

# Outsourcing the Fire of Genius: The Effects of Patent Infringement Jurisprudence on Pharmaceutical Drug Development

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## INTRODUCTION

There's no such thing as a free lunch.<sup>1</sup> There's also no such thing as free trade. But there is *freer* trade. Indeed, the last few decades have seen an almost universal movement towards enhanced trade agreements, both among regional blocs and on a global basis. The United States has been an enthusiastic participant regionally, e.g., as a member economy of the North American Free Trade Agreement (“NAFTA”) and the Asia-Pacific Economic Cooperation (“APEC”), and globally, e.g., as a member of the World Trade Organization (“WTO”) and a signatory to its many agreements, including the General Agreement on Tariffs and Trade (“GATT”) and the Trade-Related Aspects of Intellectual Property Rights (“TRIPs”).<sup>2</sup>

<sup>1</sup> MILTON FRIEDMAN, THERE'S NO SUCH THING AS A FREE LUNCH (Open Court 1975); ROBERT A. HEINLEIN, THE MOON IS A HARSH MISTRESS 162 (1966) (“There ain't no such thing as a free lunch”). Both authors helped popularize the expression, which dates to at least the 1930's. Milton Friedman, Wikiquote, [http://en.wikiquote.org/wiki/Milton\\_Friedman](http://en.wikiquote.org/wiki/Milton_Friedman) (last visited October 11, 2006).

<sup>2</sup> The gradual global progress toward free trade began in the United States in the 1930's when Franklin Roosevelt introduced the Trade Agreements Program. International negotiations and agreements have always been a seminal component of the U.S. initiative. See Paul Krugman, *Enemies of the WTO: Bonus Arguments Against the World Trade Organization*, SLATE, November 24, 1999, available at <http://www.slate.com/id/56497>. See also WORLD TRADE ORGANIZATION, UNDERSTANDING THE WTO—PRINCIPLES OF THE TRADING SYSTEM (2004), available at [http://www.wto.org/english/thewto\\_e/whatis\\_e/tif\\_e/fact2\\_e.htm](http://www.wto.org/english/thewto_e/whatis_e/tif_e/fact2_e.htm).

The fundamental objective of these trade agreements is clear and praiseworthy—to enhance the efficiency of markets, thereby creating more competitive and profitable industries and better values for consumers. It has generally been understood that there have been and will continue to be certain unavoidable adjustments of labor activity as the larger markets rationalize. However, there has been a growing and increasingly significant concern in the United States that many jobs are disappearing as work is being outsourced, not simply as an adjustment to changing markets but to markets that are being skewed by foreign and, in some cases, domestic laws or jurisprudence, which may not fully or adequately reflect the increasingly international nature of the industries affected by these laws.

#### I. BACKGROUND: GLOBALIZATION AND THE PHARMACEUTICAL INDUSTRY

The outsourcing of jobs and technology is a particularly sensitive issue facing the U.S. economy today. The drug development activities of the U.S. pharmaceutical industry offer an instructive case study to contextualize the situation. The U.S. pharmaceutical industry is one of the most productive and competitive industries in the world. Pharmaceutical research is an activity of utmost importance to this country. Sustaining its growth in the United States is considered fundamental to both the health care system and the economy. Outsourcing threatens to move the drug development segment of this industry and its technology and jobs outside of the United States.

Over the last quarter century, a multinational diffusion of individual pharmaceutical firms has rendered the term the “U.S. pharmaceutical industry” a misnomer.<sup>3</sup> Multinational firms are becoming the norm. Most large U.S.-based firms now have extensive facilities in foreign markets and many foreign-based

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<sup>3</sup> THE NATIONAL ACADEMY OF ENGINEERING, *THE COMPETITIVE STATUS OF THE U.S. PHARMACEUTICAL INDUSTRY: THE INFLUENCES OF TECHNOLOGY IN DETERMINING INTERNATIONAL INDUSTRIAL COMPETITIVE ADVANTAGE* 21 (1983).

firms have extensive operations in the United States.<sup>4</sup> The intensely competitive nature of this “globalized” pharmaceutical industry makes product innovation and development a crucial determinant of any company’s success, inside or outside the United States.

Pharmaceutical companies today are challenged by the time and cost required to bring novel, branded drug products, i.e., the so-called “pioneer” drugs, successfully to market. Companies must continually seek new and improved ways to expedite the research, development and regulatory approval phases of drug development, all the while without compromising the integrity of the process itself.<sup>5</sup> The extent and vitality of this innovation is a drug company’s most valued resource. Evaluating and ameliorating the way drug research is conducted and funding that research by product sales or licensing are essential to maintaining a competitive advantage in the globalized pharmaceutical industry.<sup>6</sup>

Intellectual property (“IP”) rights inherently affect the nature of global competition. Industries that do not enjoy the protection of IP rights, or where such protection is limited in scope or in term by a country’s legal landscape or by rapid development of new products, find themselves involved in intense competition that lowers their profits and stifles future investment. By contrast, in industries or countries where IP rights protect product sales for extended periods of time, there is limited competition, prices are less economically sensitive and profits are higher. Most importantly, companies are willing to invest significant amounts of their revenues in research on future products. If a company or

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<sup>4</sup> According to a United Nations agency, in the early 1990’s there were 37,000 international companies with 175,000 foreign subsidiaries. By 2003, there were 64,000 international companies with 870,000 subsidiaries. *A Taxing Battle*, THE ECONOMIST, Jan. 29, 2004, available at [http://www.economist.com/finance/displayStory.cfm?story\\_id=2388628](http://www.economist.com/finance/displayStory.cfm?story_id=2388628).

<sup>5</sup> See generally Jacques-Pierre Moreau, *Pharma Companies Must Shift Focus to R&D Efforts*, BOSTON BUSINESS JOURNAL, Mar. 11, 2005, available at <http://www.bizjournals.com/boston/stories/2005/03/14/focus2.html>.

<sup>6</sup> In other countries, strategies such as rigid price controls and regulations have virtually killed such innovation. See, e.g., Joseph H. Golec & John A. Vernon, *What’s at Stake in Pharmaceutical Reimportation: The Costs in Terms of Life Years, Lives, and Dollars*, 16 U. FLA. J.L. & PUB. POL’Y 135, 135–137 (2005).

industry as a whole is unable to (a) adequately protect and exploit its own IP and (b) gain appropriate access to essential IP owned by other companies or industries, then its overall functioning will be significantly impeded in the global economy.

A strong patent system is a supremely important mechanism for encouraging and fostering pharmaceutical and biomedical research, drug development, drug products, investments and ultimately jobs. The owners of patents can exclude others from making, using or selling the patented inventions.<sup>7</sup> This allows them to gain economic benefit from their inventions and to fund future improvements. Successful pharmaceutical firms and the drug research industry at large have strategically harnessed the burgeoning nature of scientific discovery by patenting their IP to form intangible assets. These intangible assets are valuable corporate assets that can make up a great portion of the total worth of a company.<sup>8</sup>

Thomas Friedman, the Foreign Affairs columnist for *The New York Times*, was among the first to recognize that the value of these intangible assets would only increase following a globalization of the industry.<sup>9</sup> He also recognized that capital, which is drawn to markets rapidly by opportunities, or even perceived opportunities, will abandon those same markets just as quickly.<sup>10</sup> It follows, therefore, that companies in the drug arena should patent their useful inventions borne of drug research, as early and as often as possible so as to maintain a competitive

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<sup>7</sup> See, e.g., 35 U.S.C. § 271(a) (2001).

<sup>8</sup> In successful organizations, IP holdings and other intangible assets constitute two to three times the value of physical assets. During 2000, the market-to-book ratios of Fortune 500 companies increased to 6.3 to 1, indicating that for every dollar of physical assets on the balance sheet, the market recognized \$6.30 worth of other intangible assets. Lesley Craig & Lindsay Moore, *Intangible Assets, Intellectual Capital Or Property? It Does Make A Difference*, FRONT RANGE TECH BIZ, Feb. 3, 2002, available at [http://www.klminc.com/articles/frt\\_feb02.html](http://www.klminc.com/articles/frt_feb02.html).

<sup>9</sup> See generally Thomas L. Friedman, *THE LEXUS AND THE OLIVE TREE: UNDERSTANDING GLOBALIZATION* (First Anchor Books) (2000) (defining intangible assets as the knowledge-based competence of a company and arguing throughout that “intangible asset companies” will succeed over “tangible asset companies” in generating profits in a globalized economy) (1999).

<sup>10</sup> See generally *id.*, at ch. 1.

advantage (or even the perception of a competitive advantage) in the globalized pharmaceutical industry. In this sense, patent protection has become inseparable from contemporary globalized capitalism in the area of pharmaceuticals and their discovery and development.

In order to have value, however, patents must provide effective economic benefit. Today, for U.S. drug companies that benefit is impacted by the U.S. patent system and to an increasing degree by the patent systems of countries around the world. Companies must manage and leverage their patent portfolios to garner financial benefits and competitive advantages in the global marketplace. A strong portfolio can, for example, support future revenue streams, erect barriers to competition, and enhance a company's perceived value to outside investors, partners and acquirers.<sup>11</sup> The degree to which companies can strategically capitalize upon the value of their own patented technology depends in part on the patent landscape, country by country, and the degree to which they can obtain access to patents held by others. Any comprehensive business strategy should be informed by competitive IP intelligence.<sup>12</sup> Because the parameters of IP rights are conceptual in nature, however, the extent to which a company can exclude others from infringing upon its intellectual space (i.e., using these intangible assets without permission) is much more uncertain than in the case of trespassing upon real property.

This paper will argue that U.S. patent jurisprudence should embrace rather than fight the phenomenon of globalization, i.e., the integration of capital, technology, and information across national borders, in a way that creates a single global market.<sup>13</sup> Patent infringement jurisprudence in the United States should not promote the outsourcing of a pharmaceutical firm's most valuable business assets or jobs. The U.S. patent system should allow U.S.-based

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<sup>11</sup> Bill Barrett & Dave Crawford, *Integrating the Intellectual Property Value Chain*, 20 NATURE BIOTECHNOLOGY BE43-BE46 (2002).

<sup>12</sup> *Id.*

<sup>13</sup> See Thomas L. Friedman, *THE LEXUS AND THE OLIVE TREE: UNDERSTANDING GLOBALIZATION* (2000), available at <http://www.thomasfriedman.com/lexusolivetree.htm> (defining globalization).

pharmaceutical companies a wide enough berth to leverage their intangible assets within a global framework while also allowing scientific innovation to continue both at home and abroad.<sup>14</sup>

Part II will provide an overview of the U.S. patent system and the scope of patent protection for the pharmaceutical industry in the United States. It will outline the tension between the patent laws and free market forces and will review the scope of patent infringement under United States law. It will provide an overview of the legal basis of patent infringement for drug research under both the common law and the Patent Laws of the United States.<sup>15</sup> It will then introduce the legal conflict with regard to the debate over the breadth of patent protection and infringement across the pharmaceutical and research tool industries.

Part III of this paper will address U.S. court decisions in the context of early stage pharmaceutical drug research and patent infringement. It will examine the conflict that has arisen based on a limited reading of the common law research exemption and the resulting development of the more broadly-read “safe harbor” research exemption to patent infringement in the context of drug development. It will address the laws that regulate patent infringement through importation and will consider the most recent positions of the United States Supreme Court and the United States Federal Circuit Court of Appeals (“Federal Circuit”) in cases that reflect the current state of early stage drug research and patent infringement in the United States.

Part IV of this paper will explore the legal climate for outsourcing early stage drug research to other jurisdictions. Specifically, it will consider the most recent positions that non-U.S. courts have taken with regard to the proper judicial treatment

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<sup>14</sup> While not the main topic of this paper, some accommodation must also be given to the developers of research tools. *See infra* note 22 and accompanying text. These tools make important contributions to drug research. Any set of patent infringement decisions that devalues them will reduce the likelihood that the research tool industry will grow. This will disadvantage drug development in the long term. Individual countries cannot affect the value of these tools in the global marketplace. The solution can only be a global one. *See discussion infra* Part V.

<sup>15</sup> Bryson Act, ch. 950, 66 Stat. 792 (1952) (codified at 35 U.S.C. § 1 et seq.) [hereinafter The Patent Act].

of research exemptions to patent infringement in the context of drug development. It will review the laws of Canada, the European Community and India, in the context of the research exemption for drug development. It will also examine how countries outside the U.S. are addressing the problem as a way of considering whether or not their decisions are encouraging the outsourcing of U.S. early stage drug research.

Part V will draw together the effects of these diverse jurisprudences on the patent infringement consequences of early stage drug research and the outsourcing debate in the United States. It will argue that current U.S. jurisprudence is forcing U.S. drug companies to outsource their early stage drug research. It will also present International Trade Commission (ITC) considerations, such as the possibility of it exercising unfair competition jurisdiction if outsourcing involves patented U.S. technology. The paper concludes by discussing possible solutions for the quagmire that recent U.S. decisions have created in outsourcing jobs and technology in early stage drug research.

In sum, a balanced solution is needed. In order to de-incentivize drug companies from outsourcing their early stage research from the United States, the 35 U.S.C. § 271(e)(1) safe harbor research exception may well need to be expanded, by the Courts or the legislature, to include such early stage drug discovery. However, at the same time, the research tool industry will need to be compensated for this shift, possibly through corporate goodwill programs or by revitalizing the unfair competition law. The benefits and drawbacks of these possible solutions will be discussed.

## II. PATENT PROTECTION IN THE UNITED STATES

An unresolved tension exists between the two purposes of the U.S. patent system: to disseminate information to the public on one hand and to reward innovation on the other. The benefit of public disclosure is clear in that it allows other innovators to build upon and to advance technological development. The value of rewarding patent holders with limited exclusive rights to protect

their discoveries is also clear in that it allows the proprietor to recoup his or her costs for inventing while also creating future incentives to invest resources to develop and commercialize new technology. However, a delicate balance exists between these costs and benefits. Companies must engage in value chain analyses in order to properly manage the huge investments that must be made in order to galvanize new discoveries, develop meaningful technology and remain competitive in the world economy.<sup>16</sup> As stated by Abraham Lincoln, himself a patentee: “The patent system added the fuel of interest to the fire of genius.”<sup>17</sup>

Under this public-private (i.e., disclosure-for-protection) bargain between the inventor and the government, a patent confers a limited, yet potentially very lucrative, monopoly. A patent owner’s right to exclude is guaranteed by the property right that inheres in a patent. A violation of the patent’s exclusivity rights constitutes patent infringement. Patent infringement in the United States is the unauthorized making, using, selling, offering to sell or importing of a patented invention, during the term of the patent.<sup>18</sup> During this period of exclusivity, a patent owner can therefore legally prohibit another from using the patented technologies (i.e., enjoin the infringing activity) or can demand payment for such infringing use through royalties or other consideration.<sup>19</sup> Additionally, a patent owner in today’s globalized economy can

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<sup>16</sup> The IP value chain starts with the inventor’s original idea and has value added by a series of steps that ultimately yields a legally protected asset. Barrett, *supra* note 11.

<sup>17</sup> Quoted in HERBERT F. SCHWARTZ, PATENT LAW AND PRACTICE 3 (BNA Books 2003) (1988).

<sup>18</sup> 35 U.S.C. § 271(a) (2001).

<sup>19</sup> The financial consideration for such use can come in almost any form as agreed by the parties and can provide a third party with either exclusive or non-exclusive rights to use a patent. Typical financial considerations include periodic fees upon sale of a product or process (royalties), up-front fees (typically due at execution of a license agreement), flat fees or milestone payments (due at certain agreed upon benchmarks during pre-commercialization), reimbursements (e.g., of patent costs), and sometimes equity or other compensation in any technology developed through the use of the patent. See, e.g., JOHNS HOPKINS TECHNOLOGY TRANSFER STANDARD OPERATING PROCEDURE, (2003) available at <http://www.ltd.jhu.edu/about/ipbooklet.html>. But cf. eBay Inc. v. MercExchange, L.L.C., 126 S. Ct. 1837 (2006) (holding that a patentee who prevails in an infringement case is not automatically entitled to a permanent injunction).

also benefit from the ability to assign the patent property or even the royalty payments for the rights to use a patent from one member of a corporate family to another (e.g., subsidiary to parent within a multinational company) by means of transfer pricing.<sup>20</sup>

The language of section 271(a) makes clear that any one of the enumerated activities (making, using, selling, offering to sell or importing) is actionable as patent infringement. The patentee does not even need to have *any* evidence of damage or lost profits to bring an infringement action.<sup>21</sup> The statute does not make clear, however, whether the accused activities must be commercial. This leads to one question underlying this paper: Should actionable infringement activities be limited to commercial activities or should the patent holder also be allowed to bar others from using the patented technology for research purposes?

In the pharmaceutical industry there are two general categories of patents. Both are critical to the development of new drugs. The first category of patents is directed to the research and development of the new drug. These patents seek to capitalize upon the so-called “research tools” used in the drug industry.<sup>22</sup> Research tool patents typically include drug targets, cell lines, transgenic animals, drug screening assays, intermediates, databases and large libraries of potential drugs. These patents are not typically infringed by the marketing of the ultimate drug product.<sup>23</sup> They are only used in research towards finding and developing the drug product. In practice, these patents are usually held by smaller

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<sup>20</sup> Transfer pricing refers to internal corporate pricing schemes used for goods and services that are traded internally between the divisions of a single multilateral corporation. This is a highly regulated practice because the choice of transfer prices affects the division of the total profits and thus the taxable income among related corporate entities. The U.S. tax law’s application of an arm’s length standard to transactions involving the exploitation of intangible assets only serves to further incentivize companies to outsource a company’s value added activities. *See* Gustafson et al., *TAXATION OF INTERNATIONAL TRANSACTIONS* 625, 660 (West Group Publishing 2001).

<sup>21</sup> *Roche Prod. v. Bolar Pharm.*, 733 F.2d 858, 861 (Fed. Cir. 1984) (citations omitted).

<sup>22</sup> A research tool is any item or method useful in conducting experiments in a research setting. *See In re Fisher*, 421 F.3d 1365, 1372 (Fed. Cir. 2005) (defining “research tool” as “a term often given to inventions used to conduct research”).

<sup>23</sup> *But see infra* note 25 and accompanying text.

biotechnology companies and research institutions that actively seek to out license the technology to finance the development of other research tools or to finance their expansion and ability to bring a branded pharmaceutical to market.

By contrast, the second general category of patents held in the pharmaceutical industry is directed to the marketed drug product or methods of using it. These patents typically cover brand name pioneer drugs and their uses, e.g., for specific indications. Pioneer drug patents include:

- (1) product patents that cover the active ingredient or compound in a drug;
- (2) process patents that cover a process for manufacturing a drug;
- (3) method-of-use patents that relate to a particular method of using a drug;
- and (4) formulation patents that cover both the active and inactive ingredients in a drug (e.g. a final dosage form tablet or capsule).<sup>24</sup>

These types of patents are infringed by the sale and use of the ultimate drug product itself. In practice, these patents are usually owned by large pharmaceutical firms that have the resources to bring the drugs to market and to distribute them to consumers globally.

An ongoing debate within the drug development industry exists concerning the extent to which companies should be allowed to operate within the scope of someone else's research tool patents in order to develop new drugs. This debate has two facets. On the one hand, the developers of the research tools and owners of the patents on those tools want those using the tools to pay royalties for their use. Research tool companies would prefer that these royalties "reach through" to the sales of the drug product discovered through use of the tool.<sup>25</sup> This segment of the industry

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<sup>24</sup> Daniela Bassan, *In Cipro We Trust: But How Do We Feel About Our Drug Patent Laws?*, in *FOOD AND DRUG LAW: AN ELECTRONIC BOOK OF STUDENT PAPERS* (Peter Barton Hutt ed. 2002), available at <http://leda.law.harvard.edu/leda/data/496/Bassan.html>.

<sup>25</sup> The goal of "reach through" claims is to have the patent apply to the ultimate product that is sold so as to collect royalties from that sale or to preserve for the patent owner the sole right to develop the product. However, courts have cast doubt on the patentability

argues that research tool patents need to be protected by the patent laws and the courts because infringement of research tool patents is common and there is little a patentee can do to benefit from their patents, once the research has been completed.<sup>26</sup> Research tool companies argue that without the ability to garner such economic benefit from their inventions, drug research will suffer and new tools will not be developed.

On the other hand, drug developers argue that having to obtain permission to use the many possible research tools potentially relevant to the development of a particular drug before development starts and to burden ultimate product sales with royalties for their use is economically unfeasible. Productivity is the key challenge in the highly competitive drug development industry and success is measured by time-to-market.<sup>27</sup> This segment of the industry argues that immediate access to useful research information is a crucial component of any drug development platform.<sup>28</sup> Pharmaceutical drug developers argue that research tool patents impose significant transaction costs that

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and enforcement of claims to products identified only by reference to the material or means used to find or identify them. *See, e.g.,* Univ. of Rochester v. G.D. Searle & Co., 358 F.3d 916 (Fed. Cir. 2004), *reh'g en banc denied*, 375 F.3d 1303 (Fed. Cir. 2004), *cert. denied*, 543 U.S. 1015 (2004) (holding a patent directed to methods of selectively inhibiting certain enzyme activity did not sufficiently describe a compound [Celebrex®] that functioned by that mechanism); Housey Pharms., Inc. v. Astrazeneca UK Ltd., 366 F.3d 1348, 1350 (Fed. Cir. 2004) (affirming judgment of patent invalidity based on lower court's broad construction of "inhibitor or activator" of a protein to include an indirect pathway-binding mechanism); Bayer AG v. Housey Pharms., Inc., 340 F.3d 1367, 1368 (Fed. Cir. 2003) (finding no patent infringement where the physical goods were manufactured from information generated by the patented process). *But see* Ariad Pharms., Inc. v. Eli Lilly & Co., Civil Action No. 02-11280-RWZ (D. Mass. 2006); *see also infra* note 142 and accompanying text.

<sup>26</sup> *See* John P. Walsh et al., *Working Through the Patent Problem*, 299 SCIENCE 1021 (2003).

<sup>27</sup> *See supra* notes 5–6 and accompanying text. The "time-to-market" describes the general length of time that it takes to get a drug product from concept to the marketplace. A reduced time-to-market is a significant competitive advantage in the pharmaceutical industry because a pioneer drug can confer significant market power. *Id.* *But cf.* Ill. Tool Works Inc. v. Indep. Ink, Inc., 126 S. Ct. 1281, 1291 (2006) (holding that patents alone do not confer a presumption of market power).

<sup>28</sup> *See generally* Walsh et al., *supra* note 26.

will delay and possibly prevent future drug development.<sup>29</sup> This is because of the need to either negotiate many license agreements in advance of beginning the research, or else to proceed at the risk of substantial damages when the product is launched.<sup>30</sup>

Recent U.S. court decisions, on the scope of the common law research exemption as well as the so-called “safe harbor” research exemption to patent infringement, have tried to split the baby.<sup>31</sup> They support research tool patents in early stage drug research and they support the drug developers in the later drug development and approval stages.<sup>32</sup> This compromise is out of step with the laws and jurisprudence of other countries.<sup>33</sup> It, therefore, has disadvantaged U.S.-based pharmaceutical firms in their attempts to develop drugs for the global market in the United States. The U.S. decisions, for example, have placed significant limitations on domestic research operations by holding that certain types of patents related to upstream, early stage discoveries, such as methods of screening, mechanism of action and targets for drug intervention, may be infringed in early stage drug research.<sup>34</sup>

That jurisprudence, when coupled with another series of U.S. decisions permitting the importation and use of information and products developed in early stage research conducted outside the U.S., may have the perhaps unintended and unanticipated effect of forcing U.S.-based firms to outsource their early stage drug research.<sup>35</sup> Outsourcing, in this context, means that pharmaceutical firms would move early stage drug discovery research and its associated technologies and jobs outside the United States and have either foreign subsidiaries or third parties in another country (or countries) perform the research and then reintegrate the results of that research back into the U.S. operations of the U.S.-based company. Jurisprudence that encourages such outsourcing is a legitimate cause of concern for those involved in

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<sup>29</sup> *Id.*

<sup>30</sup> *Id.*

<sup>31</sup> *See* 35 U.S.C. § 271(e)(1).

<sup>32</sup> *See* discussion *infra* Parts III.A., III.B.

<sup>33</sup> *See* discussion *infra* Part IV.

<sup>34</sup> *See infra* notes 114–119 and accompanying text.

<sup>35</sup> *See* discussion *infra* Part III.C.

the pharmaceutical and regulatory industries in the United States and to the U.S. economy at large. The next part will review the evolution of the common law research exemption and the “safe harbor” research exemption to patent infringement in the context of the pharmaceutical industry.

### III. EXEMPTIONS FROM PATENT INFRINGEMENT IN THE UNITED STATES

The use of a patented invention in research falls into a slightly different camp from that of patent infringement for commercial activities, as it involves the use of an invention solely for experimental purposes, such as testing whether a compound functions as claimed, re-creating a process to observe its effects from a scientific perspective, and using a patented research tool in drug discovery.<sup>36</sup> Some of these activities, indeed, are the *raison d'être* of the patent system—to encourage early publication so that others can improve upon the invention.<sup>37</sup> Other activities are not really about improving the patented invention but about using it in research for its intended use to develop other inventions. This distinction is reflected in the research exemption to patent infringement in many countries. For example, Canada, the European Community, and India have carved out varying degrees of exemptions from infringement for “experimental use” on patents by third parties.<sup>38</sup> The situation in the United States is somewhat more complicated, as there exists a common law as well as a statutory research exemption to patent infringement, both with shifting standards of interpretation and somewhat tortured jurisprudential histories.<sup>39</sup>

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<sup>36</sup> Tom Saunders, *Renting Space on the Shoulders of Giants: Madey and the Future of the Experimental Use Doctrine*, 113 YALE L.J. 261, 261 (2003).

<sup>37</sup> *See id.* at 262.

<sup>38</sup> *See discussion infra* Parts IV.A., IV.B., IV.C.

<sup>39</sup> *See discussion infra* Parts III.A., III.B.

A. *The Common Law Exemption from Patent Infringement*

United States jurisprudence has interpreted the common law exemption, or the experimental use defense, to liability for infringement rather narrowly. The common law exemption originated in the early days of patent law as an exemption for “philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects”.<sup>40</sup> Following these holdings, courts have consistently carved out a narrow exemption to patent infringement for experimental activities that have no commercial purpose. The sliver of this carving was established in *Spray Refrigeration Co. v. Sea Spray Fishing, Inc.*<sup>41</sup> where the Court found infringement for the experimental use of a freezing apparatus on a commercial fishing boat. Even though the Court acknowledged that the operators of the boat were using the freezing method experimentally, infringement was deemed to have occurred because it took place without a license on board a boat that was engaged in commercial fishing operations.<sup>42</sup> An experimental use coupled with a commercial use, therefore, even if de minimis, constitutes patent infringement.<sup>43</sup>

Despite this ruling, patent infringement defendants continue to seek protection of the experimental use and the de minimis use exemptions concomitantly. Courts, indeed, have clarified the de minimis defense with regard to patent infringement by holding it akin to the experimental use defense. The Court of Claims in *Douglas v. United States*, for example, stated that the experimental use defense is just “an expression of the maxim *de minimis non curat lex*.”<sup>44</sup> This construction has served to limit even further the common law or experimental use exemption in the United States.

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<sup>40</sup> *Whittemore v. Cutter*, 29 F. Cas. 1120, 1121 (C.C.D. Mass. 1813) (No. 17,600); *see also Poppenhusen v. Falke*, 19 F. Cas. 1048, 1049 (C.C.S.D.N.Y. 1861) (No. 11,279) (exempting experiments with a patented article which are “for the sole purpose of gratifying a philosophical taste, or for curiosity, or for mere amusement”).

<sup>41</sup> 322 F.2d 34, 37 (9th Cir. 1963).

<sup>42</sup> *Id.*

<sup>43</sup> *See id.* at 36.

<sup>44</sup> 181 U.S.P.Q. 170, 177 (Ct. Cl. Trial Div. 1974), *aff’d*, 206 Ct. Cl. 96 (Ct. Cl. 1975) (“The law does not concern itself with trifles.”).

In fact, courts often question whether any infringing use of a patent can be *de minimis*. The Federal Circuit's Judge Rader, for example, opined that since the Patent Act confers the right to preclude "use" and not "substantial use," it affirmatively precludes *de minimis* excuses.<sup>45</sup> Only somewhat more leniently, the court in *Deuterium Corp. v. United States*, held that "[d]amages for an extremely small infringing use may be *de minimis*, but infringement is not a question of degree."<sup>46</sup> This latter rationale has been used to support the view that the common law research exemption should not itself be considered a true exemption from infringement but rather a means to provide limited damages for *de minimis* infringement.<sup>47</sup>

Subsequent cases have supported this strict view of infringement and the limited defenses thereto. No activity that furthers a commercial purpose of any sort qualifies for the protection under the common law research exemption in the United States. For example, in *Embrex, Inc. v. Service Engineering Corp.*,<sup>48</sup> plaintiff Embrex was the exclusive licensee of a patented method for immunizing birds against disease *in ovo* (in egg) and was practicing this patent commercially in large scale industrial chicken farms. Defendant Service Engineering Corp. ("SEC") used the patented method in an attempt to design around it and to build its own inoculating machine.<sup>49</sup> Embrex sued and SEC contended it was performing scientific experiments that did not result in any sale, and therefore its actions were either *de minimis*, or exempt under the experimental use exception.<sup>50</sup> The Federal Circuit affirmed the trial court's refusal to set aside the

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<sup>45</sup> *Embrex, Inc. v. Serv. Eng'g Corp.*, 216 F.3d 1343, 1352 (Fed. Cir. 2000) (Rader, J., concurring).

<sup>46</sup> 19 Cl. Ct. 624, 631 (Cl. Ct. 1990).

<sup>47</sup> See, e.g., *Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860 (Fed. Cir. 2003), as corrected, 2003 U.S. App. LEXIS 27796, at \*8 (Fed. Cir. 2003), vacated and remanded by *Merck KGaA v. Integra LifeSciences I Ltd.*, 125 S. Ct. 2372 (2005).

<sup>48</sup> 216 F.3d 1343, 1346 (Fed. Cir. 2000).

<sup>49</sup> *Id.*

<sup>50</sup> *Id.* at 1349.

jury's verdict of infringement.<sup>51</sup> In its ruling, the Federal Circuit reiterated that even the slightest commercial implication will render the experimental use exemption (and the de minimis use exemption, for that matter) inapplicable.<sup>52</sup>

Despite its avowed narrowness, the experimental use exemption was for a time presumed by some to exist at academic research universities and other not-for-profit organizations. However, the law has made clear that this is not the case. A trial court denied the existence of a university qua university research exemption in *Infigen Inc. v. Advanced Cell Technology Inc.*<sup>53</sup> There, the experimental use exemption was denied for work done in university research laboratories using patented technology as controls, on the basis that "it is up to Congress to decide whether there should be an infringement exemption for university-based research laboratories. So far, Congress has not seen fit to grant one."<sup>54</sup>

In *Madey v. Duke University*, a landmark decision that once and for all ended the experimental use exemption in the context of the non-profit entity carrying out allegedly infringing commercial activities, the Federal Circuit reached a similar conclusion.<sup>55</sup> In this case, Dr. John Madey, a scientist and former professor at Duke University, claimed that Duke had engaged in the unauthorized use of his patent protected lab equipment and sued Duke for infringement.<sup>56</sup> The District Court granted summary judgment in favor of Duke, holding that Duke's use of the equipment was for experimental, non-commercial purposes.<sup>57</sup> However, on appeal, the Federal Circuit enunciated once again a narrow reading of the

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<sup>51</sup> "While SEC tries to cloak these tests in the guise of scientific inquiry, that alone cannot immunize its acts . . . Just because SEC was unsuccessful in selling its machines does not confer infringement immunity upon SEC for its infringing acts." *Id.*

<sup>52</sup> *Id.* at 1353 (Rader, J., concurring).

<sup>53</sup> 65 F. Supp. 2d 967 (W.D. Wis. 1999).

<sup>54</sup> *Id.* at 981 (citing, e.g., the Patent Competitiveness and Technological Innovation Act of 1990, H.R. 5598, 101st Cong. (1990), "which was never passed but which, [*inter alia*,] proposed exemptions from infringement liability for university research").

<sup>55</sup> 307 F.3d 1351, 1362–63 (Fed. Cir. 2002), *cert. denied*, 539 U.S. 958 (2003).

<sup>56</sup> Duke had used a laser gun, developed and patented by Dr. Madey, for its intended purpose as a research tool, not to use or study the gun itself. *Id.* at 1353.

<sup>57</sup> *Id.* at 1355–56.

common law research exemption and held that because a research university's goals were inherently commercial in nature, its non-profit status was irrelevant; Duke was, therefore, not exempt from infringement qua university.<sup>58</sup> This decision has further cabined the common law research exemption even in the context of scientific research performed at academic institutions.

The Federal Circuit's Judge Pauline Newman has taken issue with this fettering of the experimental use doctrine. She restated her dissatisfaction with the *Madey* decision and the narrow research exemption it embraced in a forceful and compelling dissent in *Integra LifeSciences I, Ltd. v. Merck KGaA*.<sup>59</sup> There, she argued that a narrowing of the common law exemption is "ill-suited to today's research-founded, technology-based economy."<sup>60</sup> In her view, the patent system is designed to promote the progress of science.<sup>61</sup> That goal cannot be achieved if all uses of a patented invention are forbidden until the patent expires. A common law research exemption must exist, therefore, to facilitate further knowledge and understanding of what the patentee has done in order to understand the patented invention, to improve upon it, to find a new use for it, or to modify or design around it.<sup>62</sup> If such research were subject to infringement prohibition, the patentee would effectively be granted a de facto monopoly enabling him or her to bar not only patent-protected competition, but also all research-based efforts to improve, evaluate, compare, challenge or avoid the patented technology.<sup>63</sup> Such jurisprudence, in Judge Newman's view, would stifle technological advancement and run

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<sup>58</sup> *Id.* at 1362–63 (explaining that research activities are infringing if they further the institution's business objectives of educating and enlightening students, increasing the status of the institution and luring lucrative research grants, students and faculty).

<sup>59</sup> 331 F.3d 860, 872–78 (Fed. Cir. 2003) (Newman, J., concurring in part, dissenting in part). In *Integra LifeSciences I*, Merck was using patented products to develop the "best" drug for the treatment of cancer. *Id.* at 861.

<sup>60</sup> *Id. as corrected*, 2003 U.S. App. LEXIS 27796, at \*35 (Fed. Cir. 2003).

<sup>61</sup> *Id.* at \*46. Her philosophy is derived from the United States Constitution, which expressly grants Congress the legislative power "to promote the Progress of Science and useful Arts." U.S. CONST. art. I, § 8, cl. 8.

<sup>62</sup> *Integra Lifesciences*, 2003 U.S. App. LEXIS 27796 at \*42.

<sup>63</sup> *See id.* at \*45.

counter to the framework of patent law, which both contemplates and facilitates research into patented subject matter.<sup>64</sup>

Ultimately, Judge Newman recognized that a narrow tight rope must be walked in order to preserve the patentee's incentive to innovate (which is secured by the patent's right to exclude) while also fostering the creation of new knowledge using the patent as the stepping off point. To balance these two societal needs, Judge Newman reasoned that the boundary of the common law research exemption must lie somewhere in between the generally distinguishable phases of "research" and "development."<sup>65</sup>

The development phase of drug discovery, referred to by Judge Newman, had previously been addressed in *Roche Products v. Bolar Pharmaceutical Co.*<sup>66</sup> This seminal case involved the limitations of the common law research exemption in the context of generic drugs.<sup>67</sup> This case involved a suit between a large research-oriented pharmaceutical company (Roche) and a manufacturer of generic drugs (Bolar).<sup>68</sup> Roche sought to enjoin Bolar from using its domestically patented drug, which Bolar had obtained from a foreign manufacturer, to conduct the federally mandated tests necessary to market, after expiration of the patent, a

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<sup>64</sup> *Id.* at \*43–45.

<sup>65</sup> *Id.* at \*45. Judge Rader's majority opinion hastily dismissed this dissent by noting that this exemption was not before the court in this case and, even if it were, the Patent Act does not include the word "experimental," let alone an experimental use exemption from infringement. *Id.* at \*43 n.2.

<sup>66</sup> 733 F.2d 858 (Fed. Cir. 1984), *cert. denied*, 469 U.S. 856 (1984).

<sup>67</sup> A general distinction in the drug industry exists between research-based pharmaceutical firms that invest heavily in the research and development of original products (i.e. brand-name pioneer drugs), and generic drug companies that do typically not engage in novel research but instead copy the active ingredient in already approved pioneer drugs to bring a competing non-brand-name product to market. These generic products, also called "copycat" or "me-too" drugs, are the bioequivalent of the branded products and can be marketed at lower prices because their manufacturers do not incur the costs associated with the creation and marketing of pioneer drugs. Moreover, generic drug companies can target only the most successful products on the market. This again reduces their costs because they do not spend monies or effort on less successful products. *See generally* United States v. Generix Drug Corp., 460 U.S. 453, 454–60 (1983).

<sup>68</sup> *Roche Products*, 733 F.2d 858.

generic drug equivalent to Roche's brand name drug.<sup>69</sup> The District Court held that Bolar's "experimental" testing was not infringement because the use was de minimis and experimental.<sup>70</sup> The Federal Circuit reversed, however, stating that the experimental use exemption is truly narrow and cannot be expanded to encompass tests, demonstrations or experiments that further legitimate business interests and thus clearly serve commercial purposes.<sup>71</sup>

Bolar argued that this decision violated public policy because it de facto extended the patent term beyond the stated limit.<sup>72</sup> The Patent Act, in force in 1984, granted to inventors a 17-year property right to their inventions.<sup>73</sup> The Federal Food, Drug, and Cosmetic Act ("FDCA"),<sup>74</sup> on the other hand, required several statutory and regulatory steps to assure the safety and efficacy of generic drugs to be marketed.<sup>75</sup> Because it could take 1–2 years for a generic company to satisfy these regulatory requirements for marketing a generic drug, Bolar argued that the arrival of generic drugs on the market would be unduly delayed, and the patent term unfairly extended, if the FDCA required tests on the patented product could not begin until after expiration of the patent term.<sup>76</sup>

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<sup>69</sup> *Id.*

<sup>70</sup> *Id.* at 860–61.

<sup>71</sup> *Id.* at 863. "We cannot construe the experimental use rule so broadly as to allow a violation of the patent laws in the guise of 'scientific inquiry,' when that inquiry has definite, cognizable, and not insubstantial commercial purposes." *Id.*

<sup>72</sup> *Id.* at 864.

<sup>73</sup> The law has since changed. *See* Uruguay Round Agreements Act, Pub. L. No. 103-465, § 532 (a)(1) (1994). The term of a patent used to be 17 years from the issue date of the patent. Now, for applications that were pending, and patents that were still in force, on June 8, 1995, the patent term is either 17 years from the issue date or 20 years from the earliest claimed filing date, whichever is longer. For applications filed on or after June 8, 1995, the patent term is 20 years from the application's earliest claimed filing date. 35 U.S.C. § 154(a)(2) (1996).

<sup>74</sup> 21 U.S.C. §§ 301–99 (1938).

<sup>75</sup> *Id.*

<sup>76</sup> *Roche Products*, 733 F.2d at 864 (citing THE NATIONAL ACADEMY OF ENGINEERING, THE COMPETITIVE STATUS OF THE U.S. PHARMACEUTICAL INDUSTRY, 79–80 (1983)). While the requirements of the FDCA had the effect of extending the term of a patent in the context of generic competition, they also had the effect of reducing the total term of patent protection in the context of the branded drug. This is because, while patents typically are granted 3–5 years after filing, the testing required to support approval by the

The Federal Circuit declined to create a new exemption to infringement for the testing of generic drugs. The *Roche Products* court found no support for such exemption in the Patent Act and refused to “engage in legislative activity proper only for the Congress.”<sup>77</sup>

### B. The Statutory Exemption from Patent Infringement

Congress responded promptly to the *Roche Products* decision and to the lobbying efforts of the branded and generic pharmaceutical industries, by enacting a statutory compromise.<sup>78</sup> The Drug Price Competition and Patent Term Restoration Act of 1984 (also known as the “Hatch-Waxman Act”)<sup>79</sup> amended the FDCA and the Patent Act to rectify the distortions enunciated in the *Roche Products* case by (a) establishing an abbreviated approval process for generic drugs; (b) restoring the patent term for pioneer drugs so as to recover patent term lost during the lengthy approval process; and (c) creating a “safe harbor” exemption—or the Bolar exemption as it is referred to outside the U.S.—from patent infringement for work that was needed to obtain drug approval.<sup>80</sup> The legislative intent of the Hatch-Waxman Act was to strike a balance between the interests of pharmaceutical companies, generic manufacturers and consumers, by encouraging greater expenditure in the area of pharmaceutical invention through longer effective patent terms while simultaneously encouraging generic drug development and ensuring greater competition immediately after the expiration or invalidity of the relevant patents.<sup>81</sup>

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Food and Drug Administration (FDA) to market a branded drug often takes 10–12 years. Thus, by the time the drug product reaches the market, only 8–10 years of patent protection remain. *See id.*

<sup>77</sup> *Roche Products*, 733 F.2d at 863–64.

<sup>78</sup> This statute did not, however, disturb the Federal Circuit’s enunciation in *Roche Products* of the parameters of the common law experimental use exception.

<sup>79</sup> Pub. L. No. 98-417, 98 Stat. 1585 (1984).

<sup>80</sup> *Id.*

<sup>81</sup> *See* H.R. Rep. No. 98-857, at 16–18 (1984), *as reprinted in* 1984 U.S.C.C.A.N. 2647, 2649–51. *See also* Samuel M. Kais, *A Survey of 35 U.S.C. § 271(e)(1) as Interpreted by the Courts: The Infringement Exemption Created by the 1984 Patent Term Restoration Act*, 13 SANTA CLARA COMPUTER & HIGH TECH. L.J. 575, 576 (1997) (citing

To address the first goal, Congress created several new provisions to encourage greater investment in pharmaceutical innovation. Specifically, the Hatch-Waxman Act restored at least a part of the patent term for pioneer drugs that had undergone protracted pre-market testing to ensure drug safety and efficacy as mandated by the FDCA, after the patent had issued.<sup>82</sup> Under these provisions, branded drugs have been entitled to an average extension of about three years in patent term.<sup>83</sup> This extension allows the patent owner more time to recoup the expenses of drug development and to fund subsequent research on new drugs by marketing the drugs at “patent” prices.<sup>84</sup>

The second goal was to ensure greater competition in the market, i.e., to maximize the post-patent availability of lower priced products, by narrowing the gap between patent expiration and generic entry.<sup>85</sup> To do this, Congress established a “safe harbor” exemption for otherwise infringing activities if they relate to the development and submission of information to the Food and Drug Administration (“FDA”).<sup>86</sup> Specifically, the statute recites that:

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. . . *solely for uses reasonably related to the development and submission of information* under a Federal law which regulates the

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Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984).

<sup>82</sup> See Kais, *supra* note 81, at 577.

<sup>83</sup> Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry*, at 4, 28 (1998) available at <http://www.cbo.gov/showdoc.cfm?index=655&sequence=5> (click “PDF”).

<sup>84</sup> The extension compensates the patent owner for a part of the time the patent was not protecting the owner from the market because the drug was not yet approved. It does so by moving a part of the ineffective patent term to the effective patent term, i.e., when the drug is on the market. A maximum of five years can be restored to the patent term. The total patent term, with an extension, cannot exceed fourteen years from the product’s approval date. See 35 U.S.C. § 156 (1994).

<sup>85</sup> See Kais, *supra* note 81.

<sup>86</sup> See Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984).

manufacture, use, or sale of drugs or veterinary biological products.<sup>87</sup>

This provision allows competitors to engage in otherwise infringing activities that are reasonably related to obtaining regulatory approval.<sup>88</sup> Research on a patented drug can thus be conducted, before expiration of the patent term and without incurring liability for patent infringement, in order to accelerate the process of getting a drug to market.<sup>89</sup> To be sure, Congress passed section 271(e)(1) with the intent of facilitating the entry of generic drugs into the market upon expiration of the brand name patent on the compound with as little barrier to entry, i.e., artificial extension of the patent monopoly, as possible.<sup>90</sup> Because of the Hatch-Waxman Act generic drugs can now enter the U.S. market almost immediately after patent protection on the brand name drug expires, or is held to be invalid or unenforceable, in contrast to the case in many other countries.<sup>91</sup> In many ways the Hatch-Waxman Act created the generic drug industry.<sup>92</sup>

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<sup>87</sup> 35 U.S.C. § 271(e)(1) (Supp. 2004) (emphasis added). The full recitation excludes new animal drugs and veterinary products from the patented inventions, presumably because the rest of the complex patent term restoration law excluded these drugs.

<sup>88</sup> See Kais, *supra* note 81.

<sup>89</sup> Other provisions were also added in the Hatch-Waxman Act to accelerate the approval process for generic drugs specifically. See, e.g., 21 U.S.C. § 355(j). Again, however, the Hatch-Waxman Act balanced the right of the generic and the drug companies. For example, it made the filing of an application for approval of a generic drug (an “ANDA”) an act of infringement that allowed patentees to sue even though such filing was *not* a making, using or selling of the patented drug. It also provided that the FDA could not approve the generic for the lesser of 30 months after the ANDA filing, patent expiration, or a court holding of patent invalidity (the “30 month stay”). This gave the branded companies the chance to enforce the patent against the generic to prevent marketing before valid patent expiration and yet allowed the generic to file for approval to market before the patent term expired. This protects customers from having to pay “patent” prices for drugs that are the subject of expired or invalid patents.

<sup>90</sup> See generally *Innovation and Patent Law Reform: Hearing on H.R. 3285, H.R. 3286 and H.R. 3605 Before the H. Subcomm. on Courts, Civil Liberties and the Administration of Justice, of the H. Comm. on the Judiciary*, 98th Cong. 527 (1984).

<sup>91</sup> See *infra* Part IV.

<sup>92</sup> Before Hatch-Waxman, only 35% of the top-selling drugs had generic competition after their patents expired; now almost all pioneer (non-biological) drugs face such competition. See Henry Grabowski and John Vernon, *Longer Patents for Lower Imitation Barriers: The 1984 Drug Act*, 76 AM. ECON. REV. 195–98 (May 1986). See also A. Maureen Rouhi, *Beyond Hatch-Waxman, Legislative Action Seeks to Close*

However, the language of the “safe harbor” of section 271(e)(1) is not limited to generic drug manufacturers or to drug patents.<sup>93</sup> This breadth of statutory language has been a hallmark of the jurisprudence construing the safe harbor. By contrast with the common law exemption, U.S. courts have construed the safe harbor exemption rather broadly. The Supreme Court, for example, has construed the term “patented invention” of 271(e)(1) to include *all* patented inventions, including medical devices and human biologics as well as drug products.<sup>94</sup> Moreover, the Federal Circuit has effectively read the provision “solely” out of the language of the statute.<sup>95</sup> Courts have also adopted a flexible reading of the phrase “reasonably related” so as to give parties some latitude in making prospective judgments about the nature and extent of activities they plan to engage in to win FDA approval.<sup>96</sup>

In *Intermedics v. Ventritex, Co.*, the California District Court reasoned that accused acts should be protected as long as it would have been reasonable for a party to believe there was a “decent prospect” that the activities in question would contribute to the generation of information relevant to the FDA approval process.<sup>97</sup> This became known as the “objective reality” test.<sup>98</sup> More recently, the U.S. District Court for the Southern District of New

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*Loopholes in U.S. Law that Delay Entry of Generics Into the Market*, 80 CHEMICAL & ENG'G NEWS 53–59 (Sept. 23, 2002), available at <http://pubs.acs.org/cen/coverstory/8038/8038biogenerics2.html>.

<sup>93</sup> See *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 666 (1990) (holding that a “Federal law” in 271(e)(1) refers to any regulation under the FDCA, not only those relating to drugs or veterinary biological products); *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 1989 U.S. Dist. LEXIS 16110, at \*177–78 (D. Mass. 1989).

<sup>94</sup> See *id.*

<sup>95</sup> *AbTox Inc. v. Exitron Corp.*, 122 F.3d 1019, 1030 (Fed. Cir. 1997) (holding that 271(e)(1) language does not look to the underlying purposes or consequences of the research activity, thus, as long as the research is reasonably related to obtaining FDA approval, the data can also be used for other purposes).

<sup>96</sup> See, e.g., *Intermedics v. Ventritex, Co.*, 775 F. Supp. 1269, 1280 (N.D. Cal. 1991).

<sup>97</sup> *Id.*

<sup>98</sup> *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 3 F. Supp. 2d 104, 111 (D. Mass. 1998). See also Katherine A. Helm & James F. Haley, Jr., *The Fine Line of the Law: Patent Infringement Exemptions in the U.S.*, LIFE SCIENCES LAW & BUSINESS, Dec. 2004/Jan. 2005.

York ruled that the use of patented intermediates that were being used as research tools in drug development but would never be submitted to the FDA for approval themselves, was exempted from infringement under the safe harbor.<sup>99</sup> In rendering its verdict, the Court applied the objective reality test and found that there was a decent prospect that the use of the patented intermediates would contribute to the generation of information relevant to FDA approval.<sup>100</sup> Based on these broad judicial constructions, therefore, the safe harbor can be invoked by any organization making or using any patented invention for purposes that are “reasonably related” to the development and submission of information for government (i.e., FDA) approval to market. The safe harbor thus eviscerates the patentees’ right to exclude in these circumstances.

Determining the precise contours of safe harbor protection from patent infringement nonetheless remains the source of much legal debate, because, in the words of the Supreme Court, the hastily drafted 1984 act is simply “not plainly comprehensible on anyone’s view.”<sup>101</sup> Bereft of clear statutory guidance, courts often look to the legislative history of the statute in an attempt to uphold the intent of encouraging greater expenditure and competition in the area of pharmaceutical innovation.<sup>102</sup> While U.S. courts have consistently held that the safe harbor applies to activities that are reasonably related to seeking FDA approval, the issue of when the safe harbor begins remains a stumbling block.<sup>103</sup> A strong undercurrent of legal and political conflict surrounds this question

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<sup>99</sup> *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, No. 95-8833, 2001 WL 1512597 (S.D.N.Y. Nov. 28, 2001) (overruled on other grounds in 326 F.3d 1226 (Fed. Cir. 2003)).

<sup>100</sup> *Id.* at \*3–4.

<sup>101</sup> *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 667 (1990), cited in William L. Warren, *Supreme Court Broadens Therapeutic Research Exemption From Patent Infringement in Merck*, IP Value 2006, available at [http://www.buildingipvalue.com/06US\\_Can/131\\_134.htm](http://www.buildingipvalue.com/06US_Can/131_134.htm).

<sup>102</sup> See *supra* note 79 and accompanying text. See also, e.g., *Merck KGaA v. Integra Lifesciences I Ltd.*, 125 S. Ct. 2372, 2383–84 (2005).

<sup>103</sup> Unlike the circumscribed clinical test periods required by the FDA (i.e., Phase I tests for safety, Phase II tests for efficacy and Phase III tests for side effects and long-term use effects), the earlier research and preclinical testing phases embraced by the safe harbor are far less delineated.

because its answer will effectively determine the worth of patents directed to upstream drug discovery technology, such as patents for methods of screening, mechanism of action and targets for drug intervention as well as patents on research tools.

Where the line is drawn with respect to whether or not early stage drug research is exempt from patent infringement is, therefore, sharply divided between drug developers on the one hand and research tool patent proprietors on the other. If early stage drug research is exempt, the research tool company loses the value of the patent. If early stage drug research is not exempt, the drug developer must either negotiate a number of licenses before beginning drug development and as a result burden the ultimate product with costs or restrictions up front or risk the spectra of injunctions and downstream damages for use of the patented tool. The controversy is ongoing.

Recent decisions of the Federal Circuit and the Supreme Court suggest that there may be some early stage drug research that is outside the safe harbor and not protected by the common law research exemption to patent infringement. The Supreme Court directly addressed the 271(e)(1) safe harbor exemption in *Merck KGaA v. Integra LifeSciences I, Ltd.*<sup>104</sup> This highly prominent case involved experiments that were conducted by the Scripps Research Institute and funded by Merck on compounds known as “RGD” peptides.<sup>105</sup> The experiments sought to determine the peptides’ efficacy as inhibitors of angiogenesis (to reduce blood flow to tumors) and suitability as potential anti-cancer drug candidates for clinical trials.<sup>106</sup> Integra brought suit against Merck for conducting drug screening, lead optimization, and preclinical tests (i.e. non-human) on drug candidates using certain Integra-patented cell adhesion-promoting RGD peptides.<sup>107</sup> The issue that rose to the Supreme Court was whether uses of patented inventions in

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<sup>104</sup> 125 S. Ct. 2372 (2005).

<sup>105</sup> RGD peptides were those that contained the tripeptide sequence Arg-Gly-Asp. *Id.* at 2377.

<sup>106</sup> *Id.* at 2377–78.

<sup>107</sup> The Integra-patented RGD peptides were used as “positive controls” against which Scripps measured the efficacy of the lead drug candidates. *Id.* at 2379.

preclinical research, the results of which were not directly included in a submission to the FDA but rather were used to identify and characterize the best drug candidate for *future clinical testing*, were within the safe harbor and thus exempt from infringement liability.<sup>108</sup>

The District Court ruled and the Federal Circuit affirmed that the safe harbor was confined to activity that would “contribute relatively directly” to information the FDA would consider in approving a drug and therefore, Merck had infringed Integra’s patents in its preclinical activities.<sup>109</sup> The Federal Circuit refused to make room under the umbrella of section 271(e)(1) for “exploratory research” testing that “at some point, however attenuated, may lead to an FDA approval process.”<sup>110</sup> The Supreme Court overruled the Federal Circuit’s strict construction of the safe harbor and created what it called a “wide berth” for the use of patented drugs in activities that necessarily include preclinical studies for the development of a potential drug candidate.<sup>111</sup> This holding is not surprising in view of the strong push by the United States Government as *amicus curia* to broadly interpret the upstream boundary of section 271(e)(1) to favor the discovery of new cancer treatments, as a matter of public policy.<sup>112</sup> Not insignificantly, the pharmaceutical industry also strongly supported Merck and Scripps, arguing that every activity during drug development generates valuable information that helps determine whether a potential new drug treatment will progress

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<sup>108</sup> *Id.* at 2376. At the trial level Merck argued both the common law research exemption defense and the safe harbor defense. But, the former was abandoned on appeal to the Federal Circuit, in part because in the recent wake of the *Madey* decision there was a perception that the common law use defense was dead. *See* discussion Part III.A. and notes 59–64 (discussing Judge Newman’s dissent). *See also*, Harold C. Wegner, *Post-Merck Experimental Use and the “Safe Harbor”*, 15 FED. CIR. B.J. 1, 13–17 (2005). Thus, the only question that remained was what constituted the upstream boundary of the safe harbor exemption.

<sup>109</sup> *See* *Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860, 867 (Fed. Cir. 2003).

<sup>110</sup> *Id.*

<sup>111</sup> *Merck KGaA*, 125 S. Ct. at 2380.

<sup>112</sup> *See generally*, Brief for the United States as *Amicus Curiae* Supporting Petitioner, *Merck KGaA*, 125 S. Ct. 2372 (No. 03-1237), 2005 WL 429972.

towards gaining FDA approval to market.<sup>113</sup> This reasoning clearly resonated with the Supreme Court, as it stated “[w]e thus agree with the Government that the use of patented compounds in preclinical studies is protected under §271(e)(1) as long as there is a reasonable basis for believing that the experiments will produce ‘the types of information that are relevant to [FDA submissions].’”<sup>114</sup>

The Supreme Court tempered its broad holding only slightly by agreeing with the Federal Circuit that the safe harbor exemption does not apply to *all* experimental activity and does not protect basic scientific research on a particular compound conducted without any intent to develop a particular drug.<sup>115</sup> Thus, the Supreme Court insinuated that early-stage exploratory research may be outside the safe harbor.<sup>116</sup> Finally, although the Supreme Court acknowledged the Federal Circuit’s suggestion that a limited construction of the safe harbor was necessary to avoid depriving research tool patents of value, the Court pithily declined to address the implications for research tool patents in its decision.<sup>117</sup>

There has been much controversy surrounding the *Merck* decision, both from the drug industry and the research tool industry. Many commentators have argued that the Supreme Court’s interpretation of the safe harbor is not one of strict constructionism and that this matter should be left for the legislature to amend and further delineate the “reasonably related” text of section 271(e)(1).<sup>118</sup> In such legislative construction, large drug companies would undoubtedly lobby for Congress to definitively broaden the safe harbor due to the time and cost involved in innovative drug development and to positively shelter

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<sup>113</sup> See generally Brief for Eli Lilly and Co., Wyeth & Pfizer, Inc. as Amici Curiae, Supporting Petitioner, *Merck KGaA*, 125 S. Ct. 2372 (No. 03-1237), 2005 WL 435888.

<sup>114</sup> *Merck KGaA*, 125 S. Ct. at 2383–84 (quoting Brief of the United States as Amicus Curiae at 23). See also Wegner, *supra* note 108, at 23–27.

<sup>115</sup> *Merck KGaA*, 125 S. Ct. at 2382.

<sup>116</sup> See *id.*

<sup>117</sup> *Id.* at 2382 n.7. The Supreme Court reasoned that because RGD peptides were not used as research tools, “[w]e therefore need not—and do not—express a view about whether, or to what extent, § 271(e)(1) exempts from infringement the use of ‘research tools’ in the development of information for the regulatory process.”

<sup>118</sup> See Wegner, *supra* note 108, at 27.

drug developers from patent infringement liability during these development activities. On the other hand, research tool companies would lobby to restrict the safe harbor so as to provide value to their patents and business models. In the absence of further legislation, the safe harbor provision will have to be revisited by the courts to determine the fate of research tool patents generally.

The future ramifications of holding certain experimental activity outside the safe harbor on the research and development operations of U.S. pharmaceutical firms are manifold. One potential ramification is that early stage exploratory drug research will be outsourced to non-U.S. jurisdictions, where it either would not constitute infringement under local jurisprudence or where no patents exist or are of limited enforceability. Uncertainty creates risk and the currently indeterminate state of section 271(e)(1)'s upstream boundary will motivate U.S.-based pharmaceutical companies to engage in risk management and move their value-added activities offshore.<sup>119</sup>

For large multinational pharmaceutical firms, the outsourcing of early stage drug research can be accomplished by transferring a particular research activity from a U.S. enterprise to an associated non-U.S. enterprise (e.g., a foreign subsidiary). U.S.-based pharmaceutical firms must carefully select an offshore location for research to optimize the legal and economic circumstances surrounding the transaction.<sup>120</sup> U.S.-based pharmaceutical firms who decide to outsource the early drug research to an optimal location must also consider the next transaction in the global supply chain: What happens when they bring information obtained

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<sup>119</sup> While lawyers may view the currently amorphous limit of the safe harbor as an invitation to test the boundaries, companies would rather alter their research operations to ensure that their practice falls under a clear set of defined rules. See Wegner, *supra* note 108.

<sup>120</sup> There are significant tax implications involved when transferring these sorts of intangible corporate assets between affiliated companies in different countries. See, e.g., Martin Sullivan, *With Billions at Stake, Glaxo puts U.S. APA Program on Trial*, 34 TAX NOTES INT'L 456 (2004) (discussing the largest transfer pricing case in history involving GlaxoSmithKline's allocation of income between its U.K. patents and its U.S. marketing intangibles).

and/or lead drug compounds identified in research conducted offshore back into the United States? This next section examines the legal implications of importing the results or products of early stage drug research that has been conducted offshore into the U.S.

### C. Exemptions from Patent Infringement Through Importation

The Patent Laws of the United States address the importation of products produced in non-U.S. jurisdictions by processes patented in the United States. Under 35 U.S.C. § 271(g), the importation of a product into the U.S. that was made abroad by a process patented in the United States is infringement.<sup>121</sup> This section thus offers a remedy to patent holders in cases where the importation of products manufactured abroad would be infringing if produced within the United States. Indeed, Congress enacted section 271(g) to provide “meaningful protection” to process patent holders and to eliminate the potential for circumvention of U.S. patent law through conduct abroad.<sup>122</sup> This protection is particularly important for research-based pharmaceutical and biotechnology companies that invest substantial capital in the process of developing and producing a drug product that may ultimately be protectable by a process patent alone.<sup>123</sup> The body of

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<sup>121</sup> 35 U.S.C. § 271(g) (1988). The statute lists two exceptions to infringement under this section: when the product is materially changed by subsequent processes or when the product becomes a trivial and nonessential component of another product.

<sup>122</sup> While U.S. law “cannot prevent a party from performing a patented process abroad, it can and does prevent a party from bringing the resulting products into this country. In doing so, the law attempts to provide full substantive protection of patentees’ exclusive rights in the United States.” See Kristin E. Gerdeman, Comment, *Subsequent Performance of Process Steps by Different Entities: Time to Close Another Loophole in U.S. Patent Law*, 53 EMORY L.J. 1987, 2003 (2004).

<sup>123</sup> Process patents can be obtained for new processes of making old products. Because many biotechnological products are inherently found in nature, biotechnological innovation frequently takes the form of finding more efficient ways to make a pre-existing “product.” A process patent is often the only patent protection a biotechnology company has for a product. Thus, the biotechnology industry was one of the strongest advocates for the enactment of section 271(g). See *Process Patent Legislation: Hearing on S. 568, S. 573, and S. 635 Before the Subcomm. on Patents, Copyrights and Trademarks of the S. Comm. on the Judiciary*, 100th Cong., 27–28 (1987) (statement of Richard D. Godown, President, Industrial Biotechnology Association) (“The very availability of these products (and associated jobs) is threatened when a company cannot

case law construing these provisions, therefore, needs to be considered insofar as it would impact the outsourcing of early stage drug research by pharmaceutical companies.

The first consideration involves the exemption to liability for infringement, under section 271(g)(1), when the product is “materially changed” by subsequent processes from the end product produced by the patented process. Initial cases generally construed the term in a straightforward manner to uphold the legislative intent of the statute and to attach liability when a process being performed abroad was deemed to constitute an “essential part of the overall process” for producing a product intended for the U.S. market.<sup>124</sup>

However, an increasingly sophisticated drug industry soon began increasingly complex issues for the courts. In *Eli Lilly & Co. v. American Cyanamid Co.*,<sup>125</sup> Eli Lilly sued generic drug manufacturer American Cyanamid for importing an antibiotic drug (cefactor) that was made by a process that included Lilly’s patented process for making an intermediate chemical (compound 6).<sup>126</sup> Lilly argued that because the only commercial use for the intermediate compound in the U.S. was to produce the drug cefactor, the intermediate was essentially the same as the drug and thus could not meet the “materially changed” requirement for exemption from infringement.<sup>127</sup> The district court disagreed and held that cefactor’s unique structural and biological properties

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be assured that its multi-million dollar research program will not be vulnerable to unfair practices.”)

<sup>124</sup> See, e.g., *Bio-Technology Gen. Corp. v. Genentech, Inc.*, 80 F.3d 1553, 1561 (Fed. Cir. 1996) (holding that a process for making a plasmid as a replicable cloning vehicle encompasses using it to express its intended protein product—human growth hormone—which was imported into the U.S. for marketing and sale).

<sup>125</sup> 82 F.3d 1568 (Fed. Cir. 1996).

<sup>126</sup> Cefactor is a complex molecule derived from forms of penicillin. American Cyanamid’s Italian manufacturer produced bulk cefactor in a nine-step process with a starting material (compound 1), eight chemically distinct intermediates (compounds 2–9), and a final end product (cefactor). Eli Lilly had obtained patents on several of the intermediates as well as the end product. Since most of these patents had expired, Lilly was only able to rely on the patent on the process of making compound 6 (that covered the process of converting compound 5 to compound 6) in this suit. *Eli Lilly & Co. v. American Cyanamid Co.*, 896 F. Supp. 851, 853–54 (S.D. Ind. 1995).

<sup>127</sup> *Id.* at 856–58.

constituted a material change from intermediate compound 6 as produced by the patented process.<sup>128</sup> On appeal, the Federal Circuit affirmed and held that the structural differences between the intermediate and the end compound rose to the level of a material change.<sup>129</sup> In its decision, the court acknowledged the overseas use of patented processes in research was a global concern, but stated it could not stretch the term “materially changed” to broaden the statute’s effectiveness in addressing the problem.<sup>130</sup> This ruling broke ground for pharmaceutical companies to outsource intermediate products and research tools in early stage drug research.

The second decision that further opened the way for outsourcing involved a construction of the non-manufacturing exemption to liability for infringement under section 271(g).<sup>131</sup> In *Bayer AG v. Housey Pharms. Inc.*,<sup>132</sup> the process patents in question were directed to methods of screening protein inhibitors and activators for compounds that indicated a potential for development as pharmaceuticals.<sup>133</sup> The issue that arose was whether Bayer was liable for importing data into the United States that was obtained from practicing these research tool process patents.<sup>134</sup> The court held that section 271(g) does not entitle the patent holder to exclude the importation into the United States of *information* obtained by carrying out the patented method overseas.<sup>135</sup> Under *Housey*, section 271(g)’s purview was limited to physically manufactured goods brought into the United States.<sup>136</sup> This ruling suggests information from early stage drug research done abroad (and likely, lead drug compounds identified

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<sup>128</sup> *Id.*

<sup>129</sup> *Eli Lilly*, 82 F.3d 1568.

<sup>130</sup> *Id.* at 1572.

<sup>131</sup> *Bayer AG v. Housey Pharms., Inc.*, 169 F. Supp. 2d 328 (D. Del. 2001), *overruled on other grounds* by 340 F.3d 1367 (Fed. Cir. 2003).

<sup>132</sup> *Id.*

<sup>133</sup> *Id.* at 329.

<sup>134</sup> Housey alleged that Bayer should be held liable upon importation of “any knowledge and information” that reflected the identification or characterization of a drug acquired from using Housey’s patented methods. *Id.*

<sup>135</sup> *Id.* at 330.

<sup>136</sup> *See id.*

in the research) may be imported into the U.S. without infringing process patents under section 271(g).

Finally, those who outsource need to consider whether the drug products or processes they develop will infringe early stage drug research patents. For example, the patents at issue in *Merck KGaA v. Integra Lifesciences I Ltd.*<sup>137</sup> claimed the RGD peptides themselves.<sup>138</sup> Therefore, while the use of those peptides in early stage drug research outside of the U.S. (under *Eli Lilly*) and the importation of information learned in the research brought into the U.S. (under *Housey*) might not be infringing activities, the ultimate sale of the peptides would potentially infringe.<sup>139</sup> By contrast, as discussed previously in this paper, “reach through” claims to products developed by patented research tools are likely not valid.<sup>140</sup> Hence, those products could likely be sold in the U.S. without infringing the research tool patents.<sup>141</sup> This untested analysis is further complicated by a perplexing recent jury decision which held the sales of two drug products infringed a patent claiming the mechanism of action of those products.<sup>142</sup>

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<sup>137</sup> 545 U.S. 193, 125 S. Ct. 2372 (2005).

<sup>138</sup> *Id.* at 2377.

<sup>139</sup> See 82 F.3d 1568 (Fed. Cir. 1996); 169 F. Supp. 2d 328 (D. Del. 2001).

<sup>140</sup> See *supra* note 25 and accompanying text.

<sup>141</sup> See, e.g., *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916 (Fed. Cir. 2004) (holding a patent directed to methods of selectively inhibiting certain enzyme activity did not sufficiently describe a compound [Celebrex®] that functioned by that mechanism). For further discussion, see Rakesh Mehta, *University of Rochester Corp. v. G.D. Searle & Co., Inc.: How to Lose Millions in Patent Royalties*, 29 DEL. J. CORP. L. 547 (2005).

<sup>142</sup> *Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.*, Civil Action No. 02-11280-RWZ, (D. Mass. May 4, 2006), LexisNexis Jury Verdicts and Settlement Report. In this unusual verdict, a federal jury held a patent owned by Harvard University, the Massachusetts Institute of Technology, and the Whitehead Institute, and licensed to Ariad Pharmaceuticals, was valid and infringed by the sale of Eli Lilly’s osteoporosis drug Evista® and septic shock drug Xigris®. The patent claims methods for treating human disease by regulating cell-signaling through the NF-kappa B molecular pathway. The jury awarded Ariad approximately \$65 million in back royalties as well as a 2.3% royalty rate on U.S. sales of the drugs until expiration of the patent in 2019. Eli Lilly has said that it will ask the trial judge to overturn the jury verdict and, if necessary, appeal the jury’s verdict. After an August evidentiary hearing, the trial court is now considering Lilly’s allegations that the Ariad patent is not enforceable. Also in August, following two *ex parte* requests for reexamination of the Ariad patent, the United States Patent and Trademark Office rejected 160 of the 203 claims as being not patentable. See Reexam. C.N. 90/007,503. Finally, in a separate proceeding, Amgen Inc. recently sued Ariad for a

Many have argued that Congress must intervene to clean up this clutter of jurisprudence and refine the Patent Laws, to ensure that infringers cannot subvert the Patent Laws to violate the rights of U.S. patentees. Some attempts have already been made to close the gaps in the law that have facilitated the use of outsourcing. Representative Jim Gerlach, for example, has proposed a new bill to amend section 271(g) to broaden the reach of the process patent infringement statute and define the term “product” to include both physical goods and information in any fixed format.<sup>143</sup> This would overcome the potential loophole created by the *Housey* decision.<sup>144</sup> It would also level the playing field between the U.S. and other countries in the context of where research for ultimate use in the U.S. can be performed. However, it could push U.S. companies to outsource even more of their drug development efforts. Under such a law, companies would probably carry out all of the drug research up to the final compound outside the United States.

Pharmaceutical companies, who choose to outsource their early stage drug research efforts and bring back elements of that research to the U.S., will undoubtedly devise a model for their business operations that minimizes their potential liability under the U.S. Patent Laws.<sup>145</sup> However, as mentioned earlier, multinational companies must be mindful of the entire legal and economic circumstances surrounding any transaction that outsource part of their businesses, in an effort to maximize their global profitability and minimize their liability at home and abroad.<sup>146</sup> The next section addresses the step in the business supply chain that entails selecting offshore locations for early stage drug research.

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declaratory judgment that two of Amgen’s drugs Enbrel® and Kineret®, both treatments for rheumatoid arthritis, do not infringe the Ariad patent and that the patent is invalid. *See* Amgen Inc. et al. v. Ariad Pharms., Inc., No. 06-259 (D. Del. Apr. 10, 2006). The cases and reexaminations are unlikely to be resolved for several years.

<sup>143</sup> *See* Informatics Act of 2005, H.R. 4208, 109th Cong. (2005).

<sup>144</sup> *See* 169 F. Supp. 2d 328 (D. Del. 2001).

<sup>145</sup> This model will operationalize the potential legal liability as best it can. *See supra* note 119 and accompanying text.

<sup>146</sup> *See supra* note 120 and accompanying text.

## IV. PATENT INFRINGEMENT OUTSIDE OF THE UNITED STATES

The principles underlying patent systems outside the United States are much the same as those in the United States. Both systems serve to encourage innovation and to promote the progress of science and technology. The principles of patent infringement are also much the same in that activities including the making, using, selling, offering for sale and importing of patented products or processes are generally held to be infringing. Likewise, the remedies for such infringement are also fairly standard and include injunctions for the future and damages (typically royalties) for the past, to make the patent holder whole.<sup>147</sup> International IP agreements between the United States and most other industrialized nations serve to promote global judicial comity and harmonize many basic tenets of patent infringement rulings and remedies.<sup>148</sup>

Attempts at global patent harmonization falter, however, in two main situations. The first is in countries where either the patent laws themselves are weak or the enforcement of those laws is virtually non-existent. South American countries, such as Brazil and Argentina, and Pacific Rim countries, such as Korea, Taiwan and China, fit this category.<sup>149</sup> As a consequence, many companies do not even file patent applications in these countries and, when they do file, companies have very low expectations that they could enforce the patent to prevent infringing activities.<sup>150</sup> Therefore, these countries are viable places for U.S.

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<sup>147</sup> *But see* eBay Inc. v. MercExchange, L.L.C., 126 S. Ct. 1837 (2006); *see also supra* note 19 and accompanying text.

<sup>148</sup> *See, e.g.*, General Agreement on Tariffs and Trade, Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, Apr. 15, 1994, LEGAL INSTRUMENTS—RESULTS OF THE URUGUAY ROUND, vol. 1 (1994), 33 I.L.M. 1125 (1994) [hereinafter GATT]; Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, LEGAL INSTRUMENTS—RESULTS OF THE URUGUAY ROUND, vol. 31, 33 I.L.M. 81 (1994) [hereinafter TRIPs]; North American Free Trade Agreement, Dec. 17, 1992, 32 I.L.M. 289 (pts. 1–3); 32 I.L.M. 605 (pts. 4–8) (entered into force Jan. 1, 1994) [hereinafter NAFTA].

<sup>149</sup> *See generally* John F. Duffy, *Harmony and Diversity in Global Patent Law*, 17 BERKELEY TECH. L.J. 685 (2002).

<sup>150</sup> *See generally id.*

pharmaceutical companies to outsource early stage drug research. Indeed, some U.S. companies have turned to research organizations in Taiwan to conduct early stage drug research.<sup>151</sup>

The second situation where harmonization between the United States jurisprudence, as applied to early stage drug discovery, and that of the rest of the world falters is in considering countries where patent laws are strong, enforcement is good and predictable but the laws or jurisprudence exempt certain research activities from patent infringement. Typically, this occurs in industrialized countries that have experienced the emergence of a global and knowledge-based economy and therefore place supreme importance upon technological advancements in society. In these countries, the use of patented subject matter to improve or advance scientific progress is paramount to protecting the rights of the innovator to exclude all uses of the patented inventions. Several of these countries, such as the United Kingdom, Germany and Japan, expressly recognize an experimental use exemption in their statutory law.<sup>152</sup> Those same countries have also generally read the statutory experimental use doctrine broadly in their jurisprudence.<sup>153</sup>

This section will examine the laws of three such countries or regions—Canada, the European Community and India. These are by and large the three most active jurisdictions for outsourced U.S. pharmaceutical research. It is known that these jurisdictions that are apt to be more liberal than the U.S. in permitting early stage research even in the face of patents. It is these jurisdictions that are thus the most fertile destinations for continued and future U.S. outsourcing of early stage drug research.

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<sup>151</sup> See *Synaptic Pharm. Corp. v. MDS Panlabs, Inc.*, 265 F. Supp. 2d 452 (D.N.J. 2002) (holding that the importation of reports containing the results of patented assays conducted in a laboratory in Taiwan did not constitute patent infringement because the diagnostic information provided to U.S. customers did not constitute a product made by a process under section 271(g)).

<sup>152</sup> Duffy, *supra* note 149, at 718 n.111.

<sup>153</sup> *Id.* at 718.

### A. Canada

The Canadian Patent Act includes a statutory exemption from infringement that is similar in some ways and very different in others to that of the U.S. section 271(e)(1) safe harbor exemption.<sup>154</sup> The Canadian provision, like section 271(e)(1), excludes from infringement activities that are for uses reasonably related to the development and submission of information for drug approval.<sup>155</sup> However, the provision is much more expansive than section 271(e)(1) in that it provides that the submission of information can be under any law of any country.<sup>156</sup> The U.S. provision is limited to submissions under U.S. federal laws which regulate the manufacture of drugs or veterinary biological products.<sup>157</sup>

This distinction is important. In the United States, only activities reasonably related to the submission of information to the FDA or other federal agency are within the safe harbor. Therefore, activities solely directed to approval outside the U.S. and not part of the U.S. application to obtain approval to market are infringing. By contrast, in Canada, the activities can be directed at approval in any country, whether or not they are also used to support approval in Canada. The Supreme Court of Canada has confirmed that the purpose of the regulatory exemption is to allow generic manufacturers to work with the patented invention, and generate data to the extent necessary, to facilitate lawful market entry in any country.<sup>158</sup> The Canadian exemption, thus, can be used to conduct research and generate data in Canada that will later be used solely and exclusively for submission to a foreign regulatory agency, such as the FDA.

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<sup>154</sup> The Canadian exemption, intended to meet NAFTA requirements, was derived from the U.S. provision and adopted shortly before the Hatch-Waxman Act was passed in the United States. It is often referred to as the “early working” exemption.

<sup>155</sup> Patent Act, R.S.C., ch. P-4, § 55.2(1) (1985) (enacted 1993, ch. 2, § 4; amended 2001, ch. 10, § 2).

<sup>156</sup> *Id.* The language broadly states “any law of Canada, a province or a country other than Canada that regulates the manufacture, construction, use or sale of any product.” *Id.*

<sup>157</sup> 35 U.S.C. § 271(a) (2001).

<sup>158</sup> *Bristol-Myers Squibb Co. v. Canada (Attorney Gen.)*, [2005] S.C.C. 26.

Similar to the U.S. safe harbor exemption, however, there are some restrictions on the type of data that is “reasonably related” to the development and submission of information under Canadian law. In *Pfizer Canada Inc. v. Apotex Inc.*,<sup>159</sup> a federal trial court held that activities relating to obtaining a provincial formulary listing for a medicine were not exempt from infringement under the “early working” exemption of section 55.2(1).<sup>160</sup> In rendering its verdict, the court rejected the notion that an application for a listing on the provincial formulary was reasonably related to the development and submission of information under law. Rather, the court reasoned that the purpose of the formulary listing is to preferentially enhance access to a market and not to regulate the “use or sale of any drug product” as required by the exemption.<sup>161</sup> This judicial construction of the reasonableness of the activity related to regulatory approval is comparable to the objective reality standard employed in the United States.<sup>162</sup>

While the limits of the statutory exemption have not been extensively tested in Canadian courts, a few recent cases have continued to expand the broad judicial reading of the exemption. For example, in *Abbott Laboratories v. Canada (Minister of Health)*,<sup>163</sup> the court held that the use of a substance that was being produced at an intermediate stage of a process in drug development but would not be submitted for regulatory approval itself was exempted from infringement under section 55.2(1).<sup>164</sup> Likewise, material that was routinely taken as samples during testing and which incorporated but did not constitute the patented drug product itself was deemed to be non-infringing use under the early working exemption.<sup>165</sup> The court held that section 55.2(1) is sufficiently broad so as to encompass intermediate lots of incoming raw

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<sup>159</sup> [2002] 20 C.P.R. 454.

<sup>160</sup> Patent Act, R.S.C., ch. P-4 (1985). In Canada, strict price controls are maintained in part by direct provincial funding of drug costs. A provincial formulary lists pharmaceutical products for which reimbursement is provided for residents on a provincial drug plan.

<sup>161</sup> *Pfizer Canada*, [2002] 20 C.P.R. 454.

<sup>162</sup> See *supra* notes 98–100 and accompanying text.

<sup>163</sup> [2006] F.C. 120 (Can.)

<sup>164</sup> *Id.*

<sup>165</sup> *Merck & Co. v. Apotex Inc.*, [2006] F.C. 524.

material “directed in one way or another” to the purpose of obtaining permission to sell the end product in Canada and the U.S., “even if such material is never sold and is ultimately destroyed”.<sup>166</sup> Based on these broad judicial constructions, therefore, Canada’s early working exemption could likely be invoked by U.S.-based pharmaceutical firms for just that: early working-stage drug research on patented inventions for purposes that are “reasonably related” to the development and submission of information for FDA approval.

In further support of early stage drug research, the Canadian Patent Act has an additional provision following the early stage exemption that says “for greater certainty,” the exemption does not affect any exception to infringement that exists at law in respect of acts done: (i) privately and on a non-commercial scale; (ii) for a non-commercial purpose; or (iii) in respect of any use, manufacture, construction or sale of the patented invention solely for the purpose of experiments that relate to the subject matter of the patent.<sup>167</sup> This provision served to codify the pre-existing common law research exception for experimental use in Canada.<sup>168</sup> No case law exists on the distinctions and applications of this section, perhaps because the Canadian common law research exemption is itself so incredibly broad.

In Canada, the common law research exemption consists essentially of a wholesale “fair dealing” exemption from infringement.<sup>169</sup> This doctrine allows the widespread use of

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<sup>166</sup> *Id.* at ¶¶ 156–58.

<sup>167</sup> Patent Act, R.S.C., ch. P-4, § 55.2(6) (1985).

<sup>168</sup> Sheldon Burshtein, *Experimental Use Exception to Patent Infringement in Canada*, BLAKE’S BULLETIN ON INTELLECTUAL PROP. REPORT, Oct. 2005, at 4, available at <http://www.blakes.com/english/publications/IP/IP-October2005.pdf> (last visited Oct. 14, 2006).

<sup>169</sup> *Micro Chem. v. Smith Kline & French Inter-Am.*, [1972] S.C.R. 506. This seminal case involved experiments to enable commercial production of a product for future compulsory licensing and laid the groundwork for a near limitless experimental use exemption. The Supreme Court stated: “Patent rights were never granted to prevent persons of ingenuity exercising their talents in a fair way. . . . if there be neither using nor vending of the invention for profit, the mere making for the purpose of experiment, and not for a fraudulent purpose, ought not to be considered within the meaning of the prohibition.” *Id.* at 519–20.

patented inventions for *bona fide* experimentation, which includes all of Judge Newman's philosophies and more: experimenting to establish that the invention works, to improve upon the invention, to better understand the invention, to find a new use for the invention, etc.<sup>170</sup> More recently, it has been held that any use of an invention that does not proceed beyond the "experimental and testing phase" is non-infringing.<sup>171</sup> Therefore, in Canada, neither the use of patented inventions to obtain information to be used for a regulatory approval process, nor the use of patented inventions for the purpose of experimental or testing activity is an infringing use.<sup>172</sup> Canada, thus, appears to be a fertile and hospitable country in which to outsource early stage basic drug research that is potentially infringing in the United States.

#### B. European Community

The 1975 Community Patent Convention ("CPC") signified an effort by the member states of the then European Economic Community to bring their laws relating to patents into conformity.<sup>173</sup> Article 31 of the CPC provides for a statutory exemption from patent infringement that encompasses both the U.S. common law and safe harbor exemptions in one.<sup>174</sup> It states that rights conferred by a patent shall not extend to "(a) acts done privately and for noncommercial purposes; or (b) acts done for experimental purposes relating to the subject matter of the patented invention."<sup>175</sup> Although the CPC is not currently in force, it nonetheless carries weight. Various individual member states of

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<sup>170</sup> European Econ. Cmty.: Plenipotentiary Conference on the Cmty. Patent art. 31, Dec. 15, 1975, 15 I.L.M. 5 (now Article 27(b) of the revised CPC 1989) [hereinafter CPC].

<sup>171</sup> *Dableh v. Ontario Hydro*, [1996] 68 C.P.R. 129.

<sup>172</sup> See Burshtein, *supra* note 168. See also Judith Robinson, Presentation on Canadian Patent Law at the Biotechnology Industry Organization 2006 Annual International Convention (Apr. 12, 2006).

<sup>173</sup> CPC, *supra* note 170.

<sup>174</sup> *Id.*

<sup>175</sup> *Id.*

the European Community have implemented several of its provisions in their national laws.<sup>176</sup>

While different member states have construed the above exemption in different ways, most courts addressing the issue have acknowledged that the experimental purposes of subsection (b) need not be totally divorced from any commercial purpose.<sup>177</sup> The degree to which the courts have exempted acts having a commercial purpose, however, has widely diverged across member states. Notably, the two most influential European jurisdictions, the U.K. and Germany, stand the farthest apart in their interpretations of the scope of their respective experimental use exceptions.

In the U.K., the leading case regarding the experimental use exception is *Monsanto Co. v. Stauffer Chemical Co. & Another*.<sup>178</sup> In this case, Stauffer sought to vary an injunction to allow it to practice under Monsanto's patent for the purposes of carrying out field trials with an infringing herbicide and relied on subsection 60(5)(b) of the 1977 U.K. Patents Act to do so.<sup>179</sup> The Court struck a compromise in the context of Stauffer's activities. It ruled that experimentation conducted on Stauffer's premises was protected by subsection 60(5)(b), even if it had a commercial purpose, as long as it was carried out to discover something unknown, i.e., to test a hypothesis, or to find out whether something will work in specific or different conditions.<sup>180</sup> However, Stauffer's activities conducted elsewhere, "in order to amass information to satisfy a third party" were not covered by the

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<sup>176</sup> For example, both the U.K. exemption, contained in section 60(5)(b) of the Patents Act 1977 and the German "experimentation privilege," contained in Section 11 No. 2 of the German Patents Act 1981, were taken nearly word-for-word from the CPC.

<sup>177</sup> See *infra* notes 179–183 and accompanying text.

<sup>178</sup> [1985] R.P.C. 515 (C.A. (Civ. Div.)).

<sup>179</sup> Section 60 of the U.K. Patents Act provides a statutory definition of direct and indirect patent infringement in subsections 1 and 2, respectively. Subsection 5 exempts activities, as recited in the CPC, that are "done privately and for purposes which are not commercial" or "done for experimental purposes relating to the subject matter of the invention" from such infringement. *Id.* at 535–36.

<sup>180</sup> *Id.* at 542.

experimental use exception.<sup>181</sup> In so holding, the court expressly held Stauffer's experiments with the patented herbicide for the purpose of obtaining marketing approval for a competing identical product to be infringing. The U.K. is, thus, one of the few countries that has taken a narrower approach than the U.S. with regard to its research exemption in the regulatory approval area.

In Germany, by contrast, the two leading cases that have shepherded in a broad experimental use exception are, aptly named, *Klinische Versuche* ("Clinical Trials") I and *Klinische Versuche* ("Clinical Trials") II.<sup>182</sup> In *Clinical Trials I*, the defendants were engaged in clinical trials to find new uses for a patented drug containing the active substance interferon-gamma.<sup>183</sup> The Federal Supreme Court held that the clinical trials were protected by the "experimental purposes relating to the subject matter of the patented invention" language of the German experimentation privilege.<sup>184</sup> In so holding, the Court reasoned that the statutory provision makes no qualitative or quantitative limit on the experimental acts.<sup>185</sup> It thus cannot matter whether the experiments are used only to scientifically verify the statements made in the patent or to obtain further research results, and whether they are employed for wider purposes, such as commercial interests.<sup>186</sup>

*Clinical Trials II* buttressed the above holding. It exempted from infringement clinical experiments with a patented erythropoietin ("EPO") that sought to specifically distinguish that EPO from the one then on the market and to obtain approval to market the modified EPO.<sup>187</sup> This holding solidified the broad

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<sup>181</sup> *Id.* The location of the activities was likely not important. Rather, the intent of the activities—to find out new information or to merely convince a third party to allow marketing—was the important factor.

<sup>182</sup> Bundesgerichtshof [BGH] [Federal Supreme Court] May 18, 1995, *Klinische Versuche* (Clinical Trials) I, [1997] R.P.C. 623 (F.R.G.) [hereinafter *Clinical Trials I*]; Bundesgerichtshof [BGH] [Federal Supreme Court] Apr. 17, 1998, *Klinische Versuche* (Clinical Trials) II, [1998] R.P.C. 423 (F.R.G.) [hereinafter *Clinical Trials II*].

<sup>183</sup> *Clinical Trials I*, [1997] R.P.C. 623.

<sup>184</sup> Patentgesetz [Patents Act], Dec. 16, 1980, BGBl. 1981 I 2, § 11 no. 2 (F.R.G.).

<sup>185</sup> *Clinical Trials I*, [1997] R.P.C. 623.

<sup>186</sup> *Id.* at 639.

<sup>187</sup> *Clinical Trials II*, [1998] R.P.C. at 423–24.

applicability of Germany's experimental use exemption. It allows third parties to test patented inventions for the express purpose of obtaining approval to market their own products if one purpose of the tests is to learn something new. The *Clinical Trials II* decision resonates with the U.S. holdings that read "solely" out of the safe harbor statute.<sup>188</sup> The German Court did not concern itself with whatever additional motivations might exist or whatever purposes the obtained results would ultimately serve beyond the actual experimental purpose of the acts.<sup>189</sup> Ultimately, in Germany, as long as the experiments are directly aimed at obtaining *new information*, the research is likely to be exempt without regard to its industrial purpose.<sup>190</sup>

As suggested in the above-noted cases, both U.K. and German courts are likely to exempt from infringement tests to discover new information. Beyond that, the courts will look to the underlying purpose of the experiments. In the U.K., preclinical experiments conducted to obtain regulatory approval to market will not be permitted.<sup>191</sup> In Germany, however, these experiments are broadly exempt from infringement and data obtained therein may plainly be used to obtain marketing approval and advance science alike.<sup>192</sup> In terms of early stage drug research, European countries that veer with Germany on the broad exemption side will be preferential locations for outsourcing. At present, these countries include Belgium, France, and Italy.<sup>193</sup> In the future, this group may expand.

The European Union's Parliament and Council has adopted a Directive on the Community Code relating to medicinal products for human use, which specifically provides for an exemption from patent infringement to "improve the operation of the marketing authorization procedures" and conduct the necessary studies and

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<sup>188</sup> See *supra* note 95 and accompanying text.

<sup>189</sup> *Clinical Trials II*, [1998] R.P.C. at 431.

<sup>190</sup> See *Clinical Trials I*, [1997] R.P.C. at 645.

<sup>191</sup> See, e.g., *Monsanto Co. v. Stauffer Chemical Co.*, [1985] R.P.C. 515 (C.A. (Civ. Div.)).

<sup>192</sup> See, e.g., *Clinical Trials I*, [1997] R.P.C. 623.

<sup>193</sup> Michael Gilbert, Presentation on European Patent Law at the Biotechnology Industry Organization 2006 Annual International Convention (Apr. 12, 2006).

trials needed to obtain marketing authorization—the so-called “EU-Bolar” provision.<sup>194</sup> Although the impact of this Directive on the patent laws of member states is not yet clear, it is likely to render the European Community an even more attractive offshore partner for early stage preclinical and clinical pharmaceutical research.

### C. India

Like many developing countries, India maintains fairly weak patent laws in order to provide relatively inexpensive products to its citizens and provide a favorable infrastructure for local facilities of multinational corporations.<sup>195</sup> In an international arbitrage game of sorts, India is offering competitive contract research services and technology transfer programs for industrialized countries, in the hope that the Indian economy will profit in return.<sup>196</sup> Indeed, many multinational companies have found it highly profitable to outsource various portions of their research operations to India<sup>197</sup> and, in turn, India’s economy has posted an average growth rate of more than 7% in the decade since 1994.<sup>198</sup>

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<sup>194</sup> Council Directive 2004/27, 2004 O.J. (L 136) 34 (EC).

<sup>195</sup> See Suresh Koshy, *The Effect of TRIPs on Indian Patent Law: A Pharmaceutical Industry Perspective*, 1 B.U. J. SCI. & TECH. L. 4, 4 (1995).

<sup>196</sup> See generally *id.*

<sup>197</sup> See, e.g., DOMINIC WILSON & ROOPA PURUSHOTHAMAN, GOLDMAN SACHS GLOBAL ECONOMICS PAPER NO. 99, DREAMING WITH BRICS: THE PATH TO 2050 (Oct. 2003), available at <http://www.gs.com/insight/research/reports/99.pdf>.

<sup>198</sup> *The India Nuclear Deal: Implications for Global Climate Change: Testimony before the U.S. Senate Committee on Energy and Natural Resources*, 109th Cong. (July 18, 2006) (statement of David G. Victor, Adjunct Senior Fellow for Science and Technology, Council on Foreign Relations), available at [http://www.cfr.org/publication/11123/india\\_nuclear\\_deal.html](http://www.cfr.org/publication/11123/india_nuclear_deal.html). Currently, it is estimated that anywhere from one-half to two-thirds of all Fortune 500 companies are outsourcing to India. Stephanie Overby, *Inside Outsourcing in India*, CIO MAGAZINE, June 1, 2003, available at <http://www.cio.com/archive/060103/outsourcing.html>. The most popular services for outsourcing include rendering software programming services and performing clinical trials for pharmaceutical companies. See *Watch Out India! China Wants to Be Outsourcing Powerhouse Too*, YAHOO! NEWS, [http://news.yahoo.com/s/afp/20060908/tc\\_afp/china\\_economybusinessitoutsourcing\\_060908110643](http://news.yahoo.com/s/afp/20060908/tc_afp/china_economybusinessitoutsourcing_060908110643) (last visited Sept. 13, 2006); Arun Bhatt, *Clinical Trials in India: Pangs of Globalization*, 36 INDIAN J. PHARMACOLOGY 207, 207 (2004), available at <http://www.ijp-online.com/article.asp?issn=0253-7613;year=2004;volume=36;issue=4;spage=207;epage=208;aulast=Bhatt>.

The Patents Act of 1970 governs current Indian patent law.<sup>199</sup> The Indian Patents Act not surprisingly includes a statutory exemption from infringement that is much broader than that of the U.S. section 271(e)(1) safe harbor exemption. The Indian provision is similar to the U.S. safe harbor in that it excludes from infringement, activities for uses reasonably related to the development and submission of information for drug approval.<sup>200</sup> The Indian provision is much broader than the U.S. safe harbor and similar to the Canadian early working exemption in that it provides that the submission of information can be under any law of any country.<sup>201</sup> Moreover, unlike the U.S. safe harbor exemption and the Canadian early working exemption, there are no judicial restrictions on the type of data that is “reasonably related” to the development and submission of information under Indian law.<sup>202</sup>

In further support of early stage drug research, the Indian Patents Act also includes an experimental use exemption. The exemption provides that any patented machine or apparatus or patented process or any article made by the use of a patented process “may be used, by any person, for the purpose merely of experiment or research including the imparting of instructions to pupils.”<sup>203</sup> There is no jurisprudence construing this provision. However, Indian courts would likely consider the following three elements in construing the breadth of this statute: (a) the so-called Golden Rule: the literal meaning of the statute; (b) the statement of objects and reasons of the statute (i.e. the legislative history); and (c) the jurisprudence in other jurisdictions.<sup>204</sup> Considering these factors, an Indian court would be likely to construe the above exemption broadly and without a limit to working on the subject matter of the invention.

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<sup>199</sup> The Patents Act, No. 39 of 1970; India A.I.R. Manual (1979), vol. 27 [hereinafter The Indian Patents Act].

<sup>200</sup> *Id.* at § 107(A).

<sup>201</sup> The language broadly states “any law . . . in India, or in a country other than India, that regulates the manufacture, construction, use or sale of any product.” *Id.*

<sup>202</sup> Himanshu Kane, Presentation on Indian Patent Law at the Biotechnology Industry Organization 2006 Annual International Convention (Apr. 12, 2006).

<sup>203</sup> The Indian Patents Act, *supra* note 199, § 47(3).

<sup>204</sup> Kane, *supra* note 202.

There is also no distinction in the Indian Patents Act between the use of patented inventions in the course of research as distinguished from the use of patented inventions for a commercial purpose. Therefore, under Indian patent law, no infringement liability attaches for the use of a patented invention in research for commercial purposes. Fundamentally, Indian courts tend to encourage and maintain a continuous flow of research and innovation to support their rapidly growing economy. Indian courts “lean against monopolies.”<sup>205</sup> They seek to accelerate the pace of research, discovery and growth in their services sector.<sup>206</sup> Overall, the legal and business climate of India makes it another appealing country in which to perform early stage basic drug research that may be patent infringing activities in the United States. The recent and rapid development of “Genome Valley” in Hyderabad is direct evidence of this phenomenon.<sup>207</sup>

#### V. A NEED FOR INCREASED HARMONIZATION

“The patent system has become sand rather than lubricant in the wheels of American technological progress.”<sup>208</sup> This statement expresses the frustration of those who believe that U.S. power and leverage are declining in view of an unresolved tension between the legislative intent and the judicial application of the Patent Laws.<sup>209</sup> Indeed, recent U.S. decisions on patent infringement in drug research have created a quandary that may end up forcing

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<sup>205</sup> *Niky Tasha India Pvt. Ltd. v. Gadgets Pvt. Ltd.*, A.I.R. 1985 Delhi 141.

<sup>206</sup> *See, e.g., WILSON & PURUSHOTHAMAN, supra* note 197. The growth rate of India’s service exports in 2002 was 8% in comparison to 5% worldwide and its services sector accounts for more than half of the country’s overall Gross Domestic Product. Much of the rise in the service sectors is attributable to the growth of India’s information technology and industrial research markets. *See Economy for the Month, Indian Economy*, ECONOMYWATCH.COM, <http://www.economywatch.com/economyoverview/oct2005-economy.html#s> (last visited Sept. 13, 2006).

<sup>207</sup> Genome Valley consists of a large biotechnology hub that advertises itself as a state-of-the-art center providing all stages of research, training, collaboration and manufacturing activities for biotechnology companies worldwide. *See* Genome Valley, <http://www.genomevalley.org> (last visited Sept. 26, 2006).

<sup>208</sup> Adam B. Jaffee, *A Patent System on Trial: Innovation and Its Discontents*, 70 PAT., TRADEMARK & COPYRIGHT J. 709, 709 (2005).

<sup>209</sup> *See id.*

U.S. companies to outsource a majority of their early stage research. At present, some pharmaceutical companies are addressing these challenges with “product sourcing solutions,” which euphemistically refer to going offshore. Other smaller research-based companies and academic institutions are simply using patented technology without a license and informally invoking a de facto broad research exemption.<sup>210</sup>

This self-help response of the drug and research industries to the patent situation is perhaps understandable. The current jurisprudence fundamentally fails to recognize how drug research is done. Pre-clinical testing and the early stage screening of compounds to find a lead candidate are part and parcel of development and the approval process. U.S. courts have perhaps paid too little attention to the regulatory approval scheme in their jurisprudential reasoning. Given that the FDA requires an incredible amount of preclinical research to be done before a new drug compound will be approved,<sup>211</sup> the courts (with increased instruction from Congress) need to recognize and help establish a means for keeping this value-added research in the United States. Yet, in that endeavor, the courts still need to encourage global expansion of the industry and the patent laws and to provide an appropriate value for research tool screening patents and methodologies. This seeming Gordian knot is something the Supreme Court, perhaps understandably, side-stepped in *Merck KgaA v. Integra LifeSciences I Ltd.*<sup>212</sup>

It would be a failure of the patent system if corporate research efforts were shunted to offshore sites merely to evade U.S. patent infringement. This costs jobs and hurts the economy. More importantly, the patent laws and the jurisprudence construing them should not incentivize companies to locate the most valuable intangible aspects of their business outside the United States. Congress should pay attention to the public policy considerations that have led many other countries to expand the research exemption to patent infringement, far beyond that which U.S.

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<sup>210</sup> See generally Walsh et al., *supra* note 26.

<sup>211</sup> See *supra* note 103 and accompanying text.

<sup>212</sup> 125 S. Ct. 2372 (2005); see also *supra* note 117 and accompanying text.

courts have done. Preferably, the courts or the legislature could do this by expanding the breadth of the safe harbor exemption to provide a more explicit and useful exemption to patent infringement and thereby encourage pharmaceutical companies to conduct early stage drug research in the United States.

Given the inevitability of globalization, a harmonized patent regime that encompasses an expanded safe harbor research exemption for early stage drug research may well be the remedy. Without it, the trend toward exporting research to offshore locations could accelerate and the race to the bottom, lowest common denominator, will proceed at the great expense of the healthcare and economic infrastructure of the United States.

#### A. *Proposals for Reform*

A broadening of the safe harbor exemption coverage would provide enhanced convergence with and predictability in the global market. It would also enable drug companies and other researchers to better plan the operations of their businesses and to decide how best to conduct such early stage drug research work. Yet, it would still encourage globalization because there would be no artificial barriers to the industry and its research.

The proper scope of the safe harbor exemption to infringement, however, cannot be set in a vacuum. Because a broadened exemption will effectively tear down protectionist scaffolding and devalue the worth of research tool patents, some accommodation must be given to the developers of these important properties. As indicated earlier, research tool companies make important contributions to drug research.<sup>213</sup> Any market-wide depreciation in the value of these tools will reduce the likelihood that the research tool industry will grow and this will disadvantage global drug development in the long term.

There are no easy solutions. Nonetheless, efforts should be made to find remedies to treat research tools in a principled, cooperative manner, as an alternative to the traditional adversarial

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<sup>213</sup> See *supra* notes 14 and 22 and accompanying text.

process of patent infringement litigation.<sup>214</sup> Goodwill, for example, plays a strong role in multinational companies and could be capitalized upon to generate growth and investment in the research tool industry. One prospective remedy could include some sort of tax-based incentive for pharmaceutical firms to participate in “goodwill” programs that would invest a portion of the firms’ revenues in future research and development programs at research tool companies. Such an allocation of revenues would benefit that industry as well as the drug industry, which needs those tools for ongoing research.

Large drug companies might well be amenable to such programs, when viewed as an opportunity cost. Rather than making tax payments on divested research operations and on the subsequent transfers of intangible assets into the U.S., drug companies could instead invest that income in a program that would fund domestic research tool operations and then receive profit-enhancing tax deductions for their investments. These offerings would in turn help compensate the research tool companies for their contribution to the early stage research that was performed under the safe harbor exemption in the United States. Accordingly, the investment rate of any program could be comparable to the royalty payments that the company would have made had the research not been exempted from infringement or moved offshore.

This type of a solution would serve to better protect the consumer, as the drug research would now be conducted using helpful research tools in the United States and thus under the assiduous watch of U.S. regulatory agencies. It would also be

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<sup>214</sup> Models in other industries could provide some guidance, for example, the compulsory licensing scheme in copyright law, where the government requires users to pay royalties into a common fund for the privilege of retransmitting certain copyrighted broadcasts. *See* 17 U.S.C. §§ 111, 119 (2000). Another model would be Advance Pricing Agreements (“APA”) that are used to remedy transfer pricing disputes in tax law. An APA involves a forward contract between the U.S. government and a taxpaying entity (e.g., a multinational drug company), by which both parties agree to a transfer pricing method for the company’s tax payments in advance. This allows the company to obtain certainty as to part of its future tax burden. *See* Gustafson et al., *TAXATION OF INTERNATIONAL TRANSACTIONS* 625, 667–681 (West Group Publishing 2001).

economically effective, in that the drug industry's prior use of the research tool would contribute to its subsequent value. Goodwill programs could therefore allocate funding in a manner commensurate with the worth of the specific tool or company, i.e. as a percentage of the present value of the future earnings of the drug that was developed, in part, through the use of that tool.<sup>215</sup>

### *B. International Trade Considerations*

However, globalization means that individual measures in individual countries cannot affect the value of research tools in the global marketplace. A contextual mechanism would still be needed to counter any practice that would stifle the research tool industry in the global marketplace. For example, if U.S. drug companies continued to outsource their early stage research after an expansion of the safe harbor exemption in order to avoid making the appropriate payments to the goodwill programs (or to otherwise compensate research tool companies), such a practice would thwart the research tool industry. In this respect, the jurisprudence involving unfair competition as regulated by the United States International Trade Commission ("ITC") could be of assistance when considering the extent to which information or products developed through the use of unfunded research tools offshore should be equitably allowed into the United States. Any practice that sought to evade compensating research tool companies would not constitute patent infringement but would still be fundamentally unfair to the research tool industry. A claim predicated upon such facts would potentially fall within the ITC's jurisdiction.

The ITC regulates activities of entities that unfairly compete with U.S. industries in the United States under the Tariff Act of 1930.<sup>216</sup> Prior to the enactment of 35 U.S.C. § 271(g),<sup>217</sup> a U.S.

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<sup>215</sup> In this manner, the goodwill funding program would resemble an APA in that a company could determine the relative value of the tool and weigh it to reflect its relative contribution to the overall profitability of the drug company's business. Presumably this could also be done in advance to allow the drug company to better manage its investment burden.

<sup>216</sup> Tariff Act of 1930, Pub. L. No. 76-515, 54 Stat. 724 (1930), amended by 19 U.S.C. § 1337(a)(1)(A)(i)-(ii) (1982).

patent owner's only legal recourse was to seek an exclusion order for imported products made by its patented process from the ITC under the Tariff Act.<sup>218</sup> With the emergence of global competition, opposition to any perceived U.S. extraterritorial jurisdiction for unfair trade has waned and the Tariff Act's reach has broadened.<sup>219</sup> Specifically, section 1337(a)(1)(B)(ii) of the Tariff Act makes it unlawful to import into the United States articles that are made, produced, processed or mined under or by means of a process covered by the claims of a United States patent.<sup>220</sup>

The U.S. biotechnology industry has made attempts to seek relief from the ITC for acts performed abroad. In one of a string of complaints filed by Amgen with the ITC, Amgen argued that the Congressional intent of Tariff Act section 1337(a)(1) was to provide assistance to emerging U.S. industries to compete in a global marketplace without interference due to unfair acts of foreign competitors.<sup>221</sup> In this case, Chugai Pharmaceuticals Co. Ltd. was using Amgen's patented intermediates (DNA sequences and host cells) outside of the U.S. to import into the U.S. a product, EPO, that was made using the patented intermediates.<sup>222</sup> To remedy the situation, Amgen sought an injunction, based on unfair trade practices, to bar the importation and sale of the drug by the foreign corporation's U.S. subsidiary (Chugai U.S.A. Inc.).<sup>223</sup>

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<sup>217</sup> See *supra* Part III.C., describing infringement through importation.

<sup>218</sup> 19 U.S.C. § 1337(f)(2) provides for injunctive relief, preventing goods from entering the United States, and issue cease and desist orders against corporations importing the goods. Unlike 35 U.S.C. § 271(g), the Tariff Act does not provide for an award of damages.

<sup>219</sup> For a general discussion of the effects of globalization on the aggrandizement of the U.S.'s jurisdictional reach, see Terry Calvani, *Conflict, Cooperation, and Convergence in International Competition*, 72 ANTITRUST L.J. 1127 (2005).

<sup>220</sup> 19 U.S.C. § 1337(a)(1)(B)(ii) (2000).

<sup>221</sup> In the Matter of Certain Recombinant Erythropoietin, 10 U.S.P.Q. 2d (BNA) 1906 (U.S.I.T.C. 1989). Amgen alleged a violation under section 1337(a)(1)(A)(i)–(ii) (1994), making unlawful any practice that would destroy or substantially injure an industry in the United States; or prevent the establishment of such an industry. *Id.* at 1907 n.4. It is worth noting that the now thriving field of biotechnology was then in its infancy and Amgen was then a small company. Its EPO product (EPOGEN®) was the biotech industry's first blockbuster and Amgen is now the world's largest biotech firm and a Fortune 500 company.

<sup>222</sup> *Id.* at 1908

<sup>223</sup> *Id.* at 1907

The ITC dismissed Amgen's complaint for lack of subject matter jurisdiction.<sup>224</sup> It stated that section 1337 of the Tariff Act may be invoked only when process patent claims exist, i.e. those that actually describe the processes that Chugai performed abroad.<sup>225</sup> On appeal, the Federal Circuit likewise held that that importation of the drug made from those intermediates was not a violation of section 1337(a) because Amgen's product claims did not cover the process performed overseas.<sup>226</sup> The Federal Circuit enunciated that section 1337(a) was enacted to prohibit imports made using a patented *process* abroad and not to prohibit imports made by a process abroad that employs a patented *article*.<sup>227</sup>

This narrow construction of section 1337(a), however, must be considered in the context of the broader intent of the statute, which was to prohibit doing offshore that which could not lawfully be done in the United States.<sup>228</sup> Other provisions of section 1337(a) restrict, for example, unfair methods of competition and unfair acts in the importation of articles that may restrain or monopolize trade or commerce in the United States.<sup>229</sup> Currently, if drug companies decide to outsource their early stage drug research to avoid patent infringement liability, they may well be engaging in the practice of unfair trade under such provisions. Likewise, if drug companies in the future decide to outsource their early stage drug research to avoid making payments to a research tool funding program or agency, they might also then be engaging in the practice of unfair trade under such provisions.

Indeed, the Federal Circuit has expanded the ITC's jurisdiction to potentially adjudicate and impose liability in such cases. In *Kinik Co. v. ITC*,<sup>230</sup> the Federal Circuit affirmed the ITC's holding that the defenses to patent infringement available under section 271(g) do not apply to infringement actions involving the offshore

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<sup>224</sup> *Id.* at 1911.

<sup>225</sup> *Id.* at 1909, 1914.

<sup>226</sup> *Amgen, Inc. v. United States Int'l Trade Comm'n.*, 902 F.2d 1532, 1540 (Fed. Cir. 1990).

<sup>227</sup> *Id.* at 1538.

<sup>228</sup> *Id.* at 1539.

<sup>229</sup> 19 U.S.C. § 1337(a)(A)(iii).

<sup>230</sup> 362 F.3d 1359, 1363 (Fed. Cir. 2004).

practice of a patented process before the ITC.<sup>231</sup> The Federal Circuit reasoned that a victim of unfair competition should not be limited in his or her ability to be remedied by the defenses to patent infringement.<sup>232</sup> Under this ruling, therefore, research tool companies may be able to obtain relief, based on the unfair practice of outsourcing early stage drug research to evade *either* research tool patents *or* future payments to a research tool-funding program, upon importation of the products of those processes or information developed from them into the United States. This route might thus ultimately provide an equitable remedy to counterbalance an expansion of the safe harbor exemption within the global marketplace, while still encouraging international expansion.

The bottom line is that the research playing field between the U.S. and other countries needs to be leveled. An increased harmonization of patent laws on a global scale will serve to increase the value of all patents and, in turn, increase the incentive to innovate and to disclose new technologies and inventions, so as to ultimately enhance technological innovation in this country and around the world. This was the rationale put forth in the early 1980's to support the creation of the Federal Circuit.<sup>233</sup> Indeed, throughout its existence the Federal Circuit has repeatedly invoked its congressional mandate of promoting "national patent law uniformity" and has expansively interpreted and defined its jurisdiction in furtherance of that goal.<sup>234</sup> U.S. patents are worth more today as a result of this change.<sup>235</sup>

This rationale should thus be used again to achieve a globalized application of the patent laws to reduce the uncertainty regarding, *inter alia*, the scope of enforceability of research tool patents and to increase the indelible value of innovation in a global market.

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<sup>231</sup> See generally Richard L. Rainey & Paul M. Schoenhard, *Tariff Act and Imports of Products Manufactured by Patented Processes*, INTELLECTUAL PROPERTY-USA, June 14, 2004.

<sup>232</sup> *Kinik Co.*, 362 F.3d at 1362.

<sup>233</sup> See e.g., SCHWARTZ, *supra* note 17, at 5.

<sup>234</sup> See Gerald J. Flattmann, Jr. & Krista M. Rycroft, *Is Uniformity in Patent Law Still Achievable?*, N.Y. L.J., May 12, 2003, at S6.

<sup>235</sup> *Id.*

This increased certainty will also serve to sustain the growth of pharmaceutical research in the United States, and will embrace the integration of information across borders. A broader read of the safe harbor exemption to patent infringement and to unfair competition laws (in view of future research tool funding mechanisms) will give pharmaceutical companies the ability to capitalize upon their intangible business assets while allowing scientific innovation to continue in the United States.