codify a Broader Experimental Use Exception

Since the *Bolar* decision, Congress has on a few occasions introduced proposed legislation to codify a broader experimental use exception. But these efforts have not resulted in adoption of a change to the law. For example, in 1990, Congress introduced a bill that would have excepted from infringement any making and use for "research or experimentation purposes," unless the primary purpose of the patented

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42 307 F.3d at 1360. *See also id.* at 1361 (recognizing the exception exists "in the very narrow form articulated by this court" in *Embrex* and *Bolar*).

43 *Id.* at 1362.

44 *Id.*

45 *Id.* at 1363.

46 Madey v. Duke Univ., 336 F. Supp. 2d 583, 591-92 (M.D.N.C. 2004).

47 *See, e.g.,* Third Wave Techs., Inc. v. Stratagene Corp., 381 F. Supp. 2d 891, 911-12 (W.D. Wisc. 2005) (rejecting arguments that testing of products for cleaving nucleic acids that might infringe patented cleaving methods allegedly to obtain FDA approval for the products would not qualify as experimental use, given the narrow scope of the exception in *Madey* and the commercial motivation to market the products); Eli Lilly and Co. v. Emisphere Techs., Inc., 408 F. Supp. 2d, 668, 678 n.2 (S.D. Ind. 2006) (noting pleading of experimental use defense to infringement counterclaim, and citing to *Madey* for a discussion of the doctrine, but refusing to address the issue as premature).

48 331 F.3d 860 (Fed. Cir. 2003).

49 *See id.* at 863 n.2.

50 *Id.* at 875 (Newman, J., concurring in part and dissenting in part).

invention was for research (*i.e.,* intended for use as a research tool) and in that case it would not be an act of infringement to study the invention or use it to develop new inventions outside the scope of the patent.[51] Similarly, in 2002, Congress introduced a bill that would have excepted from infringement any patented genetic sequences "for purposes of research," but not applying to commercial manufactures and sales.[52] In contrast, in 2007, Congress introduced a bill that would prospectively ban the patenting of any "nucleotide sequence, or its functions or correlations, or the naturally occurring products it specifies."[53] The bill thus would preclude a particular category of patents (not only gene patents but all patents on polynucleotides), which may be used as research tools. However, the biotechnology industry and others have expressed significant opposition to the bill,[54] and it currently appears unlikely to be enacted into law.

In 2002, the Federal Trade Commission (FTC) conducted hearings in which more than 300 panelists, including "business representatives from large and small firms, and the independent inventor community; leading patent and antitrust organizations; leading antitrust and patent practitioners; and leading scholars in economics and antitrust and patent law," were invited to testify on a variety of issues relating to patent law and policy.[55] Much of the testimony focused on the effects of research tool patents on third-party research and innovation. The panelists voiced general approval for codifying a broader experimental use exemption that would apply to research directed at understanding if and how a patented invention works (recall the statement in *Whittemore* regarding sufficiency of the machine to produce its desired effects).[56] They were more divided on the question of whether an exception should apply to research directed at improvement or follow-on innovation resulting from use of patented research tools, and generally rejected the idea of providing an exemption for use of a research tool to develop another product (recall the statement in *Whittemore* regarding philosophical experiments).[57] A report based on the hearings concluded that developers of research tools "need an income stream from those who use their inventions," and that the "hearing record provides no basis for exempting such tools from patent protection"[58]

Proposals to explicitly codify an experimental use exception have also come from the private sector. A 2004 report sponsored by the National Academy of Sciences

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[51] Patent Competitiveness and Technological Innovation Act, H.R. 5598, 101st Cong. § 402 (1990) (proposed 35 U.S.C. § 271(j)).

[52] Genomic Research and Diagnostic Accessibility Act of 2002, H.R. 3967, 107th Cong. § 2 (2002) (proposed 35 U.S.C. § 271(j)(1)).

[53] Genomic Research and Accessibility Act, H.R. 977, 110th Cong. § 2 (2007) (proposed 35 U.S.C. § 106).

[54] *See, e.g., Stifling or Stimulating – The Role of Gene Patents in Research and Genetic Testing Before the Subcomm. on Courts, the Internet and Intellectual Property*, 110th Cong. (2007) (statement of Jeffrey Kushan on behalf of the Biotechnology Industry Organization (BIO)), *available at* http://judiciary.house.gov/media/pdfs/Kushan071030.pdf (last visited Feb. 7, 2008) and (statement of E. Jonathan Soderstrom, president-elect of the Association of University Technology Managers (AUTM)), *available at* http://judiciary.house.gov/media/pdfs/Soderstrom071030.pdf (last visited Feb. 7, 2008).

[55] FEDERAL TRADE COMMISSION, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy,* Executive Summary 3-4 (2003), *available at* http://www.ftc.gov/os/2003/10/innovationrpt.pdf (last visited Feb. 22, 2008) [hereinafter "FTC Report"].

[56] *Id.* Chapter 4 at 34-36.

[57] *Id.*

[58] *Id.* Chapter 4 at 36.

(NAS) recommended codification of an experimental use exception in light of the *Madey* decision, given that "there should be some level of protection for noncommercial uses of patented inventions."[59] The report also recommended taking various administrative actions to assure access, given that legislative enactment might not occur.[60] Some members of the committee consulted in the preparation of the report expressed the opinion that any codified experimental use exception should be conditioned upon the researcher agreeing to refrain from patenting the results of the protected research, the results of the research not undermining a patentee's commercial markets, a covenant not to use the research results for commercial purposes, and provision for terminating the exemption if the protected research yields patents that are asserted against another party lacking the exemption.[61]

Later in 2004, the American Intellectual Property Lawyer's Association (AIPLA) endorsed the NAS recommendation and proposed language for a broader, codified experimental use exception.[62] Specifically, the AIPLA proposal would have excepted from infringement the acts of:

> (1) evaluating the validity of the patent and the scope of protection afforded under the patent; (2) understanding features, properties, inherent characteristics or advantages of the patented subject matter; (3) finding other methods of making or using the patented subject matter; and (4) finding alternatives to the patented subject matter, improvements thereto or substitutes therefor.[63]

In 2006 the NAS published a report focused more specifically on the impact of patents on genomic and proteomic research.[64] This report recommended:

> Congress should consider exempting research "on" inventions from patent infringement liability. The exemption should state that making or using a patented invention should not be considered infringement if done to discern or to discover: (a) the validity of the patent and scope of afforded protection; (b) the features, properties, or inherent characteristics or advantages of the invention; (c) novel methods of making or using the patented invention; or (d) novel alternatives, improvements, or substitutes.
>
> Further making or using the invention in activities incidental to

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[59] *See* NAT'L RESEARCH COUNCIL OF THE NAT'L ACADS., A PATENT SYSTEM FOR THE 21ST CENTURY 82, 109 (Stephen A. Merrill et al. eds., 2004), *available at* http://books.nap.edu/html/patentsystem/0309089107.pdf (last visited Feb. 22, 2008) [hereinafter "Patent System Report"].

[60] *See id.* at 108-17.

[61] *See id.* at 115.

[62] *See* AM. INTELLECTUAL PROP. LAW ASS'N, AIPLA RESPONSE TO THE NATIONAL ACADEMIES REPORT ENTITLED "A Patent System for the 21st Century" 22-26 (2004) ("AIPLA Response"), *available at* http://www.aipla.org/Content/ContentGroups/Issues_and_Advocacy/Comments2/Patent_and_Trademark_Office/2004/NAS092304.pdf (last visited Feb. 22, 2008).

[63] *Id.* at 25.

[64] NATIONAL RESEARCH COUNCIL. COMMITTEE ON INTELLECTUAL PROPERTY RIGHTS IN GENOMIC AND PROTEIN RESEARCH AND INNOVATION, *Reaping the Benefits of Genomic and Proteomic Research: Intellectual Property Rights, Innovation, and Public Health*, (2006), *available at* http://fermat.nap.edu/catalog/11487.html?onpi_newsdoc11172005 [hereinafter "Reaping the Benefits"].

> preparation for commercialization of noninfringing alternatives also should be considered noninfringing. Nevertheless, a statutory research exemption should be limited to these circumstances and not be unbounded. In particular, it should not extend to unauthorized use of research tools for their intended purpose, in other words, to research "with" patented inventions. Accordingly, our recommendation would not address the circumstances of the *Madey* case, which clearly entailed research "with" the patented laser; but it would shield some types of biomedical research involving patented subject matter.[65]

Scholars also have debated for many years the need for the U.S. to implement an expanded experimental use exception for a wide range of activities.[66] Some have advocated the creation of broad exemptions for use of patented technologies by university and non-profit researchers,[67] while others have pointed out a host of practical difficulties that might arise if such plans were implemented.[68] Some worry that a broad experimental use exception would remove incentives for the development of new research tools.[69] Others question whether patent protection is needed to develop research tools, although often recognizing that patents can play a useful role when investment is needed to make the technology practically available.[70] Some commentators have proposed application of the doctrine of fair use to promote access to research tools,[71] but others have criticized this approach.[72] A number of scholars have proposed hybrid systems combining limited experimental use exceptions with compulsory licensing or other alternative approaches, some of which are discussed in more detail below in Section VII.[73]

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[65] *Id.* at 145.

[66] *See, e.g.,* Harold C. Wegner, PATENT LAW IN BIOTECHNOLOGY, CHEMICALS & PHARMACEUTICALS 460, *et seq.* 2d ed. (1994); Lauren C. Bruzzone, *The Research Exception: A Proposal*, 21 AIPLA Q.J. 21 52, 53 *et seq.* (1993); Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017, 1019 *et seq.* (1989); Irving N. Feit, *Biotechnology Research and the Experimental Use Exception to Patent Infringement*, 71 J. PAT. & TRADEMARK OFF. SOC'Y 819, 832 (1989); Steven J. Grossman, *Experimental Use or Fair Use as a Defense to Patent Infringement*, 30 IDEA 243, 247 (1990); Ned A. Israelsen, *Making, Using, and Selling without Infringing: An Examination of 35 U.S.C. Section 271(e) and the Experimental Use Exception to Patent Infringement*, 16 AIPLA Q.J. 457, 458, 472, 474 (1988-1989);); Jordan P. Karp, *Experimental Use as Patent Infringement: The Impropriety of a Broad Exception*, 100 YALE L.J. 2169, 2170 (1991); Suzanne T. Michel, Comment, *The Experimental Use Exception to Infringement Applied to Federally Funded Inventions*, 7 HIGH TECH. L.J. 369, 376, 389 (1992); Patricia M. Thayer & Richard A. De Liberty, *The Research Exception to Patent Infringement: The Time Has Come for Legislation*, 4 J. BIOLAW & BUS. 1, 2, 6 *et seq.* (2000).

[67] *See, e.g.*, Eyal H. Barash, Comment, *Experimental Uses, Patents, and Scientific Progress*, 91 NW. U. L. REV. 667, 699-700 (1997); Kevin Sandstrom, Note, *How Much Do We Value Research and Development?: Broadening the Experimental Use Exemption to Patent Infringement in Light of Integra Lifesciences Ltd. v. Merck*, 30 WM. MITCHELL L. REV. 1059, 1067 (2004).

[68] Elizabeth A. Rowe, *Closing in on Open Science: Trends in Intellectual Property & Scientific Research: The Experimental Use Exception to Patent Infringement: Do Universities Deserve Special Treatment?*, 59 ME. L. REV. 283, 308-10 (2007).

[69] Mueller, *supra* note 7, at 4.

[70] Michael S. Mireles, *States as Innovation System Laboratories: California, Patents and Stem Cell Technology,* 28 CARDOZO L. REV. 1133, 1152 (2006).

[71] *See, e.g.,* Maureen A. O'Rourke, *Toward a Doctrine of Fair Use in Patent Law*, 100 COLUM. L. REV. 1177, 1249-50 (2000).

[72] *See, e.g.,* Rowe, *supra* note 68, at 308-09.

[73] *See, e.g.*, Katherine J. Strandburg, *What does the Public Get? Experimental Use and the Patent Bargain*, 2004 WIS. L. REV. 81, 143-144 (2004)

5. Initial Federal Circuit and Subsequent Supreme Court Interpretations of the Regulatory Approval Exception in the *Merck v. Integra* Case

In 2003, in *Integra Lifesciences I Ltd. v. Merck KGaA,*[74] the Federal Circuit narrowly construed the regulatory approval exception of Section 271(e)(1). The District Court had found that early-stage experiments using cyclic peptides to assess their potential to block certain receptors (and thereby inhibit angiogenesis) qualified for the experimental use exception, but that later pre-clinical experiments using a particular cyclic peptide did not qualify for the regulatory approval exception and infringed the patents at issue. On appeal, the Federal Circuit held that the pre-clinical experiments were not "'solely for uses reasonably related to the development and submission of information,'" because they did not "reasonably relate to the development and submission of information for FDA's safety and effectiveness approval processes."[75] Because *Integra* did not appeal the finding that the experimental use exception applied to the early-stage experiments, and because *Merck* did not argue the experimental use exception applied to the pre-clinical experiments, the majority opinion did not provide a holding on the application of this doctrine. However, the dissent suggested that, for the pre-clinical experiments, "the statutory immunity of § 271(e) takes effect wherever the research exemption ends…."[76]

In 2005, the Supreme Court in *Merck, KGaA v. Integra LifeSciences I Ltd.*[77] reversed the Federal Circuit's narrow construction of the regulatory approval exception of Section 271(e)(1). The Court held that the exception was not limited to tests that generate safety and effectiveness data; rather, it included any tests (including basic research on biological mechanisms) that might generate data submitted to the FDA.

> At least where a drugmaker has a reasonable basis for believing that a patented compound may work, through a particular biological process, to produce a particular physiological effect, and uses the compound in research that, if successful, would be appropriate to include in a submission to the FDA, that use is "reasonably related" to the "development and submission of information under . . . Federal law."[78]

The Court, however, explicitly declined to address the application of the regulatory approval exception to patented research tools,[79] and did not address the scope of the experimental use exception.

Following the *Merck* Supreme Court decision, commentators have noted that research tools were involved in at least some of the allegedly infringing experiments at issue on appeal, notwithstanding the parties' arguments to the contrary. For example, the patented peptides at issue were used as positive controls to measure the effectiveness of other compounds.[80] Commentators also have raised concerns that application of

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[74] 331 F.3d 860 (Fed. Cir. 2003).
[75] *Id.* at 865-66 (quoting 35 U.S.C. § 271(e)(1)).
[76] *Id.* at 875-76 (Newman, J., concurring in part and dissenting in part).
[77] 545 U.S. 193 (2005).
[78] *Id.* at 207.
[79] *Id.* at 205 n.7.
[80] *See, e.g.,* Benjamin G. Jackson, Note, *Merck v. Integra: Bailing Water Without Plugging the Hole*, 20 BYU J. PUB. L. 579 (2006) (noting the court's statement that "Scripps used the RGD peptide in . . . tests as 'positive controls' against which to measure the efficacy of the mimetics.");

Section 271(e)(1) to research tool inventions would eviscerate patent rights and incentives.[81] To avoid this result, they have argued that the term "patented inventions" within Section 271(e)(1) should be interpreted to be limited to patented drug and medical device inventions that are subject to regulatory approval and term extension under Section 156, which was the focus of the broader legislation enacting Section 271(e)(1).[82]

In contrast, other commentators have suggested that the effects of the *Merck* decision on research tool inventions will be minimal, because "the sanctioned research is *into*, not *using*, patented technology and patents have a smaller impact on research tools and instruments than on drug development."[83] Other commentators have suggested expanding the exception further to minimize incentives for drug companies to "outsource[e] their early stage research from the United States,"[84] to jurisdictions where broader experimental use exceptions exist or where patent rights in research tool inventions do not exist.

6. Cases Interpreting the Regulatory Approval Exception Since the 2005 Supreme Court Decision in *Merck*

Cases since the Supreme Court's 2005 *Merck* decision not only have followed the trend of construing the regulatory approval exception of Section 271(e)(1) broadly,[85] but also have explicitly extended the exception to research tools. In 2005, in *Classen Immunotherapies, Inc.v. Biogen IDEC,*[86] a District Court dismissed infringement claims against defendants for participating in a study evaluating vaccination risks of existing products, given the broad construction of Section 271(e)(1) in *Merck*.[87] Specifically, the District Court rejected the argument that Section 271(e)(1) applied only to data for regulatory decisions made prior to initial regulatory approval to market products.[88]

Paul Wiegel, *Was the FDA Exemption to Patent Infringement, 35 U.S.C. § 271(e)(1), Intended to Exempt a Pharmaceutical Manufacturer's Activities in the Development of New Drugs?*, 2007 B.C. INTELL. PROP. & TECH. F. 112901 (2007).

[81] *See, e.g.,* Daniel J. Ford, *Merck v. Integra: Implications for the Common Law and Statutory Exemptions*, 7 LOY. L. & TECH. ANN. 123 (2006-2007); Francine Haight, *Illegal Sales of Pharmaceuticals on the Internet*, 16 ALB. L.J. SCI. & TECH. 195 (2006); Vihar R. Patel, *Are Patented Research Tools Still Valuable? Use, Intent, and a Rebuttable Presumption: A Proposed Modification for Analyzing the Exemption from Patent Infringement Under 35 U.S.C. 271(e)(i)*, 47 IDEA 407 (2007); Tara Stuart, *Has the Supreme Court Incorrectly Expanded § 271(E)(1) to Risk a Regulatory Taking?*, 5 J. MARSHALL REV. INTELL. PROP. L. 216 (2006).

[82] *See* 35 U.S.C. § 156; N. Scott Pierce, *A New Day Yesterday: Benefit as the Foundation and Limit of Exclusive Rights in Patent Law*, 6 J. MARSHALL REV. INTELL. PROP. L. 373 (2007). This argument has also been made by a patent holder in litigation. *See, e.g.*, Oral Arguments in Proveris Scientific Corp. v. Innovasystems, Inc., (Fed. Cir) (No. 2007-1428), *available at* www.cafc.uscourts.gov/oralarguments/.

[83] Daniel A. Lev, *A Realist Approach to Merck KGaA v. Integra*, 5 NW. J. TECH. & INTELL. PROP. 135 (2006).

[84] Katherine A. Helm *Outsourcing the fire of genius: the effects of patent infringement jurisprudence on pharmaceutica drug development*, 17 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 153 (2006).

[85] *But cf.* Third Wave Techs., Inc. v. Stratagene Corp., 381 F. Supp. 2d 891, 912-13 (W.D. Wisc. 2005) (holding that products tests using a patented method performed during a "'start-up phase'" with only "a remote desire to obtain FDA approval" for sales for the diagnostic assay market were neither "reasonably" related to obtaining such approval, nor performed "*solely*" for such uses).

[86] 381 F. Supp. 2d 452 (D. Md. 2005).

[87] *See id.* at 455-56.

[88] *See id.*

In 2006, in *Genentech, Inc. v. Insmed Inc.*,[89] a District Court granted summary judgment to one defendant that had supplied patented insulin-like growth factor for experiments performed by another company.[90] The Court held that Section 271(e)(1) applied to the experiments, as "even if the allegedly infringing experiments were conducted, in part, for commercial reasons, the experiments would produce information that would be given to the FDA in order to get FDA approval."[91]

In 2006, in *Amgen, Inc. v. F. Hoffman-LaRoche Ltd.*,[92] a District Court held that Section 271(e)(1) is an affirmative defense, rather than "'part of the statutory definition of infringement that [the plaintiff] must establish.'"[93] Accordingly, the District Court rejected a motion to dismiss for failure to state a claim, given that the plaintiff had sufficiently alleged infringement without pleading specific acts of infringement that fell outside the scope of Section 271(e)(1).[94] Further, the complaint alleged importation of an allegedly infringing patented drug, which was sufficient given that the District Court could not conclude as a matter of law that importation was solely for uses reasonably related to submitting information for regulatory approval.[95]

In 2006, in *Classen Immunotherapies, Inc. v. King Pharmaceuticals, Inc.*,[96] a District Court held that Section 271(e)(1) applied to a patented process arguably used as a research tool. Specifically, the patents addressed methods of identifying and commercializing new uses of existing drugs, and infringement was alleged from bioavailability studies of existing drugs that led to submission to FDA (with the data) of a citizen's petition and a labeling supplement. The District Court held the experiments were reasonably related to the submission of information to the FDA, and found "extension of the safe harbor to cover the use of these tools warranted by the language of *Merck* and a plain reading of the statute."[97]

In 2007, in *Integra Lifesciences I Ltd. v. Merck KGaA*,[98] on remand from the Supreme Court's decision, a majority opinion the Federal Circuit held that Section 271(e)(1) applied to experiments with patented compounds that at the time were candidates for but were not ultimately the subject of the regulatory approval application. The experiments developed information "after the biological mechanism and physiological effect of a candidate drug have been recognized, such that if the research is successful it would appropriately be included in a submission to the FDA."[99] Significantly, the majority held that whether the experiments were "reasonably related" to submission "does not depend on the success or failure of the experimentation or actual submission of the experimental results."[100] The majority also noted that the parties agreed that the patented compounds were not used as "research tools," and thus did not address whether Section 271(e)(1) applies to

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89 436 F. Supp. 2d 1080 (N.D. Cal. 2006).
90 *See id.* at 1094-95.
91 *Id.* at 1095.
92 456 F. Supp. 2d 267 (D. Mass. 2006).
93 *Id.* at 273 (quoting Amgen, Inc. v. Hoechst Marion Roussel, Inc., 3 F. Supp. 2d 104, 109 (D. Mass. 1998)).
94 *See id.* at 274.
95 *See id.*
96 466 F. Supp. 2d 621 (D. Md. 2006).
97 *Id.* at 625 n.2.
98 496 F.3d 1334 (Fed. Cir. 2007).
99 *Id.* at 1339. *See id.* at 1340.
100 *Id.* at 1341.

patented inventions used as research tools. However, the dissent argued that the decision did apply to research tools as some of the patents claimed methods that could not have been potential regulatory approval drug candidates.[101] The dissent thus argued that the holding effectively "eliminate[s] protection for research tool inventions."[102]

In 2007, in *Forest Laboratories, Inc. v. Ivax Pharmaceuticals, Inc.,*[103] the Federal Circuit upheld a prospective but limited injunction against a foreign producer of patented drug products that was supplying production information and would supply products for experiments within the scope of the regulatory approval exception of Section 271(e)(1). The injunction prohibited the domestic experimenter from commercial exploitation following FDA approval and during the life of the patent, and the court held it was appropriate to include the foreign producer as such supply would induce infringement under Section 271(b) following such approval. [104]

Finally, in 2008, the Federal Circuit may address (and has heard oral argument) in *Proveris Scientific Corp. v. Innovasystems, Inc.*, No. 07-1428.[105] The *Proveris Scientific* case has the potential to resolve the scope of the Section 271(e)(1) exemption A district court found Innovasystems liable for infringement, based on sales of a patented instrument to three drug companies, solely for the purpose of the drug companies' development of data for submission to the FDA.[106] Innovasystems argued on appeal that the sales were exempt under Section 271(e)(1), noting that the instruments were sold solely for use in generating data for FDA submission. In particular, Innovasystems argued that the language of 271(e)(1) applies to the sale of patented inventions, and that there is no explicit, relevant restriction in the statutory language on the nature of the patented invention that is made, used, or sold for uses reasonably related to obtaining regulatory approval.[107] (The statute expressly excludes from a "patented invention" that is excepted from infringement for these purposes only a "new animal drug or veterinary biological product … primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques." [108])

In deciding this case, the Federal Circuit in *Proveris* will have the opportunity to address two important questions: (1) is a laboratory instrument (or any other research tool) a "patented invention" under 271(e)(1); and (2) does the 271(e)(1) exemption apply to a party selling the patented invention, if a third party uses the invention to develop data for submission (or if the third party does not ultimately submit data) to the FDA? Assuming the court answers both questions in the affirmative, additional questions arise regarding: (3) how "reasonably related" to the development and submission of information are particular types of research tools used in different ways; and (4) how is "solely" for reasonably related uses to be determined (e.g., does

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101 *Id.* at 1350-51 (Rader, J., dissenting).

102 *Id.* at 1348.

103 501 F.3d 1263 (Fed. Cir. 2007).

104 *See id.* at 1272.

105 Oral Argument, Proveris Scientific Corp. v. Innovasystems, Inc., *available at* www.cafc.uscourts.gov/oralarguments/.

106 The district court's 271(e)(1) ruling was made from the bench immediately prior to trial and does not appear in a reported decision, but is discussed in the oral argument and is extensively addressed in detail in the parties' appellate briefs.

107 *See, e.g.,* "Corrected" Brief of Appellant Innovasystems, Inc. at 12-16, Proveris Scientific Corp. v. Innovasystems, Inc., 2007 WL 2888553 (Fed. Cir. Aug. 27, 2007) (No. 2007-1428).

108 35 U.S.C. § 271(e)(1) (2008).

intent or actual conduct matter, and does the sale of any product for a non-reasonably-related use affect the characterization of the sale of all other products for reasonably-related uses)? For an example taken from the oral argument, would the sale of a patented cell phone solely for use by drug researchers to communicate during development of information for submission to the FDA be "reasonably related," and would it matter if the patented cell phone was sold to third parties for different uses (domestically or internationally)?

In summary, the Federal Circuit has narrowed but simultaneously clarified the scope of the experimental use exception, and under that scope almost no scientific research – including university-based, non-profit basic research – will qualify for the exception. Such research is likely to be performed with commercial intent or to further the legitimate business of the experimenter's business. In contrast, the Supreme Court has expanded the scope of the regulatory approval exception of Section 271(e)(1), which will apply to a broad range of experiments that may generate data that regulators would be interested in reviewing. However, the limits of the regulatory approval exception remain unclear. In particular, the courts have yet to draw clear lines for determining: (1) in regard to scientific experimentation not excepted from infringement under the experimental use exception, when protected regulatory approval activities begin: (2) whether and when patented research tools may be subject to the regulatory approval exception (because used in a manner reasonably relating to development and submission of information to the FDA); and (3) when such patented research tools should be considered made, used, or sold solely for regulatory approval purposes.

IV. Recent Studies of Scientific Researcher and Patent Holder Practices

The following section discusses existing studies of the practices of scientific researchers and patent holders regarding the researchers' acquisition of patented technologies used as research tools, and liability for such research uses. The empirical analysis is important, not only to understand the effects of the legal developments described above but also to discern potential trends in regard to changing social practices or the need for further changes to the legal rules. Unfortunately, the factual results of the surveys are subject to dispute regarding what they suggest for continuation of or changes to existing patent system policies.

Since the *Madey* decision, a number of studies have been conducted to evaluate the effects of that decision, particularly regarding whether patents on inventions intended to function as research tools have impeded or delayed basic scientific research. These concerns reflect earlier theoretical work regarding the potential for development of an "anticommons," or patent thicket requiring licensing of multiple patented inputs, that would result in higher costs, delay, and potentially abandonment of important scientific research (particularly in regard to biomedical and gene-based research).[109] These concerns also reflect the fact that genetic inventions are

[109] *See, e.g.,* Heller & Eisenberg, *Can Patents Deter Innovation? The Tragedy of the Anticommons in Biomedical Research*, 280 SCIENCE 698, *passim* (1998); Kyle Jensen & Fiona Murray, *Intellectual Property Landscape of the Human Genome*, 310 SCIENCE 239, 239-40 (2004); Carl Schapiro, *Navigating the Patent Thicket: Cross licenses, patent pools, and standard-setting, in* 1 INNOVATION POLICY AND THE ECONOMY 119, 120 (Adam Jaffe et al. eds., 2001). *Cf.* Lori Andrews et al., *When Patents Threaten Science*, 314 SCIENCE 1395, 1395-96 (2006). *But see* Ted Buckley, *The Myth of the Anticommons*, BIO DIRECTOR OF ECONOMIC POLICY *available at* http://www.bio.org/ip/domestic/TheMythoftheAnticommons.pdf (last visited Mar. 12, 2008);

fundamental, and thus patents on genetic sequences cannot be designed around.[110] The results of these studies demonstrate that relatively few current (but potentially a growing number of) serious problems have resulted from the expanded legal potential for patent liability (particularly of academic researchers). But the reason for this result may be because patent holders have not aggressively asserted their patents and because scientific researchers have continued to act in ways that (in light of the *Madey* decision) infringe such patents. The studies also demonstrate that there has been an increase in warning letters and internal efforts at universities to discourage patent infringement, but neither have yet had significant effects on researcher behaviors. Stated differently, there is a significant gap between the law on the books and the practices to which the law applies, and the stability of the current situation remains a subject of significant concern.

1. The Walsh, Arora, and Cohen Study (2003)

Around the time of the *Madey* decision, various researchers studied the effects of research tool patents on biomedical innovation, as part of broader research leading to proposals for reforming the U.S. patent system that was commissioned by the NAS Board on Science, Technology, and Economic Policy (STEP).[111] In this study, the researchers specifically sought to address two questions: (1) "whether an emergent anticommons is in fact impeding the development and commercialization of new drugs, diagnostics, and other therapies"; and (2) "whether restricted access to patents on upstream, foundational discoveries is blocking important follow-on research and innovation."[112] The research did not find that the growth of patents on fundamental upstream discoveries and more aggressive licensing by non-profit research institutions, small businesses, and research universities had to that time impeded the development of drugs or other therapies in a significant way. Significantly, "firms and other institutions have developed a number of 'working solutions' that limit the effects of the intellectual property complexities that exist," including "fairly pervasive infringement of patents in the course of laboratory research at the pre-product stage."[113] Pervasive infringement was "informally rationalized as causing no commercial harm and, in any event [was believed to be] shielded from infringement liability by the court interpreted 'research exception.'"[114] However, the *Madey* decision clearly called these common beliefs into question, and "undermine[d] one of the working solutions that has contributed to the progress of biomedical research."[115]

More specifically, the researchers "conducted 70 interviews with IP attorneys, business managers, and scientists from 10 pharmaceutical firms and 15 biotechnology firms, as well as university researchers and technology transfer officers from 6 universities, patent lawyers, and government and trade association personnel."[116] The interviews probed whether proliferation of patents had resulted in failures to

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Timothy Caulfield et al., *Evidence and Anecdotes: An Analysis of Human Gene Patenting Controversies*, 24 NATURE BIOTECHNOLOGY 1091, 1091-94 (2006);

[110] *See, e.g.,* John H. Barton, *Emerging Patent Issues in Genomic Diagnostics*, 24 NATURE BIOTECH. 939 (2006).

[111] *See* NRC Report, *supra* note 9, at 285. The recommendations are published in Patent System Report, *supra* note 59.

[112] NRC Report, *supra* note 9, at 13.

[113] *Id.* *See* NRC Report *supra* note 9, at 322-34.

[114] NRC Report *supra* note 9, at 13. *See* Walsh, Arora & Cohen, NRC Report, *supra* note 9, at 324-28.

[115] NRC Report *supra* note 9, at 13 n.4.

[116] NRC Report, *supra* note 9, at 292.

license beneficial patented technologies and whether patents on upstream discoveries had impeded subsequent research. The researchers identified the development of "defensive" patenting strategies in genomics (where patents are obtained principally as a method of discouraging litigation rather than for use in protecting the patented innovation),[117] and that research tool patents were owned by "different parties with different agendas."[118] Nevertheless, the researchers found that the number of ongoing R&D projects stopped because of patent problems was "small,"[119] finding little evidence that patent-holding entities were refusing to license needed technologies, that the need to license multiple patents was resulting in excessive royalties, or that the increased costs of licensing individual research tool patents were unreasonable (given beliefs that the "productivity gains conferred by the licensed research tools were thought to be worth the price").[120] Patent holders also generally tolerated infringing academic uses of research tools (except for diagnostic tests used in clinical research), as such use could increase the value of the technology and the potential benefits from such lawsuits were typically outweighed by the legal fees, risks of having the patent narrowed or found invalid, and bad publicity from suing universities.[121]

In contrast, "at least for licensing relationships between universities and small firms, access to relatively upstream discoveries … is commonly restricted."[122] However, it was not clear that such restrictive (typically exclusive) licensing impeded follow-on discovery, given that it may lead to increased motivation for further development of the upstream technology by the licensee.[123] The study noted the potential for the *Madey* decision to "chill" some of the infringing biomedical research occurring in university settings[124] and concluded that:

> Through a combination of luck and appropriate institutional response, we appear to have avoided situations where a single firm or organization using its patents has blocked research in one or more broad therapeutic areas. However, the danger remains that progress in a broad research area could be significantly impeded by a patentholder trying to reserve the area exclusively for itself.[125]

Further, the researchers noted significant concerns with increasing secrecy of scientists and with the ability of scientists to share or to obtain access to physical materials needed for research.[126] The process of negotiating material transfer agreements had become significantly longer, resulting in delays of research and in exceptional cases in abandonment of research.[127] Conversely, some university scientists noted that commercial licensing of reagents may result in increasing access given the difficulty of alternative methods of filling demand.[128] The researchers

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117 *See id.* at 295.
118 *Id.* at 296.
119 *Id.* at 303.
120 *Id.* at 300. *See id.* at 298-302.
121 *See* John P. Walsh, Ashish Arora, and Wesley M. Cohen, *Working Through the Patent Problem,* 299 SCIENCE 1021 (2003) [hereinafter "Working Through"].
122 *Id.* at 309.
123 *See id.* at 309-10.
124 *See id.* at 335.
125 *Id.*.
126 *See id.* at 319-21.
127 *See id.* at 321.
128 *See id.* at 322.

concluded that "to the degree that the patenting of biomedical discoveries may impose additional costs and delays in material transfers, it is partly because the Bayh-Dole Act[129] and related acts have provided university administrations, and especially their technology transfer offices, a vested commercial interest in the disposition of intellectual property."[130]

Finally, the researchers noted several institutional responses that had helped to increase access to research tools. These included the creation of public and quasi-public databases of basic research information (such as GenBank and the SNPs Consortium), and efforts of the National Institutes of Health (NIH) to negotiate greater access to research tools or to require funding recipients not to patent their research.[131] Further, researchers avoided research tool patents by performing research outside the United States.[132]

2. The Walsh, Cho, Cohen Study (2005)

Following the earlier Wash, Cohen, Arora study, some of the same researchers sought to determine what effect the *Madey* decision may have had on practices and on their prior conclusions.[133] They surveyed 414 biomedical researchers in universities, government, and non-profit institutions to assess their patent and patented technology acquisition practices.[134] By the time of the study, the researchers found little evidence that the *Madey* decision had significantly changed academic practices in regard to checking for patents – finding only five percent (5%) of respondents regularly checked for patents on knowledge inputs and only two percent (2%) had begun checking since *Madey*.[135] Only a small percentage – eight percent (8%) of respondents – believed their research used information or knowledge covered by a third-party's patent, and there was little effect of such knowledge on scientific research practices – no one reported abandoning research, about one percent (1%) changed their research approach, and about one percent (1%) were delayed more than one month. Thus, the researchers concluded that "for the time being, access to patents on knowledge inputs rarely imposes a significant burden on academic biomedical research," noting the difference between the "'law on the books'" and "'law in action.'"[136]

Nevertheless, the researchers noted (compared to five years earlier) an increase in institutional notifications to respect intellectual property rights – from fifteen percent (15%) to twenty two percent (22%) – and a slight increase in warning letters from patent holders – from three percent (3%) to five percent (5%).[137] The researchers also noted more significant concerns regarding material transfers, identifying more substantial impediments to academic research from lack of physical access. Specifically, they noted that nineteen percent (19%) of respondents had their most

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[129] *See* The Patent and Trademark Act Amendments of 1980, Pub. L. No. 96-517 94 Stat. 3019 (1980) (commonly referred to as the Bayh-Dole Act after its legislative sponsors and codified in relevant part at 35 U.S.C. §§ 200-212).

[130] NRC Report, *supra* note 9, at 322.

[131] *See id.* at 329.

[132] *See* Working Through, *supra* note 121, at 1021.

[133] John P. Walsh, Ashish Arora, and Wesley M. Cohen, *View from the Bench: Patents and Material Transfers*, 309 SCIENCE 2002 (2005).

[134] *See id.*

[135] *See id.*

[136] *Id.*

[137] *Id.*

recent request for a material denied, and that such non-compliance was growing.[138] However, they were unable to conclude "whether patent policy contributes to restricted access to materials, although commercial activities fostered by patent policy do seem to restrict sharing, as do the burden of producing the materials and scientific competition."[139]

[138] *See id.* at 2002-2003.
[139] *Id.* at 2003.

3. The AAAS Study (2006-2007)

In a pilot phase of the AAAS study, the survey was administered in 2005 to 4,017 AAAS members, of which 1,111 responded (twenty-eight percent (28%)).[140] Of the forty-six percent (46%) of respondents who reported obtaining intellectual property for their scientific discoveries or technologies since 2001, fifty-five percent (55%) reported obtaining at least one patent, and of these forty-one percent (41%) described their most important patented invention as a research tool.[141]

In contrast, twenty-four percent (24%) of respondents had acquired patented technology for use in their research since 2001, with rates of use and sources of acquisition varying by technology and by industrial or academic setting.[142] Similarly, the methods of acquiring patented technologies (including material transfer agreements (MTAs), exclusive and non-exclusive licenses, confidentiality and sponsored research agreements, and informal transfers) and the time required to do so varied significantly among respondents, with significant percentages taking more than six months (approximately thirty percent (30%) of respondents took more than six months in regard to acquisition by exclusive licenses).[143]

Unlike in the Walsh, Cho, Cohen study, which used a different methodology, the AAAS study found that forty percent (40%) of respondents to the question found that their research had been affected by difficulties in obtaining patented technology since 2001.[144] Of those respondents, fifty-eight percent (58%) reported delays in research, fifty percent (50%) reported changing their research, and twenty eight percent (28%) reported abandoning their research, particularly because of the need to engage in overly complex licensing negotiations (fifty eight percent (58%)), high individual royalties (forty nine percent (49%)), the patents were not licensable (forty percent (40%), and licensing breakdowns (thirty six percent (36%)).[145]

The second phase of the AAAS study produced comparable results. The survey was administered in 2006 to scientists in the United States, the United Kingdom, Germany, and Japan.[146] In the United States, the survey was administered to 8,000 AAAS members, of which 2,157 responded (twenty seven percent (27%)).[147] Fifty two percent (52%) of those respondents answering the question had created (or contributed significantly) to a technology considered eligible for intellectual property protection, with the largest percentage for industry, academic, and government and others acquiring at least one patent.[148] Of those acquiring patents, academics principally patented research tools (forty five percent (45%)), in contrast to industry (twenty eight percent (28%)).

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[140] STEPHEN HANSEN, AMANDA BREWER, JANA ASHER & MICHAEL KISIELEWSKI, THE EFFECTS OF PATENTING IN THE AAAS SCIENTIFIC COMMUNITY 5 (2006).

[141] *See id.* at 7.

[142] *See id.* at 14-17.

[143] *See id.* at 18-20.

[144] *See id.* at 21. *See also id.* at 21 n.14 (noting differences in survey methodology between the studies).

[145] *See id.* at 22.

[146] SCIENCE & INTELLECTUAL PROPERTY IN THE PUBLIC INTEREST, AMERICAN ASSOCIATION FOR THE ADVANCEMENT OF SCIENCE, EFFECTS OF INTELLECTUAL PROPERTY PROTECTIONS ON THE CONDUCT OF SCIENTIFIC RESEARCH: RESULTS OF A SURVEY OF U.S. AAAS MEMBERS 2-3 (Jan. 16, 2007).

[147] *See id.* at 2.

[148] *See id.* at 3

Thirty two percent (32%) of those respondents answering the question had acquired a technology protected by intellectual property for use in their research since 2002. Of these, fifty four percent (54%) classified their last acquired technology as a research tool.[149] Various methods were used to acquire their last technology, but a low percentage or acquired research tools involved exclusive licenses (seven percent (7%) for academic and thirteen percent (13%) for industrial researchers).[150]

Of those who responded that they had acquired technologies protected by intellectual property, thirty two percent (32%) reported encountering difficulties since 2002.[151] Most research tools were acquired within one month; in contrast, most non-research tool acquisitions took longer than six months.[152] The most common problem reported was overly complex licensing negotiations, the most common effect for academics was delay and for industry was changed research, and relatively few (nineteen (19) total) reported abandoning projects.[153]

4. The Holman Human Gene Patent Litigation Study (2007)

In 2007, one of the authors of this report (Holman) published the results of a comprehensive survey, which attempted to identify (using various databases) all lawsuits that have been filed asserting infringement of a human gene patent.[154] Although human gene patents represent a relatively small subset of patents covering research tools, they have raised a disproportionate level of concern both in the U.S. and abroad, which has led to proposals in Congress to codify a broader experimental use exception for gene sequence patents (as noted earlier), to limit the enforceability and remedies associated with gene patents, or to ban gene patents outright.[155] Although the Holman study does not directly address social practices or measure the extent to which research activities have been curtailed or modified due to the potential for patent liability (e.g., from cease and desist letters that are not followed by lawsuits), it does provide some objective insight into patent holder and research tool user behaviors for this important class of research tool patents. Other commentators have posited a correlation between assertion of a patent in court and patent value,[156] and the Holman study relies on this correlation as a useful indicator of the effects of patents on research and innovation.[157]

Holman identified a total of thirty one (31) distinct lawsuits involving human gene patents, in only seven (7) of which there was an allegation of infringement involving the use of a patented human gene in research (*i.e.,* use as patented research tools). In sixteen (16) of the lawsuits, the alleged infringer was a biotechnology company using a patented human gene in the manufacture of a recombinant therapeutic protein. In six (6) of the lawsuits, the alleged infringer was a provider of genetic diagnostic testing services. The remaining two (2) lawsuits involved patented DNA probes

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149 *See id.* at 2.
150 *See id.* at 2-3.
151 *See id.* at 3.
152 *See id.*
153 *See id.*
154 Christopher M. Holman, *The Impact of Human Gene Patents on Innovation and Access: A Survey of Human Gene Patent Litigation*, 76 UMKC L. REV. 295 (2007), *available at* http://ssrn.com/abstract=1090562.
155 *See id.* at 2, 66.
156 *See generally*, John R. Allison et al., *Valuable Patents*, 92 GEO. L. J. 435 (2004).
157 *See* Holman, *supra* note 154, at 10-11.

useful in forensic identification and paternity testing.[158]

None of the seven (7) lawsuits involving patented research tools resulted in a final judicial decision. In one (1) lawsuit, a lower court found in favor of the patent holder, but the parties settled while the case was on appeal, with the defendant reportedly paying $718,000 for "'licensing fees and other expenses.'"[159] Five (5) of the lawsuits settled before a final ruling by the district court.[160] One (1) lawsuit, which alleged that a non-exclusive licensee had exceeded the scope of its license, was stayed pending the results of an arbitration of the underlying contract dispute.[161]

In five (5) of the lawsuits involving patented research tools, the patent holder was actively using the patented technology in a commercial context at the time of the lawsuit.[162] Two (2) of the lawsuits appear to have involved non-practicing patent holders, but both of the patent holders demonstrated a willingness to license the technology on a non-exclusive basis.[163] In all of the seven (7) research tool lawsuits, the infringer was alleged either to be selling the gene (or the protein encoded by the gene) as a research tool or to be employing the gene in a commercial drug discovery effort specifically targeting the protein encoded by the gene.[164] In some cases, the drug discovery was part of a company's own internal research efforts, although in one (1) case it was conducted on a contract basis.[165]

The Holman study identified no instance in which a lawsuit was filed to address basic, noncommercial research using gene patents. This is consistent with unpublished findings of one of the authors; Holman searched for but was unable to identify any instance after the *Madey* decision where a university researcher was sued for infringement for conducting basic research of a purely non-commercial nature. It is also consistent with the often made observation that a *de facto* research use exception exists for noncommercial research.[166] Reasons for the lack of such lawsuits may include: the desire to rely on such research to broaden markets for research tools; and the limited damages that may be obtained for such uses relative to the costs of litigation (particularly given the uncertain legal status of reach-through royalties for any products developed from the research uses).[167]

One of the lawsuits identified in the Holman study exemplifies the reluctance of patent holders to use their patents to block non-commercial research. The defendant was engaged in substantial commercial drug development efforts targeting the protein

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158 *See id.* at 29-58.

159 *See id.* at 48 (citing to CISTRON BIOTECHNOLOGY, INC., ANNUAL REPORT (FORM 10-K), NOTES TO FINANCIAL STATEMENTS, at n.9 (Sept. 28, 1999), *available at* http://sec.edgar-online.com/1999/09/28/15/0000793725-99-000013/Section30.asp).

160 *See id.* at 48-52.

161 *See id.* at 52.

162 *See id.* at 48-52.

163 *See id.*

164 *See id.* at 47-48.

165 *See id.*

166 *See, e.g., Stifling or Stimulating – The Role of Gene Patents in Research and Genetic Testing Before the Subcomm. on Courts, the Internet and Intellectual Property*, 110th Cong. (2007) (statement of Dr. Marc Grodman, CEO, Bio-Reference Laboratories, Inc.), *available at* http://judiciary.house.gov/media/pdfs/Grodman071030.pdf (last visited Feb. 7, 2008).

167 *See, e.g.,* NRC Report, *supra* note 9, at 109-110; Working Through, *supra* note 121, at 1021; Holzapfel & Sarnoff, *supra* note 11; Bayer AG v. Housey Pharm., Inc., 228 F. Supp. 2d 467, 470–71 (D. Del. 2002) (suggesting that such reach-through royalties as contractual licensing conditions could constitute patent misuse).

product of the patented gene, and the patent holder was pursuing a research program targeting the same protein. The parties settled at an early stage, prior to any substantive rulings by the court, with the defendant agreeing to discontinue commercial drug discovery efforts involving the patented gene. However, the settlement agreement explicitly provided that the defendant and others were free to continue using the patented gene in conjunction with basic, non-commercial research activities.[168]

The Holman study also found no evidence from the lawsuits of an anticommons, or patent thicket, problem in regard to gene patents and research. If a researcher were to be sued for using a gene that is only one of multiple genes being studied, this might indicate a patent thicket problem. However, all of the lawsuits identified in the study allege the use of a specifically patented human gene as a central element of a substantial commercial product or research program.[169] Conversely, the Holman study provided evidence of gene patents being designed around (although not in the research tool context), and of a research tool patent being circumvented by off-shoring research activities (to Taiwan) and importing the resulting data back into the United States.[170]

Finally, the Holman study suggests that gene patent holders have generally chosen not to file lawsuits to assert their patents against researchers using the patented technologies, choosing instead to tolerate infringement (even though the other studies noted above suggest that significant amounts of infringement and legal liability exist). To illustrate this point, consider the 2004 study by Kyle Jensen and Fiona Murray that identified a total of 4270 human gene patents claiming 4382 human genes (roughly 20% of human genes known at the time).[171] It is reasonable to assume that a significant number of these patented genes are the subject of research in the U.S.[172] However, Holman found that these 4270 patents had resulted in only six (6) lawsuits involving eighteen (18) patents with claims reciting thirteen (13) distinct human genes.[173] Most of these lawsuits settled early, and the only lawsuit reaching a substantive decision held that the patent had not been infringed.[174] Furthermore, only one (1) of the lawsuits involved the use of a patented gene as a research tool.[175] In that case, a genomics company filed an infringement lawsuit in retaliation after being sued by a research tool company for patent infringement. The parties quickly settled under terms granting the research tool company a non-exclusive license under the gene patents.[176]

In summary, it appears that the growing numbers of patents on research tools and the expanded liability for research uses of patented inventions resulting from the *Madey* decision have not yet let to serious problems for the conduct of scientific research in the U.S. In large part, this is because there remains a widespread practice of

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168 *See* Holman, *supra* note 154, at 51-52.
169 *See id.* at 47-52.
170 *See id.* at 43-44, 51.
171 *See* Jensen & Murray, *supra* note 109, at 239-40.
172 *See id.* at 240 (noting that "heavily patented genes tended to have relevance to human health and diseases").
173 *See* Holman, *supra* note 154, at 59-60. Most of the litigated human gene patents found by Holman were not identified in the Jensen & Murray study. *Id.* at 62.
174 *See id.* at 60.
175 *Id.* at 49-50. Four of the lawsuits were brought against providers of genetic diagnostic testing services, and one against a biotechnology company producing a therapeutic protein.
176 *Id.*

conducting what (in light of the *Madey* decision) can now only be considered infringing research, and because patent holders have continued to restrain themselves from aggressively asserting patents. Nevertheless, the studies demonstrate an increasing trend towards restriction of access and some delays in or changes to research, and the potential exists for patent holders to expand their efforts to enforce their patents (particularly if reach-through damages become available on discoveries made using their patented research tools). Thus, significant concerns remain, particularly regarding the stability of the working solutions that have been employed in the past.

V. Recent Changes to Patenting and Licensing Policies and Practices

The following section discusses recent changes to licensing policies, particularly with regard to patented research tools, adopted by various governmental, academic, and industrial institutions. These new policies may further affect developing scientific researcher and patent holder practices, potentially disturbing the working solutions currently in place but potentially providing additional stability to the informal norms of patent infringement and forbearance of patent assertions in non-commercial contexts.

A substantial proportion of research tools patents, particularly those relating to genetics and biomedical research, arise out of government-funded and university research. Thus, one approach to addressing concerns that research tool patents might impede research and innovation is to encourage these institutions to adopt patenting and licensing practices that promote broad and non-discriminatory access to patented research tools. Government funding agencies, including the NIH, which is the primary source of biomedical research funding in the U.S., have implemented internal policies and external funding practices and have published guidelines. These practices and guidelines are aimed at discouraging the patenting of certain inventions and at encouraging licensing practices that promote the dissemination of and access to biomedical research tools. Universities also have adopted patenting and licensing practices aimed at addressing concerns regarding the potential adverse effects of research tool patents.

For example, laboratories funded by the NIH and the U.S. Department of Energy (DOE) have agreed to adhere to the so-called Bermuda Rules,[177] which encourage early and open access to genetic sequence information and discourage the patenting of genes by DNA sequencing laboratories.[178] The National Human Genome Research Institute (NHGRI), part of the NIH, has required that major genome sequencing centers receiving grant funding agree to abide by the Bermuda Rules,[179] and NHGRI strongly encourages all of its grantees to follow these principles. The rapid public release of newly generated sequence information dictated by the Bermuda Rules serves to generate prior art that can block later patenting activities relating to the disclosed sequence information. It has been suggested that prevention of DNA patenting was one factor behind the push to encourage rapid entry of genetic sequence information into public domain.[180] Although the Bermuda Rules are generally not binding on U.S. grant recipients, in practice a failure to abide by the rule would likely jeopardize the grantee's ability to secure future grant funding.[181]

In 1999, the NIH issued a set of principles and guidelines (the Research Tool Guidelines) that encourage grant recipients to adopt practices promoting broad access

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[177] *See* Wellcome Trust Statement on Genome Data Release, *available at* http://www.ornl.gov/sci/techresources/Human_Genome/research/bermuda.shtml.

[178] Eliot Marshall, *Bermuda Rules: Community Spirit, With Teeth*, SCIENCE MAGAZINE, February 16, 2001, at 1192, *available at*, http://www.sciencemag.org/cgi/content/full/291/5507/1192.

[179] NATIONAL HUMAN GENOME RESEARCH INSTITUTE, CURRENT NHGRI POLICY FOR RELEASE AND DATABASE DEPOSITION OF SEQUENCE DATA (1997), *available at* http://www.genome.gov/page.cfm?pageID=10000910#old.

[180] Rebecca S. Eisenberg, *Genomics in the public domain: strategy and policy*, NATURE REVIEWS GENETICS, October 2000 at 70, *available at* http://www.nature.com/nrg/journal/v1/n1/full/nrg1000_070a.html#B26.

[181] *See* Marshall, *supra* note 178, at 1192. For example, in 1997 U.S. officials made clear that failure to comply with the rules "could be a black mark on future grant reviews."

to NIH-funded research tools, in a manner that facilitates further biomedical research.[182] Although the Research Tool Guidelines are only directly applicable to recipients of NIH grant support, NIH expressed its hope that they would be adopted by the wider research community "so that all biomedical research and development can be synergistic and accelerated."[183] These guidelines are not regulations, and therefore technically are not legally enforceable. At the time they were published, the NIH expressed its view that legally enforceable regulations were not necessary, but warned that at some point in the future it might promulgate legally enforceable regulations if widespread problems continued with respect to access to NIH funded research tools.[184] NIH further noted that, on a case-by-case basis, the expectations set forth in the Research Tool Guidelines might be imposed as specific requirements of NIH funding awards where the grant recipient has failed to demonstrate sufficient progress in implementing the Research Tool Guidelines. Subsequently, compliance with the guidelines became an explicit consideration in the award of NIH grants and contracts.[185] The Research Tool Guidelines are reportedly regarded by at least some university technology transfer officers as *de facto* federal policy.[186]

The Research Tool Guidelines specifically note that inappropriate patenting and licensing practices are likely to thwart rather than promote utilization, commercialization and public availability of research tool inventions.[187] According to the guidelines, restrictive licensing practices are generally only appropriate in cases where further research, development and private investment are needed to realize the inventions' usefulness as a research tool.[188] In all other cases, dissemination by publication, deposit in an appropriate databank or repository, or widespread nonexclusive licensing are encouraged.[189] In those instances where an exclusive license is necessary to promote investment in commercial application of a research tool, the guidelines state that a license should ordinarily be limited to the commercial field of use, with the grant recipient retaining rights regarding use and distribution as a research tool.[190]

The Research Tool Guidelines also provide model language to be used in licensing agreements entered into by grant recipients, designed to promote broad dissemination of research tools. For example, the guidelines recommend that recipients reserve in their licenses the right of nonprofit institutions to use licensed technologies internally.[191]

In 2005, NIH published a final notice of "Best Practices for the Licensing of Genomic Inventions" (Genomic Best Practices).[192] The Genomic Best Practices are generally

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[182] DEPARTMENT OF HEALTH AND HUMAN SERVICES, PRINCIPLES AND GUIDELINES FOR RECIPIENTS OF NIH RESEARCH GRANTS AND CONTRACTS ON OBTAINING AND DISSEMINATING BIOMEDICAL RESEARCH RESOURCES: FINAL NOTICE, 64 Fed. Reg. 72090 (1999), *available at* http://ott.od.nih.gov/policy/rt_guide_final.html [hereinafter "Research Tool Guidelines"].

[183] *Id. at* 72090.

[184] *Id.*

[185] Lori Pressman et al., *The Licensing of DNA Patents by US Academic Institutions: An Empirical Survey*, 24 NATURE BIOTECHNOLOGY 31, 32 (2006).

[186] *Id.*

[187] *See* Research Tool Guideline, *supra* note 182, at 72093.

[188] *Id.*

[189] *Id.*

[190] *Id.* at 72095.

[191] *Id.*

[192] U.S. NATIONAL INSTITUTES OF HEALTH, BEST PRACTICES FOR THE LICENSING OF GENOMIC INVENTIONS: FINAL NOTICE, 70 FED. REG. 18413 (Apr. 11, 2005), *available at*

consistent with the Research Tool Guidelines, although more explicit in clarifying that they represent recommendations of best practices, not legally binding regulations.[193] For example, the Genomic Best Practices specify that:

> [w]henever possible, nonexclusive licensing should be pursued as a best practice. . . . In those cases where exclusive licensing is necessary to encourage research and development by private partners, best practices dictate the exclusive licenses should be appropriately tailored to ensure expeditious development of as many aspects of the technology as possible. Specific indications, fields of use, and territories should be limited to be commensurate with the abilities and commitment of licensees to bring the technology to market expeditiously.[194]

The Genomic Best Practices also recommend that license agreements be written with development milestones and benchmarks to ensure that the technology is fully developed by the licensee. "Best practices provide for modification or termination of licenses where progress toward commercialization is inadequate."[195]

In a recent survey of the 30 U.S. academic institutions that have received the largest number of DNA patents, the researchers found that their licensing practices were largely in agreement with NIH's Research Tool Guidelines and Genomic Best Practices.[196] For example, universities prefer to enter into non-exclusive licensing arrangements with respect to most research tool DNA patents.[197] Some survey respondents also reported having difficulty determining whether or not an invention constituted a research tool.[198]

A coalition of some the most prestigious U.S. universities have recently published a document identifying and encouraging adoption of technology licensing guidelines designed to promote broad dissemination of and access to research tool inventions. The document, entitled "In the Public Interest: Nine Points to Consider in Licensing University Technology" (Nine Points Paper)[199] arose out of a 2006 meeting at which representatives of the universities gathered to discuss societal, policy, legislative and other issues in university technology transfer. The licensing principles and practices identified are designed to balance the business needs of universities with their broader mandate to serve society and the public interest. The Nine Points Paper states that many of the principles were already being implemented by universities, and encourages all universities and non-profit research entities to strive to adopt similar policies.[200]

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http://ott.od.nih.gov/policy/genomic_invention.html (last visited Mar. 12, 2008).

193 *Id.* at 18413 ("the recommendations are not intended to constitute additional regulations, guidelines, or conditions of award for any contract or grant").

194 *Id.* at 18415.

195 *Id.*

196 *See* Pressman, *supra* note 185.

197 Id. at 34, 38-39.

198 *Id.* at 34-35.

199 IN THE PUBLIC INTEREST: NINE POINTS TO CONSIDER IN LICENSING UNIVERSITY TECHNOLOGY (2007), *available at* http://news-service.stanford.edu/news/2007/march7/gifs/whitepaper.pdf (last visited Feb. 26, 2008).

200 *Id.* at 1.

In particular, the Nine Points Paper encourages universities that license patented technologies to reserve rights, in all fields of use, for themselves and for other nonprofit and government organizations to practice inventions for research and educational purposes (including research sponsored by commercial entities), even in cases where the invention is licensed exclusively to a commercial entity.[201] It acknowledges that in some cases the grant of an exclusive license is appropriate, perhaps even necessary, when a significant investment of time and resources in the technology are needed in order to achieve its broad implementation. However, it urges universities to strive to grant only those rights necessary to encourage development of the technology.[202]

As an overarching principle, the Nine Points Paper stresses that exclusive licenses should always be structured in a manner that encourages technology development and use.[203] For example, in cases where substantial investment is required to develop a research tool into a commercial product, it might be appropriate for the university to grant an exclusive license for the sale, but not the use, of such products. In doing so, the university ensures its freedom to grant other nonexclusive licenses to use the patented technology.[204] The Nine Points Paper notes that, absent the need for significant investment, broad nonexclusive licensing of tools such as genomic and proteomics inventions can help maximize the benefits derived from those technologies, in part by removing obstacles to further innovation.[205] It also emphasizes that universities are expected to make research tools as broadly available as possible.[206] Finally, the Nine Points Paper recommends that licensing agreements include performance milestones to promote diligent development and broad dissemination of the licensed technology.[207]

The Wisconsin Alumni Research Foundation (WARF) is the technology licensing affiliate of the University of Wisconsin, and although university-based may act like a commercial entity in licensing its patented technologies. On January 23, 2007, WARF announced changes to its licensing policies that improve the terms of access for academic and nonprofit researchers.[208] WARF has been widely criticized for what many have characterized as overly restrictive licensing policies with respect to its broadly claimed human embryonic stem cell patents.[209] Pursuant to the new policies, researchers at academic and non-profit institutions will not need a license to use WARF patented stem cells, even in private company-sponsored research.[210] However, this policy does not extend to any right to "develop and/or use [the human embryonic stem cells] for any therapeutic or commercial purpose, including the right to [] perform services (including diagnostic services) for consideration, or for the

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201 *Id.* at 2.
202 *Id.*
203 *Id.*
204 *Id.*
205 *Id.* at 3.
206 *Id.* at 5.
207 *Id.* at 3.
208 WISCONSIN ALUMNI RESEARCH FOUNDATION, WISCONSIN ALUMNI RESEARCH FOUNDATION CHANGES STEM CELL POLICIES TO ENCOURAGE GREATER ACADEMIC, INDUSTRY COLLABORATION, *available at* http://www.warf.org/news/news.jsp?news_id=209 (last visited Feb. 26, 2008) [hereinafter "WARF Press Release"]; Joyce E. Cutler, *Wisconsin Research Foundation Amends Stem Cell Policies*, 73 PAT. TRADEMARK & COPYRIGHT J. 368 (2007) (discussing changes announced in 2007 to ease licensing requirements for academic and nonprofit researchers).
209 *See* Thayer & De Liberty, *supra* note 66.
210 *See* WARF Press Release, *supra* note 208.

production or manufacture of products for sale or distribution to third parties."[211] Therapeutic or commercial users of the cells are required to seek an additional license from WARF, the terms of which do not appear in WARF's announcement.[212] According to a statement by WARF Managing Director Carl E. Gulbrandsen, "WARF's stem cell policies have evolved over the years, always in favor of increasing access and making it easier for scientists to move the technology forward. These latest changes reflect an ongoing dialogue with researchers and university administrators across the country."[213]

Studies of industrial licensing practices in regard to patented research tools are not generally available, but are needed to provide a more complete assessment of the current licensing environment in regard to patents held by commercial entities and used as research tools. In part, such studies may be impeded by commercial desires to keep secret the terms of commercial licenses and the results of licensing negotiations.

The effects of these new patenting and licensing policies have yet to be evaluated. In particular, it remains to be seen how these policies will interact with the changes to the experimental use and regulatory exceptions and the social practices that have developed in regard thereto. Nevertheless, these policies are likely to ameliorate to some extent restrictions on access to patented technologies used in scientific research that may develop. In turn, implementation of these policies and their effectiveness in assuring access may be affected by broader changes to legal standards within the patent system.

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[211] WiCell Research Institutes' Memorandum of Understanding – ESI Materials, http://www.wicell.org/index.php?option=com_content&task=blogcategory&id=124&Itemid=190#faq2 (last visited Feb. 26, 2008).

[212] National Stem Cell Bank, FAQs for Requesting Stem Cells, http://www.wicell.org/index.php?option=com_content&task=blogcategory&id=124&Itemid=190&limit=1&limitstart=1 (last visited Feb. 26, 2008).

[213] See WARF Press Release, *supra* note 208.

VI. Recent and Proposed Changes to the Patent System That May Affect Patents For and Use of Research Tools.

Since the turn of the century, concerns have been expressed by government agencies, non-profit institutions, bar associations, and academic commentators regarding the current state of the U.S. patent system, resulting in varying suggestions for judicial and legislative reform.[214] These concerns have addressed, among other things: the administrative processes and legal standards for granting patents (resulting in patents that arguably should not have been issued and that are subsequently protected by a statutory presumption of validity interpreted to impose a heightened evidentiary burden of proof[215]); and expansion of patent rights and remedies (resulting in routine grants of injunctions that provide excessive negotiating leverage and excessive damage awards compared to the inventive contribution of the patented invention to the infringing product).[216] These concerns thus have led to proposals for judicial or legislative reforms of existing patent law doctrines.

Recent decisions of the Supreme Court, and (to a lesser extent) of the Federal Circuit and the U.S. Patent and Trademark Office (PTO), have responded to these concerns and have significantly changed the patent law landscape in the U.S.[217] These decisions may affect the patentability of inventions contemplated for use as research tools and have the potential to significantly reduce concerns regarding access to patented technologies for use in research. Congress also is considering comprehensive legislation to reform the patent statute, and many provisions of the current draft legislation would have similar effects.[218] However, these legal changes also have the potential to induce unanticipated and adverse changes to patent holders' and scientific researchers' behaviors regarding the assertion of and attention to patent rights.

This section describes specific judicial changes and proposals for legislative reform that the authors believe are most relevant to research tool patents and liability for research uses of patented technologies. Some of these changes have raised the bar

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[214] *See, e.g.,* FTC Report, *supra* note 55; PATENT SYSTEM REPORT, *supra* note 59; AIPLA Response, *supra* note 62; *Patent Law Academics' Positions on Patent Law Reform Issues,* Submitted to the Committee on the Judiciary and the Subcommittee on Courts, the Internet, and Intellectual Property of the United States House of Representatives (June 27, 2005), available at http://www.bna.com/webwatch/patentreformmarch07.html; Mark A. Lemley, Douglas Lichtman & Bhaven N. Sampat, *What to Do About Bad Patents,* 28 REGULATION 10 (2005-06).

[215] *See* 35 U.S.C. § 282; American Hoist & Derrick Co. v. Sowa & Sons, 725 F.2d 1350, 1359-60 (Fed. Cir. 1984).

[216] *See, e.g.,* Mark A. Lemley & Philip J. Weiser, *Should Property or Liability Rules Govern Information?,* 85 TEX. L. REV. 783 (2007); Joshua D. Sarnoff, Bilcare, KSR, *Presumptions of Validity, Preliminary Relief, and Obviousness in Patent Law,* 25 Cardozo Arts & Ent. L.J. 1003 (2008).

[217] *See, e.g.,* KSR Int'l Co. v. Teleflex Inc., 127 S. Ct. 1727 (2007); eBay, Inc. v. MercExchange, L.L.C., 126 S. Ct. 1837 (2006); Lab. Corp. of Am. Holdings, Inc. v. Metabolite Labs., Inc.,126 S.Ct. 2921, 2922 (2006) (Breyer, J., dissenting from dismissal as improvidently granted); *In re* Fisher, 421 F.3d 1365, 1369-78 (Fed. Cir. 2005); UNITED STATES PATENT AND TRADEMARK OFFICE, INTERIM GUIDELINES FOR EXAMINATION OF PATENT APPLICATIONS FOR PATENT SUBJECT MATTER ELIGIBILITY, 1300 Off. Gaz. Pat. & Trademark Office, 142 (2005), *available at* http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/guidelines101_20051026.pdf (last visited Mar. 12, 2008) [hereinafter "Interim Guidelines"]; *Ex Parte* Lundgren, 76 U.S.P.Q.2d 1385, 1388 (B.P.A.I. 2004); *Ex Parte* Bilski, 2006 WL 4080055 (B.P.A.I. 2006), appeal pending No. 2007-1130 (Fed. Cir.).

[218] Patent Reform Act of 2007, H.R. 1908, 110th Cong. (2007); Patent Reform Act of 2007, S. 1145, 110th Cong. (2007).

to granting patents on research tools, and others have limited or may limit the remedies that are available in regard to infringing research uses. These changes may help to reduce concerns over the potential for research tool patents to create barriers to access.[219] However, these changes are quite recent, and it will take some time to determine their full impact, as courts and the PTO apply the decisions to patents claiming genes and other research tools. Additional future changes to patent law doctrines also may affect patent holders' and scientific researchers' practices in unanticipated ways. It also bears noting that there have been and will likely continue to be changes to patent claim scope and application requirements (e.g., written description and enablement requirements and literal and doctrine of equivalents infringement doctrines) that may affect the scope of such patents and whether any particular research uses infringe issued patents.[220]

1. The Utility Requirement of Section 101

In order to be patentable under Section 101, an invention must be "new and useful," with the latter term interpreted to require some identified, practical use.[221] This doctrine, referred to as the utility requirement, serves to limit the patenting of certain research tools, particularly those involving genetic sequences and other biomolecules. In order to satisfy the utility requirement, a patent application must show that an invention provides some immediate practical benefit to the public that does not require further research to identify or confirm.[222] The requirement is not satisfied by a showing of utility only discovered after the application was filed.[223]

In response to concerns that patents were being issued that claimed genetic sequences of unknown function or of unknown practical significance – *e.g.*, the controversial patent applications for expressed sequence tags (ESTs), which essentially are fragments of expressed genes, filed by the NIH in the early 1990s – the PTO in 2001 issued revised Utility Examination Guidelines (Utility Guidelines).[224] The Utility Guidelines required patent applicants to articulate for their inventions a "specific and substantial utility that is credible."[225]

In 2005, in *In re Fisher*,[226] the Federal Circuit essentially affirmed the Utility Guidelines. The court held that claims directed to ESTs were unpatentable given that the functions of the underlying genes were unknown, that the only asserted uses for the ESTs at that stage were as research intermediates to isolate and experiment on the relevant genes, and that the asserted uses were only possibilities that any EST

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219 *See, e.g., Stifling or Stimulating – The Role of Gene Patents in Research and Genetic Testing Before the Subcomm. on Courts, the Internet and Intellectual Property*, 110th Cong. (2007) (Statement of Lawrence M. Sung) 5-7, *available at* http://judiciary.house.gov/media/pdfs/Sung071030.pdf (last visited Feb. 7, 2008) [hereinafter "Sung Statement"].

220 *See, e.g., Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722 (2002) (doctrine of equivalents standards); Enzo Biochem, Inc. v. Gen-Probe Inc., 323 F.3d 956 (Fed. Cir. 2002) (written description standards); *In re* Curtis, 354 F.3d 1347, 1355 (Fed. Cir. 2004) (enablement standards).

221 35 U.S.C. § 101 (2008). *See* Brenner v. Manson, 383 U.S. 519 (1966).

222 *See, e.g.,* Manual of Patent Examining Practice, § 2107.01(I)(C) (8th ed. Rev. 6 Sept. 2007) (discussing "Research Tools").

223 *See, e.g., In re* Fisher, *supra* note 217, at 1371.

224 Utility Examination Guidelines, 66 Fed. Reg. 1092 (Jan. 5, 2001), *available at* http://www1.uspto.gov/go/notices/utilexmguide.pdf (last visited Feb. 22, 2008).

225 *Id.* at 1098.

226 421 F.3d 1365 (Fed. Cir. 2005).

could achieve but which for these ESTs had not yet been used in the real world.[227] Further, following the Utility Guidelines, the court held that the status of an invention as a research tool is not dispositive; rather, the question is whether the invention has "a specifically identified substantial utility … [rather than an] asserted utility [that] requires further research to identify or reasonably confirm."[228]

The utility standard articulated by the PTO and approved in *Fisher* should preclude patents for many of the most criticized patents claiming genes, as well as for other biomedical discoveries lacking an established use beyond that as a pure research tool. In particular, this utility standard should bar patents on gene fragments or genetic sequences of unknown function or significance.

2. The Patentable Subject Matter Requirement of Section 101

The patentable subject matter doctrine, which limits the types of inventions that are patentable, also may be used in the future to restrict patenting of certain genetic and research tool inventions. The statutory language of Section 101 defines the scope of inventions that are patentable in the U.S. as any new and useful "process, machine, manufacture, or composition of matter."[229] While the Supreme Court has interpreted this language broadly to potentially encompass any product or process that is "made by man,"[230] it has also stressed on numerous occasions that it does not extend to "laws of nature, physical phenomena, and abstract ideas."[231] Since 1981, when the Supreme Court last addressed patentable subject matter in an issued opinion, the Federal Circuit dramatically altered the boundary lines to permit patenting of a wide range of new technologies and practices.[232] In turn, this change in law required the PTO to grant patents for such inventions, including many new genetic and biomedical invention used in research.[233] However, the Federal Circuit as a whole will soon revisit its standards for patentable subject matter, in the *In re Bilski* case that addresses a method for managing commodity sales risks,[234] and it is foreseeable that the Supreme Court will soon revisit the standards for patentable subject matter.

In 2006, the Supreme Court in *Laboratory Corporation of America Holdings, Inc. v. Metabolite Laboratories, Inc.* originally accepted and later dismissed without an opinion a case that raised significant questions regarding patentable subject matter.[235] The patent claim broadly recited a method for detecting a vitamin deficiency, involving the two steps of: (1) assaying a patient's body fluid for an amino acid; and (2) mentally correlating the knowledge of an elevated level of the amino acid to the existence of the vitamin deficiency.[236] Although the Court as a whole decided not to

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227 *See id.* at 1373.
228 *See id.* at 1372.
229 35 U.S.C. § 101 (2008).
230 Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980) (quoting S.Rep.No.82-1979 at 5 (1952), and H.R.Rep.No.82-1923 at 6 (1952)).
231 *Id.* (citing Parker v. Flook, 437 U.S. 584 (1978), and O'Reilly v. Morse, 56 U.S. 62, 112-21 (1854)). *See* Diamond v. Diehr, 450 U.S. 175, 185 (1981).
232 *See, e.g.,* A. Samuel Oddi, *Assault on the Citadel: Judge Rich and Computer Related Inventions,* 39 HOUS. L. REV. 1033, 1040 (2002).
233 *See* Interim Guidelines, *supra* note 217.
234 *See In re* Bilski, 2008 WL 417680, No. 2007-1130 (Fed. Cir. 2008), *available at* www.cafc.uscourts.gov/dailylog.html (last visited Feb. 22, 2008).
235 126 S.Ct. 2921 (2006).
236 *See, e.g.,* Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings., 370 F.3d 1354, 1358-64 (Fed. Cir. 2004).

decide the case (likely because of a failure to plead Section 101 and because the issue had not been adequately addressed below), three Justices would have decided the case and would have found the patent invalid under the exclusion for laws of nature, natural phenomena, and abstract ideas.[237] These Justices voiced strong reservations with respect to patents broadly claiming biological correlations, and an eagerness to rein in, or even reverse, a trend in the lower courts towards an overly expansive definition of patentable subject matter. Further, they suggested constitutional concerns with such patents, implying that Congress lacks the power to authorize them.[238] If the Court is presented with another case raising patentable subject matter issues and in better condition for appellate review, the Court might decide it in a manner consistent with the views of the dissenting Justices.

If the Federal Circuit or the Supreme Court do restrict patentable subject matter, their holdings may significantly affect the patentability of some genetic and research tool discoveries. Some genetic technology companies clearly recognized the potential for such a result in the *Laboratory Corporation* case, filing amicus briefs and arguing that a decision could substantially affect genetic inventions, especially those involving "correlations." For example, as amicus Perlegen (a personalized medicine company patenting discoveries regarding genetic disease correlations) argued:

> Virtually every patent claim concerning a diagnostic method is based, explicitly or implicitly, by correlation between a disease or medical condition. Thus, the repercussions for biotechnology, particularly diagnostics, if [the Court were to invalidate the claim at issue for encompassing unpatentable subject matter] would be staggering. Hundreds, if not thousands, of patents would at once be called into question.[239]

Similarly, amicus Affymetrix analogized the claim at issue to controversial patents on a breast cancer gene and to patents claiming SNPs, and urged the Court to invalidate the claim in a manner that would bar the patenting of what it characterized as "natural genetic phenomena."[240]

Less than two months after the Supreme Court dismissed the *Laboratory Corporation* case, a district court in an unreported order held in *Claussen Immunotherapies, Inc. v. Biogen IDEC,* that various method claims were invalid for encompassing unpatentable natural phenomena.[241] Specifically, the claims recited methods for determining vaccination protocols, based on comparing the incidence of immune disorders between two or more groups of subjects immunized under different schedules. The court characterized the claims as indirect attempts to patent the idea of a correlation between the vaccination schedules and chronic immune-mediated

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[237] *See* Lab. Corp. of Am. Holdings, Inc. v. Metabolite Labs., Inc.,126 S.Ct. 2921, 2922 (2006) (Breyer, J., dissenting from dismissal as improvidently granted).

[238] *See id.*

[239] Brief for Perlegen Sciences, Inc. and Mohr, Davidow Ventures as Amici Curiae Supporting Respondents, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S.Ct. at 2922, 2006 WL 303908 (No. 04-607).

[240] Brief for Affymetrix, Inc. and Professor John H. Barton Amici Curiae Supporting Petitioner, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S.Ct. at 2922 (2006), 2005 WL 3597814 (No.04-607).

[241] *See* Classen Immunotherapies, Inc. v. Biogen IDEC, Memorandum Order, Civ. No. 04-2607 (D. Md. Aug. 16, 2006).

disorders. The case was appealed (No. 2006-1634) and argued before the Federal Circuit on August 8, 2007.[242] An affirmance may suggest invalidity of many such correlation claims, and may therefore reduce some of the concerns that have been voiced with regard to biomedical research tool patents.

3. The Nonobviousness Requirement

Section 103 of the U.S. patent statute imposes a patentability requirement of nonobvious invention (or inventive step), which also might restrict the patenting of many research tool inventions. Specifically, Section 103 denies patentability "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains."[243] For many years, the Federal Circuit and its predecessor court employed a restrictive approach to proving obvious, requiring "a teaching, suggestion, or motivation to combine known elements" of the claimed invention that were found in the prior art.[244]

However, the Supreme Court in *KSR International Co. v. Teleflex, Inc.* held that a more flexible approach should be applied to determining obviousness. The Court criticized the Federal Circuit's approach to determining whether there was "an apparent reason to combine" prior art elements of the claimed invention as "rigid,"[245] and noted four specific errors of the Federal Circuit's approach in the case (which addressed a combination of an electronic sensor with an adjustable automotive foot pedal assembly). These were: (1) looking only to the problem that the patentee was trying to solve; (2) assuming the persons having ordinary skill in the art will look only to prior art designed to solve the same problem; (3) concluding that an invention cannot be proved obvious "merely by showing that the combination of elements was 'obvious to try,'" at least when there is a design or market need and limited alternative; and (4) seeking to prevent hindsight bias by adopting "[r]igid preventative rules that deny factfinders recourse to common sense."[246]

Based on the *KSR International* decision, the PTO has adopted examination guidelines[247] that provide many potentially expansive rationales for the PTO (and by extension courts) to find a claimed invention obvious. These include:

> (A) Combining prior art elements according to known methods to yield predictable results; (B) Simple substitution of one known element for another to obtain predictable results; (C) Use of known technique to improve similar devices (methods, or products) in the same way; (D) Applying a known technique to a known device (method, or product) ready for improvement to yield predictable

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[242] Oral Argument, Classen Immunotherapies v. Biogen IDEC, *available at* www.cafc.uscourts.gov/oralarguments/.

[243] 35 USC § 103(a) (2008).

[244] KSR Int'l Co. v. Teleflex, Inc., 127 S. Ct. 1727, 1741 (2007) (citing Application of Bergel, 292 F.2d 955, 956-57 (C.C.P.A. 1961)).

[245] *Id.* at 1739, 1741.

[246] *Id.* at 1742-43 (quoting Teleflex, Inc. v. KSR International Co., 119 Fed. Appx. 282, 289 (Fed. Cir. 2005)). *See* Holzapfel & Sarnoff, *supra* note 11, at 1032.

[247] *See* Examination Guidelines for Determining Obviousness Under 35 U.S.C. §103 in View of the Supreme Court Decision in *KSR International Co. v. Teleflex Inc.,* 72 Fed. Reg. 57526 (2007).

> results; (E) 'Obvious to try'—choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success; (F) Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations would have been predictable to one of ordinary skill in the art; [and] (G) Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.[248]

These rationales may have a significant effect on the patenting of research tool inventions, particularly given that a market motivation for creating such tools may exist and that there may be limited alternatives, and given that the need for such tools may make the solution obvious to try.

With specific relevance to gene patents and other biotechnology inventions that can be used as research tools, the Federal Circuit's 1995 decision in *In re Deuel*[249] (relied on by the Federal Circuit in its *KSR International* decision[250]) had been widely interpreted as creating an extremely high bar for the PTO and challengers to prove that claimed inventions are obvious.[251] The Federal Circuit in *Deuel* had relied on earlier precedent rejecting the "'obvious to try'" approach to proving obviousness[252] to reverse a PTO determination of obviousness of claimed isolated and purified DNA and complementary DNA sequences relating to human and bovine growth factors.[253] The Federal Circuit had found that the prior art references teaching a method of gene cloning and a partial amino acid sequence of a protein were not sufficient to prove obviousness, as "the PTO has not cited a reference teaching cDNA molecules, but instead has improperly rejected the claims based on the alleged obviousness of a method of making the molecules."[254] A dissenting opinion in *In re Fisher* (discussed above in regard to Section 101) later argued that claims to isolated and purified genetic sequences (*e.g.*., the ESTs at issue in *Fisher*) may not be sufficiently inventive to warrant patentability, but the *Deuel* precedent has precluded the PTO from rejecting such claims as obvious under Section 103.[255]

The effects over time of the *KSR International* have yet to be felt or adequately assessed. However, since the *KSR* decision, the PTO issued a decision in *Ex Parte Kubin*[256] that further calls into question the viability of the *Deuel* precedent. In *Kubin*, the PTO cited *KSR* and the obvious-to-try rationale in affirming a patent examiner's rejection of a claim reciting a genus of novel genetic sequences in light of prior art that was analogous to (but more current than) the prior art at issue in *Deuel*.[257] The decision is on appeal to the Federal Circuit, No. 2008-1184, which

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248 72 Fed. Reg. at 57529.
249 51 F.3d 1552 (Fed. Cir. 1995).
250 *See* Teleflex, Inc., 119 Fed. Appx. at 289 (quoting *Deuel*, 51 F.3d at 1559).
251 *See, e.g.,* Dan L. Burk & Mark A. Lemley, *Is Patent Law Technology-Specific?*, 17 BERKELEY TECH. L.J. 1155, 1178-81 (2002).
252 *See In re* Deuel, 51 F.3d 1552, 1559 (citing *In re* O'Farrell, 853 F.2d 894, 903 (Fed. Cir. 1988)).
253 *See id.* at 1555, 1557.
254 *Id.* at 1557.
255 *See In re* Fisher, *supra* note 217, at 1382.
256 *See, e.g., Ex Parte* Kubin, No. 2007-0819, 2007 WL 2070495 (B.P.A.I. 2007).
257 *See id.* at *3,-*6.

should hear oral argument sometime in 2008. Depending on how the Federal Circuit decides the case, a post-*KSR/Kubin* obviousness test might preclude the patentability of many genetic inventions that were once considered patentable. In any event, what is obvious to a person skilled in the relevant art changes over time, as does the scope of the prior art, and the *Deuel* precedent may now be obsolete as applied to modern genetic discoveries.

In summary, the standards for utility, patentable subject matter, and nonobviousness have been changing in ways that may make it more difficult obtain patents for genetic and other inventions that are likely to be used in scientific research. It is possible that such changes may lead to alternative sources of funding to provide incentives for investment, invention, and disclosure of such new technologies. Similarly, as discussed immediately below, changes to patent remedies may also affect the desire to patent and alternatives for funding research tools. If so, there may be corresponding changes to behaviors of the remaining patent holders regarding licensing and assertion of their patents against scientific researchers who use their technologies.

4. Injunctive Relief Under Section 283

The recent Supreme Court decision in *eBay, Inc. v. MercExchange, L.L.C.*,[258] and cases following *eBay* that deny injunctive relief to patent holders,[259] may help to alleviate concerns that patents on research tools will be used to restrict scientific research. Conversely, to the extent that denial of injunctive relief diminishes the commercial exclusivity of patent holders and reduces their revenue or their ability to bargain for higher licensing fees, *eBay* and its progeny may reduce incentives for the creation and patenting of research tools. Further, the denial of injunctive relief (and the imposition of prospective compensatory damages in the form of ongoing royalty payments[260]) may have a similar effect to the granting of a compulsory license (which is discussed below), on commercial terms determined by a judge through litigation. Because they directly affect commercial returns to patent holders, these changes to the available remedies for patent infringement also have the potential to change existing practices and working solutions.

Under Section 283 of the Patent Act, district courts "may grant injunctions in accordance with the principles of equity."[261] Prior to *eBay*, Federal Circuit precedent essentially mandated that, after finding patents to be valid and infringed, trial courts permanently enjoin future infringements, at least absent some compelling public policy rationale for denying an injunction, such as a public health emergency.[262] The Supreme Court in *eBay* rejected this strong presumption in favor of granting injunctions in patent cases, holding that nothing in the patent act suggested that patent law should depart from traditional principles of equity law, and thus a patent holder can only obtain a permanent injunction as a remedy for infringement if he or she can demonstrate: (1) that the patent holder suffered an irreparable injury due to the infringement; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that irreparable injury; (3) that, considering the balance of hardships between the patent holder and the infringer, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction.[263] However, the Court also issued two concurring opinions of seven of the Justices, which reflect very different views about when injunctions are likely to be found appropriate after finding infringement of a valid patent.[264]

Thus, after the *eBay* decision, a trial court has substantially more discretion to deny an injunction – a decision which can only be reversed under the highly deferential

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[258] 126 S. Ct. 1837 (2006).

[259] *See, e.g.,* Andrew Beckerman-Rodau, *The Aftermath of* eBay v. MercExchange, *126 S.Ct. 1837 (2006): A Review of Subsequent Judicial Decisions,* 89 J. Pat. & Trademark Off. Soc'y 631 (2007) (discussing the holdings of post-*eBay* decisions on patent law injunctions); Joseph S. Miller, Injunctions, http://www.thefireofgenius.org/injunctions (providing a comprehensive list through Dec. 31, 2007 of decisions regarding preliminary and permanent injunctive relief in patent, copyright,and trademark law that apply the *eBay* approach) (last visited Feb. 22, 2008).

[260] *See, e.g.,*Paice LLC v. Toyota Motor Corp., 504 F.3d 1293, 1313-16 (Fed. Cir. 2007) (holding that ongoing royalty payments rather than injunctions may be appropriate, but vacating and remanding the ongoing royalty payment at issue).

[261] 35 U.S.C. § 283 (2008).

[262] *See, e.g.,* MercExchange, L.L.C. v. eBay, Inc., 401 F.3d 1323, 1338 (Fed. Cir. 2005) (citing Federal Circuit precedents that established a "general rule … that a permanent injunction will issue once infringement and validity have been adjudged"); Accumed L.L.C. v. Stryker Corp., 483 F.3d 800, 811 (Fed. Cir. 2007) (recognizing that the Supreme Court in *eBay* "struck down" the Federal Circuit's general rule).

[263] *See* eBay, *supra* note 217, at 1839.

[264] *Compare id.* at 1841-42 (Roberts, C.J. concurring) *with id.* at 1842 (Kennedy, J., concurring).

"abuse of discretion" standard.[265] Denial of injunctions is more likely to occur in cases where the patented technology makes up a relatively small portion of the infringing product or process, where the patent holder is not practicing the invention, money damages and ongoing royalty payments are sufficient to compensate the patent holder, or an injunction might unduly injure the infringer and/or adversely affect public interests.[266] For example, the Federal Circuit in *Innogenetics N.V. v. Abbott Laboratories*[267] held that a trial court abused its discretion in granting an injunction against an infringer of a gene patent, given that the patent holder had requested and obtained a jury verdict that included or contemplated an ongoing royalty for continued use, and thus the patent holder could not be considered irreparably harmed by continued infringement.[268] The court remanded for further assessment of the terms of the ongoing royalty for continued access to the patented technology, which claimed methods of genotyping hepatitis C virus (which depending on the end use could be considered a research tool patent).[269]

In contrast, an injunction is more likely to issue if the patent holder is producing and selling the patented invention and if the infringer competes in the market for such sales. In such cases, courts may consider price erosion, loss of goodwill, potential reductions in workforce, and other factors.[270] Such considerations are less likely to apply to research uses of patented inventions than to sales of inventions intended for use as research tools.

The Federal Circuit has yet to develop a clear understanding of the "public interest" consideration in granting or denying injunctive relief after the *eBay* case. For example, in the context of affirming a trial court's grant of a preliminary injunction, one panel of Federal Circuit judges recently held that the public interest factor is neutral in regard to the competing public interests in the benefits of lower prices (for printer and facsimile machine toner cartridges) from free competition and in enforcing patent rights.[271] Conversely, a different panel of Federal Circuit judges held that there was no abuse of discretion in a trial court holding that the public interest in acquiring lower cost pharmaceuticals (and potential deaths that would result if consumers did not purchase them) was outweighed by the public's interest in encouraging pharmaceutical research and development by enforcing patent rights.[272]

It is possible that a court would refuse to grant an injunction where a patented invention was used by an infringer as a research tool, particularly if the patent holder was engaged in a pattern of licensing its invention or if the research at issue was particularly important. As the 2004 NAS report suggested, injunctive relief "would rarely be an appropriate remedy in a research infringement case, because from these

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265 *Id.*

266 *See, e.g.,* Beckerman-Rodau, *supra* note 259, at 653-57 (discussing some of these and other factors and noting that direct competition with the patent holder is the most significant predictive factor regarding whether a permanent injunction will issue); Andrew Beckerman-Rodau, *The Supreme Court Engages in Judicial Activism In Interpreting the Patent Law in eBay, Inc. v. MercExchange L.L.C.,* 10 Tul. J. Tech. & Intell. Prop. 165, 201-02 (2007) (discussing the component product – or "complex invention" – concern) (citing *eBay,* 126 S.Ct. at 1842 (Kennedy, J., concurring)).

267 512 F.3d 1363 (Fed. Cir. 2008).

268 *See id.* at 1380-81.

269 *See id.*

270 *See, e.g.,* Sanofi-Synthelabo v. Apotex, Inc., 470 F.3d 1368, 1381-83 (Fed. Cir. 2006).

271 *See* Canon, Inc. v. GCC Int'l Ltd., 2008 WL 213883, at *5 (Fed. Cir. 2008) (No. 2006-1615).

272 *See* Sanofi-Synthelabo, *supra* note 270, at 1383-84.

research uses there would rarely be ongoing commercial losses to the patent holder."[273] Further, as the Supreme Court noted in *eBay,* the trial court had focused on the patent holder's willingness to license the technology and its failure to itself practice the invention.[274] However, the Court nevertheless cautioned that no broad, categorical rule could be adopted, and the for certain patent holders such as universities a willingness to license might not weigh against issuing the injunction.[275]

In summary, the four-part equitable test is highly sensitive to the facts of each case and to the discretionary judgments of particular judges. This renders the potential for obtaining injunctive relief in regard to research tool uses of patented inventions highly uncertain. Nevertheless, it is clear that the potential to obtain an injunction has been reduced, and consequently that the threat that scientific researchers will be prohibited from continuing to conduct experiments (or forced to negotiate licenses prior to or after litigation at higher rates, given the threat or grant of an injunction) is correspondingly reduced. Additional studies are needed to assess the extent to which these changes will affect incentives to develop and patent research tools, as well as the ability of scientific researchers to acquire and their willingness to use patented technologies as research tools.

5. Potential Legislation Affecting Damages Remedies Under Section 284

The U.S. Congress is considering as part of comprehensive legislation to reform the U.S. Patent Act a provision that would alter the existing rules governing calculation of royalty damages for infringement of patent rights.[276] The proposed change to the law would respond to perceived excesses in jury damage awards that are based on calculating royalty rates with regard to the entire value of the infringing product, even though the patent holder's invention may represent only a fraction of the patented and unpatented technologies included in the infringing product.[277] For example, the proposed changes in the U.S. Senate would: (1) limit reliance on the "entire market value" rule for calculating the royalty base to cases where the patent holder's invention was the predominant basis for the market demand for the infringing product; (2) permits royalties to be based on similar, non-exclusive licenses if enough such licenses indicate that the royalty terms are reasonable; (3) if neither (1) nor (2) apply, limiting the royalty base to the portion of the economic value of the infringing invention attributable to the patented invention's contribution over the prior art (which for inventions consisting of novel combinations of prior art elements may consist of the additional function or enhanced value of the combination).[278]

Although it is difficult to predict whether such revisions will be enacted into law, they would clearly tend to limit recoverable royalty damages in regard to technologies incorporated into commercial products and to patents that are non-exclusively licensed. Thus, such changes could affect the damages recoverable for competing sales of research tool inventions (or products incorporating those inventions) for scientific research uses. Similarly, such changes could affect royalties recoverable

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[273] Patent System Report, *supra* note 59, at 116.

[274] *See* eBay, *supra* note 217, at 1840.

[275] *See id.*

[276] *See* H.R. 1908, 110th Cong. § 5 (1st Sess. 2007); S. 1145, 110th Cong. § 4 (2nd Sess. 2007) (as reported by the Senate Committee on the Judiciary, January 24, 2008)

[277] *See, e.g.,* SENATE COMM. ON THE JUDICIARY, THE PATENT REFORM ACT OF 2007, S. Rep. No. 110-259 at 12 (2008).

[278] *See id.* at 13-14.

for scientific uses of research tool inventions, as well as potential royalties for new products resulting from the research and incorporating the research tool (which therefore infringe the rights of making and of sale, as well as of use). Further, such changes could affect reach-through royalties that might be recoverable for scientific research uses of patented inventions to develop valuable information, products, or processes that do not infringe the patented invention. As with injunctive relief, reducing the potential scope of damage awards could affect incentives for investment in and invention and patenting of research tools, as well as willingness to use patented technologies in scientific research.

VII. Alternatives to Experimental Use and Regulatory Approval Exceptions to Infringement

The previous sections of this report have discussed the historic development of the experimental use exception and regulatory approval exception, the effects of these legal developments on the practices of seeking patents on research tools and of using patented technologies for scientific research and commercial development, and responses taken by the government, academic institutions, and industry to assure that patents do not restrict access to the technologies or their use for scientific research and commercial development. This section addresses existing and proposed legal and practical alternatives to these exceptions, which can help to assure access and continued use of patented technologies in scientific research and commercial development. These alternatives include: (1) compulsory licensing and functional equivalents thereto; (2) government licenses and march-in rights regarding federally funded inventions; (3) reach-through licensing agreements; (4) patent pools; (5) antitrust remedies; and (6) off-shoring of research activities. Additional legal development and studies are needed to determine the extent to which such alternatives can be and will be used to assure access to patented inventions for use in scientific research.

1. Compulsory licensing

Compulsory licensing provisions were considered for possible incorporation into the 1952 revision of the U.S. patent laws – the most recent comprehensive revision to and codification of U.S. Patent Act. However, these provisions were removed from draft legislation before the final bill was introduced.[279] Since then, "[c]ompulsory licensing of patents often has been proposed, but it has never been enacted on a broad scale."[280] As late as 2005, a bill was introduced in Congress that would have provided for compulsory licensing of certain patented inventions relating to health care emergencies, but the bill never became law.[281] The patent reform bills currently being considered by Congress include no compulsory licensing provisions.[282] As noted in a 2004 report of the NAS on the patent system, there is a prevalent hostility in industry and among patent holders generally to any form of compulsory licensing.[283]

Nevertheless, U.S. law does provide some limited forms of compulsory licensing of patented technologies. For example, the Clean Air Act provides for the compulsory licensing of patents on pollution control devices to those parties who cannot use substitutes to meet pollution control requirements imposed under the statute.[284] The existing compulsory licensing provisions, however, have little if any relevance to the use of patented research tools, particularly those used in the context of biomedical research.

Of greater relevance, use by the U.S. government of any and all patented inventions is

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279 *See* HOUSE COMMITTEE ON THE JUDICIARY, 81ST CONG., PROPOSED REVISION AND AMENDMENT OF THE PATENT LAWS: PRELIMINARY DRAFT 91 (Comm. Print 1950).

280 Dawson Chemical Co. v. Rohm & Haas Co., 448 U.S. 176, 215 & n.21 (1980).

281 Public Health Emergency Medicines Act, H.R. 4131, 109th Cong. (2005).

282 Patent Reform Act of 2007, H.R. 1908, 110th Cong. (2007); Patent Reform Act of 2007, S. 1145, 110th Cong. (2007).

283 *See* NRC Report, *supra* note 9, at 115.

284 *See* 42 U.S.C. § 7401 (2008).

fully authorized by statute (and is consistent with the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (the TRIPS Agreement), subject to the payment of adequate remuneration but taking into consideration any anti-competitive practices).[285] Under 28 U.S.C. § 1498(a), a patent holder's sole legal remedy for an infringing manufacture, use or sale of a patented invention by the U.S. government -- or by any person or entity working under the "authorization and consent" of the U.S. government (*i.e.*, a government contractor) -- is a legal claim for "reasonable compensation." This legal claim requires the patent holder to file a lawsuit against the U.S. Government in the U.S. Court of Claims to prove infringement (and where challenged to defend the validity of the patent). However, unlike a normal patent infringement lawsuit, the patent holder cannot obtain injunctive relief to prohibit continuing infringement by the government. (The patent holder may seek to prohibit a third-party's use by filing a lawsuit in a federal district court seeking an injunction, and the third party must prove authorization under Section 1498 as an affirmative defense.[286]) Like ongoing royalty damages, Section 1498 operates similarly to a compulsory license, particularly as the U.S. government might invoke its authorization on behalf of third-parties[287]

All of the research conducted by, and much of it for, the U.S. government falls under the protection of Section 1498(a). (As discussed below, use by the government and its contractors also may be authorized by a statutory license arising from the use of federal funds in the development of the invention, and the existence of such a license and its scope in regard to infringing activity may only be resolved in a suit seeking compensation under Section 1498.[288] Conversely, use by state governments is immunized from compensatory liability by the 11th Amendment to the U.S. Constitution, but injunctive relief may still be available.[289]). The provision is often explicitly invoked on behalf of grantees or contractors to assure access to patented technologies.[290] The authors are unaware of any instance where Section 1498(a) has been explicitly invoked to induce voluntary licensing of a patented research tool (although voluntary licensing of such tools may routinely occur given recognition that use without permission of the patent holder may be authorized by Section 1498(a)). However, the government has on occasion explicitly threatened to invoke Section 1498(a) in order to compel a patent holder to license its patent, in rare cases where the patent is perceived to cover the only viable means to address a potential massive public health emergency. Notable recent examples involved Roche's Tamiflu and Bayer's Ciprofloxacin, thought to be critical in responding to fears of an avian flu pandemic or anthrax bioterrorism attack, respectively. [291] In both cases, the government was reportedly able to use the threat to gain significant concessions from patent holders without actually authorizing third-party production under Section 1498(a).[292]

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[285] *See* Agreement on Trade-Related Aspects of Intellectual Property Rights, Art. 31, Apr. 15, 1994, 33 I.L.M. 81 (1994)

[286] *See* Madey v. Duke Univ., 413 F. Supp. 2d 601, 607 (M.D.N.C. 2006).

[287] Brian T. Yeh, *Influenza Antiviral Drugs and Patent Law Issues*, CRS Report for Congress, CRS Report RL33159 (2005).

[288] *See* Madey, *supra* note 286, at 608.

[289] *See* U.S. CONST., AMEND. XI; Florida Prepaid Postsecondary Education Expense Board v. College Savings Bank, 527 U.S. 627, 633-635 (1999).

[290] *See* Madey, *supra* note 286, at 607-08.

[291] Yeh, supra note 287, and John R. Thomas, *Intellectual Property Issues in Homeland Security*, CRS Report for Congress, CRS Report RL32051 (last updated 2007).

[292] James P. Love, *Recent Examples of Compulsory Licensing of Patents*, Knowledge Ecology Int'l

Given that legislative enactment of a broad experimental use exception might not occur, the 2004 NAS report on the patent system recommended that the federal government consider assuming liability under the "authorization and consent" provision of 1498(a) for the infringement of research tool patents by investigators whose work it supports under contracts, grants, and cooperative agreements.[293] However, the report noted that authorization under Section 1498(a) has not often been extended to federal grantees in this context, and has never been formally extended to the NIH (although reportedly the DOE has exercised this option).[294] One member of the NAS committee issuing the 2004 report recommended that the government consider providing authorization under Section 1498(a) for scientific research uses of patented inventions only in cases where access to research tool technologies is not resolved in the marketplace by licensing on reasonable terms, and predicted that in all likelihood the threat of its use would lead to a negotiated solution.[295] The report itself recommended that federal agencies include explicit authorization and consent "as a reasonable step that addresses the need to maintain research tool access."[296]

Similarly, as noted above, an ongoing royalty damage award (which may be considered a compulsory license[297]) can be achieved in instances where a court declines to enter an injunction against a party found liable for infringing a research tool patent. As noted above, *eBay* has significantly expanded the courts' discretion to deny injunctions, and courts may in the future do so for research uses of patented inventions. In Genomic Best Practices the NRC recommended that "[c]ourts should continue to decline to enjoin patent infringement in those extraordinary situations in which the restricted availability of genomic or proteomic inventions threatens the public health or sound medical practice."[298]

Given that compulsory licensing, and its functional equivalents of governmental authorization under Section 1498(a) and refusals to enjoin continued infringement, can assure research uses of patented inventions, a number of academic commentators have proposed that the U.S. institute some form of compulsory licensing (or codify an experimental use exception either providing for compensation to patent holders or specifically targeting certain types of research uses) so as to promote access to patented research tools in certain situations. For example, Rebecca Eisenberg has proposed a compulsory licensing regime that would deny "patent holders an injunctive remedy to prevent subsequent researchers from using their inventions to make further advances in the same field," but would allow the patent holder a reasonable royalty. [299]

Research Note 2007:2 at 3 (2007), *available at* http://www.keionline.org/index.php?option=com_content&task=view&id=41 (last visited Feb. 28. 2008).

293 *See* NRC Report, *supra* note 111, at 115.

294 *See id.*

295 *See id.* at 117.

296 *Id.*

297 *Compare* Paice LLC v. Toyota Motor Corp., 504 F.3d 1293, 1313 n.13 (Fed. Cir. 2007) (distinguishing the two because there is no authorization for third party use other than by the parties to the lawsuit) *with id.* at 1316 (Rader, J., concurring) ("calling a compulsory license an 'ongoing royalty' does not make it any less a compulsory license").

298 *See* Reaping the Benefits, *supra* note 64, at 146-47.

299 R. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI L. REV. 1017, 1075-77 (1989).

In contrast, Katherine Strandburg has proposed that the tool inventor be granted an initial period of a few years of complete exclusivity, after which the technology would be subject to compulsory licensing.[300] This proposal is designed to provide adequate compensation for the inventor while ensuring that the research tool is not withheld from other researchers for the entire length of the patent term.[301] Strandburg has predicted that the compulsory license provision would rarely be invoked, but would incentivize the patent holder to negotiate a voluntary license during the initial period of complete exclusivity.[302]

Janice Mueller has proposed "a 'liability rule' model that permits the non-consensual 'development use' of research tools not readily available for licensing or purchase, while providing an ex post royalty payment to the patent owner that would be correlated to the commercial value of the new product developed from the non-consensual use. This 'reach-through' royalty approach provides the best approximation of the true worth of the research tool to its user. It ensures a royalty award of sufficient amount to maintain incentives for the development and patenting of new research tools, yet alleviates the access restrictions and up-front costs currently associated with acquisition and use of many proprietary research tools." [303]

Rochelle Dreyfus has proposed a plan pursuant to which a university or other nonprofit research institution that wanted to use patented material and cannot obtain a license from the patentee on reasonable terms could use the technology without permission if it were willing to sign a waiver of potential patent rights.[304] The waiver would require the institution to promptly publish the results of work conducted with the patented technology and to refrain from patenting discoveries made in the course of that work.[305] Richard Nelson has proposed a modification of the Dreyfus waiver plan, which would allow the researchers to patent their work but would require them to agree to license on a nonexclusive basis for reasonable royalties.[306]

Jordan Karp has proposed a "modified experimental use exception whereby an inventor is paid a 'reasonable royalty' by those who experiment on her patented innovation. This type of scheme treats experimental use as a type of limited compulsory licensing, ...Under this paradigm, the royalty payment required from the experimenter could be tied to the commercial success of any innovation resulting from the experimental activity on the patented invention. An experimenter would only have to compensate the patentee when the experimental activity actually resulted in a benefit to the experimenter (thus, allowing "pure" scientific research to continue unhindered)." [307] This proposal would effectively impose reach-through royalty licensing for research tool uses, which is a controversial approach (as discussed below).

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300 Strandburg, *supra,* 2004 WIS. L. REV. at 143-144.
301 *Id.* at 143-45.
302 *Id.* at 141-42.
303 *See* Mueller, *supra* note 7, at 14-15.
304 Rochelle Dreyfuss, *Protecting the Public Domain of Science: Has the Time for an Experimental Use Defense Arrived*, 46 ARIZ. L. REV. 457, 471-72 (2004).
305 *Id.* at 471
306 Richard R. Nelson, *The Market Economy, and the Scientific Commons*, 33 RES. POL'Y 455, 467 (2004).
307 Jordan P. Karp, Note, *Experimental Use as Patent Infringement: The Impropriety of a Broad Exception*, 100 YALE L.J. 2169, 2188 (1991).

David Parker has suggested that a statutory research exemption could undermine the value of patents covering basic research tools by rendering them essentially incapable of infringement.[308] Thus, Parker has proposed that "[i]f an exception for 'commercial' research and development is warranted," the approach should be "based upon the concept of allowing the commercial use of a patented invention in research and development and only making this commercial research activity subject to infringement once a decision has been made to commercialize the fruits of that endeavor. Of course, if the activity results in a product or process within the scope of the patented technology, the end product or process itself would be actionable without regard to the underlying technology used in its development. In short, only the research activities would receive the 'limited- time' protection, not the end result of that research."[309]

At a recent Congressional hearing relating to the patenting of human genes, Lawrence Sung proposed that the U.S. establish a research use exception limited to basic, noncommercial research.[310] Under his proposal, academic researchers and institutions would be exempt from infringement liability for noncommercial research activities, with the caveat that the researchers and institutions must provide actual notice to the patent holder of the open and notorious use of the patented technology for basic research uses, and agree to dedicate the results of the research to the public.[311]

2. Government Rights to Inventions Patented Under the Bayh-Dole Act

As summarized in a 1998 report by the NIH Working Group on Research Tools:

> The Bayh-Dole Act ["Bayh-Dole"] provides the statutory basis and framework for federal technology transfer activities, including the patenting and licensing of federally funded inventions by recipient organizations. The Act permits recipients of federal grants and contracts to elect title to patentable "subject inventions" that arise with the use of federal funds. If recipients elect title, the Act requires them to file patent applications, seek commercialization opportunities, and report back to the funding agency on efforts to obtain utilization of their inventions. *The Act also retains for the funding agency certain residual rights in subject invention.*[312]

Bayh-Dole has led to dramatic changes in the economic structure of research and norms of open science, as well as to increased patenting of basic research discoveries by federally funded academic research institutions.[313]

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[308] David L. Parker, *Patent Infringement Exemptions for Life Science Research*, 16 HOUS. J. INT'L L. 615, 659 (1994).

[309] *Id.* at 659-60

[310] *See* Sung Statement, *supra* note 219, at 11-14.

[311] *Id.* at 13-14

[312] REPORT OF THE NATIONAL INSTITUTES OF HEALTH (NIH) WORKING GROUP ON RESEARCH TOOLS, APPENDIX D, *available at* http://www.nih.gov/news/researchtools/appendd.htm [hereinafter NIH Report].

[313] *See generally* Arti K. Rai & Rebecca S. Eisenberg, *Bayh-Dole Reform and the Progress of Biomedicine,* 66 L. & CONTEMP. PROBS. 289 (2003).

Under Bayh-Dole, for all inventions made in the course of federally funded research the federal government retains "a non-exclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world."[314] However, the NIH Working Group noted that while "[t]his license gives the NIH, and any other agency of the Federal government, the right to use any patented research tool arising in the course of federally-sponsored research without liability for patent infringement[, it] is not clear whether NIH's retained license [] allows NIH to authorize use of subject inventions by other recipients of NIH grants. Some agencies take the position that the activities of grantees are covered by the exemption, but NIH has considered it an open question."[315]

Bayh-Dole also provides that a federal agency engaged in research funding, such as NIH, can "march-in" and grant licenses to patented inventions arising out of funded research under certain specified circumstances, including when the agency determines that such action is necessary because the grantee has "not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use," or when such "action is necessary to alleviate health or safety needs which are not reasonably satisfied by the" grantee.[316]

The NIH Working Group suggested that NIH might exercise the march-in right "on a case by case basis to improve access to particular research tools." However, the Working Group noted that "[i]n order to exercise march-in rights, the funding agency must comply with a lengthy administrative process," and that "[e]ach particular case can be expected to be lengthy and uncertain." The NIH Working Group also noted that, because of this administrative burden the mechanism "does not lend itself to routine use."

The NIH has never asserted its march-in rights in the nearly twenty eight (28) years since the Act was enacted. It has denied at least three (3) formal requests to exercise the right (none of which was brought with respect to a patented research tool), concluding that the patented technologies were being made reasonably available under the patent.[317] In denying the requests, NIH noted that it was concerned that exercising its march-in rights would act as a disincentive for investment in the development of commercial products based on inventions patented under Bayh-Dole. It has also stated that the march-in right is not intended to be used to compel patent holders to make patented technology available at lower prices, and that "manufacture, practice, and operation ….[by the patent holder providing for] availability and use by the public" is sufficient to meet the standard..[318]

Absent a sharp departure from past practice or a legislative change, it seems unlikely that the NIH or other federal agencies will exercise their march-in rights with respect to a research tool patent absent some showing that the restrictive practices of the

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[314] 35 USC 202(c)(4) (2008).

[315] NIH Report, *supra* note 313.

[316] 35 USC 203(a) (2008).

[317] *See, e.g.*, NATIONAL INSTITUTES OF HEALTH OFFICE OF THE DIRECTOR, IN THE CASE OF NORVIR® MANUFACTURED BY ABBOTT LABORATORIES, INC., *available at* http://www.essentialinventions.org/docs/usa-ritonavir/zerhouni29jul04.pdf (last visited Feb. 25, 2008).

[318] *Id.* at 5. *See id.* at 5-6.

patent holders are precluding all access to the technology or substantially impairing the "health or safety needs" of the U.S. public. This would likely be a difficult showing to make. However, a witness at a recent Congressional hearing on gene patents strongly urged Congress to consider legislation that would encourage more active use of the march-in provision to promote accessibility to genetic diagnostic testing services, and if Congress acts on this proposal it could perhaps open the door to the use of march-in rights more broadly with respect to patented research tools.

3. Reach Through Licensing Agreements

Under a reach-through licensing agreements (RTLA), the licensor receives a share of the profits generated by the ultimate commercial product, if and only if the research tool is used in the development of such a product.[319] However, RTLAs are controversial because they raise potential antitrust and patent misuse issues, given that the patent holder may require as a condition of use of the patented invention that the licensee provide compensation (at least in part) for uses or sales of unpatented aspects of the products developed with the patented invention.[320] The legal resolution may depend in part on the market power of the patent holder and the specific form of the licensing offer in conditioning access to the patented technology.[321] According to the 2003 FTC report on the patent system, some representatives of the biotechnology industry reported that RTLAs have been successfully employed to provide commercial researcher with access to patented research tools.[322] These representatives expressed the view that RTLAs can promote access to a wide range of research tools at low up-front cost, and facilitate risk-sharing between licensor and licensee. However, other panelists interviewed for the FTC report argued that RTLAs promote anticommons problems, and might violate antitrust and patent misuse laws.[323]

4. Patent Pools

Patent pools involve "patents [from multiple patentees being] licensed in a package, either by one of the patent holders or by a new entity established for this purpose, usually to anyone willing to pay the associated royalties."[324] The Biotechnology Industry Organization (BIO), a leading trade association representing biotechnology companies, has stated that voluntary patent pools are "one of the most important potential solutions to concerns regarding overlapping patents."[325] Similarly, the

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319 *See, e.g.,* Thomas J. Kowalski & Chrisitan M. Smolizza, *Reach-Through Licensing; a US Perspective,* J. COMMERCIAL BIOTECH, http://pharmalicensing.com/public/articles/view/963567614_396edffe132c5 (last visited Feb. 25, 2008).

320 *See, e.g., id.* n.1; Research Tool Guidelines, *supra* note 182 ("imposing reach-through royalty terms as a condition of use of a research tool is inconsistent with this principle [of ensuring appropriate distribution of NIH-funded tools].").

321 *See, e.g.,* Zenith Radio Corp. v Hazeltine Research, Inc., 395 US 100, 139 (1969) (while "a licensee must pay if he uses the patent . . .he may insist upon paying only for use, and not on the basis of total sales" because "[t]here is nothing in the right granted the patentee . . .which empowers him to insist on payment not only for use but also for producing products which do not employ his discoveries at all"); Bayer AG v. Housey Pharm., Inc., 228 F. Supp. 2d 467, 470–71 (D. Del. 2002) (rejecting allegation that reach through licensing agreement constituted patent misuse where the licensee voluntarily agreed to the royalty provision).

322 *See* FTC Report, *supra* note 55, Chapter 3 at 26-28.

323 *Id.*

324 Carl Schapiro, *supra* note 109, at 119–150.

325 FTC Report, *supra* note 55, Chapter 3 at 27.

PTO has released a report entitled "Patent Pools: A Solution to the Problem of Access and Biotechnology Patents?," which discusses the use of patent pools as a means of fostering access to patented research tools.[326] The 2003 FTC report on the patent system notes that the "centralized management that the patent pools entails may help in avoiding the royalty stacking/complements problem that economists have suggested may develop when multiple patents are needed for follow-on activities, and each patentee independently determines its own royalty rates.[327]

Nevertheless, some have questioned whether high transaction costs might substantially limit the ability to form and use of patent pools in the context of genetic inventions.[328] It has been noted that these technologies are fundamentally different from the electronics sector, in which patent pools are used more frequently because of the importance of standards and interoperability.[329] Further, the greater unpredictability of biotechnological inventions that may result in wider differences in valuation of patented technologies, and the potentially greater reliance of biotechnology companies on maximizing licensing revenues may reduce incentives for particular patent holders to join or to agree to standard licensing terms of patent pools.[330]

Nevertheless, various proposals have been put forward for creating specific research tool patent pools. For example, Affymetrix, a leading DNA microarray company, has been an outspoken advocate for the creation of gene patent pools.[331] A group of European scholars has published a series of articles discussing the potential use of patent pools to facilitate access to genetic technologies for use in diagnostic testing.[332] Merrill Goozner of the Center for Science in the Public Interest has proposed a patent pool for the California Institute of Regenerative Medicine and other funders of stem cell research.[333] Similar approaches could prove useful for biomedical research tools. However, to date patent pooling has not played a significant role in the biotechnology sector. The best known example of a biotechnology patent pool is probably the collection of patent rights cobbled together to provide freedom of operation to produce "Golden Rice" (a genetically engineered rice that produces

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326 Jeanne Clark, Joe Piccolo, Brian Stanton, Karin Tyson, with assistance from Mary Critharis, Stephen Kunin, *Patent Pools: A Solution to the Problem of Access in Biotechnology Patents?* UNITED STATES PATENT AND TRADEMARK OFFICE, *available at* http://www.uspto.gov/web/offices/pac/dapp/opla/patentpool.pdf.

327 *See* FTC Report, *supra* note 55, Chapter 3 at 42.

328 *See* FTC Report, *supra* note 55, Chapter 3 at 28.

329 *Id.*

330 *Cf.* Ted J. Ebersole, Marvin C. Guthrie & Jorge A. Goldstein, *Patent Pools as a Solution to the Licensing Problems of Diagnostic Genetics,* 17 Int. Prop. & Tech. L.J. 1, 5 (2005) (discussing differences among the genomics industry that make it difficult to identify "essential patents").

331 Barbara Caulfield, *Intellectual Property and Diagnostics*, http://www.law.asu.edu/files/Centers_and_Programs/LST/Conferences_&_Events/caulfield.pdf

332 Brigit Verbeure, Gert Matthijs, & Geetrui Van Overwalle, *Analyzing DNA Patents in Relation with Diagnostic Genetic Testing*, 14 EUR. J. HUM. GENETICS 1 (2006) at 26-33; Esther van Zimmeren, Brigit Verbeure, Gert Matthijs, & Geetrui Van Overwalle, *Models for Facilitating Access to Patents on Genetic Inventions*, 7 NATURE REVIEWS: GENETICS 143 (2006); Esther van Zimmeren, Brigit Verbeure, Gert Matthijs, & Geetrui Van Overwalle, *Patent Pools and Diagnostic Testing*, 24 TRENDS IN BIOTECHNOLOGY 3 (2006) [hereinafter "Patent Pools"]; Esther van Zimmeren, Brigit Verbeure, Gert Matthijs, & Geetrui Van Overwalle, *A Clearing House for Diagnostic Testing: The Solution to Ensure Access to and Use of Patented Genetic Inventions?*, 84 BULL. OF THE WORLD HEALTH ORGANIZATION 5, 337 (2006).

333 *See* Merill Goozner, *Innovation in Biomedicine: Can Stem Cell Research Lead the Way to Affordability?,* 3 PLOS MED. 126, 612 (2006).

β-carotene, the precursor to vitamin A, which give the rice grains a yellow hue).[334] Golden Rice is not considered a commercially relevant crop, and licenses under the pool were granted free of charge, essentially for humanitarian reasons.[335] There has also been an attempt to create a pool of patents relating to SARS research, but so far there appears to have been no report that this attempt has been consummated.[336]

5. Antitrust approaches

Some commentators, including Rochelle Dreyfus, have argued that competition law should be invoked in certain circumstances to compel patent holders to make patented research tools available, particularly where the patent holder is effectively blocking downstream research on a biologic target of significant clinical importance, *e.g.*, the BRCA breast cancer genes.[337] There is a long history in the United States of judicially imposed compulsory licenses to remedy antitrust violations or concerns, where patent holders exercise or seek to acquire monopoly market power or engage in other prohibited practices, as well as compulsory licenses imposed or agreed to in regard to administrative reviews (in the context of merger and acquisition reviews by the Federal Trade Commission, the U.S. agency that formulates and enforces much of the U.S. antitrust law and policy).[338]

The FTC (along with the U.S. Department of Justice (DOJ)) recently indicated their views that although unilateral refusals to license were permissible, conditional refusals will be reviewed under a "rule of reason" analysis.[339] Nevertheless, the FTC and DOJ have shown some willingness in merger context to require licensing of patented research tool technology in cases where the merger has the potential to decrease the number of firms researching in a particular area.[340] For example, when the large biotechnology companies Amgen and Immunex merged, the FTC required them to agree to license out some of their patented research tools relating to the development of drugs targeting interleukin-1.[341]

However, U.S. courts have shown little if any inclination to apply the antitrust laws to compel access to research tools. For example, in *Digene Corporation v. Third Wave*

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334 Patent Pools, *supra* note 332.

335 *Id.*

336 *Id.*

337 Rochelle Cooper Dreyfuss, *Unique Works/Unique Challenges at the Intellectual Property/Competition Law Interface*, New York university, Law and Economics Research Paper Series, Working Paper No. 05-13, *available at* http://ssrn.com/abstract=763688.

338 Jerome H. Reichman, *Compulsory Licensing of Patented Inventions: Comparing United States Law and Practice with Options under the TRIPS Agreement* (2006), *available at* http://www.aals.org/documents/2006intprop/JeromeReichmanOutline.pdf (last visited Feb. 26, 2008). *See generally* J.H. Reichman & Catherine H. Hasenzahl, NONVOLUNTARY LICENSING OF PATENTED INVENTIONS, PART I, HISTORICAL PERSPECTIVE, LEGAL FRAMEWORK UNDER TRIPS AND AN OVERVIEW OF THE PRACTICE IN CANADA AND THE UNITED STATES OF AMERICA (UNCTAD/ICTSD 2002).

339 *See* U.S. DEPARTMENT OF JUSTICE AND THE FEDERAL TRADE COMMISSION, ANTITRUST ENFORCEMENT AND INTELLECTUAL PROPERTY RIGHTS: PROMOTING INNOVATION AND COMPETITION 15-32 (Apr. 2007) (citing, *inter alia,* Image Technical Services, Inc. v. Eastman Kodak Co., 125 F.3d 1195 (9th Cir. 1997), and *In re* Indep. Serv. Organ. Antitrust Litigation, 203 F.3d 1322 (Fed. Cir. 2000)).

340 *See* Dreyfus, *supra* note 337, at 12.

341 Federal Trade Commission, Resolving Anticompetitive Concerns, FTC Clears $16 Billion Acquisition of Immunex Corp. by Amgen Inc., (July 12, 2002), *available at* http://www.ftc.gov/opa/2002/07/amgen.shtm (reporting consent agreement requiring Amgen and Immunex to license intellectual property rights relating to IL-1 inhibitors in view of the potential therapeutic relevance of these drugs).

Technologies Inc.,[342] a district court recently rejected allegations that a patent infringement plaintiff violated the Sherman Act[343] by monopolizing the market for human papilloma virus (HPV) testing.[344]

Federal Circuit and Supreme Court precedents effectively preclude using antitrust and misuse law to address unilateral refusals to license, as well as conditional refusals to license so long as the conditions are within the scope of patent rights. This is true even when the patent holder is not actively exploiting the technology, or is even suppressing it. For example, in *Rite-Hite Corp. v. Kelley Co.*,[345] an en banc panel of the Federal Circuit held that "[t]here is no requirement in this country that a patentee make, use or sell its patented invention."[346] The *Rite-Hite* Court did suggest, however, the court might in some circumstances refuse to enjoin patent infringement in cases of non-use, in effect creating a compulsory license: "if a patentee's failure to practice in the invention frustrates an important public need for the invention, a court need not in joining infringement."[347] Subsequent to *eBay*, courts have more discretion to act upon this suggestion.

As the Federal Circuit held in *Monsanto Co. v. McFarling,*[348] its earlier decision in *Mallinkrodt, Inc. v. Medipart, Inc.,*[349] established that in "the cases in which the [conditional licensing] restriction is reasonably within the patent grant, the patent misuse defense can never succeed," because such conditions cannot extend the patent right beyond the patent's scope.[350] Similarly, as the court noted in *Virginia Panel Corp. v. Mac Panel Co.,*[351] attempted monopolization claims under Section 2 of the Sherman Act require proof of an intent to monopolize, market power, and antitrust-relevant damages related to the conduct, and conduct that does not constitute patent misuse cannot constitute an antitrust violation.[352] However, the continuing validity of *Mallinkrodt* and its progeny was recently called into question during an oral argument in *Quanta Computer Inc. v. LG Electronics, Inc.*,[353] in which the Supreme Court will decide the scope of the patent exhaustion doctrine (and possibly whether conditional licensing can override such exhaustion or constitutes patent misuse).[354] Finally, the Supreme Court recently held in *Verizon Communications Inc. v. Law Offices of Curtis V. Trinko, LLP*[355] that the right to refuse to deal is not unqualified, but that it has "been very cautious in recognizing [abuse of dominant position, essential facilities, or other] exceptions, because of the uncertain virtue of forced sharing and the difficulty of identifying and remedying anticompetitive conduct by a single firm."[356] This is in contrast with the European Union, where doctrines such as essential facilities and abuse of dominant position tend to hold

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342 Digene Corp. v. Third Wave Techs., Inc., No. 07-0022, 2008 WL 450467 (W.D. Wisc. 2008).
343 15 U.S.C. § 2 (2008).
344 *See Digene,* 2008 WL 450467, at *8-*10.
345 56 F.3d 1538 (Fed. Cir. 1995) (en banc).
346 *Id.* at 1547 (citing Continental Paper Bag Co. v. Eastern Paper Bag Co., 210 U.S. 405, 424-30 (1908)). *See also, e.g.,* Cygnus Therapeutics Systems v. ALZA Corp, 92 F.3d 1153 (Fed. Cir. 1996).
347 *Id.* at 1547.
348 363 F.3d 1336 (Fed. Cir. 2004).
349 976 F.2d 700, 708 (Fed. Cir. 1992).
350 363 F.3d at 1341.
351 133 F.3d 860 (Fed. Cir. 1997).
352 *See id.* at 872-73.
353 Transcript of oral argument at 33-34, No. 06-937, *available at* http://www.supremecourtus.gov/oral_arguments/argument_transcripts/06-937.pdf.
354 *Cf.* LG Elec., Inc. v. Bizcom Elec., Inc., 453 F.3d 1364 (Fed. Cir. 2006).
355 540 U.S. 398 (2004).
356 *Id.* at 408.

greater sway.[357]

Absent a substantial shift in U.S. policy, it seems unlikely that antitrust law will play a significant role in compelling research tool patent holders to expand access to the patented technology. To the contrary, some have expressed the concern that antitrust laws could restrict the availability of certain private ordering approaches to deal with the effect of research tool patents, such as patent pools or licensing arrangements.[358]

6. Off-shoring Research

One commentator has argued that "current U.S. jurisprudence is forcing U.S. drug companies to outsource their early stage drug research" to other countries.[359] Indeed, U.S. patent law would allow many research tool patents to be avoided by off-shoring certain uses of research tools to other countries where the tool is not patented, where patent enforcement is more difficult, or where use of the research tool would be more likely to fall under an experimental or research use exception. In general, U.S. patent law only reaches activities performed within the U.S., and the Supreme Court recently expressed its view that U.S. patent law should generally be interpreted in a manner that minimizes the impact of U.S. law on extra-territorial activities.[360] However, U.S. patent law does include certain exceptions to this general principle, some of which could be relevant with respect to the susceptibility of U.S. patents to avoidance by off-shoring of research activities.

For example, Section 271(g) of the Patent Act[361] provides that, under certain circumstances, a party can be held liable for infringement based on the importation into the U.S., or use or sale in the U.S., of a product produced outside the country by a process covered by a U.S. patent. Thus, in some cases the extraterritorial use of patented research tool process could result in liability for infringement under Section 271(g) if a physical product of the process is imported into the U.S. An example might be a cell line created outside the U.S. by a process patented in the U.S. However, a 2003 decision by the Federal Circuit makes clear that Section 271(g) only applies to physical products, and does not apply to information generated by a patented process.[362] Thus, a U.S. company should be free to off-shore certain research activities to avoid a U.S. patent, and then bring the resulting data and insights back into the U.S. for subsequent drug development activities.

Conversely, a U.S. firm might be liable for patent infringement under Section 271(f)[363] for exporting a component of a patented research tool that is subsequently incorporated into the patented research tool extraterritorially. For example, export of a non-infringing DNA vector which is subsequently used to create a cell line that would infringe a U.S. patent might, under certain circumstances as limited by the language of the statute, be the basis for a finding of infringement under Section 271(f). However, a recent Supreme Court decision, *Microsoft v. AT&T*, indicates that the

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357 *Id.* at 13.

358 FTC Report, *supra* note 55, Chapter 3 at 26-28.

359 Katherine A. Helm, *Outsourcing the Fire of Genius: The Effects of Patent Infringement Jurisprudence on Pharmaceutical Drug Development*, 17 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 153 (2006).

360 Microsoft Corp. v. AT&T Corp., 127 S.Ct. 1746, 1751 (2007).

361 35 U.S.C. § 271(g) (2008).

362 Bayer v. Housey, 340 F.3d 1367 (Fed. Cir. 2003).

363 35 U.S.C. § 271(f) (2008).

export of information, or software, which is later incorporated extraterritorially into a research tool covered by a U.S. patent will not infringe under Section 271(f), which requires at least the export of tangible embodiments of the information that are capable of being used in a claimed process or product.[364] In *Microsoft*, the Supreme Court held that Section 271(f) was not applicable where computer software was first sent from the United States to a foreign computer manufacturer on a master disk, or by electronic transmission, and then copied by the foreign recipient for installation on computers made and sold abroad, since the copies, as "components" installed on the foreign made computers, were not supplied from the United States.[365]

In summary, to the extent that the failure to provide a broad experimental use or regulatory approval exception provides incentives for off-shoring of research using patented technologies, current law does not meaningfully restrict the ability to develop and import into the U.S. new products or processes that do not themselves infringe the claims of the patent. There is no current consensus on whether broader exceptions are desirable to prevent such off-shoring of research.

[364] *See Microsoft*, *supra* note 360.
[365] *Id.* at 1755-59.

VIII. Conclusions

The law regarding the experimental use and regulatory approval exceptions to patent infringement has changed over time. In recent years, the scope of the experimental use exception has been narrowly construed by the Federal Circuit, in ways that largely preclude is application to patented research tools used in academic or commercial scientific research. In contrast, the Supreme Court and the Federal Circuit have construed the regulatory approval exception broadly, and district courts have determined that the exception applies to at least some research tools and may soon determine that it applies to sales for research tool uses.

These legal developments have led to varied practical responses by academic and commercial scientists. Although the effects of the developments on access to patented technologies and on scientific research and development are uncertain, large-scale adverse effects have to date been avoided by adoption of working solutions to restrictions on access. These solutions include perceived widespread infringing activity and consequent forbearance from assertion of patents by patent holders. Nevertheless, the discontinuity between the law on the books and the law in practice continues to pose concerns that more serious problems of access may develop.

Further, the stability of the existing working solutions is uncertain, particularly in light of significant changes that are occurring to various patent law doctrines and to governmental, academic, and industrial licensing practices. The sensitivity of existing practices to these changes also is uncertain. Consequently, it is difficult to predict whether these changes, and possible consequential or extrinsic changes to patenting behaviors, funding for innovation, and patent holders' licensing behaviors, will alleviate or further exacerbate access problems regarding research uses of patented inventions. What is certain is that the issues of the scope of experimental use and regulatory approval exceptions, their application to research tools, practical responses and the social consequences of the rules and practices, and alternative legal and practical means for assuring access to patented inventions for research uses will remain a focus of concern and will continue to warrant careful scrutiny and empirical and theoretical analysis.

資料２　イギリス

United Kingdom

Jeremy Phillips

1.1 Monsanto Co v Stauffer Chemical Co and another

1.2 [1985] Reports of Patent Cases 515. 31 July 1984 (Patents Court), 11 June 1985 (Court of Appeal).

1-3-1 Summary

In an action for patent infringement relating to a herbicide, Monsanto obtained interim injunctive relief against Stauffer, restraining Stauffer from further using or selling its allegedly infringing TOUCHDOWN product. After the injunction had been issued by the trial judge and affirmed by the Court of Appeal, Stauffer sought to vary the terms of the injunction by the addition of the proviso that

"Nothing in this Order shall prevent the Defendants ... from doing any of the said acts for the purposes of

(i) carrying on field trials by themselves or by others of their TOUCHDOWN herbicide

(ii) performing experiments by themselves or by others for the purposes of this Action or Counterclaim".

Before these proceedings began, Stauffer had carried out some field trials in the United Kingdom, obtaining limited safety clearance for use post-harvest and in non-crop areas; Stauffer however wished to obtain further safety clearances for use of TOUCHDOWN before harvest time. There were three different proposed trials:

(i) trials carried out by Stauffer's own personnel at its own farm;

(ii) trials carried out by Stauffer's own personnel on other farms;

(iii) trials carried out by third parties that might become customers.

Stauffer maintained that all these trials were permitted experiments within the Patents Act 1977, s.60(5)(b). Monsanto opposed the application to vary the injunction on the basis that the alleged experiments were not true experiments but had a clear commercial purpose, to obtain clearance for eventual sales and to convince prospective customers that TOUCHDOWN was safe. The trial judge, Mr Justice Falconer, dismissed the application. In his view,

- the proposed trials were directed at the acceptance of a commercial embodiment of Stauffer's product;
- the phrase "experimental purposes relating to the subject matter of the invention" in s.60(5)(b) limited the defence to experiments that were directed to the patented invention as such, not to its commercialisation;

- even if this were not so, Stauffer could not supply their allegedly infringing product to third parties for the purpose of carrying out such trials. Any permitted experiments had to be private and not involve third parties;
- permitted experimentation had to be small-scale, having regard to the nature of the subject-matter of the invention, and done for the purpose of finding something out about the invention.

1-3-2 Reason for appeal

Stauffer maintained that the construction placed upon s.60(5)(b) was unduly narrow and that their proposed trials fell within its purview.

1-3-3 Judgment

The Court of Appeal dismissed the appeal, making one small modification to the Order so as to provide that it should not extend to acts done for experimental purposes relating to the subject matter of the invention in laboratories or glass-houses in the United Kingdom or in Stauffer's farm.

1-3-4 Analysis of judgment

The Court of Appeal declined to consider the authorities relating to judicial decisions that were given in the United Kingdom before the enactment of the Patents Act 1977, s.60(5)(b). Since the Patents Act 1977 was enacted so as to implement the provisions of the European Patent Convention, no guidance could be gained by the consideration of case law relating to the law as it stood before the implementation of that Convention.

The Court of Appeal did not consider that the fact that the alleged experimentation had a commercial objective prevented it from being for an "experimental purpose". The word "experiment" was an ordinary English word, not a legal term of art, and its ordinary meaning did not exclude a commercial objective.

1-3-5 Effect and evaluation of judgment

Experiments can be performed even when patented products, so long as the parameters of the Court of Appeal's guidance in this decision are respected.

Experiments which designed to elicit new knowledge — that is, which can be considered to advance scientific knowledge — will in principle always be exempted. However, those experiments which are performed purely for commercial purposes and which have no knowledge-based content, will in principle always infringe.

1-3-6 Relation to (i) exemption of research or experimental use and (ii) award granting of unused patent

This decision appears to be neutral with regard to the granting of rights to use an unused patent.

1-4 Comment and other description

The sentiment has been expressed in some quarters that the result of this decision is unclear and that further clarification or reform is needed, whether through amendment of the European Patent Convention or through a Directive within the European Union. The fact that neither of these events has come to pass would suggest either that no lack of clarity is perceived in legislative circles or that, while such a lack of clarity is perceived, there is no consensus as to the manner of its resolution.

1-5 reference ID number 1

United Kingdom/Jeremy Phillips

1.1 Smith Kline & French Laboratories Limited v Evans Medical Limited

1.2 [1989] Fleet Street Reports 513, 10 November 1988 (Patents Court).

1-3-1 Summary

In a patent infringement action relating to the drug cimetidine, (SK&F) relied on three patents (the Generic patent, the Master patent and the Polymorph patent). The Master patent was a patent of addition to the Generic patent and both of these were endorsed licenses of right before the date of this application. Evans was an applicant for a licence of right under these two patents.

SK&F applied for summary judgment in respect of infringement of the Master and Generic patents. In response, Evans applied to strike out the action. Before these proceedings, SK&F had applied to amend the Polymorph patent, which was due to expire in some four years time. This application was opposed by Evans which, in the course of opposition, had conducted in-house experiments to support evidence given by statutory declaration in those proceedings. Those experiments involved the high-speed tabletting of a substantial quantity of cimetidine tablets in the same dosage forms as those then sold by SK&F; the cimetidine with which these tablets had been made had not been purchased from SK&F.

Evans gave evidence of these experiments in the amendment proceedings. Thereafter and before the evidence in the amendment proceedings had closed, SK&F instituted the present infringement proceedings and, in their particulars of infringements, pleaded the experiments which Evans had performed in the Patent Office amendment proceedings, the import of the material for them and the fact that Evans was an applicant for licences of rights under the Master and Generic patents, asking that the relevant inference be drawn from this evidence.

Evans admitted the acts identified in the pleading but submitted inter alia that the Patents Act 1977, s.60(5)(b) provided a defence of experimental use.

1-3-2 Reason for appeal

There was no appeal in this case, which relates to the initial proceedings.

1-3-3 Judgment

The Patents Court dismissed both SK&F's application for summary judgment and Evans' application for SK&F's action to be struck out.

1-3-4 Analysis of judgment

The Court first stated categorically that there was no question of a general implied consent on the part of a patentee to permit the public to conduct experiments for the purpose of examining a patent and, if appropriate, challenging its validity.

The Court then examined the scope of the Patents Act 1977, s.60(5)(b) itself. It concluded that what is regarded as experimental use must depend on the facts of each case but could

include experiments that were designed with a commercial end in view:

- If an act is to be permitted by s. 60(5)(b) it must be done for purposes relating to the subject matter of the invention and within the claims of the patent alleged to be infringed.
- Section 60(5)(b)covered acts done for experimental purposes, including experiments with a commercial end in view—but the purpose had to relate to the claimed subject-matter of the patent in suit in the sense of having a real and direct connection with that subject-matter.
- Since Evans' experiments repeated an example of the Master patent with a view to challenging the Polymorph patent, s.60(5)(b) did not provide a defence to infringement of the Generic patent.

1-3-5 Effect and evaluation of judgment

The judgment in this case applied the same principles as Monsanto v Stauffer (above), but emphasised that they did not enable s.60(5)(b) to permit experiments that were conducted for the purpose of challenging a granted patent.

1-3-6 Relation to (i) exemption of research or experimental use and (ii) award granting of unused patent

This decision demonstrates that experimentation for the purpose of deciding whether to apply for a licence to use an unused patent would not be permitted.

1-4 Comment and other description

Since the infringing acts in this instance related to tests that were conducted for the purposes of challenging the validity of a patent, it would appear reasonable that tests that did not obviously affect the market position of patented products or the supply of patented services were of no relevance to the market and should therefore be permitted. This line of argument was firmly blocked in this case.

1-5 reference ID number 2

United Kingdom/Jeremy Phillips

1.1 McDonald and another v Graham

1.2 [1994] Reports of Patent Cases 407, 16 December 1993 (Court of Appeal).

1-3-1 Summary

McDonald was the proprietor of patent relating to a sheet of printed material intended for publicity purposes and which, when folded, was the shape and size of a credit card. Graham, who was engaged as a marketing consultant by McDonald, procured a stock of such products. In subsequent patent infringement proceedings before the Patents County Court, in which the acts complained of included the supply of cards to third parties, Graham was held liable.

1-3-2 Reason for appeal

Graham appealed on the ground that, among other things, that he was not committing an infringement in that products in his possession which he supplied to third parties were supplied for "experimental purposes" under the Patents Act 1977, s.60(5)(b).

1-3-3 Judgment

Dismissing the appeal, the Court of Appeal considered that, on the evidence, Graham had clearly kept the cards in stock for the purpose of his own business, in order to make such use of them as was beneficial to do so. Such keeping and making use of the products for non-private and overtly commercial purposes could not be regarded as use for experimental purposes relating to the subject matter of the patent.

1-3-4 Analysis of judgment

The reasoning of the Court of Appeal was based as much on an appraisal of the evidence as an analysis of the law, concluding that such keeping and making use of the products for non-private and overtly commercial purposes could not be regarded as use for experimental purposes relating to the subject matter of the patent.

1-3-5 Effect and evaluation of judgment

This decision is of little significance. The "experimental purposes" defence appears to have been raised for the first time at the appellate level; it was quite unsupported by the evidence and did not require any analysis of development of the doctrine relating to the s.60(5)(b) defence.

1-3-6 Relation to (i) exemption of research or experimental use and (ii) award granting of unused patent

This decision appears to be of no relevance with regard to the granting of rights to use an unused patent.

1-4 Comment and other description

This decision merits no further comment.

1-5 reference ID number 3

1.1 Thomas Ralph Auchinloss and Antec International Ltd v Agricultural & Veterinary Supplies Ltd., Vincent Rooney, South Western Chicks Ltd and South Western Chicks (Warren) Ltd

1.2 [1999] Reports of Patent Cases 397, 29 October 1998. [1998] EWCA (Civ.) 1642

1-3-1 Summary

The claimant's patent 0260293 set out the ingredients of the composition, including in claim 1 "(a) 0.01 to 5 parts by weight of water soluble inorganic halide". As the defendants' biocidal composition "Virucidal Extra" ("VE") did not contain an inorganic halide, the defendants believed there could not be infringement. However, some of the ingredients that were used at various times to produce VE contained a contaminant (sodium chloride) which, the claimants submitted, resulted in the VE infringing.

At trial, the judge held that VE made with a specific ingredient ("CDB 63") did not infringe because the claimants had not established that the oxidising agent, which was present in the claimed amount, "in aqueous solution, reacts with the halide to generate hypohalite ions" as required by integer (b) of claim 1. The defendants objected that infringement through the use of VE containing CDB should not have been considered by the judge because this was not a ground of infringement that the claimants had pleaded.

The defendant also used a surfactant ("Ufaryl 80") which contained sodium chloride. In use by the defendant, the crystalline form of sodium chloride had disappeared but, according to the judge, ions of sodium and chlorine were present. In his opinion the dissociated ions of these elements were not, when added together, an amount by weight "of water-soluble inorganic halide", and sodium chloride was not the same thing as a dissociated collection of sodium and chloride ions. He also held that, reading the patent as a whole, the skilled man would understand that what was being described and claimed was the use of the dry crystalline form. He therefore held that it had not been established that use of Ufaryl 80 caused infringement of claim 1.

1-3-2 Reason for appeal

The claimants, in their appeal, submitted that in reaching this conclusion the judge had put a gloss on integer (b) and introduced the requirement that the hypohalite ions had to provide a substantial biocidal action, this being a feature that was not claimed. The defendants disputed this but also submitted that, even if VE with CDB 63 fell within claim 1, there was no infringement because the only use that had been established was experimental use within s.60(5)(b) of the Patents Act 1977. The trial judge rejected the submission that the manufacture of a sample sent to the Ministry of Agriculture, Fisheries and Food ('MAFF') fell within s.60(5)(b) of the 1977 Act.

1-3-3 Judgment

The Court of Appeal held as follows:

1. Integer (b) of the claim required that there be a certain amount by weight of an oxidising

agent which, in aqueous solution, reacted with the halide of integer (a) to generate hypohalite ions. Providing that the required oxidising agent was present, in an amount within the specified range, and it was established that it would react with the halide of integer (a) to generate hypohalite ions, the requirements of integer (b) would be satisfied. This reaction must be real in the sense that the skilled addressee of the patent would consider that what took place was a reaction generating hypohalite ions.

2. There was nothing in the claim requiring that the generated hypohalite ions should be materially or substantially responsible for the biocidal action of the composition. To introduce such a requirement, as the judge did, was impermissible and introduced, by way of construction, a requirement that the claim must be fairly based on the patent specification. This was a requirement under the (now-repealed) Patents Act 1949 but not under the (currently in force) Patents Act 1977.

3. Once it was accepted that sodium chloride within the range specified in integer (a) was present in CDB 63, the only question remaining was whether the oxidising agent reacted in aqueous solution with the sodium chloride in order to generate hypohalite ions. If it did, there was infringement.

4. The evidence taken as a whole established that the reaction claimed in integer (b) took place when VE was dissolved in water and the claimants had therefore established that VE containing CDB 63 infringed claim 1 in the sense that it fell within the ambit of claim 1.

5. The court would not interfere with the judge's rejection of the defendants' submission that the claimants should not be allowed to contend that the use of CDB63 infringed because it was not pleaded.

6. The trial judge was correct to hold that the manufacture of a sample sent to MAFF was not a non-infringing use within s.60(5)(b) of the Patents Act, as the aim of that use was to obtain official approval, not to discover something unknown or to test something as a hypothesis (applying Monsanto Co v Stauffer Chemical Co, above). If however,the sample sent to MAFF had been produced during genuine experiments and been used for such experiments, such experiments would have been done in relation to the subject matter of the invention since VE was a biocidal composition which, among other things, acted through hypochlorite generation.

7. In relation to Ufaryl 80, a person could properly refer to a solution of sodium chloride as containing sodium chloride. However, the skilled reader of the patent would conclude that the inorganic halide of integer (a) was intended to be a solid, not a dissociated collection of ions. If asked whether the patentee intended to exclude such a collection, he would consider whether the use would make a material difference to the way that the invention was said to work. On the evidence in this case, he would not know. Integer (a) of claim 1 should not be interpreted to include the dissociated collection of ions in Ufaryl 80. The trial judge was right and use of Ufaryl 80 did not bring VE within the ambit of the claim.

1-3-4 Analysis of judgment

This is a good example of a dispute concerning a fairly low-technology invention, between

two relatively non-sophisticated parties, being resolved by a flight into the technical details of the patented technology and the alleged infringements. The outcome is unexceptionable, in that—so far as it affects the issues of infringement and experimental use—the decision is founded on well-established principles of patent interpretation and upon the precedent of the earlier decision of the same court in Monsanto v Stauffer (the House of Lords, which is the ultimate chamber of appeal in the United Kingdom, is not bound to follow its earlier decisions but it has ruled that this privilege is not open to the Court of Appeal).

1-3-5 Effect and evaluation of judgment

The claimants' appeal was allowed in part and the defendants' cross-appeal was rejected.

1-3-6 Relation to (i) exemption of research or experimental use and (ii) award granting of unused patent

The interpretation of the scope of the Patents Act 1977, s.60(5)(b) was neither broad nor narrow, in the sense that it neither sought to bring within the experimental use defence any activity that was not contemplated by the terminology of that provision, nor did it seek to exclude from that provision any activity that might have been described as naturally falling within it. In the light of the earlier authority in Monsanto v Stauffer and the principle that an exception to a patent right will be construed narrowly in the event that there is any ambiguity in its meaning, it was improbable that the defence could have succeeded on the facts. The real ground of the defence was that the manufacture and supply of a sample to MAFF was not a commercially significant activity that resulted in any identifiable and quantifiable damage to the patent owners—but the absence of commercial consequence for the patent owner is not a defence under the Patents Act 1977.

In conclusion, this decision has no bearing on the nature of research and experimental use by a non-patentee, since such activity was not at issue in this dispute.

1-4 Comment and other description

The trial judge in this case was a senior barrister who was serving as a Deputy Judge of the Patents Court—a not infrequent occurrence in patent disputes where the level of technological sophistication is relatively low. This factor probably had no impact on the outcome of the dispute.

Of more significance is the fact that the case involved a finely-balanced dispute that both went to trial and was the subject of a subsequent appeal. Following the introduction of more mediation-friendly Civil Court Procedure Rules in the early years of this century, given the uncertainty of the outcome of a trial and the fact that the market for the patented product was not so small as to preclude two or more parties from manufacturing competing products profitably, there would have been a substantial likelihood that the parties would have settled on terms that required the payment by the defendant to the claimant of the reasonable royalty.

1-5 reference ID number 4

2 No known cases are currently pending

3-1 Domestic trend

There is no identifiable trend as such, since the word "trend" suggests that something is actually happening. Since the same businesses that are prevented from conducting research and experiments outside the scope of the Patents Act 1977, s.60(5)(b) are the very same businesses that can invoke patent infringement law against others who do the same, and since the likelihood of research and experimentation reaching the eyes of the patent owner is relatively low on account of confidentiality, there is little consensus as to whether anything need be done at all and, if so, what should be done.

3-2 Trend in political circles

The Gowers Review of Intellectual Property (December 2006), at p. 47, indicates a political commitment on behalf of the present Labour Government to legislate in favour of a clearer and broader research exception than that currently provided under the Patents Act 1977, s.60(5)(b). States the Review:

"4.11 The experimental use exception should be clarified to enable researchers to examine, learn from and improve upon inventions. The Swiss research exception, which was recently changed, provides a good example of a clearer exception.

4.12 The Review believes that clarifying the research exception along Swiss lines will foster research without damaging the interests of rights holders"

Box 4.1: Swiss research exception

The effects of a patent do not extend:

(a) to acts undertaken in the private sphere for non-commercial purposes

(b) to acts undertaken for experimental and research purposes in order to obtain knowledge about the object of the invention, including its possible utilities; in particular all scientific research concerning the object of the invention is permitted

(c) to acts necessary to obtain a marketing authorisation for a medicament according to the provisions of the law of 15 December 2000 on therapeutic products.

(d) to the use of the invention for the purpose of teaching in teaching establishments

(e) to the use of biological material for the purposes of selection or the discovery and development of a plant variety

(f) to biological material obtained in the field of agriculture which was due to chance or which was technically unavoidable

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3-3 Trend in legal circles

There is no clearly identifiable trend in legal circles, on account of the absence of opportunities for members of the judiciary to express their opinions as to the efficacy of the present legal arrangements.

3-4 Trend in academic circles

The predominant opinion in academic circles is that the exception in favour of research and experimentation should be permitted to the greatest possible extent that is consonant with the protection of the reasonable expectations of the intellectual property owner. This sentiment is most strongly expressed in the field of copyright law, since that is the field that impinges most powerfully upon the ability of academics to make copies, to cite other works and to publish their own research findings—this being an activity that lies at the heart of modern academic life.

資料３　ドイツ

The Permissibility of Using Patented Research Tools Under German Patent Law

A study of the
Institute for Future Technology

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Table of Contents

1. Scope of the Study

The present study has been prepared for the Institute for Future Technology. It analyzes the legal situation under German patent law with respect to permissible access to patented research tools, in particular the scope of the exemptions to the patent rights and the potential application of compulsory licensing provisions.

Legal provisions which specifically facilitate the use of patented research tools – either as a specific exception to the patent rights or by means of a specific compulsory licensing provision[366] – are absent in German patent law. The introduction of such provisions is currently neither debated in the legislature, nor called for by users or scholars in Germany. Consequently, the present study will analyze whether and in how far the use of research tools in experiments is permissible under the general patent law provisions. After defining research tools (Part II), the study will focus on the experimental use privilege of Sec. 11 No. 2 German Patents Act (GPA), the newly introduced regulatory review exemption of Sec. 11 No. 2b GPA, the plant breeders' exemption of Sec. 11 No. 2a GPA (Part III), and the compulsory licensing provisions of Sec. 24 GPA (Part IV).

[366] Such as, *e.g.* the newly introduced Sec. 40 b Swiss Federal Law on Patents for inventions, which provides for a right to a non-exclusive license for the use of patented biotechnological research tools. *See* Law of June 22, 2007 amending the Federal Law on Patents for inventions, available at http://www.admin.ch/ch/d/ff/2007/4593.pdf (last accessed February 24, 2008).

2. Definining Research Tools

While there is no generally accepted definition of research tools,[367] the Federal Trade Commission (FTC) proposed the following narrow definition:

> [A] technology that is used by pharmaceutical and biotechnology companies to find, refine, or otherwise design and identify a potential product of properties of a potential drug product. As such, it serves as a springboard for follow-on innovation.[368]

Essentially, the FTC definition distinguishes research tools from products with commercial application by the market they serve.[369] Research tools are sold generally to private and public scientists,[370] whereas the market for commercial applications consists of the general public.[371] However, this distinction does not take into consideration that research tools may also serve both markets and would seem to exclude research tools that have an additional commercial application beyond their use in a laboratory setting.[372] Therefore, the broader, more inclusive definition proposed by the National Institutes of Health will be adopted for this study:

> We use the term 'research tool' in its broadest sense to embrace the full range of resources that scientists use in the laboratory, while recognizing that from other perspectives the same resources may be viewed as 'end products.' For our purposes, the term may thus include cell lines, monoclonal antibodies, reagents, animal models, growth factors, combinatorial chemistry libraries, drugs and drug targets, clones and cloning tools (such as PCR), methods, laboratory equipment and machines, databases and computer software.[373]

Research tools that have no use but in research (i.e. research tools according to the

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[367] The very attempt to define a category of research tools has been criticized because it is sometimes impossible to distinguish between 'things that are used only in the laboratory and things that might potentially be sold to non-research consumers. Natalie M. Derzko, *In Search of a Compromised Solution to the Problem Arising from Patenting Biomedical Research Tools*, 20 Santa Clara Computer & High Techn. L.J. 347, 352 (2004). As an example, *Derzko* names a DNA sequence that, at first, is thought to be useful only for research purposes but ultimately turns out to a diagnostic marker or to encode a therapeutic protein. *Id.*

[368] Federal Trade Commission, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy* Ch.3 p.18 (2003), http://www.ftc.gov/os/2003/innovationrpt.pdf [hereinafter FTC Report]

[369] *Id.*

[370] David Malakoff & Robert F. Service, *Genomania Meets the Bottom Line*, 291 Science 1193 (2001).

[371] FTC Report, *supra* note 3, chapter 3 p. 18.

[372] Derzko, *supra* note 2, at 352. *See also* Michael S. Mireles, *An Examination of Patents, Licensing, Research Tools, and the Tragedy of the Anticommons in Biotechnology Innovation*, 38 U. Mich. J.L. Reform 141, 149 (2004).

[373] National Institutes of Health, *Report of the National Institutes of Health (NIH) Working Group on Research Tools* (1998), http://www.nih.gov/news/researchtools/index.htm (last accessed March 3, 2008) [hereinafter NIH, Research Tools]. The Guidelines issued by NIH for recipients of NIH research grants use the terms 'unique research resource" and 'biomedical research resource" instead of research tools. The terms 'research tools' and 'materials' are used . . . interchangeably with 'unique research resources.' National Institutes of Health, *Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources: Final Notice*, 64 Fed. Reg. 72,090, 72.092 note 1 (Dec. 23, 1999). The notable difference from the definition of the NIH Research Tool Working Group, however, is that this definition does not include drugs or drug targets.

FTC definition) will be referred to as 'pure research tools' and research tools with a further commercial application will be referred to as 'dual purpose research tools' wherever such distinction is necessary. Examples of patented research tools include recombinant DNA techniques, polymerase chain reaction (PCR), animal models, such as the Harvard Oncomouse or the CreLox-Mouse, or Expressed Sequence Tags (ESTs).[374]

Regardless of how the term 'research tool' is defined, it should be noted that the term is not neutral, but already reflects the perspective of a consumer and not of the manufacturer.[375] The classification from a user's perspective is less controversial for biological discoveries, such as (partial) gene sequences, promoters, ligands and receptors controlling pathological symptoms and methods for their identification or manufacture.

3. Research Tools Under Patent Law Exemptions

The Experimental Use Privilege of Sec. 11 No. 2 GPA

Germany codified an experimental use exemption in Sec. 11 No. 2 GPA:

> The effects of a patent shall not extend to…. acts done for experimental purposes relating to the subject matter of the patented invention.[376]

The wording of the provision is identical to Art. 31(b) of the Community Patent Convention (CPC) 1975 exempting from infringement 'acts done for experimental purposes relating to the subject-matter of the patented invention'.[377] Even though the CPC has never entered into force and thus has no binding legal effect, most, if not all member states have codified a similar provision in their national patent laws.[378]

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[374] For a description of these and other research tools *see* Tanuja V. Garde, *Supporting Innovation in Targeted Treatments: Licenses of Right to NIH-Funded Research Tools*, 11 Mich. Telecomm. & Tech. L. Rev. 249, 273 *et seq.* (2005).

[375] Derzko, *supra* note 2; at 350. The different perspectives are already acknowledged in the summary of the NIH Report: 'One institution's research tool may be another institution's end product." *See* NIH, *Research Tools*, *supra* note 8. The report further showed that private firms were concerned with the broad definition of 'research tools" due the difficulty of distinguishing between pure research tools and research tools which were considered to be a final product that is potentially sold to the general public. *Id.*

[376] Sec. 11 No. 2 German Patent Act. The provision has been introduced as then Sec. 6b GPA by Art. 8 No. 4 of the Gemeinschaftspatentgesetz [Law on the Community Patent] of July 26, 1979, BGBl. I, 1269. It entered into force on January 1, 1981.

[377] The Convention for the European Patent for the common market, signed at Luxembourg on 15 December 1975, is commonly referred to as the Community Patent Convention (CPC 1975). An identical provision is contained in Art. 27 (b) CPC 1989. The provision has been codified without any reference to existing national provisions and has to be interpreted autonomously, *cf.* Peter Chrocziel, *Die Benutzung patentierter Erfindungen zu Versuchs- und Forschungszwecken* [The Use of Patented Inventions for Experimental and Research Purposes] 163, 166 (1986) [hereinafter Chrocziel, *Use of Inventions*]; Thomas Hieber, *Die Zulässigkeit von Versuchen an patentierten Erfindungen nach § 11 Nr. 2 PatG 1981* [The Admissibility of Experiments on Patented Inventions under § 11 No. 2 German Patent Act 1981], GRUR 1996, 439, 443.

[378] William Cornish, *Experimental Use of Patented Inventions in European Community States*, 29 IIC 735, 736 (1998), (with reference to similar or identical national provisions in note 2 and

The legislative history of Sec. 11 No. 2 GPA states that the provision was introduced in identical wording to meet the objective of harmonizing European and national patent law,[379] and consequently, no independent comment but solely a reference to the Memorandum on the Community Patent Convention was included in the legislative explanation.[380]

Requirements

Sec. 11 No. 2 GPA exempts acts from infringement which are a) experimental and b) relate to the object of the patented invention. The courts have defined experiments as 'any (planned) procedure for obtaining information, irrespective of the purpose which the information gained is eventually intended to serve'.[381] This intrinsically broad concept is limited by the second prong requiring that the experiments have to be related to the patented subject matter. It does not permit uses of a patented invention in experiments which are directed to third objects, *i.e.* where the patented invention is not the *object*, but the *means* of the experiments.[382] The German Federal Court of Justice held in its first *Clinical Trials* decision that Sec. 11 No. 2 GPA

> in principle exempts all experimental acts as long as they serve to gain information and thus to carry out scientific research into the subject-matter of the invention, including its use.[383]

The disclosure requirement under patent law warrants that third parties can test the invention during the patent term and further develop the technology based on the information obtained through the permissible trials.[384] Clinical trials required for the

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diverging Dutch and Portuguese provisions in note 3).

379 Explanatory Preamble to the German draft act, BR-Drs. 216/78, p. 20 A I 3; Bl.f.PMZ 1979, 276.

380 Denkschrift zum Gemeinschaftspatentübereinkommen [Memorandum on the Community Patent Convention], Bl.f.PMZ 1979, 325, 333.

381 *Cf., e.g.,* Bundesgerichtshof [BGH] [Federal Court of Justice], July 11, 1995 – *Clinical Trials I*, [1997] R.P.C. 623, 638, 28 IIC 103 (1997) [hereinafter *Clinical Trials I*].

382 Memorandum on the CPC, Bl. f. PMZ 1979, 333; Rudolf Kraßer, *Patentrecht* [Patent Law] 813 (2004), Peter Chrocziel, *Benutzung zu Versuchszwecken als Einwand gegenüber einem Anspruch wegen Patentverletzung (Q 105)* [Use for Experimental Purposes as Defense Against a Claim of Infringement (Q105)], GRUR Int. 1992, 148 *et seq.*, 195 *et seq.* [hereinafter Chrocziel, *Experimental Use*].

383 *Clinical Trials I*, [1997] R.P.C. 623, 639. *Cf. also,* BGH, Decision of April 17, 1998 – *Clinical Trials II*, [1998] R.P.C. 423, 438 [hereinafter *Clinical Trials II*]; Keukenschrijver, *in* Rudolf Busse, *Patentgesetz* [Patent Act] (2003), Sec. 11 marginal note 17; Kühnen, *in* Rainer Schulte, *Patentgesetz mit Europäischem Patentübereinkommen* [Patent Act and European Patent Convention], Sec. 11 marginal note 12. *See also* Wolfgang v. Meibom & Johann Pitz, *Experimental Use and Compulsory License Under German Patent Law,* 94 Patent World 27 (1997).

384 *See Clinical Trials I*, at 639; BGH, June 2, 1984 – *Erythronolid*, GRUR 1985, 734. *See also* v. Meibom & Pitz, *supra* note 18, at 28.

approval of a new indication by the Federal Health Agency were thus held to constitute experimentation *on* the patented subject matter and thus exempted from infringement.[385] In the later decision *Clinical Trials II*, the court extended the experimental use exemption to clinical trials on the patented compound even if they were not conducted for approval of a new indication as long as the experiments were directed to eliminating 'an existing insecurity'.[386] This is also the case where clinical trials are not conducted to find a new indication, but in order to determine the best form of administration of a pharmaceutical composition (containing the patented active agent) within a known indication.[387]

Though none of the two decisions explicitly addressed the issue, tests which solely aim at proving that the substance under testing is bio-equivalent to a known drug are generally considered to fall outside the scope of the exemption as they are not directed at finding new information, but merely serve to confirm that one substance has the same properties as the patented substance, and therefore can no longer to be qualified as *experiments* in the meaning of Sec. 11 No. 2 GPA.[388]

Limitations to the Experimental Use Privilege

Commercial Purposes

The *Clinical Trial* jurisprudence clarified that a (further) commercial purpose of the experiments does not have any influence on their permissibility. In stating that

> it cannot matter whether the experiments are used only to check the statements made in the patent or else to obtain further research results and whether they are employed for wider purposes, such as commercial interests,[389]

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385 *Clinical Trials I*, [1997] R.P.C. 623, 638. *Cf.* Cornish, *supra* note 13, at 753 (expecting the other European countries to follow the approach of the German Federal Court of Justice in the *Clinical Trials* decisions.)

386 Clinical *Trials II*, [1998] R.P.C. 423, 433

387 *Id.* at 435-36. *See* also Keukenschrijver, *in* Busse, *supra* note 18, Sec. 11 marginal note 18.

388 Cornish, *supra* note 13, at 753; Joseph Straus, *On the Admissibility of "Biological Equivalence Tests" During the Patent Term for Obtaining a Regulatory Approval for Patented Drugs by Third Parties*, AIPPI Journal 1998, 211, 230 *et seq.* Reformulating the requirements set forth in the *Clinical Trials* decisions, academics defined 'experiment" as necessarily presupposing the existence of uncertainty. *See* Rolf Pietzcker, *Patentrechtliche Fragen bei Klinischen Versuchen - eine Erwiderung* [Questions of Patent Law relating to Clinical Trials - A Response], GRUR Int. 1995, 319, 320; Hieber, *supra* note 12, at 441; Wolfgang v. Meibom & Johann Pitz, *Klinische Versuche - eine transatlantische Betrachtung vor dem Hintergrund der Entscheidung des BGH "Klinische Versuche II"* [Clinical Trials - A Transatlantic Review in Regard to the Federal Court of Justice's decision "Clinical Trials II"] Mitt. 1998, 244, 248 [hereinafter v. Meibom & Pitz, *Clinical Trials*]; Hidero Niioka, *Klinische Versuche im Patentrecht* [Clinical Trials in Patent Law] 276-278 (2003). *See* also Andreas van der Merwe, *Experimental Use and Submission of Data for Regulatory Approval*, 31 IIC 380, 380 (2000).

389 *Clinical Trials I*, at 639. *See also Clinical Trials II*, at 431 (the mere fact that the results obtained by the experiments are not solely used for research purposes but 'above all" serve

the court clarified that research performed by universities or non-profit institutions is subject to the same standards and does not enjoy a broader privilege than research conducted by commercial enterprises or research that is focused on commercial applications.[390]

Nevertheless, the exemption does not extend to experiments with a patented invention which are not directed at obtaining technical information, but solely to gather information necessary for a commercial or entrepreneurial decision, *i.e.* where the experiments are no longer directed to 'the further elucidation of the conditions, effects, applicability, and producibility of the object of the invention, but [to] a clarification of commercial facts such as the needs of the market, acceptance of prices, and possibilities of distribution.'[391]

Furthermore, the experimental use defense is inapplicable where the experiments reach a dimension that can no longer be justified on research grounds, or when they are aimed at disrupting or hindering the inventor's distribution of the product.[392]

Constitutional Guarantee of Property - Art. 14 (1) Basic Law

In *Clinical Trials I*, the BGH rejected the patentee's argument that the constitutional guarantee of property of Art. 14 Basic Law[393] pre-empted an interpretation of Sec. 11 No. 2 GPA that would encompass experiments with ultimate commercial purposes.[394] The court reasoned that the exemption had been introduced to balance the patentee's interest in maximal protection and the public interest in further technical development. Patentees should not be able to 'impede or preclude experiments in the research sector which are necessary for further technical development and have a close connection with the patented invention'.[395]

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commercial purposes as well does not render an experiment infringing). *Cf.* v. Meibom & Pitz, *Experimental use*, *supra* note 18, at 30.

390 *Cf. also* Scharen, *in* Georg Benkard, *Patentgesetz, Gebrauchsmustergesetz* [Patent Law, Utility Law] (2006), Sec. 11 marginal note 7; Kraßer, *supra* note 17, at 813-815; Kühnen, *in* Schulte, *supra* note 18, Sec. 11 marginal note 12; v. Meibom & Pitz, *Clinical Trials*, *supra* note 23, at 249; Henrik Holzapfel, *Das Versuchsprivileg im Patentrecht und der Schutz biotechnologischer Forschungswerkzeuge* [Patent Law's Experimental Use Privilege and the Protection of Biotechnological Research Tools] 205-07 (2004) [hereinafter Holzapfel, *Experimental use*]; Chrocziel, *Use of Inventions*, *supra* note 17, *passim*; Chrocziel, *Experimental Use*, *supra* note 12, at 205.

391 *Clinical Trials II*, at 433 *et seq.*

392 *Id.* at 436.

393 Art. 14 reads: '(1) Property and the right of inheritance shall be guaranteed. Their content and limits shall be defined by the laws. (2)…"

394 *Clinical Trials I*, [1997] R.P.C. 643 *et seq.*

395 *Id.* at 643.

That a product patent reserves all possible uses to the proprietor irrespective of whether the patentee realized the individual possibilities does not require a more restrictive interpretation because the economic value of the patent will not be diminished by third parties obtaining patents on specific uses of the invention. Although the proprietor of the (younger) use patent may exclude the proprietor of the (older) product patent from using the invention for the specific patented use, she cannot use it without a license to the product patent either, and the discovery of new uses rather increases the value of the product patent.[396]

The court's interpretation of Sec. 11 No. 2 GPA has been upheld by the Federal Constitutional Court as a permissible interpretation of the limits of the constitutional guarantee of property.[397] Though patents enjoy constitutional protection as property, property rights are not guaranteed without limits and, pursuant to Art. 14 (1), 2nd sentence German Basic Law, the legislator can determine their boundaries.[398] The Federal Constitutional Court held that the experimental use exemption codified in Sec. 11 No. 2 GPA constitutes a permissible limitation of the property rights conveyed by a patent.[399]

The court acknowledged that Art. 14 (1) Basic Law guarantees the patentee's principle claim to be allocated the economic benefits of his invention as long as reasons of public interest do not take priority over the interest of the patentee. Losses directly incurred by the patentee as a consequence of clinical trials have to be accepted because these losses will be limited if the clinical trials actually are *experiments* as defined under the jurisprudence of the Federal Court of Justice.[400] However, disproportional losses could be incurred if the experimental use privilege were abused by actually exploiting the patented compound, and an extension of the privilege to such cases would violate the constitutional guarantee of property under Art. 14 (1), 1st sentence Basic Law.[401]

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396 *Id.* at 644.
397 BVerfG, 1 BvR 1864/95 – *Klinische Versuche* [Clinical Trials], GRUR 2001, 43.
398 *Id.*
399 *Id.* at 44.
400 *Id.* at 45.
401 *Id.*

Application to Research Tools

General Remarks

Although no higher court decision explicitly addressed the question, whether and how far the use of a patented research tool may be exempted from infringement under Sec. 11 No. 2 GPA, the rationale underlying the *Clinical Trial* cases establishes a clear line of demarcation. Undoubtedly, experiments *on* research tools are exempted from infringement, *i.e.* any experiment directed at obtaining new information on a patented research tool is exempted from liability.

On the other side, as the German Federal Court of Justice explicitly stated in *Clinical Trials I*, the experimental use exemption does not extend to uses 'which make the invention the *means* for experimental acts.'[402] As a consequence, the experimental use exemption Sec. 11 No. 2 GPA has to be interpreted as not extending to the use of a research tool according to its patented purpose, *e.g.* when it is used to identify other useful compounds or to elucidate their properties.[403]

The Federal Constitutional Court's reasoning in rejecting the challenge to the *Clinical Trials I* decision clearly suggests that extending the exception to the use of research tools would no longer be reconcilable with the constitutional guarantee of property. Permitting experiments with biotechnological research tools under the experimental use exemption of Sec. 11 No. 2 GPA would permit the full exploitation of the patented invention because the research tools would be used for the very purpose that merited the grant of the patent. The economic effect of such extension would be quite different because the information obtained by experimenting with the research tool – contrary to information obtained from experiments on the patented invention – does not enhance the value of the research tool patent. The owner of a patented research tool does not benefit from a successful market approval of the final drug/product as it

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402 *Clinical Trials I*, [1997] R.P.C. 623, 641-42 (emphasis added). *Cf. also* LG Berlin, GRUR 1985, 375, 376 – *Klinischer Test*, where the court determined with respect to the exemption of the predecessor provision Sec. 6 GPA that the use of the drug Nifedipin in experiments for the development of a different drug is not exempted as it is not used in an experiment *on* Nifedipin, but solely impermissible use with Nifedipin.

403 Rüdiger Wolfrum *et al.*, *Die Gewährleistung freier Forschung an und mit Genen und das Interesse an der wirtschaftlichen Nutzung ihrer Ergebnisse*, 65 *et seq.* (2002) [The Guarantee of Free Research on and with Genes and the Interest in the Economic Exploitation of its Results]; Niioka, *supra* note 23, at 341-346; Holzapfel, *Experimental Use*, *supra* note 25, at 327 *et seq.*; Chrocziel, *Experimental Use*, *supra* note 17; Joseph Straus, *Zur Zulässigkeit klinischer Untersuchungen am Gegenstand abhängiger Verbesserungserfindungen* [The Admissibility of Clinical Trials on Dependent Improvement Inventions], GRUR Int. 1993, 308, 311; v. Meibom & Pitz, *Clinical Trials*, *supra* note 23, at 247.

regularly will not be covered by his patent.

The Federal Constitutional Court considered the patentee's participation in the economic value of a dependent invention justified because the dependent invention was made possible only through the (experimental) use of her original invention. It constitutes a kind of compensation for the patentee's having to tolerate the experimental use of his invention and ensures that the 'economic value of the product patent remains allocated to its owner as principally required under Art. 14 (1) Basic Law'.[404] Following the rationale of the *Clinical Trials* decisions and the limitations imposed by Art. 14 (1) Basic Law, the use of research tools does not constitute a permissible act under Sec. 11 No. 2 GPA.[405]

Simultaneous Gathering of Information on Tool and Compound

Especially in biotechnology, the use of research tools in experiments may yield not only information on the compound under testing, but also on the research tool itself. For example, screening with a receptor or a pharmaceutical compound will also yield information on the binding characteristics of the receptor respectively on the biologically active regions of the patented compound. Consequently, it has been argued that the distinction between 'research *on*' and 'research *with*' becomes blurred and does no longer allow a distinction in such cases because the experiments at least also will yield information that relate to the subject matter of the invention – the research tool.[406] While this argument can certainly be made, it is solely result-based and neglects an inquiry into the purpose of the respective experiments. Where the experiments are directed at obtaining information about another molecule, the research tool is nonetheless used according to its technical teaching whose commercial exploitation has been allocated to the patentee by virtue of the patent

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404 BVerfG, GRUR 2001, 43, 45 – *Clinical Trials*.

405 Henrik Holzapfel, *Die patentrechtliche Zulässigkeit der Benutzung von Forschungswerkzeugen* [The Admissibility of the Use of Biotechnological Research tools under Patent Law], GRUR Int. 2006, 10, 16 [hereinafter Holzapfel, *Research Tools*]; Holzapfel, *Experimental Use*, *supra* note 25, at 330. A different conclusion may be reached for dual purpose research tools, where the final pharmaceutical product would fall into the scope of the research tool patent because the patentee could still stop the use of the pharmaceutical product, meaning that the patent would not yet be stripped of any value. *Id.* *Cf. also* Trevor Cook, *A European Perspective as to the Extent to Which Experimental Use and Certain Other Defences to Patent Infringement, Apply to Differing Types of Research* 135-136 (2006) who concludes that the distinction laid down by the *Clinical Trials* jurisprudence provides the most appropriate framework for the application of the experimental use defence also with regard to research tools.

406 Alan W. White, *Problems of Patents for Research Tools*, 4 Bioscience L. Rev. 138 (1998/1999); Bernhard Fischer, *Germany: Reach-through claims and experimental use*, Managing Intellectual Property, Supplement - IP Strategy Yearbook 2001, at 10. *But see* Holzapfel, *Experimental Use*, *supra* note 25, at 328-29.

grant. Exempting these uses under the experimental use exemption would completely eviscerate the economic value of patents for pure research tools, and appears to constitute a clear violation of Art. 14 (1) GPA.[407]

It has been argued that the situation has to be appraised more differentiated with regard to dual-purpose research tools.[408] As the exploitation for purposes outside the scope of Sec. 11 No. 2 GPA remains reserved to the patentee, the economic encroachment on the patentee's rights may be considerably smaller, especially when the patented molecule has a therapeutic application. It is argued that the exemption should extend to such situations as the negative impact for the patentee would regularly be negligible in view of the much more lucrative market for therapeutic purposes and justifiable in view of outweighing public interests.[409] Only where the pharmaceutically active molecule is used for screening as part of industrially manufactured test kits, *e.g.* to screen cells to verify the existence of certain receptors, as one could no longer faithfully argue that information on the molecule is being collected, and thus, such uses should not fall under the experimental use exception.[410]

Comment

Even under the premise that the use of the invention will also yield information on the patented research tool, using the economic impact on the patentee as the decisive criteria neglects the necessary inquiry into the purpose of the experiments, *i.e.* whether the experiments are directed at obtaining information on the patented research tool or whether they are directed at obtaining information on the compound(s) under testing with any information on the research tools being only ancillary benefits. Under the rationale of the *Clinical Trials* decision, it would seem that such an encroachment on the patentee would no longer be justifiable under the experimental use defence.[411]

Furthermore, an approach that would ultimately determine the permissibility of

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[407] *Cf. also* Holzapfel, *Research Tools*, *supra* note 40, at 14 (with regard to the use of a receptor for screening).

[408] Holzapfel, *Research Tools*, *supra* note 40, at 15.

[409] *Id.* at 15. (Scenario 2) Holzapfel recognized that such extension would not be conforming to the European patent law doctrine of absolute product protection, but are nevertheless to be accepted as that doctrine should be relativized with respect to the experimental use exemption, *id.* at 12-13. Under that doctrine, the scope of a patent for a product extends to all use of the product, whether they have been disclosed in the patent or not. *See* BGH, March 14, 2003 – *Imidazoline*, GRUR 1972, 541; EPO, Enlarged Board of Appeal, December 11, 1989 G2/88 – Friction Reducing Additive/MOBILE OIL III. *See* also Keukenschrijver, *in* Busse, *supra* note 18, Sec. 9 marginal note 51.

[410] Holzapfel, *Research Tools*, *supra* note 40, at 15.

experiments depending on the relative negative impact on the patentee would disregard that this impact can significantly change. For example, when a new (first) therapeutic application is found for the patented research tool, the value of the patent will significantly increase and the profits lost by exempting the use of the research tool would relatively decrease. On the contrary, should the patent for a therapeutic molecule be restricted to cover only its use as a research tool, the relative lost profits would significantly increase and the economic value of the patent be practically eviscerated. In both cases, the absolute losses of the patentee for not being able to market his invention as research tool would be the same. A case-by-case determination based on how far exempting the use of the research tool would diminish the economic value of the patent seems impractical and would yield inconsistent results, respectively would have to be consistently re-evaluated, which would introduced a further element of uncertainty. Furthermore, as a practical matter, such differentiation would be easy to circumvent by filing for an additional/separate patent which is solely directed to the use as research tool.

The general rule should remain that the use of a research tool for research purposes – *i.e.* as a *means* of the experiments in accordance with its technical teaching – should not be exempted even when dual-purpose research tools are used. Where information is simultaneously obtained both on the research tool and on the compound under experimentation, the distinction between permissible and impermissible uses must be made based on a subjective inquiry into the purpose of the experiments. The question has to be asked (and answered) whether the experiments are (primarily) directed at gathering information on the research tool or on another compound. The Federal Court of Justice has recognized that according to its wording, Sec. 11 No. 2 GPA 'is concerned not with particular types of act but *exclusively* with the purpose of the acts in question'.[412] That the purpose of the experiments – thus a subjective element – can be decisive is explicitly acknowledged in *Clinical Trials II*:

> The same would be considered to be case if experiments are carried out with the purpose of persistently disturbing or hindering the inventor's distribution of his product. In such cases the research does not serve the purpose of technological progress, rather it serves as a means for the accomplishment of competitive purposes.[413]

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411 *Cf. Clinical Trials II*, at 436.
412 *Clinical Trial I,* at 638 (emphasis added).
413 *Clinical Trials II,* at 436.

The Decision of the District Court Düsseldorf

Although German appellate courts have yet to decide a case on experimental use involving the use of a research tool, the principles set forth in the *Clinical Trials* decisions are clear and have been applied accordingly by a trial court in 2003 when it was faced with such situation.[414] In the German part of the infringement proceedings between *Bayer* and *Housey* with respect to the use of their patented screening process, the District Court Düsseldorf rejected *Bayer*'s argument that their use of the invention was exempted under Sec. 11 No. 2 GPA.

Facts

Housey owned the European Patent EP 403506, relating to a method for screening of protein-inhibitors and -activators. Simplified, the screening process involved several steps: In a first step, a modified cell line is created which expresses the protein of interest and which exhibits a phenotypic response to the protein. The modified cell line has a lower level of expression and a lesser degree of phenotypic response compared to the original cell line. Agents are applied to both cell lines; based on a comparison of their phenotypic responses it can be determined whether the agent is an inhibitor or activator of the protein of interest.[415]

The district court determined that *Bayer* used the patented process to identify whether a compound inhibits or activates a protein of interest. Its studies were targeted at generating a new cell line for the characterization of different types of sGC activators in a well defined cellular environment; the created cellular system was described as 'a new screening system for the search of new types of activators of sGC'.[416]

The court rejected *Bayer*'s argument that use of the process to determine whether certain compounds can be used for activating or inhibiting soluble Guanylatcyclase (sGC) did not constitute screening as claimed in the plaintiff's patent. Likewise, it rejected the argument that the experiments were solely directed at establishing cell lines without using the invention. The court determined that the experiments had the (additional) purpose to analyze the characteristics of certain activators of sGC which

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[414] Landgericht Düsseldorf [LG] [District Court Düsseldorf], 4a O 362/02, Decision of October 28, 2003 (unpublished), available at http://cip.bravo771.server4you.de/www/ddorf_entsch/?q=node/395 (last accessed January 3, 2008).

[415] LG Düsseldorf, 4a O 362/02, at I. For details on the invention and on the parallel proceedings in the U.S., *see* Bayer AG v. Housey Pharmaceuticals, Inc., 340 F.3d 1367 (Fed. Cir. 2003).

were known only from cell-free systems.[417] After a detailed claim analysis, the court found that the procedure used by the defendant and described in the defendant's publication realized all elements of the claimed invention.

Rejection of the Experimental Use Defence

After establishing that *Bayer* made use of the patented process, the court rather summarily rejected the defendant's argument that such use was privileged under Sec. 11 No. 2 GPA.[418] As *Bayer* had used the patented method as means of their screening process, thus in accordance with the patented purpose, it determined that the experimental use privilege did not apply.[419] Citing the Federal Court of Justice's decision *Clinical Trials I* it stated that permissible uses under Sec. 11 No. 2 German Patent Act must be directed at obtaining information *on* the patented invention. Experiments that make the patented invention the *means* of the experiments cannot benefit from the privilege as the use of the invention occurs in accordance with the purpose of the patented invention and no longer for experimental purposes.[420] Accordingly, the court rejected the experimental use privilege as *Bayer* used the process according to its patented purpose as a *means* to identify inhibitors and activators of a protein of interest, namely sGC.

The Regulatory Review Exemption of Sec. 11 No. 2b GPA

As described in the preceding part, the distinction between experiments 'on' and 'with' the patented invention is settled law in the context of the experimental use exemption. No case law exists with respect to the regulatory review exemption which was introduced to implement the European Directive 2004/27/EC.[421]

The German experimental use exemption and corresponding provisions in most European countries have generally been interpreted as not allowing experiments to prove bioequivalence. Such experiments were deemed as not being directed at obtaining new information on the patented compound but merely at confirming that

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416 LG Düsseldorf, 4a O 362/02, at II.
417 *Id.*
418 *Id.*
419 *Id.*
420 *Id.*
421 Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004, amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, O.J. L 136, 30.4.2004, p. 34. The directive had to be implemented into national laws by October 30, 2005.

the generic product had the claimed properties.[422]

This restrictive interpretation stifled competition between original and generic drug manufacturers and forced manufacturers to conduct the required testing for drug approval abroad. The generic sector lobbied for the introduction of a regulatory review exception after the Supplementary Protection Certificate had been established in 1993, and was supported by the European Parliament.[423] The European Commission softened its position only after the WTO complaint against Canada had been resolved,[424] and, in order to secure a sufficient supply of inexpensive drugs and to allow generic drug producers to conduct the required experiments within Europe, it proposed an amendment of the Directive 2001/83/EC on the *Community code relating to medicinal products for human use* which was eventually adopted with some amendments as European Directive 2004/27/EC.[425] Besides harmonizing and streamlining the drug approval process for generic drugs in Europe, the directive introduced a new *Bolar*-type provision in amended Art. 10 (6), stipulating that studies and trials necessary for generic drug approval and 'consequential practical requirements'[426] are not to be regarded as 'contrary to patent rights or supplemental protection certificates for medicinal products'.[427]

The German legislator implemented the exemption in Sec. 11 No. 2b German Patent Act which now exempts from the effect of the patent

> [s]tudies and trials and the consequential practical requirements necessary to obtain a permission to market in the European Union or to obtain an authorization in the Member States or in third countries according to the

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422 *Cf. supra*, note 388.

423 European Parliament Resolution A4-0104/96(1) of April 16, 1996 on 'Industrial Property for the Pharmaceutical Sector", OJ EC C 141, 13.5.1996, p.63. *See also* Cook, *supra* note 40, at 49 *et seq.*

424 WT/DS/114, Canada – *Patent Protection of Pharmaceutical Products*.

425 Council Directive 2004/27/EC, O.J. (L 136) 34 (EC).

426 The 'consequential practical requirements" were included to clarify that the submission of documents and samples to the drug approval authorities were comprised by the experimental use defence, Common Position (EC) No. 61/2003, (2003/C 297 E/02) (OJEC 297 E, 9.12.2003 p.41) paragraph 11:

> *Amendment 134* relating to the so called Bolar clause on patent protection has been accepted in principle except the part referring to products for exports. In relation to submission of applications and granting of an authorisation, the Council believes that these activities, being of an administrative nature, will not infringe patent protection. The Council and the Commission have underlined this in a joint statement (1). Thus, it is neither necessary nor appropriate to include those activities in a provision on exemptions from patent protection. As concerns the submission of samples, this will be covered by the addition agreed by the Council: 'and the consequential practical requirements'.

427 Art. 10 VI reads: 'Conducting the necessary studies and trials with a view to the application of subsections 1, 2, 3 and 4 and the consequential practical requirements shall not be regarded as contrary to patent rights or to supplementary protection certificates for medicinal products." Subsections 1, 2, 3 and 4 specify the data which has to be submitted for drug approval process in case of generic drugs.

effective pharmaceutical regulations.[428]

The broad wording of the provision does not expressly limit the exception to studies and trials *on* the patented subject matter, which could be (mis-)understood as exempting from infringement the use of *any* patented invention including the use of research tools, if they are used for experiments necessary for the drug approval process.[429] However, the better arguments favor a more restrictive interpretation.

Legislative history

The legislative history of Sec. 11 No. 2b GPA and of its European root give no indication that the provision should extend to the use of research tools. Whenever the legislator discussed the necessity to exempt generic drug manufacturers during clinical trials, reference was only made to the patent or supplementary protection certificate on the *original product*.[430] Furthermore, the provision has to be interpreted in the systematic context of the experimental use exemption of Sec. 11 No. 2 GPA and thus – due to the absence of any diverging intent of the legislator – has to be read consistent with the *Clinical Trials* jurisprudence limiting the exception to experiments on the patented subject matter.[431] At last, an extension to research tools would violate Art. 14 (1) Basic Law for the reasons given *supra* with respect to Sec. 11 No. 2 GPA.[432]

The Plant Breeders' Exemption of Sec. 11 No. 2a GPA

With the implementing the Biotech Directive into German law, the legislator

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[428] The provision has been introduced as part of the 14. Law amending the German Pharmaceuticals Act and entered into force on September 6, 2005. The legislative proposals referred to the provision as a '*Roche-Bolar-Rule*." *See* BT-Drs. 15/5656 at 1-3, 75-77; BT-Drs. 15/5316, at 1-3, 31-34.

[429] *See* Holzapfel, *Research Tools*, *supra* note 40, at 16.

[430] *Cf.* with respect to the European's provision the Commission Proposal for a Regulation of the European Parliament and of the Council laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products, COM (2001) 404 final, at 72, 130, 197 (Nov. 26, 2001) (provision allows the testing required 'prior to the expiry of the originator product's period of patent protection). With respect to the German provision, compare the Legislative Proposals BT-Drs. 15/5316, at 31, 48 and BT-Drs. 15/5656, at 18 as well as the Final Report of the Committee for Health and Social Security, BT-Drs. 15/5728, at 84. Furthermore, the amendment is not found in legislation directed at amending the German patent law, but in a revision of the medicinal laws, which suggests that the legislators were concerned with the patents covering medicinal products and not with any other patent affected during the clinical trials. *See* Esther Pfaff, *"Bolar" Exemptions - A Threat to the Research Tool Industry in the U.S. and the EU?*, 38 IIC 258, 270-71 (2007).

[431] *See* Holzapfel, *Research Tools*, *supra* note 40, at 16; Pfaff, *supra* note 65, at 271-72. *Cf. also* Cook, *supra* note 40, at 52 *et seq.*

introduced Sec. 11 No. 2a GPA to alleviate concerns of plant breeders.[433] The plant breeders feared that the patenting of biological materials would *de facto* negate the breeders' exemption under the Plant Variety Protection Act.[434] Consequently, the International Seed Foundation demanded:

> Therefore ISF considers that a commercially available variety protected only by Breeders' Rights and containing patented elements should remain freely available for further breeding. If a new plant variety, not an essentially derived variety resulting from that further breeding, is outside the scope of the patent's claims, it may be freely exploitable by its developer. On the contrary, if the newly developed variety is an essentially derived variety or if it is inside the scope of the patent's claims, a consent from the owner of the initial variety or of the patent must be obtained.'[435]

The newly introduced Sec. 11 No. 2a GPA exempts from the effect of a patent

> 'the use of biological material for the purpose of breeding, discovering and developing a new plant variety'.

The provision has been introduced into the German Patent Act to regulate the conflict of patent protection and plant variety protection with regard to the development of new plant varieties. Though introduced by the Law Implementing the Directive on the Legal Protection of Biotechnological Inventions,[436] a comparable provision is absent from the directive. The German legislator intended to prevent any unreasonable barriers to the development of new plant varieties which make use of patent protected biological material.[437]

The wording seems to suggest that the provision allows *any* use of patented biological material for the purpose of developing a new plant variety.[438] Consequently, the scope of the exemption has been criticized as going beyond the necessary as it applies

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[432] *Cf. supra*, 0.

[433] Art. 1 No. 7 of the Law Implementing the Directive on the Legal Protection of Biotechnological Inventions, 2005 BGBl. I, 146 [Gesetz zur Umsetzung der Richtlinie über den rechtlichen Schutz biotechnologischer Erfindungen vom 21.1.2005].

[434] *Cf.* Sec. 10(a)(1)(3) German Plant Variety Protection Act [Sortentschutzgesetz] of December 19, 1997 and Art. 15(c) Regulation (EC) No. 2100/94 on Community Plant Variety Rights (CPVR) of 17 July 1994.

[435] International Seed Federation, 2003, Position; quoted from Michael A. Kock *et al., The Legal Protection of Plant-Biotechnological Inventions and Plant Varieties in Light of the EC Biopatent Directive*, 37 IIC 135, 151 footnote 113 (2006).

[436] Art. 1 No. 7 of the Law Implementing the Directive on the Legal Protection of Biotechnological Inventions, 2005 BGBl. I, 146 [Gesetz zur Umsetzung der Richtlinie über den rechtlichen Schutz biotechnologischer Erfindungen vom 21.1.2005].

[437] *Cf.* Draft of a Law Implementing the Directive on the Legal Protection of Biotechnological Inventions of October 15, 2003, BT-Drs. 15/1709, p. 9 note 1.

[438] Michael Haedicke, *Die Harmonisierung von Patent- und Sortenschutz im Gesetz zur Umsetzung der Biotechnologie-Richtlinie* [The Harmonisation of Patent and Plant Variety Protection in the Law Implementing the Biotechnology Directive], Mitt. 2005, 241, 244.

'not only to the genetic background of a patent-protected plant but also to the subject of the patent per se', and as amounting to a *de facto* compulsory licence at no cost.[439] However, the systematic context of Sec. 11 No. 2a GPA as having been introduced next to Sec. 11 No. 2 GPA where the exemption is limited to experiments on the patented subject matter warrants a limited interpretation.[440] Though the provision allows the use of patented biological material, it should be interpreted as allowing the use only where it is being used as part of the intended new plant variety, and should not allow its use as research tool which is not intended to become part of the newly developed plant variety.[441] To be read consistent with the case law interpreting Sec. 11 No. 2 GPA, the provision should be read as allowing 'the use of biological material for the purpose of breeding, discovering and developing a new plant variety *where the biological material is intended to become part of the new plant variety'*.[442]
The suggested (restrictive) interpretation would fully address all concerns of the plant breeders, while at the same time keeping limited the encroachment on the patent rights.

Practical Relevance of the Exemptions with Regard to the Use of Research Tools

Gold and *Gallochat*[443] describe two schools of thought for the interpretation of the experimental use defense with respect to biological materials. Whereas the second approach corresponds to the existing state of the law outlined in the previous paragraphs, the more comprehensive first approach would permit any research using DNA sequences except for using the DNA sequence to commercially manufacture a good.[444] The Nuffield Council on Bioethics assumes that the existing experimental use defenses do not extend to the use of research tools when it recommends:

> 5.45 … The knowledge embodied in patents claiming DNA sequences should, in our view, be freely available for all scientists to apply in the pursuit of non-commercial research. **We**

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439 *Cf.* Proposed amendment of draft Sec. 11 No. 2a GPA, submitted by the German Liberal Party, cited in the Recommendation and Report of the Judiciary Committee of the German Federal Parliament of December 1, 2004, BT-Drs. 15/4417 p. 7; Kock *et al., supra* note 70, at 152.

440 This is explicitly acknowledged by Kock *et al., supra* note 70, at 152.

441 *Cf.* Scharen, *in* Benkard, *supra* note 25, Sec. 11 marginal note 9, who considers the general principles developed under the case law on Sec. 11 No. 2 GPA with regard to the element of finality also applicable with regard to the interpretation of 'purpose of" in Sec. 11 No. 2a GPA.

442 Another proposal for a different wording altogether which would nevertheless take into account the interests of the plant breeders had been discussed in the parliamentary hearings on September 9, 2004: 'The effect of the patent does not extend to … the use of biological material that is released commercially by the patentee or with his consent for the purpose of breeding, discovering and developing a new plant variety'. *See* Kock *et al., supra* note 70, at 153.

443 E. Richard Gold & Alain Gallochat, *The European Biotech Directive: Past as Prologue*, 7 European L.J. 331 (2001)

444 *Id.* at 358 without further references.

> **recommend that the 'research exemption' is given a statutory basis in the US and clarified in Europe by policymakers as a matter of urgency.** We recognise that when such knowledge from an existing patent is used for commercial purposes, the researcher is obliged to acquire a licence from the patent owner. However, as we have seen, several thousand patents which assert rights over DNA sequences have already been filed and may yet be granted (paragraph 5.33). The need to seek multiple licences for many such sequences may hinder research and development. **We further recommend that companies work together to extend the concept of the 'research exemption' throughout industry for DNA sequences which appear in patents and which have a use in research**.[445]

In Germany, the Deutsche Forschungsgemeinschaft (DFG) had submitted a proposal for the broadening of the experimental use privilege to exempt (at least) the use of inventions as a tool to conduct research on other objects.[446] However, the proposal of one of the most eminent German research foundations has not found a wide echo among users or legal scholars. The lack of case-law and legal scholarship suggests that access to research tools is not perceived as a real problem in Germany. Furthermore, the fact that –contrary to the situation in the U.S.[447]– the introduction of a *liability rules concept* with respect to the use of patented research tools has been neither proposed nor intensively discussed by German patent scholars, also suggests that the scope of the exemption is considered to be adequate.[448]

The German section in the OECD Study on Genetic Inventions noted several reasons why the situation is not perceived as problematic:

> Some research tools are staple goods, like enzymes, which can be purchased without declaring their intended use. Moreover, it is difficult to detect infringement of research tools which are used behind laboratory doors. While endproducts may be suspected of having been developed using a patented research tool, many biotechnology companies do not yet have such commercialised products, making it difficult to claim infringement. Public research bodies claim that their staff members are often unaware of the legal implications of using patented research tools. However, fear of litigation is low in the public sector, as research institutions usually generate no revenue through the use of the research tool and thus the patent owner has little incentive to sue. In short, many groups act as if an "informal research exemption" exists for the use of patented research tools.[449]

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[445] Nuffield Council on Bioethics, *The ethics of patenting DNA: a discussion paper* 61 (2002)

[446] Deutsche Forschungsgemeinschaft, Senatskommission für Grundsatzfragen der Genforschung, *Mitteilung 1 – Genforschung - Therapie, Technik, Patentierung* 32, 38 (1997). Incidentally, both the DFG's proposal as well as the proposal by the Nuffield Council on Bioethics assume that the use of research tools in experiments would not be permissible under the current state of law.

[447] *Cf., e.g.*, Derzko, *supra* note 2; Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. Chi. L. Rev. 1017, 1078 (1989); Irving N. Feit, *Biotechnology Research and the Experimental Use Exception to Patent Infringement*, 71 J. Pat. & Trademark Off. Soc'y 819, 840 (1989).

[448] *Holzapfel* analyzes the concepts proposed in the U.S. and rejects them both as violating Art. 14 Basic Law and Art. 27 (1) and 30 TRIPS and as impractical, especially in view of the problems of determining an adequate remuneration. *See* Holzapfel, *Experimental Use*, *supra* note 25, at 332-348.

[449] OECD, *Genetic Inventions, Intellectual Property Rights and Licensing Practices* 47-48 (2002); Joseph Straus *et al.*, *Genetic Inventions and Patent Law* 25 *et seq.* (2004).

4. Compulsory Licensing

Though a compulsory licensing provision has been introduced into German patent law already in 1911[450], it has been applied only sparingly. In the period of 1961 to 2003, only 12 applications for a compulsory license have been filed at the competent German Federal Patent Court.[451] Only one compulsory licence has been granted after 1945,[452] but subsequently has been revoked by the German Federal Court of Justice.[453]

The low number of applications has been ascribed to the high threshold of public interest required under Sec. 24 (1) No. 2 GPA.[454] However, most commentators view the impact of compulsory licensing provision not as much in their actual application, but in their mere existence, *i.e.* in their *potential* application which strengthens the bargaining position of the license-seeker.[455]

The compulsory licensing provisions have been completely revised in 1998 to comply with the requirements of the TRIPS agreement[456]. Since then, the German Patent Act provides for two different kinds of compulsory licensing: compulsory licensing in the public interest in Sec. 24 (1) GPA and for compulsory licensing in case of dependent patents in Sec. 24 (2) GPA. Subsection 3 applies the requirements of Subs. 2 *mutatis mutandis* to cases where the exploitation of a plant breeders right would infringe a patent. Subsections 4 to 7 stipulate additional requirements corresponding to those of Art. 31 lit. c) to lit. h) TRIPS. [457]

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[450] Rogge *in* Benkard, *supra* note 25, Sec. 24 marginal note 1; Dietrich Scheffler, *Monopolwirkung und Informationsfunktion von Patenten aus heutiger Sicht* [Monopoly Effect and Informatory Function of Patents from Today's Point of View], GRUR Int. 1989, 798.

[451] Astrid Buhrow & Jan Nordemann, *Grenzen ausschließlicher Rechte geistigen Eigentums durch Kartellrecht (Q187)* [Limitations on exclusive IP rights by competition law], GRUR Int. 2005, 407, 409. For statistics of earlier periods, *cf.* Siegfried Greif, *Ausübungszwang für Patente - Ökonomische Möglichkeiten und Grenzen unter besonderer Berücksichtigung der Entwicklungsländer* [Requirement of Use for Patents – Economic Possibilities and Limitations Under Special Consideration of Developing Countries], GRUR Int. 1981, 731, 733.

[452] BPatG, June 7, 1991, 3 Li 1/90 – *Compulsory Licence*, GRUR Int. 1994, 98 (=BPatGE 32, 184).

[453] BGH, December 12, 1995, X ZR 26/92 – *Polyferon*, 28 IIC 242 (1997). *See infra,* 0

[454] Andreas Heinemann, *Immaterialgüterschutz in der Wettbewerbsordnung: eine grundlagenorientierte Untersuchung zum Kartellrecht des geistigen Eigentums* [Protection of Intangible Goods in the Competition Order: A Fundamental Analysis on the Anti-Trust Law of Intellectual Property] 183 *et seq.* (2002); Scheffler, *supra* note 85, at 99 *et seq.* The notion of 'public interest" also recurs in the form of 'interest of public welfalre' as a requirement for a grant of an exploitation order for government use under Sec. 13 GPA.

[455] Anna-Maria Schieble, *Abhängige Genpatente und das Institut der Zwangslizenz* [Dependent Gene Patents and the Instrument of Compulsory Licensing] 158 *et seq.* (2005); Kraßer, *supra* note 17, at 619; Schwendy, *in* Busse, *supra* note 18, Sec. 24, marginal note 16.

[456] Art. 2 No.5 of the Second Law Amending the German Patent Act of July 16, 1998, BGBl. I, S. 1827.

[457] Subsections 3 to 7 read:

Compulsory licensing in public interest – Sec. 24 (1) GPA

Sec. 24 (1) GPA reads:

> A non-exclusive authorization to commercially exploit an invention shall be granted by the Patent Court in individual cases in accordance with the following provisions (compulsory license) if
>
> 1. the applicant for a license has unsuccessfully endeavored during a reasonable period of time to obtain from the patentee consent to exploit the invention under reasonable conditions usual in trade; and
> 2. public interest commands the grant of a compulsory license.

The provision imposes two requirements for compulsory licensing in the public interest, namely a) that the licensee unsuccessfully attempted during a reasonable period of time to secure a contractual license under reasonable conditions, and b) that the grant of the licence is commanded by the public interest. The restrictive element is requirement of the 'public interest'.

The Requirement of Public Interest

The notion of *public interest* is an indefinite legal term which has not been concretized in the German Patent Act, neither with regard to *what* constitutes a public interest nor with regard to *when* a public interest is sufficiently high to warrant the grant of a compulsory licence. Like any general term, it is subject to change and its interpretation is decisively influenced by socio-political assessments and the economic situation of the respective times.[458] In *Polyferon*, the BGH stated.

> There can be no universally valid definition of public interest. On the contrary, this term, like any general term, is subject to change. The assessment of the balancing of the interests of the

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(3) Subsection 2 applies mutatis mutandis when a plant breeder is unable to attain or exploit a plant breeder´s certificate without infringing a patent of earlier date

(4) A compulsory license under subsection (1) may be granted for a patented invention in the field of semi-conductor technology only if such grant is necessary to remove an anti-competitive practice on the part of the patentee that has been established in judicial or administrative proceedings.

(5) If the patentee does not use the patented invention or does not use it predominantly in Germany, compulsory licenses under subsection (1) may be granted to ensure an adequate supply of the patented product to the domestic market. Importing shall be deemed to constitute use of the patent in Germany in such case.

(6) The grant of a compulsory license in a patent shall be permissible only after the grant of the patent. It may be granted subject to restrictions and made dependent upon conditions. The scope and duration of use shall be restricted to the purpose for which they have been permitted. The patentee shall be entitled to remuneration from the holder of a compulsory license that shall be commensurate with the circumstances and shall take into consideration the commercial value of the compulsory license. In the event of a significant change, with respect to the repeated remuneration that will become due in future, in the circumstances on which the determination of the amount of the remuneration was based, each party shall be entitled to require a corresponding adjustment. If the circumstances on which the grant of a compulsory license was based no longer apply and if it is unlikely that they will reoccur, the patentee may require the withdrawal of the compulsory license.

(7) A compulsory license in a patent may only be transferred together with the enterprise concerned by the exploitation of the invention. A compulsory license in an invention that is the subject matter of a patent of earlier date may only be transferred together with the patent of later date.

[458] BPatGE 32, 184, 189 – *Compulsory Licence*.

> patent holder and of the general public is subject to varying points of view [citations omitted]. The decision depends entirely on the circumstances of the individual case [citations omitted]. Public interest cannot be established merely on the basis of the exclusive position enjoyed by the patent holder, even if the latter enjoys an actual monopoly on the market. As a reward for the publication of his invention and the efforts, risk and costs involved, the patent holder is granted by law an exclusive right which he is able to exploit irrespective of the competitive position. For this reason, public interest can only be affected if there are particular circumstances that subordinate the unrestricted recognition of the patent holder's exclusive right and interests to the interest of the general public in the exploitation of the patent by the party seeking a license. Only then is there justification for a major impairment of the patent holder's rights against his will in the form of a compulsory license.[459]

A decision on the grant of a compulsory licence has to take into consideration all circumstances of the particular case and carefully weight the legitimate interest of the patentee against the interests of the general public.[460] Individual interest such as the specific interests of the licence applicant cannot be taken into consideration.[461] In particular, the mere strengthening of the competitive position of the licensee is insufficient;[462] to the contrary, the applicant has to show that the grant of a compulsory licence to the particular applicant is demanded by the public interest.[463] However, that the applicant for a compulsory licence additionally pursues his own financial interests does not negatively impact the decision.[464]

Prior to 1945, courts have assumed public interest for the grant of a compulsory licence, *inter alia*, in order to avert danger to an entire industry sector,[465] due to the need to improve supplies to the domestic market,[466] to promote promoted the health of the general public,[467] to improve medical care of the public,[468] or to realize proven advantages for the health protection.[469] Although these reasons have to be considered with a caveat as a consequence of changed socio-economic circumstances,[470] the well being of the general public, especially in the field of health care, has to be taken into due consideration and may in cases of serious illnesses

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459 BGH 28 IIC 242, 245 (1997) – *Polyferon*.
460 Schwendy, *in* Busse, *supra* note 18, Sec. 24 marginal note 36.
461 BpatG, December 15, 1995, 3 LiQ 1/95 – *Einstweilige Verfügung in einer Zwangslizenzsache*, citing BGH, February 12, 1963, Ia ZB 3/63 (unpublished).
462 Schwendy, *in*: Busse, *supra* note 18, Sec. 24 marginal note 41.
463 Schieble, *supra* note 90, at 162; BPatG, GRUR 1994, 98 – *Compulsory Licence.*
464 RGZ 113, 115,125.
465 RGZ 83, 9, 14
466 RGZ 93, 50
467 RG GRUR 1930, 177, 179 – *Teigauftrageplatte*, RG GRUR 1935, 877 – *Hygienischer Spülapparat*; BPatG GRUR 1994, 98, 100 – *Compulsory Licence*.
468 RG GRUR 1935, 877 – *Hygienischer Spülapparat*
469 *Id.*; BPatG GRUR 1994, 98, 101 – *Compulsory Licence*.
470 BGH 28 IIC 242, 245 (1997) – *Polyferon*; Schwendy, *in* Busse, *supra* note 18, Sec. 24 marginal note 47.

justify the grant of compulsory licence to make specific drugs available to patients.[471] However, unavailability due to high drug prices seems unlikely to be sufficient. In the past, both the German Federal Patent Court and the German Federal Court of Justice have rejected granting compulsory licences in order to reduce the costs for the public health system.[472]

The BGH has established a high threshold for compulsory licensing even with regard to reasons of public health. It determined that neither the finding of a new (medical) use for an existing drug,[473] nor the approval of the Federal Health Agency (FHA) of a drug can justify a finding of public interest *in itself*.[474] As compulsory licensing constitutes a significant encroachment on the constitutionally protected exclusive rights of a patentee, the principle of reasonableness has to be observed. The grant of a compulsory licence constitutes the *ultima ratio* and can not be justified where a less intrusive solution can be found.[475]

Consequently, the court revoked a compulsory licence granted by the German Federal Patent Court as 'it ha[d] as yet not been found with certainty that there a significant improvement in the therapeutic possibilities […] as compared with traditional medicaments'.[476] Though the administration of the drug *Polyferon* arguably resulted in improved tolerance and absence of serious side effects compared with second-choice standard preparations, the court found that it did not have any importance from the medical point of view in the treatment of chronic polyarthritis compared to the standard medications and thus denied the existence of public interest.[477]

At last, the court imposed a high burden of proof. It deemed insufficient the *probability* that the drug would constitute the only possible method of treatment for a group of patients, and also the possibility that the administration of the drug would produce favourable effects and could become the first-choice medication for this

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471 BGH 28 IIC 242, 246, 248 (1997) – *Polyferon*; BGH, Decision of March 27, 1974, partially published by Volker Vorwerk, *Probleme der Zwangslizenzregelung* [Problems of Compulsory Licensing] GRUR 1976, 64, 69; Karolina Herrlinger, *Die Patentierung von Krankheitsgenen* [Patenting of Disease Genes] 311 (2005).

472 BPatG, Bl.F.PMZ 1974, 319 – *Valium*; GRUR 1996, 870 – *Ranitidinhydrochlorid*; BGH GRUR 1952, 393 – *Paladon*. *See also* Vorwerk, *supra* note 106.

473 BGH 28 IIC 242, 246-247 – *Polyferon*. The BGH's subsequent finding that the grant of a use patent does not change the assessment, has to be qualified due the amendment of the compulsory licensing requirements for dependent inventions in Sec. 24 (2) GPA. *Cf. infra*, 0

474 BGH 28 IIC 242, 247 (1997) – *Polyferon*.

475 *Id.* at 246.

476 *Id.* at 248.

477 *Id.*

group of patients, because the court expert was unable to quantify the degree of probability due a lack of appropriate investigations and the high degree of placebo effects of up to 40% of results in rheumatoid arthritis.[478] In order to determine the necessary degree of probability of superior effects, the applicant may be required to conduct comparative clinical studies between the drug of interest and drugs that are available for the treatment of the disease.[479]

To successfully apply for a compulsory licence for the use of a drug, the applicant has to prove beyond a mere probability that a) his drug is necessary and beneficial for the treatment of a group of patients, and b) that there is no other drug on the market that could achieve similar effective results, even if it had not been approved for the particular indication. No difference can be made with respect to patents on gene sequences. In her analysis of compulsory licensing of gene patents, *Schieble* determined that the mere finding of a gene function alone cannot warrant a finding of public interest which would justify the grant of a compulsory licence.[480] In view of the legislator's decision to grant absolute product protection, it has to be required that the new application is of particular high value, *e.g.*, that the discovered function contains the key to the treatment of a severe, previously untreatable illness. The elucidation of the functional relationship of a gene and an ordinary illness, such as common cold, or an unimportant body function would not be sufficient.[481]

Application to research tools

In view of the high threshold imposed by the requirement of public interest, it seems not very likely that a compulsory licence will be granted for research tools under Sec. 24 (1) GPA.

A person applying for a compulsory licence to a specific research tool would have to show that the use of the research tool for a specific project would be commanded by the public interest. At first, the applicant would have to demonstrate that the furtherance of a specific research project is in the public interest, *e.g.* that the intended use of the research tool would allow the development of a cure against a severe, currently incurable illness. Secondly, he would have to prove that the use of the specific research tool would produce results that would not be attainable by the use of

478 *Id.* at 249.
479 *Id.*
480 Schieble, *supra* note 90, at 167.
481 *Id.* at 168.

available research tools. With respect to compulsory licensing of gene patents, the empirical study by *Straus et al.* showed that biotech companies and research institutions themselves considered the potential benefit of gene sequences too hypothetical to establish the public interest.[482] Under the high requirements with regard to meeting the burden of proof imposed by the BGH in *Polyferon*, a mere probability of achieving superior results will not be sufficient.

Furthermore, it seems unlikely that research – though protected by Art. 5 (3) German Basic Law – can in itself constitute a public interest justifying the grant of a compulsory licence. The public interest in research is recognized in the German Patent Act through means of the research exemption codified in Sec. 11 No. 2 GPA, which represents a careful balance between the constitutionally protected interests of research on the one hand and of property on the other hand, and establishes a demarcation by not exempting from infringement the use of research tools.[483] This careful balance would be contradicted when research by itself would be recognized as justifying the grant of a compulsory license.

Compulsory Licensing in Case of Dependent Inventions

Sec. 24 (2) GPA addresses the situation where a patented invention cannot be exploited without necessarily infringing an earlier patent which is commonly referred to as a situation of dependent patents. The special provision aims to adequately balance the interests of the two patentees in cases where a younger invention cannot be exploited without the consent of the owner of an older patent.[484] Its primary function is to facilitate the public interest in an effective advancement of technology.[485]

General remarks

Sec. 24 (2) GPA has been amended in 2005 in order to adjust the requirements for compulsory licensing in case of dependent inventions to those imposed by Art. 31 TRIPS Agreement.[486] In its current wording, the provision reads:

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482 Straus *et al.*, *supra* note 84, at 23.
483 Cf. *supra* 0, p. 9.
484 Klaus Pfanner, *Die Zwangslizenzierung von Patenten: Überblick und neuere Entwicklungen* [Compulsory Licensing of Patents: Overview and New Developments], GRUR Int. 1985, 357, 361.
485 Schieble, *supra* note 90, at 161.
486 Art. 1 No. 9 of the Act Implementing the Directive on the Legal Protection of Biotechnological Inventions of January 21, 2005, BGBl. I, p. 146.

(2) If the applicant for a license is unable to exploit an invention for which he holds protection under a patent of later date without infringing a patent of earlier date, he shall be entitled to request the grant of a compulsory license with respect to the owner of the patent of earlier date, if

1. the requirements of subsection 1 are fulfilled, and
2. his own invention comprises, in comparison with that under the patent of earlier date, an important technical advance of considerable commercial significance.

The patentee may require the applicant for a license to grant him a counter license under reasonable conditions for the exploitation of the patented invention of later date.

Under the predecessor provision, the illogical situation persisted that the grant of a compulsory licences for the use of a patented invention had to meet higher requirements than for the use of an unpatented invention as the then-Sec. 24 (2) GPA incorporated by reference all requirements of Sec. 24 (1) GPA. Its practical relevance especially with regard to dependent DNA-patents was considered marginal.[487]

Consequently, the abolition the additional requirement of public interest has been interpreted as lowering the previously high requirement for the grant of a compulsory licence.[488] The general requirement of public interest has been legally defined for cases of dependent inventions as being satisfied where the dependent inventions comprise an 'important technical progress of considerable economic importance' compared to the invention of the older patent,[489] which is deemed easier to prove than the previous commanding public interest.[490]

The 'technical progress' realized by the invention of the younger patent has to be important in view of the invention of the older patent and has to be determined taking into consideration the specific circumstances on the relevant market.[491] Individual interests of the applicant for a compulsory licence had no relevance under the previously incorporated requirement of public interest.[492] Its abolition has been interpreted as allowing also for the recognition of *individual* interests of the

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[487] Joseph Straus, *Abhängigkeit bei Patenten auf genetische Information - ein Sonderfall?* [Dependency of Patents on Genetic Information - A Special Case?], GRUR 1998, 314, 317; Scheffler, *supra* note 85, at 98; Wolfrum *et al.*, *supra* note 38, at 68.

[488] Ulrich Dörries, *Patentansprüche auf DNA-Sequenzen: ein Hindernis für die Forschung?*[Patent Claims for DNA-Sequences: An Obstacle for Research?], Mitt. 2001, 15, 20. *But see* Schieble, *supra* note 90, at 179 *et seq.*, who considers it unlikely that the notion of the general public interest will be completely irrelevant for interpretation of the new provision. The requirement of public interest has so strongly characterized compulsory licensing for so long that may be viewed as an intrinsic requirement for the grant of a compulsory licence. *Id.*

[489] Rogge, *in* Benkard, *supra* note 25, Sec. 24 marginal note 22.

[490] Dörries, *supra* note 123, at 20.

[491] Kühnen, *in* Schulte, *supra* note 18, Sec. 24 marginal note 22.

[492] *See* Reasons relating to Art. 2 Nr. 5 of the 2. Law Amending the Patent Act, Bl.f.PMZ 1998, 393, 400. *Cf. also supra,* footnotes 461 to 464 and accompanying text.

prospective licensee for the determination of 'considerable economic importance'.[493] Though somewhat altering the bargaining positions of the two patentees, the amendment did neither change the fundamental situation of opposing interests nor significantly strengthen the position of the owner of the dependent patent,[494] and Sec. 24 (2) GPA will most likely continue to have only limited practical relevance.[495] Furthermore, the other restrictions remain: the owner of the patent with the younger priority will have to fail in securing a contractual licence, prove before a court that his invention constitutes an 'important technical progress of considerable economic importance' over the patent with older priority, and may only after the adjudication in his favour start using the older invention without incurring liability for infringement.

Application to research tools

Despite the perceived lowering of the requirements for compulsory licensing in case of dependent patents, it seems likely that the amended Sec. 24 (2) GPA will have only a very limited application in facilitating easier access to patented research tools. So far, its application in the biotech sector is mostly discussed in the context the discussion on absolute product protection, *e.g.* with regard to the situation where a new use for a gene sequence, cannot be exploited without the consent of the owner of the product patent of the gene sequence or of a partial gene sequence.[496]

Though the ordinarily required public interest of Sec. 24 (1) No. 2 GPA has been substituted by requiring an 'important technical progress of considerable economic importance', it should not be overlooked that the application of Sec. 24 (2) GPA is subject to additional limitations: a) it can be applied only where the exploitation of a product of process will necessarily infringe the patent, and b) the younger, dependent product or process has to be patented.

Researchers can benefit from Sec. 24 (2) GPA only after they have made an invention *and* have obtained a patent, *i.e.* is only well after the invention phase has been completed. Consequently, the provision cannot facilitate access to research tools in any experiments on non-patented subject matter, *e.g.* for basic research.

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493 Michael Nieder, *Zwangslizenzklage - Neues Verteidigungsmittel im Patentverletzungsprozeß?* [The Claim for a Compulsory Licence – A New Method of Defence in Patent Infringement Proceedings?], Mitt. 2001, 400, 401.

494 Wolfrum *et al.*, *supra* note 38, at 68.

495 Scheffler, *supra* note 85, at 98.

496 *See, e.g.,* Schieble, *supra* note 90, at 179 *et seq.*; Wolfrum *et al.*, supra note 38, at 66 *et seq.*; Scheffler, *supra* note 85; Straus, *supra* note 122, at 316 *et seq.*

Furthermore, even in case of experiments that take place after a patent has been granted, *e.g.* in clinical trials, the provision will continue to have only very limited impact as the exploitation of the patented invention must be impossible without infringing the patent for the research tool. This would certainly be the case where the use of the patented invention would necessarily infringe the patent for the research tool, *i.e.* in cases where the invention incorporates the research tool.[497]

However, it is questionable whether the use of a research tool merely for experimenting on the patented invention, *e.g.* in order to find out new properties or to determine toxicity or efficacy, could be deemed *necessary* for the exploitation of the invention. Though an invention may have to undergo testing before it can be exploited, *e.g.* to obtain marketing approval in case of pharmaceuticals, it seems questionable whether this relationship would be sufficiently direct to qualify as *necessary* for the exploitation of the patented invention, especially if there are alternative research tools which would – even if less efficient or more costly – allow the performance of the necessary tests.

A court generally has to assume in compulsory licensing proceedings that the intended use falls into the scope of the patent[498] unless the opposite is obvious or legally bindingly determined by a court.[499] The case-law that a court also has to make the same assumption if it is disputed that a younger patent is dependent from an older patent,[500] however, stems from a time where no special provision for compulsory licensing for dependent invention existed and seems outdated. In view of the present different requirements for compulsory licensing in case of dependent inventions as compared to compulsory licensing in the public interest, it seems at least questionable that a court will rely on the assumption when it is obvious or contested by the owner of the older patent that the younger invention can be used without infringing the research tool.

Practical Relevance of Compulsory Licensing of Research Tools

An empirical study by *Straus et al.*, conducted on behalf of the Federal Ministry of Education and Research in 2002 surveyed 25 German genomics-associated enterprises and research institution with regard to the impact of patent rights on their

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497 *E.g.*, where the use of a gene sequence implies the use of a patented partial gene sequence.
498 RG GRUR 1934, 246, 248 – *Tonaufnahmeverfahren*.
499 RG GRUR 1928, 131, 132 – *Fernsprechanlage*.
500 RGZ 91, 188, 190 *et seq.* – *Gleisrückmaschine*; RGZ 126, 266, 267 – *Teigauftrageplatte*.

business and research activities.[501] The study's goal was to produce reliable empirical data to prove or disprove the perceived blocking effect of patents in the field of genomics. The respondents generally did not view compulsory licensing as an essential issue, and partially even wondered whether there was a gentlemen's agreement not to apply for such license.[502] Furthermore, a compulsory licence was deemed insufficient basis for essential investments due to its non-exclusive nature and due to the uncertainty that the public interest could cease to exist if the patentee changes its strategy of exploitation.[503]

5. Patent Pooling for Research Tools

Patent pools do not play a prominent role in the German biotech sector. The only empirical study available, conducted by *Straus et al.,* noted that both cross-licensing and patent pooling were unpopular, and that only 3 of the surveyed enterprises used these measures.[504] They were considered ineffective, and as a result of a feared imbalance of contribution and profits from the arrangement, licence fees increased.[505]

[501] Straus *et al., supra* note 84.
[502] *Id.* at 22.
[503] *Id.* at 23.
[504] *Id.* at 22.
[505] *Id.*

6. Conclusion

Though there is only one trial court decision addressing the question of the permissibility of using a research tool under the experimental use exemption,[506] the case law on the experimental use defence suggests a clear demarcation. The use of research tools in experiments is not exempted where the experiments are not directed to obtaining information on the research tool itself (Sec. 11 No. 2, 2b GPA), or to the development of a new plant variety where the research tool (*e.g.* a gene sequence) is incorporated (Sec. 11 No. 2a).

It seems unlikely that a compulsory licence will be granted for the use of a research tool under Sec. 24 (1) GPA in view of the high requirement of commanding public interest, both as regards the material requirement and the burden of proof. Likewise, it seems likely that the recently amended Sec. 24 (2) GPA, allowing for compulsory licensing in case of dependent invention, will be applied only very sparingly – if at all – to facilitate the use of research tools.

The lack of case-law and scholarly literature addressing the problem, as well as the results of an empirical study conducted in 2002 suggest that access to research tools is not perceived as a real problem in Germany. This may be partly due to the perception of an informal research exemption, especially by non-profit researchers, as well as differential licensing conditions favouring academic research.

[506] *See supra* 0

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Joseph Straus	*On the Admissibility of "Biological Equivalence Tests" During the Patent Term for Obtaining a Regulatory Approval for Patented Drugs by Third Parties*, AIPPI Journal 1998, 211
Joseph Straus	*Zur Zulässigkeit klinischer Untersuchungen am Gegenstand abhängiger Verbesserungserfindungen* [The Admissibility of Clinical Trials on Dependent Improvement Inventions], GRUR Int. 1993, 308
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資料４　フランス

IFTECH REPORT
French Survey

PREAMBLE

This report addresses the French situation concerning:

- the research exemption (I)
- the research tool approach (II)
- the compulsory licensing (III)

I – THE RESEARCH EXEMPTION

There is a statutory provision in the French Law, namely in Article L. 613-5 b) CPI [Intellectual Property Code] which provides that:

> "*The rights afforded by a patent shall not extend to:*
> *a)* …
> *b) acts done for experimental purposes relating to the subject matter of the patented invention.*
> c) …"

The case law enabled us to better appreciate the scope of such a provision, reminding that the interpretation of said provision should be of strict application: in other words, the "research exemption" should be limited in making a clear difference between:

- experimental acts aimed at checking the technical interest of the invention (for instance possibility of reproducing the specification by the man skilled in the art) or developing said invention in order improve the general knowledge; such acts fall within the scope of the exemption, and

- acts aimed at commercial purposes for which such exemption does not apply.

Some decisions of interest can illustrate what is intended by "aimed at commercial purposes":

- Court of Appeal of Lyon (March 5, 1992 – BABOLAT / BOSCHIAN) stated that:

> "*The presentation of a product in a show (exhibition) does not meet the requirement of checking the technical interest of the invention, or to study its scope, or to improve it, but said presentation is aimed to look for the commercial value of said invention by studying the opinion of the public on it*".[507]

- Court of Appeal of Paris (July 3, 2002 – PARIENTI / AUTOMOBILES PEUGEOT) stated that:

> "*The presentation of a prototype, extensively commented in the national newspapers, goes beyond the mere experimentation*".[508]

- Court of Appeal of Paris (October 7, 2005 – AGROSOL / SODIFAG) stated that:

> "*A prototype which is placed at the disposal of potential customers cannot be deemed as a mere experimental prototype, but has clearly a commercial aim*".[509]

The above case law can be summarized as follows: as soon as a product, derived from experimentation, is presented to potential customers, the presentation of said product is deprived of the benefit of the research exemption.

This issue of research exemption has a serious impact on inventions addressing public health and the French case law has varied substantially.

Initially, the clinical trials in order to get a visa were considered as deprived of the benefit of the research exemption.

- Court of Appeal of Paris (November 27, 1984 – SCIENCE UNION & SERVIER / CORBIERE) stated that:

> "*The granting of a visa clearly demonstrates that the manufacture of the product (active substance) before said granting had a commercial purpose, could not get the benefit of the research exemption and therefore should be considered as an infringement*".[510]

More recently French Courts have overruled the previous cited decision:

- Court of Appeal of Paris (January 27, 1999 – WELLCOME / PAREXEL & FLAMEL) stated that:

> "*The preliminary trials, whatever the final purpose can be – including a future commercialization – are still covered by the experimental exemption, the granting of a visa not being an infringement*".

- Tribunal de Grande Instance – TGI – of Paris (which is a 1st instance Court) in its decision of February 20, 2001 (WELLCOME / PAREXEL & FLAMEL) stated that:

> "*Only the acts which are carried out after the granting of the visa can be deemed*

[507] Published in PIBD 1992, n° 525.III.363
[508] Published in PIBD 2005, n° 819.III.685
[509] Published in PIBD 2005, n° 819.III.685
[510] Published in PIBD 1985, n° 366.III.118

as having a commercial purpose".[511]

- TGI of Paris (October 12, 2001 – SCIENCE UNION & SERVIER / EXPANPHARM) confirmed that:

  "*Clinical trials which are conducted with a view of getting a visa are not an infringement*"[512]

- TGI of Paris (January 25, 2002 – SCIENCE UNION & SERVIER / BIOPHELIA)[513] confirmed the above decisions.

This issue of clinical trials in view of getting a visa has been finally settled with a change in the French law[514] transposing in our national law a European Directive[515]; Article 10 of said French law provides that:

"*The rights afforded by a patent shall not extend to:*

a) …
b) …
c) …
d) *trials and tests carried out in view of getting a visa for a medicine, as well as the acts which are necessary for carrying out them and for getting such a visa*".

Such Article 10 of said French law has been moved as a paragraph d) in Article L. 613-5 CPI.

Taking into consideration the definition of "medicine" which is given by Articles L. 5111-1 and L. 5121-1-14 of our Public Health Code, it can be deemed that some biological products fall within said definition of "medicine", benefiting therefore of the research exemption has described above.

II – THE RESEARCH TOOL APPROACH

- The research tools

  - Patentability

    It is well accepted in France that a research tool is an ordinary invention which has to fulfil the patentability criteria in order to be protected by a patent; there are no specific rules concerning such an invention to be patented.

    In order to illustrate what has just been stated, there are no specific provisions in our CPI concerning the patentability of a research tool.

  - Exploitation

    The specificity of a research tool lies more likely in its exploitation, it being understood that when such a research tool is used during experimental trials, the research exemption described above shall apply, and therefore, the use of said tool shall not be considered as an infringement. But the picture is dramatically different when there is a commercial use of said research tool, said use being then a potential infringement.

511 Published in PIBD 2001, n° 729.III.530
512 Published in PIBD 2002, n° 739.III.155
513 Published in PIBD 2002, n° 747.III.342
514 Law n° 2007-248 of February 27, 2007
515 European Directive n° 2004/27/CE

So as to illustrate that issue, I take the example of a French research institution which used the PCR (Polymerase Chain Reaction), a patented technology aimed to replicate for instance a DNA sequence which is present in a very small amount in a sample (too small to be detected), said replication leading to an amount of such DNA sequence sufficient to be detected with a diagnostic kit.

French research institution utilized the PCR technology according to two ways:

- in its labs to develop new diagnostic kits for specific human diseases leading to file several patent applications covering said kits: under such circumstances, French research institution benefited of the research exemption above described and had no royalties to pay to the patent owner;

- in its blood analysis Centre where the patients were invoiced for the diagnosis carried out using said PCR technology: in that case the French research institution had to pay royalties to said patent owner who accepted to grant a license on reasonable terms because of the status (and name) of said institution..

As a final remark, I have to add that said French research institution decided to abandon its patent portfolio of patents covering diagnostic kits carrying out said PCR technology because the patent owner refused to grant any license (or at extremely high conditions) to commercial companies.

Another difficulty appeared concerning the patented research tools involved in the screening of potentially valuable molecules. The owner of the patents when granting a license on their patents, calculated the royalties to be paid on the net sales of the medicines including such molecules. That method of calculation was based on their claim (known as a "reach through claim") covering the drug screened, thanks to the use of said screening research tool. But generally such a claim is not accepted because of lack of support by the specification. Moreover the licensee (pharmaceutical companies) refused such a method of calculation.

Eventually, a preferred way was to sell such a research tool as a mere chemical reactive, with the difficulty of determining the selling price.

There is presently no debate among the professionals, nor any envisaged change in our Law concerning the research tools.

- The patent pooling

Although the patent pooling is potentially an appropriate way for solving problems (for instance in the case of a multiplicity of patents owned by different owners which are necessary for commercializing a product or a methodology), we do not have, so far, in France such a patent pooling system. Some research organizations or universities tried to initiate a debate on that issue, but it must be admitted that till now, there is no concrete result which arises from said debate; I have no knowledge of any official attempt (from National Authorities) to address such issue.

III – THE COMPULSORY LICENSING

The French system has two compulsory licenses categories; whatever category is envisaged, it is a non exclusive royalty-bearing license. Such categories correspond to who is in charge of granting such a compulsory license:

a) the compulsory licenses which are granted by a Court

i) for non exploitation of the French Patent (Article L. 613-11 to L. 613-14 CPI)

It is provided that, after the expiration of a three-year period (as from the granting of the patent) or four-year (as from the filing date of the patent application – whichever term is longer – a compulsory license shall be granted by the Court, provided that the patentee:

- has not initiated any preparations for the exploitation of his patent ;
- has not commercialized his products in order to satisfy the French market.

There are many decisions[516] from French Courts allowing such licenses and refusing the legitimate excuse from the patentee opposing such a granting of a compulsory license; however, since a modification of the French Law[517], the mere importation from a country which is a member of WTO will be deemed as an exploitation of the French patent, therefore limiting substantially the scope of this article (such a compulsory license is likely intended to disappear).

ii) for improvements (Article L. 613-15 CPI)

Rather than improvements, it should be appropriate to speak about licenses on "depending" patents, the invention covered by said depending patents not being always an improvement (for instance in case of a new application of a product).

Such licenses are granted provided that:

- the applicant for such a compulsory license has requested unsuccessfully the patentee to grant him a license ; and,

- the "improvement" presents an important technical progress and an economical substantial interest as compared with the invention covered by the "dominating" patent.

As already mentioned, such a compulsory license is non exclusive and royalty-bearing (the rate of royalty is fixed by the Court).

b) the compulsory licenses which are granted by an Administration (Ministry)

i) for the needs of the Public Health (Articles L. 613-16 and L. 613-17 CPI)

The decision comes from the Minister in charge of Industrial property (generally speaking, the Ministry in charge of Industry), at the initiative of the Minister in charge of the Public Health.

Until the recent French law[518], such a compulsory license was limited to patents covering medicines and their manufacturing process. Said recent law broadened significantly the scope of said Article L. 613-16.

In its present writing, a compulsory license for the needs of the Public Health shall apply to any granted patent covering:

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516 Supreme Court (January 11, 2000), Court of Lyon (September 11, 1997), TGI of Lyon (December 19, 1996)
517 Law n° 96-106 of December 18, 1996.
518 Law n° 2004/800 of August 6, 2004

- a medicine, a medical device, a medical device for an *in vitro* diagnosis, or a related therapeutic product ;
- the process for their production, a product which is necessary for such a production or a process for manufacturing such a necessary product ;
- a method of *ex vivo* diagnosis (this covers genetic tests).

The regime of compulsory license for the needs of the Public Health shall apply only:

- when such products, processes or methods are made available to the public:
  - in an insufficient quality or quantity ;
  - at a price abnormally high.
- or when the patent is exploited under conditions which have been deemed either contrary to the public health interest or constituting anticompetitive practices according to a final decision given by a Court or by an Administration.

When the decision to put the patent under the regime of compulsory license for the needs of the Public Health is made by the Minister, any interested party can get such a non exclusive license. Both parties must agree on the financial conditions of the license and submit them to the Minister. In case of disagreement of this latter, the royalty rate is fixed by the Court.

Eventually, a new compulsory license has been created, resulting from a European Regulation[519] resulting from the Doha declaration and decision of November 2001 and August 2003 concerning the manufacturing of medicines in favour of countries suffering health crisis, such medicines being manufactured in countries where such medicines are patented, but such manufacturing being limited to the exportation of said medicines towards said countries. Therefore our CPI was modified in October 2007 by adding a new Article L. 613-17-1 (dedicated to the above mentioned possibility of manufacturing medicines in favour of countries suffering health crisis) and a new Article L. 613-17-2 (confirming that the re-importation of such medicines in France as considered as an infringement).

ii) for the needs of the National Economy (Article L. 613-18 CPI)

The decision comes from the Minister in charge of Industrial property who orders the patentee to satisfy the needs of national economy through the exploitation of his patent. In case the patentee does not obey such order, under determined conditions, the patent is placed under the regime of the compulsory license system, through a Decree by the Conseil d'Etat, enabling any interested party to apply for such a license. In case the parties disagree on the rate of royalty of said license, said rate is fixed by a Court. There is no case law for the application of this Article.

iii) for the needs of the National Defence (Article L. 613-19 CPI)

The decision comes from the Minister in charge of Industrial property, at the initiative of the Minister in charge of the Defence; the process is similar to that of a compulsory license for the needs of the National Economy. However, due to the sensitive aspect of such inventions, the discussions before the Court are secret. There is no known case law for the application of this Article.

[519] European Regulation n° 816/2006/CE

ADDITIONAL REPORT

French Survey

1. Research exemption

(1) The article L. 613-5 b) CPI provides that the research exemption is granted in case of "experimental purposes"; when stakeholders had to interpret such a provision, this approach of "experimental purposes" was opposed to the approach of "commercial purposes": in this latter approach, i.e. when the utilization of the product (as patented and/or improved) had a commercial aim, the research exemption did not apply. The question which was raised at that time was to know whether the "commercial purpose" should be immediate (an act of commercialization following immediately such use) or could take place later on (for instance when getting a visa for a drug, and waiting for the expiration of the patent before commercializing the generic).

Considering the case law that I mentioned in my report, the utilization consisted in presenting the product as a prototype (cases referenced under footnotes 1, 2, 3), such prototype being presented to potential customers: in such a case, the Courts have decided that there was a clear "commercial purpose" because of such a presentation of the prototype to such potential customers.

Concerning medicines, the case law, as I mentioned, varied substantially. In a first step, it was decided that the getting of the visa was deemed as an infringement, because the "commercial purpose", although not immediate, was the final aim and therefore, infringement was retained by the Court (decision under footnote 4). In the late 1990's and early 2000's, decisions extended the approach of "experimental purposes" to acts such as filing a visa application, getting the visa, conducting clinical trials in view of getting a visa, all such acts not being considered as an infringement.

This issue of the clinical trials was clearly controversial, opposing pharmaceutical companies (such as WELLCOME or SCIENCE UNION & SERVIER), supporting that such trials were carried out in view of a commercialization and therefore should not be included in the exemption, and generic manufacturers (such as PAREXEL & FLAMEL, EXPANPHARM, BIOPHELIA) supporting the opposite argument.

In between the decisions of our Courts, there was a debate among stakeholders, but nothing significant at the level of the French authorities.

Finally, the law maker did not need to be an arbitrator, because of a European Directive (n° 2004/27/CE) which provided that the clinical trials carried out in view of getting a visa for a generic, should not be considered as an infringement, such trials benefiting of the research exemption. Such a Directive obliged France to adapt its law accordingly, hence the law n° 2007-248 of February 27, 2007 referred to in my report. Curiously, our law does not limit the exemption to such clinical trials carried out for getting a visa in case of a generic but for any visa concerning a medicine (without any further precision on the medicine, i.e. either a generic or not).

2. Research tool approach

As I told you, the debate on such issue is presently still quite hazy and it is difficult to answer right now your questions.

A patent pool is intended to promote technology by reducing the difficulties in licensing it and by presenting to a potential licensee a unique patents portfolio either owned by different

patentees but managed by a “Clearing House” (alternative A) or by said ”Clearing House” who would be the unique owner of the patents, the participants of said pool having abandoned contractually their rights in favour of said “Clearing House” (alternative B).

Of course, the anti-trust law regulations have to be respected.

3. Compulsory licensing

a) As I told you, there is, so far, no compulsory license granted in France in the interest of Public Health. However, some interesting event took place quite a long time ago.

   In the 1970's, Roussel Uclaf, a French pharmaceutical company, intended to commercialize an abortive pill; that company was threatened of international boycotting of all of its products and was ready to withdrawn such pill from the market. The Minister who was in charge of Public Health at that time, informed Roussel Uclaf that, should the pill be withdrawn from the market, he had the intent to place its patent under the regime of a compulsory license, because said Minister was convinced of the importance of said pill for Public Health.

   Finally, Roussel Uclaf decided to maintain its pill on the market: as a consequence, there was no compulsory license and, happy end, its products were not boycotted.

b) Concerning Myriad Genetics and their patents on BRCA1 and BRCA2, when the problem appeared there was the previous regulation limiting the compulsory license to patents covering medicines (the ex vivo diagnostic methods were not covered) and the grounds were limited to insufficient quality or quantity, or abnormal price (anticompetitive behaviour was not applicable). The only possibility was then to lodge an opposition to all their patents when they were granted by the European Patent Office. Eventually, Myriad Genetics had to substantially reduce the scope of said patents; I am not aware of any lawsuit initiated by them against any French laboratory, such as Institut Curie, which is using a method falling in part within the initial scope of their patents.

4. Relationship between a European Directive and the French government

According to the European rules, when a Directive is adopted by the Council and the European Parliament, each country must adapt its Law in order to implement the content of said Directive; it can be a complete adaptation, by reproducing exactly and completely said content in the Law but the member states have also some flexibility in said adaptation. It should be reminded that in case of discrepancy between the Directive and the national Law, the Directive prevails; in case of substantial discrepancies, the European Commission has also the possibility to initiate a lawsuit against the country having so badly adapted its Law.
As an example, the European Directive n° 98/44 of July 1998 gave a delay till the end of July 2000 in order for the member states to adapt consequently their Laws. In France, it took some time, because of a very controversial debate concerning ethical issues, such as the patentability of human genes. Finally France adapted its Law in August (Law n° 2004-808) and December 2004 (Law n° 2004-1138) using that possibility of flexibility in said adaptation (see for instance articles L. 611-10, and L. 613-2-1 to L. 613-2-4 CPI). I am not aware of any complaint from the European Commission concerning a “bad” adaptation by the French authorities.

5. Which documents do you need: case law? Laws? European Directives? Others? I can order those of interest for you.

資料５　ベルギー

Research Tools in the R&D Phase

Belgian Report

Prepared for The Institute for Future Technology (IFTECH), Tokyo, and Commissioned by the Japanese Patent Office, Tokyo

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INTRODUCTION

Concepts

In the present report we apply the following definitions. We use the term "research tool" in its broadest sense to embrace a wide range of resources that scientists use in the laboratory, while recognizing that for other institutions the same resources may be viewed as end products or (diagnostic) services. For our purpose, the term may thus include *genes,* cell lines, monoclonal antibodies, reagents, animal models, growth factors, clones and cloning tools (such as PCR) and other methods (cf. Report of the National Institutes of Health (NIH), Working Group on Research Tools, Presented to the Advisory Committee to the Director, June 4, 1998, see http://www.nih.gov/news/researchtools/index.htm).

Research and development (R&D) commonly refers to "creative work undertaken on a systematic basis in order to increase the stock of knowledge, including knowledge of man, culture and society, and the use of this stock of knowledge to devise new applications" (Organization for Economic Co-operation and Development). Research often refers to basic experimental research, involving the identification of possible chemical compounds or theoretical mechanisms. Development refers to the exploitation of research into solid products and is concerned with proof of concept, safety testing, and determining ideal levels and delivery mechanisms. We use the term “R&D” in its widest sense. For our purpose the term also encompasses the development of *diagnostic tests*. The major difference with conventional R&D in pharmaceutics is that the overall R&D efforts in the diagnostics field are relatively low and R&D expenditures are rather modest. Another difference is that R&D efforts do not always lead to a product or drug, but to a service, unless of course, diagnostic kits are developed.

Approach and methodology

In the present report we aim at providing information on two major issues concerning research tools in the R&D phase.

1. The *legal status* of research tools in Belgian patent law. This issue raises questions such as: Are research tools patentable? Is the use of research tools

by third parties considered an infringement? Or is the use of research tools exempted from the rights of a patent holder by the *research exception*?

2. The *licensing policy* with regard to research tools in daily Belgian patent practice. This issue raises questions such as: Are (patented) research tools – when not exempted from patent law – easily licensed? On what conditions? To whom? And if the patent holder refuses to license a research tool, is any recourse possible? By way of a *compulsory license*? Or otherwise?

In addition, we would like to draw the attention to some recent efforts which have been initiated to the pooling of (research) tools. It is suggested that collaborative licensing mechanisms, such as patent pools and clearing houses, could facilitate access to patented research tools (*See* section 12).

The present report is based on information gathered through the examination of Belgian case law, Belgian legislative reforms and related parliamentary documents, Belgian legal doctrine, as well as newspapers. Additionally, information has been collected through interviews with stakeholders, which have been carried out in February 2008.

1. SETTLED LAWSUITS AND LEGAL ANALYSIS

Not applicable

2. PENDING LAWSUITS AND INCIDENTS AND TROUBLES

2.1. *Myriad Genetics* (Belgian Opposition before the European Patent Office, Munich)

2.1.1. Name of both parties

Belgian Society of Human Genetics *v.* Myriad Genetics

2.1.2. Bibliographic description (date of file, trial case number etc).

In the course of 2001 a series of European patents dealing with diagnostic testing for early onset breast and ovarian cancer based on the genes BRCA1 and BRCA2 were granted to Myriad Genetics (at present the patent proprietor is the University of Utah Research Foundation). Three patents related to BRCA1 (EP0699754, EP0705902 and EP0705903) and one patent related to BRCA2 (EP0785216). All four patents designated a series of European member states, amongst which Belgium. Opposition was filed against all four patents by institutions (mostly) located in France, Germany, the Netherlands and Belgium. The Belgian oppositions were lodged by the Belgian Society of Human Genetics.

- EP0699754 related to a 'Method for diagnosing a predisposition for breast and ovarian cancer' and was granted on 10/01/2001. Opposition was filed on 10/10/2001 by the Belgian Society of Human Genetics (Representative of Opponent was W. Bird). An appeal has been lodged following opposition on 14/01/2005 (T0080/05). The date of the oral proceedings has been set on 18/11/2008. *
- EP0705902 related to 'Nucleic acid probes comprising a fragment of the 17q-linked breast and ovarian cancer susceptibility gene' and was granted on 28/11/2001. Opposition was filed on 28/08/2002 by the Belgian Society of Human Genetics. A first appeal against the Opposition decision was lodged on 15/11/2005 (T1213/05) but was rejected on 27/09/2007. A second appeal was lodged on 16/03/2005 (T1213/05). On 24/09/2007 the oral proceedings took place.*
- EP0705903 related to 'Mutations in the 17q-linked breast and ovarian cancer susceptibility gene' and was granted on 23/05/2001. Opposition was filed on 25/02/2002 by the Vereniging van Stichtingen Klinische Genetica (the Netherlands, but also encompassing Belgian members) (represented by W. Bird). An appeal was lodged on 01/08/2005 (T0666/05). The oral proceedings will take place on 12/11/2008.*
- EP0785216 related to 'Chromosome 13-linked breast cancer susceptibility gene BRCA2' and was granted on 08/01/2003. Opposition was filed on 08/10/2003 by the Belgian Society of Human Genetics. The oral proceedings

took place on 29/06/2005 and led to the decision that the patent will be maintained in amended form (B2 New Specification of the European patent on 07/06/2006).*

* This information is collected from the European Patent Office (EPO) Register Plus Database (http://www.epoline.org).

The grant of the BRCA patents to Myriad, as well as the various discussions before the EPO Opposition Division were widely commented in the Belgian press (*See* section 5.1.5.).

2.1.3. Trouble description

2.1.3.1. Summary

As to the BRCA1 patents, the Opposition proceedings resulted in one patent being revoked (EP0699754) and two patents being upheld in amended form (EP0705902 and EP0705903), after which appeals have been lodged by the patent proprietor. As to the BRCA2 patent (EP0785216) oppositions have resulted in the patent being upheld in amended form after proceedings at the European Patent Office (EPO).

2.1.3.2. Reason of trouble

Patents on diagnostics and patents on human genes are not novel, but patents on **genes** for diagnostics are a rather unseen combination. The grant by the EPO of a series of patents covering the breast cancer gene, its mutations, as well as diagnostic and therapeutic applications based on the gene's sequence, evoked strong reactions and led to the questioning of the nature, legitimacy and scope of gene patents and diagnostic methods instrumental to public health. Although several of the initially granted breast cancer patents have been revoked or restricted, the discussion lingers on, as no final decision is available on the exact scope of the patents at present.

2.1.3.3. Forecast of settlement

At present, no prediction is possible on the outcome of the appeal procedures.

2.1.3.4. Analysis of the case

In all cases arguments were put forward challenging novelty and inventive step of the claimed inventions (cf. articles 52 to 57 European Patent Convention, abbr. EPC), as well as adequacy of enabling disclosure (cf. art. 83 EPC).

2.1.3.5. Effect and evaluation of the trouble (if not finished, please fill the effect of the trial)

The opposition proceedings did not have any suspensive effect. Appeal against opposition decision where the patent has been upheld has no suspensive effect either: the granted patents are considered valid and enforceable.

2.1.3.6. Relation to exemption to research or experimental use, and award granting of unused patent

Why is the Myriad case relevant in the framework of the present study on research tools? The importance of the Myriad case relates to the twofold role ***genes*** may play. Genes are "dual purpose" research tools*, in the sense that they do not only have (commercial) value for diagnostic or therapeutic purposes, but can also be used in research. As has been argued before**, it is unclear to what extent the use of genes in the framework of genetic diagnostic testing falls within the research exemption. On the one hand, one could claim that genetic diagnostic testing cannot fall within the exemption because once a diagnostic test is established, the act of diagnosis could be defined as and/or confined to the act of providing the referring medical doctor with an opinion as to whether or not the patient carries a deleterious mutation. On the other hand, one could argue that the use of genes related to genetic diagnostic testing falls within the research exemption, because the use of genes, patient blood or tissue sampling is often necessary to do research.

One can easily imagine that in case of monopolization of genes useful as research tools, progress might be stalled, as the search for novel defects in disease related genes would slow down.

* See STRANDBURG, K., 'Sharing Research Tools and Materials: Homo Scientificus and User Innovator Community Norms', Lecture presented at an in-house seminar at the Centre for Intellectual Property Rights, K.U.Leuven, Belgium, 7 March 2008.

** *See* VAN OVERWALLE, G., VAN ZIMMEREN, E., VERBEURE, B., MATTHIJS,

G., 'Models for facilitating access to patents on genetic inventions', 7 *Nature Review Genetics*, February 2006, 143-148

2.1.4. Comment and other description

The Opposition Division of the EPO can only pass a judgment on the validity of patents, more in particular on novelty, inventive step, industrial applicability and enabling disclosure. The Opposition Division is not competent to judge on infringement, and subsequently, on the scope of the research exemption. Nevertheless, it is interesting to note that the Opposition proceedings before the EPO seem to suggest that genes are patentable, irrespective of their use in genetic diagnostic testing or in research.

2.2. Ablynx v. The Medical Research Council and Domantis (Lawsuit before the Judge of Seizure, Ghent)

2.2.1. Name of both parties

Ablynx *v*. The Medical Research Council and Domantis

2.2.2. Bibliographic description (date of file, trial case number etc).

Judge of seizure Ghent, public hearing 7 December 2004 (Algemene Rol nr. 04/4210/A). In the case infringement of European patent EP 368.684, entitled 'Cloning immunoglobulin variable domain sequences', was discussed.

2.2.3. Trouble description

2.2.3.1. Summary

On 20 October 2004, and on request of the Medical Research Foundation and Domantis (the defendants), the Judge of Seizure of Ghent granted permission for preliminary measures, namely a Discovery order, at Ablynx' premises. Ablynx (the claimant) started a third-party opposition against the aforementioned judgment in order to apply for the withdrawal of the judgment and, in subsidiary order, to obtain the limitation of the descriptive measures.

On 7 December 2004 the Judge of Seizure of Ghent decided that the scope of the Discovery order had to be narrowed down substantially.

2.2.3.2. Reason of trouble

The claimant is under suspicion of infringement of European patent EP 368.684. In order to provide evidence of infringement, the defendants have started a suit for preliminary measures. The claimant started a third-party opposition against the judgment allowing these measures.

2.2.3.3. Forecast of settlement

A decision has been taken as to the preliminary measures (Judge of Seizure, Ghent, 7 December 2004). To our knowledge no court decision has later been taken as regards the substance of the matter.

2.2.3.4. Analysis of the case

On 9 March the EPO granted European patent (EP 368.684 B1) relating to a pioneering invention in the field of antibody technology and, in particular, in the field of generating antibody libraries, also called ***expression libraries***. The patent focuses on single domain ligands derived from molecules in the immunoglobulin (Ig) superfamily, receptors comprising at least one such ligand, methods for cloning, amplifying and expressing DNA sequences encoding such ligands, preferably using the polymerase chain reaction, methods for the use of said DNA sequences in the production of Ig-type molecules and said ligands or receptors, and the use of said ligands or receptors in therapy, diagnosis or catalysis.

The defendants, Medical Research Foundation and Domantis, allege that the single variable domain antibodies which are developed and used by Ablynx, a spin off company from the University of Brussels, are produced through processes of cloning as described in claims 1 to 31 of patent EP 684 B1 and isolated from expression libraries as described in claim 32 of the patent.

The claimant, Ablynx, strongly disputes the scope of the descriptive measures. In particular, the claimant rejects the defendants' argument that, to assess infringements of the patent, one must also assess the *product leads*, i.e. the end results, considering these can be the result of the patented process.

The defendants do not dispute the fact that the scope of protection of the patent

exclusively relates to the process of cloning and to the expression libraries which are generated, and *not* to the final individual variable domain *product leads* which derive from these libraries through a certain amount of intermediary steps. They argue, however, that on the path to the single variable domain product leads, the preliminary activity of cloning and using the expression libraries is absolutely essential to develop subsequently product leads and finally to commercialize products. The commercial value of the patented expression libraries lies, according to them, in the considerable commercial value of single variable domain product leads. The defendants believe indeed that when a patent is granted for a process, the rights conferred by the patent include rights to products which are *directly* obtained by the patented process (Article 27 Section 1 (c) Belgian Patent Act; Article 64 Section 2 EPC).

The Judge of Seizure decides that the scope of protection of the patent is limited to the patented process and the expression libraries, as claimed in the patent claims, but does *not* cover end products leads which are not directly obtained by the patented process, neither are they claimed in the patent claims. The Judge orders that descriptive measures against the claimant shall be limited to a description of the alleged infringing activities of the claimant to which the newly granted patent EP 0.368.684 B2 prima facie relates, and namely:

a) All processes for cloning sequences as claimed in the process claims Nrs. 1 to 31 of the patent EP 368.684 B2;

b) Expression libraries comprising a repertoire of nucleic acid sequences for the expression of a repertoire of proteins, each comprising an immunoglobulin variable domain;

c) The use of such expression libraries, being understood that such description may not relate to "product leads" (as this concept is being referred to in the unilateral application of the defendants in third-party opposition), information on "products leads" or even the products developed with this information, and that this information shall not be reported in the expert's report.

2.2.3.5. Effect and evaluation of the trouble (if not finished, please fill the effect of the trial)

2.2.3.6. Relation to exemption to research or experimental use, and award granting of unused patent

Why is the Ablynx case relevant in the framework of the present study on research tools? The importance of the Ablynx case closely relates to the scope of the notion of research tool. If one applies the concept of research tool narrowly, only assays to carry out research can probably be regarded as a research tool. In such a view, expression libraries cannot not be considered research tools. If one interprets the concept of research tool somewhat wider, however, anything that can be used in research might be considered as research tools. As expression libraries are used in the execution of research, expression libraries might be qualified as research tools.

Interesting in this regard is the correspondence between the defendants and the claimant which seems to suggest that the claimant used the expression libraries as a research tool. In a letter of 2 April 2004, the defendants informed the claimant of their patent and they expressed their concern over possible infringements of that patent by the claimant. Interesting is that in a letter of 14 May 2004, the claimant responded that it never sold any expression libraries as commercial products and never used them to produce commercial products. The claimant admitted that it used the expression libraries in the past *for limited experimental use*, but stated that they were no longer relevant for its business activities.

The Judge of Seizure orders that descriptive measures against the claimant shall be limited to a description of the alleged infringing activities of the claimant to which the newly granted patent EP 0.368.684 B2 prima facie relates, and namely: […] "b) expression libraries comprising a repertoire of nucleic acid sequences for the expression of a repertoire of proteins, each comprising an immunoglobulin variable domain", without distinction between libraries which have been used for experimental use or otherwise. The approach of the Judge of Seizure suggests that expression libraries when used for experimental use, in other words, expression libraries put to work as research tools, are not exempt from patent infringement.

2.2.4. Comment and other description

The approach of the Judge of Seizure of Ghent suggests that expression libraries when used for experimental use, in other words, expression libraries put to work as research tools, are not exempt from patent infringement.

2.2.5. Reference ID number (serial number ex. 2-## , short note to each document required)

- ***Annex 1.*** Ghent, Judge of Seizure, Public court hearing of 7 December 2004, Case No: 04/4210/A (Ablynx N.V. against The Medical Research Council and Domantis Ltd.) (*Informal translation*)

3. TREND OF LAW AND REGULATION

Not applicable

4. DISCUSSION AND BACKGROUND OF RESEARCH TOOL LAW OR REGULATION MOVEMENT

In Belgium, a variety of opinions existed on the use of research tools, before the enactment of a new provision on the research exemption in 2005 (*See* section 5.2).

4.1. Research tools in pharma

4.1.1. Position of Belgian pharmaceutical companies

In recent years pharmaceutical companies got used to carrying out freedom to operate studies for research tools, in other words "to clear the **research tools** that were used by scientists to check whether the company was free to use the research tools" (Filip De Corte, head of the patent department of Janssen Pharmaceutica N.V., Belgium, until July 2004).* When it turned out that research tools were actually proprietary the research, there seemed to be wide consensus that "the company had to go out and get a license. […] and *getting a license* to use the research tool is one thing and is *only fair*". However, concern was raised on royalties which would have to be paid because of reach-through provisions on the product that still needed to be invented, and this only because the company used the research tools in one of the tests to find out whether a compound is at all a potential candidate for development: " … license deals were made where a license for the tool was rewarded with the same milestone payments and royalties on sales of the drug, […] but with just this minute difference: the compound that would become the final drug on the market still had to be

invented".*

* DE CORTE, F., Licensing in the Medical Sector, in *Gene Patents and Public Health,* VAN OVERWALLE, G. (ed.), Brussels, Bruylant, 2007, 87.

4.1.2. Research tools and diagnostic testing

4.1.2.1. Position of Belgian hospitals

Prof. dr. Gert Matthijs, head of the Laboratory for Molecular Diagnostics at the Center for Human Genetics in Leuven (Belgium) and frontrunner in the opposition proceedings at the European Patent Office against the BRCA patents (see section 2.1.) launched a strong plea for easy access to patented ***gene sequences.*** His appeal was based on the patenting and licensing practice by the patent owners (Hospital for Sick Children of Toronto and the University of Michigan) of the cystic fibrosis (CF) gene. The patent owners applied a two-tiered system, where no royalties where charged from public hospitals, and where (reasonable), non-exclusive licenses were agreed for use in private business: "When the [CF] gene was identified in 1989, a patent which covers the genetic sequence and its use in diagnostics was filed jointly by the Hospital for Sick Children of Toronto and the University of Michigan. The patentees have never enforced their patent towards the use of the sequence for clinical diagnostics and […] as soon as private companies either embarked on diagnostics for this gene or started to develop commercial kits for the detection of (the more common) mutations in this gene, the sequence was shared on the basis of licensing. […] the patients and the community have strongly benefited from the open and non-exclusive licensing policy of the patentees. While the latter collect royalties because most of these laboratories are now using the commercial kits, others are bothering to constantly improve the test and promote its use".*

The advent of the *Polymerase Chain Reaction* (PCR) has greatly increased the possibilities for molecular diagnosis. PCR technology has no major rivals yet, and all the tests presented, including the upcoming chip technologies, directly or indirectly depend on it.

The viewpoint of Prof. Matthijs was largely followed by the Belgian Society of Human Genetics during the Opposition Proceedings before the EPO.

* MATTHIJS, G., 'DNA Diagnostics in Practice', in *Gene Patents and Public Health,* VAN OVERWALLE, G. (ed.), Brussels, Bruylant, 2007, 27.

4.1.2.2. Position of Belgian biotech-companies

"Certain tools are essential for a certain diagnosis and without those tools the kit cannot be made. If the validity of the patent cannot be challenged and circumvention of the patent is not possible, the only alternative is the *in-licensing* of the **tool**. This depends, however, on the availability of the license and on the cost for the license. Often when different tools are used in the kit, multiple licenses are *needed*." "There is a noticeable change in attitude over the last years in that certain licenses are not available or are only available at too high prices. Sometimes patent holders require that samples be sent to the holder's own lab for testing at unreasonably high prices. As a result, it happens that a diagnostic kit cannot be commercialized by these biotech small or medium size companies." "Innogenetics also has a policy of broadly out-licensing its important diagnostic technology on very reasonable terms in order to make these important tests readily available to the public. It has out-licensed its strong IP on diagnostic tools to different diagnostic companies." This viewpoint was taken by Katrien Vlassak (Patent Counsel with Innogenetics N.V. in 1998).*

* Katrien Vlassak & Kees Schüller, 'The Effect of Patents on Diagnostic Research and Kit Development', in Gene Patents and Public Health, VAN OVERWALLE, G. (ed.), Brussels, Bruylant, 2007, 99.

5. ALTERING PROCESS AND BACKGROUND OF THE MODIFYING LAW (EX. BELGIUM)

5.1. Compulsory license for public health

5.1.1. The history of altering, including political and social process

One major event triggered the modification of the Belgian Patent Act and the introduction of the compulsory license for public health. It was the grant of a series of patents dealing with diagnostic testing for early onset breast and ovarian cancer based on the genes BRCA1 and BRCA2 to Myriad Genetics (at present the patent proprietor is the University of Utah Research Foundation) and the subsequent restrictive licensing policy, as well as the exorbitant prices for the test from the patent owner. Three of the Myriad patents related to BRCA1 (EP0699754, EP0705902 and EP0705903) and one of the Myriad patents related to BRCA2 (EP0785216). The Belgian genetics community reacted with disbelief, disgust and despair.

A multitude of strategies was considered to deal with Myriad's restrictive licensing behavior. First, oppositions were filed against all Myriad patents at the European Patent Office (EPO). Belgium, together with France, took a leading role: the minister of Social Affairs (Frank Vandenbroucke), the minister of public health (Magda Aelvoet) and the minister of Economic Affairs (Charles Picqué) officially supported the opposition in March 2002, officially lodged by the Belgian Society for Human Genetics (see section 2.1.2). The proceedings raised considerable societal interest in Belgium and elsewhere: "The experience in filing oppositions against these [BRCA1 and BRCA2] patents is that they are highly focused affairs that can generate considerable interest in the press and in the scientific community. Examples of the interest can be derived from several major international seminars having included time for discussing the issues of these oppositions. The interest can also be deduced from the fact that major scientific journals have followed the oppositions and have reported the results and that the issues have been discussed on international and local radio and television. Moreover, major legal works have included several pages on the issues raised by the oppositions against BRCA1 and BRCA2 patents. And, last but not least, university and other projects have been started to investigate the social benefit of patenting of diagnostic methods and it effect on society and health care."*
Second, a debate was opened on the suitability of the existing compulsory license regime for non-working or dependency for public health reasons.
Third, reluctantly at the start, all Belgian universities finally decided to neglect all

BRCA patents and continue in-house testing, and face the risk of law suits for infringement and damages.

* W. BIRD, 'Using the EPO Opposition Procedure as a Strategy Against Patents on Diagnostic Methods', in *Gene Patents and Public Health,* VAN OVERWALLE, G. (ed.), Brussels, Bruylant, 2007, 73. (William Bird represented the Belgian Society for Human Genetics in the Opposition proceedings before the EPO). Also see, VERBEURE, B., MATTHIJS, G. & VAN OVERWALLE, G., 'Analysing DNA patents in relation with diagnostic genetic testing', 14 *European Journal of Human Genetics (EJHG),* vol. 1, January 2006, 26-33.

5.1.2. The action and reaction of political circle

On 6 July 1998 the European Parliament adopted the Directive on the legal protection of biotechnological inventions (Directive 98/44/EC of 6 July 1998 of the European Parliament and of the Council on the legal protection of biotechnological inventions, *Official Journal L* 213, 30/07/1998 p. 0013, see http://europa.eu.int/eur-lex/en/lif/dat/1998/en_398L0044.html) (abbr. EU Biotechnology Directive). With ceaseless effort, the Belgian legislator labored over the implementation of the Directive in the Belgian Patent Act (Act of 28 March 1984 on Invention Patents, *Official Gazette,* 9 March 1985) (abbr. BPA). The transposition of the Directive took so long, mainly because of political delays (interim elections) and heated debates in parliament and society relating to content and scope of the implementation.*

A first draft bill was prompted on 29 October 1998 (Under the Minister for Economic Affairs Elio Di Rupo). As a result of some changes in government, this first draft was dropped. A second draft bill was disclosed on 8 August 2000 (Under the Minister for Economic Affairs Charles Picqué). After the many comments from a series of consultative institutions and organizations, the draft bill was seriously revised. This revised draft bill was approved by the Council of Ministers and submitted to the House of Representatives on 21 June 2001 (DOC 50 1886/001). However, the bill was hardly discussed in parliament.

The lingering on of the transposition of the Directive led to the condemnation of Belgium on 9 September 2004 by the European Court of Justice in an action for

failure to fulfill its obligations under Art. 226 EC introduced by the European Commission (ECJ, 9 September 2004, Case C-454/03, ECR n.y.r.). The Court took the view that Belgium did not fulfill its obligations under Art. 15 of the Directive, because it failed to adopt the laws, regulations and administrative provisions, necessary to comply with the Directive, in time. The Belgian government argued that the legislative procedure to transpose the Directive was running and that all the necessary measures would be taken to complete this procedure as soon as possible. This argument was denied by the ECJ since there were no implementing measures in force in Belgium at the date set by the European Commission. If Belgium would fail to take the necessary measures to comply with the Court's judgment, the Court could impose a lump sum or penalty payment in a later procedure ex Art. 228 EC.

After the vigorous language of the Court of Justice and some changes in government, a new draft bill was formulated (under the governance of Minister for Economic Affairs, Fientje Moerman) which was later taken over by the then Minister for Economic Affairs (Mark Verwilghen). A political agreement on this draft bill was reached in the Council of Ministers on 23 April 2004. After the advice of the Council of State, the draft bill was then submitted to the House of Representatives on 21 September 2004 (DOC 51/1348/001). Subsequently, the bill was subject to expert hearings in the competent parliamentary commission, the Commission for Trade and Industry.** After lengthy discussions the bill was finally accepted in the Commission for Trade and Industry on 1 March 2005. The bill was then submitted and voted in plenary session of the Chamber on 10 March 2005. The Senate evoked the bill, discussed it in the competent Commission, and finally accepted it in plenary session on 14 April 2005. On 28 April 2005 the bill was promulgated and finally published in the Official Gazette on 13 May 2005, taking effect 10 days later (Act of 28 April 2005 to modify the Act of 28 March 1984 on Invention Patents, with Regard to the Patentability of Biotechnological Inventions, *Official Gazette*, 13 May 2005).

During the Commission sessions, the plenary meetings in the Chamber and the Senate, dozens of amendments were submitted. The majority of those amendments, however, was either withdrawn or rejected. Only the amendment from the government parties relating to the compulsory license for public health was admitted. The explanation for this large scale withdrawal or rejection of amendments is – as the Minister repeatedly admitted – the political agreement achieved in the Council of Ministers on 23 April 2004. This agreement delineated the strict boarders of the Belgian implementation

model: literal transposition to comply with the European obligations, and introduction of some extra measures, to accommodate the concerns of Belgian civil society. No maneuvering room was thus left to alter basic provisions of the Directive, but some leeway was created to introduce some extra provisions.

The first bill of 21 June 2002 (DOC 50 1886/001) departed considerably from the Directive. Witness the reluctant wording with regard to the patenting of human genes, the wide interpretation of the exclusions from patentability on the basis of *ordre public* and morality, the many additional patentability requirements, such as the informed consent and the geographical origin condition, and the restriction in scope of biotech patents. The first bill aimed at reconciling voices pro and con the patenting of biological material, by restricting patentable *subject matter* in the field of human genetics, and by introducing additional prerequisites.
The second bill of 21 September 2004 (DOC 51/1348/001) beared close resemblance to many of the basic principles of the first bill. When embedding these principles into patent law, however, the second bill opted for a wording and interpretation which fitted more closely to the Directive. The bill no longer focused on reconciling antagonist opinions by restricting the *subject matter* of biotech patents, but much more by regulating and curtailing, the (far reaching and possible negative) *effects* of such patents, through the introduction of two additional measures which exceed the strict finality of the Directive. The significant widening of the research exemption and the introduction of a compulsory license for domestic public health are clear emanations of this approach.

* This is a more detailed version of the legislative history as described in Geertrui VAN OVERWALLE, 'The Implementation of the Biotechnology Directive in Belgium and its Aftereffects. The Introduction of a New Research Exemption and a Compulsory License for Public Health', 37 *International Review of Intellectual Property and Competition Law (IIC),* 2006, 889-920
**** The author of the present report, Geertrui VAN OVERWALLE, was heard as an expert during the parliamentary hearings.

5.1.2.bis. The content of the new, modifying law *

The second bill of 21 September 2004 (DOC 51/1348/001) was finally passed in the House of Representatives on 10 March 2005 and in the Senate on 14 April 2005. It was then promulgated on 28 April 2005 and published in the Belgian official journal, the so-called 'Belgisch Staatsblad' or 'Moniteur belge' on 13 May 2005 (*Belgisch Staatsblad – Moniteur belge,* 13 May 2005 (available at http://www.ejustice.just.fgov.be/cgi/welcome.pl).

The compulsory licensing mechanism for public health reasons, established by Article 13 of the amending Act of 28 April 2005, led to the introduction of a new article 31 bis BPA.**

The scope of application of the compulsory license for public health is mainly determined by three elements: the ground for which a license may be granted, the inventions susceptible for licensing and the geographical scope of application.

Public Health Interest. The new compulsory licensing mechanism may be invoked in cases where the public health interest is affected. In this regard, Article 31 bis § 1 BPA explicitly stipulates that "*In the interest of public health*, the King, by decree established after consultation in the Council of Ministers, can grant a license for the exploitation and application of an invention protected by a patent" (italics added).

The Ministerial Statement clarifies that the notion of public interest, like the concept of 'ordre public and morality', is susceptible to changes over time. It is therefore not expedient to give a strict definition. Rather, it is recommendable to put forward some examples where the public health interest may be at stake. This is notably the case when products, processes or diagnostic methods are put at the disposal of the public in insufficient quantity or quality, or at abnormally high prices, or when the patent is exploited under conditions which are contrary to the public health interest or which constitute anti-competitive practices. This explanation is by and large a reflection of the criteria established in the French Patent Act by the French government.** The proposal to include this more detailed wording in the Belgian Patent Act to increase the transparency and compulsory nature of the provision was refused.

Relevant Inventions. This aspect of the Belgian Patent Act has again been modeled

after the French system. The inventions which may be susceptible to a compulsory license for public health reasons, are explicitly mentioned in Article 31 bis § 1 BPA: In the interest of public health, the King can grant a license for the exploitation and application of an invention protected by a patent for:

a) a medicine, a medical appliance, a medical appliance or product for diagnosis, a derived or combinable therapeutic product;
b) the process or product necessary for the manufacture of one or more products indicated under a);
c) a diagnostic method applied outside of the human or animal body.

The Ministerial Statement underlines that the medical sector at large is envisioned and not a particular sector within the medical sector, for reasons of non-discrimination. In this regard the Belgian system differs from the mechanism established in Switzerland focusing on diagnostic testing ex Article 40 (c) of the Swiss Patent Act.

Geographical Scope - Domestic Market. During the debate in the Belgian parliament several members suggested to widen the geographical scope of application of the compulsory licensing mechanism for public health reasons to the extent that it would be applicable to export to developing countries. The Ministerial Statement highlighted the importance of this suggestion, but referred to the European proposal for a regulation of the European Parliament and of the Council on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems of 29 October 2004. This proposal obliges the Member States to grant a compulsory license for the manufacture and sale of patented pharmaceutical products for the export to countries without or with insufficient production facilities in the pharmaceutical sector, in case a number of conditions is fulfilled. As European regulations have direct effect, it was not considered necessary to include a specific provision in the Belgian Patent Act.

**This section is largely based on*

VAN OVERWALLE, G., 'The Implementation of the Biotechnology Directive in Belgium and its Aftereffects. The Introduction of a New Research Exemption and a Compulsory License for Public Health', 37 *International Review of Intellectual Property and Competition Law (IIC),* 2006, 889-920; and VAN OVERWALLE, G. en VAN ZIMMEREN, E., 'Reshaping Belgian Patent Law: The Revision of the

Research Exemption and the Introduction of a Compulsory License for Public Health, *IIP Forum* (Japan), 64 February 2006, 42-49 [Publication in Japanese; For an English translation, see http://www.iip.or.jp/e/index.html)
It is recommended to consult these journal articles for more details.

****** Unfortunately, no official English translation of the amending act of April 28 2005 or of the updated Belgian Patent Act of 1984 is available for the moment. In *Annex 4* an informal translation has been provided.

******* "Les brevets de ces produits, procédés ou méthodes de diagnostic ne peuvent être soumis au régime de la licence d'office dans l'intérêt de la santé publique que lorsque ces produits, ou des produits issus de ces procédés, ou ces méthodes sont mis à la disposition du public *en quantité et qualité insuffisantes* ou *à des prix anormalement élevés*, o*u lorsque le brevet est exploité dans des conditions contraires à l'intérêt de la santé publique ou constitutives de pratiques déclarées anticoncurrentielles* à la suite d'une décision administrative ou juridictionnelle devenue définitive" (italics added), Article 18 *Loi n° 2004-800 du 6 août 2004 relative à la bioéthique,* amending Articles L. 613-15 and L. 613-16 *Code de la propriété intellectuelle*, *Journal Officiel français*, n° 182, 7 August 2004 (available at http://www.legifrance.gouv.fr/WAspad/UnTexteDeJorf?numjo=SANX0100053L).

5.1.3. The action and reaction of academia

Some Belgian legal scholars were supportive of the new compulsory license, but have raised concerns. I myself have stated that "these 'revolutionary' measures might put Belgium on the international map as an actor who is deeply concerned by public health interests and who tries to reconcile both private (patent holder) and public (patient) interests". However, I have also suggested that "the effectiveness of the compulsory licensing mechanism is uncertain and will depend on the willingness of companies to apply for such a license. One may regret that the Minister of Social Security and Public Health has not been given a right of initiative as well. Moreover, one may have doubts as to whether the long periods for decision-making will not turn the compulsory licensing mechanism into another tool of symbolic law-making. However, one should realize that the compulsory licensing regime for public health

reasons may indirectly function as a threat to compel a non-cooperative patent holder to enter into fair and reasonable licensing negotiations".*

* VAN OVERWALLE, G., 'The Implementation of the Biotechnology Directive in Belgium and its Aftereffects. The Introduction of a New Research Exemption and a Compulsory License for Public Health', 37 *International Review of Intellectual Property and Competition Law (IIC),* 2006, 889-920. Also see VAN OVERWALLE, G., 'Zonder trommels en trompetten. De definitieve omzetting van de EU-Biotechnologierichtlijn in het Belgisch recht' *Intellectuele Rechten – Droits Intellectuels (IRDI)*, 2005, 349 – 378.

In February 2006, Prof. Mary-Claire King, international frontrunner in breast cancer research and critical voice against patenting and restrictive licensing of the BRCA genes, was awarded an Honorary Doctorate at the KULeuven. The genetics community considered this award recognition of both her scientific and political (critical) viewpoints on BRCA research and patenting.

5.1.4. The action and reaction of business circle

The Belgian business circles, through the Belgian Association for Bioindustries (http://www.belgobiotech.be) and the Algemene Vereniging van de Geneesmiddelenindustrie (AVGI) (http://www.pharma.be), formally reacted on the *first proposal* (Belgian Chamber DOC 50 1886/001 - 21 June 2002) at the end of 2002 (see *Annex 2*). None of their remarks and criticisms relate to the issue of research tools. However, they express concern with regard to measures which have a different, and more negative effect on smaller, Belgian companies than on bigger or foreign companies.* They are equally reluctant with regard to measures that lead to differing legislation between member states.**: "Indien België beslist de Europese Richtlijn 98/44 niet correct te implementeren, en bijkomende eisen toe te voegen voor wat betreft de octrooieerbaarheid van biotechnologische uitvindingen, zal men dus voornamelijk de kleinere Belgische bedrijven - die nog werken via de Belgische Dienst voor Industriële Eigendom - in een economisch benadeelde positie plaatsen ten opzichte van de grotere of buitenlandse bedrijven die via het Europees Octrooibureau werken." "Dit leidt onvermijdelijke tot

discrepanties tussen de wetgevingen van de lidstaten, die de richtlijn precies beoogt uit te schakelen."

The Flanders Institute for Biotechnology (VIB) (www.vib.be), pharma.be ((http://www.pharma.be), the Belgian Association for Bioindustries (http://www.belgobiotech.be), and Flanders Bio (http://www.flandersbio.be) also publicly reacted on the *second* proposal (Belgian Chamber, DOC 51 1348/001 – 21 September 2004) and the compulsory license for public health (see *Annex 3).*

The first objection they put forward relates to the field of application of the compulsory license in the interest of public health. According to VIB etc. the field of application of the compulsory license is phrased in a far too general fashion and leads to an excessive and unnecessary erosion of patent law, which ultimately will discourage scientific research in Belgian universities, research institutions and companies. Innovative scientific research and the subsequent inventions should be protected by patent law. Granting patent protection for inventions is the very basis and an absolutely essential condition to stimulate technological innovation and progress. When public health would be threatened by patent law, it may be justified that the government provides a mechanisms to react quickly. The Myriad case, where the diagnostic research on BRCA1 en BRCA2 was only allowed at unreasonably high prices, was a striking example. However, the Myriad patents are declared null and void by the EPO by now [Remark from the author: not all patents are completely declared invalid, *see* section 2.1.1.]. The introduction of a compulsory license in the interest of public health with a wide scope of application, namely "a) a medication, a medical appliance, a medical appliance or product for diagnosis, a derived or combinable therapeutic product; b) the process or product necessary for the manufacture of one or more products indicated under a); c) a diagnostic method applied outside of the human or animal body", is out of proportion with the objective to be achieved. The further erosion of patent law has as effect that every incentive is taken away to do further investments in the Belgian biomedical research, both at universities and research institutes, as in companies. This is regrettable for a country that holds a top position in research and development at present. The introduction of a compulsory license for public health could mean that companies, such as Innogenetics, Janssen Pharmaceutica, UCB, Solvay and Glaxo Smith Kline (GSK) Biologicals will be forced to shift/displace their strongly developed research activities

to other European countries. This is even more so, as in the neighboring countries, with exception of France, the compulsory license in the interest of public health does not exist as a separate legal instrument. Other European countries, such as the Netherlands, the UK and Germany employ the general compulsory license in this case, license which has always acted as an exception in European patent law. Such a general compulsory license already exists in Belgium in the current article 31 of the Belgian Patent Act.

A second objection they set forth relates to the procedure, which in their view is not in conformity with the fundamental principles of procedural law, thus running the risk of being misused (also by the companies amongst themselves) to fight one another. The suggested compulsory license system allows that the applicant for a license starts the procedure to obtain a compulsory license on his own initiative by simply submitting a request at the Belgian Advisory Committee for Bioethics. This means that anyone, without any threshold [Remark from the author: this critique is not correct, as the applicant for a compulsory license "must demonstrate that he has, should the compulsory license be granted to him, the resources or the *bona fide* intention to obtain resources that are necessary for actual and continual manufacture and/or application in Belgium of the patented invention"] can start a procedure, without having to consult the patent owner beforehand. [Remark from the author: this point is well taken, as TRIPs obliges to negotiate with the patent holder before granting a compulsory license]. Furthermore, the foreseen terms are not sufficiently restricted in time, as a result of which the patent owner may remain in legal uncertainty during too long a period. Indeed, each procedure relating to a claim for infringement on a patent is being suspended from the moment the request has been submitted with the Belgian Advisory Committee for Bioethics until the moment the Minister takes a decision. In the present situation this may mount to 12 months from request to grant of the compulsory license. Additionally, no sanctions are foreseen in case the terms are exceeded. Besides, the basic right of parties to be heard during proceedings is not respected. The fundamental right of defense is clearly violated. Last but not least, there is an under representation of expert with hands on practice in the Belgian Advisory Committee for Bioethics which only has expertise with ethical issues, not with economical ones. In that regard, it is cumbersome that nor the biotechnology sector, nor the pharmaceutical industry is represented.

In their public statement, the Flanders Institute for Biotechnology (VIB), pharma.be,

BelgoBiotech, Belgian BioIndustries Association (BBA) and Flanders Bio, suggest to amend article 31bis in an aim to narrow down the field of application to diagnostic products on the basis of a gene._

Here and there, very critical voices were heard in business circles, with the restrictive license policies from Myriad, even though the criticism was not directly explicit toward Myriad itself but in a more general manner, witness Vlassak: "The patent system has developed from a system to foster innovation in a fastly developing sustainable industry to a system which serves the needs of a quick and extraordinary profit. This latter can only be achieved if patents are treated as purely economic goods serving to obtain maximum revenue. The patent system, if used in this way, is subject to extensive criticism especially in the area of diagnostic tools. It is documented that there is extensive protest against this blocking use of patents. These monopolies are perceived as blocking the development and availability of needed diagnostics leaving the persons in need of diagnostics as victims."* Katrien Vlassak (Patent Counsel with Innogenetics N.V. in 1998)

**** Katrien Vlassak & Kees Schüller, 'The Effect of Patents on Diagnostic Research and Kit Development', in Gene Patents and Public Health, VAN OVERWALLE, G. (ed.), Brussels, Bruylant, 2007, 99.***

Biotech law firm: "The 2005 Act also added a number of provisions on compulsory licensing. The new article 31*bis* of the BPA explicitly allows the Belgian government to grant compulsory licenses in case of public health concerns. The rule that all legal proceedings relating to an alleged infringement are stayed during the application period of the compulsory license remains unchanged. From the grant of the compulsory license, the relationship between licensor and licensee is deemed to be a normal contractual license. Concern was raised that the compulsory license for public health "might affect the ability of the patent owner to stop parallel imports, where production under a compulsory license is not normally considered to amount to consent by the patent holder".*

*Linklaters Brussels, *Intellectual Property News*, November 2005

5.1.5. The action and reaction in the press

The leading Belgian newspapers (*De Standaard* and *De Morgen)* extensively and critically reported on the Opposition proceedings against the BRCA patents before the EPO, witness the series of articles published on the Myriad case between 2000 and 2007 (keyword used in text: Myriad; breast cancer gene).

'Biotechpatenten onder vuur', *De Standaard,* 10/05/2007 - (kidr)

'Borstkankertest blijft vrij beschikbaar**.** Het bedrijf Myriad Genetics moet zijn monopolie op een borstkankertest laten varen', *De Standaard,* **04/10/2007 (Kim De Rycke)**

'Geen Europees verbod op borstkankertests', *De Standaard,* 27/01/2005 (Hilde Van den Eynde)

'Patent borstkankergen opgeschort', *De Standaard,* 19/05/2004 (Kim De Rycke)

'Recht op testen', *De Standaard,* 14/05/2004 (Hilde Van den Eynde)

'Privatisering kan uw gezondheid schaden', *De Standaard,* 20/05/2003 (Dirk Barrez)

'Achterpoortje voor peperdure borstkankertest', *De Standaard,* 24/01/2003 (Hilde Van den Eynde)

'Uitspraak Amerikaans patent borstkankertest ten vroegste over drie jaar', *De Standaard,* 03/04/2002

'Ministers tekenen bezwaar aan tegen patent op borstkankergen', *De Standaard,* 23/02/2002

'Verzet tegen octrooien borstkankergen', *De Standaard,* 18/01/2002

'Bedrijf maakt onderzoek naar erfelijke borstkanker onbetaalbaar', *De Standaard,* 14/11/2001

'Borstkankertest straks peperduur', *De Standaard,* 12/11/2001(Hilde Van den Eynde)

'Rendement ten koste van gezondheid?', *De Standaard,* 08/08/2000 - Els

Torreele & Marleen Boelaert.

Amerikaans bedrijf verliest strijd om patent borstkankergen, *De Morgen,* 01-10-2007

Amerikaanse Borstkankerpionier en KU Leuven-eredoctor Mary-Claire King over haar weinig alledaags Curriculum Vitae, *De Morgen,* 02-02-2006

Borstkankertests blijven voorlopig betaalbaar, *De Morgen,* 19-05-2004

'Europees patentbureau spreekt zich weldra uit over strijd tussen Europese erfelijkheidscentra en amerikaans bedrijf Gevraagd: patente uitspraak over borstkankergen', *De Morgen,* 14-05-2004

'Genetisch onderzoek borstkanker moet betaalbaar blijven', *De Morgen,* 18-02-2003

'Rechtszaak over dure borstkankertest zal jaren aanslepen', *De Morgen,* 04-04-2002

'Belgisch-Nederlands offensief tegen dure borstkankertest', *De Morgen,* 22-02-2002

'Een ethische grens aan de markt', *De Morgen,* 22-02-2002

'Plots is genetica niet meer zo ver van ons bed', *De Morgen,* 19-01-2002

'Borstkankertest wordt onbetaalbaar', *De Morgen,* 18-01-2002

Also the modification of the Belgian Patent Act was commented, be it much less

'Octrooiwet om genetische tests betaalbaar te houden', *De Morgen,* 03-06-2005

5. 2. Research exception

5.2.1. The history of altering, including political and social process

The event that triggered the modification of the Belgian Patent Act and the introduction of widened research exemption, was the same event that led to the introduction of the compulsory license for public health. It was the grant of a series of patents dealing with diagnostic testing for early onset breast and ovarian cancer based on the genes BRCA1 and BRCA2 to Myriad Genetics (at present the patent proprietor is the University of Utah Research Foundation) and the subsequent restrictive

licensing policy, as well as the exorbitant prices for the test from the patent owner (*see* section 5.1.1.). It was argued that if access and use of genes was restricted for diagnostic testing, that would equally hamper research. One can easily imagine that in case of monopolization of genes useful as research tools, progress might be stalled, as the search for novel defects in disease related genes would slow down.*

* MATTHIJS, G., 'DNA Diagnostics in Practice', in *Gene Patents and Public Health,* VAN OVERWALLE, G. (ed.), Brussels, Bruylant, 2007, 27.

5.2.2. The action and reaction of political circle

The political action and reaction with regard to the use of research tools, is largely similar to the action and reaction with regard to the blocking licenses (*See* section 5.1.2.)

*5.2.2bis. The content of the new, modifying law**

The bill modifying the research exemption in Belgian patent law (article 28 § 1 (b) of the Belgian Patent Act), was finally passed in the House of Representatives on 10 March 2005 and in the Senate on 14 April 2005. The bill was then promulgated on 28 April 2005 and published in the Belgian official journal, the so-called 'Belgisch Staatsblad' or 'Moniteur belge' on 13 May 2005 (*Belgisch Staatsblad – Moniteur belge,* 13 May 2005 (available at http://www.ejustice.just.fgov.be/cgi/welcome.pl).

The new article 28 § 1 (b) of the Belgian Patent Act (BPA) stipulates that the rights of a patent holder do not extend to acts carried out for scientific purposes *on* or *with* the subject matter of the invention.

Two major questions governed the discussion on the new, enlarged research exemption. The first question was how the twin concept 'on and/or with' was to be understood. The second question concerned the notion 'scientific purposes'. The Minister clarified both issues in a special address to the Parliament.

- *Direct Goal of the Experimental Acts: 'On and/or With'*

The Ministerial Statement clarified that 'on' refers to experiments where it is verified whether the patented invention works the way it is described in the patent or whether the invention is indeed novel and inventive as claimed in the

patent. The Statement explained that 'with' refers to experiments where the patented invention is used to investigate something else; the patented invention is used as an instrument, as an "Apparativ". For instance, a patented scale which is used to weigh compounds for manufacturing a vaccin. The Minister underlined that the new Article 28 aims at both exempting research 'on' and research 'with' the subject matter of the invention to guarantee a maximum freedom to operate for research activities.

- *Indirect Goal of the Experimental Acts: Scientific and/or Commercial Purpose*

The Ministerial Statement clarified that the term 'scientific purposes' refers to acts that aim at collecting knowledge. In the debate on whether to opt for a *strict* or a *wide* interpretation of the notion 'scientific purpose', Minister Verwilghen supported a wide scope of interpretation. The research exemption encompasses both acts with a strict scientific purpose, and acts with a mixed scientific/commercial aim, in the sense that mixed research should *mainly* be scientific in nature, which excludes companies with *mainly* commercial goals, from the scope of the exemption. It remains to be seen, how this interpretation will be applied in practice. In day-to-day practice borderline cases may regularly arise. For instance with regard to spin-offs originating from university-based research with commercial objectives, or pharmaceutical and/or biotechnology companies having a clear-cut commercial mission, but hosting large research activities as well.

In infringement cases, courts should take up this wide interpretation. Nevertheless, purely commercial acts, such as the preparation of the registration dossier for clinical trials and acts required in order to be eligible for a license to commercialize so-called *me too-medicines*, do not fall under the renewed research exemption. However, the latter will be exempted from patent infringement in the light of an upcoming European directive relating to medicinal products for human use (See Article 1, sub 8) of Directive 2004/27/EC of the European Parliament and the Council of 31 March 2004 amending Directive 2001/83/EC on the Community Code relating to medicinal products for human use, [2004] *OJEC* L136/34, replacing Article 10, para. 6) and the equivalent Belgian variant of the so-called 'Bolar exemption'.

**This section is largely based on*

VAN OVERWALLE, G., 'The Implementation of the Biotechnology Directive in Belgium and its Aftereffects. The Introduction of a New Research Exemption and a

Compulsory License for Public Health', 37 *International Review of Intellectual Property and Competition Law (IIC),* 2006, 889-920; and VAN OVERWALLE, G. en VAN ZIMMEREN, E., 'Reshaping Belgian Patent Law: The Revision of the Research Exemption and the Introduction of a Compulsory License for Public Health, *IIP Forum* (Japan), 64 February 2006, 42-49 [Publication in Japanese; For an English translation, see http://www.iip.or.jp/e/index.html)
It is recommended to consult these journal articles for more details.

5.2.3. The action and reaction of academia

Some legal scholars have raised some concerns on the widened research exemption. I myself have put forward that "The widened research exemption holds great promise for the future, but it remains to be seen to which extent it will indeed solve problems of access and freedom to operate, and stimulate (mixed fundamental and commercial) research in the field of biotechnology. Taking into account current practice in many scientific (university) labs, where mixed scientific and commercial goals are pursued on a daily basis, it will remain very difficult, to draw the line between research that is mainly scientific and research that is less so, and to apply this delicate yardstick in borderline cases."*. Moreover, I have suggested that the research exemption might discourage industries, focused on the development of research tools.**

* VAN OVERWALLE, G., 'The Implementation of the Biotechnology Directive in Belgium and its Aftereffects. The Introduction of a New Research Exemption and a Compulsory License for Public Health', 37 *International Review of Intellectual Property and Competition Law (IIC),* 2006, 889-920
** VAN OVERWALLE, G., 'Zonder trommels en trompetten. De definitieve omzetting van de EU-Biotechnologierichtlijn in het Belgisch recht' *Intellectuele Rechten – Droits Intellectuels (IRDI)*, 2005, 349 – 378.

The Technology transfer office of the K.U.Leuven (LRD) (http://lrd.kuleuven.be/) takes the view that a patent system should stimulate innovation. Blocking of research activities by patent-troll like activities is not desirable. Therefore, LRD is a proponent of a robust research exemption, as the one in force in the current Belgian Patent Act. LRD hopes that the current research exemption indeed offers such strong protection,

although they know that there is not case law as yet. In their view, patent law should include a research exception, analogous with article 52(4) EPC which stipulates that "method of medical treatments" are not patentable. For example, a provision stating that "methods of research" are not patentable, whereas the commercial sale of product "for use in research" would remain patentable. Such a distinction could prevent that a researcher is alleged of infringement for a sole lab experiment, and could at the same time contain incentives for companies to develop innovative marketable research products (apparatus and kits) because they can temporarily prevent other, commercial "me-too's", aiming to free ride on the investment in innovation. Such an approach could offer a correct balance between the need of research freedom, on the one hand, and the importance of knowledge protection for an efficient encouragement of innovation and the general interest of mankind.

Personal communication Ivo Roelants, Head of Protection & Exploitation of Intellectual Property Department, K.U.Leuven R&D, 21 February 2008

5.2.4. The action and reaction of business circle

The Flanders Institute for Biotechnology (VIB), pharma.be, BelgoBiotech, Belgian BioIndustries Association and Flanders Bio also publicly reacted on the *second* proposal (Belgian Chamber, DOC 51 1348/001 – 21 September 2004) and suggested a few amendments (see *Annex 3).*

A first objection against the modified research exemption was that the term "scientific objectives" was subject to differing interpretations. If "scientific objectives" means activities which contribute to the development of knowledge, then that also applies to a lot of research activities in commercial companies. It is unclear of such research would also be exempted, or only research that takes place in academic institutions. Conversely, research can also take place in academic institutions having a long term commercial objective. The distinction between commercial and non-commercial research leaves too much room for interpretation and the use of alternative terms does not offer a solution.

A second objection related to the phrasing which in practice leads to a narrowing down of the patent protection, which, subsequently can lead to more trade secrecy. At present the research exemption is usually interpreted in a rather strict sense: acts carried out *on* the subject matter of the invention may (e.g. acts aiming at testing,

improving or finding new applications of the invention), whereas acts carried out *with* the subject matter of the invention may not. In practice, however, there is a "laisser passer" or a tolerant attitude where patent holders will not prosecute academic institutions, or only in exceptional cases. The new research exemption aims at regularizing this tolerance, but risks to lead to more trade secrecy in actual practice.

The third objection related to the problems which could be expected when applying the research exemption to process inventions. The new research exemption would have as effect that research methods, used for scientific purposes, would not fall under the research exemption. This would run counter against an international consensus stating that at least the invention of certain, important research methods should be rewarded with patent protection. This is of great importance in a sector such as biotechnology, where a large part of the inventions relates to technological means and an improvement of research practices.

The Flanders Institute for Biotechnology (VIB), pharma.be, BelgoBiotech, Belgian BioIndustries Association and Flanders Bio pushed for the abolishment of the research exemption, as in its present form, it entails serious risks of unintended effects. When renegotiating a future research exemption, it should be borne in mind that designing a research exemption is a delicate balancing exercise between the protection of the interests of the patent holder, on the one hand, and the promotion of scientific progress, on the other hand. A research exemption must not only bear those contradictory interests in mind, but equally serve them. The present research exemption does not serve both interests in a sufficient way and will therefore lead to more trade secrecy in actual practice, what runs counter to scientific progress.

Europabio (the European Association for Bioindustries) (http://www.europabio.org). has not formulated any point of view with regard to the current Belgian situation.

Personal communication Dirk Carrez (Public Policy & Industrial Biotech Director Europabio), 18 February 2008

6. THE PROCESS AND BACKGROUND TO START THE PROCESS TO MODIFY THE LAW (EX. UK, SWISS) *NOT APPLICABLE*

Not applicable

7. THE GUIDELINE TO PROTECT AND USE RESEARCH TOOL PATENTS

Under current Belgian patent law a wider research exemption has been introduced. However, there are no explicit provisions relating to the protection or use of research tools. We have conducted several interviews to bring current practices, based on the renewed and enlarged research exemption, to the fore within leading research organizations.

7.1. Flanders Institute for Biotechnology (VIB) (http://www.vib.be/VIB/EN).

Mission: VIB is a non-profit scientific research institute. Using advanced gene technology, VIB studies the functioning of the human body, plants and microorganisms.

VIB develops three complementary core activities: 1. Strategic basic research, 2. An active technology transfer policy to transfer the inventions to consumers and patient, 3. Scientific information for the general public.

The VIB takes the view that the Belgian research exemption is phrased far too wide, and hardly taken into account in real life, where rather the international consensus reigns. Therefore, the VIB applies a pragmatic approach and attempts to achieve optimal use of new technologies, without getting mixed up in too many legal disputes. This approach is based on two principles:

1. Research tools are easily – and almost always - placed at the disposal of academic groups at no cost. Annually, more than 500 research teams receive material from the VIB at no cost, with a simple material transfer agreement.
2. Research tools are generally offered to companies through a non-exclusive, reasonably priced license. Conversely, new candidate drugs/diagnostics are mostly exclusively licensed to companies.

Personal communication RudyDekeyzer (Managing Director VIB) and René Custers (Regulatory Affairs Manager), 18 February 2008.

7.2. Technology transfer office of the K.U.Leuven (LRD) (http://lrd.kuleuven.be/)

The K.U.Leuven rather seldom submits patent applications, which purely aim at protecting a research tool. First, because the cost of patenting is usually higher than the gains from valorization. Patent protection for a research apparatus or a research

kit might be contemplated if it could be developed and marketed as a well defined technological product, and only in the case where the lack of knowledge protection, would no longer motivate industry to develop the product so that the innovative product would no longer be put at the disposal of the research community. But patents, which solely aim at protecting a gene, a biomarker or a target and which only encompass a research tool without being translated in a diagnostic, medicinal or biotechnological product, will usually not be submitted, because the valorization value is very low.

1. In the exceptional case that in a patent genes, biomarker and targets are claimed as research tools, LRD applies a policy of no or narrow (in the framework of transfer of know how) reach-through rights, wide and non-exclusive licenses and low transactions costs for the private sector.
2. Within the public sector, those research tools are generally exchanged in the form of biomaterials, with a license at zero cost, further elaborated with or without a Material Transfer Agreement.

Personal communication Ivo Roelants, Head of Protection & Exploitation of Intellectual Property Department, K.U.Leuven R&D, 21 February 2008

8. THE STATUS QUO OF USING THE GUIDELINE

9. OTHER INFORMATION (TECHNOLOGICAL FIELD, BIBLIOGRAPHIC ITEM, PRICE TO LICENSE ETC.)

10. OECD GUIDELINES

Under current Belgian patent law no licensing guidelines have been implemented, nor are the OECD-guidelines enforceable. However, we have conducted several interviews which demonstrate that although this legal vacuum, various leading research institutions largely apply the principles laid down in the OECD-guidelines.

10.1. Flanders Institute for Biotechnology (VIB) (http://www.vib.be/VIB/EN)

Mission: see section 7.1.

Even though the OECD-Guidelines have not formally been adopted within the VIB, their licensing policy largely reflects the main principles laid down in the Guidelines. At one point their policy might differ from the Guidelines, more in particular as regards VIB's start-ups. The VIB will more easily grant exclusive licenses for basic technologies to start-ups, than suggested in the Guidelines.

Personal communication RudyDekeyzer (Managing Director VIB) and René Custers (Regulatory Affairs Manager), 18 February 2008.

10.2. Technology transfer office of the K.U.Leuven (LRD) (http://lrd.kuleuven.be/)

The OECD licensing guidelines are well known at the LRD, and the office is also closely involved in drafting guidelines for collaborative mechanisms. The licensing policy, and in a wider context the valorization activity, fits in closely with the principles and practices laid down in said guidelines. First and foremost, it is important that research results which have been obtained in an academic setting, are widely dispersible and that licensing activities or collaborations with industry may not impose permanent restrictions on the publication of research results, which have been obtained in academic labs. LRD is trained in reducing any delays during contract negotiations to a strict minimum. Furthermore, it is the objective of LRD to develop services and products through the protection of knowledge. Dissemination prevails, however, over direct revenue. Quite often an IP asset is licensed for various fields of application to different parties, in particular to parties which are best positioned or specialized to develop a product or service in that field of application.

Personal communication Ivo Roelants, Head of Protection & Exploitation of Intellectual Property Department, K.U.Leuven R&D, 21 February 2008

The EU-FP7 Framework Programs for R&D contain specific provisions with regard to licensing, although these provisions rather provide a general context, rather than detailed arrangements. The underlying philosophy always is that one research partner may not use its – by the Commission financed – research results ("Foreground"), even though he holds IP rights to prevent another party to employ his Foreground. A

research partner may neither block any Background, unless they have announced beforehand that they would bring in certain IP rights ("exclude from Access Rights"). The current provisions are a result from the initial Framework Programs, which were mainly situated in the ICT-sector. Non-exclusive access-rights (in fact a kind of contractual compulsory licenses) are not that evident in the pharmaceutical and in the biotech sector and the imposed provision are not always fit for collaborations in biotech. Therefore, LRD has suggested during a meeting with MEP Philippe Busquin to allow slightly diverging provisions in different scientific domains, but this suggestion was ultimately not followed.
LRD has no special policy as to the European provisions. On the basis of the input of the collaborating university inventor, LRD tries to negotiate the consortium agreements in such a way that they will experience as little discomfort and nuisance as possible, during their research or during later valorization.

Personal communication Bruno Lambrechts (Head Contract Research Department, K.U.Leuven Research & Development), 22 February 2008.

11. NIH GUIDELINES

Not applicable

12. PATENT POOLS

Recently, it has been suggested that the pooling of (research) tools would facilitate access to those patented tools.

12.1. Opinion in small biotech companies

"Also patent pools could help overcome some of the potential problems related to licensing diagnostic tools. It would make it easier to negotiate licenses, it would eliminate blocking patents, and would exert some market pressure to

lower licensing prices). [520] As indicated above, the rights to the HIV-1 group O patents, owned by Innogenetics and Dade Behring, for example, have been pooled and are available for non-exclusive licensing." "The biotech diagnostic industry should follow the example of the electronics industry: extensive (cross-)licensing at reasonable rates, licensing broadly and non-exclusively, or pooling patents. The alternative, blocking monopolies, will not lead to sustainable business."

Katrien Vlassak (Patent Counsel with Innogenetics N.V. in 1998).

* Katrien Vlassak & Kees Schüller, 'The Effect of Patents on Diagnostic Research and Kit Development', in Gene Patents and Public Health, VAN OVERWALLE, G. (ed.), Brussels, Bruylant, 2007, 99.

12.2. Viewpoints in academia

Belgian legal scholars have been most active, innovative and even trend-setting, in their reflection on how to adopt collaborative license mechanisms to improve access to patented genetic inventions in general, and genes in particular. As has been explained above (See section 2.1), genes can be considered as research tools in research on genetic diseases, and therefore, models facilitating access to gene patents is relevant in the context of the present report.

For more details, see

VAN OVERWALLE, G., VAN ZIMMEREN, E., VERBEURE, B., MATTHIJS, G., 'Models for facilitating access to patents on genetic inventions', 7 *Nature Review Genetics,* February 2006, 143-148

VERBEURE, B., VAN ZIMMEREN, E., MATTHIJS, G., VAN OVERWALLE, G., 'Patent pools and diagnostic testing', 24 *Trends in Biotechnology (TIB)*, vol. 3, March 2006, 115-120

VAN ZIMMEREN, E., VERBEURE, B., MATTHIJS, G., & VAN OVERWALLE, G.,

'A Clearinghouse for Diagnostic Testing: the Solution to Ensure Access to and Use of Patented Genetic Inventions?', *Bulletin of the World Health Organization*, 2006, 352-359.

At present, a survey is being carried out on 'Patent Licensing in Medical Biotechnology in Europe'. In the US , Australia , and Switzerland , over the last 10 years several surveys have been carried out regarding patenting and licensing practices in the area of genetics. Until now, in Europe no extensive empirical research has been published on licensing practices focusing on this particular field. Moreover, these previous surveys reviewed existing practices and their problems and consequences and did not consider new collaborative licensing strategies to clear third party's patent rights.

The major aim of the survey is to bridge this gap and to provide an overview of the current licensing practices among various stakeholders in the field of medical biotechnology in Europe and in particular to evaluate their knowledge of, experience with and attitude towards new collaborative licensing models as an instrument to clear third party's patent rights (in particular to safeguard freedom to operate and prevent royalty stacking).

The survey focuses on medical biotechnology, as this is an area prone to the emergence of problems with regard to freedom to operate, especially in booming fields such as kit development and pharmacogenomics. It is important to note that "medical biotechnology" for the purpose of this survey encompasses pharmaceutical, therapeutic and diagnostic applications as well as research applications. In other words it includes amongst others drug discovery, pharmaceuticals, vaccines, gene therapy, diagnostics, genetic testing, medical devices, research tools, genomics, proteomics and pharmacogenomics.

The outcome of the survey is potentially relevant to the current debates and policy reflections on knowledge transfer and patent licensing. Thus, though the survey was neither commissioned nor funded by the European Commission, the Institute for Prospective Technological Studies (IPTS; Joint Research Centre, European Commission), Eurogentest (Network of Excellence Sixth Framework), the European Association for Bioindustries (EuropaBio), the Licensing Executives Society International (LESI) and ProTon-Europe, these organizations strongly encourage all

relevant stakeholders to take part in this survey, so as to ensure that its results will accurately reflect the current situation and the needs of all the stakeholders involved, and they look forward to its outcome.

Addressees of the survey are established in the contracting states of the European Patent Convention (Austria, ***Belgium***, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Monaco, the Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom).

For more details, see

http://www.law.kuleuven.be/cir/research/survey.htm

12.3. Action in political circles

Various governmental and non-governmental international organizations, have suggested that patent pools and clearing houses might offer an interesting solution to current problems of access in the field of genomic research. Even though this topic has not been picked up in Belgian political circles yet, the European Parliament and the European Commission have shown a great interest and have started the debate.

The European Parliament has suggested that "Both patent pools and clearing houses make the existing technology landscape more transparent and also reduce transaction costs for the participants. Accordingly, the Working Group recommends in-depth investigation of collaborative rights models, such as patent pools and clearing houses, and the extent to which these could become leading models for enhancing access to and use of patented inventions within the European patent system".*

The European Commission has equally launched the debate. The Research Directorate General (Directorate C) organized a brainstorming workshop on 'Patent pooling in the biotech sector' on 13 June 2007, where the scientific collaborators of the Centre for Intellectual Property Rights of the K.U.Leuven (see above) were

invited to present their views and the outcome of their research. A wide range of patent experts from industry and academia were present, and participated in the discussions.

**** COWAN, R., VAN DER EIJK, W., LISSONI, F., LOTZ, P., VAN OVERWALLE, G. and SCHOVSBO, J., Policy options for the improvement of the European patent system, Report commissioned by STOA (Scientific Technology Options Assessment) of the European Parliament and coordinated by Bjørn Bedsted of The Danish Board of Technology/ETAG, 2007, 67 p.***

(http://www.europarl.europa.eu/stoa/publications/studies/stoa16_en.pdf***)***

資料６　スイス

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Switzerland
Experimental use defence (research exemption) and research tools

Preliminary remarks

The modifications of Swiss Patent Act approved by Swiss parliament on June 22, 2007 adapt the patent law to the technological progress and the international developments of the past years. Its main focus is to ensure an adequate and effective patent protection for inventions in the field of biotechnology. The changes include the clarification of exclusions of patentability by reason of ordre public or morality, the clarification of the scope of protection of biotechnological patents, the enactment of the research and Bolar-exemption, and the introduction of an obligation to disclose the origin of genetic resources and traditional knowledge. However, it includes other important legislative goals such as the transposition into the Swiss law of the WTO decision of August 30, 2003 on the implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, the ratification of the Patent Law Treaty, and the introduction of effective measures to combat counterfeiting and piracy.

1. The key event initiating the revision of Swiss Patent Act

The adoption of the Directive 98/44/EC of the European Parliament and of the Council of July 6, 1998 on the legal protection of biotechnological inventions was the starting point of the revision of Swiss patent law. Switzerland is not a member of the European Community or the European Economic Area (but a member of the European Patent Convention), and is therefore not obliged to adjust its law to accord with the Directive 98/44/EC of the European Parliament and of the Council of July 6, 1998 on the legal protection of biotechnological inventions. Switzerland is however a country which in practice seeks so far as possible to align its intellectual property laws with those of the European Community. Furthermore, Swiss industry expressed a need of common and clear legal rules in Europe in the field of patenting of biotechnological inventions since patents in this field were disputed in public. On April 20, 1999, the Swiss Parliament moved on Motion which called for the Federal Council to conform Swiss patent law to Directive 98/44/EC of the European Parliament and of the Council of July 6, 1998 on the legal protection of biotechnological inventions.

A preliminary bill to revise the Swiss Patent Act was drafted in 2000. A public consultation procedure on this bill was carried out in 2001/2002. This consultation marked the beginning of a public discussion about patenting of biotechnological inventions in Switzerland. The consultation revealed, among other things, that there is a general lack of empirical evidence on this topic. The Federal Council therefore requested the Swiss Federal Institute of Intellectual Property to analyze certain issues which came up in the opinion-gathering more in detail. Two areas which were investigated in detail are presented in this report, namely:

- The impact of patents (in particular gene patents) on biotechnological inventions in basic and applied research;
- The economic implications of patents (in particular gene patents) for biotechnological inventions.

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In this context, the Federal Institute of Intellectual Property conducted a survey of the biotechnology industry in Switzerland in 2003. A report titled "Research and Patenting in Biotechnology- A survey in Switzerland" presents the findings. In the consultation procedure and in the survey of the biotechnology industry in Switzerland the issue of the private use defence was raised.

At that time the OECD started to examine the issue of the experimental use defence as part of its wider study of biotechnology. Its first examination of the issue took place 2002 and the results were published in „Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies". This publication was followed by a second OECD Report published in 2004 entitled „Patents and Innovation: Trends and Policy Challenges". This report also made several recommendations in relation to the issue of experimental use. The discussion of the experimental use defence at international level had also influence on the reform in Switzerland.

2. The relation between innovation and patent (especially research exemption) when the discussion of the revision of Swiss Patent Act started

Economic theory states that patents are a facilitator for the diffusion of knowledge and innovation and, as such, they are an important element of economic growth. However, recent studies have found that too much patenting can potentially deter research, development and innovation. The difficulty is finding the right balance between incentives for research and providing access to patented research at the same time. A careful balance has to be found between the interest to commercialise a first patent and to create downstream inventions that could potentially be beneficial for society. On the one side, too little protection of inventions can lead to free-riding and overuse of an invention and, hence, to an underinvestment in research and development, combined with a loss of incentives for these investments. On the other side, too much protection can lead to the underdevelopment of downstream research and can limit research and competition. With regard to the effects o research, patent protection poses difficult questions regarding the need to exclude competition in the use of inventions in research and thus of the proper scope of the experimental use exception and its application to research tools. Although these concerns may be minimized by licensing policies, even the costs of licensing patented general purpose technologies (implicit in the purchase price of such technologies) may delay or restrict the progress of scientific research.

The issue of patents and their influence on access to research has been one particular focus of the survey of the biotechnology industry in Switzerland conducted by the Federal Institute of Intellectual Property in 2003. It can be referred to the findings of this survey.

With regard to the findings of the survey, to factual elements should be born in mind:

- The research environment has changed in the recent years: Today's universities are actively involved in contract research for the private sector. Most universities in Europe have established technology transfer organisations internally or companies to hold, manage, license and enforce their intellectual properties. The distinction line between commercial and non-commercial research has vanished.

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- In contrast to the national legislation of most European countries, the Swiss Patent Act does not provide for a statutory defence for private and non commercial use or for use for experimental purposes in relation to the subject matter of the invention. Such a defence is however recognized in practice. The exact metes and bounds of this exemption are, however, not wholly clear.

The lacking statutory defence and the unclear scope of the defence gave rise to legal insecurity among researchers (in publicly funded research institutions and in private companies). Furthermore, referring to the example of the PCR-technology, the respondents to the survey voiced concerns that scientists may be restricted from using important research tools since biotechnological inventions may concern a relatively early stage of the innovative process and cannot be duplicated. Therefore, the respondents to the survey of the biotechnology industry in Switzerland in 2003 ranked a "broad research exemption" as the most efficient remedy for reducing the transaction costs of operating in biotechnology, and the Report concluded that "in comparison to other remedies, the introduction of a broad research exemption is believed to be relatively beneficial". Against this background the introduction of a statutory experimental use defence was discussed in Switzerland as a means to prevent possible negative effects of patents on research.

3. The range of research exemption/Commercial uses and non-commercial uses/The purpose of research

The modified Swiss Patent Act approved by Swiss parliament on June 22, 2007 provides for the following defences:

Art. 9
G. Exceptions to the protection conferred by the patent
I. General

1 The scope of protection conferred by the patent does not extend to:

a. to acts undertaken in the private sphere for non-commercial purposes;

b. to acts undertaken for experimental and research purposes in order to obtain knowledge about the object of the invention, including its possible utilities; in particular all scientific research concerning the object of the invention is permitted;

c. to acts necessary to obtain a marketing authorisation for a pharmaceutical product in Switzerland or in countries with comparable regulation on marketing authorisation for pharmaceutical products;

d. the use of the invention for teaching purposes at educational institutions;

e. the use of biological material for the purpose of the production or the discovery and development of a plant variety;

f. biological material that is obtained in the field of agriculture by chance or through an unavoidable technical process.

2 Agreements that which limit or exclude the exceptions foreseen under paragraph 1 are null and void.

New Articles 9)(1)(a) and (b) correspond to those limitation of the rights of patentees that are found in Art. 9 of the draft Community Patent Regulation of 2004. These provisions provide for a statutory defence for private and non commercial use or for use for experimental purposes in relation to the subject matter of the invention. The language of Article 9)(1)(b) does not preclude the use of an invention in experiments designed with a commercial end in view. It does however not cover experiments that are conducted for the purpose of interfering with the marketing efforts of the patentee.

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New Article 9)1)(c) is a regulatory review defence („Bolar-exemption") as has been introduced in the European Community in response to the New Legislation but which is not limited to applications for national authorisations only.

New Article 9)(1)(d), a defence for "teaching use", does not exist elsewhere in Europe in patent law.

New Article 9)(1)(e) addresses the plant breeding issue and new Article 9)(1)(f) the sort of situation that could in theory arise when a patented strain is grown by one farmer on a field adjacent to that of another and cross pollinates that other's crop, whose saved seed may thus accidentally incorporate patented genetic material. New Article 9)(2) preserves the various defences of Article 9)(1) in the face of agreements seeking to restrict or nullify them.

4. Compulsory uses of patents

The modified Swiss Patent Act approved by Swiss parliament on June 22, 2007 provides for the following compulsory license:

> *Art. 40b*
> F. Research tools
> Whoever intends to use a patented biotechnological invention as an instrument or means in research, is entitled to a non-exclusive license.

New Article 40b) provides a compulsory non exclusive license for those experimental uses of biotechnological research tool patents that do not meet the „object of the invention" limitation in Article 9)(1)(b). However, because this is expressed to extend only to the use of such a patented biological research tool it does not act as a compulsory license permitting competitors of the patentee to manufacture or supply such biotechnological research tools.

The terms „instrument or means in research" refer to biotechnological inventions that are used almost exclusively to carry out experiments which do not relate to the subject-matter of the biotechnological invention. The term "biotechnological invention" has to be understood to be an invention which concerns a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used (Article 3(1) of the Directive 98/44/EC and Rule 26(2) EPC 2000). "Biological material" signifies any material containing genetic information and capable of reproducing itself or being reproduced in a biological system (Article 2(1) (a) of the Directive 98/44/EC and Rule 26(3) EPC 2000). Since Article 40b refers to biotechnological inventions only, the terms "tools and means for research" do not include laboratory equipment and machines, databases and computer software.

Article 40b is intended to prevent a situation in which research and technological innovation would be adversely affected and unreasonably restrained. Such a situation may specifically arise in the context of biotechnological inventions that are used to carry out experiments. Such inventions (e.g. PCR) are essential in order to make downstream research. Unlike non biotechnological instruments they can neither be substituted nor replaced by other technical solutions (bottleneck situation). In order to assure and

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promote research and the dissemination of technological knowledge the provision strikes a balance between the interests of producers and users of technological knowledge.

5. Major public comments of the revision of Swiss Patent Act

Articles 9 and 40b of the Swiss Patent Act has been consulted with and approved by the biotechnology and pharmaceutical industry in Switzerland (including multinational companies, SMEs, universities and research institutes) and also by economiesuisse (the organization representing the Swiss economy).

The Gowers Review of Intellectual Property recommended the clarification of the U.K. experimental use exception along the lines of Article 9 of the modified Swiss Patent Act (see p. 45-47, n. 4.3-4.12).

平成１９年度　特許庁産業財産権制度問題調査研究報告書

研究で用いる特許権の取扱に関する調査研究
調査研究報告書

平成２０年３月
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