WORKING PAPER

PHARMACEUTICAL PATENT VALIDITY: AN EMPIRICAL STUDY OF THE RECENT DECISIONS OF THE U.S. COURT OF APPEALS FOR THE FEDERAL CIRCUIT (2008-2011)

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I. INTRODUCTION

The pharmaceutical industry is at a crossroads[2]. With no new blockbuster drugs in sight, the innovator firms are changing their strategies. Some are focusing on reducing their operational costs by cutting their R&D budgets, closing labs and generally downsizing[3]. Others are consolidating through mergers and acquisitions[4]. Yet others are forming loose partnerships with start-ups and other bio-technology companies[5]. More importantly, generic manufacturers have moved in aggressively and the general perception is that availability of generic drugs will reduce the drug

[1] LL.M, Fordham University, May 2011. I wish to thank Prof. J. W. Appleman for introducing me to the important concepts in the Patents in Pharmaceutical Industry field.
[2] D. Wilson, Drug Firms Face Billions in Losses in '11 as Patents End, The New York Times, March 7, 2011, p. 1
[3] A. Jack, New Pfizer Chief's Remedy Unlikely to Cure Longer-term Ills, Financial Times, February 3, 2011, p. 16.
[4] A. Jack, Genzyme Move Eases Way for Sanofi-Aventis, Financial Times, February 1, 2011, p. 18.
[5] A. Jack, Eli Lilly Funds Will Aim to Share Costs and Benefits of Drug R&D, Financial Times, February 14, 2011, p. 1.

costs considerably[6].What is the effect of current pharmaceutical patent law, especially, the Hatch-Waxman Act and the courts' decisions on innovation in the pharmaceutical industry? The District Courts and the Federal Circuit along with the U.S. Federal Court of Appeals for the Federal Circuit play a key role in shaping pharmaceutical patent policy. Therefore, patent law experts, the regulatory agencies and pharmaceutical companies must attempt to get a sense for the decision making processes of the courts. Pioneer and generic drug companies can then carefully develop their patent applications and attempt enforcement and ensure the validity of their patent, rather than spend enormous sums of money in an environment of uncertainty, litigating their prospects.

Based on a brief prior study[7], this exploratory empirical study analyzes the pharmaceutical patent cases that ended up in the U.S. Court of Appeals for the Federal Circuit over the 2008-2011period. This study has 3 goals:

1. *Is the U.S. Court of Appeals for the Federal Circuit upholding or invalidating drug patents in a particular pattern? Is it invalidating more patents than upholding patents?*
2. *Does the Court rule more in favor of generic manufacturers as opposed to pioneers?*

[6] B. Kendall, White House Seeks to Speed Up Generic Drugs' Path to Market, The Wall Street Journal, February 15, 2011, p. D2.

[7] See R. Schulman, "Is it harder to enforce pharmaceutical patents?" The National Law Journal, 8/28/2006 for this view based on his study of cases in the U.S. Federal Court of Appeals for Federal Circuit, 2005-2006.

3. What are the key issues the Court is ruling on, in validating or invalidating a patent?

In addition, I will compare the results of my study to that of the 2006 study[8]. Health care policy experts, the pharmaceutical industry and the regulatory agencies, all agree that pharmaceuticals generally require patent protection to promote innovation[9]. Although the research-based pharmaceutical industry has traditionally discovered critical drugs, the public perception of it is less than satisfactory. The general conclusion is the drug manufacturers make huge profits on very costly drugs. This is the antithesis of the debate about the need to reduce health care costs in general, and prescription drug costs in particular. How does one achieve a balance between the costly and uncertain R&D need to discover new drugs vis-à-vis the need to make drugs more affordable across the globe? In this regard, the patenting process plays a critical role, especially in the innovator-generic conundrum. It was in response to the 1984 Federal Circuit decision in *Roche Products, Inc. v. Bolar Pharmaceutical Co.*[10] that Congress passed the Drug Price Competition and Patent Term Restoration Act of 1984[11], popularly known as the Hatch-Waxman Act. This Act modified the 1952 Patent Act by creating a statutory exemption from certain claims of patent

[8] Id.
[9] See J. R. Thomas, *Pharmaceutical Patent Law*, 23-25 (2005).
[10] 733 F. 2d 858, 221 USPQ 937 (Fed. Cir. 1984).
[11] Pub. L. No. 84-417, 98 Stat. 1585 (1984).

infringement. As codified in 35 U.S.C. §271(e)(1), this provision mandates: "It shall not be an infringement to make, use, offer to sell, or sell within 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." As a result, generic manufacturers may start work on a generic version of an approved drug anytime during the life of the patent as long as the work complies with FDA regulations. The Hatch-Waxman Act has been subjected to a series of amendments resulting in the Medicare Prescription Drug and Modernization Act of 2003[12]. Considering the scale and complexity of the drug patenting process, courts play a significant role in deciding the winners and losers. This study attempts to shed a bit of light on process by looking at the decisions of the U.S. Court of Appeals for the Federal Circuit where all appeals from the District Courts are heard. By understanding the decision processes of this Court the various stakeholders can get a better idea of the enforcement and validity of pharmaceutical patents. First, I discuss briefly the legal environment, primarily focusing on the Hatch-Waxman Act and its implications. Next, I briefly describe the methodology. Third, I provide my analysis and key findings. Last, I offer my conclusions.

[12] Pub. L. No. 198-173, 117 Stat. 2066 (2003).

II. BACKGROUND

The patent law is based upon the Patent Act of 1952, codified in Title 35 of the U.S.C. This statute allows inventors to obtain patents on processes, machines, manufactures, and compositions of matter that are *useful, new and nonobvious*. The patents that are granted confer the right to exclude others from making, using, selling, offering to sell, or importing into the United States the patented invention[13]. The patent system is grounded in Article I, Section 8, Clause 8, of the U.S. Constitution and is intended to stimulate new discoveries and their reduction to practice, commonly known as innovation. The Constitution states that "The Congress Shall Have the Power…To Promote the Progress of Science and Useful Arts, be securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries…" The award of a patent permits the inventor of the idea to exclude others temporarily from use of that idea without compensation (currently twenty years from date of filing). It also places the information associated with an invention within the public domain[14]. The participants within the pharmaceutical industry typically claim inventions that are compositions of matter or processes. In addition to such things as mixtures and

[13] W. H. Schacht & J. R. Thomas, CRS Report for Congress, 1/10/2005, Patent Law and Its Application to the Pharmaceutical Industry: An Examination of the Drug Price Competition and Patent Term Restoration Act of 1984 ("The Hatch-Waxman Act").
[14] Id.

alloys, compositions of matter include chemical compounds[15]. When a composition of matter is presented in the form of a patent claim, it is defined in terms of its constituent elements.

Section 101 of the Patent Act also mandates that patents issue only to 'useful inventions'[16]. Utility typically presents a minimal requirement that the invention be capable of achieving a practical result[17]. Patent applicants need only supply a single, operable use of the invention that is credible to persons of ordinary skill in the art. Although the utility requirement is routinely met in most fields, it may present a significant obstacle to patentability for drug inventions. Here, inventors sometimes synthesize compounds without a precise knowledge of how they may be used to achieve a practical working result. When patent applications are filed claiming such compounds they may be rejected as lacking utility within the meaning of the patent law[18].

The Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the "Hatch-Waxman Act" "emerged from Congress's efforts to balance two conflicting policy objectives[19]: to induce pioneer pharmaceutical companies to

[15] See *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).
[16] 35 U.S.C. §101.
[17] *Mitchell v. Tilghman*, 86 U.S. (19 Wall.) 287, 396 (1873).
[18] W. H. Schacht & J. R. Thomas, CRS Report for Congress, 1/10/2005, Patent Law and Its Application to the Pharmaceutical Industry: An Examination of the Drug Price Competition and Patent Term Restoration Act of 1984 ("The Hatch-Waxman Act").
[19] T. Chen, "Authorized Generics: A Prescription for Hatch-Waxman Reform." Virginia Law Review, 2007, Vol. 93: 459-512.

make the investments necessary to research and develop new drug products, while simultaneously enabling competitors to bring cheaper generic copies of those drugs to market[20].” Congress recognized that the earlier regulatory regime established by the FDA was unduly burdensome to both pioneer and generic drug firms[21]. Previously, generic drug firms were required to duplicate the pioneer’s clinical trials to demonstrate safety and efficacy before obtaining FDA approval[22]. Moreover, they could not begin this extremely lengthy and extensive testing process until after the relevant drug patent had expired because clinical testing before hand would have constituted patent infringement[23]. These entry barriers created an undesirable default extension of drug patents, ultimately delaying consumer access to affordable drugs[24]. Pioneer drug companies also faced their own difficulties. Drug patent applications filed early in the drug discovery process often issues long before FDA approval of the corresponding New Drug Application (NDA), leaving only a few years of effective patent life once a drug entered the market [25]. This dilemma threatened to undermine pioneers’ innovation

[20] *Abbot Labs v. Young*, 920 F. 2d 984, 991 (D.C. Cir. 1990).
[21] W. H. Schacht & J. R. Thomas, CRS Report for Congress, 1/10/2005, Patent Law and Its Application to the Pharmaceutical Industry: An Examination of the Drug Price Competition and Patent Term Restoration Act of 1984 (“The Hatch-Waxman Act”).
[22] See FTC, Generic Drug Entry Prior to Patent Expiration: An FTC Study 3 (2002), available at http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf
[23] Id. at 4; see *Roche Products v. Bolar Pharm. Co.,* 733 F. 2d 858, 863 (Fed. Cir. 1984).
[24] See *Roche Prods.,* 733 F. 2d at 864.
[25] See FTC Generic Drug Study, supra note 13, at 4.

incentives and thereby deprive consumers of important discoveries in drug therapy[26].

Hatch-Waxman created a streamlined regulatory system to mitigate these problems. The newly designated Abbreviated New Drug Application (ANDA) adopted "bioequivalence as the new standard for generic drug approval in order to facilitate and accelerate FDA review.[27]" A generic drug manufacturer is now only required to demonstrate that its product contains the same active ingredient and basic pharmacokinetics as the brand-name drug[28].

The generic manufacturer can now rely on the pioneer's clinical trial data to satisfy the FDA's safety and efficacy requirements[29]. This standard simultaneously ensured generic drug quality while eliminating duplicative research costs. This has the potential to greatly accelerate consumer access to affordable drugs. Additionally, Hatch-Waxman created an experimental use exception, which immunizes ANDA-related clinical research from patent infringement liability[30]. This allows generic drug manufacturers to begin bioequivalence testing even while

[26] See generally T. Chen, "Authorized Generics: A Prescription for Hatch-Waxman Reform." Virginia Law Review, 2007, Vol. 93: 459-512, p.
[27] 21. U.S.C. §355(j)(2)(A)(iv) (2000); FTC Generic Drug Study, supra note 13, at 5.
[28] See T. Chen, "Authorized Generics: A Prescription for Hatch-Waxman Reform." Virginia Law Review, 2007, Vol. 93: 459-512, p. 463.
[29] FTC Generic Drug Study, supra note 13, at 5.
[30] 35 U.S.C. §271(e)(1) (2000); see also, T. Chen, "Authorized Generics: A Prescription for Hatch-Waxman Reform." Virginia Law Review, 2007, Vol. 93: 459-512, p. 464.

the drug patent remains in force, often leading to generic drug availability immediately upon patent expiration[31].

To balance these pro generic provisions, Hatch-Waxman provides pioneers with patent term restoration to offset certain losses caused by FDA regulatory delays[32]. However, patent term restoration is subject to various constraints. The entire restoration may not exceed five years[33], and the remaining patent life following FDA market approval may not exceed fourteen years[34]. Additionally, delays caused by the pioneer's lack of due diligence during the regulatory review period will reduce the restored patent term accordingly[35]. Despite these limitations, the patent term extensions ultimately confer significant economic benefits, which provide the necessary incentive for further research and development[36].

Hatch-Waxman employs a unique procedural framework to manage the interplay between pioneer NDAs and their generic ANDA counterparts. Upon filing an NDA, a pioneer firm must provide a list of relevant patents which are then listed in an FDA publication known as the "Orange Book.[37]" Subsequent ANDAs must

[31] See T. Chen, "Authorized Generics: A Prescription for Hatch-Waxman Reform." Virginia Law Review, 2007, Vol. 93: 459-512, p. 463.
[32] See generally 35 U.S.C. §156 (2000).
[33] Id. §156(g)(6)(A).
[34] Id. §156©(3).
[35] Id. §156©(1).
[36] See generally T. Chen, "Authorized Generics: A Prescription for Hatch-Waxman Reform." Virginia Law Review, 2007, Vol. 93: 459-512.
[37] Electronic Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations, Available at http://www.accessdata.fda.gov/scripts/cder/ob/

reference these Orange Book listings and make one of four "certifications" for each patent[38]:

I. The required patent information has not been filed;

II. The patent has already expired;

III. The patent has not yet expired, but will do so prior to FDA approval of the ANDA; or

IV. The patent is invalid or will not be infringed by the ANDA.

The most significant and debatable of these is the Paragraph IV Certification, because a generic firm seeks market entry prior to patent expiration, while the other certifications simply confirm there are no extant patent rights that would prevent generic entry[39]. Generic applications making Paragraph IV Certifications must notify the pioneer firm which then has forty five days to initiate a patent infringement lawsuit[40]. Pioneers typically pursue litigation automatically triggering a thirty-month stay that prevents FDA approval of the ANDA until the earliest of the following dates: patent expiration, a final resolution of the patent litigation, or expiration of the thirty-month period[41].

[38] See 21 U.S.C. §355(j)(2)(A)(vii) (2000).
[39] See generally T. Chen, "Authorized Generics: A Prescription for Hatch-Waxman Reform." Virginia Law Review, 2007, Vol. 93: 459-512.
[40] See id. §355(j)(5)(B)(iii) (Supp. III 2003).
[41] Id.

If the generic drug firm prevails in the Paragraph IV patent litigation, it is rewarded with a 180-day marketing exclusivity period, during which the FDA cannot approve subsequent generic versions of that drug[42]. This 180-day 'exclusivity' can be immensely profitable, and it thus rewards the first Paragraph IV filer for bearing the risks and expenses of patent litigation, which typically costs $10 million[43]. Hatch-Waxman originally provided for two events that would trigger the 180-day exclusivity period: (1). Commercial marketing of the drug, or (2). A final court decision holding the relevant drug patents invalid or not infringed[44]. Once the exclusivity period has been triggered and expires, the FDA may approve subsequent generics to enter the market[45].

In summary, Paragraph IV has created the following model for generic firms: they rush to file the first Paragraph IV Certification in anticipation of being successful in their challenge to drug patent(s) in litigation and obtaining the benefits of the 180-day exclusivity. This process serves to provide a method for patent quality oversight. Invalid patents are revealed and consumers have faster access to generic drugs[46].

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[42] See id. §355(j)(5)(B)(iv).
[43] See Jenna Greene, Big Pharma's Big Leap, IP L. & Bus., Jan. 2006 Available at http://www.law.com/jsp/cc/PubArticleCC.jsp?id=900005445644
[44] See Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, §101, 98 Stat. 1585, 1589 (codified as amended at 21 U.S.C. §355(j)(5)(B)(iv) (Supp. III 2003).
[45] See generally T. Chen, "Authorized Generics: A Prescription for Hatch-Waxman Reform." Virginia Law Review, 2007, Vol. 93: 459-512.
[46] Id.

The downside, as per Chen[47] is that the Paragraph IV entry, if implemented carefully, can be quite strategic generating for generic firms in generating high profits in the short time. This is possibly at a huge expense often to the pioneer. Therefore, pioneer firms have also engaged in creative manipulations and abuses that have attracted FTC scrutiny and enforcement[48]. The early FTC enforcements targeted anticompetitive settlement agreements between pioneer and generic drug firms[49] [50]. Under these purported collusive agreements, the first Paragraph IV applicant would agree to refrain from entering the market to exploit its 180-day exclusivity in return for substantial monetary payments[51]. The result was that a pioneer could block all subsequent generic competitors, whose market entry was contingent upon the triggering and expiration of 180-day exclusivity, which had now been 'benched' indefinitely[52]. These arrangements are sometimes referred to as reverse settlements or exit payments, because the patentee pays an alleged

[47] Id.
[48] Id.
[49] See Generic Pharmaceuticals Marketplace Access and Consumer Issues: Hearing before the S. Committee on Commerce, Science & Transportation, 107th Congress. 23-24 (2002) (statement of Timothy J. Muris, Chairman, Federal Trade Commission) (hereinafter Muris)..
[50] M. A. Carrier, "Unsettling Drug Patent Settlement: A Framework for Presumptive Illegality," Michigan Law Review, Vol. 108, 2009, pp. 37-80.
[51] Id.
[52] Id. at 24. See also L. Burford, Note, In re Cardizem & Valley Drug Co.: The Hatch-Waxman Act, Anticompetitive Actions, and Regulatory Reform, 19 Berkeley Tech. L. J. 365, 369 (2004).

infringer to exit the generic market in order to postpone the onset of generic competition[53].

The public concern over increasing health care costs combined with relentless FTC action led to statutory reform with the Medicare Prescription Drug Improvement and Modernization Act of 2003[54]. Title XI of the Act "Access to Affordable Pharmaceuticals" introduced several changes to the original Hatch-Waxman Act designed to eliminate the dilatory effects of anticompetitive settlements and fraudulent Orange Book listings[55]. To reduce 'first generation' anticompetitive settlements, Title XI requires pioneer and generic firms to notify the FTC and Department of Justice within ten days of any agreements involving the 180-day exclusivity period[56] [57]. Furthermore, Paragraph IV generics must exploit their exclusivity period within certain time limits or risk forfeiture of their reward[58]. To limit "second generation" fraudulent Orange Book listings, Title XI generally allows only one automatic thirty-month stay[59] [60] and also provides generics with

[53] Muris, supra note 32, at 24; see also D. A. Crane, Exit Payments in Settlement of Patent Infringement Lawsuits; Antitrust Rules and Economic Implications, 54 Fla. L. Rev. 747, 748 (2002).
[54] Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066.
[55] See J. R. Thomas, *Pharmaceutical Patent Law*, 23-25 (2005).
[56] See Medicare Prescription Drug, Improvement, and Modernization Act §§1111-13.
[57] See generally T. Chen, "Authorized Generics: A Prescription for Hatch-Waxman Reform." Virginia Law Review, 2007, Vol. 93: 459-512.
[58] See 21 U.S.C. §355(j)(5)(D) (Supp. III 2003).
[59] See Medicare Prescription Drug, Improvement, and Modernization Act §1101(a)(2)(A)(ii)(I).
[60] See generally T. Chen, "Authorized Generics: A Prescription for Hatch-Waxman Reform." Virginia Law Review, 2007, Vol. 93: 459-512.

the option of filing counterclaims to de-list allegedly improper Orange Book patent[61] .

Another issue that arose is that the FDA is not required to review patents before listing them[62] which has led to concerns about the abuse of the Orange Book by the pioneers[63]. As reported by Ouellette[64], Professor Rebecca Eisenberg has summarized the process of 'evergreening' drug patents:

"In recent years drug innovators have sought to prolong their effective periods of patent protection through various 'evergreening' strategies that add new patents to their quivers as old ones expire. Examples include patents on 'metabolites' (i.e., the products into which drugs are transferred in a patient's body); patents on intermediate products used in producing drugs; patents on new uses for drugs; and patents on new formulations or preparations. Some innovating firms have succeeded in getting such patents issued by the PTO, and in using them to defer FDA approval of generic products for years pending resolution of patent infringement claims. The industry's track record in actually winning these infringement claims, however, has been considerably worse…..[65]" In particular,

[61] 21 U.S.C. §355(j)(5)(C)(ii (Supp. III 2003); id. §355(c)(3)(D)(ii).
[62] *Apotex, Inc. v. Thompson*, 347 F. 3d 1335, 1349 (Fed. Cir. 2003).
[63] L. L. Ouellette, *How Many Patents Does It Take To Make a Drug?* Follow-on Pharmaceutical Patents and University Licensing, Michigan Telecommunications and Technology Law Review, Vol. 17, 2010, pp. 299-336.
[64] Id.
[65] R. S. Eisenberg, The Role of the FDA in Innovation Policy, Michigan Telecommunications and Technology Law Review, Vol. 13, 2007, p. 354.

commentators have suggested that many of the follow-on patents may be rendered obvious in light of *KSR v. Teleflex*[66]. These and other implications of implementing the Hatch-Waxman Act and related amendments pose major challenges to the District Courts and U.S. Court of Appeals for the Federal Circuit. I now turn to the methodology and analysis of my review of the cases in the Federal Circuit.

III. METHODOLOGY

A search was conducted in Westlaw for the period 1/1/2008 to 2/15/2011 to retrieve all pharmaceutical patent cases in the U.S. Court of Appeals for the Federal Circuit. The search resulted in 63 cases. A case by case analysis revealed that 22 cases were either irrelevant to pharmaceutical drugs or were about medical devices. These cases were deleted from the sample. The resulting 40 cases were examined in detail. I read each brief and ruling completely.

IV. RESULTS AND DISCUSSION

Appendix 1 summarizes, case by case, the specifics of each case. This forms the core of the analysis. Further extraction from *Appendix 1* resulted in the summary tables in *Appendices 2*, *3* and *4*.

U.S. Court of Appeals for Federal Circuit Patent Validity Decisions

[66] 550 U.S. 398, 415 (2007).

Appendix 2 gives the counts of Federal Circuit decisions for the District Courts and the PTO. The classification includes the District Court and PTO/Board rulings of whether the patent was valid or invalid. The Federal Circuit decisions of whether the rulings were affirmed, reversed or partly affirmed/reversed were also counted. As seen in *Appendix 2*, the Federal Circuit affirmed 11 patents as valid and 7 as invalid; and 2 each of the PTO/Board findings. The Court reversed 5 patents declared valid by the District Court and 1 by the PTO/Board. The Court also reversed 4 patents declared invalid by the District Court and 2 by the PTO/Board. Finally, the Circuit Court affirmed in part and reversed in part 3 each of the District Courts' valid and invalid patents. The results show that the Federal Circuit generally affirmed and upheld validity of patents found valid by the District Courts (11) and affirmed and upheld invalidity of patents found invalid by the District Courts (7). It reversed fewer patents found valid (5) or invalid (4) by the District Courts when compared to the total it affirmed valid or invalid. The broad conclusion is the Federal Circuit is upholding District Court findings overall. Out of a total of 19 patents found valid by the District Courts, the Federal Circuit has upheld the decisions in 11 fully and 3 partly, thereby affirming a majority. With regards to the invalid patents, out of a total of 14 found invalid by the District Courts, 7 were affirmed fully and 3 partly, thereby affirming a majority of patents found invalid. Likewise, with regards to the PTO, it affirmed 4 in total and

reversed 3 in total. What does this show? It shows that the Federal Circuit is adopting a case by case approach and there is no overarching theme or grand design in its decisions[67].

U.S. Court of Appeals for Federal Circuit Innovator v. Generic Patent Validity Decisions

Appendix 3 breaks down the cases by parties' to the lawsuits. Three categories are derived, namely, Innovator v. Generic, Innovator v. Innovator, and Innovator v. PTO. Notice 21 patents in total were found valid and 14 found invalid. A total of 5 patents were partly validated. In the Innovator v. Generic category, generally, there are an equal number of patents found valid (8) and invalid (7). This indicates, the Court does not favor one or other, or has a political agenda or is predisposed to Innovator or Generic. On the other hand, there is sharp divide in the Innovator v. Innovator category with the Court finding 9 patents valid and 4 invalid. The Court is upholding more patents as valid if it is Innovator v. Innovator. Therefore, it is possible to say, when innovators are equally matched, the Court rules in favor of the plaintiff innovator. With regards to the Innovator v. PTO, there are an equal number of valid (4) and invalid (3) patents implying the Court is again looking at rule making and procedures on a case by case basis.

[67] See R. Schulman, "Is it harder to enforce pharmaceutical patents?" The National Law Journal, 8/28/2006 for this view based on his study of cases in the U.S. Federal Court of Appeals for Federal Circuit, 2005-2006.

How do the results compare with a previously done and reported study for the period 1/1/2005 to 8/31/2006? In that study, an alarm was sounded that the U.S. Court of Appeals for the Federal Court "has completely or partially invalidated or held unenforceable nearly every pharmaceutical patent it had reviewed – more than two dozen in all, with only one upheld" for the period 2005-2006[68]. The author of that study speculated that the earlier result was hopefully a "mere statistical coincidence not indicative of any ax the Federal Circuit has to grind with the pharmaceutical industry." As the author concedes, it was perhaps a coincidence that a poor set of patents made their way to the Federal Circuit. Or, the pharmaceutical industry attempted to enforce marginal patents since no new blockbuster patents drugs were discovered. Additionally, the industry had no choice but to rely on very marginal improvements to existing drugs. The author also points out that it is possible the PTO had become too relaxed in its review of patent applications, resulting in the Federal Circuit scrutinizing patents carefully and applying the statute, consistent with the precedent[69]. In that study, the author speculated that the large number of validations he found might be a consequence of a "fundamental change in the application of the law" making it easier for a challenger to invalidate an issue patent. Additional theories include the notion that it may reflect a change in the makeup of the court. Or, public policy and political

[68] Id.
[69] Id.

pressure on the government to control prescription drug costs may impinge on the court. *However, this study does not indicate any overriding preference to rule in favor of generics.* The current study finds the net ruling of the Federal Circuit to be balanced and nuanced with a nearly equal number of affirmations and reversals, among both valid and invalid patents. It is conceivable the Court pendulum, at that time, swung in favor of generics or innovator firms wanting to bring similar less expensive products to the market. According to the author, of 27 cases in a five-year period of Federal Circuit decisions extending from 2000 to 2004, the Federal Circuit upheld validity in 12 and found 10 invalid. Therefore, he draws the conclusion that the pharmaceutical patents had "fared much worse" in the period 2005-2006 when compared to the previous years. My study suggests that the Federal Circuit has returned to ruling in a pattern similar to the 2000-2004 period. The 2005-2006 decisions are collectively perhaps an anomaly and not a trend.

U.S. Court of Appeals for Federal Circuit – Key Issues in Decisions

Appendix 4 gives an approximate count of how many times a key legal issue surfaced in a case. *As seen, topping the list is obviousness (or lack of it), followed by written description (or lack of it). Other issues cited include anticipation, lack of enablement, term extension, doctrine of equivalents, counter-claim provision, safe harbor provision, and inequitable conduct. I discuss the most significant*

issues below along with the key cases in each. Overall, as seen, lack of obviousness and lack of written description are the two key issues that make a patent invalid.

OBVIOUSNESS (NONOBVIOUSNESS)

"To be patentable, a pharmaceutical invention must be judged both new and nonobvious[70]. To be considered novel, the invention must not be wholly anticipated by the so called 'prior art' or public domain materials such as publications and other patents[71]. The nonobviousness requirement is met if the invention is beyond the ordinary abilities of a person of ordinary skill in the art in the appropriate field[72]." Section 101 of the Patent Act mandates that patents issue only to 'useful' inventions[73]. This prerequisite for patenting referred to as the 'utility requirement' requires only a minimal showing that the invention be capable of achieving a pragmatic result[74]. Patent applicants need only demonstrate a single, operable use of the invention that is credible to persons of ordinary skill in the art[75].

It is important to remember that merely because an invention is novel does not mean it is patentable. Not only must a patentable invention not be strictly described by a single reference, it also must not have been obvious to persons of ordinary

[70] W. H. Schacht & J. R. Thomas, CRS Report for Congress, 1/10/2005, Patent Law and Its Application to the Pharmaceutical Industry: An Examination of the Drug Price Competition and Patent Term Restoration Act of 1984 ("The Hatch-Waxman Act").
[71] 35 U.S.C. §102.
[72] 35 U.S.C. §103(a).
[73] 35 U.S.C. §101 (2004).
[74] *Mitchell v. Tilghman*, 86 U.S. (19 Wall.) 287, 396 (1873).
[75] *Raytheon Co. v. Roper Corp*., 724 F. 2d 951, 958, 220 USPQ 592, 598 (Fed. Cir.1983).

skill in the art at the time it was made in light of the prior art[76]. This 'novelty plus' requirement is known as nonobviousness. The nonobviousness standard allows courts to consider whether combinations of prior art references, viewed in light of the knowledge of the skilled practitioners, should prevent an invention from being patented. Thus, in order to merit a patent, not only must the invention be new, but it must also constitute more than a trivial variation of the state of the art. In practice, novelty presents the first stage of a prior art-based analysis, with nonobviousness conducted next.

In *Eli Lilly v. Teva Pharma*[77], patentee brought action against generic manufacturer seeking permanent injunction to prevent the manufacture or distribution of generic version of drug using raloxifene to treat post menopausal osteoporosis. Following bench trial, the District Court for Southern District of Indiana granted injunction as to four of patentee's patents, but ruled that certain claims as to two of patentee's patents were invalid. *Teva Pharma* appealed and *Eli Lilly* cross appealed. The Federal Circuit ruled that "person of ordinary skill in the art would not have considered it obvious to use raloxifene to successfully treat postmenopausal osteoporosis at time of invention," among other holdings. The court ruled in the opposite in the case of *Daiici Sankyo v. Matrix Lab et al*[78] when it said patent was

[76] J. R. Thomas, *Pharmaceutical Patent Law*, 2nd Ed. 2010, BNA Books, p. 86.
[77] 619F. 3d 1329.
[78] 619F. 3d 1346.

not invalid as obvious, affirming the District Court for New Jersey ruling. The plaintiffs who invented and produced active ingredient in hypertension medications filed infringement action against generic manufacturers. The validity of the '599 patent of the plaintiff was sustained under 35 U.S.C. §103.

On the other hand, in *Sun Pharma v. Eli Lilly*[79], the generic drug manufacturer brought action against patent holders for the manufacture of cancer treatment drug and sought declaratory relief that the patent was invalid or that the generic drug did not violate the patent. *Eli Lilly* filed an infringement counterclaim. The District Court for the Eastern District of Michigan granted generic drug manufacturer's motion for partial summary judgment on counter claims, and subsequently granted the patent holder's motion for entry of final judgment. Eli Lilly appealed. The holdings in this case included that claims in the first patent for pharmaceutical were not patentably distinct from claims in subsequent patent for use of pharmaceutical, and that specifications of issued patent could be consulted to ascertain relevant disclosed uses of claimed compound. The District Court had originally found that some claims in '826 patent were invalid for obviousness-type double patenting over '614 patent and the Federal Circuit affirmed. Further, the District Court had correctly followed the double patenting analysis of the *Geneva* line of cases, which addressed the situation in which an earlier patent claimed a

[79] 611F. 3d 1381.

compound and disclosed the utility of that compound in the specification. Then, a later patent claimed a method of using that compound for a particular use described in the specification of the earlier patent[80]. In *Bayer Schering v. Barr Labs*[81], plaintiff filed action against competitor alleging infringement. The District Court for New Jersey concluded that the patent was invalid due to obviousness and the Federal Circuit affirmed holding that "the innovation of micronized rospirenone to increase its bioavailability, and that micronized drospirenone would absorb with normal pill, was obvious." In two other cases, the Federal Circuit affirmed the nonobviousness of the claims in the patents. In *Altana v. Teva Pharma*[82], the patent owner and exclusive licensee brought action against competitors alleging infringement of patent directed toward active ingredient in antiulcer drug. The District Court for New Jersey consolidated the cases and denied owner and licensee's motion for a preliminary injunction[83]. The owner and licensee appealed. The Federal Circuit affirmed the findings holding that the District Court's determination that alleged infringer's obviousness defense had substantial merit was not clearly erroneous, and that the owner and licensee failed to demonstrate irreparable harm was not clearly erroneous. Finally, in *Sanofi et al. v. Apotex*[84], the owners of patent covering clopidogrel bisulphate brought infringement action

[80] Geneva, 349 F. 3d at 1385.
[81] 575F. 3d 1341.
[82] 566 F. 3d 999.
[83] 532 F. Supp. 2d 666.
[84] 550 F. 3d 1075.

against competitors. The competitors counter claimed that patent was invalid and unenforceable. The District Court for Southern District for New York ruled in a bench trial that patent was valid and enforceable[85]. The competitors then appealed. The Federal Circuit rule that the prior art patents did not anticipate the patent and that the District Court did not clearly err in making finding of nonobviousness. This suit had arisen in accordance with the provisions of the Hatch-Waxman Act, codified at 35 U.S.C. § 271 (e) and 21 U.S.C. § 355 (j). The patent at issue was the '265 patent owned by *Sanofi-Synthelabo* and related companies and covered the pharmaceutical product having the common name clopidogrel bisulfate and the brand name Plavix. The product has the property of inhibiting the aggregation of blood platelets, and is used to treat or prevent blood thrombotic events such as heart attacks and strokes. The Federal Circuit affirmed the ruling sustaining patent validity.

The holdings of the U.S. Court of Appeals for the Federal Circuit appear to be a mixed bag in the case of nonobviousness. It has ruled on a case by case basis, sometimes ruling in favor of the innovator and at other times in favor of the generic manufacturer, sending no particular signal.

WRITTEN DESCRIPTION

[85] 492 F. Supp. 2d 353.

Section 112, first paragraph, reads as follows: *The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention*[86]. The written description requirement has become a key doctrine in the courts' evaluation of patent validity[87].

In *Centocor Ortho Biotech et al., v. Abbot Labs*[88] plaintiff alleged that defendant's Humira infringed claims of its '775 patent. The Federal Circuit *reversed* the District Court's denial of judgment as a matter of law (JMOL) and held the asserted claims invalid for failure to meet the statutory written description requirement under 35 U.S.C. §112. The court suggested that the requirement demands that one of skill in the art can "visualize or recognize" the claimed antibodies based on the specification's disclosure[89]. In other words, the specification must demonstrate constructive possession, and the "775 patent's" specification fails to do so[90]. In *Ariad Pharma v. Eli Lilly*[91], a landmark case, *Ariad* brought suit against *Eli Lilly* in the District Court for Massachusetts alleging

[86] http://www.uspto.gov/web/offices/pac/mpep/documents/appxl_35_U_S_C_112.htm
[87] W. E. Ridgway, Realizing Two-Tiered Innovation Policy Through Drug Regulation, Stanford Law Review, Vol. 58, 2006, pp. 1221-1250.
[88] (2011 WL 625291 (C.A. Fed. (Tex.))).
[89] Eli Lilly, 119F. 3d at 1568.
[90] Ariad, 598 F. 3d at 1352.
[91] 598 F. 3d 1336.

infringement of the '516 patent. At trial a jury found infringement, but then found none of the asserted claims invalid. A panel of the Federal Circuit reversed the District Court's denial of Lilly's motion for judgment as a matter of law (JMOL) and held the asserted claims invalid for lack of written description[92]. *Ariad* petitioned for rehearing en banc, challenging the court's interpretation of 35 U.S.C. § 112, first paragraph, as containing a separate written description requirement. Because of the importance of the issue, the Federal Circuit granted *Ariad's* petition and directed the parties to address whether § 112, first paragraph, contained a written description requirement separate from the enablement requirement and, if so the scope and purpose of that requirement. The Court reaffirmed that §112, first paragraph, contained a written description requirement separate from enablement and therefore reversed the District Court's denial of JMOL and held the asserted claims of the '516 patent invalid for failure to meet the statutory written description requirement. The important holdings include that the statute requiring that patent specification contain a written description of the invention contained a written description requirement separate from enablement, and that '516 patent was invalid for failure to provide adequate written description. In the interesting case of *K. Alonso v. the PTO Board of Appeals*[93], the Appeals examiner finally rejected the claim of patent application. The Federal Circuit affirmed the Board's

[92] *Ariad Pharma, Inc. v. Eli Lilly & Co.,* 560 F. 3d. 1366 (Fed. Cir. 2009).
[93] 545 F. 3d 1015.

conclusion that "substantial evidence supported the Board's conclusion that the application lacked adequate written description. *In summary, written description is an important issues that pharmaceutical companies in general, and inventors in particular, must consider when applying for a patent or attempting to enforce it. The Court in numerous cases has ruled patent invalid due to lack of written description (as seen in Appendix 1).*

ENABLEMENT (LACK OF)

A relationship exists between the utility requirement of 35 U.S.C. §101 and the so-called enablement requirement of 35 U.S.C. §112[94]. The first paragraph of Section 112 of the Patent Act requires that patent instruments contain a full and clear description of the patented invention. The description must be sufficiently complete as to enable others to use the patented invention. Plainly, one cannot describe how to use an invention if that invention is useless. As a result, arguments about the lack of usefulness of the invention are often made in the context of both the utility requirement of 35 U.S.C. §101 and the enablement requirement of 35 U.S.C. §112. In *Eli Lilly v. Actavis et al*[95], the plaintiff submitted a motion for an injunction to prevent the defendants from launching generic version of its patented drug, pending disposition of its appeal. The District Court of New Jersey held that

[94] J. R. Thomas, *Pharmaceutical Patent Law*, 2nd Ed. 2010, BNA Books, p. 58.
[95] (2010 WL 3374123 (C.A. Fed. (NJ))).

the defendants induced infringement of *Eli Lilly's* patent. The District Court also held that patent was invalid for lack of enablement because inter alia, there was no timely demonstration of utility. Likewise, in *Janssen Pharma et al. v. Teva et al*[96]. the exclusive licensees of patent claiming a method for treating Alzheimer's disease with galanthamine brought infringement actions against several generic drug manufacturers. After the actions were consolidated and the drug manufacturers conceded infringement, the District Court for Delaware found the patent invalid for lack of enablement. Exclusive licensees appealed. The appeal was also taken from order of the District Court of New Jersey. The Federal Circuit affirmed that the patent was invalid for lack of enablement.

ANTICIPATION

In order to obtain a patent, an inventor must create something new. This fundamental concept is known as 'novelty.' The resolution of novelty questions under U.S. patent law involves a two-part analysis. The first determination is whether s single source of information – such as a journal article or earlier patent – fully describes the claimed invention. When an invention has been completely set out in a qualifying source of information, it is said to be 'anticipated' and no patent can issue. The standard of anticipation is strict. Each and every element of the claimed invention must have been disclosed. In addition, that source of information

[96] 583 F. 3d 1317.

must enable persons of skill in the art to put the disclosed information into practice[97].

Second, assuming that a fully anticipatory source of information exists, it must be determined whether that source can be permissibly cited against a patent or patent application, a particular journal article, earlier use of the invention, or other source of information must qualify under one of the seven paragraphs of 35 U.S.C. §102. Commonly termed 'references' such materials include evidence of actual uses or sales of a technology within the United States, as well as such documentary materials as patents and publications. The sum of these references is termed the 'prior art' in patent parlance[98].

Anticipation requires the presence in a single prior art disclosure of each and every element of the claimed invention[99]. As the Federal Court explained: "A judgment of invalidity for anticipation requires that a single prior art reference disclose every limitation in a patent claim. Even the presence of minor or insubstantial differences between the claimed invention and the reference will mean that there is no anticipation and will allow us to conclude that the invention meets the test of novelty. However, in such circumstances, a nonobviousness analysis might well prove fatal to the patentability of the claimed invention."

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[97] J. R. Thomas, *Pharmaceutical Patent Law*, 2nd Ed. 2010, BNA Books, p. 84.
[98] Id.
[99] J. R. Thomas, *Pharmaceutical Patent Law*, 2nd Ed. 2010, BNA Books, p. 87.

Anticipation cannot occur unless a prior art reference is 'enabling.' In the words of the Supreme Court, an anticipatory prior art reference must contain a 'substantial representation of the patented improvement in such full, clear, and exact terms as to enable any person skilled in the art or science to which it appertains to make, construct, and practice the invention to the same practical extent as they would be enabled to do so if the information was derived from a prior patent.[100]" This so-called enablement requirement finds anticipation, and thus denies patentability, only where earlier efforts have truly enriched the technological arts.

In the case of *King Pharma v. Eon Labs et al.* [101] the patent holder, that is, *King Pharma,* alleged infringement of patents directed toward methods of informing patents about and administering muscle relaxant metaxalone. *Eon Labs et al.* asserted affirmative defenses and counter claims for invalidity, fraud and unclean hands. The District Court for Eastern District for New York invalidated the patents. *King Pharma* then appealed. The Federal Circuit partly reversed. Among the many holdings, the claim directed towards the methods of informing was invalid due to anticipation; the claims limiting time frame in which patent had to ingest metaxalone had been anticipated by priori; the instructional limitation, that taking drug with food increased bio availability of drug, was anticipated; also, the printed label was anticipated. In summary, while the District Court erred in

[100] Id. p. 92.
[101] 616 F. 3d 1267.

invalidating several of the claims as unpatentable under § 101, all the claims of the '128 and '102 patents were ultimately anticipated under 35 U.S.C. §102 or obvious under 35 U.S.C. § 103 in light of the prior art. Again, in a case we saw above, *Sanofi et al. v. Apotex*[102], the Federal Circuit affirmed that "prior art patents did not anticipate patent" and there was no finding of obviousness."

DOCTRINE OF EQUIVALENTS

The doctrine of equivalents evolved to prevent unscrupulous copyists from avoiding patent infringement by making insubstantial changes to a patented invention that take it outside the literal scope of the patent's claims[103]. In doing so, courts have recognized that patent claims are made up of words, which "are not always the optimal medium for conveying inventive concepts." The persistence of the doctrine of equivalents reflects the desire of courts to ensure that the scope of patent protection is broad enough to remain an incentive for inventors to publicly disclose their innovations.

In *Adams Respiratory v. Perrigo Co.*[104] the owner of the patent for extended release formulations of expectorant brought suit, alleging that generic manufacturer's proposed production and marketing of generic version of the product would infringe its patent. The District court for the Western District of

[102] 550 F. 3d 1075.
[103] http://en.wikipedia.org/wiki/Doctrine_of_equivalents
[104] 616 F. 3d 1283.

Michigan granted the defendant summary judgment of non-infringement. The Federal Circuit reversed in part. The Court said that a fact question as to equivalence precluded summary judgment. While the District Court correctly constrained bio availability the summary judgment of non infringement on doctrine of equivalents was improper. In yet another case, *Amgen v. F. Hoffman-LA Rouche*[105], the plaintiff owned patents relating to the production of erythropoietin (EPO) using recombinant deoxyribonucleic acid (DNA) technology. It filed declaratory judgment action alleging that the competitors' product would infringe patents if imported into the United States. *Hoffman-LA Rouche* filed counterclaims asserting that the patents were invalid and noninfringed. Then, following an entry of summary judgment of no invalidity for obviousness[106] and jury verdict in patentee's favor, the District Court for Massachusetts vacated the jury's verdict that the claim of one patent was infringed under the doctrine of equivalents (DOE) but granted patentee declaratory relief and permanently enjoined competitor from marketing its product in United States. Among other holdings, the Federal Circuit held that the patentee failed to present particularized testimony of equivalents. In Abbot et al. v. Sandoz et al. the competitor brought action against patent licensee and sough declaratory judgment of non infringement of patent for crystalline cefdinir. The District Court for Eastern District of Virginia construed patent, and

[105] 580 F. 3d 1340.
[106] 581 F. Supp. 2d 160.

entered summary judgment of non-infringement[107]. The licensee appealed. In another action, licensee brought patent infringement action against competitors. The District Court for Northern District of Illinois construed patent[108] and denied licensee's motion for preliminary injunction. Licensee appealed. The appeals were consolidated. The Federal Circuit following sua sponte order of review en banc held that the patent was limited to 'Crystal A' form of compound; the process terms in product-by-process claims serves as limitations in determining patent infringement - this overruled *Scripps Clinic & Research Foundation v. Genentech, Inc.*[109]; the phrase 'obtainable by' introduced limiting process steps; the patent's claims could not be extended under doctrine of equivalents to embrace known but unclaimed subject matter; and, the District Court did not abuse its discretion in denying preliminary injunction. Therefore patent was found invalid. The Federal Circuit held that the Eastern District of Virginia correctly construed the '507 patent's recitation of 'crystalline' in each of the asserted claims as limited to Crystal A, as outlined in the specification. Because Abbott removed all references to Crystal B in the '507 patent's specification, which were present in the '507 patent's parent foreign application, Abbott clearly demonstrated its intent to limit the '507 patent to Crystal A. This intent was further underscored by comments made during prosecution. As such Abbott was unable to recapture Crystal B

[107] 491 F. Supp. 2d 563.
[108] 486 F. Supp. 2d 767.
[109] 927 F. 2d 1565.

through broad claim language or under the doctrine of equivalents. The Eastern District of Virginia therefore properly concluded on summary judgment that *Lupin's* cefdinir product did not infringe claims by equivalency. Similarly, the N.D. of Illinois did not abuse its discretion when it declined to enter a preliminary injunction against Sandoz and Teva's cefdinir products.

COUNTERCLAIM PROVISION

The Hatch-Waxman Act provided a limited counterclaim to a generic manufacturer in an infringement action only if the drug patent did not claim any approved methods of using the tested drug, and therefore counter claim was not available on ground that drug patent did not claim "all approved methods.[110]" The *Novo Nordisk v. Caraco Pharma et al*[111] [112] case involved an appeal from the District Court for Eastern District of Michigan. The case involved the statutory construction of a critical provision of the Hatch-Waxman Act that had previously not been construed. The Federal Circuit denied petition of defendant for rehearing and enbanc hearing. The dissent in this case was scathing and is worth discussing. In 2003, Congress enacted the counterclaim provision in order to prevent patent holders from making unwarranted or inaccurate claims of patent coverage in the Orange Book. Patent holders previously made such claims in order to delay the

[110] 21 U.S.C. §355(j)(5)(c)(ii) ("counterclaim provision)."
[111] 615 F. 3d 1374.
[112] 601 F. 3d 1359.

onset of competition from generic drug manufacturers, by preventing or delaying FDA approval of a generic manufacturer's Abbreviated New Drug Application (ANDA). In *Mylan Pharma v. Thompson*[113], the Federal Circuit held that generic drug manufacturers could not sue to correct inaccurate and expensive Orange Book listings, thus inspiring Congress to amend the Hatch-Waxman Act to include the counterclaim provision. According to the dissent, the majority's opinion construed the counterclaim provision contrary to its manifested Congressional purpose. That construction rendered 21 U.S.C. §355(j)(2)(A)(viii) (Section viii) carve-out statements a virtual nullity and left generic drug manufacturers without a remedy to challenge the inaccurate Orange Book listings with respect to method of use patents. Indeed, the dissent in the District Court opinion explained that the "the majority's opinion adopted an overly narrow construction of 'patent information' and an overly broad construction of "an approved method of using the drug." Both constructions were irreconcilable with pre-existing FDA regulations, the text of the Hatch-Waxman Act, and Congressional intent. Furthermore, according to the dissent, not only was the majority's construction of the counterclaim provision erroneous it also eliminated the careful balance Congress had struck between encouraging pharmaceutical discoveries and ensuring that the American people had access to low cost generic drugs. Specifically, the majority opinion seriously

[113] 268 F. 3d 1323 (Fed. Cir. 2001).

undermined Section viii, a critical provision of the Hatch-Waxman Act that facilitated the approval and marketing of lower-cost generic drugs for uses no longer protected by a patent under the Hatch-Waxman Act. Section viii comes into play when a patent listed in the Orange Book "claims one, but not all approved methods of using a drug.[114]" Section viii permitted a generic manufacturer that sought to market an approved use of a drug to certify that its method of using the drug as described on its label is not covered by a patent in the Orange Book. Normally, the label associated with the generic version of a drug must be exactly the same as the label associated with the drug approved in the original New Drug Application[115]. A Section viii statement allows a generic manufacturer to avoid infringement by deleting patented use from its proposed label information, thus allowing it to avoid infringement[116].

Congress had intended Section viii to facilitate the approval and marketing of lower-cost generic drugs while still respecting the patent rights of pioneers. The pioneers, however, "have found another way to game the system by subverting Section viii carve-out statements and delaying the onset of generic competition by submitting overbroad and inaccurate use codes." Use codes are codes created by patent holders in Orange Book listings to identify the scope of their Orange Book

[114] Id. at 365.
[115] 21 U.S.C. §355(j)(2)(A)(v), (j)(4)(G); 21 C.F.R. §314.94(a)(8)(iv).
[116] 21 U.S.C. §355(j)(2)(A)(viii)].

patents. The FDA will not approve a generic manufacturer's Section viii proposed label amendment if a use code covers the proposed label. Importantly, the FDA makes no effort to determine the accuracy of use codes.

The dissent argues that to defeat the Section viii carve-out statement of *Caraco Pharma*, *Novo* changed the Orange Book use code associated with the '358 patent from "use of repaglinide in combination with metformin to lower blood glucose" to "a method for improving glycemic control in adults with type 2 diabetes mellitus." The later code unmistakably covered both patented and unpatented uses (FDA declined to police this inaccurate listing). Note: *Caraco* had made it clear with the carve-out statement it was not seeking approval to market the use of repaglinide in combination with metformin and limiting its label to the monotherapy use.

Caraco had asserted the counterclaim provision in the underlying litigation and requested that *Novo* revise its use code to reflect the '358 patent's true scope. The majority opinion however held that counterclaim relief is not available because the '358 patent covered at least one approved use. This effectively allows a patent holder to extend its monopoly to unpatented uses. Could this be the fault of the FDA? This necessitated a change in the indication part of drug label for therapeutic reasons. However, the FDA did not require *Novo's* inaccurate listings to be changed.

The dissent scathingly suggested that "the majority opinion thus eviscerates Section viii. A generic like *Caraco* cannot use Section viii if the pioneer's use code is erroneously broad. With the majority's blessing, pioneers now have every incentive to follow *Novo's* lead and draft exceedingly broad use codes thereby insulating themselves from generic competition and rendering Section viii a dead letter." The majority opinion would likely leave generic manufacturers with no other remedy. The FDA declined to grant *Caraco's* Section viii carve out because the broad use code for the '348 patent appeared to cover *Cara co's* proposed carve-out label. *Caraco* also cannot disprove infringement in the infringement lawsuit because the FDA required it to use *Novo's* original label, which included information regarding the patented combination therapy. Thus *Caraco* would have to wait to launch its generic repaglinide product until 2018, the date on which *Novo's* '358 patent on the combination therapy expires despite the fact that the '358 patent concededly does not cover the use for which *Caraco* seeks to market the drug. This position was untenable and contravened the intent of Congress for counterclaim provision. Finally, the majority opinion effectively invalidated the FDA's effort to define 'patent information' for the purposes of the counterclaim provision. Therefore, it is my opinion that the counterclaim provision needs to be reassessed and perhaps an amendment passed in the near future.

SAFE HARBOR PROVISION

In *Boehringer v. Barr Labs et al*.[117] patentee brought action alleging infringement of patent for drug approved for treatment of Parkinson's disease. The District Court of Delaware entered final judgment following bench trial holding patent invalid. The Federal Circuit reversed on appeal. The key holding was that the "retroactive terminal disclaimer filed after expiration of earlier patent was in effective to overcome invalidity of patent for obviousness – type double – patenting." However, statutory safe harbor [118] could apply to a divisional of application in which restriction requirement was entered; and divisional application that matured into patent was filed "as a result of PTO restriction requirement to withdraw claims to patentably distinct invention from original patent application." *Boehringer* argued that in alternative that the safe harbor provision of 35 U.S.C. §121 shielded the '812 patent from invalidity on the basis of double patenting in view of the '086 patent. Section 121 provides in relevant part: if two or more independent and distinct inventions are claimed in one application, the Director may require the application to be restricted to one of the inventions. If the other invention is made the subject of a divisional application which complies with the requirements of Section 120 of this title it shall be entitled to the benefit of the filing date of the original application. A patent issuing on an application with respect to which a requirement for restriction under this section has been made, or

[117] 592 F. 3d 1340.
[118] Safe Harbor Provision of 35 U.S.C. § 121.

on an application filed as a result of such a requirement shall not be used as a reference either in the PTO or in the courts against a divisional application or against the original application or any patent issued on either of them, if the divisional application is filed before the issuance of the patent on the other application. The Federal Circuit concluded that *Boehringer's* terminal disclaimer did not overcome obviousness-type double patenting with respect to the '086 patent, but that the safe-harbor provision of §121 was applicable. In another case discussed previously, *Amgen v. F. Hoffman-LA Roche*[119], the Federal Circuit held that the patents could not receive protection of statutory safe harbor.

TERM EXTENSION

In *Ortho-McNeil et al. v Lupin Pharma*[120], the latter appealed the judgment of the District Court for the District of New Jersey, which sustained the extension of the term of the '407 patent, assigned to Daiichi Sankyo and exclusively licensed to *Ortho-McNeil*. The '407 patent was directed to an enantiomer of a racemic compound that had previously been approved by the FDA. On cross motions for summary judgment the District Court agreed with the positions of the PTO and the FDA, and held that the statutory requirements for term extension were met for the '407 patent. The District Court enjoined *Lupin Pharma* from infringement during

[119] 580 F. 3d 1340.
[120] 603 F. 3d 1377.

the extended term of the patent. The Federal Circuit affirmed the decision. In another case also the Federal Circuit affirmed the term extension. In *Photocure SA v. PTO*[121], the Federal Circuit held that the compound that permitted drug to work effectively had to be present in drug in order to qualify as 'active ingredient' under provision of statute providing for extension of drug patent; and, agency's statutory interpretation was not entitled to Chevron or Skidmore deference[122]. This case concerns the applicability of the statute governing patent term extension, 35 U.S.C. §156, to the drug product having as its active ingredient the chemical compound MAL hydrochloride, brand name Metvixia. The PTO denied the extension and *Photocure* sought review in the District Court under the Administrative Procedure Act, 5 U.S.C. §702. The District Court for the Eastern District of Virginia held that the PTO's ruling was "not in accordance with law" and that the patent on MAL hydrochloride is subject to term extension. The Director appealed, stating that the District Court did not correctly define or apply the statutory terms "drug product" and "active ingredient". The Federal Circuit affirmed the District Court ruling. The PTO's statutory interpretation, which would exclude MAL hydrochloride from term extension, was contrary to the statutory purpose, for MAL

[121] 603 F. 3d 1372.

[122] "One of the most important principals in administrative law, established by the Supreme Court in *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984). The case raised the issue of how courts should treat agency interpretations of statutes that mandated that agency to take some action. The Supreme Court held that courts should defer to agency interpretations of such statutes unless they are unreasonable." http://topics.law.cornell.edu/wex/chevron_deference

is the active ingredient of a new and improved drug product. The District Court had correctly applied 35 U.S.C. §156 to extend the term of the patented product that is subject to regulatory review. In the case of *Eli Lilly v. Teva Pharma*[123], the pioneer (*Eli Lilly*) filed action against generic drug manufacturer alleging patent infringement. The District Court for the Southern District of Indiana granted six-month extension of thirty month statutory stay. The holdings included that the Federal Circuit Court of Appeals had jurisdiction over appeal of the District Court's grant of six-month extension of thirty month statutory stay; and, the District Court acted within its discretion to grant six-month extension of thirty month statutory stay. This case arose under the Hatch-Waxman Act. The Act strikes a balance between the sometimes – competing policy interests of inducing pioneering research and development of new drugs and enabling production of low-cost, generic copies of those drugs. A manufacturer that sought to market a generic drug would submit an ANDA for approval by the U.S. FDA rather than submitting a full NDA showing the safety and efficacy of the generic drug. Thus, the generic manufacturer may rely on safety and efficacy studies of the pioneer manufacturer upon showing the generic drugs bioequivalence with the previously approved drug product[124]. The Hatch-Waxman Act also required a pioneer drug manufacturer to notify the FDA of all patents that "claim the drug for which the

[123] 619 F. 3d 1329.
[124] 21 U.S.C. §355(j)(2)(A)(2003).

[NDA]applicant submitted the application.[125]" The FDA listed such patents in its Approved Drug Products with Therapeutic Equivalence Evaluations known as the "Orange Book." Under 35 U.S.C. §271 (e) (2), a generic manufacturer infringes a patent by filing an ANDA to obtain approval for a generic drug product claimed by a valid and unexpired patent.

JUSTICIABLE CONTROVERSY

In *Teva Pharma v. EISAI Co.*, Ltd[126], the generic drug manufacturer brought suit seeking declaratory judgment that its generic version of Donepezil for Alzheimer's disease did not infringe four patents listed in the Orange Book. The District Court for New Jersey dismissed the case for lack of justifiable controversy[127]. The plaintiff appealed. The Federal Circuit reversed saying the case presented actual controversy and that the District Court should not have declined to entertain suit. This was a declaratory judgment action arising under the Hatch-Waxman Act. The court had to decide whether the District Court properly dismissed the case for lack of jurisdiction, specifically, lack of a justifiable controversy under Article III of the U.S. constitution. Nothing in the Hatch-Waxman Act bars a company from filing

[125] 21 U.S.C. §§355 (b)(1) & (c)(2)(2003).
[126] 620 F. 3d 1341.
[127] "Justiciability concerns the limits upon legal issues over which a court can exercise its judicial authority. It includes, but is not limited to, the legal concept of standing, which is used to determine if the party bringing the suit is a party appropriate to establishing whether an actual adversarial issue exists. Essentially, justiciability in American law seeks to address whether a court possesses the ability to provide adequate resolution of the dispute; where a court feels it cannot offer such a final determination, the matter is not justiciable." http://en.wikipedia.org/wiki/Justiciability

multiple ANDAs covering different formulation of the same drug like *Teva* did here. Nor was it improper for those ANDAs to be filed under different corporate names, particularly since this filing decision was made at the FDA's request. Therefore, a declaratory judgment would settle the legal relations in dispute and afford relief from uncertainty and insecurity[128].

PROSECUTION OF LACHES AND INEQUITABLE CONDUCT

In the case of *Cancer Research Technology et al. v Barr Labs*[129], the holder of cancer drug patent and assignee brought action against competitor, alleging infringement. After a bench trial on unenforceability defenses, the District Court for Delaware, entered final judgment, finding '291 patent unenforceable for prosecution laches and inequitable conduct. *Cancer Research et al.* then appealed from final decision of District Court. According to the Federal Circuit, both the Supreme Court and their cases established that the evidence of intervening rights was required to establish "an unreasonable and unexplained delay in prosecution (*Symbol Techs)*[130] Barr has failed to establish either it or that others developed or invested in temozolomide or any other claimed tetrazine compound between 1982 and 1991, the period of delay. Accordingly, *Barr* could not establish prosecution laches as a matter of law. The Federal Circuit reversed the District Court holding

[128] See *SanDisk Corp. v ST Microelectronics, Inc.,* 480 F. 3d 1372 1383 (Fed. Cir. 2007) & *Genentech v. Eli Lilly & Co*. 998 F. 2d 931, 937 (Fed.Cir. 1993).
[129] 625 F. 3d 724.
[130] 422 F. 3d at 1385.

that neither competitor nor public was prejudiced by delay in prosecuting patent; and, the drug inventor did not withhold data from studies with intent to deceive PTO. In another case also the Federal Circuit did not find inequitable conduct. In *Purdue Pharma et al. v. Par Pharma*[131], the patentees appealed from a decision of the District court for Delaware holding their patents claiming controlled – release tramadol formations suitable for once-daily oral dosing invalid for obviousness. The generic drug manufacturer cross appealed from the decision finding the patents not unenforceable due to inequitable conduct. The Federal Circuit affirmed that patents were invalid for obviousness; and, even assuming the patent applicants withheld material data and submitted a materially misleading declaration, there was no clear error in the District Court's finding of a lack of clear and convincing evidence of intent to deceive so as to render drug patents unenforceable due to inequitable conduct.

CONCLUSION

My comprehensive study of forty cases that appeared before the U.S. Federal Court of Appeals for the Federal Circuit shows that the Court's rulings are evenly balanced. The Court appears to have ruled on a case by case basis. Contrary to the

[131] 377 Fed. Appx. 978, 2010 WL 2203101 (C.A. Fed. (Del.)).

claims of a prior study[132] this study does not suggest either a statistical anomaly or the notion that the Court is biased against pioneers in the Court's declaration of nearly all patents invalid in the period 2005-2006. Therefore, it is not harder to enforce pharmaceutical patents. Rather, the Court continues to look at key issues such as obviousness, lack of written description, enablement etc. A pioneer that carefully files for a patent completing all the requirement has no reason to worry that the Court will arbitrarily hold patent claims invalid. Also, a generic firm has a fair chance as well if a pioneer intentionally stacks the Orange book with unwarranted claims. The Hatch-Waxman Act generally appears to meet its objectives in encouraging both pioneers and generics.

[132] See generally R. Schulman, "Is it harder to enforce pharmaceutical patents?" The National Law Journal, 8/28/2006 for this view based on his study of cases in the U.S. Federal Court of Appeals for Federal Circuit, 2005-2006.

Appendix 1: Table of Cases Analyzed (2008-2011)

	Case #	Parties	Issue	District Court/PTO/Board of Patent Appeals.	Federal Circuit Court of Appeals	Holdings	Patent Validity
1.	(2011 WL 625291 (C.A. Fed.(Tex.))	Centocor et al. v Abbot (*)	'775 patent claim infringement.	Denied JMOL.	Reversed	Patent claims lacked written description under 35 U.S.C. §112.	Innovator Invalid patent
2.	(630 F. 3d 1026)	Re Glatt Air Techniques (*) No 2010-1141 V PTO Board	Patent claim obvious.	PTO rejected claim as obvious.	Reversed	Evidence did not support Board's determination of obviousness.	Innovator Valid patent
3.	2010 WL 5393659 (C.A. Fed. (N.J.))	Sanofi-Aventis v Sandoz et al.(*)	Consent judgment and injunction barring sale of generic.	DC for NJ entered consent judgment and injunction.	DC erred in interpretation of terms in license agreement. Vacated.	Remanded for further proceedings.	Innovator Invalid patent
4.	2010 WL 5080936 (C.A. Fed. (N.J.))	Altana Pharma et al. (*) v Teva, Sun et al.	Patent infringement	DC for NJ issued Order & Final judgment against Teva et al.	Dismissed appeal as premature.	Claims still pending.	Innovator Valid patent
5	(625 F. 3d 1359)	Abraxis V Navinta (*)	Assignee of patents brought action against ANDA of competitor.	DC for NJ judgment in favor of assignee.	Abraxis's complaint must be dismissed. Reversed.	Assignee did not have title to asserted patents on date it filed action.	Innovator Invalid patent
6.	(625 F. 3d. 724)	Cancer Research Technology et al. (*) v Barr Labs	Patent infringement	DC for Del. found patent unenforceable for prosecution laches and inequitable conduct.	DC decision reversed.	Evidence of intervening rights is required to establish an unreasonable and unexplained delay in	Innovator Valid patent

						prosecution.	
7.	(620 F. 3d 1341)	Teva Pharma (*) V EISAI Co., Ltd.	Generic manufacturer sought declaratory judgment that its generic version did not infringe 4 patents listed in Orange Book.	DC for NJ dismissed case for lack of justiciable controversy under Article III of the U.S. Constitution.	Action arose under Hatch-Waxman Act. Case presented actual controversy. DC should not have declined to entertain suit. Reversed.	Nothing in the Hatch-Waxman Act bars a company from filing multiple ANDAs covering different formulations of the same drug Teva did here.	Innovator Invalid patent
8.	(619 F. 3d 1346)	Daiichi Sankyo (*) V Matrix Lab et al	Inventors & producers filed patent infringement action against generic drug manufacturers.	DC held patent was not invalid as obvious.	Affirmed.	Patent was not invalid for obviousness.	Innovator Valid patent
9.	(619 F. 3d 1329)	Eli Lilly (*) V Teva Pharma	Patentee brought action competitor seeking permanent injunction preventing manufacture of distribution of generic version.	DC for S.D. of IN granted injunction as to four of patentee's but ruled that certain claims as to two of patents were invalid. All appealed.	Affirmed.	Person of ordinary skill in the art would not have considered it obvious. Raloxifene patents met enablement requirements. Finding that patent was invalid for failure to comply with written description requirement was not	Innovator Partly valid patents

						clearly erroneous.	
10.	(2010 WL 3374123 (C.A. Fed. (NJ)))	Eli Lilly (*) V Actavis et al.	Eli Lilly seeks injunction to prevent defendant from launching generic version pending appeal.	DC for NJ held defendants induced infringement of Eli Lilly's patent. Also held that patent was invalid for lack of enablement because, inter alia, there was no timely demonstration of utility.	Affirmed	Plaintiff has met burden to obtain an injunction pending appeal.	Innovator Valid patents
11.	(616 F. 3d 1283)	Adams Respiratory (*) V Perrigo Co.	Suit alleged generic version would infringe patent.	DC for W.D. of MI granted defendant summary judgment for non-infringement.	Reversed in part.	Fact question as to equivalence precluded summary judgment. Dc correctly construed bioavailability. Summary judgment of non-infringement on doctrine of equivalents was improper.	Innovator Partly valid patents
12.	(616 F. 3d 1267)	King Pharma (*) V Eon Labs Elan Pharma	Patent holder alleged infringement of patents. Competitor asserted affirmative defenses and counterclaims for	DC for E.D. of NY invalidated patents. Plaintiff appealed.	Partly reversed. DC erred in invalidating several claims as unpatentable under §101, all claims of the '128 and '102	Claim directed toward methods of informing was invalid due to anticipation. Broad terms used in claims cannot be limited to	Innovator Partly valid patents

			invalidity, fraud and unclean hands.		patents are ultimately anticipated under 35 U.S.C. §102 or obvious under 35 U.S.C. §103 in light of the prior art. DC also erred in entering judgment of invalidity against Elan because no case or controversy exists between Elan and Eon.	specific food conditions disclosed in written description. Claims limiting time frame had been anticipated a priori. Instructional limitation is anticipated. Printed label is anticipated. Commercial success was not objective indication of non-obviousness. Patent claim toward methods was obvious. Actual case or controversy did not exist after all interests disposed off.	
13.	(390 Fed. Appx. 989, 2010 WL 3035222 (C.A. Fed. (Minn.)))	Biopolymer Engg V Immunocorp (*)	Action alleged defendants infringed fourteen of its patents.	DC for MN granted in part and denied in part summary judgment for both parties. Should action be dismissed for lack of case or controversy?	Appeal dismissed as moot.	Patent holder had entered into settlement agreements with defendants.	Innovator Valid patents
14.	(615 F. 3d 1374)	Novo Nordisk (*) V	Appeal from DC for E.D. of MI.		Petition of defendant for	*see discussion in paper.	Innovator Valid

		Caraco Pharma et al.	Case involved the statutory construction of 21 U.S.C. §355 (j)(5)(c)(ii) ("counter claim provision).		rehearing and enbanc was denied.		patents
15.	(611 F. 3d 1381)	Sun Pharma (*) V Eli Lilly	Generic manufacturer sought declaratory relief that patent was invalid or that generic drug did not violate patent. Patent holder filed infringement counter claim.	DC for E.D. of MI granted generic drug manufacturer's motion for partial summary judgment on counter claims. Claims found invalid for obviousness – type double patenting. Subsequently granted patent holder's motion for entry of final judgment. Patent holder appealed.	Affirmed. DC correctly followed the double patenting analysis of the Geneva line of cases. Geneva 349 F. 3d at 1385.	Claims in first patent were not patentably distinct from claims in subsequent patent for use of pharmaceutical. Specification of issued patent could be consulted to ascertain relevant disclosed uses of claimed compound.	Innovator Invalid patents
16.	(377 Fed. Appx. 978, 2010wL 2203101 (C.A. Fed. (Del.)))	Purdue Pharma et al. V Par Pharma (*)	Patentees appealed from Dc holding their patents invalid for obviousness. Generic drug manufacturer cross appealed DC finding patents not unenforceab	DC for DE decision that patents were invalid for obviousness. Patents not unenforceable due to inequitable conduct.	Affirmed.	Patents were invalid for obviousness. Affirmed there was no clear and convincing evidence of intent to deceive so as to render drug patents unenforceable due to	Innovator Invalid patents

			le due to inequitable conduct.			inequitable conduct.	
17.	(603 F. 3d) 1377)	Ortho-McNeil et al. (*) V Lupin Pharma	Lupin appealed DC judgment.	DC for NJ sustained the extension of the term of '407 patent licensed to Ortho-McNeil. The DC enjoined Lupin from infringement during extended term of the patent.	Affirmed.	The '407 patent is directed to an enantiomer of a racemic compound that had previously been approved by the FDA. Statutory requirements for term extension were met for the '407 patent.	Innovator Valid patents
18.	(603F. 3d 1372)	Photocure SA (*) V PTO	The PTO denied extension and Photocure sought review in the DC under the Administrative Procedure Act, 5. U.S.C. §202.	DC for E.D. of VA held that PTO's ruling was not in accordance with law and patent was subject to term extension.	Affirmed DC decision.	Compound that permitted drug to work effectively has to be present in drug in order to qualify as 'active ingredient' under provision of statute providing for extension of drug patent. Agency's statutory interpretation was not entitled to Chevron or Skidmore deference.	Innovator Valid patent
19.	(601 F. 3d	Novo	Patentee	DC for E.D of	Reversed	Hatch-	Innovat

	1359)	Nordisk (*) V Caraco	brought action against generic drug manufacturer, alleging infringement of patent for blood glucose-lowering drug.	MI 656 F. supp.2d 729 entered injunction directing patentee to request FDA to replace patent use code listing for drug '358 patent in Orange Book with the former listing.	and vacated.	Waxman Act provided a limited counterclaim to a generic manufacturer in an infringement action only if the drug patent did not claim any approved methods of using the listed drug, and therefore counterclaim was not available on ground that drug patent did not claim "all approved methods."	or Valid patents
20.	(598 F. 3d 1336)	Ariad Pharma V Eli Lilly (*)	Alleged infringement of '516 patent	Jury found infringement but found none of the asserted claims invalid. DC of MA denied Eli Lilly's JMOL.	Reversed denial of JMOL and held the asserted claims invalid for lack of written description.	Statute requiring that patent specification contain a written description of the invention contained a written description requirement separate from enablement. Patent was invalid for failure to provide adequate written description.	Innovat or Invalid patents
21.	(592 F. 3d	Boehringer	Patentee	DC for Del.	Reversed	Held that	Innovat

	1340)	V Barr Labs et al	alleged infringement of patent for drug approved for treatment of Parkinson's.	entered final judgment following bench trial holding patent invalid.	and remanded.	Boehringer's terminal disclaimer does not overcome obviousness-type double patenting with respect to the '086 patent, but that the safe-harbor provision of §121 is applicable.	or Valid patent
22. *	(591 F. 3d 1364)	Wyeth et al. (*) V PTO	Challenged methods used by PTO to calculate adjustments for patent terms due to delay in prosecuting applications.	DC for District of Columbia granted patent owners summary judgment.	Affirmed.	Held that owners were entitled to extended patent term of adjustments under 35 U.S.C. §154(b).	Innovator Valid patent
23.	(583 F. 3d 1317)	Janssen Pharma et al. (*) V Teva, Mylan et al.	Exclusive licensees brought infringement actions against generic drug manufacturers.	DC for District of Columbia found patent invalid for lack of enablement.	Affirmed.	Patent was invalid for lack of enablement.	Innovator Invalid patents
24.	(580 F. 3d 1340)	Amgen (*) V F. Hoffman-LA Roche	Owners of patents filed declaratory judgment action alleging that competitor's product would infringe patents if imported into U.S.	DC for MA Entry of summary judgment of no invalidity for obviousness 581 F. Supp. 2d 160, and jury verdict in patentee's favor, DC vacated jury's	Affirmed in part, vacated in part, and remanded.	Patents could not receive protection of statutory safe harbor provision. Patents were not invalid for obviousness-type double-patenting. Accused product	Innovator Valid patents

			Competitor filed counterclaims asserting that patents were invalid and non-infringed.	verdict that claim of one patent was infringed under doctrine of equivalents (DOE) but granted patentee declaratory relief and permanently enjoined competitor from marketing its product in the U.S.		literally infringed patent. Patentee failed to present particularized testimony of equivalents.	
25.	(345 Fed. Appx. 594, 2009 WL2905997 (C.A. fed. (N.J.))	Sanofi-Aventis (*) V Sandoz et al.	Alleged infringement against generic manufacturer.	DC for NJ construed patent and entered summary judgment of non-infringement. Patentee appealed.	Vacated and remanded.	Concluded DC erred when construing the claims, therefore vacate judgment of non-infringement and remand.	Innovator Valid patents
26.	(579 F. 3d 1363)	Martek Biosciences (*) V Nutrinova	Patentee brought infringement action against competitor for infringement of patents.	The DC for DE construed patents, entered judgment on jury verdict that competitors had willfully infringed patents, and granted in part and denied in part competitors' motion for JMOL. 520 F. Supp. 2d 537. Parties appealed.	Affirmed jury findings.	Food product patent was entitled to priority date of parent application. Support for other jury findings.	Innovator Valid patents

27.	(344 Fed. Appx. 595, 2009 WL2604919 (C.A. Fed. (N.J.)))	Ortho-McNeil (*) V Teva Pharma et al.	Patent holder brought action against generic drug manufacturers alleging infringement of patent on pain-relief drug.	DC for NJ granted in part and denied in part defendants' motions for summary judgment. Patent holder appealed.	Affirmed in part, vacated In part, remanded.	Fact issuer precluded summary judgment invalidating certain claims as obvious, and others as anticipated. Patent claim reciting a composition comprising tramadol and acetaminophen in an about 1:5 ration was invalid as obvious.	Innovator Partly valid patents
28.	(575 F. 3d 1341)	Bayer Schering Pharma V Barr Labs (*)	Patent owner filed action against competitor alleging infringement.	DC for NJ concluded patent was invalid due to obviousness. Owner appealed.	Affirmed.	Held that innovation to micronized drospirenone to increase its bioavailability and that micronized drospirenone would absorb with normal pill, was obvious.	Innovator Invalid patents
29.	(566 F. 3d 1282)	Abbott et al. V Sandoz et al. (*)	Competitor brought action against patent licensee seeking declaratory judgment of non-infringement of patent for crystalline cefdinir.	DC for E.D. of VA construed patent, and entered summary judgment of non-infringement 491 F. supp. 2d 563. Licensees appealed.	Affirmed.	Patent was limited to 'Crystal A' form of compound. Patent's claims could not be extended under doctrine of equivalents to embrace known but unclaimed	Innovator Invalid patents

						subject matter.	
30.	(566 F. 3d 999)	Altana Pharma (*) V Teva Pharma et al.	Patent owner and exclusive licensee brought action against competitors' alleging infringement of patent directed to active ingredient in antiulcer drug.	DC for NJ, 532 F. Supp. 2d 666 denied owner and licensee's motion for a preliminary injunction. Owner and licensee appealed.	Affirmed.	DC's determination that alleged infringers' obviousness defense had substantial merit was not clearly erroneous. DC's determination that owners and licensee failed to demonstrate irreparable harm was not clearly erroneous.	Innovator Invalid patents
31.	(566 F. 3d 989)	P&G Co (*) V Teva Pharma	Owner of patent claiming compound risedronate, the active ingredient of an osteoporosis drug brought infringement action against competitor.	DC for Del. 536 F. Supp. 2d 476, in a bench trial entered judgment in favor of patent owner. Competitor appealed.	Affirmed.	Competitor failed to establish case of obviousness. Secondary considerations also supported nonobviousness. Patent claiming an intermittent dosing method for treating osteoporosis qualified as prior art. Patent claiming risedronate was not invalid based on	Innovator Valid patent

						obviousness-type double patenting.	
32.	(561 F. 3d 1372)	Takeda Pharma V PTO (*)	Patent assignee filed suit challenging PTO Board's rejection of patent covering process to make cephem compounds.	DC for Dist. Of Columbia 511 F. Supp. 2d 81 granted assignee summary judgment. PTO appealed.	Vacated and remanded.	The genuine issues of fact cloud the date of availability of materially distinct processes, as well as viability of those processes.	Innovator Invalid patent
33.	(560 F. 3d 1366)	Ariad Pharma V Eli Lilly ←→	Owners of patent claiming methods comprising the single step of reducing Nuclear Factor Kappa B brought infringement action against competitor.	Jury found infringement and concluded asserted claims were not invalid for anticipation, lack of enablement, or lack of written description. The DC for MA denied competitor's JMOL. Final judgment was entered.	Affirmed in part and reversed in part.	Patent owners failed to provide adequate written description of claims. Figure containing errors was insufficient to satisfy intent element of inequitable conduct claim. DC did not clearly err by finding no intent to deceive PTO.	Innovator Partly invalid patents
34.	(559 F. 3d 1345)	Triantafyllas Tafas et al. V PTO ←→	Rulemaking Action against PTO challenged newly adopted rules that limited number of continuing applications, requests for	DC for E.D. of VA 541 F. Supp. 2d 805 granted summary judgment for plaintiffs. PTO appealed.	Affirmed in part, vacated in part and remanded.	PTO not vested with any general substantive rulemaking power. Not entitled to Chevron deference. Rule that limited applications	Innovator Valid patent

			continued examination (RCE) and claims that applicants can make.			was invalid.	
35.	(557 F. 3d 1346)	Eli Lilly V Teva Pharma (*)	Pioneer filed action against generic alleging patent infringement.	DC for the S.D. of IN granted 6-month extension of 30-month statutory stay.	Affirmed	Court of Appeals had jurisdiction. DC acted within its discretion to grant additional stay.	Innovator Valid patents
36.	(550 F. 3d 1075)	Sanofi et al. (*) V Apotex	Owners of patent covering clopidogrel bisulphate brought infringement action against competitors and competitors counterclaimed that patent was invalid and unenforceable.	DC for S.D. of NY 492 F. Supp. 2d 353, in a bench trial ruled that patent was valid and enforceable. Competitor appealed.	Affirmed	Prior art patents did not anticipate patent. DC did not clearly err in making finding of nonobviousness. Patent validity sustained.	Innovator Valid patents
37.	(549 F. 3d 1381)	Takeda (*) V Mylan et al.	Patentee brought action against generic alleging infringement of patent when defendants filed ANDA.	DC for S.D. of NY entered judgment in plaintiff's favor. It also found case to be exceptional and awarded attorney fees.	Affirmed	DC did not commit error in finding ANDAs were filed in bad faith. DC did not abuse its discretion in awarding attorney fees of $16,800,000. No abuse in awarding	Innovator Valid patents

						patentee its expert fees.	
38.	(545 F 3d 1373)	DBC, LLC V PTO Board (*)	Appeals examiner's rejection of all pending claims as obvious under 35 U.S.C. §103.		Affirmed	Evidence supports Board's determination that claims would have been obvious. DBC waived challenging the appointment of the administrative patent judges who presided over its appeal.	Innovator Invalid patents
39.	(545 F. 3d 1015)	K. Alonso V PTO Board (*)	Appeals examiner's final rejection of claim of patent application.		Affirmed	Substantial evidence supported Board's conclusion that application lacked adequate written description.	Inventor Invalid patents
40.	(544 F. 3d 1341)	Abbot (*) V Sandoz	Action against competitor alleging infringement of its patents relating to extended release formulations of Clarithromycin.	DC granted owner's motion for preliminary injunction and denied competitor's motion for stay of injunction pending appeal 500 F.Supp. 2d 846. Competitor appealed.	Affirmed	Patent owner had substantial likelihood of success on merits of claim. Owner would likely suffer irreparable harm. Balance of hardships favored preliminary injunction. Public	Innovator Valid patents

						interest supported grant of preliminary injunction.	

*Won

←→ Partly valid patents

Appendix 2: Table of U.S. Court of Appeals for Federal Circuit Patent Validity Decisions

U.S. Court of Appeals for Federal Circuit	**District Court Valid**	**District Court Invalid**	**PTO/Board Valid**	**PTO Board Invalid**
Affirmed	11	7	2	2
Reversed	5	4	1	2
Partly	3	3		
Total	**19**	**14**	**3**	**4**

Appendix 3: Table of U.S. Court of Appeals for Federal Circuit Innovator v. Generic Patent Validity Decisions

Parties	**Valid Patent**	**Invalid Patent**	**Partly Valid**
Innovator v. Generic	8	7	3
Innovator v. Innovator	9	4	2
Innovator v. PTO	4	3	
Total	**21**	**14**	**5**

ppendix 4: Table of U.S. Court of Appeals for Federal Circuit – Key Issues in Decisions

Key Issue	Approximate # of Cases
Obviousness Nonobviousness Obviousness-Type Double Patenting	14
Written Description	6
Inequitable conduct	2
Term Extension	4
Doctrine of Equivalents	3
Prosecution of laches	1
Justiciable controversy	2
Lack of enablement	2
Likelihood of success, bad faith, public interest etc.	1
Anticipated	2
Counterclaim Provision	2
Chevron deference	2
Safe Harbor Provision	2

Note: some decisions involved two or more issues