VIRGINIA JOURNAL OF LAW & TECHNOLOGY

SPRING 2019 UNIVERSITY OF VIRGINIA VOL. 22, NO. 05

The Promise and Peril of Industry-Specific Patent Law

MAXIMILIAN SCHELLHORN*

* PhD candidate at the University of Osnabrueck, Germany, LL.M. graduate from the University of Virginia (2018). The author would like to thank John F. Duffy and Jennifer E. Catterson for their comments on earlier drafts.

ABSTRACT

Traditionally patent law has treated inventions similarly independent of their industrial origin and in 1996 the tradition was cast into law by the prohibition of discrimination as to the field of technology in Article 27(1) of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs Agreement). It is not a secret that modern patent law has occasionally deviated from this fundamental principle. Some of these deviations re-level the playing field. Others, however, are discriminatorily implemented and are based on dubious arguments. The latter type of industry-specific patent laws undermines the general legitimacy of a nuanced approach to patent law and opens the floodgates for concerns about special-interest groups crafting their own favored patent law.

This Article recognizes the important role of courts and the lawmaker in shaping contemporary patent law in a time of increasing diversity among industries. It argues that industry-specific law should be approached reservedly without denying its place in modern patent law. Relics of early industry-specific laws that found their way into the Patent Act through the Hatch-Waxman Act in 1984 demonstrate both the need for and promise of nuanced patent law on one hand and the associated perils of discrimination and the influence of special-interest groups on the other. The courts' nuanced approach to patent remedies is a promising supplement to statutory solutions. However, due to the inherent limitations of court-introduced diversity it does not rule out Congress's role in shaping a contemporaneous patent law.

TABLE OF CONTENTS

I. INTRODUCTION

When Congress introduced the Patent Act of 1952, both Houses of Congress seemed to accept the premise that patent protection shall be available "for anything under the sun that is made by man."[1] That premise opened the door of patent protection for a wide variety of inventions, but it alone does not guarantee that inventions in diverse industries will be treated equally. Yet lawmakers, including those in the United States, largely rely on a homogenous corpus of regulations with few adjustments for disparate circumstances in different industries. In addition to the long-standing tradition of American patent law, the TRIPs Agreement also favors a uniform approach to patent law. The TRIPs Agreement stipulates in Article 27(1) that "patents shall be available for any inventions . . . in all fields of technology" and "that . . . patent rights [shall be] enjoyable without discrimination as to . . . the field of technology."[2]

In rare instances, lawmakers have tailored regulations to specific industries. When speaking of industry-specific patent law, one may instantly think of the extension of the patent term codified in §156 of the Patent Act prolonging the lifetime of patents covering products or methods subject to pre-marketing approval, or the physician immunity clause in §287(c) of the Patent Act.[3] The exceptions from the standard direct infringement requirement of §271(a) found in §271(e) of the Patent Act are another example.

In addition, courts have developed the law and, in particular, the field of remedies in a way that impacts some industries more than others.

---

[1] Diamond v. Diehr, 450 U.S. 175, 182 (1981) (citing S. REP. NO. 82-1979, at 5 (1952); H.R. REP. NO.82-1923, at 6 (1952)).

[2] Graeme B. Dinwoodie & Rochelle C. Dreyfuss, *Diversifying Without Discriminating: Complying with the Mandates of the TRIPS Agreement*, 13 MICH. TELECOMM. & TECH. L. REV. 445, 456 (2007) (arguing that the TRIPs Agreement does not generally preclude industry-specific laws and conclude that "industry-specific patent laws are fully consistent with the comparative advantages philosophy that undergirds the modern trade regime."); JOHN R. THOMAS, CONG. RESEARCH SERV., R43264, TAILORING THE PATENT SYSTEM FOR SPECIFIC INDUSTRIES 12 (2015) (concluding: "As a result, the membership of the United States within the WTO provides a possible constraint against tailoring the patent system to meet the perceived needs of specific industries.").

[3] THOMAS, *supra* note 2, at 6.

In this context, the Supreme Court's decision *eBay v. MercExchange* and the Federal Circuit's decision *Lucent v. Gateway* were understood as gateways for industry-specific fine tuning.[4]

The "One Size Fits All" approach of intellectual property law and patent law in particular, has been subjected to scholarly debate for more than a decade.[5] Increasing diversity among different industries is fuel for a more nuanced approach of patent law. However, such an approach comes together with the risk of discrimination against certain technologies and is susceptible to influence by special-interest groups. Noteworthily, not every differentiated treatment can be considered discrimination. Discrimination occurs when similar circumstances are treated differently, but not when *different* circumstances are treated differently. Indeed, this Article reveals that the current law struggles with the inherent perils of industry-specific law and shows that some of the arguments in favor of their implementation are questionable. However, it argues that, although the refinements of the widely uniform patent system are perilous and a juggling act that lawmakers and courts have not yet performed satisfactorily, industry-specific patent law is both promising and needed.

Part II of this Article illustrates the challenges the patent system faces in different industries and explains why industry-specific law has traditionally been approached with reservation. Part III examines industry-specific regulations introduced through the Hatch-Waxman Act. It shows both how industry-specific rules are necessary to counterbalance regulatory schemes and how the Hatch-Waxman Act discriminates against other industries that are subject to similar regulatory obligations. Following this, part IV surveys the physician immunity clause – which is often seen as a paradigm of industry-specific legislation. Part V examines how a flexible approach to remedies allows

[4] *Id.* at 12 ("The timely issuance of *eBay* and *Lucent v. Gateway* may have contributed to congressional belief that courts were appropriately addressing injunctions and damages, respectively. As a result, Congress did not endeavor to reconcile the perceived needs of industries with different innovation and marketplace environments.").

[5] Michael W. Carroll, *One for All: The Problem of Uniformity Cost in Intellectual Property Law*, 55 AM. U. L. REV. 845 (2006); Andrew F. Christie & Fiona Rotstein, *Duration of Patent Protection: Does One Size Fit All?*, 3 J. INTELL. PROP. L & PRAC. 402 (2008); Michael W. Carroll, *One Size Does Not Fit All: A Framework for Tailoring Intellectual Property Rights,* 70 OHIO ST. L.J. 1361 (2009).

courts to craft an industry-specific approach to patent law. The different types of industry-specific rules and doctrines are characterized in part VI. Against the backdrop of the promise and perils of industry-specific patent law, part VII concludes that there may be a promising future for a nuanced patent law, but a reserved approach is necessary.

II. DIVERSE INDUSTRIES IN A GREATLY UNIFORM PATENT SYSTEM

Industries differ with respect to a wide variety of aspects in the innovative process. Dan L. Burk and Mark A. Lemley succinctly stated: "The economic evidence is overwhelming that innovation works differently in different industries, and that the way patents affect innovation also differs enormously by industry."[6]

Industries' needs and processes may be determined by reference to the duration and costs associated with research and development. For instance, the pharmaceutical industry, which has been described as the "poster child" of the patent system,[7] is characterized by massive investments in new drugs,[8] a lengthy development process and a high

[6] DAN L. BURK & MARK A. LEMLEY, THE PATENT CRISIS AND HOW COURTS CAN SOLVE IT 4–5 (2009).

[7] Lisa L. Ouellette, *How Many Patents Does It Take to Make a Drug – Follow-On Pharmaceutical Patents and University Licensing*, 17 MICH. TELECOMM. & TECH. L. REV. 299, 300 (2010) (relying on WILLIAM M. LANDES & RICHARD A. POSNER, THE ECONOMIC STRUCTURE OF INTELLECTUAL PROPERTY LAW 316 (2003) ("[T]he strongest case for patents in something like their present form is said to be found in a subset of the drug industry.")).

[8] Joseph A. DiMasi et al., *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. HEALTH ECON. 20 (2016) (estimating the average total capitalized costs of R&D for a new drug plus getting it approved to be more than $2.5 billion); though skepticism about the asserted high number of R&D costs has been expressed. *See* Jason Millman, *Does It Really Cost $2.6 Billion To Develop a New Drug?*, WASH. POST (Nov. 18, 2014), https://www.washingtonpost.com/news/wonk/wp/2014/11/18/does-it-really-cost-2-6-billion-to-develop-a-new-drug/?noredirect=on&utm_term=.74534b6806a2. In contrast, the costs for developing a generic drug are substantially lower. *See* Ouellette, *supra* note 7, at 302 (relying on David Reiffen & Michael R. Ward, *Generic Drug Industry Dynamics*, 87 REV. ECON. & STAT. 37, 47 (2005)).

risk of failure.[9] Not surprisingly, the reliance on patent protection is of particular importance in the pharmaceutical industry.[10] In other industry sectors, such as information technology, innovative companies are confronted with the challenge of rapid innovation cycles. The dynamic of these industries places practical limits on the time to recoup investments before the innovation becomes outdated.[11]

Another major difference is the patent concentration which companies encounter in their industry. In the information and communication technology industries, innovations are often incremental and highly dependent on prior inventions.[12] Companies in such industries may find themselves exposed to so-called "patent thickets," which is understood to mean "an overlapping set of patent rights."[13] To illustrate, the large number of patents found in just one single product in some high-tech industries contrasts strongly with the generally readily comprehensible number of patents per drug in the pharmaceutical industry.[14]

---

[9] Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1582 (2003).

[10] In a study evaluating data from 100 randomly chosen firms from 1981–83, Edwin Mansfield found that "patent protection was judged to be essential for the development or introduction of 30 percent or more of the inventions in only two industries-pharmaceuticals and chemicals." Edwin Mansfield, *Patents and Innovation: An Empirical Study*, 32 MGMT SCI. 173, 174–75 (1986). With respect to the pharmaceutical industry Mansfield found that 65% of the inventions would not have been introduced and 60% would not have been developed if patent protection could not have been obtained. *Id.* at 175.

[11] Stefano Comino & Fabio Manenti, JRC SCI. AND POL'Y REP., EUR 27549 EN, *Intellectual Property and Innovation in Information and Communication Technology*, 8 (2015); THOMAS, *supra* note 2, at 4.

[12] Comino & Manenti, *supra* note 11, at 8.

[13] Carl Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard-Setting, in* INNOVATION POLICY AND THE ECONOMY 119, 120 (Adam B. Jaffe, Josh Lerner & Scott Stern eds., 2001). The epitome for patent thickets is encountered in today's smartphone world where thousands of patent protected inventions are implemented into a single phone. An often cited study from 2011 the number of patents per smartphone was estimated to be more than 250,000. RPX Corp., Form S-1, 59, http://www.sec.gov/Archives/edgar/data/1509432/000119312511240287/ds1.htm (last visited April 16, 2018).

[14] Graeme B. Dinwoodie & Rochelle C. Dreyfuss, *supra* note 2, at 445 ("In some fields, like pharmaceuticals, the ratio is close to one (one patent covers one product).");

Finally, other means of protection outside patent law might be available to protect innovations. In some instances, for example, innovative software in the information and communications technology sector can be secured through copyright protection.[15] Other possible ways of seeking protection where feasibility may vary among industries is the reliance on trade secrets or the so-called "first mover advantages."[16]

For the purpose of this article, the term "industry-specific" and "industry diversity" shall refer to distinguished treatment of patentees or users of the patented technology within a predefined group or industry field. Distinguished treatment is understood as a favorable or disadvantageous treatment in comparison to the majority group of patentees or users of the patented technology subject to the uniform rules of the patent law as provided for by the Patent Act and the courts.

Though this section only touches the surface of the complexities, it shows that the role of the patent system is not necessarily the same among different industries. In fact, the crafting of industry-specific patent norms shines like a bright promise on the horizon.

Why then does patent law widely rely on uniformity? One of the reasons lies in the nature of technology. It changes and evolves rapidly

---

Mark A. Lemley, *Ten Things To Do About Patent Holdup of Standards (and One Not To)*, 48 B.C. L. REV. 149, 150 (2007) (". . . generally, one patent covers one drug").

[15] 17 U.S. Code § 102(a)(1) provides that literary works are copyrightable works. Congress made it clear when it passed the Copyright Act of 1976 that "[t]he term 'literary works' . . . includes . . . computer programs to the extent that they incorporate authorship in the programmer's expression of original ideas, as distinguished from the ideas themselves."H.R. REP. No. 94-1476, at 51 (1994), *reprinted in* 1976 U.S.C.C.A.N. 5659, 5667.

[16] The idea of first mover advantages, which originates in the game theory, looks at the advantages that come along with just being the first one to launch a new innovation onto the market, such as, for example, reputational benefits of being a very innovative and superior firm. Frederic M. Scherer, *First Mover Advantages and Optimal Patent Protection* 2 (HKS Working Paper, Paper No. RWP14-053, 2014), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2538621. For a critical view on first mover advantages in the software industry, *see* Paul Morinville & Gene Quinn, *First Mover Advantage, a False Premise in Software Innovation*, IP WATCHDOG (Jan. 24, 2016), http://www.ipwatchdog.com/2016/01/24/first-mover-advantage-false-premise-software-innovation/id=65168/.

so that today's technology can be already outdated tomorrow.[17] Innovation is not static but inherently dynamic. Think about technological relics such as Walkmans, cassette tapes, VHS or floppy disks. Widespread Congress-made industry-specific law would require an enormous amount of financial and personnel resources. A further peril of industry-specific law-making is that it can encourage rent-seeking and opportunistic behavior by certain industry groups.[18] In this regard, it has been pointed out that Congressional lobbying has increased in the field of intellectual property rights.[19] Finally, there is the TRIPs Agreement that provides an additional reason for the limited existence of diversity in today's patent law. Article 27(1) of the TRIPs Agreement provides:

> [P]atents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. Subject to [the transitional provisions relating to developing countries and patent protection for pharmaceutical and agricultural products], patents shall be available and patent rights enjoyable *without discrimination* as to the place of invention, the *field of technology* and whether products are imported or locally produced.

TRIPs: Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) [hereinafter TRIPs Agreement] (emphasis added).[20]

---

[17] Craig Allen Nard & John F. Duffy, *Rethinking Patent Law's Uniformity Principle,* 101 NW. U. L. REV. 1619, 1651 n.109 (2007).

[18] Dan L. Burk & Mark A. Lemley, *supra* note 9, at 1637; Nard & Duffy, *supra* note 17.

[19] Robert P. Merges, *One Hundred Years of Solicitude: Intellectual Property Law, 1900-2000,* 88 CAL. L. REV. 2187, 2235 (2000).

[20] Burk & Lemley, *supra* note 9, at 1634; Nard & Duffy, *supra* note 17, at 1637 n. 59.

III. INDUSTRY-SPECIFICITY INTRODUCED THROUGH THE HATCH-WAXMAN ACT

A. EXTENSION OF THE PATENT TERM

1. THE CORRELATION OF REGULATORY REVIEW AND PATENT PROTECTION

The normal lifetime of a patent is twenty years from the date on which the application for the patent was filed.[21] By granting a temporary exclusive right, patent law "promotes[s] the progress of science and the useful arts" and "secures the financial rewards" of the inventor.[22] Scaling the duration of the patent term strives to balance, on one hand, the public interest in free access to the patented invention and, on the other, creating sufficiently strong incentives for inventors by securing the prospect of recouping investments. Because the patent term starts as of the filing date, the time of protection is effectively shortened by the time the patent is pending for issuance.[23] In some circumstances, the time the inventor can yield his investments can be subject to further limitation. This is true when pre-market approval for a product is

[21] 35 U.S. Code § 154(a)(2). Patents filed before March 16, 2013, prior to the effective date of the America Invents Act (A.I.A), are awarded with a patent term of 20 years as of the date on which the application for the patent was filed in the United States. Similarly, the TRIPs Agreement provides in Article 33 that "the term of protection available shall not end before the expiration of a period of twenty years counted from the filing date." TRIPS: Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) [hereinafter TRIPS Agreement].

[22] United States v. Univis Lens Co., 316 U. S. 241, 250 (1942); *see also* U.S. CONST. art. I, § 8, cl. 8.

[23] According to data provided by the USPTO, the average time from the date of the filing of the application to the date the application has reached final disposition, i.e. the decision whether to grant or not to grant the patent, is an average of 24.2 months as of February 2018. The period the application is pending at the PTO can be significantly longer, for instance, if the application gets appealed to the Patent Trial and Appeal Board (PTAB, on the cited website it still refers to the Board of Appeals and Interferences, the name of the PTAB prior to the A.I.A.). The average pending time is stated including appeal to the PTAB to be 72.9 months as at February 2018. *Data Visualization Center, Data on Pendency Duration*, USPTO, https://www.uspto.gov/corda/dashboards/patents/main.dashxml?CTNAVID=1004 (last visited Apr. 24, 2018).

required. For instance, prior to approval by the United States Food and Drug Administration (FDA), the marketing of any new drug in interstate commerce is illegal.[24] Consequently, companies that want to bring new drugs to the market must first seek agency approval.

The approval of a new drug is a lengthy process. After a new drug has been developed, the standard drug approval process with the FDA comprises three phases. In the initial, pre-clinical phase, the company seeking approval is required to conduct animal testing and file an investigational new drug (IND) application with the FDA, which must, inter alia, contain information about how the drug is going to be tested on humans. The FDA reviews the IND and, if approved, phase two of the approval process can be entered. During phase two, the clinical trial phase, the new drug is tested on human beings in a three-step process. Upon successfully passing the second phase, the new drug enters the third phase, that of actual review and approval, which commences with the submission of a new drug application (NDA) and ends with a decision by the FDA to approve or deny the application. In the final stage, not only is the application itself reviewed, but so too are the drug labeling and the facilities where the drug will be manufactured.[25]

The average time from FDA application until the final approval of the drug is stated to be twelve years.[26] In order to secure patent protection, inventors are well-advised to file their applications with the Patent and Trademark Office (PTO) in a timely manner. It can be presumed that most patent applications for new drugs are filed shortly before the date of the inception of the approval process. The need to file patent applications early, and the duration of the approval process can severely shorten the effective protection term granted by a patent. Lawmakers have recognized the interference of regulatory law within the patent system, and have attempted to mitigate it, as explained below.

---

[24] 21 U.S. Code § 355(a); Wyeth v. Levine, 555 U.S. 555, 592 (2009) ("The statute prohibits the interstate marketing of any drug, except for those that are federally approved.").

[25] *Drug Approval Process*, FDA, https://www.fda.gov/downloads/drugs/resourcesforyou/consumers/ucm284393.pdf (last visited Apr. 27, 2018).

[26] Van Norman, *Drugs, Devices, and the FDA: Part 1 – An Overview of Approval Processes for Drugs*, 1 JACC BASIC TRANSLATIONAL SCI. 170, 178 (2016).

2. STATUTORY FOUNDATION

The impact of the regulatory review on the patentee's chances to recoup his or her investment was picked up by Congress in the Drug Price Competition and Patent Term Restoration Act in 1984,[27] the so-called Hatch-Waxman Act, and has led to the enactment of §156 of the Patent Act, which allows for an extension of the patent term of protection in certain circumstances.

The extension is available only for patents that claim protection with respect to predefined products: drug products, medical devices, food additives and color additives, which are subject to regulatory approval under the Federal Food, Drug, and Cosmetic Act.[28] According to statutory requirements, an extension can be granted if: 1) the term of the patent has not yet expired before applying for an extension; 2) the term has not previously been extended; 3) the product has been subject to a regulatory review period before its commercial marketing or use; 4) the commercial marketing or use after such regulatory review is the first permitted commercial marketing or use of the product; 5) the patent sought to be extended claims the approved product or method; and 6) an application for an extension of the patent term is submitted within sixty days, beginning on the date of approval.[29] Generally, the term of a patent that meets the extension requirements will be extended by the time period equal to the regulatory review period for the approved product, after the patent has issued.[30]

3. RATIONALES

At first sight, the patent term extension looks like a concession given to the pharmaceutical and medical device industries. It has been said that "[n]o other industry enjoys such a government subsidy."[31] However, a closer look at the period and scope of the extension reveals that it is less a unique industry-specific advantage but rather a counterbalance of regulatory provisions.

---

[27] H.R. 3605, 98th Cong. (1983-1984).

[28] 35 U.S.C. § 156(f)(1). Note that also patent that claims a method of using such a product or manufacturing such a product can be extended. 35 U.S.C. §156(f)(3).

[29] 35 U.S.C. § 156(a)– (d) (West 2015).

[30] 35 U.S.C. § 156(c) (West 2015).

[31] Alfred B. Engelberg, *Special Patent Provisions for Pharmaceuticals: Have They Outlived Their Usefulness?*, 39 IDEA 389, 421 (1999).

According to §156(c), the term of a patent that meets the prerequisites "shall be extended by the time *equal to the regulatory review period* for the approved product which period occurs *after the date the patent is issued*." Notwithstanding the general restoration of the time period lost through the approval process, the statute provides a maximum length of extension of five years, even if, the actual approval process took longer.[32] What does that mean? With regard to the lifetime of its right, the patentee regains at most the time lost during the application process or five years, whichever is less.

Turning to the substantial reach of the extension, it becomes apparent that the additional protection period is narrowly tailored to reflect the parameters of FDA approval. This can be clearly seen when looking at §156(b)(1) of the Patent Act. In that section, it stipulates that the rights derived from any extended product patent during the time of extension are limited to the uses approved for the product.[33] Consequently, the protection that derives from an extended patent is narrower than the protection enjoyed by the patentee during the normal lifetime of the patent. Instead of being protected against any use of his or her invention, the patent owner can only assert rights against those who use his invention for the approved purpose.[34] In summary, the patentee who meets the requirements for an extension of §156 of the Patent Act is not advantaged with a more "effective" lifetime, meaning more time to recoup investments, than other patentees.

Speaking of a patent term "extension", although technically correct, is somewhat misleading as it suggests that the patentee enjoying such an extension would be entitled to more than other patentees. In fact, the effect is such that the patentee is afforded an opportunity to recoup investments similar, if not identical, to that which he or she would have been in but for the regulatory approval requirements. In this way, it seems more accurate to speak of patent term restoration.[35] This finding is also reflected by the declared purpose of the extension of the patent term to create "a new incentive for increased expenditures for

[32] 35 U.S. Code § 156(g)(6)(A) (West 2015).

[33] The same applies to approved processes, 35 U.S.C. § 156(b)(2)–(3) (West 2015).

[34] 35 U.S. Code § 156(b) (West 2015).

[35] The use of this term is also indicated by the name of the statute introducing the provision, the Drug Price Competition and Patent Term Restoration Act, H.R 3605, 98th Cong. (1983–84).

research and development of certain products which are subject to premarket government approval," the new incentive being "the *restoration* of some of the time lost on patent life while the product is awaiting pre-market approval" (emphasis added).[36] It is true that a 'new incentive' is created through the patent term extension, though at the end of the day, it is not a greater incentive as compared to other inventions. Consequently, §156 of the Patent Act is not a bounty for patentees in specific industries, but its effect is to put the eligible patentee in the same position as patentees in other industries. The aforementioned example demonstrates how industry-specific patent law can be a promising tool where other laws interfere with the patentee's ability to recoup his or her investments. However, criticism has been voiced that the patent term extension for the pharmaceutical industry is outdated and that "[t]he uninterrupted growth in the sales and earnings of large pharmaceutical companies plainly supports the conclusion that the pharmaceutical industry is doing well financially and does not need additional patent-term extensions."[37] This argument ignores the finding that the patent term extension is not a bounty to patentees but merely levels the playing-field compared to other industries.

Regardless of the question of whether the patent term extension is outdated, the current form of the patent extension provision is incomplete and discriminatory as the example of the pesticide industry illustrates.

4. PREMARKET APPROVAL IN THE PESTICIDE INDUSTRY

In modern times, the agricultural industry can hardly be imagined operating without the use of pesticides. Pesticides prevent pests, protect crops and ensure greater yields.[38] Yet the use of pesticides is not free of risk. Pesticides are not only deadly to pests but can also be harmful to "nontarget organisms and endangered species."[39] From 2006

[36] H.R. REP. NO. 98-857(I), at 15 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2648.

[37] Alfred B. Engelberg, *supra* note 30, at 421.

[38] Jerry Cooper & Hans Dobson, *The Benefits of Pesticides to Mankind and the Environment*, 26 CROP PROTECTION 1337, 1347 (2007); Christos A. Damalas & Ilias G. Eleftherohorinos, *Pesticide Exposure, Safety Issues, and Risk Assessment Indicators*, 8 INT. J. ENVIRON. RES. PUB. HEALTH 1402 (2011).

[39] EPA, *Data Requirements for Pesticide Registration*, https://www.epa.gov/pesticide-registration/data-requirements-pesticide-registration (last visited April 29, 2018).

to 2010, not less than 130,000 times on average per year poison control centers were contacted due to pesticide related causes with more than 17,000 cases annually treated in health care facilities.[40] The potential risks for humans range from skin and eye irritations to hormone and endocrine system derogations and even possible adverse effects on the nervous system.[41] In order to minimize the risks associated with pesticides, they are subject to regulatory approval, including extensive evaluation of potential harm.

Pesticides and drugs share, as odd as it may sound, many similarities.[42] Not only do both rely on chemicals that present potential threats to human health and the environment,[43] but they are also subject to approval processes that can take several years until the starting gun is fired for a product to be launched onto the market.[44]

The Federal Insecticide Fungicide and Rodenticide Act (FIFRA) provides that anyone who wants to sell or distribute pesticides in the United States is required to register them with the Administrator of the Environmental Protection Agency (EPA).[45] The FIFRA defines pesticides to mean "any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest," "any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant" and "any nitrogen stabilizer."[46] According to 7 U.S.C. §136j(a)(1)(A) "it shall be unlawful for any person in any State

[40] Ricky L. Langley & Sandra Amiss Mort, *Human Exposures to Pesticides in the United States,* 17 J. AGROMEDICINE 304 (2012).

[41] For a detailed analysis of short-run and long-run effects of human exposure to pesticides, *see* WHO, PUBLIC HEALTH IMPACT OF PESTICIDES USED IN AGRICULTURE 46-59 (1990).

[42] Clarence J. Swanton et al., *Similarities Between the Discovery and Regulation of Pharmaceuticals and Pesticides: in Support of a Better Understanding of the Risks and Benefits of Each,* 67 PEST MGMT. SCI. 790 (2011).

[43] *Id.*

[44] Damalas & Eleftherohorinos, *supra* note 36, at 1405 ("Pesticide registration is a complex process and takes considerable time"); U.S. CONGRESS OFFICE OF TECHNOLOGY ASSESSMENT, PATENT-TERM EXTENSION AND THE PHARMACEUTICAL INDUSTRY 73 (1981) ("The regulatory process in 1975 required about 7 years to complete in contrast to a little less than 3 years in 1960.").

[45] 7 U.S.C. § 136.

[46] 7 U.S.C. § 136(u).

to distribute or sell to any person any pesticide that is not registered . . . or whose registration has been canceled or suspended."

The approval process is initiated by the applicant who seeks to sell or distribute a pesticide. A registration for a new pesticide is approved if the administrator of the EPA determines that: 1) the pesticide's composition is such as to warrant the proposed claims for it; 2) its labeling and other materials required to be submitted comply with the requirements of the FIFRA; 3) the pesticide will perform its intended function without unreasonable adverse effects on the environment; and 4) when used in accordance with widespread and commonly recognized practice, it will not generally cause unreasonable adverse effects on the environment.[47] The applicant has to submit comprehensive data, such as the product chemistry, product performance, and studies on hazards to humans and domestic animals.[48]

According to §156(a) of the Patent Act, "the term of a patent which claims a *product*, a method of using a product, or a method of manufacturing a product shall be extended" if the other requirements of the section are met. The term 'product' is defined in that section to comprise "drug product(s)" and "any medical device, food additive, or color additive subject to regulation under the Federal Food, Drug, and Cosmetic Act (FFDCA)." Drug products include new drugs, antibiotic drugs, and human biological products, as those terms are used in the FFDCA and the Public Health Service Act, and new animal drugs and veterinary biological products, as those terms are used in the FFDCA and the Virus-Serum-Toxin Act.[49]

Consequently, the statutory framework limits the availability of a patent term extension to a narrow field of products. By its narrow definition of the term 'product', the statute forecloses other products subject to pre-market approval from being eligible for extension of the patent term under §156 of the Patent Act. A patent term extension for inventions in the pesticide industry can therefore not be issued under that section.

[47] 7 U.S.C. § 136a(c)(5).

[48] EPA, *supra* note 37. The details on the data to be submitted are laid out in 40 C.F.R. § 152.50 (2017).

[49] 35 U.S.C. § 156(f)(1)(2).

The examination of the USPTO's Manual of Patent Examining Procedure, which devotes chapters 2750-2764 to the extension of the patent term, buttresses the fact that pesticides are not considered to fall within the scope of §156 of the Patent Act.[50] Paragraph II of chapter 2751 of the manual outlines the meaning of the word "product" as defined in 156(f) of the Patent Act. The remarks are silent with respect to pesticides or products approved by the EPA. A thorough search of secondary sources and case law did not reveal any means for extending patents on pesticides subject to EPA approval. Therefore, at this point, it appears that patents in the pesticide industry are not eligible for patent term extension in the United States.[51]

Medical devices, drugs, and pesticides are all subject to pre-market approval by regulatory agencies. The approval process can effectively shorten the time the patentee will have to recoup his or her investments. For the pharmaceutical and the medical device industries, Congress has addressed this problem in §156 of the Patent Act. The pesticide industry does not enjoy a comparable restoration of the time lost during the approval process by the EPA.

This finding raises the question of whether denying a patent term extension for pesticide patents is reconcilable with the TRIPs Agreement. It seems worth highlighting that at the time the patent term extension provision was enacted, the prohibition against discrimination as to the field of technology stipulated in the TRIPs Agreement had not yet been adopted. The Agreement came only into force more than a decade later, in 1995. During the Uruguay Round negotiations the issue of patent term extensions for products requiring pre-marketing approval

[50] The United States Patent and Trademark Office, 2750 PATENT TERM EXTENSION FOR DELAYS AT OTHER AGENCIES UNDER 35 U.S.C. 156, https://www.uspto.gov/web/offices/pac/mpep/s2750.html (last visited Apr. 29, 2018).

[51] Taking a look across the big pond reveals that patentees in the European Union a somewhat different picture is revealed. Within the European Union patentees cannot only seek an extension of the patent term not only for pharmaceutical products but also for plant protection products. Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products 2009, O.J. (L 152); Regulation (EC) No 1610/96 of the European Parliament and of the Council of 23 July 1996 concerning the creation of a supplementary protection certificate for plant protection products 1996, O.J. (L 198).

was discussed, yet not incorporated into the Agreement.[52,] Despite the long-standing tradition of industry and technology neutrality of patent law, at the time Congress passed the Hatch-Waxman Act it was not coerced to craft non-discriminatory rules, but, if anything, bound by tradition.[53] However, the laws of the game have changed: if a country now decides to provide restoration for some technologies subject to pre-market approval but not for others, this raises the issue of compliance with the prohibition of discrimination with regard to the field of technology in the TRIPs Agreement.[54]

Discrimination can generally be found where there is an unjustified imposition of differentially disadvantageous treatment.[55] However, differential treatment does not always result in a finding of discrimination. For instance, it may aim to offset recognized differences.[56] Instead, Article 27 allows "bona fide exceptions to deal with problems that may exist only in certain product areas."[57]

Unlike pharmaceuticals and medical devices, patented products in the pesticide industry do not enjoy the possibility of a patent term extension. Therefore, pesticide patents are treated less favorably. The similarities between the industries are readily discernible. Products in all three industries are subject to lengthy approval processes that reduce the time for recoupment of investments. The former congressional Office of Technology Assessment published a report on the patent term extension in 1981.[58] The report focuses on patent term extension for patents in the pharmaceutical industry, but also discusses in its appendix

---

[52] *Pharmaceutical Patents and the TRIPS Agreement*, WTO, https://www.wto.org/english/tratop_e/trips_e/pharma_ato186_e.htm#fnt1 (last visited Apr. 22, 2018). The term "Uruguay Round" refers to the negotiations that led to the establishment of the World Trade Organization (WTO) and spawned the TRIPs Agreement. Martin Will & Alan L. Winters, *The Uruguay Round: Widening and Deepening the World Trading System*, 6 WORLD BANK POL'Y RES. BULL. 1 (1995).

[53] The TRIPs Agreement only entered into effect in on January 1, 1995 whereas the Hatch-Waxman Act already became effective on September 24, 1984.

[54] Nuno Pires de Carvalho, THE TRIPS REGIME OF PATENT RIGHTS 112 (2010) (arguing that extension should be granted in every instance where pre-marketing approval is required).

[55] Report of the Panel, *Canada – Patent Protection of Pharmaceutical Products*, WT/DS114/R, at 171 (Mar. 17, 2000).

[56] Pires de Carvalho, *supra* note 52, at 279.

[57] Report of the Panel, *supra* note 53, at 170–71.

[58] U.S. CONGRESS OFFICE OF TECHNOLOGY ASSESSMENT, *supra* note 42.

potential extensions in the medical device, pesticide, and chemical industries. It concluded that the pesticide and pharmaceutical industries are "subject to similar regulations."[59]

Looking for potential justifications for unequal treatment, the legislative history of the Hatch-Waxman Act remains mostly unrevealing. In 1980, Representative Robert W. Kastenmeier and Senator Birch E. Bayh proposed bills to introduce a patent term extension that would cover human drugs; animal drugs; food additives; human or veterinary biological products; *pesticides*; chemical substances or mixtures; and medical devices.[60] However, upon referral to Senate Judiciary Committee and the House Committee on the Judiciary, the possibility of patent term extension for pesticides was not pursued.[61] In the following years, further bills for patent term extensions were introduced that also covered pesticides and chemical substances.[62] The congressional materials and hearings that led to the enactment of the Hatch-Waxman Act are not instructive as to why pesticides were not included in the final bill.[63] However, the 1981 report by the former Office of Technology assesses three aspects potentially prompting the

[59] *Id*.

[60] H.R. 7952, 96th Cong. (1980); S 2892, 96th Cong. (1980). An overview of the legislative history can be found at Erika Lietzan, *The History and Political Economy of The Hatch-Waxman Amendments,* 49 SETON HALL L. REV. 54 (2019) (providing a contextualized history of the Hatch-Waxman Act and describing its political economy).

[61] Lietzan, *supra* note 58, at 154.

[62] H.R. 17937, 97th Cong. (1981); S. 255, 97th Cong. (1981); H.R. 3502, 98th Cong. (1983); S. 1306, 98th Cong. (1983).

[63] The respective documents are made available by the University of New Hampshire: *Legislative IP Acts (LIPA)/History Archive: Patent Legislative Histories*, U.N.H., http://www.ipmall.info/content/legislative-ip-acts-lipa-history-archive-patents-0 (last visited Apr. 21, 2018). The entire record has been scanned for reasons why pesticides were not included in the final bill. Besides a report by the Office of Technology Assessment, the only noteworthy finding is the following statement quoted from a hearing: "Finally, there is the issue of pesticides. Pesticides have not been included in this bill, but that issue is covered in a separate bill, H.R. 5529, that would actually grant a more favorable patent extension to the pesticide companies. And again, our position would be that there should be no extension for the pesticide companies. They haven't made the case, and certainly they should not get a more favorable extension." *Drug Price Competition and Patent Term Restoration Act of 1984: Hearing on S. 2748 Before the Committee on Labor and Human Resources United States Senate,* 98th Cong. 261 (1984) (statement by Mr. William Shultz, Public Citizen Litigation Group). H.R. 5529 proposed the Agriculture Patent Reform Act of 1984, which was later re-proposed as H.R. 6034 but neither were passed.

lawmakers' decision not to expand the patent term extension to pesticides: 1) a high innovation rate despite the increasing costs and time associated with the approval process; 2) the increasing amounts flowing into R&D; and 3) the risk of double rewards for patentees.[64]

In 1972, the FIFRA was amended and now requires that companies submit a demonstration of human safety, which has resulted in an increasingly resource-intensive approval process for pesticides. Nevertheless, the report found a continuing increase in innovations from 1967-79, and concluded: "The measures of innovation available in the pesticide industry indicate innovation has, thus far, been virtually unaffected by the increased costs and times required for regulatory approval."[65] This suggests that the Office thought there might be no need for a patent term extension. The assertion of uncertainties as to whether research and development (R&D) expenditures would be positively affected if there was a patent term extension for pesticides, points in the same direction.[66] Finally, the federal government is recognized to play an important role in the R&D of pesticides. According to the report, the involvement of the government could lead to a double reward of patentees, where public research funds result in privately-owned patents.[67]

Comparing the evaluation of the Office of Technology Assessment, regarding the pesticide industry to the pharmaceutical industry, indicates disparate needs between the two industries. In particular, their innovation trends deserve closer consideration. Unlike in the pesticide industry, the innovation rate in the pharmaceutical industry had shown a less positive trend in the decades prior to the enactment of the Hatch Waxman Act. The report concluded: "[I]nterpretations of trends of innovation depend on the measures used at the time period being measured, but, by most measures, innovation does not appear to be increasing."[68] Due to the tenuous information available on why pesticides were not included in the bill that led to the

[64] U.S. CONGRESS OFFICE OF TECHNOLOGY ASSESSMENT, *supra* note 42.

[65] *Id.*

[66] *Id.* Examining the effect of a patent term extension on the R&D expenditures for pharmaceutical drugs the report concludes: "Although patent-term extension lacks a mechanism that would assure increases in R&D activities, the incentives it provides may be sufficient to encourage additional R&D expenditures." *Id.* at 45.

[67] *Id.* at 7374.

[68] *Id.* at 26.

Hatch-Waxman Act, it will be assumed that the unequal innovation trends were at least one critical factor.[69] Allowing different treatment based on innovation data is perilous. All too easily, the gates would be opened for disparate treatment of patents from different fields of technology. The process of innovation is complex and predicting innovation rates is often not more than a shot in the dark. Innovation data is influenced by a myriad of factors—many of them stemming from outside the specific industry sector, like the global economy and user demand. Further, the process of innovation is diverse.[70] Innovation in different industries varies in terms of the pace of innovation, actors involved and degree of change. If differences in innovation pace were sufficient to overcome the prohibition of discrimination against certain field of technology the prohibition itself would become an empty phrase. The disadvantageous treatment of pesticide patents raises serious doubts about the United States' compliance with respect to the discrimination prohibition articulated in Article 27(1) of the TRIPs Agreement.

The implications of this finding are not limited to the pesticide industry. There are other industries subject to regulatory approval. One example is the aviation industry. The Code of Federal Regulations prescribes airworthiness approval by the Federal Aviation Agency (FAA) for certain products related to aircrafts.[71] In order to determine a violation of Article 27(1) TRIPs Agreement, the specifics of each of the approval processes have to be examined. For example, an argument might be made that if the approval process is more akin to a non-time-

[69] It cannot be said with absolute certainty that the innovation trend was dispositive for Congress's decision not to include pesticides in the bill finally passed. Similar to the pesticide industry the medical device industry showed increasing innovation data and yet the patent term extension is available for medical devices. The report of the Office for Technology Assessment concluded: "In summary, the medical devices industry is likely to continue to be reasonably competitive and innovative in many product lines and patent-term extensions may, therefore, be unnecessary." *Id.* at 72. Yet regulation of the medical devices industry was deemed to be included within the parameters of the legislation "in the early stages" and, thus, reliability of its influence on innovation trends might be limited. *Id.* at 72.

[70] Franco Malerba, *Sectoral Systems: How and Why Innovation Differs Across Sectors, in* THE OXFORD HANDBOOK OF INNOVATION 380–406 (Jan Fagerberg, David C. Mowrey & Richard R. Nelson eds., 2005).

[71] The regulatory basis is outlined in 14 C.F.R. § 21 (2018).

consuming registration process, there is a stronger case for not granting a patent term extension.[72]

This Article concluded above that the patent term extension for pharmaceuticals and medical devices is not a bounty for some industries and, in fact, a promising example of industry-specific patent law. This finding still stands, albeit only with some reservations. Denying the patent term extension to the pesticide industry is a manifestation of the perils of industry-specific law: similar industries are treated differently for weak reasons. Cynics might say it is not surprising that the pharmaceutical industry pushed their claim for a patent extension through, given it is represented by the strongest special-interest group in the country.[73] One can have his or her own opinion about the demonization of lobbying groups, but the fact remains that the Patent Act in its current form treats the pesticide industry discriminatorily compared to the pharmaceutical and medical device industries.

B. MODIFICATION OF INFRINGING ACTIVITIES

The Hatch-Waxman Act also amended traditional infringement provisions. The statutory focal point for determining which acts constitute patent infringing conduct is set forth in §271 of the Patent Act. The centerpiece of the provision on infringing conduct is §271(a) of the Patent Act, which stipulates that "whoever without authority makes, uses, offers to sell, or sells any patented invention, within the

[72] The report of the Office of Technology Assessment distinguished the regulation of chemicals from pharmaceuticals and pesticide regulation in that the former does not require government approval prior to the marketing of the product but only asks for a notification of the Environmental Protection Agency 90 days prior to the market launch. 15 U.S.C. § 5. The reports concludes that "[b]ecause EPA is given only 90 days to review a chemical notice . . . patent-term extension will not be applicable to the great majority of chemical products." However, it notes that for some chemicals which required to be tested in accordance with the TSCA, an extension could be "meaningful." U.S. CONGRESS OFFICE OF TECHNOLOGY ASSESSMENT, *supra* note 42, at 74.

[73] The Center for Responsive Politics lists the pharmaceutical/health products industry as the top spending lobbying group with lobbying expenditures in the amount of $3,937,011,122 between 1998-2018. *Top Industries*, CENTER FOR RESPONSIVE POLITICS, https://www.opensecrets.org/lobby/top.php?indexType=i&showYear=a (last visited Aug. 1, 2018).

United States or imports into the United States any patented invention during the term of the patent therefore, infringes the patent."

1. NON-INFRINGING COMMERCIAL ACTIVITIES OR THE SAFE HARBOR PROVISION OF §271(E)(1)

The Federal Circuit's decision in *Roche Products v. Bolar Pharmaceutical* revealed the problem of undesired de facto protection beyond the expiration date of the patent.[74] This de facto protection extension was caused by the testing necessary for a generic drug manufacturer in advance of filing a drug approval application. Under standard infringement law, testing constituted an infringing act so that tests could only be performed after the patent had expired and thereby led to delays in the market entrance of new drugs. In order to remedy the recognized deficiency, Congress introduced the safe harbor provision of §271(e)(1) of the Patent Act which allows companies certain otherwise unlawful acts to assure market entrance of generic drugs as early as possible and thereby minimizing de facto patent term extensions.

Roche was the owner of a patent covering among others the compound flurazepam hydrochloride (flurazepam hcl) that was used in one type of the company's sleeping pills.[75] Bolar is a generic drug company that decided in early 1983 to market a generic version of Roche's pills after the expiration of Roche's patent. The same year, Bolar received a load of the patented compound flurazepam hcl from a foreign manufacturer that was intended to be used for studies necessary for the application for drug approval to the FDA. Roche filed suit seeking to enjoin Bolar from using flurazepam hcl for any purpose whatsoever during the life of the patent.[76] The District Court for the Eastern District of New York found that Bolar was not infringing Roche's patent as the use was *de minimis* and experimental.[77] On appeal, the Federal Circuit reversed the District Court's decision. In the court's opinion, Bolar's use was not excluded from infringement under the defense of experimental use and the court found that the use was not

[74] Roche Prods. v. Bolar Pharmaceutical, 733 F.2d 858 (Fed. Cir. 1984); H.R. REP. NO. 98-857(I), at 46 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2679.

[75] U.S. Patent No. 3,299,053 (filed Feb. 11, 1964).

[76] *Roche*, 733 F.2d at 860.

[77] ROCHE PRODS. V. BOLAR PHARMACEUTICAL, 572 F.SUPP. 255 (E.D.N.Y. 1983).

merely *de minimis*.[78] It was held that "unlicensed experiments conducted with a view to the adaption of the patented invention to the experimentor's [sic] business is a violation of the rights of the patentee to exclude others from using his patented invention."[79]

Shortly afterwards, Congress reacted and overruled *Roche Products v. Bolar Pharmaceutical* explicitly by enacting §271(e)(1) of the Patent Act, which now stipulates that "it shall not constitute an 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 manufacture, use, or sale of drugs or veterinary biological products."[80] The provision reiterates that the policy objective of the Hatch-Waxman Act, that is "getting safe and effective generic substitutes on the market as quickly as possible after the expiration of the patent."[81]

The deviation from standard patent law rules is prompted by regulatory scrutiny of drugs and veterinary biological products. The scope of the provision is narrower than the one governing patent term extensions, in the sense that medical devices are eligible for patent term extension just as drugs, but do not fall within the ambit of §271(e)(1) of the Patent Act.[82] Its basis therefore lies in the specific requirements for generic drug approval. Applicants seeking to manufacture a generic drug must show bioequivalence.[83] The House Report emphasizes: "The only activity which will be permitted by the bill is a limited amount of testing so that generic manufacturers can establish bioequivalence of a

[78] *Roche*, 733 F.2d at 862–63.

[79] *Id.* at 863.

[80] 35 U.S.C.A. § 271. The Federal Circuit in *Roche Products v. Bolar Pharmaceutical* explicitly referred to the then-ongoing legislative process declining to follow Bolar's policy arguments and to "rewrite the patent laws" but passes on the responsibility to Congress: "It is the role of Congress to maximize public welfare through legislation. Congress is well aware of the economic and societal problems which the parties debate here, and has before it legislation with respect to these issues." *Id*. at 865.

[81] H.R. REP. NO. 98-857 (II), at 9 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2686, 2693.

[82] *Id.* at 2692.

[83] 21 U.S. Code §355(j)(2)(A)(iv). A definition of the term bioequivalence is provided for in 21 U.S.C. §355(i)(8)(B).

generic substitute."[84] As there is no such thing as an ANDA application for medical devices, there was no reason to include medical devices. In §271(e)(1) Congress implemented a promising amendment of the Patent Act that limits negative effects on the patentee and ensures that generic drugs enter the market—in the interest of the public and as early as possible. Whereas §156 of the Patent Act in general warrants that patentees whose inventions are subject to premarket approval are not worse off compared to other patentees, the narrowly tailored character of §271(e)(1) of the Patent Act makes sure that patentees' are not overcompensated through de facto extended patent protection.

Unfortunately, the lawmakers leave us with a puzzle. A comparable situation to the ANDA for generic drugs might be found regarding approvals of so-called "me-too-products" or "fast track products" in the pesticide industry. The "fast track" registration allows registrants to rely on previously submitted data for already approved pesticides.[85] The option to submit applications for pesticides that are identical or substantially similar in composition and labeling to a currently-registered pesticides is set forth in 7 U.S.C. §136a(c)(3)(B)(i). Further, §3(c)(7) FIFRA stipulates the requirements to be met in order for the EPA to approve an application for registration of a pesticide product, each of whose active ingredients is contained in one or more other registered pesticide products. Against this statutory background, it seems that a similar problem to that identified with respect to de facto patent term extensions for pharmaceutical patents arises in this context. If the manufacturer of a generic pesticide wants to enter the market as soon as possible after the patent for an approved pesticide has expired and rely on the data of the original pesticide, the generic pesticide company might need to perform tests to examine whether its pesticide is "identical or substantially similar." Provided that the testing activities would constitute a patent infringement, the generic pesticide manufacturer would be worse off than the manufacturer of a generic drug as it has to wait until the patent expires before tests are permissible. Consequently, similarly to the finding with regard to the patent term

[84] H.R. REP. NO. 98-857 (II), at 8 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2686, 2692.

[85] LYNN L. BERGESON, FIFRA – FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT 23 (2000). There are certain limitations regarding the reliance on data from previous registrations. *See* Federal Insecticide, Fungicide, and Rodenticide Act of 1910 §3(c)(1)(F), 7 U.S.C. § 136a(c)(1)(F).

extension, here, Congress has allowed a different treatment of two industries that show similar peculiarities which is concerning with regard to the TRIPs Agreement. The clear wording of the statute prevents any extended application to inventions from other industries, where similar de facto patent extensions may occur.

2. NON-COMMERCIAL INFRINGING ACTIVITIES – THE SUBMISSION OF DRUG APPLICATIONS AND §271(E)(2)

In §271(e)(2) the Hatch-Waxman Act has yielded another change of the traditional infringement doctrine that has been described as a "highly artificial act of infringement."[86] It is yet another example of industry-specific tailoring of the Patent Act. The provision transforms behavior that—under normal circumstances—does not constitute patent infringement into infringing activity.

The approval of a new drug is a lengthy journey and can easily take more than a decade. The Hatch-Waxman Act has introduced two application formats intended to expedite drug approval: the abbreviated new drug application (ANDA)[87] and the paper new drug application (paper NDA).[88] Generic companies seeking approval of a new drug that is the same as an already-approved innovation drug, or that differs only in specific ways, may submit an ANDA. Deviating from applications for new innovator drugs, the applicant for a generic drug can substitute bioequivalence data for animal and human studies of safety and effectiveness.[89] In the case of a paper NDA, applicants provide published literature instead of the aforementioned studies.[90]

It has already been touched upon that new drugs cannot be legally commercialized without prior administrative approval. The submission of a respective application constitutes, however, no infringing act under §271(a) of the Patent Act. Only when the drug enters the market after its approval do the default infringing activities of §271(a) apply.[91] Launching a generic drug onto the market can have

[86] Eli Lily & Co. v. Medtronic, Inc., 496 U.S. 661, 678 (1990).
[87] 21 U.S.C.§355(j).
[88] 21 U.S.C. §355(b)(2).
[89] *Eli Lily*, 496 U.S. at 676 ((citing 21 U.S. Code §355(j)(2)(A)(iv)).
[90] *Id.* (referencing 21 U.S. Code §355(b)(2)).
[91] §271(a) only prohibits others to make, use, offer to sell or sell the patented invention without authority of the patentee the patented invention.

severe and definite impacts on the market price of the original product.[92] To remedy this problem, Congress has created in §271(e)(2) a 'highly artificial act of infringement'[93], making the submission of an ANDA or a paper NDA to the FDA for a drug claimed in a patent, or for the use of which is claimed in a patent, an act of patent infringement. The act of infringement can be described as 'artificial', in contrast to the default infringing activities in §271(a) as it does not require market-related behavior. Again, just as with §156, a specifically crafted provision was necessary to assure that the patentee can recoup his or her investments. Therefore, the statutory framework allows litigation on the issue of infringement prior to conduct occurring that constitutes a default infringing act under §271(a). The patent owner is thereby put in the situation that allows him "to have a court determine whether, if a particular drug were put on the market, it would infringe the relevant patent."[94]

The infringement modification has to be seen in light of a system of patent declaration regulations for both the applicant of innovator drugs and those who file ANDAs and paper NDAs. Applications for innovator drugs shall, according to §355(b)(1), include the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application. The applicant submitting an ANDA or a paper NDA is likewise required to make certain certifications with respect to patents related to the pioneering drug.

One type of certification contains the applicant assertion that the patent claiming the pioneering drug is invalid or not infringed by the application.[95] This certification can trigger a patent infringement proceeding for if it is provided the applicant is required to inform the

[92] Scott C. Hemphill & Bhaven N. Sampat, *When Do Generics Challenge Drug Patents?,* 8 J. EMPIRICAL LEGAL STUD. 613, 614 (2011) ("Once generic firms enter the market, prices fall, often to less than 10 percent of the brand-name drug."); Tyler J. Klein, Comment, *Antitrust Enforcement Against Pharmaceutical Product Hopping: Protecting Consumers or Reaching Too Far?,* 10 ST. LOUIS U. J. HEALTH L. & POL'Y 213, 219 (2016).

[93] *Eli Lily*, 496 U.S. at 678.

[94] Bristol-Myers Squibb Co. v. Royce Lab., Inc., 69 F.3d 1130, 1135 (Fed. Cir. 1995).

[95] 21 U.S. Code § 355(j)(2)(A)(vii)(IV). According to FDA regulations unenforceability can also be certified by the applicant, cf. 21 C.F.R. §314.94(a)(12)(i)(A)(4)(2018) for ANDA and §314.50(i)(1)(i)(A)(4)(2018) for paper NDA.

respective patent owner.[96] Unless the patentee files an infringement suit within forty-five days upon receipt of the notice, the approval is made effective immediately. The initiation of such a proceeding will cause the FDA to stay the approval process for thirty months.[97]

Not only does §271(e) create a unique act of infringement in paragraph (2), but it also sets forth specific provisions regarding available remedies in paragraph (4). In the event that the district court finds that an ANDA or a paper NDA infringes a patent, the statute provides three remedies. First, paragraph (4) subparagraph (A) provides that if a patent is infringed through the application for FDA approval the court shall order the effective date of any approval of the product involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed. If, however, the application for the new drug has already been approved by the FDA, the district court's order would be directed to alter the effective date of the application, thereby converting a final approval into a tentative approval.[98] Notably, the statute in subparagraph (A) uses the word shall in contrast to the word may that is commonly found in remedial provisions and in those regarding injunctive relief. Second, subparagraph (B) grants the district court the authority to issue injunctive relief and, third, subparagraph (C) provides the statutory basis for the award of damages. The prescribed remedies are conclusive and exclude the possibility of the court to resort to the default remedy statutes with an exception for attorney fees. Injunctive relief and damages are limited to cases where actual commercial behavior has commenced. This limitation of remedies has to be seen in view of the artificial nature of the infringing act defined in §271(e)(2) which does not require commercial activities.[99]

[96] 21 U.S.C. § 355(j)(2)(B)(i)-(iv).

[97] 21 U.S.C. § 355(j)(5)(B)(iii).

[98] H.R. REP. NO. 98–857 (II), at 46 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2679; In re Omeprazole Patent Litig., 536 F.3d 1361, 1367-68 (Fed. Cir. 2008); Ortho–McNeil Pharm., Inc. v. Mylan Labs., Inc., 520 F.3d 1358, 1366 (Fed. Cir. 2008); Mylan Labs., Inc. v. Thompson, 389 F.3d 1272, 1281–82 (D.C. Cir. 2004).

[99] The Federal Circuit has pointed out that "§271(e)(4)(C) recognizes the artificial nature of the filing of an ANDA by limiting monetary relief to unauthorized commercial manufacture, use, offer for sale, or sale of the patented invention," Zeneca Ltd. v. Mylan Pharm., Inc., 173 F.3d 829, 836 (Fed. Cir. 1999).

The scope of § 271(e)(2) is narrowly tailored and greatly purpose driven. It does not modify the infringement inquiry for disputes involving drugs generally but only for certain drugs, namely only for generic drugs for which an ANDA is submitted and for drugs that rely on a paper NDA. The Supreme Court described §271(e)(2) in *Eli Lily v. Medtronic* as a "creation of a highly artificial act of infringement that consists of submitting an ANDA or a paper NDA containing the fourth type of certification that is in error as to whether commercial manufacture, use, or sale of the new drug (none of which, of course, has actually occurred) violates the relevant patent."[100] It further elaborates that the purpose of this artificial act of infringement is "to enable the judicial adjudication upon which the ANDA and paper NDA schemes depend."[101] The creation of the artificial act of infringement provided for by §271(e) allows "the early resolution of patent disputes between generic and pioneering drug companies."[102] For one thing, this allows patentees to bring suit before market entrance of the alleged infringer and thus anticipate potentially irreversible impact on drug prices. In this sense the provision provides special protection of the innovator drug group of the pharmaceutical industry. For another, it is also a chance for other drug companies, especially generic companies, to contest validity at an early stage or to bring to the market a product which they consider not to fall within the scope of the patent.[103] Again this could be understood as an industry-specific modification to ensure early market entry of generic drugs.

Moreover, it seems worthwhile considering the relationship between agency policies, in this case the drug approval process by the FDA, and patent law. In light of legislative history, §271(e) appears to be a counterbalance to ANDAs and paper NDAs. The Hatch-Waxman Act consists of two titles: title I of the Act is aimed "to make available more low cost generic drugs by establishing a generic drug approval procedure for pioneer drugs."[104] Creating "a new incentive for increased

[100] *Eli Lily*, 496 U.S. at 678.

[101] *Id.*

[102] Caraco Pharm. Labs., Ltd. v. Forest Laboratories, Inc., 527 F.3d 1278, 1283 (Fed. Cir. 2008); Endo Pharm. Inc. v. Amneal Pharms., 2015 WL 9459823 (S.D.N.Y. Aug. 18, 2015).

[103] H.R. Rep. No. 98-857(I) (1984), at 27, *reprinted in* 1984 U.S.C.C.A.N. 2647, 2660.

[104] H.R. REP. NO. 98-857(I) (1984), at 14, *reprinted in* 1984 U.S.C.C.A.N. 2647. Prior to the Hatch-Waxman Act ANDAs were only available for generic drugs that

expenditures for research and development of certain products which are subject to premarket government approval" is the objective of title II.[105]

Having analyzed the industry-specific changes introduced through the Hatch-Waxman Act, where does this leaves us? The infringement provisions and the respective remedies set forth in §271(e), just as the patent extension in §156, can be described as modules of a complex framework having its basis in the field of regulatory law and is aimed at satisfying and balancing industry needs and public interests. The amendment of the Patent Act dovetails the practical changes of the regulatory law. The industry-specific character is thus a reflex reaction to regulatory changes. To a large extent the narrowly tailored provisions reflect promising traits of industry-specificity, as they seek to assure adequate compensation of the patentee, on one hand, and early public access to generic drugs, on the other. However, the finding cannot stop here. The amendments of the Hatch-Waxman Act demonstrate the enormous complexity of crafting industry-specific patent law and the inherent risks of discrimination. Striking the right balance between brand companies, generic drug companies and the public requires immensely complex legal schemes. Unsurprisingly, concerns regarding short-comings of the Hatch-Waxman have been voiced.[106] Further, the survey of the pesticide regulatory provisions reveals that the Hatch-Waxman Act has led to discrimination between similar industries and has thus cast one of the fundamental perils of industry-specificity into law.

---

were bioequivalent to pioneer drugs approved prior to 1962. Generic drugs that were bioequivalent to post 1962 pioneer drugs had to file regular new drug approval applications, see H.R. REP. NO. 98-857(I) (1984), at 16, *reprinted in* 1984 U.S.C.C.A.N. 2647, 2649.

[105] H.R. REP. NO. 98-857(I) (1984), at 15, *reprinted in* 1984 U.S.C.C.A.N. 2647, 2648.

[106] Matthew Avery, *Continuing Abuse of the Hatch-Waxman Act by Pharmaceutical Patent Holders and the Failure of the 2003 Amendments*, 60 HASTINGS L.J. 171, 179 (2008) ("There has long been a concern that patent holders have used loopholes in the Hatch-Waxman Act to deter or delay generic competition.").

IV. THE PHYSICIAN IMMUNITY CLAUSE OF §287(C)

The so-called physician immunity clause as provided for in §287(c) of the Patent Act provides an interesting and extremely controversial example of industry-specificity. Under current U.S. patent law, medical procedures are eligible subject matter of patent protection that can be patented subject to the general requirements of the Patent Act. However, remedies for infringement of these types of patented inventions is severely restricted by § 287(c) of the Patent Act. The statute declares the provisions on remedies, namely injunctive relief, award of damages and attorney fees, inapplicable against a medical practitioner or against a related health care entity, with respect to medical practitioners' performance of medical and surgical procedure on a body. The ambit of the exemption goes beyond the person performing the medical activity and encompasses health care entities such as nursing homes, hospitals, universities, medical schools, health maintenance organizations, group medical practices, and medical clinics.[107] The practical importance of the "physician immunity" provision is so far negligible. In the only decision on §287(c) that could be found, the Court of Federal Claims delineated the dogmatic nature of the immunity clause holding that it was not a mere limitation, but a defense, and thus "a complete bar to any recovery or relief."[108] Unlike §271(e) of the Patent Act, §287(c) does not draw on the question of whether an act constitutes an infringing act, but expressly imposes a defense to the remedies available. As a consequence, the patentee, though, unable to obtain relief against directly infringing activities, can still successfully sue and obtain relief against third parties that induce the directly infringing conduct under §271(b), (c) of the Patent Act.[109]

[107] 35 U.S.C. § 287(c)(2)(C).

[108] Lamson v. United States, 117 Fed. Cl. 755, 762 (2014).

[109] In contrast, German and European patent law follow a different approach. Both rely on field restrictions for medical procedures. For example, § 2a(1) no. 2 of the German Patent Act provides that patents shall not be granted for "methods for the treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body. This shall not apply to products, in particular to substances or compositions, for use in one of these methods." A similar provision can be found in the European Patent Convention, cf. Art. 53(c) EPC providing that European patents shall not be granted in respect of "methods for treatment of the

The legislative process for § 287(c) was initiated against the backdrop of the case of *Pallin v. Singer*.[110] Dr. Pallin owned a patent directed to a method for "self-sealing" surgical incisions performed to treat cataracts.[111] Cataracts are medical conditions where the lens of an eye turns cloudy and scatters the incident light, preventing the lens from focusing and thus causing vision problems.[112] In surgery, the affected lens material is removed through an incision in the outer region of the eye and replaced by an artificial lens. Prior to Dr. Pallin's discovery, sutures were used to close the incision which often caused astigmatism. His patent claimed an incision in a specific area of the eye and in a specific shape and allowed sealing without sutures. In 1993, Dr. Pallin's attorney contacted Dr. Singer and the Hitchcock Associates clinic by sending them a cease-and-desist letter with the option to take a license.[113] After failed settlement negotiations and Dr. Singer's successful mobilization of the medical community against the restraining of medical procedures through patents,[114] Congress picked up the issue of protection of medical procedures through the means of patent law.[115]

The Congressional record reveals the rationale behind the defense set forth in § 287(c) of the Patent Act. During the legislative procedure, it was pointed out that the issuance of patents in the medical field is generally accepted and is a necessity to ensure recoupment of investments. However, with respect to patents on medical procedures, a

---

human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body; this provision shall not apply to products, in particular substances or compositions, for use in any of these methods." Patentgesetz [Patent Act], Oct. 8, 2017, BGBL I at 1, § 2(a)(1) (Ger.).

[110] Pallin v. Singer, Civ. No. 5:93–202, 1995 WL 608365 (D. Vt. 1995) (denying defendant motion for summary judgment).

[111] U.S. Patent No. 5,080,111.

[112] *Cataract*, AMERICAN OPTOMETRIC ASS'N, https://www.aoa.org/patients-and-public/eye-and-vision-problems/glossary-of-eye-and-vision-conditions/cataract (last visited May 9, 2018).

[113] Katherine J. Strandburg, *Derogatory to Professional Character? Physician Innovation and Patents as Boundary-Spanning Mechanisms* 33 (N.Y.U. L. & Econ. Working Paper, Paper No. 357, 2013), https://core.ac.uk/download/pdf/18469655.pdf (relying on Complaint at ¶ 15, Letter from John M. White to Jack L. Singer, Entry No. 1, Exhibit B.).

[114] *Id.* at 35-36.

[115] 142 CONG. REC. 26825 (1996) (Senator Frist explicitly referenced the dispute between Dr. Pallin and Dr. Singer and the Hitchcock Associates clinic).

distinction is drawn based on a fundamental aspect of patent law—the provision of sufficient incentives. As Senator Frist put it, "innovations in pure procedure . . . are constantly being made without the need of significant research investments."[116] According to the Senator, the incentive argument does not apply to pure medical and surgical procedures, because innovations in this field would occur even without the inducement of the patent system.[117] In addition, the needs for investment protection are pointed out as being different between medical devices and drugs, on one hand, and medical procedures on the other.[118] Senator Frist further elaborated that allowing doctors to charge licensing fees for new medical or surgical techniques would be a windfall to them and a "huge and costly burden for the patient community"—a burden that was "wholly unnecessary" because these innovations would occur anyway."[119] Potential conflicts with patients' rights to privacy were also named as justification.[120] More important, though, seems to be the point that the field of medical treatment is largely driven by inherent incentives that act as catalysts for innovation. It was asserted by Senator Frist that doctors would seek the best care for their patients due to their ethical duties, and that peer recognition would provide sufficient incentive to secure innovation.[121] Finally, concerns were voiced with respect to potential FDA scrutiny of medical procedures.[122]

Due to the limited scope of the provision, the path taken by Congress can adequately be described as "narrowly tailored legislation."[123] Despite the limited scope of § 287(c), the opposition against curtailing remedies for patents on medical procedures was in part drastic. Senator Hatch, for example, concluded that the proposed change of law violated "a fundamental principle of our law under which patent protection is available without discrimination as to field of invention or technology."[124] Indeed, the statutory approach taken by Congress might be considered disconcerting in the patent system.

[116] *Id.*
[117] *Id.*
[118] *Id.* at 26826.
[119] *Id.*
[120] *Id.*
[121] *Id.*
[122] *Id.*
[123] 142 CONG. REC. 26825 (1996).
[124] 142 CONG. REC. 26643 (1996).

Congressional and scholarly debate touched upon its potential conflicts with regard to the TRIPs Agreement.[125] The provision is a unique phenomenon in the canons of remedies and the limitations as set forth in §287 of the Patent Act. For one thing, it forecloses patentees from enforcing their exclusive rights against a guild, namely physicians, and for another, it prevents remedies being granted against sub-industries of the health care providers and services industry.[126]

Especially, the economic argument reflects one of the concerns regarding industry-specific patent law as it is based on the status quo and on future predictions of innovative behavior. The argument bears some resemblance to the argument made in the context of the patent term extension as to why it is awarded to the pharmaceutical industry but not the pesticide industry. It is true that patent protection creates a short-run deadweight loss in order to provide a long-run incentive for innovation and that if innovation occurs without the inducement of the patent system, the deadweight loss associated with it is not warranted.[127]

---

[125] 142 CONG. REC. 26642 (1996) (statement by Senator Hatch); the general counsel of the U.S. Trade Representative expressed concerns during the legislative process: "USTR has serious concerns about the consistency of this provision with the TRIPs Agreement. Moreover, we believe that the proposal sets a damaging precedent that other TRIPs Members might apply to other technologies. Although TRIPs Article 27:3 permits Members to exclude diagnostic, therapeutic and surgical techniques from patentability, we believe that if a member makes patents available for this field of technology, a Member must accord the full rights required under the TRIPs Agreement. Article 27:1 requires that patent rights be enjoyable without discrimination as to the field of technology. Those rights are specified in Article 28 and include the right to prevent third parties from the act of using a patented process. Moreover, TRIPs Articles 44 and 45 specify remedies, including injunctions and damages; that must be made available to address patent infringement." reprinted in 142 CONG. REC. S11,843 (Sept. 30, 1996); Cynthia M. Ho., *Patents, Patients, and Public Policy: An Incomplete Intersection at 35 U.S.C. 287(c),* 33 U.C. DAVIS L. REV. 601, 660, 670 (2000) (finding that §287(c) violates Articles 27 and 28 of the TRIPs Agreement as it "restricts the patent holder's right to exclude and treats medical procedure patents differently from other patents" and the lack of "an excuse under another provision of TRIPS"); Leisa T. Peschel, *Revisiting the Compromise of 35 U.S.C. § 287(C),* 16 TEX. INTELL. PROP. L.J. 299, 321 (2008) ("§ 287(c) likely violates the TRIPs Agreement").

[126] For a detailed classification of the different industries, *see Global Industry Classification Standard* (Aug. 31, 2016), (available at https://www.msci.com/documents/1296102/1339060/GICSSectorDefinitions.pdf/fd3a7bc2-c733-4308-8b27-9880dd0a766f).

[127] Tom Nicholas, *Are Patents Creative or Destructive?*, 79 ANTITRUST L.J. 405 (2014). The patent provides an exclusive right that allows the patentee to charge *supra-*

Provided that the assumption that innovations with respect to medical procedures are sufficiently incentivized by other factors, such as peer recognition holds true, the exceptional treatment is socially beneficial. However, the reliance on innovation trends comes with the risk of being outdated fairly quickly.

Further, despite this criticism as to the policy behind §287(c) and the concerns regarding the compliance with the TRIPs Agreement, there might also be something further promising about the provision. Departing from standard law can lead to controversy, new insights and ultimately improvement of the law.[128]

V. LEGAL DOCTRINES CRAFTED BY THE COURT TO ALTER REMEDIES

A. COURT-MADE DIVERSITY

This section focuses on how courts, as opposed to Congress, can, and already have, created diversity among different industries. Burk and Lemley have analyzed the merits of leaving it to the courts to consider the peculiarities of each field of industry. Aside from the limitations provided for by the TRIPs Agreement, they point to the difficulties of implementing economic-based policy considerations into statutes; the enormous administrative costs and uncertainty associated with crafting statutes for each industry; the problem of overlapping industries and rapidly developing technologies; and the risk of opening the doors to excessive lobbying by special interest groups.[129] Within the limits of the statutory language, courts can give consideration to special circumstances pertinent to the case at hand. In the context of remedies, the value rule as part of the damage calculation and the four-factor test

competitive prices and restrict output. William Hubbard, *The Debilitating Effect of Exclusive Rights: Patents and Productive Inefficiency*, 66 FLA. L. REV. 2045, 2056 (2015).

[128] *See* John F. Duffy, *Harmony and Diversity in Global Patent Law*, 17 BERKELEY TECH. L.J. 685 (2002) (arguing in favor of allowing diversity in the context of global patent law).

[129] Burk & Lemley, *supra* note 6, at 97–100.

for injunctive relief provide gateways to court-made diversity in the patent system.

B. DAMAGES

1. ADEQUATE COMPENSATION

One infringement case is not like another. Sometimes the patentee suffers huge financial losses by infringing conduct, sometimes a product might be infringed, but the product would be just as valuable without the patented feature. Against this background, the statutory language of the Patent Act provides that "the court shall award the claimant damages adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer . . .."[130] In order to adequately compensate the patentee, damages are commonly measured by either determining lost profits or by inquiring as to the reasonable royalty.[131] Reasonable royalties are usually measured in one of two ways: 1) the analytical method, which looks at the infringer's prognosis of profit for the infringing product, and, more commonly, or 2) by looking at the "royalty to which a willing licensor and a willing licensee would have agreed at the time the infringement began."[132] From the wording of the Patent Act, it follows that the reasonable royalty provides "a floor below

[130] 35 U.S.C. § 284.

[131] Lucent Tech., Inc. v. Gateway, Inc., 580 F.3d 1301, 1324 (Fed. Cir. 2009).

[132] Radio Steel & Mfg. Co. v. MTD Prods., Inc., 788 F.2d 1554, 1557 (Fed. Cir. 1986); *see also Lucent*., 580 F.3d at 1324; Goodyear Tire & Rubber Co. v. Overman Cushion Tire Co., 95 F.2d 978, 984 (9th Cir. 1937); Egry Register Co. v. Standard Register Co., 23 F.2d 438, 443 (6th Cir. 1928) ("In fixing a reasonable royalty, the primary inquiry, often complicated by secondary ones, is what the parties would have agreed upon, if both were reasonably trying to reach an agreement");. Another approach to determine reasonable royalties is the "analytical approach", TMW Mfg. Co., Inc. v. Dura Corp., 789 F.2d 895, 899 (Fed. Cir. 1986). *See also* factor 15 of the so-called Georgia-Pacific factors for determining reasonable royalties listing "[t]he amount that a licensor (such as the patentee) and a licensee (such as the infringer) would have agreed upon (at the time the infringement began) if both had been reasonably and voluntarily trying to reach an agreement […]" as one of the factors to determining reasonable royalties. Georgia-Pacific Corp. v. Plywood Corp, 318 F.Supp. 1116, 1120 (S.D.N.Y. 1970), *modified and aff'd sub nom.,* Georgia-Pacific Corp. v. United States Plywood-Champion Papers, 446 F.2d 295 (2d Cir. 1971), *cert. denied*, 404 U.S. 870 (1971).

which the courts are not authorized to go."[133] Even before the reasonable royalty standard was implemented into the Patent Act in 1922, courts had recognized its function in ensuring minimum compensation of the patentee.[134] In the context of determining the terms on which the parties would have agreed, the Georgia-Pacific factors have become a frequently referred-to framework.[135] Calculating damages often involves the Herculean task of figuring out the true value of the patented invention.[136] This is even truer when the patented invention covers only one out of many features of a more complex infringing product.[137] In these cases, the threat of overcompensation of the patentee is pervasive.[138] Courts try to ensure that the patentee will not be compensated beyond the value of her patent, and on the basis of non-infringing components of the multi-component product.[139] As early as the 19th century, the Supreme Court established the fundamental idea of

[133] Del Mar Avionics, Inc. v. Quinton Instruments Co., 836 F.2d 1320, 1326 (Fed. Cir. 1987).

[134] Dowagiac Mfg. Co. v. Minnesota Moline Plow Co., 235 U.S. 641, 648 (1915) (stating that absent an established royalty rate it is permissible to determine the value of the patent considering "the nature of the invention, its utility and advantages, and the extent of the use involved."); note that nowadays the distinction between established royalty rate and royalty rate is essentially conflated as courts use the established royalty rates in their reasonable royalty rate analysis. *See* Georgia-Pacific, 318 F.Supp. at 1120 (the court applying as the first factor in its reasonable royalty assessment "the royalties received by the patentee for the licensing of the patent in suit, proving or tending to prove an established royalty.").

[135] Georgia-Pacific, 318 F.Supp. at 1120. Aside from the vast number of district court decisions involving the Georgia-Pacific factors, the Federal Circuit and its predecessors have likewise relied on the factors compiled by the District Court for the Southern District of New York, *see* Trio Process Corp. v. L. Goldstein's Sons, Inc., 612 F.2d 1353, 1357 (3rd Cir. 1980); Hanson v. Alpine Valley Ski Area, Inc., 718 F.2d 1075, 1077 (Fed. Cir. 1983); Exmark Mfg. Co. Inc. v. Briggs & Stratton Power Prods. Grp., LLC, 879 F.3d 1332, 1349 (Fed. Cir. 2018).

[136] Dowagiac, 235 U.S. at 648 ("As the exclusive right conferred by the patent was property, and the infringement was a tortuous taking of a part of that property, the normal measure of damages was the value of what was taken"); AstraZeneca AB v. Apotex Corp., 782 F.3d 1324, 1344 (Fed. Cir. 2015) (quoting Dowagiac).

[137] LaserDynamics, Inc. v. Quanta Comput. USA, Inc., 694 F.3d 51, 66 (Fed. Cir. 2012) ("To assess how much value each patented and non-patented component individually contributes to the overall end product—e.g., a personal computer—can be an exceedingly difficult and error-prone task.").

[138] Brian J. Love, Note, *Patentee Overcompensation and the Entire Market Value Rule*, 60 STAN. L. REV. 263 (2007).

[139] LaserDynamics, 694 F.3d at 67.

separating patented and unpatented features when determining the patentee's damages.[140]

2. THE ENTIRE MARKET VALUE RULE

By way of exception, the entire market value rule allows the patentee to base damages not on a separated feature or component, but on the entire product. As a prerequisite, the patentee has to show that "the patent related feature is the basis for consumer demand."[141] The concept of the entire market value rule is exemplified in two cases: *Lucent Technologies v. Gateway* and *LaserDynamics v. Quanta Computer*.

Calculating damages for the infringement of a small component in a complex product can lead to skewed damage awards, if the product, rather than the component, builds the basis for the calculation. In *Lucent Technologies v. Gateway, Inc.*, Lucent sought damages from Microsoft for infringement of their "Day patent" [142] based on Microsoft's software Microsoft Money, Microsoft Office, and Windows Mobile.[143] The patent in this suit was "directed to a method of entering information into fields on a computer screen without using a keyboard."[144] Microsoft's software Office includes a calendar allowing date entries by selecting the desired date from a grid of number dates with a graphical control, such as a computer mouse.[145] The jury found that Microsoft's software infringed the "Day patent," and awarded Lucent a lump-sum royalty payment in the amount of $357,693,056.18.[146] On appeal, Microsoft, inter alia, contested the jury's damage award. It argued that the jury

[140] Garretson v. Clark, 111 U.S. 120, 121 (1884) (quoting Justice Blatchford, who formulated that the patentee "must in every case give evidence tending to separate or apportion the defendant's profits and the patentee's damages between the patented feature and the unpatented features, and such evidence must be reliable and tangible, and not conjectural or speculative; or he must show, by equally reliable and satisfactory evidence, that the profits and damages are to be calculated on the whole machine, for the reason that the entire value of the whole machine, as a marketable article, is properly and legally attributable to the patented feature.").

[141] State Indus., Inc. v. Mor-Flo Indus., Inc., 883 F.2d 1573, 1580 (Fed. Cir. 1989); Imonex Serv., Inc. v. W.H. Munzprufer Dietmar Trenner GMBH, 408 F.3d 1374, 1379 (Fed. Cir. 2005).

[142] U.S. Patent No. 4,763,356.

[143] Lucent Tech. v. Gateway, 580 F.3d 1301 (Fed. Cir. 2009).

[144] *Id.* at 1308.

[145] *Id.* at 1317.

[146] *Id.* at 1308.

could only have reached this figure by basing the calculation on the total sales figure of the infringing software, and thereby erroneously applied the entire market value rule.[147] The Federal Circuit sided with Microsoft regarding the application of the entire market value rule. It cited, "the lack of evidence demonstrating the patented method of the Day patent as the basis—or even a substantial basis—of the consumer demand for Outlook." Considering the other features of Microsoft's Outlook software, the court reached the "unmistakable conclusion that the invention described in … the Day patent is not the reason consumers purchase Outlook," vacated the award, and remand for a new trial on damages.[148]

In *LaserDynamics v. Quanta*,[149] LaserDynamics, plaintiff-appellant, owned a patent directed to a method enabling optical disc drives (ODD) to automatically identify whether the optical disc inserted into the player-device was a CD or a DVD, thereby making manual user identifications redundant.[150] Quanta (QCI), defendant-cross appellant, assembled laptop computers for companies such as Dell and Apple, including the installation of ODDs. After QCI had entered the U.S. market, LaserDynamics filed suit for induced infringement and sought reasonable royalty damages. After the jury awarded LaserDynamics damages in the amount of $52 million in the first trial, QCI filed a motion for and was granted a new trial due to LaserDynamics' improper reliance on the entire market value as the basis for its damage calculations.[151] In the following second trial QCI's objections regarding the application of the entire market value rule were sustained.[152] LaserDynamics appealed the district court's granting of a new trial. In the ensuing appeal, the Federal Circuit dwelled on the problem of damages in cases involving multi-component products and the application of the entire market value rule.

The court explained that royalties generally cannot be based on the entire product, but instead on the "smallest salable patent-practicing

[147] *Id.* at 1336.

[148] *Id.* at 1337, 1340.

[149] LaserDynamics v. Quanta, 694 F.3d 51 (Fed. Cir. 2012).

[150] U.S. Patent No. 5,587,981.

[151] LaserDynamics, Inc. v. Quanta Computer, Inc., No. 2:06–cv–348–TJW–CE, 2010 WL 2331311 (E.D. Tex. June 9, 2010).

[152] Laser-Dynamics, Inc. v. Quanta Computer, Inc., No. 2:06–cv–348–TJW–CE, 2011 WL 7563818, at *2 (E.D. Tex. Jan. 7, 2011).

unit."[153] Just as in Lucent, the court stated that it can only deviate from this general rule if the patentee can show "that the patented feature drives demand for an entire multi-component product."[154] The patented feature must be *condition sine qua non* for the customers' demand for the product.[155]

The court found that LaserDynamics could not rely on the entire market value rule, because it failed to show that its patented invention drove consumer demand for laptop computers.[156] According to the judges, in order to use the entire market value as the basis for damages, it is not sufficient that the patented invention is viewed as "valuable, important, or even essential to the use of the laptop computer" or even that the product would be "commercially unviable" without the patented invention.[157] With respect to the method protected by LaserDynamics patent in suit, the court concluded that it was "a useful commodity-type feature that consumers expect will be present in all laptop computers" and that it was not enough to justify the reliance on the entire market value rule.[158]

3. INDUSTRY-SPECIFICITY OF THE ENTIRE MARKET VALUE RULE

The benefits and goals of the entire market value rule are most clearly visible with respect to high-technology products. Patentees are more likely to be overcompensated where patents cover only minor features of a complex product. Where patents cover entire products, or major parts, the risk is lower. The tailored application of the Patent Act

[153] *LaserDynamics*, 694 F.3d at 67.

[154] *Id*. at 67, relying on Rite-Hite Corp. v. Kelley Co., Inc., 56 F.3d 1538, 1551 (Fed. Cir. 1995).

[155] *Id*. at. 67, referring to Lucent v. Gateway, 580 F.3d 1301, 1336 (Fed. Cir. 2009) (quoting TWM Mfg. Co. v. Dura Corp, 789 F.2d 895, 901 (Fed. Cir. 1986)). One may suppose that the entire market value rule could not be counterbalanced by adjusting the license rate accordingly. However, courts have repeatedly emphasized that such a calculation is inadmissible as it involves the disclosure of the profits made with the entire product which would likely skew the jury's damage determination. Uniloc USA, Inc. v. Microsoft Corp., 632 F.3d 1292, 1320 (Fed. Cir. 2011) (involving the infringement of a patent for a software registration system directed towards reducing the unauthorized use of software and an attempt to justify reasonable royalties while taking into account Microsoft's total revenue for Office and Windows of more than $ 19 billion); *LaserDynamics*, 694 F.3d at 68.

[156] *LaserDynamics*, 694 F.3d at 68.

[157] *Id.*

[158] *Id.* at 69.

shows promisingly how the recognition of differences can help in assuring just and appropriate application of patent law.

Recently, the District Court for the Southern District of New York asserted with respect to the application of the entire market value rule in the context of pharmaceuticals that "there is little reason to import these rules for multi-component products like machines."[159] On appeal, the Federal Circuit refused to follow such a general rule, explaining "[w]hile we do not hold that the entire market value rule is per se inapplicable in the pharmaceutical context, we concur with the district court that the rule is inapplicable to the present case."[160] As will be analyzed in the following section, in the context of injunctions, the Federal Circuit has explicitly rejected limiting the causal nexus requirement to cases of complex products.[161] Even though one might recognize that the Federal Circuit does not intend to create industry specific rules, in practical terms, however, the entire market value rule has far broader implications for high-technology companies, as compared to other industries, where products consist of fewer components.

C. INJUNCTIONS IN PATENT LITIGATION

1. INJUNCTIONS UNDER US PATENT LAW – A FLEXIBLE INSTRUMENT

The right to exclude others from using a patented invention can be understood as the centerpiece of the patent right. Injunctions are the patentee's sharp sword to protect this right, and may be a bogeyman to infringers. Despite the neutral wording of the injunction provision, for more than a decade, case law has evolved with diverse impacts across the industries.

[159] AstraZeneca AB v. Apotex Corp., 985 F.Supp.2d 452, 490 (S.D.N.Y. 2013).

[160] AstraZeneca AB v. Apotex Corp.,782 F.3d 1324, 1337-38 (Fed. Cir. 2015) ("This case does not fit the pattern in which the entire market value rule applies. Astra's formulation patents claim three key elements—the drug core, the enteric coating, and the subcoating. The combination of those elements constitutes the complete omeprazole product that is the subject of the claims. Thus, Astra's patents cover the infringing product as a whole, not a single component of a multi-component product. There is no unpatented or non-infringing feature in the product.").

[161] Apple Inc. v. Samsung Elecs. Co., Ltd. 735 F.3d 1352, 1362 (Fed. Cir. 2013).

The statutory basis for injunctions in patent infringement proceedings is anchored in §283 of the Patent Act. Courts are vested with the authority to grant "injunctions in accordance with the principles of equity to prevent the violation of any right secured by patent, on such terms as the court deems reasonable." It has long been courts' practice that once a patent is found valid and infringed, courts would issue an injunction.[162] In *eBay Inc. v. MercExchange, LLC,* the Supreme Court set an end to the rigid rule previously applied by the Federal Circuit.[163] In its decision, the Court pointed to the equitable roots of injunctions and subjected the grant of an injunction to the traditional four-factor test.

In compliance with the four-factor test, an injunction shall only be issued when the plaintiff demonstrates that 1) it has suffered an irreparable injury; 2) remedies available at law, such as monetary damages, are inadequate to compensate for that injury; 3) considering the balance of hardship between the plaintiff and defendant, a remedy in equity is warranted; and 4) the public interest would not be disserved by a permanent injunction.[164] The Supreme Court has expressly rejected rigid rules with respect to the issuance of injunctions, both in favor of

[162] Smith Int'l, Inc. v. Hughes Tool Co., 718 F.2d 1573, 1578 (Fed. Cir. 1983) ("The patent owner would lack much of the 'leverage,' afforded by the right to exclude, to enjoy the full value of his invention in the market place. Without the right to obtain an injunction, the right to exclude granted to the patentee would have only a fraction of the value it was intended to have, and would no longer be as great an incentive to engage in the toils of scientific and technological research"); KSM Fastening Systems, Inc. v. H.A. Jones Co., Inc., 776 F.2d 1522, 1524 (Fed. Cir. 1985) ("While the grant of injunctive authority is clearly in discretionary terms, injunctive relief against an infringer is the norm."); W.L. Gore & Assocs., Inc. v. Garlock, Inc., 842 F.2d 1275, 1281–82 (Fed. Cir. 1988) ("Although the district court's grant or denial of an injunction is discretionary depending on the facts of the case, injunctive relief against an adjudged infringer is usually granted"); Richardson v. Suzuki Motor Co. Ltd., 868 F.2d 1226, 1238 (Fed. Cir. 1989) ("It is the general rule that an injunction will issue when infringement has been adjudged, absent a sound reason for denying it."); MercExchange, LLC v. eBay, Inc., 401 F.3d 1323, 1338 (Fed. Cir. 2005) ("Because the 'right to exclude recognized in a patent is but the essence of the concept of property,' the general rule is that a permanent injunction will issue once infringement and validity have been adjudged.").

[163] eBay Inc. v. MercExchange, LLC, 126 S. Ct. 1837 (2006).

[164] *Id.* at 1839.

the infringer[165] and the patentee[166]. Instead, the four-factor test is a flexible standard which, at least in theory, allows for consideration of the specifics of each individual case.

The eligibility of the four-factor test to embrace the peculiarities of inventions from different fields of technology is reflected in Justice Kennedy's concurring opinion: "The equitable discretion over injunctions, granted by the Patent Act, is well suited to allow courts to adapt to the rapid technological and legal developments in the patent system."[167] Given the flexible character of the four-factor test, it can readily be discerned how courts might pick up on it and embrace a de facto diversity in the patent system in different industries.[168]

The way the *eBay*-framework is interpreted and applied can have great impact on industries. The following section will examine a series of four decisions by the Federal Circuit in the ongoing patent war between Apple and Samsung. In the course of the series, the Federal Circuit articulated a causal nexus requirement between the alleged harm and the infringing activity. The causal nexus places a heavy burden on some industries with respect to the availability of injunction and a very limited one on others.

2. THE CAUSAL NEXUS REQUIREMENT – APPLE I – IV

For years, Apple and Samsung have fiercely competed for the ascendancy in the market for smartphones. The disputes circle not only around infringement of utility patents, but also involve design patents.

---

[165] The District Court for the Eastern District of Virginia rejected MercExchange's motion for an injunction mainly because it inferred from the plaintiff's non-practicing character and its willingness to license its patents that it would not suffer irreparable harm absent an injunction and that remedies at law would provide adequate compensation. MercExchange, LLC v. eBay, Inc., 275 F.Supp.2d 695, 711–13 (E.D. Va. 2003).

[166] In sharp contrast to the District Court's approach, the Federal Circuit formulated that as a general rule a patentee would be entitled to an injunction given an infringement of its patent, MercExchange, LLC v. eBay, Inc., 401 F.3d. 1323, 1339 (Fed. Cir. 2005).

[167] *eBay*, 126 S. Ct. at 1842.

[168] In contrast, a rigid rule that the infringement of a valid patent justifies an injunction, as compared to those in place in Germany and most other European countries, prevents courts from creating de facto diversity among industries with respect to the availability of injunctive relief.

The series was opened when Apple sued Samsung for infringement of three design patents and one utility patent in the District Court for the Northern District of California. Two of the design patents were related to a design generally embodied in Apple's iPhone.[169] The third one was directed to a tablet computer design.[170] The utility patent covered the so-called "bounce-back" feature, which is activated when the user of a smartphone or tablet scrolls past the end of a document and then takes his finger off the screen, whereupon the document bounces back.[171] The district court denied granting a preliminary injunction on any of the patents in suit.[172]

Except for the design patent on the tablet design, the Federal Circuit affirmed the district court's decision (*Apple I*).[173] The court held that the district court was correct in requiring the showing of some causal nexus between Samsung's infringement and the alleged harm to Apple, in the context of the irreparable harm injury.[174] The court went on to explain:

> Sales lost to an infringing product cannot irreparably harm a patentee if consumers buy that product for reasons other than the patented feature. If the patented feature does not drive the demand for the product, sales would be lost even if the offending feature were absent from the accused product.[175]

The same year as *Apple I*, the Federal Circuit had to decide another dispute between the Californian and the Korean competitors (*Apple II*). Apple had filed suit against Samsung for several patents, inter alia, the '604 patent[176] titled "Universal interface for retrieval of information in a computer system."[177] Nine months after Apple initiated

[169] U.S. Patents Nos. D593,087 and D618,677.

[170] U.S. Patent No. D504,889 (filed Mar. 17, 2004).

[171] U.S. Patent No. 7,469,381 (filed Dec. 14, 2007).

[172] Apple Inc. v. Samsung Electronics Co. Ltd., No. 11–CV–01846–LHK, 2011 WL 7036077 (N.D. Cal. 2011).

[173] Apple Inc. v. Samsung Electronics Co. Ltd., 678 F.3d 1314, 1333 (Fed. Cir. 2012).

[174] *Id.* at 1324.

[175] *Id.* at 1324.

[176] U.S. Patent No. 8,086,604 (filed Dec. 1, 2004).

[177] Apple Inc. v. Samsung Electronics Co. Ltd., 695 F.3d 1370 (Fed. Cir. 2012).

the lawsuit, it fell to the Federal Circuit to decide whether Samsung's Galaxy Nexus smartphone was infringing claim 6 of the '604 patent, which was directed to an apparatus for locating information in a network by the use of heuristic modules. In particular, Apple contended that Samsung's Quick Search Box, an Android feature, makes use of the teaching protected by claim 6. The District Court for the Northern District of California had granted a preliminary injunction in favor of Apple, based on Samsung's infringement of claim 6.[178]

The Federal Circuit started off considering the traditional four-factor test and turned at first to the question of whether Apple would suffer irreparable harm absent an injunction. Similar to the decision in *Apple I*, the court dwelled on the issue of whether Apple had satisfactorily demonstrated the causal nexus between Samsung's infringement and Apple's harm. In this context, the court articulated the following rationale for the causal nexus requirement: "[T]he causal nexus inquiry…informs whether the patentee's allegations of irreparable harm are pertinent to the injunctive relief analysis, or whether the patentee seeks to leverage its patent for competitive gain beyond that which the inventive contribution and value of the patent warrant."[179]

The court explained that the patentee is required to "show that the infringing feature drives consumer demand for the accused product."[180] In its view, Apple failed to convince the court that there was sufficiently strong evidence to support the required link between its alleged harm and Samsung's infringement. In particular, the court rejected Apple's argument that its Siri application made use of the patented invention in suit, that Siri was a driver of consumers' demand for Apple's iPhone, and that the implementation of the technology in Samsung's Galaxy Nexus must thus also be a driver of consumer demand. [181]

In *Apple III*, the Federal Circuit softened its position regarding the 'driving demand' requirement. Again, Apple set forth to fight off

[178] Apple Inc. v. Samsung Electronics Co. Ltd, 877 F.Supp.2d 838 (N.D. Cal. 2012).

[179] *Apple*, 695 F.3d at 1375.

[180] *Id.* (citing Apple Inc. v. Samsung Electronics, 678 F.3d 1314, 1324 (Fed. Cir. 2012)).

[181] *Id.* at 1376–77.

Samsung's allegedly infringing activities with respect to three design and three utility patents.[182] With regard to the design patents, the Federal Court affirmed the judgment of the District Court for the Northern District of California and vacated and remanded with respect to the utility patents. The court clarified that the causal nexus was not a unique element of multi-component product disputes.[183] Apple had contended that the Federal Circuit's understanding of the causal nexus would lead in turn to the question of whether an injunction was granted on the distinction between complex and simple products. The court responded explaining "the causal nexus requirement applies regardless of the complexity of the products" but concedes "[i]t just may be more easily satisfied (indeed, perhaps even conceded) for relatively 'simple' products."[184] Thus, the causal nexus requirement is expressly designed not as a unique threshold for certain technologies, but as an element of the injunction inquiry generally to be considered. Yet the court itself recognizes that the element of the irreparable harm factor has a tendency to make it harder for some patentees to prevail on their motions for injunctive relief. In addition, the court eased its standard for demonstration of a causal nexus. It explained, "rather than show that a patented feature is *the exclusive reason* for consumer demand, Apple must show some connection between the patented feature and demand for Samsung's products."[185]

In the latest remake of the ongoing battle between Apple and Samsung, for the time being, Apple has once more brought suit against Samsung, alleging infringement of several patents *inter alia* the notorious "slide to unlock" patent.[186] Apple appealed a decision by the District Court for the Northern District of California denying Apple's motion for a permanent injunction. The court highlighted that "[f]irst and most importantly, Apple has not satisfied its burden demonstrating irreparable harm and linking the harm to Samsung's exploitation of any

[182] Two of the design patents and one of the utility patents were also litigated in Apple I, namely U.S. Patents Nos. D593,087; D618,677; and 7,469,381. The other patents in suit were: U.S. Patents Nos. D604,305; 7,844,915; and 7,864,163.

[183] Apple Inc. v. Samsung Electronics Co., Ltd., 735 F.3d 1352, 1362 (Fed. Cir. 2013).

[184] *Id.*

[185] *Id.* at 1364.

[186] The patents involved in the suit were U.S. Patent Nos. 5,946,647, 8,046,721, and 8,074,172 (the last of which covers the slide to unlock feature).

of Apple's three infringed patents."[187] On appeal, the Federal Circuit endorsed his departure from a strict 'driving demand' standard, as initiated in *Apple III*, repeating that the causal nexus requires the patentee only to show some connection between infringing conduct and alleged irreparable harm.[188] The court explained that the district court erred when requiring the patentee to show that it suffered harm solely from the infringing acts.[189] It emphasized the difficulties a patentee would otherwise face to master challenges when the accused device has thousands of features potentially driving consumers' demand, and that "barring entire industries of patentees—like Apple and other innovators of many-featured products—from taking advantage of these fundamental rights is in direct contravention of the Supreme Court's approach in *eBay.*"[190] The district court's order denying Apple's motion for injunctive relief was vacated, and the Federal Circuit remanded for further proceedings.[191] In its conclusion, the court pointed again to the risk of foreclosing certain groups from injunctive relief: "[i]f an injunction were not to issue in this case, such a decision would virtually foreclose the possibility of injunctive relief in any multifaceted, multifunction technology."[192]

3. INDUSTRY-SPECIFIC IMPLICATIONS

On its face, §283 of the Patent Act and eBay's four-factor test are industry-neutral with regard to whether granting an injunction is appropriate. Patentees from all industries are subject to the same standard. Yet the concurring opinion by Justice Kennedy in *eBay* emphasized that the four-factor test might be a suitable tool to remedy the problem associated with infringement of small component patents and issuing injunctions against complex products.[193] Notwithstanding Justice Kennedy's concurrence, the Supreme Court favored a flexible application of the four-factor test and argued against the application of rigid rules. A recent study by Christopher B. Seaman provides empirical

[187] Apple Inc. v. Samsung Electronics Co., Ltd., 12–CV–00630–LHK, 2014 WL 7496140 at *23 (N.D. Cal. 2014).

[188] Apple Inc. v. Samsung Electronics Co., Ltd., 809 F.3d 633, 640 (Fed. Cir. 2015).

[189] *Id.* at 641.

[190] *Id.* at 642.

[191] *Id.* at. 647.

[192] *Id.*

[193] eBay, Inc. v. MercExchange, LLC, 126 S. Ct. 1837, 1842 (2006) (Kennedy, J., concurring).

data on the real-world effects of *eBay*, revealing the industry-specific implications of the landmark case.[194] Seaman's results show that in some fields of technology injunctions are almost always granted. For instance, in disputes involving biotechnology or pharmaceuticals, injunctive relief was granted in 100% and 92%, respectively, of the post-*eBay* cases.[195] On the other side of the scale, infringers of patents on software or medical devices were enjoined from their activities in only 53% and 65% of the cases.[196] The disparity between these numbers provides some testimony as to how the application of a uniform statute and a uniform standard, can lead to diverging effects in different industries. Concerns, expressed after the Supreme Court handed down its decision in *eBay* that moving away from a rigid injunction rule would harm the pharmaceutical industry, have proven unfounded.[197] Instead of making injunctive relief generally less available, certain fields of technology are noticeably more effected, which, consequently, means that different industries face diverse challenges. Despite this observed diversion, at least one reservation must be articulated: One of the most critical aspects courts consider when an injunction is to be issued is whether the parties are competitors.[198] The diverging number thus certainly also reflects differences with regard to the proliferation of non-practicing entities, i.e., companies that do not themselves practice their

---

[194] Christopher B. Seaman, *Permanent Injunctions in Patent Litigation After eBay: An Empirical Study*, 101 IOWA L. REV. 1949, 1952 (2016).

[195] *Id.* at. 1984.

[196] *Id.*

[197] Brief for Pharmaceutical Research and Manufacturing of America as Amici Curiae Supporting Respondent, eBay, Inc. v. MercExchange, LLC, 126 S. Ct. 1837 (2006) (No. 05-130), 2006 WL 622122; Jeremiah S. Helm, Comment, *Why Pharmaceutical Firms Support Patent Trolls: The Disparate Impact of eBay v. MercExchange on Innovation*, 13 Mich. Telecomm. Tech. L. Rev. 331, 343 (2006) ("moving away from an automatic injunction will almost certainly reduce the incentive for pharmaceutical firms to innovate, especially as compared to firms in other areas."); for skepticism expressed early on about the impact on the biotech and pharmaceutical industries, *see* Michael Bekylkin, *Much Ado About Nothing: The Biotech and Pharmaceutical Industries Have Little to Fear in the Post-eBay World*, 6 J. Telecomm. & High Tech. L. 179 (2007).

[198] Seaman's empirical study found that motions for injunctive relief by non-practicing entities (referred to by Seaman as patent assertion entities) were only granted in 16% of the examined cases, whereas in 80% for practicing entities. Further, in 84% of the cases where injunctive relief was sought by a competing party an injunction was granted and only in 21% of the cases where a non-competing brought suit. Seaman, *supra* note 189, at 1988, 1990.

inventions but generate profits by licensing their patents, in each industry.[199]

The aforementioned caveat does not preclude courts from developing the law in a way favoring some and disadvantaging other industries. As the Supreme Court has provided only a framework for determining whether to issue an injunction, the industry-specific effects depend greatly on how lower courts fill in the blanks. With its interpretation of the irreparable harm requirement, the Federal Circuit has, in its decisions *Apple I-IV*, provided a vivid example of how the interpretation of neutral statutes and standards can lead to diversity among industries.

The Federal Circuit's approach in *Apple I* and *Apple II*, equating the causal nexus requirement to showing that, but for the infringing feature, the consumer would not have made the purchase, creates an obstacle that will be hard, if not impossible, to overcome in many cases involving multi-component products. In its two subsequent decisions, the Federal Circuit moved to a more liberal standard. It expressly recognized that foreclosing injunctive relief to a whole group of patentees is not in line with *eBay*'s idea of a flexible standard.[200]

Yet in spite of the more liberal recent approach, it can readily be discerned that, even under the Federal Circuit's new interpretation of the causal nexus requirement, implications will vary among different industries. Many patents in the field of pharmaceuticals are directed to the active ingredient of a drug.[201] Thus, consumers will generally base

[199] Regarding non-practicing entities and injunctive relief in general, *see* Miranda Jones, Note, *Permanent Injunction, A Remedy By Any Other Name Is Patently Not the Same: How eBay v. MercExchange Affects the Patent Right of Non-Practicing Entities,* 14 GEO. MASON L. REV. 1035 (expressing concerns about foreclosing non-practicing entities from obtaining injunctive relief).

[200] Apple Inc. v. Samsung Electronics Co., Ltd., 735 F.3d 1352, 1364 (Fed. Cir. 2013).

[201] The patenting scheme in the pharmaceutical industry is complex and characterized by attempts to obtain secondary patents, for example on coatings, salt forms etc., in order to extend exclusivity beyond the termination date of the primary patent. Aaron S. Kesselheim & Jonathan J. Darrow, *Hatch-Waxman Turns 30: Do We Need a Re-Designed Approach for the Modern Era?,* 15 YALE J. HEALTH POL'Y L. & ETHICS 293, 304 (2015). This strategy of often extending protection is often referred to as "evergreening." Scott C. Hemphill & Bhaven N. Sampat, *Evergreening, Patent*

their purchase decisions on the patented invention, namely the active ingredient. For other industries, especially those where patents are often granted for incremental improvements of complex products, the causal nexus requirement places a heavy burden on patentees.

The court's 'driving demand' standard inevitably reminds one of the requirements laid out by the court with respect to the application of the entire market value rule applied when determining damages. Causal nexus is essentially used to gauge the market value of a patent, though not as precisely as in the context of damages. The value of the patent, and whether an injunction is justified, depends on how desirable the patented feature is to consumers. Looking at the value consumers ascribe to the patented invention raises a further puzzling question: will looking at the value of a patent by asking whether or not it was critical for consumers' purchases favor design patents over utility patents? This may not hold true in every field of technology, but it seems a reasonable assumption where complex products are sold to private persons. In addition, the timing of the suit might greatly influence the outcome of the causal nexus analysis. It might encourage earlier filing of suits and deter parties from trying to find an amicable solution, because patentees might fear that a patent will soon lose value. This applies especially to dynamic industries in which features are hip and desired one day and out of fashion and undesired the next. Despite the concerns one might have regarding the adequacy of the 'driving demand' concept when deciding whether to grant an injunction, the causal nexus and the entire market value rest upon a similar consideration, namely, ensuring that certain groups of patentees are not compensated beyond their actual contribution to the progress in science. The promise of embracing industry and technology diversity comes at a cost. The flexibility of industry-specificity introduced by courts can result in legal uncertainty as it takes time for courts to come up with appropriate reactions to industry needs and technological changes. The development of the causal nexus requirement demonstrates that. Also, broader policy adjustments may need the intervention of Congress as courts can only operate within the scope of the statutory framework. Some adjustments such as the patent term extension can only be introduced by Congress.

Challenges, and Effective Market Life in Pharmaceuticals, 31 J. HEALTH ECON. 327 (2012).

VI. FRAMING THE RESULTS

It has been shown that industry-specificity has various facets in today's patent system. The following section systemizes the different types of tailoring the law.

A. REGULATORY INDUCED INDUSTRY-SPECIFIC DEVIATIONS

The first category of industry-specific provisions is what I call 'regulatory induced' deviations from standard patent provisions. The patent term extension provision of §156 of the Patent Act; the permission of testing of generic drugs with regard to regulatory approval in §271(e)(1); and the introduction of liability for otherwise non-infringing activities under §271(e)(2) fall within this category. Characteristic for these types of provisions is that they cause deviations from the uniform patent system in response to regulatory schemes. The regulatory approval process effectively shortens the lifetime of patents subject to approval. As a response, the Patent Act provides a restoration provision that balances the effects associated with the approval process. For generic drugs, Congress has designed specific means to abbreviate approval processes in order to assure early market entrance. The adjustment of the Patent Act in §271(e)(1) ensures that the regulatory goals regarding generics can be achieved, and that patent laws are not used to jeopardize regulatory policies. In this context, §271(e)(2) mitigates the consequences of the policy for fostering generic drugs by allowing innovative drug companies to bring infringement suits if generic companies submit approval applications to the FDA prior to the expiration of their patents. The aforementioned provisions deviate from the standard patent system in that they give consideration to rules outside patent law that affect only some industries. Therefore, they create diversity between regulated and non-regulated industries. This kind of industry-specific adjustments can prove promising in a world where innovation is increasingly influenced by different bodies of law.

Furthermore, an examination of the regulatory induced industry-specific provisions in this article revealed that even among regulated industries, diverse treatments occur. Where similar regulatory frameworks govern different industries, one would assume that the

patent system would treat them equally. Yet, as the comparison of the pharmaceutical and the pesticide industries has shown with respect to the patent term extension and the testing for approval exception, there is no strict adherence to uniform treatment of regulated industries. Such identified diversity opens the door for concerns regarding compliance with the prohibition of discrimination as to the field of technology, as stated in the TRIPs Agreement and the influence of special-interest groups. Therefore, when drafting regulatory-induced industry specific provisions, lawmakers should think outside the box and consider whether industries, other those primarily targeted, might be similar enough to fall within the ambit of the considered provision.

B. PATENT SYSTEM INDUCED GROUP/INDUSTRY-SPECIFIC REGULATIONS

In contrast to regulatory-induced industry diversity, patent system-induced diversity has its roots in the fundamental ideas of the patent system. The reason for the deviation from normal rules lies within the fundamental idea of patent laws to incentivize innovation. The deviation is not induced by outside laws, but by a recognized inadequacy of default patent law. The 'physician immunity' clause of §287(c) of the Patent Act is such a provision. With regard to the TRIPs Agreement, this type of patent system-induced deviation from the uniform standards of patent law is certainly the most concerning. Congress decided that there was no need for the incentivizing forces of the patent system to ignite innovations in the field of medical treatment, and thus curtailed remedies for infringing activities. Further, it is susceptible to obsolescence as innovation trends can quickly change and continuous Congressional answers are cumbersome.

C. INDUSTRY-NEUTRAL DOCTRINES WITH INDUSTRY-SPECIFIC IMPLICATIONS

In this category, the industry-specific implications arise out of the technology most commonly found in a particular industry. Typical for this category is that the statute mandates differentiation in its application with regard to predefined groups or industries. For instance, §283 of the Patent Act authorizes courts in the most general way to grant

injunctive relief. Only through application of the law by courts, does industry-specific diversity come to light. The application of the four-factor test for injunctive relief, and the entire market value rule for damages, provide two vivid examples of this. The industry-specific implications in this category are not direct, but rather ancillary effects of a certain approach to applying the law. For instance, both the entire market value rule and the causal nexus requirement aim to assure that patentees are not overcompensated. As an ancillary effect, injunctive relief is easier to obtain for patentees in some industries than in others, and the use of an entire product as a royalty basis might be suitable in disputes arising between competitors of some industries, but not others. Industry-specific application of the law is a useful tool to account for diversity. However, as courts are limited by binding precedent, industry-specific application has its restrictions and Congressional steps are thus necessary.

Compared to the two other categories, concerns with regard to the discrimination prohibition as to the field of technology, articulated in Article 27 of the TRIPs Agreement, seem less alarming. First of all, TRIPs objections could avail only if and to the extent that court practices are subject to TRIPs scrutiny.[202] In addition, the finding that a rule has dissimilar implications for different industries does not mean there are discriminating forces at work. As long as courts apply the same rules, in the same way, to all fact patterns, the threat of discrimination appears remote. Nevertheless, there might still be limitations where the asymmetrical application of law by the courts leads to a systematic disadvantage to certain industries.[203] Determining when this threshold is passed is clearly subject to uncertainty, which militates in favor of great reserve.

[202] One might argue that if member states to the TRIPs Agreement allow their courts to apply laws in a discriminatory way, the member states themselves will let discrimination occur through their courts, and thereby violate TRIPs standards.

[203] Burk and Lemley are "skeptical" that using injunctive relief as a macro policy lever instead of as a micro policy lever is "either a good idea or consistent with international treaty obligations." Burk & Lemley, *supra* note 6, at 140.

VII. CONCLUSION

Tradition and the TRIPs Agreement favor a patent system that operates uniformly. Nevertheless, its uniform façade is furnished with niches of industry diversity. Diversity in patent law is not confined to a certain aspect of patent protection, but appears in different phenotypes, from the duration of protection to the infringing activities and remedies for infringement. Certainly, industry-specificity as currently present in the patent system has its flaws and it reminds us of the perils of a nuanced-approach to patent law. This can most clearly be seen by the discrimination against the pesticide industry with regard to the Hatch-Waxman amendments. This calls for a reserved approach when introducing industry-specific treatment into the patent system and not for excessive skepticism against any deviation from the tradition of industry-neutrality. Industry-specificity has various promising sides in light of diverse industries. It balances the different interests between patentees, users, and the public, not only when introduced by the courts but also by Congress.

***