

PROVERIS v. INNOVASYSTEMS: REDEFINING A PATENTED INVENTION UNDER § 271(E)(1): An Examination of the Federal Circuit's Narrowing of the § 271(e)(1) “Safe Harbor” Exemption

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INTRODUCTION

The Food and Drug Administration's (“FDA”) regulation of drugs and medical devices impacts the everyday lives of Americans in both noticeable and inconspicuous ways. [1] For example, a recall of contaminated food or adulterated pharmaceuticals illustrates how the FDA noticeably affects impacts our everyday lives. [2] Additionally, unobservable consequences springing from the overlap between FDA regulations and patent law also affects the lives of Americans by stimulating market competition and providing incentives for medical research and development. [3]

Attempting to promote continued innovation in medical science, while at the same time provide the public with “more low cost generic drugs,” the U.S. Government amended both FDA regulations and patent laws through the Price-Competition and Patent Term Restoration Act (“the Act”). [4] The Act, commonly known as the Hatch-Waxman Act, consists of two sections, Title I and Title II, which function in tandem “affect[ing the] introduction procedures and patent requirements for certain kinds of generic new drugs.” [5] Title I of the Act provides for a new route of FDA regulatory approval for generic drugs (also known as “generics”), the Abbreviated New Drug Application (“ANDA”). [6] Congress's intent behind the ANDA process was to allow generic drug manufacturers to get generics on the market sooner and at lower costs. [7] Title II of the Act made several amendments to the U.S. patent laws regarding how they apply to federally regulated products. [8]

The “safe harbor” provision of 35 U.S.C. § 271(e)(1) is a patent law amendment created by Title II of the Act. [9] Utilized in conjunction with the ANDA provision in Title I, Congress believed § 271(e)(1) would aid generics in obtaining market approval “between 18 months and 2 years earlier.” [10] Under § 271(e)(1), the otherwise infringing use of a “patented invention” is immunized from liability if the infringing use is “reasonably related” to the development of data for FDA approval. [11] Although § 271(e)(1) appears to lend itself to a fairly straightforward interpretation, its scope has been the source of much judicial and commentator debate over the last two decades. [12] Since the enactment of § 27(e)(1), the Supreme Court has weighed in on its scope only twice. [13] In both cases the Court held the plain language and legislative intent behind the Act indicated that § 271(e)(1) was supposed to immunize a broad scope of inventions and actions, related to FDA approval, from patent infringement. [14] Despite the Court's broad holdings in both cases, the United States Court of Appeals for the Federal Circuit (the “Federal Circuit”) recently narrowed the scope of § 271(e)(1) with its holding in *Proveris Scientific Corp. v. Innovasystems, Incorporated*. [15] The Federal Circuit employed a narrow test, termed the “perfect product fit” analysis, for determining what constitutes a “patented invention” under § 271(e)(1). [16] Under *Proveris'* perfect product fit analysis, in order for infringement of a patented invention to be immunized by § 271(e)(1), the “patented invention” must be eligible for a 35 U.S.C. § 156(e)(1) patent term extension. [17]

While *Proveris* may appear to comport with sound patent policy, the reasoning of the Federal Circuit fails to properly consider Congress's overall purpose for the Act. Additionally, *Proveris'* new interpretation of “patented invention” flatly contradicts the meaning previously assigned to the statutory phrase by the Supreme Court in *Eli Lilly & Company v. Medtronic, Incorporated*. [18] Further, the Federal Circuit misinterprets Lilly's discussion of statutory symmetry (between § 271(e)(1) and § 156), through which the Court intended to broaden the § 271(e)(1) term “drugs,” not narrow the phrase “patented invention.” [19]

By reducing the scope of “patented inventions” within § 271(e)(1) to only inventions comporting with the “perfect product fit” analysis, *Proveris* has drastically altered the function of § 271(e)(1) and potentially impairs the ability of generic manufactures to fully utilize the ANDA process created in Title I of the Act. [20] Adherence to *Proveris'* “perfect product fit” rule risks establishing loopholes that potentially allows patent holders of pioneer

drugs and medical devices to delay generic manufacturers from bringing less expensive generics to the market. [21]

This Note critiques the Federal Circuit's recent narrowing of § 271(e)(1) in *Proveris*. Part I provides a historical overview of FDA regulations on drugs and medical devices, the promulgation of the Act, and judicial interpretations of § 271(e)(1). Part II furnishes an in-depth review of the Federal Circuit's holding in *Proveris*, and discusses the reasons cited as supporting the court's narrowing of § 271(e)(1). Part III analyzes the Federal Circuit's "perfect product fit" test, found to control the scope of § 271(e)(1), and discusses how the "perfect product fit" test contradicts the judicial precedent cited by the court as supporting its holding. Part IV illustrates how *Proveris* operates contrary to Congress's intention for the Act, and suggests a "sliding scale" analysis for Federal courts when faced with a § 271(e)(1) defense.

I. A HISTORICAL LOOK AT THE PROMULGATION AND JUDICIAL INTERPRETATIONS OF § 271(E)(1)

Federal regulation of pharmaceuticals and medical devices dates as far back as the early 1800s. [22] During the latter half of the 1900s, Federal requirements for selling drugs and medical devices grew increasingly stringent, bringing about tension between the FDA's regulatory laws and U.S. patent policy. [23] Prior to the passage of the Act in 1984, drug and device manufacturers concerned with realizing a return on their investments found themselves at odds with the expensive and time consuming demands of the FDA approval process. [24] Furthermore, the concerns of drug and device manufacturers were also at odds with society's desire to see an increase in market competition and a reduction in price. [25] By passing the Act, Congress sought to strike a compromise which addressed both drug and device manufacturer's concerns related to recouping investments, and society's interest in increasing market competition with an improved process for generics to enter the market. [26]

Although considered landmark legislation for its balancing of both corporate and societal interests, the Act has become a source of legal disputes centering on intellectual property rights of regulated drug and medical devices. [27] One basis of dispute involves the scope of § 271(e)(1), a provision of the Act designed to address a patent term distortion that, prior to the Act, prevented generic manufacturers from starting market approval testing until after the drug and device manufacturer's patents expired. [28] Congress intended § 271(e)(1) to cure this distortion by allowing generic manufacturers to perform required ANDA testing during drug and medical device patent terms. [29] By allowing generic manufacturers to complete required ANDA testing during the patent terms of FDA approved drugs or devices, generics could enter the market immediately upon the expiration of the approved product's patent. [30] This Part gives a brief overview the FDA regulatory landscape leading to enactment of § 271(e)(1) and the judicial decisions that have shaped its application.

A. *Prior to § 271(e)(1)*

Congress created the first Federal regulations on pharmaceuticals in 1813, when it passed a temporary statute governing the safety and effectiveness of smallpox vaccines. [31] During the course of the twentieth century, Federal regulations on drugs, and eventually on medical devices as well, continued to become more demanding. [32]

First, in 1906 the Federal Food and Drug Act was enacted, creating a national standard for drug manufacturers regarding the "purity and quality" of drugs. [33] Then, in 1938, the Food, Drug and Cosmetic Act (hereinafter the "FDCA") was signed into law by President Roosevelt, adding "safety" to the FDA's enforcement of drugs. [34] Also of significance, the FDCA placed medical devices within the purview of the FDA's enforcement authority. [35] Later, Congress passed the Drug Amendments of 1962, mandating that new drug manufacturers demonstrate, through "substantial evidence," that new drugs are "effective" as well as safe before they can be marketed. [36] Although recognized for their benefits in forestalling potential medical tragedies, the 1962 Drug Amendments were criticized for causing increases in drug prices as well as delays in the introduction of new drugs to the market. [37]

Attempting to curb the increased cost and delays created as a result of the more demanding regulatory approval process, Congress established the first ANDA process in 1969. [38] The 1969 ANDA process allowed generic versions of drugs approved prior to 1962 to forgo the full regulatory review process and to simply submit bioavailability data and manufacturing control information. [39] Although the 1969 ANDA process increased the number of generics on the market, its benefits did not extend to manufacturers of generics for new drugs approved

after the passage of the 1962 Drug Amendments. [40] As a result, market approval of generics for post-1962 drugs required manufacturers to “virtually duplicate” the safety and effectiveness data generated by the pioneer drug manufacturer, a lengthy and expensive process. [41] Congress, aware of the shortcomings in the 1969 ANDA process, considered many options for extending the ANDA process to generic manufacturers of all drugs. [42] However, an extension of the 1969 ANDA process did not occur until the passage of the Act in 1984. [43]

Prior to Congress passing the Act, the Federal Circuit paid notice to the growing tension between the interests of patent owners of FDA approved drugs and society's interest in quick market entry of generics. [44] This tension was at the heart of the Federal Circuit's 1984 decision in *Roche Products, Inc. v. Bolar Pharmaceuticals Co.* [45] Roche, the patent owner for the FDA approved drug Dalmane, alleged Bolar's use of the drug in bioequivalence testing (required for ANDA approval) constituted patent infringement. [46] Bolar asserted bioequivalence testing did not equate to infringement, arguing, in part, that the court should apply public policy to “create a new exception to the use prohibition” of patented drugs when used for ANDA approval. [47] Bolar argued such an exception was essential to resolving the conflicts “between the FDCA and the Patent Act.” [48] Further, Bolar explained that preventing generic manufacturers from using patented ingredients of FDA approved drugs, for mandatory bioequivalence testing, extended patent terms of new drugs indefinitely. [49]

The Federal Circuit rejected Bolar's arguments and found Bolar's bioequivalence testing did infringe Roche's patent, regardless of whether the infringement was for “FDA required test[ing].” [50] The court further stated it would not, as Bolar had urged, “rewrite the [patent laws]” with regards to their application to drugs simply because of the inconsistencies caused by the FDCA regulations. [51] Additionally, the Federal Circuit explained that Congress was the proper branch of government to address the “economic and societal problems” presented by the arguments of both Roche and Bolar. [52] In a bit of foreshadowing, the court noted Congress was, at that time, considering two statutes aimed at addressing faster market entry for generics as well as the patent term losses resulting from FDA regulatory approval. [53] The Federal Circuit concluded by pointing out that its function “is only to interpret and apply ... legislation ... not apply laws that have not yet been written.” [54]

B. The Enactment of § 271(e)(1)

Congress acted swiftly in overturning Roche, passing the Act just five months after that decision. [55] Hailed by proponents as “the best possible compromise between two competing economic interests,” Congress intended the Act to strike a balance between the concerns of the general public, pioneer drug manufacturers, and generic manufacturers. [56]

Addressing society's desire for increased market competition of FDA approved products, Title I of the Act created a new ANDA process. [57] The new ANDA process established a mechanism by which generics of post-1962, as well as pre-1962, drugs could receive FDA approval without having to duplicate the expensive and time consuming clinical studies already performed by the pioneer drug manufacturer. [58] Under the new ANDA process, generics could receive FDA approval by demonstrating its product was a “bioequivalent” to an approved pioneer drug. [59] Additionally, the Act devised a scheme by which generic manufacturers could legally prepare and submit their ANDA applications during the patent term of the pioneer drugs. [60] Congress felt allowing generic manufacturers to prepare and submit ANDA applications during the patent terms of pioneer drugs would get generics to market eighteen to twenty-four months sooner. [61]

Although the new ANDA process was created in Title I of the Act, the patent law amendments created in Title II of the Act provided essential mechanisms for carrying out the ANDA process. [62] Title II made two substantive changes to pioneer drug patent rights, both of which were imperative in the proper operation of Title I's new ANDA provision. [63]

The first substantive change created in Title II was the addition of 35 U.S.C. § 156 to the Patent Act. [64] Congress intended § 156 to address the concerns of patent owners, worried that increased FDA pre-market approval requirements were eroding drug patent terms and thus decreasing the incentive to invest in research and development. [65] Section 156 acts to “extend the normal [20] year term ... of a patented product ... subject to premarket clearance” by up to five years. [66] In relevant part, § 156 states that “[t]he term of a patent ... claim[ing]

a product ... shall be extended [up to five years] if ... the product has been subject to regulatory review ... before its commercial marketing.” [67] Further, Congress defined the term “product,” for purposes of § 156, as “[a] drug product ... [a]ny medical device, food additive, or color additive subject to regulation under the Federal Food, Drug, and Cosmetic Act.” [68] Thus, Congress intended for both FDA regulated medical devices and drugs to recoup some of the marketable patent life lost as a result of lengthy regulatory review. [69]

In addition to ensuring five additional years of marketable patent life, § 156 also provides incentives for continued investments in developing new medical devices and drugs by functioning in conjunction with the ANDA process. [70] Under the ANDA provision, created in Title I, developers of new FDA approved drugs or devices are granted five years of “market exclusivity.” [71] Although the first four years of “market exclusivity” are granted irrespective of having a valid patent covering the drug or device, in order to receive the fifth year of exclusivity a valid patent term is essential. [72] Congress, in extending the patent life of approved products by five years (from the date of FDA approval), sought to ensure patent owners could recognize the full extent of market exclusivity provided in Title I. [73]

Title II of the Act also amended the patent infringement statute, 35 U.S.C. § 271, by adding subsection (e), which provides: “[i]t shall not be an act of infringement to make, use ... or sell ... 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 [.]” [74] By adding subsection (e) to § 271, Congress specifically overruled Roche and created an important mechanism for generic manufacturers to utilize during the preparation of ANDA applications. [75] Viewed in light of Roche, § 271(e)(1) immunizes the infringement of “patented inventions” during generation of data required for ANDA submissions. [76]

Drug and device patent holders opposed Congress's approval of § 271(e)(1), claiming it amounted to a Fifth Amendment taking of personal property rights. [77] However, Congress rejected this Fifth Amendment argument, explaining it was focused on balancing “the need for innovation against the goal of furthering the public interest.” [78] Further, Congress considered the “economic impact” of § 271(e)(1) and concluded the societal benefits from § 271(e)(1) would be substantial, whereas any detriment to patent holders was speculative. [79] Additionally, Congress felt “the very nature of the [FDA regulated] industry” compelled a need for § 271(e)(1)'s interference with patent rights. [80]

Summing up his reasons for approving the Act, President Ronald Reagan remarked that it would “speed up the process of Federal approval of inexpensive generic versions of many brand name drugs, make the generic versions more widely available ... and grant pharmaceutical firms added incentives to develop new drugs.” [81] President Reagan concluded that the amendments to FDA regulatory and patent laws would give Americans access to “safe and effective drugs at the lowest possible costs,” while continuing to “promote medical breakthroughs and drug innovation.” [82]

C. Judicial Interpretations of §271(e)(1)

Although Congress's intent for the Act seemed simple, applying the amendments created by the Act has been anything but straightforward. [83] One frequent topic of debate among commentators and courts has been the scope of § 271(e)(1). [84] Due to poor “draftsmanship,” courts have been left to define statutory phrases such as “patented invention,” “reasonably related [to FDA approval],” and the intended scope of the term “drugs.” [85] This Section examines how Federal courts have resolved these issues in analyzing § 271(e)(1) within various contexts.

1. Eli Lilly & Co. v. Medtronic, Inc.:

In 1990, the Supreme Court heard Lilly, its first case relating to the scope of § 271(e)(1). [86] In Lilly, the Court held the use of a patented medical device was reasonably related to the development and submission of information under “a Federal law which regulates the manufacture, use or sale of drugs.” [87] In its opinion, the Court addressed two questions: first, what is the scope of “patented inventions” that § 271(e)(1) immunizes from infringement; and second, do acts reasonably related to the FDA approval process apply only to regulated “drugs,” or does § 271(e)(1) cover regulated medical devices as well?

Lilly, the owner of a patent covering an FDA approved defibrillator, alleged Medtronic's use of an infringing device for FDA approval testing constituted patent infringement. [88] Medtronic defended by asserting its use of the infringing device was immunized from liability under the "safe harbor" provision of § 271(e)(1) because its use was solely to obtain FDA approval." [89] Although the District Court found for Lilly, the Federal Circuit reversed, holding § 271(e)(1) applies to uses related to FDA approval of both drugs and medical devices. [90]

The Supreme Court granted certiorari and expanded upon the Federal Circuit's holding. [91] The Court did not find § 271(e)(1) "plainly comprehensible," and agreed with the Federal Circuit that the phrase "a patented invention," as used in § 271(e)(1), included "all inventions [as defined by 35 U.S.C. § 100(a)], not drug related inventions alone." [92]

Next, the Court addressed what it considered the "core of the present controversy," namely whether the phrase "a Federal law" included only FDCA regulations governing drugs, or if this phrase included any product regulated by the FDCA. [93] The Court relied on the "structure of the [Act] taken as a whole" in determining Congress intended the phrase "a Federal law" to encompass all products (including medical devices) regulated by the FDCA. [94]

The Court supported its holding by pointing out that both patent term distortions resulting from "the requirement that certain products must receive pre-market regulatory approval" affected both medical devices and drugs equally. [95] Additionally, the Court noted that Congress intended § 156 and § 271(e)(1) to "respond to [these] two unintended distortions" together. [96] The Court further reasoned that because patented medical devices were generally eligible to receive the benefits of § 156, Congress likely intended to include medical devices (along with drugs) within the purview of § 271(e)(1). [97] Thus, following Lilly, § 271(e)(1) essentially read, "[i]t shall not be ... infringement to ... use ... a patented invention ... for uses reasonably related to [FDA approval] of drugs [or medical devices]." [98]

2. Federal Court Interpretations of § 271(e)(1) Following Lilly:

After Lilly, Federal courts began the task of applying Lilly's broad interpretation of § 271(e)(1) to various scenarios involving FDCA regulated products. [99]

The United States District Court for the Northern District of California, in *Telectronics Pacing Systems, Inc. v. Ventritex, Inc.*, held that displaying an infringing medical device at a medical conference, in an effort to raise venture capital, was "reasonably related" to the generation of information under the FDCA. [100] Concluding these activities were within the scope of § 271(e)(1), the court reasoned that as long as the infringer could reasonably believe there was a "decent prospect" of generating information relevant to the FDA approval process, then the "acts" of infringement were immunized under § 271(e)(1). [101]

In 1993, and again in 1997, the Federal Circuit found that infringement of patented inventions during the FDA approval process of Class I and Class II medical devices was immunized under § 271(e)(1). [102] As in Lilly, the patented inventions being infringed in both *Chartex International PLC v. M.D. Personal Products Corp.*, and *AbTox Inc. v. Exitron Corp.*, were also FDA regulated medical devices. [103] Unlike in Lilly, though, neither of the regulated medical devices in Chartex and AbTox were eligible for patent term extensions under § 156. [104] However, the court in both cases concluded that because the infringement was reasonably related to developing information for the FDA, § 271(e)(1) immunized the infringing activity. [105]

In Chartex, the patent owner argued § 271(e)(1) should only apply to Class III medical devices because Class III devices are the only medical devices eligible for § 156. [106] The court however adopted a broad interpretation of § 271(e)(1), and explained "section 271(e)(1) does not mention the 'class' distinction for ... devices." [107] Further the court stated the patent owner's argument "would read limitations that may apply to [§ 156] into section 271(e)(1)," something the court was unwilling to do. [108]

The Federal Circuit reaffirmed its stance against reading a statutory symmetry limitation into § 271(e)(1) in

AbTox. [109] Again the owner of an infringed patent argued § 271(e)(1) did not immunize infringement of its patented Class II medical device because its Class II device was not eligible for § 156. [110] Once again, the Federal Circuit rejected this limited interpretation of § 271(e)(1). [111] The court explained the “statutory symmetry” or “perfect product fit” analysis in Lilly was preferred but not required, and that it “must follow [Lilly]’s broader holding” that § 271(e)(1) encompassed all products (drugs and medical devices) regulated by the FDCA. [112]

In 2001, the owner of patents claiming compound intermediates and the process for making those intermediates, in *Bristol-Myers Squibb Co. v. Rhone-Poluenc Rorer Inc.*, argued only “products covered under Section 156 should be considered ‘patented inventions’ within the scope of Section 271(e)(1).” [113] The court however, relying on what it considered “clear Federal Circuit precedent” in both *Chartex* and *AbTox*, expressly rejected the patent owners’ argument. [114] Noting the Federal Circuit’s refusal to read limitations from § 156 into § 271(e)(1), the court reasoned both *Chartex* and *AbTox* reaffirmed Lilly’s broad interpretation of the phrase “patented invention” as meaning “all patented inventions or discoveries.” [115]

3. *Integra Lifesciences I, Ltd. v. Merck KGaA*:

The Federal Circuit, in 2003, would again hear arguments relating to the scope of § 271(e)(1) in *Integra Lifesciences I, Ltd. v. Merck KGaA*. [116] This time, however, the court would reverse the judicial trend of interpreting § 271(e)(1) broadly by analyzing what “acts” are “reasonably related” to required FDA regulations. [117]

At issue in *Merck* were four patents, two of which claimed methods for performing laboratory experiments and two of which claimed small peptides. [118] Although not specifically addressed by the court, none of the four infringed patents were eligible for a § 156 patent term extension. [119] Instead of focusing on a “patented invention” analysis, the Federal Circuit focused on whether the “use” of the patented inventions “facilitate[d] the immediate entry of safe, effective generic drugs into the market place upon expiration of a pioneer drug patent.” [120] Ultimately the court concluded the exploratory nature of “general biomedical research [for identifying] new pharmaceutical compounds” was not reasonably related to the FDA regulatory approval process. [121] Therefore, the court refused to extend § 271(e)(1) “back down the chain of experimentation,” and thus *Merck*’s infringement of the four patents was not immunized. [122]

Within two years the Supreme Court overruled the Federal Circuit’s narrow interpretation of § 271(e)(1). [123] Finding *Merck*’s use of the patented peptides and methods covered by § 271(e)(1), the Court reasoned it was “apparent from the statutory text that section 271(e)(1)’s exemption from infringement extends to all uses of patented inventions that are reasonably related to the development and submission of any information under the FDCA.” [124] In sum, the Court extended § 271(e)(1) to cover infringement of patented inventions used in basic research and discovery of new drugs. [125]

On remand, the Federal Circuit agreed with the Supreme Court and concluded the infringing use of the four patents was within the scope of § 271(e)(1) because their “use” was reasonably related to seeing market approval for an FDA regulated product. [126] However, Circuit Judge Rader strongly dissented at the court’s inclusion of the two method patents, arguing these patents were “research tool” patents whose “use” is not reasonably related to FDA approval of a particular drug. [127] Judge Rader feared the court’s holding allowed § 271(e)(1) to absorb research tool patents, valuable only in the early stages of drug discovery. [128] The majority however, felt the method patents did not meet the National Institutes of Health’s definition of a research tool, and thus concluded Judge Rader’s concerns were not before the court. [129]

II. *PROVERIS V. INNOVASYSTEMS*: THE FEDERAL CIRCUIT LIMITS § 271(E)(1)

One year after *Merck*, a case in which the Federal Circuit held two experimental method patents were within the scope of § 271(e)(1), the Federal Circuit in *Proveris* curiously concluded infringement of a patented device solely used for developing FDA required regulatory information was outside the scope of § 271(e)(1). [130] The court’s analysis in *Proveris* does not reach an examination of the infringing “use” of *Proveris*’ patent; instead the court focuses on defining the phrase “patented invention” as it applies to § 271(e)(1). [131] This Part examines the

controversy between the parties in *Proveris* and examines the reasoning cited by the Federal Circuit as supporting its limiting interpretation of the statutory phrase “patented invention.”

A. Factual Scenario and Patents Involved

Proveris owned U.S. patent number 6,785,400 (“the ‘400 patent”) which claimed a spray data acquisition system used in measuring the performance of inhaler-based drug-delivery systems. [132] Although inhaler-based drug-delivery systems are medical devices requiring FDA approval, *Proveris*’ patented data acquisition system did not qualify as such, thus it could be marketed without prior FDA approval. [133] Even though it was not FDA regulated, *Proveris*’ data acquisition system was important in the development and regulatory testing required for FDA approval of inhaler-based drug-delivery devices. [134] As such, the ‘400 patent stated that *Proveris*’ data acquisition system was “an integral part of the regulatory submissions necessary for [FDA] approval [of inhaler-based drug-delivery devices].” [135]

Innovasystems Incorporated (“*Innova*”) manufactured and sold the Optical Spray Analyzer (“*OSA*”). [136] Similar to *Proveris*’ patented data acquisition system, the *OSA* was used to measure performance characteristics of inhaler-based drug-delivery devices required by the FDA for regulatory approval. [137] Also similar to *Proveris*’ data acquisition system, the *OSA* was not FDA regulated and thus not subject to pre-market regulatory approval. [138] Because of its specialized utility, *Innova* only marketed the *OSA* to the FDA or companies using it in conjunction with FDA regulatory submissions. [139]

In 2005, *Proveris* sued *Innova* alleging the sales and use of the *OSA* device infringed *Proveris*’ ‘400 patent. [140] As part of its defense, *Innova* claimed immunity from infringement under § 271(e)(1). [141] The District Court concluded, as a matter of law, that *Innova*’s *OSA* device infringed *Proveris*’ ‘400 patent and that § 271(e)(1) did not immunize *Innova*’s infringement from liability. [142] *Innova* subsequently appealed the court’s decisions to the Federal Circuit. [143]

B. Arguments Regarding Innova’s § 271(e)(1) Affirmative Defense

On appeal, *Innova* vigorously argued that the meaning of “patented invention,” as used in § 271(e)(1), was unambiguous and had been expressly defined by the Supreme Court in *Lilly*. [144] *Innova* pointed to both *Lilly* and *Merck* as Supreme Court precedents expressly defining the scope of “patented inventions” within § 271(e)(1) as “any invention or discovery” consistent with § 100(a). [145] Further, *Innova* asserted both *Lilly* and *Merck* further demonstrate that the scope of patented inventions, immunized by § 271(e)(1), is only limited by the “use” of the invention. [146]

Innova argued that if Congress had intended the statutory phrase “patented invention” to mean “product,” as *Proveris* was suggesting, then they could have easily used the term “product.” [147] Additionally, *Innova* claimed *Proveris*’ attempt to limit the scope of “patented invention,” to only “products” eligible for § 156(f), was “hindsight legislation” which is inconsistent with typical canons of statutory interpretation. [148]

Last, *Innova* suggested that limiting the phrase “patented invention,” as *Proveris*’ was suggesting, would allow patent owners of FDA approved drugs to block generics from entering the market until years after their patents expired. [149] Such an effect, *Innova* contended, would destroy Congress’s intent in enacting the Act. [150] Next, *Innova* offered a hypothetical situation to illustrate how *Proveris*’ requested definition for “patented invention” would allow patent owners of FDA approved drugs to prevent generics from performing required ANDA experiments. [151] *Innova* explained patent owners could purchase the patent rights to “the only device capable of developing data required for FDA approval” and then enforce those patents in order to prevent generic manufacturers from performing required ANDA experiments. [152] *Innova* asserted this situation would create an “artificial extension” of patent protection, “exactly the type of situation that Congress intended to prevent when it enacted § 271(e)(1).” [153]

Proveris urged the Federal Circuit to limit the definition of “patented inventions,” under § 271(e)(1), to same meaning assigned to “products” in § 156(f). [154] Supporting its argument, *Proveris* asserted that neither *Lilly* nor

Merck endorsed a scope of § 271(e)(1) that would apply to its '400 patent because its patent was not eligible for a patent term extension under § 156. [155] Proveris also alleged that Lilly supports its contention that “patented inventions,” under § 271(e)(1), correspond to “products,” in § 156(f), because Lilly's discussion of statutory symmetry (between § 271(e)(1) and § 156) was intended to modify the phrase “patented invention.” [156]

Additionally, Proveris stated the infringing “use” of the OSA device was not “reasonably related” to developing FDA regulatory data. [157] Proveris argued its patented data acquisition system was not “inherent [in] the development of [§ 156(f)] ‘products,’” and, as such, infringing it could not be “reasonably related to” developing FDA required information. [158] Last, Proveris claimed judicial precedent and the overall statutory scheme of the Act supported only applying § 271(e)(1) to infringers engaged in developing their own FDA regulatory information. [159]

In addition to briefs from Proveris and Innova, the court also received an amicus brief from Patients Not Patents (“Patients”), a nonprofit organization “committed to ensuring access to healthcare through litigation, advocacy and education.” [160] Patients considered the main issue before the court to be properly defining the phrase “patented invention” in § 271(e)(1). [161] To answer this question, Patients urged the court to interpret the statutory phrase according to its plain meaning, which it asserted was unambiguous. [162] Further, Patients explained that if the court found the phrase ambiguous, it should follow judicial precedent, which Patients felt established clear binding precedent that the phrase “patented invention” includes all inventions. [163]

Patients admitted that it may have been “tempting ... for [the] court to construe [§ 271(e)(1)] in terms ... it considers to be good patent policy,” but cautioned the court against “read[ing] into patent laws limitations and conditions which the legislation has not expressed.” [164] Additionally, Patients pointed out that the court was bound by judicial precedent, and that adopting Proveris' interpretation would require “invent[ing] a novel restriction on the phrase.” [165] Last, Patients urged the court not to engage in a policy analysis, but to simply interpret the unambiguous phrase “patented invention” as it is intended in § 271(e)(1), which it felt included “all inventions.” [166]

C. The Federal Circuit Speaks

In Proveris, the Federal Circuit limited the reach of § 271(e)(1) by restricting the definition of the statutory phrase “patented invention” to only those patents achieving a “perfect product fit” with § 156. [167] The court framed the central issue before it as, “whether section 271(e)(1) immunizes [infringement of a patented device during] the development of FDA regulatory submissions [when the patented device] is not itself subject to the FDA premarket approval process.” [168] Ultimately the court concluded that in order for infringement of a device patent to be immunized under § 271(e)(1), the patented device must be eligible for a § 156 patent term extension. [169]

Before determining if Innova's infringement of Proveris' patented device qualified for § 271(e)(1), the Federal Circuit felt defining the statutory phrase “patented invention” was “critical.” [170] In order to do so, the court began by examining the purpose of Title II of the Act. [171] The court found that § 271(e)(1) was Congress's attempt to prevent the “de-facto” patent term extension received by patent holders of Federally regulated products. [172] The court also recognized § 156 as Congress's attempt to cure a portion of the lost patent term suffered by patent owners who were required to undergo FDA regulatory approval prior to commercially marketing their patented inventions. [173]

After considering Congress's purposes for § 156 and § 271(e)(1), the court examined judicial precedent for additional guidance in defining “patented inventions” within § 271(e)(1). [174] Finding Lilly instructive, the court focused on Lilly's discussion of the statutory symmetry between § 271 and § 156 and noted that it believed Lilly applied this relationship to modify the phrase “patented invention.” [175] Additionally, the Federal Circuit found the reasoning in Lilly, that § 271(e)(1) and § 156 operate in tandem creating a “perfect product fit” between the two statutes, controlling regarding the issue of what patented inventions fell within § 271(e)(1). [176]

The court also mentioned AbTox as supporting its finding that Lilly's “perfect product fit” discussion defines “patented inventions” under § 271(e)(1). [177] However, because the infringed invention in AbTox was not eligible

for § 156, and thus did not conform to the court's "perfect product fit" analysis, the Federal Circuit reasoned that AbTox simply broadened the phrase "patented invention" to include all medical devices (Class I-III), not simply those medical device eligible for § 156. [178]

Last, the court briefly mentioned Merck as shedding light on the types of infringing acts considered "reasonably related" to developing or submitting FDA regulatory information. [179] Recognizing Merck, "does not require actual submission of information to the FDA," the Federal Circuit appears to indicate Innova's "use" of the OSA device would fit within Merck's standards of "a reasonably related use," but the question is never reached. [180]

When Innova's use of the OSA device is analyzed under Proveris' interpretation of "perfect product fit" symmetry, the question of "reasonably related use" is never reached because the infringed patent is not eligible for § 156. [181] As explained by the Federal Circuit in Proveris, because the '400 patent, "for purposes of section 271(e)(1)" is not a "patented invention," the "use" of the device is irrelevant. [182] In order for the '400 patent to be a § 271(e)(1) "patented invention," under the "perfect product fit" analysis, it must also be eligible for § 156 or at least be "subject to a required FDCA approval process." [183] Because the '400 patent was neither, the court concluded no "perfect product fit" existed, and thus Innova's infringement of the '400 patent was not immunized by § 271(e)(1)." [184]

III. ANALYZING THE PROVERIS APPROACH

The lack of "perfect product fit" symmetry between Proveris' patented data acquisition system and Innova's infringing OSA device was explained by the Federal Circuit as "Proveris' patented product ... is not eligible for ... 35 U.S.C. § 156 [therefore] ... Innova's OSA device ... does not need ... U.S.C. § 271(e)(1)." [185] However, in this author's opinion the Federal Circuit incorrectly applies Lilly's discussion of statutory symmetry, between § 156 and § 271(e)(1), to the phrase "patented invention" instead of the term "drugs" as Lilly intended. Further, it is this author's opinion that the reasoning relied on in Proveris conflicts with the judicial precedent cited for support, as well as the statutory scheme of the Act as a whole. [186] This Part examines the application of § 271(e)(1) under Proveris' "perfect product fit" test and reviews the court's reasoning in light of other judicial precedent and the overall purpose behind the Act.

A. Applying § 271(e)(1) Under Proveris

Section 271(e)(1) represents the only statutory defense to patent infringement. [187] In Lilly, the first Supreme Court case relating to the statutory defense, the Court found § 271(e)(1) required a two part analysis. [188] The questions to be analyzed were characterized as, is the infringed invention a "patented invention" within the meaning of § 271(e)(1), and if so was its otherwise infringing use "reasonably related" to the development and submission of information for FDA approval? [189] In Lilly, the Court seemingly eliminates the need to further analyze the first question when it expressly states "[t]he phrase 'patented invention' [in § 271(e)(1)] ... includes all inventions." [190] Thus, following Lilly, a § 271(e)(1) review was reduced to a determination of whether the infringing use was "reasonably related" to FDA approval. [191] However, in Proveris the Federal Circuit breathes life back into the "patented invention" question when it asserts the "perfect product fit" test for determining the scope of patents which can be infringed under § 271(e)(1). [192]

Under Proveris' "perfect product fit" analysis, in order to determine if an infringed patent qualifies as claiming a "patented invention" within § 271(e)(1), a court must make two initial determinations. [193] First, the patent must be eligible for a § 156 patent term extension. [194] If it is, then the infringing product must require regulatory approval (for the infringing use) prior to being marketable. [195] In order to achieve Proveris' "perfect product fit" symmetry, the answer to both these questions must be yes. [196]

The court states Proveris' patented data acquisition system is not eligible for § 156, although it does not explain how the patent fails to meet the eligibility requirements for § 156. [197] In order to qualify for a § 156 patent term extension, a patent, regardless of whether it claims a tangible entity or a method, must have been subject to regulatory approval before it could be commercially marketed. [198] Further, the FDA approval of the "invention" claimed in the patent must be the first commercial use of that invention. [199] In addition to these two substantive

requirements, there are several procedural requirements a patent must meet before it is eligible for § 156. [200] Thus, under *Proveris*, regardless of the infringing “use” of a patented product, if the court determines the patent fails to meet the requirements for § 156, the claimed invention is not a “patented invention” for § 271(e)(1) purposes. [201]

If the court's analysis reveals the patent is eligible for § 156, then the court will review the infringing product to determine if it requires FDA approval before it can be sold. [202] Only if the reviewing court determines both, that the patent is eligible for § 156 and that the infringing product requires FDA pre-market approval, will the court undertake the second part of the § 271(e)(1) analysis. [203] According to *Proveris*, only if a “perfect product fit” is achieved does the court attempt to ascertain if the infringing use was “reasonably related” to the development and submission of information for FDA approval. [204]

B. The Proveris Approach: In Conflict with Judicial Precedent

This author believes *Proveris* incorrectly applies *Lilly* in two key ways. First, as this Section points out, the *Proveris* court failed to recognize that, in *Lilly*, the Court gave the phrase “patented invention” a definitive and unambiguous meaning. [205] Further, this Section highlights how the court in *Proveris* applied *Lilly*'s statutory symmetry analysis to the phrase “patented invention,” not the term “drugs” as *Lilly* intended. [206] This Section also contends *Proveris* contradicts numerous cases which have: (a) previously found infringement exempted from liability under § 271(e)(1), that under *Proveris* would be denied immunization; and (b) rebuked direct arguments that the “perfect product fit” test controls the scope of what is a “patented invention” under § 271(e)(1). [207]

In *Lilly*, the issue before the Supreme Court was “whether [§ 271(e)(1)] exempts from infringement the use of patented inventions to develop and submit information for marketing approval of medical devices [or only drugs] under the FDCA.” [208] The Court began its analysis by expressly stating that the phrase “‘patented invention’ in § 271(e)(1) is defined to include all inventions, not drug-related inventions alone.” [209] The Court held that “Federal law ... naturally summons up the image of an entire statutory scheme of regulation,” which in the Court's opinion meant that the term “drugs” included FDA regulated medical devices. [210] Thus, following *Lilly*, § 271(e)(1) immunized infringement of any patented invention when the infringing use was reasonably related to developing and submitting Federally regulated information regarding a FDA approved drug or device. [211]

Supporting its expansion of the term “drugs,” to include “devices,” the Court explained there are “textual indications” that § 156 and § 271(e)(1) “are meant generally to be complementary.” [212] The Court believed these textual indications demonstrated Congress's intent that the phrase “under Federal law which regulates ... drugs” was meant to include at least all products eligible for § 156. [213] The Court noted (Class III) medical devices are, in general, eligible for § 156. Further, the Court recognized § 271(e)(1) was intended to correct the de-facto patent term extension created because of the requirement that both generic drugs and medical devices undergo FDA pre-market approval. [214] Although the Court, in *Lilly*, seemingly made clear that the phrase “patented invention” in § 271(e)(1) is to be construed inline with 35 U.S.C. § 100(a) (and thus includes all patented inventions) and that the court's discussion of statutory symmetry broadened the word “drugs,” *Proveris* stretched *Lilly* to stand for a limitation of the phrase “patented invention.” [215]

In addition to misapplying *Lilly*'s discussion of statutory symmetry (by applying the statutory symmetry analysis to the phrase “patented invention” instead of the term “drugs”), the Federal Circuit in *Proveris* also failed to distinguish its rationale for the “perfect product fit” analysis in light of numerous cases finding “patented inventions” within the scope of § 271(e)(1), even though they were not eligible for § 156. [216] For example, *Proveris* cites *Merck* as helping to define the “uses” of patented inventions considered “reasonably related” to FDA approval. [217] However, if the facts of *Merck* are analyzed under the Federal Circuit's analysis in *Proveris*, because none of the four patents (in *Merck*) meet the eligibility requirements for § 156, the “perfect product fit” test would not be satisfied. [218] Therefore, under *Proveris*, the four patents at issue in *Merck* would not be considered “patented inventions” under § 271(e)(1), and the Court would not have reached the second question relating to the “use” of the infringing invention. [219] Analyzed in light of *Lilly* however, *Merck* plainly illustrates that *Lilly* intended the phrase “patented inventions” was to include “all inventions” as defined in § 100(a). [220]

If the facts of Proveris are analyzed under the Federal Circuit's approach in Merck, Proveris' patented data acquisition system is first considered a "patented invention" as defined by § 100(a). [221] Thus, the Federal Circuit reaches the second question of a § 271(e)(1) analysis, and must analyze if Innova's "use" of the infringing OSA device was "reasonably related" to obtaining market approval of an FDA regulated drug or medical device. [222] If the court determines Innova's use meets the "reasonably related" requirement, Innova's actions would be immunized from infringement under §271(e)(1). [223] The Federal Circuit in Proveris fails to address its inconsistent treatment of the "patented inventions" at issue in Merck and Innova's OSA device. [224]

In addition to Merck and Lilly, the Proveris court cites AbTox as supporting its "perfect product fit" analysis, although the court never fully explains how the "patented invention" in AbTox fits within its holding. [225] The "patented invention" at issue in was a Class II medical device and thus not eligible for § 156. [226] As such, if the facts of AbTox are analyzed under Proveris, it is clear the patented medical device at issue in AbTox does not achieve the required "perfect product fit" symmetry. [227] Nevertheless, in AbTox the Federal Circuit (applying Lilly) concluded the medical device was a "patented invention" within § 271(e)(1). [228] The Proveris court, however, cites AbTox as standing for the addition of all regulated medical devices to Lilly's holding that "patented inventions" under § 271(e)(1) is limited to "all inventions within section 156." [229] But, as noted above, Lilly expressly found the phrase "patented invention" in § 271(e)(1) includes "all inventions" within § 100(a) and that the term "drugs" (though a statutory symmetry analysis) includes medical devices within § 156. Thus, by limiting the phrase to only products within § 156, Proveris adopts an argument unsupported by, and contrary to the holding in, Lilly. [230]

In addition to contradicting numerous cases finding "patented inventions" within the scope of § 271(e)(1) although not eligible for § 156, Proveris' "perfect product fit" analysis further opposes other cases which specifically rejected arguments that Lilly intended its statutory symmetry analysis to apply to the phrase "patented invention." [231] For example, just three years after Lilly, in *Chartex International, PLC v. M.D. Personal Products Corp.*, the Federal Circuit rejected a patent owners argument that because the patented product was not eligible for § 156, it should not be immunized from infringement under § 271(e)(1). [232] In rejecting the patent owner's argument, the court stated that,

"[the patent owner] would read limitations that may apply to [§ 156] into section 271(e)(1). [Section 156], however deal[s] with term extensions for patents relating to products subject to lengthy regulatory delays. Although section 156 and section 271(e)(1) ... pass[ed] Congress as [parts] of the [Act], this court declines to read possible limitations from one section into another." [233]

Several years later the patent owner in *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer Inc.* argued "only products ... covered under Section 156 should be considered 'patented inventions' within the scope of Section 271(e)(1)." [234] The U.S. District Court for the Southern District of New York, however, rejected this argument, based on what it called "clear Federal Circuit precedent that the term 'patented invention' means all patented inventions or discoveries, and not merely those that are covered by Section 156." [235]

IV. MOVING FORWARD WITH THE *PROVERIS* INCONSISTENCY

As discussed in this Note, by narrowing the broad Lilly and Merck interpretations of the phrase "patented invention," Proveris creates a technicality which pioneer drug and device manufacturers can use to preclude generic manufacturers from starting the ANDA process during certain patents. Because of this loophole, Proveris' "perfect product fit" analysis conflicts with the primary purpose for the Act; aiding generics in obtaining market approval and providing investments for continued investments in medical sciences. [236] Further, Proveris highlights a growing tension between patent law policy and the expanded applicability § 271(e)(1) has previously received from Federal Courts over the last two decades. [237] This tension underscores the difficulty in accurately articulating a rule which specifically defines what patents may be infringed, and the specific uses of infringing products § 271(e)(1) immunized from infringement liability. [238] This Part illustrates how Proveris' "perfect product fit" analysis is contrary to the overall intent behind the Act, by creating a mechanism which risks delaying market entry of generic drug and device manufacturers. Further, this Part suggests a "sliding scale" analysis Federal courts should employ when addressing § 271(e)(1) defenses.

A. Potential Issues Arising as a Result of Proveris

As this Note has documented, Congress intended the Act to provide a means for increasing market competition of FDA regulated products, while at the same time providing incentives for continued research and development in medical sciences. [239] Title I of the Act provided generic manufacturers with a mechanism, the ANDA process, for gaining market approval in a cost effective and efficient manner, such that when a new drug or device patent expires the generic can immediately enter the market. [240] In order for Title I of the Act to be effectively utilized though, specific patent laws relating to infringement need to be modified. Therefore, Title II of the Act created § 271(e)(1), thus giving generic manufacturers a vehicle for performing ANDA required testing without fear of infringement liability. [241] By limiting the meaning of “patented inventions” under §271(e)(1) to a “perfect product fit” test, Proveris has disrupted Title II's relationship with the Act's overall framework, which is essential to carrying out the purpose of the Act. [242] By disrupting § 271(e)(1)'s relationship with the Act's overall statutory scheme, Proveris placed a sword in the hands of patent owners which can be used to repel market competition and delay the commercialization of generics.

Innova, in a brief to the Federal Circuit, proffers a hypothetical which, if slightly modified, demonstrates how Proveris allows patent owners of FDA regulated products to disrupt the overall intention of the Act. [243] For example, if a pioneering company (PC) develops a new medical product, PC would likely patent protect the new medical product prior to expending a large amount of time and money gaining FDA approval. [244] Once FDA approval was obtained, and assuming PC meets the other statutory requirements, PC may seek a patent term extension under § 156. [245]

Under Title I of the Act, a generic manufacturer (GM) can submit an ANDA application for marketing a generic version of PC's new medical product five years after PC receives FDA approval for its new medical product. [246] In preparation for its ANDA submission, GM will be required to demonstrate that performance characteristics of its generic product are equivalent to the performance characteristics of PC's new medical product, a process which takes approximately two years to complete. [247] Under the interpretation of the phrase “patented invention” in Proveris, or any case this author has found on point, PC's new, patented medical product would fall within the scope of § 271(e)(1). Thus GM would be immune from patent infringement if GM used PC's new, patented medical product in GM's preparation of its ANDA submission to the FDA. Thus, GM can begin its ANDA testing (immediately after PC receives FDA approval on the new medical product) in order to ensure GM's ANDA approval will become effective upon the first day the patent covering PC's new medical product expires. [248]

Now assume, for example, that during its FDA approval process PC creates or discovers (and subsequently patents) a novel control essential for quantifying performance characteristics of PC's new medical product. [249] In order for GM to demonstrate its generic product possesses performance characteristics equivalent to PC's new medical product, GM must perform tests using the novel control. [250] But, under Proveris' “perfect product fit” rule, GM would not be immunized from infringement liability for use of PC's patented control, regardless of the control's imperative bearing on completing the ANDA process. As illustrated, when the patents GM may infringe are limited by Proveris' “perfect product fit” analysis, generic manufacturers may find themselves unable to utilize the ANDA process as it was intended. [251]

However, if GM's infringing use of PC's patented control is analyzed under the logic of Lilly or Merck, market competition is increased immediately upon the expiration of PC's patent covering the FDA approved product (regardless of when the control's patent expires). Under either Lilly or Merck, GM is immunized from infringing any patent for uses reasonably related to developing and submitting data for FDA approval. [252] Thus GM could complete the ANDA process without fear of infringement, and receive market approval made effective upon the expiration of the patent covering PC's FDA approved new medical product. As exemplified by the aforementioned hypothetical, Lilly's and Merck's analyses of § 271(e)(1) account for the possibility that generic manufacturers may be forced to infringe multiple patents (some of which may not be eligible for § 156) which are essential in completing the ANDA process. Further, Lilly's and Merck's analyses demonstrate an understanding (which Proveris' “perfect product fit” analysis lacks) of the relationship between Title I and Title II of the Act, essential to ensure the ANDA process operates as intended. [253]

B. Suggesting a Judicial Sliding Scale Analysis

Although many commentators suggest § 271(e)(1) lends itself to straightforward interpretation, two decades of judicial decisions straining to force square pegs of facts into round holes of reasoning have left the scope and application of § 271(e)(1) anything but obvious. [254] In *Proveris*, the Federal Circuit applies Lilly's discussion of statutory symmetry between § 271(e)(1) and § 156 for supporting a modification of the phrase "patented invention," not "drugs" as Lilly intended. [255] Although *Proveris* exemplifies the forced reasoning that has become commonplace for courts dealing with § 271(e)(1), [256] it also creates binding precedent which patent owners may use as ammunition for precluding generic manufacturers from utilizing the Act for its intended purpose.

While *Innova* has yet to request reconsideration or certiorari, this author believes it is imperative that *Proveris*'s precedential value be eliminated in subsequent adjudications. Instead of applying *Proveris*' "perfect product fit" when analyzing a § 271(e)(1) defense, this author suggests Federal courts should look to Judge Rader's dissent in *Merck* for guidance. [257]

In his dissent, Judge Rader points out that the majority did not properly examine the "use" of the two method patents in relation to their bearing on the FDA submission process. [258] Examining the use of a patented invention, as it relates to FDA submissions, inherently requires an inquiry into the type of invention patented. As illustrated by Judge Rader, if a patented chemical compound genus is infringed during experiments designed to isolate a species of compounds (from the patented genus) suitable for FDA approval, such "use" is likely reasonably related to FDA regulations. [259] Alternatively, infringing a patented microscope during basic research is likely outside the scope of § 271(e)(1). [260]

In this author's opinion, Judge Rader's dissent lays the framework for Federal court's to engage in a "sliding scale" analysis when faced with a § 271(e)(1) defense to patent infringement. A "sliding scale" review would involve analyzing the purpose of using an infringed invention, and the significance using that "patented invention" bears to the FDA review process. [261] In a sliding scale analysis, courts would be able to consider several factors including the totality of different uses the patented invention has, whether or not other "patented inventions" accomplish the same "use," and whether the use of the patented invention is essential for meeting FDA approval requirements. Although a reviewing court, as part of its sliding scale analysis, could consider the applicability of § 156 to the infringed patented invention, it would not be a dispositive requirement as in *Proveris*' "perfect product fit" analysis. [262]

Thus, under the "sliding scale" analysis recommended in this Note, if a patented invention's only "use" is a general research method, far removed from testing inherent to FDA approval, then § 271(e)(1) would likely not apply. However, if the patented invention claimed an experimental process for assessing the bioavailability of an FDA approved drug, [263] and use of the invention was imperative to obtaining FDA approval, then infringement of the invention for bioavailability testing would likely be within § 271(e)(1). Likewise, if a patented bio-receptor was an essential control required in FDA bioequivalence experiments, then "use" of the patented receptor during bioequivalence testing would be immunized under § 271(e)(1). [264] However, if any of the three hypothetical patents discussed in the Section are analyzed under *Proveris*, none meet the "perfect product fit" analysis and thus, regardless of their bearing on the ANDA approval process, all would be outside the scope of § 271(e)(1). [265]

As explained by this Note, a similarity exists between the infringed method patents in *Merck* and *Proveris*'s infringed data acquisition system causing none of these inventions to lend itself to an easy interpretation under § 271(e)(1). Because of this difficulty, this author advocates re-examining the "use" of *Innova*'s infringing OSA device to decide if its "use" should be immunized under § 271(e)(1). If the court determines *Innova*'s use of the infringing OSA device was essential for assessing a specific and mandatory performance characteristic of an FDA regulated product, then the *Innova*'s infringement should be immunized under § 271(e)(1). In its review, the court should assess if the analysis performed by the OSA device was mandatory in FDA approval submissions, and if there were other options available for performing this required analysis. If the court determines the OSA device's results are not mandatory for FDA approval or that ample options exist for performing the analysis, the court's analysis should slide towards finding *Innova* liable for patent infringement.

Although it may be argued that a judicial "sliding scale" analysis could be more difficult to administer than a

“bright line” rule or possibly create uncertainty for generic manufacturers, this author believes the contrary would be true and that the benefits of a “sliding scale” analysis would outweigh any of the concerns noted above. Evaluating the “use” of any patented invention, in relation to its bearing on the FDA approval process, would prevent abuse of § 271(e)(1) and eliminate potential problems presented by Proveris’ “perfect product fit” rule.

Under a judicial sliding scale analysis, a patented control (as exemplified in Section A of this Part) would not be able to block generic market entry through the ANDA process. Additionally, research tools such as experimental methods or general research devices could not be infringed without liability by hiding behind the unpredictable scope which currently defines § 271(e)(1). [266] Further, assessing an infringed invention’s “use,” in relation to its bearing on the FDA approval process, would allow § 271(e)(1) to operate as it was intended, to aide generic manufacturers in completing the ANDA process without fearing patent infringement liability. [267] In sum, a sliding scale analysis would not disturb the incentives (created in the Act) for pioneering companies because § 271(e)(1) would only apply to those patented inventions hindering generic manufacturers’ use of the ANDA process.

CONCLUSION

As this Note illustrates, Proveris has redefined the phrase “patented invention,” as it applies to § 271(e)(1), in a manner that is inconsistent with United States Supreme Court precedent and, as such, Proveris significantly altered the § 271(e)(1) analysis. [268] While Proveris appears to be rooted in sound principles of patent law and fairness, an examination of the reasoning and precedent relied on by the Federal Circuit reveals the court misinterpreted Lilly’s statutory symmetry analysis and the function § 271(e)(1) plays in the overall framework of the Act. [269] However, Proveris highlights the difficulty in clearly articulating a rule encompassing Congress’s intentions for the application of § 271(e)(1). As this Note recommends, Proveris’ “perfect product fit” analysis should be reconsidered and rejected because of its potential for disrupting the spirit and intent behind the Act. Further, courts should engage in a sliding scale analysis, examining any infringed patented invention’s “use” as it relates to the FDA approval process.

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[1]. Peter Hutt, Richard Merrill, & Lewis Grossman, *Food And Drug Law, Cases and Materials* at 1, 5 (3d ed., Foundation Press 2007).

[2]. *Id.* at 35-37.

[3]. *Generic Drug Entry Prior to Patent Expiration: An FTC Study*, Federal Trade Commission at i, July 2002, available at www.ftc.gov/os/2002/07/genericdrugstudy.pdf (last visited Feb. 25, 2008) (stating that generics now comprise forty seven percent of filled prescriptions, up from nineteen percent prior to the Act).

[4]. *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562 (Fed. Cir. 1997) (citing Statement on Signing S. 1538 into Law, 20 Weekly Comp. Pres. Doc. 1359, 1360 (Sept. 24, 1984)); *See also* David Bickart, *The Hatch-Waxman Act*, 944 PLI/PAT 205, 213-14 (2008).

[5]. H.R Rep. No. 98-857, pt. 2, at 11 (1984) as reprinted in U.S.C.C.A.N. 2686, 2695; *See also* Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. 98-417, 98 State 1585 (1984).

[6]. H.R Rep. No. 98-857 at 5, 11-12.

[7]. *Glaxo, Inc.*, 110 F.3d at 1568 (discussing the legislative purpose for enacting the Act).

[8]. H.R Rep. No. 98-857 at 11-12.

[9]. *Id.* at 26-27.

[10]. *Id.* at 29.

[11]. 35 U.S.C. § 271(e)(1)(2004).

[12]. Daniel Wobbekind, Note, *Integra Lifesciences I, Ltd. v. Merck KGaA: Re-Examining the Broad Scope of the § 271(e)(1) Safe Harbor*, 23 Berkley Tech. L.J. 107, 108-13 (2008)(discussing Congress's intent for §271(e)(1) to provide “a fairly straightforward answer to Roche” but the “imprecise drafting of the [statute] spawned a number of ... cases”).

[13]. See *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661 (1990); See also *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193 (2005).

[14]. *Eli Lilly & Co.*, 496 U.S. at 665; *Merck KGaA*, 545 U.S. at 193; See also Anna McMinn, Comment, *Judicial Interpretation of 35 USC 271(e)(1): An improper Expansion beyond the Legislative Intent*, 16 Alb. L.J. Sci. & Tech. 195, 198 (2006).

[15]. *Proveris Scientific Corp. v. Innovasystems, Inc.*, 536 F.3d 1256, 1265-66 (Fed. Cir. 2008).

[16]. *Id.* at 1265-66.

[17]. *Id.*

[18]. *Eli Lilly & Co.*, 496 U.S. at 665 (defining “patented invention” as used in § 271(e)(1) to mean “all inventions”).

[19]. *Id.* at 674.

[20]. *Proveris Scientific Corp.*, 536 F.3d at 1265-66; See also Thomas F. Poche, Note, *The Clinical Trial Exemption From Patent Infringement: Judicial Interpretation of Section 271(e)(1)*, 74 B.U.L. Rev. 903, 913-14 (1994)(discussing how § 271(e)(1) aides generic manufacturers in utilizing the ANDA process).

[21]. *Proveris Scientific Corp.*, 536 F.3d at 1265-66; See also Michelle Meadows, *Greater Access to Generic Drugs: New FDA Initiatives to Improve FDA Initiatives and Reduce Legal Loopholes*, FDA Consumer Magazine, available at http://www.fda.gov/fdac/features/2003/503_drug.html (last visited Feb. 28, 2009)(stating that the average price of a generic prescription is \$30.26 whereas a pioneer drug is \$84.20.).

[22]. See Hutt, *supra* note 1 at 8.

[23]. *Roche Prods., Inc. v. Bolar Pharms. Co.*, 733 F.2d 858, 865 (Fed. Cir. 1984); Wobbekind, *supra* note 12 at 111.

[24]. Poche, *supra* note 20.

[25]. *Id.*

[26]. See, e.g., Hutt, *supra* note 1 at 760-63 (citing Peter Barton Hutt, *Landmark Pharmaceutical Law Enacted*, 1 Health Scan, No. 3, p.11 (1984); Statement on Signing S. 1538 into Law, 20 Weekly Comp. Pres. Doc. 1359, 1360 (Sept. 24, 1984).

[27]. See Wobbekind, *supra* note 12 at 111.

[28]. *Id.*

[29]. See, e.g., Poche, *supra* note 20 at 914.

[30]. H.R Rep. No. 98-857 at 12, 14.

[31]. See Hutt, *supra* note 1 at 8.

[32]. *Id.*

[33]. *Id.* at 10.

[34]. *Id.* at 12-14.

[35]. *Id.* at 968-69 (explaining the FDCA gave the FDA jurisdiction for seizure of medical devices but did not grant the FDA premarket approval authority over devices until the 1976 Amendments).

[36]. *Id.* at 580.

[37]. *Id.* at 774-75.

[38]. Abbreviated New Drug Application Regulations, 57 Fed. Reg. 17,950, 17,950-51 (April 28, 1992)(codified at 21 C.F.R. pt. 60).

[39]. Hutt, *supra* note 1 at 583.

[40]. See, e.g., *Id.*; Abbreviated New Drug Application Regulations, 57 Fed. Reg. at 17,950-51.

[41]. H.R Rep. No. 98-857 at 1, 4.

[42]. Abbreviated New Drug Application Regulations, 57 Fed. Reg. at 17,950-51.

[43]. *Id.* at 17,951.

[44]. See Roche Prods., Inc., 733 F.2d at 865; *See also* Wobbekind, *supra* note 12 at 111.

[45]. *Id.*

[46]. Roche Prods., Inc., 733 F.2d at 861.

[47]. *Id.* at 863.

[48]. *Id.*

[49]. *Id.* at 864.

[50]. *Id.* at 863.

[51]. *Id.* at 864.

[52]. Roche Prods., Inc., 733 F.2d at 865.

[53]. *Id.* (citing Sony Corp. of America v. Universal City Studios, Inc., 464 U.S. 417 (1984)).

[54]. *Id.*

[55]. Poche, *supra* note 20 at 911.

[56]. H.R Rep. No. 98-857 at 7.

[57]. Abbreviated New Drug Application Regulations, 57 Fed. Reg. at 17,950-51.

[58]. H.R Rep. No. 98-857 at 5.

[59]. Guidance for Industry: Bioavailability and Bioequivalence Studies for Orally Administered Drug Products - General Considerations, U.S. Food and Drug Administration Center for Drug Evaluation and Research, available at <http://www.fda.gov/cder/guidance/4964dft.htm> (last modified July 15, 2002) (defining bioequivalence as “the absence of a significant difference in the rate and extent to which the active ingredient ... in [a generic drug] becomes available at the site of drug action when administered ... in an appropriately designed study.”).

[60]. H.R Rep. No. 98-857 at 5.

[61]. *Id.* at 29.

[62]. *Id.* at 5.

[63]. *Id.* at 8.

[64]. *Id.* at 6.

[65]. *Id.*

[66]. H.R Rep. No. 98-857 at 21.

[67]. 35 U.S.C. § 156(a)-(f)(2004)

[68]. *Id.*

[69]. Abbreviated New Drug Application Regulations, 57 Fed. Reg. at 17,950-51.

[70]. *See generally* 21 U.S.C. § 355(j)(5)(F)(ii)(2004).

[71]. *Id.* (explaining “market exclusivity” is a period of time which the FDA will not accept generic drug ANDA applications for review).

[72]. *Id.*

[73]. *Id.*

[74]. 35 U.S.C. § 271(e)(1).

[75]. H.R Rep. No. 98-857 at 27.

[76]. See, Roche Prods., Inc., 733 F.2d at 865; *See also* 35 U.S.C. § 271(e)(1).

[77]. H.R Rep. No. 98-857 at 29.

[78]. *Id.* at 30.

[79]. *Id.* at 29-30.

[80]. *Id.* (commenting that the addition of subsection (e) would facilitate the presence of generic drugs on the market two years sooner (following the expiration of the pioneer drug patent) and listing other economic benefits).

[81]. See Reagan Statement, *supra* note 4.

[82]. *Id.*

[83]. *See generally*, Wobbekind, *supra* note 12 at 107; *See also* Jonathan McPherson, The Impact of the Hatch-Waxman Act's Safe Harbor Provision on Biomedical Research Tools after Merck KGaA v. Integra Lifesciences I, Ltd., 10 Mich. St. J. Med. & Law 369, 370 (2006).

[84]. See *Id.*

[85]. See *Id.*

[86]. Eli Lilly & Co., 496 U.S. 661.

[87]. *Id.* at 678.

[88]. *Id.* at 665-67.

[89]. *Id.* at 664 (emphasis added).

[90]. *See generally* Eli Lilly & Co. v. Medtronic, Inc., 872 F.2d 402 (Fed. Cir. 1989).

[91]. See Eli Lilly & Co., 496 U.S. 661.

[92]. *Id.* at 665.

[93]. *Id.*

[94]. *Id.* at 668.

[95]. *Id.* at 669.

[96]. *Id.*

[97]. Eli Lilly & Co., 496 U.S. at 672-74.

[98]. *Id.* at 673 (emphasis added).

[99]. See McMinn, *supra* note 14 at 195.

[100]. Telectronics Pacing Sys., Inc. v. Ventritex, Inc., 755 F.Supp. 1269 (N.D. Cal. 1991) (aff'd at 26 U.S.P.Q. 2d (BNA) 1524 (Fed. Cir. 1993)).

[101]. *Id.* at 1280.

[102]. Chartex Int'l PLC v. M.D. Personal Products Corp., 5 F.3d 1505, 1993 WL 306169 (Fed. Cir. 1993); AbTox, Inc. v. Exitron Corp., 122 F.3d 1019, 1027 (Fed. Cir. 1997).

[103]. Chartex Int'l PLC, 5 F.3d at 5; AbTox, Inc., 122 F.3d at 1027.

[104]. *Id.*

[105]. *Id.*

[106]. Chartex Int'l PLC, 5 F.3d at 5.

[107]. *Id.*

[108]. *Id.*

[109]. AbTox, Inc., 122 F.3d at 1029.

[110]. *Id.* at 1027-28.

[111]. *Id.* at 1030.

[112]. *Id.*

[113]. Bristol-Myers Squibb Co. v. Rhone-Poluenc Rorer, Inc., 2001 U.S. Dist. Lexis 19361 at 5 (S.D.N.Y. 2001); *See also* Bristol-Myers Squibb Co. v. Rhone-Poluenc Rorer, Inc., 326 F.3d 1226 (Fed. Cir. 2002) (holding the patents at issue to be invalid and thus the Federal Circuit never addresses the § 271(e)(1) question at issue).

[114]. Bristol-Myers Squibb Co., 2001 U.S. Dist. Lexis 19361 at 5-9.

[115]. *Id.*

[116]. Integra Lifesciences I, Ltd. v. Merck KGaA, 331 F.3d 860 (Fed. Cir. 2003).

[117]. Wobbekind, *supra* note 12 at 108.

[118]. Integra Lifesciences I, Ltd., 331 F.3d at 863.

[119]. *See generally* U.S. Patent No. 4,792,525 (filed June 17, 1985); U.S. Patent No. 5,695,997 (filed June 2, 1995); U.S. Patent No. 4,879,237 (filed May 24, 1985); U.S. Patent No. 4,789,734 (filed Aug. 6, 1985).

[120]. Integra Lifesciences I, Ltd., 331 F.3d at 866 (finding the facilitation of generic drugs to market as the "express objective" of § 271(e)(1)).

[121]. *Id.* at 865-66.

[122]. *Id.*

[123]. Merck KGaA, 545 U.S. at 193.

[124]. *Id.* at 202 (emphasis added by the Court).

[125]. *Id.*; *See also* McMinn, *supra* note 14 at 234-35.

[126]. Integra Lifesciences I, Ltd. v. Merck KGaA, 496 F.3d at 1348, 1350-51.

[127]. *Id.* at 1349.

[128]. *Id.* at 1349.

[129]. *Id.* at 1348 (citing the definition of research tools as, “tools that scientist use in the laboratory including ... reagents, animal models ... cloning tools (such as PCR), methods, laboratory equipment and machines”).

[130]. Proveris Scientific Corp., 536 F.3d at 1259-60 (emphasis added).

[131]. *Id.* at 1265-66.

[132]. U.S. Patent No. 6,785,400 (filed Aug. 16, 2000).

[133]. *Id.*

[134]. Proveris Scientific Corp., 536 F.3d at 1259-60; *See also* '400 patent, *supra* note 132.

[135]. '400 patent, *supra* note 132 at col. 1.41-45.

[136]. Proveris Scientific Corp., 536 F.3d at 1259.

[137]. *Id.* at 1259-60.

[138]. *Id.*

[139]. *Id.* at 1264.

[140]. *Id.* at 1259.

[141]. *Id.*

[142]. Proveris Scientific Corp., 536 F.3d at 1260.

[143]. *Id.*

[144]. Reply Brief of Appellant Innovasystems, Inc. at 2-3, Proveris Scientific Corp. v. Innovasystems, Inc., 536 F.3d 1256 (Fed. Cir. 2008) (No. 2007-1428).

[145]. *Id.* at 5; *See also* Corrected Brief of Appellant Innovasystems, Inc. at 12, Proveris Scientific Corp. v.

Innovasystems, Inc., 536 F.3d 1256 (Fed. Cir. 2008) (No. 2007-1428).

[146]. Corrected Brief of Innova, *supra* note 145 at 14-15.

[147]. Reply Brief of Innova, *supra* note 144 at 3.

[148]. *Id.*

[149]. Corrected Brief of Innova, *supra* note 145 at 16.

[150]. *Id.*

[151]. *Id.*

[152]. *Id.*

[153]. *Id.* at 16-17.

[154]. Second Corrected Brief for Plaintiff Proveris Scientific Corp. at 19, Proveris Scientific Corp. v. Innovasystems, Inc., 536 F.3d 1256 (Fed. Cir. 2008) (No. 2007-1428).

[155]. *Id.* at 18.

[156]. *Id.* at 24.

[157]. *Id.* at 22.

[158]. *Id.* at 22, 30.

[159]. *Id.* at 30.

[160]. Brief of Patients Not Patents, Inc. as Amicus Curiae in Support of Neither Party at 1, Proveris Scientific Corp. v. Innovasystems, Inc., 536 F.3d 1256 (Fed. Cir. 2008) (No. 07-1428).

[161]. *Id.*

[162]. *Id.* at 2.

[163]. *Id.* at 3-5 (citing AbTox as precedent illustrating the court is bound by Lilly's broad interpretation of the statutory phrase).

[164]. *Id.* at 7 (citing Brogan v. U.S., 522 U.S. 398, 408 (1998) and Diamond v. Chakrabarty, 447 U.S. 303, 308 (1980) standing for the policy that the court will not read limitations into the patent law which Congress has not created).

[165]. *Id.* at 6.

[166]. *Id.* at 4.

[167]. Proveris Scientific Corp., 536 F.3d at 1265-66.

[168]. *Id.* at 1265.

[169]. *Id.* at 1265-66.

[170]. *Id.* at 1261.

[171]. *Id.* at 1260-61.

[172]. *Id.* at 1261.

[173]. Proveris Scientific Corp., 536 F.3d at 1260.

[174]. *Id.* at 1261-62.

[175]. *Id.* at 1265.

[176]. *Id.* at 1265-66.

[177]. *Id.* at 1263.

[178]. *Id.* (noting the medical device in AbTox was a Class II medical device and thus not eligible for a § 156 patent term extension because only Class III medical devices are eligible for § 156).

[179]. Proveris Scientific Corp., 536 F.3d at 1263-64.

[180]. *Id.* at 1266.

[181]. *Id.*

[182]. *Id.* at 1265-66.

[183]. *Id.*

[184]. *Id.* at 1266.

[185]. Proveris Scientific Corp., 536 F.3d at 1266.

[186]. *Id.* at 1265 (citing Lilly's approach as instructive).

[187]. 35 U.S.C. § 271(e)(1).

[188]. Eli Lilly & Co., 496 U.S. at 665.

[189]. AbTox, Inc., 122 F.3d at 1027-30.

[190]. Eli Lilly & Co., 496 U.S. at 665.

[191]. *Id.*

[192]. Proveris Scientific Corp., 536 F.3d at 1265-66.

[193]. *Id.* at 1266.

[194]. *Id.*

[195]. *Id.*

[196]. *Id.* at 1265-1266.

[197]. *Id.* at 1265; *See also* 37 C.F.R. § 1.720 (2000).

[198]. 37 C.F.R. § 1.720 (defining the criteria for eligibility to receive the patent term extension under § 156).

[199]. *Id.*

[200]. *Id.*

[201]. Proveris Scientific Corp., 536 F.3d at 1265-66.

[202]. *Id.*

[203]. *Id.* at 1266.

[204]. *Id.*

[205]. *Eli Lilly & Co.*, 496 U.S. at 665.

[206]. *Id.* at 678; *See also* Poche, *supra* note 20 at 918 (citing Lilly as recognizing the statutory symmetry between federally regulated drugs and medical devices).

[207]. *See, e.g.*, Chartex Int'l PLC, 5 F.3d 1505; Abtox, Inc., 122 F.3d 1019; Bristol-Myers Squibb Co. v. Rhone-Poluenc Rorer, Inc., 2001 U.S. Dist. Lexis 1936.

[208]. *Eli Lilly & Co.*, 496 U.S. at 665 (stating that the “core of the present controversy is that petitioner interprets the statutory phrase, ‘a Federal law which regulates the manufacturer, use or sale of drugs,’ to refer only to those individual provisions of federal law that regulates drugs, whereas respondent interprets it to refer to the entirety of any Act”).

[209]. *Id.* at 665 (citing 35 U.S.C. § 100(a) as defining the scope of “patented inventions” immunized by § 271(e)(1) when the use of those patented inventions is “reasonably related to the development and submission of drugs [and devices] under federal law”); *See also* Paul Wiegel, Was the FDA Exemption to Patent Infringement, 35 U.S.C. § 271(e)(1), Intended to Exempt a Pharmaceutical Manufacturer's Activities in the Development of New Drugs?, 2007 B.C. Intell. Prop. & Tech. F. 112901, 6 (2007).

[210]. *Eli Lilly & Co.*, 496 U.S. at 665.

[211]. *Id.* (emphasis added).

[212]. *Id.* at 673-74.

[213]. *Id.* at 665, 667 (discussing and rejecting the patent owner's argument that “patented invention” is limited to “patented drug invention”).

[214]. *Id.* at 673-74.

[215]. Proveris Scientific Corp., 536 F.3d at 1265-66.

[216]. *Id.* at 1263-64 (failing to recognize the “patented inventions” in Merck, held to be within the scope of § 271(e)(1), would not pass the perfect product fit test).

[217]. *Id.*

[218]. Integra Lifesciences I, Ltd., 496 F.3d at 1336.

[219]. *See generally, supra* Part III Section A.

[220]. *See generally* Eli Lilly & Co., 496 U.S. 661; *See also* Poche, *supra* note 20 at 918.

[221]. 35 U.S.C. § 100(a)(2000)(defining term “invention” as “invention or discovery”).

[222]. Proveris Scientific Corp., 536 F.3d at 1265-66.

[223]. *Id.*

[224]. *Id.*; *See also* Integra Lifesciences I, Ltd., 496 F.3d at 1348, 1350-51.

[225]. Proveris Scientific Corp., 536 F.3d at 1263.

[226]. AbTox, Inc., 122 F.3d at 1020 (explaining that this device was a Class II medical device thus ineligible for § 156 because only Class III medical devices are eligible for § 156).

[227]. *Id.*

[228]. AbTox, Inc., 122 F.3d at 1027-28 (emphasis added).

[229]. Proveris Scientific Corp., 536 F.3d at 1263.

[230]. *See supra* Part III.A-B.

[231]. *See generally* Chartex Int'l, PLC, 5 F.3d 1505.

[232]. *Id.* at 5.

[233]. *Id.*

[234]. Bristol-Myers Squibb Company v. Rhone-Poulenc Rorer Incorporated, 2001 WL 1512597 (S.D.N.Y. 2001) (finding the patent invalid based on inequitable conduct, upheld at the Federal Circuit and thus the Federal Circuit never reaches the § 271(e)(1) question).

[235]. Bristol-Myers Squibb Company, 2001 U.S. Dist. LEXIS 19361 at 8 (citing Chartex and AbTox as “clear Federal Circuit precedent that the term “patented invention” [in § 271(e)(1)] means all patented inventions”).

[236]. *See* H.R. Rep. No. 98-857 at 3-6.

[237]. See generally, McMinn, *supra* note 14 at 199.

[238]. *Id.* at 233.

[239]. See Reagan Statement, *supra* note 4.

[240]. See H.R Rep. No. 98-857 at 26-30.

[241]. See also Poche, *supra* note 20 at 913.

[242]. See generally, Abbreviated New Drug Application Regulations, 57 Fed. Reg. at 17,950-51; H.R Rep. No. 98-857 at 3-6.

[243]. Corrected Brief of Innova, *supra* note 145 at 16 (offering a hypothetical of specific problems a limited interpretation of “patented inventions” might create).

[244]. See Meadows, *supra* note 21 (explaining the FDA approval process for a new drugs cost on average 897 million dollars and uses 14 years or the patent term).

[245]. See generally 35 U.S.C. § 156.

[246]. Abbreviated New Drug Application Regulations, 57 Fed. Reg. at 17,950-51.

[247]. *Id.*

[248]. *Id.*

[249]. Corrected Brief of Innova, *supra* note 145 at 16.

[250]. Abbreviated New Drug Application Regulations, 57 Fed. Reg. at 17,950-51.

[251]. H.R Rep. No. 98-857 at 1, 4.

[252]. See Eli Lilly & Co., 496 U.S. at 665; See also Merck KGaA, 545 U.S. at 202-03 (emphasis added).

[253]. See generally, *supra* Part IV Section A.

[254]. See Wobbekind, *supra* note 12 at 113.

[255]. See generally, Proveris Scientific Corp., 536 F.3d at 1265-66.

[256]. See generally, Integra Lifesciences I, Ltd., 496 F.3d at 1348 (Judge Rader dissenting) and Eli Lilly & Co., 496 U.S. 661 (reversing Medtronic, Inc. v. Eli Lilly & Co., 872 F.2d 402 (Fed.Cir.1989)).

[257]. 496 F.3d at 1348-53.

[258]. *Id.* at 1350.

[259]. *Id.* at 1349.

[260]. See *Id.* at 1352 (Judge Rader criticizing the majority's holding as overly broad and “obliterat[ing] all value”

for patented research tools such as microscope).

[261]. *See also* Wolrad Prinz Waldeck und Pymont, Article, Research Tool Patents after *Integra v. Merck*-Have They Reached a Safe Harbor, 14 Mich. Telecom. Tech. L. Rev. 367, 427 (2008)(emphasis added).

[262]. *See generally*, *Proveris Scientific Corp.*, 536 F.3d 1256; *See also, supra* Part III Section A.

[263]. *See generally*, Guidance for Industry, *supra* note 59 (defining bioavailability as “the rate and extent to which the active ingredient [of a drug] ... is absorbed ... and becomes available at the site of action”).

[264]. *Id.* (defining bioequivalence as “the absence of a significant difference in the rate and extent to which the active ingredient ... in [a generic drug] becomes available at the site of drug action when administered ... in an appropriately designed study”).

[265]. *See generally, supra* Part III Section A.

[266]. *Wobbekind, supra* note 12 at 107-08.

[267]. Abbreviated New Drug Application Regulations, 57 Fed. Reg. at 17,950-51.

[268]. *See generally, supra* Part III Section A (explaining under *Proveris* the question of “use” will not be reached when the “patented invention” does not meet the perfect product fit test).

[269]. *See generally, supra* Part III Section B (explaining Lilly's discussion of statutory symmetry between § 271(e)(1) and § 156 was intended to broaden the scope of § 271(e)(1)'s term “drugs,” to include all “products” regulated by the FDCA, not limit § 271(e)(1)'s phrase “patented invention”).