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The Doctrine of Equivalents: Fairness and Uncertainty in an Era of Biologic Pharmaceuticals

D. Alan White

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THE DOCTRINE OF EQUIVALENTS: FAIRNESS AND UNCERTAINTY IN AN ERA OF BIOLOGIC PHARMACEUTICALS

ABSTRACT

Research in the rapidly developing area of biologic pharmaceuticals promises to improve the lives of millions of patients suffering from disorders that were, until very recently, untreatable. The staggering potential market for such treatments has attracted enormous investment from the pharmaceutical industry, with a concomitant increase in related patent disputes. This investment, coupled with proposed legislation that would pave the way for the creation of “follow-on” biologic treatments via a statutory pathway similar to the one created for generic pharmaceuticals by the Hatch–Waxman legislation of the early 1980s, should ensure that the number of patent disputes involving biologic pharmaceuticals will continue to rise dramatically in the coming years.

This Comment focuses on the patent law concept known as the doctrine of equivalents, and observes that the very complexity that makes biologic pharmaceuticals so valuable for treating previously untreatable disorders also creates difficulties in the field of patent law, particularly when the doctrine of equivalents is involved. This Comment notes that there is considerable evidence that juries have difficulty dealing with cases involving technologically advanced subject matter of the type that is often at issue in biologics cases, and discusses illustrative cases involving the doctrine of equivalents. This Comment also argues that the doctrine of equivalents increases the uncertainty of the scope of biologic patents. This uncertainty has the potential to chill vital biologics innovation in a way that often cannot be overcome by such remedies as cross-licensing. Finally, this Comment proposes solutions to these problems, including the judicious application of legal limitations on the doctrine of equivalents in biologics cases, the impaneling of expert juries that are able to better understand the complex issues involved in such cases, and the denial of injunctive relief in biologics cases where infringement is found under the doctrine of equivalents.

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INTRODUCTION

Recently, at a local hospital, a patient consulted with her doctor about a problem with her vision. This patient was most likely in her fifties or sixties, and complained of symptoms such as difficulty reading before bed, trouble adjusting to dim light after entering a room from the outside, an inability to perceive fine detail, and blurring of her central visual fields.¹ Her symptoms were classic indicators of age-related macular degeneration (AMD), a progressive blinding disease that is the leading cause of blindness in individuals fifty years and older, the primary blinding disorder in developed countries, and the third leading cause of blindness worldwide.² As recently as 2007, her physician would have had few treatment options to offer.³ Today, however, her physician is able to prescribe a simple series of monthly injections that may not only prevent her vision loss, but could actually improve her visual acuity.⁴

The vision of this patient, and thousands of others like her, is being preserved by a drug called Lucentis, which the Food and Drug Administration (FDA) approved for treatment of AMD in 1996.⁵ To date, Lucentis is the most effective treatment for AMD and is also one of the more expensive medicines on the market, costing around \$1,950 per treatment.⁶ Lucentis is not a traditional chemical pharmaceutical, but rather a fragment of a humanized antibody, which when injected into the eye inhibits the action of a protein

¹ R.E. Hogg & U. Chakravarthy, *Visual Function and Dysfunction in Early and Late Age-Related Maculopathy*, 25 *PROGRESS RETINAL & EYE RES.* 249, 252 (2006).

² Luis Javier Hernandez-Pastor et al., *Ranibizumab for Neovascular Age-Related Macular Degeneration*, 65 *AM. J. HEALTH-SYS. PHARMACY* 1805, 1805 (2008).

³ See Michael Waisbourd et al., *Targeting Vascular Endothelial Growth Factor: A Promising Strategy for Treating Age-Related Macular Degeneration*, 24 *DRUGS & AGING* 643 (2007) (providing an early description of AMD treatments involving the inhibition of vascular endothelial growth factor (VEGF)).

⁴ See Edwin M. Stone, *A Very Effective Treatment for Neovascular Macular Degeneration*, 355 *NEW ENG. J. MED.* 1493, 1494 (2006).

⁵ *Id.* Lucentis is the brand name for Ranibizumab, which is a recombinant, humanized version of a fragment of a mouse antibody. See Waisbourd et al., *supra* note 3, at 650–54.

⁶ Robert Steinbrook, *The Price of Sight—Ranibizumab, Bevacizumab, and the Treatment of Macular Degeneration*, 355 *NEW ENG. J. MED.* 1409, 1409 (2006). Indeed, it has been estimated that it would cost over \$50,000 “to prevent one patient with predominantly classic neovascular AMD from losing visual acuity over a 12-month period.” Hernandez-Pastor et al., *supra* note 2, at 1812 (describing the pharmacoeconomics of Ranibizumab treatment for AMD). Lucentis sales for 2009 totaled \$2.34 billion dollars in revenue. R&D PIPELINE NEWS, LA MERIE BUSINESS INTELLIGENCE, TOP 20 BIOLOGICS 2009, at 2 (2010), http://www.pipelinereview.com/free-downloads/top_20_biologics_2009_rd_pipeline_news.pdf.

responsible for the formation of new blood vessels.⁷ As such, Lucentis represents a very successful example of a relatively new class of pharmaceuticals called biologics, which the FDA defines as comprising “a wide range of products such as vaccines, blood and blood components, allergenics, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins.”⁸ Sales of biologics totaled around \$80 billion in 2008, accounting for more than 10% of global pharmaceutical sales.⁹ Recognizing the growth and importance of this class of pharmaceuticals,¹⁰ Congress recently passed the Biologics Price Competition and Innovation Act of 2009,¹¹ which is intended to facilitate the development of generic, or “follow-on,” biologics,¹² in much the same way that the Hatch–Waxman Act of 1982 led to the widespread availability of generic versions of brand-name pharmaceuticals.¹³

⁷ Stone, *supra* note 4, at 1493. The antibody binds to and inhibits the protein VEGF, which is responsible for neovascularization (the induction of new blood vessel growth). *Id.* Ranibizumab was initially developed as an anti-tumor therapeutic for cancer patients (inhibiting neovascularization retards tumor growth), but has recently become a widely prescribed treatment for the “wet” form of AMD, which is caused by neovascularization in the eye. *Id.* at 1493–94; *see also* Waisbourd et al., *supra* note 3 (describing further the use of Ranibizumab for treating AMD).

⁸ *Consumers (Biologics)*, FOOD & DRUG ADMIN., <http://www.fda.gov/BiologicsBloodVaccines/ResourcesForYou/Consumers/default.htm> (last updated Sept. 28, 2010). *See generally* Ronald A. Rader, *(Re)defining Biopharmaceutical*, 26 NATURE BIOTECHNOLOGY 743 (2008).

⁹ R&D PIPELINE NEWS, LA MERIE BUSINESS INTELLIGENCE, TOP 20 BIOLOGICS 2008, at 2 (2009), http://www.pipelinerreview.com/free-downloads/TOP_20_Biologics_2008_in_RD_Pipeline_News.pdf. Global pharmaceutical sales totaled around \$770 billion in 2008. Krishan Maggon, *Global Pharmaceutical Market Review & World Top Ten/Twenty Drugs 2008*, KNOL.GOOGLE.COM, <http://knol.google.com/k/global-pharmaceutical-market-review-world-top-ten-twenty-drugs-2008> (last visited Feb. 3, 2011).

¹⁰ It has been predicted that biologics will surpass sales of traditional pharmaceuticals by 2014. *Biotech Set to Dominate Drug Industry Growth*, EVALUATEPHARMA (June 17, 2009), <http://www.evaluatepharma.com/Universal/View.aspx?type=Story&id=188700§ionID=&isEPVantage=yes>; *see also* Andrew Pollack, *Costly Drugs Known as Biologics Prompt Exclusivity Debate*, N.Y. TIMES, July 22, 2009, at B1 (documenting the legislative push for biosimilars legislation as a cost-saving measure commensurate with the overall goals of health care reform).

¹¹ Pub. L. No. 111-148, tit. VII, 124 Stat. 804 (to be codified at 42 U.S.C. §§ 201–262). The Biologics Price Competition and Innovation Act was part of the much larger Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010) (to be codified at 20, 21, 25, 26, 29 and 42 U.S.C.).

¹² In the pharmaceutical industry, a “pioneer” or “brand-name” drug is a drug that is the first of its kind on the market, while a “follow-on” drug applies to generics that are subsequently created and marketed. In the case of biologics, pioneer biologics like Lucentis may be followed by generic versions that would be termed follow-on biologics, biosimilars, or generic biologics. Sanya Sukduang & Jonathan Davies, *Follow-On Biologics: A Patent Litigation Perspective*, PHARMACEUTICAL COM. (Aug. 22, 2009), http://www.pharmaceuticalcommerce.com/frontEnd/1262-Follow_on_Biologics:_APatentLitigationPerspective.html; *see also* Megan Thisse, *Working the Bugs Out of Biologics: A Look at the Access to Life-Saving Medicines Act and Follow-On Biologics*, 18 ALB. L.J. SCI. & TECH. 543, 543 n.1 (2008).

¹³ The Drug Price Competition and Patent Term Restoration Act of 1984, also referred to as the Hatch–Waxman Act, amended the Food, Drug, and Cosmetic Act, outlining the approval process used for modern

The popularity of biologic pharmaceuticals, as well as incentives present in the Patient Protection and Affordable Care Act, should encourage the development of generic follow-on versions of pioneer biologics; accordingly, the future will likely see increased litigation over the patent rights protecting biologic pharmaceuticals.¹⁴ As a result, courts will be forced to resolve questions of validity and infringement with respect to patents involving rapidly evolving, cutting-edge therapeutics, and may be hard-pressed to apply traditional doctrines of patent law to such a novel and complex class of technology. One such traditional doctrine of patent law is the doctrine of equivalents.

This Comment argues that the doctrine of equivalents substantially broadens patent scope when applied to disputes involving biologics patents, which could chill innovation in an area of vital interest to the public. Part I of this Comment provides a brief description of patent law concepts, with particular attention to the historical development of the doctrine of equivalents. Part II explores the difficulties that can be encountered when courts attempt to apply the doctrine of equivalents in a biologics context, and briefly discusses two recent cases that illustrate these difficulties. Part III argues that application of the doctrine in such situations should be limited for two reasons: first, because juries have difficulty deciding technologically complex cases, and second, because the uncertainty inherent in the doctrine's application exerts a chilling effect upon biologics innovation, which cannot be effectively addressed through remedies such as cross-licensing. Finally, Part IV of this Comment explores several proposals for limiting the use of the doctrine of

generic pharmaceuticals. See Drug Price Competition and Patent Term Restoration Act of 1984 § 505, 21 U.S.C. § 355 (2006).

¹⁴ For example, in 2004, over half of the abbreviated new drug applications (or ANDAs, which are a type of patent application allowed for generic drugs under the Hatch–Waxman Act) filed by Teva Pharmaceuticals were “Paragraph IV filings,” in which Teva essentially initiated litigation with a pioneer drug patent holder by preemptively challenging any claims of infringement asserted by the pioneer patent holder. See Michelle L. Kirsche, *Best May Be Yet to Come for Generic Drug Makers*, DRUG STORE NEWS (Feb. 14, 2005), available at http://findarticles.com/p/articles/mi_m3374/is_2_27/ai_n10018295/. With the potential for huge profits, manufacturers of follow-on biologics can be expected to initiate similar litigation if allowed to do so under future legislation. In the absence of such legislation, litigation may arise over attempts by follow-on manufacturers to “design around” existing biologics patents. See Robert N. Sahr, *The Biologics Price Competition and Innovation Act: Innovation Must Come Before Price Competition*, 2009 B.C. INTELL. PROP. & TECH. F. 070201, 45–47 (discussing the impact on biologics innovation of follow-on products that “design around” existing biologics patents); see also David M. Dudzinski, *Reflections on Historical, Scientific, and Legal Issues Relevant to Designing Approval Pathways for Generic Versions of Recombinant Protein-Based Therapeutics and Monoclonal Antibodies*, 60 FOOD & DRUG L.J. 143, 168–72 (2005) (reviewing the Hatch–Waxman legislation and the prospects of similar legislation for biologics); Thisse, *supra* note 12.

equivalents to overly broaden biologics patent rights, including legal limitations on the doctrine, the use of specialized juries to aid in resolving technologically complex biologics cases, and the denial of injunctions (thus mandating compulsory licenses) as a remedy for infringement in biologics cases involving the doctrine of equivalents.

I. PATENTS, INFRINGEMENT, AND THE DOCTRINE OF EQUIVALENTS

Patents exist to provide an incentive for inventors to innovate.¹⁵ This incentive comes in the form of a limited monopoly that allows the patentee to prevent others from engaging in certain uses of the patented invention.¹⁶ In return for this monopoly, the patent holder must make the details of the invention public, allowing others to study its workings and (hopefully) use the knowledge gained to develop further innovations.¹⁷ Patents may therefore be understood as a delicately balanced set of rights in which a patentee is granted the “right to exclude” others from certain uses of her invention,¹⁸ but only to the extent that this encourages the spread of new ideas and inventions to the public as a whole.¹⁹ This Part begins by briefly reviewing basic patent law concepts and continues on to a more specific discussion of the doctrine of equivalents and its history.

In the United States, a patent consists of a written specification describing the patented invention followed by a list of claims delineating specific

¹⁵ *Beidler v. United States*, 253 U.S. 447, 453 (1920) (“[A] correct and adequate description or disclosure of a claimed discovery . . . is essential to the validity of a patent, for the reason that such a disclosure is necessary in order to give the public the benefit of the invention after the patent shall expire.”).

¹⁶ Currently, this protection begins on the day the patent issues and ends twenty years after the filing date of the patent application. 35 U.S.C. § 154 (2006).

¹⁷ See *Beidler*, 253 U.S. at 453. Although the courts stress this quid pro quo view of patents, the classic academic justification is that patents are “needed to counter the public good nature of information.” See Timothy R. Holbrook, *Possession in Patent Law*, 59 SMU L. REV. 123, 125, 132 (2006) (discussing the public good problem and arguing that disclosure requirements are actually more important for demonstrating possession of an invention—and therefore the right to a patent—than for teaching the public about the invention); see also Mark A. Lemley, *Ex Ante Versus Ex Post Justifications for Intellectual Property*, 71 U. CHI. L. REV. 129 (2004) (criticizing *ex post* justifications for patent rights, such as downstream coordination or improvement of inventions, in favor of *ex ante* justifications that view patents as combating the public good problem).

¹⁸ *Bloomer v. McQuewan*, 55 U.S. (14 How.) 539, 549 (1852).

¹⁹ *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 146 (1989) (“The Patent Clause itself reflects a balance between the need to encourage innovation and the avoidance of monopolies which stifle competition . . .”).

elements of the invention that the inventor desires to patent.²⁰ Patents do not grant the patent holder a positive right to practice the invention, but rather the right to exclude others from making, using, selling, offering to sell, or importing the patented invention.²¹ A patent holder who believes that another party has violated the rights described above may, among other things, initiate legal proceedings against that party with an infringement action.²² If successful, such an action can result in a court order enjoining the infringing party from practicing the patented invention, an award of damages payable by the infringing party to the patent holder, or both.²³ In defending against an action for infringement, the accused infringer will generally attempt either to show that the allegedly infringed patent is invalid, or to demonstrate that her actions did not actually infringe the patent in question.²⁴

To determine if an accused invention indeed infringes upon the patent in question, a court will first engage in the process of claim construction, in which it determines as a matter of law the scope of the claims at issue, attempting to define their limits as would a person having ordinary skill in the art at the time of the claim's filing.²⁵ After the claims have been properly construed, infringement analysis involves a factual comparison of the claims at issue to the accused invention, which is a matter for the fact-finder.²⁶ To literally infringe a patent, the accused invention must be identical to each element of one of the claims at issue.²⁷

²⁰ See generally CRAIG ALLEN NARD, *THE LAW OF PATENTS* 39 (2008) (describing the patent application). Patent law is codified by the statutes collected in Title 35 of the U.S. Code, which were passed (and may be modified) by Congress under its constitutional authority "[t]o promote the Progress of the Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." U.S. CONST. art. I, § 8, cl. 8.

²¹ 35 U.S.C. § 271(a) (2006); see also *Bloomer*, 55 U.S. (14 How.) at 549.

²² 35 U.S.C. § 281. Generic drug manufacturers may preemptively initiate such litigation through a Paragraph IV filing of an abbreviated new drug application. See Elizabeth H. Dickinson, *FDA's Role in Making Exclusivity Determinations*, 54 *FOOD & DRUG L.J.* 195, 197-99 (1999) (summarizing this process).

²³ 35 U.S.C. §§ 281, 283, 284.

²⁴ *Id.* § 282.

²⁵ *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 374 (1996) ("Victory in an infringement suit requires a finding that the patent claim 'covers the alleged infringer's product or process,' which in turn necessitates a determination of 'what the words in the claim mean.'" (quoting HERBERT F. SCHWARTZ, *PATENT LAW AND PRACTICE* 80 (2d ed. 1995))).

²⁶ *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1323 (Fed. Cir. 2002).

²⁷ *Southwall Tech., Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1575 (1995) ("To establish literal infringement, every limitation set forth in a claim must be found in the accused product, exactly."). An invention that literally infringes each limitation of a claim is said to "read on" the claim. *Id.*

Yet even if an accused invention does not literally infringe a claim, the accused infringer may still be liable for infringement under the doctrine of equivalents.²⁸ The doctrine of equivalents is a concept in patent law that originated to prevent “the unscrupulous copyist [from making] unimportant and insubstantial changes and substitutions in the patent which, though adding nothing, would be enough to take the copied matter outside the claim, and hence outside the reach of the law.”²⁹ The doctrine of equivalents has existed since the early nineteenth century, before the establishment of patent claims as they are known today.³⁰ Without specific claims to follow, juries of the time used what some scholars have described as a “substantiality” test to determine infringement, comparing the written description found in the patent to the accused infringing invention.³¹ Ultimately, this type of analysis proved unsatisfactory, as the lack of specificity in patent drafting often made it unclear where a patent holder’s rights ended and a fellow inventor’s began.³² Attempting to bring clarity and security to patent law, patent lawyers and trial courts developed what is now considered the modern form of claiming, the procedures for which were ultimately codified in 1836.³³ Yet even though courts recognized the advantages of a more specific claiming system that clearly delineated the breadth of patent protection, they often balked at being forced to rule against patent holders in cases where a patented invention had

²⁸ See NARD, *supra* note 20, at 435–36 (providing a basic description of infringement under the doctrine of equivalents, accompanied by selected cases).

²⁹ Graver Tank & Mfg. Co. v. Linde Air Prods. Co., 339 U.S. 605, 607 (1950) (“One who seeks to pirate an invention . . . may be expected to introduce minor variations to conceal and shelter the piracy. [Exact] duplication is a dull and very rare type of infringement. To prohibit no other would place the inventor at the mercy of verbalism and . . . would deprive him of the benefit of his invention and would foster concealment rather than disclosure of inventions, which is one of the primary purposes of the patent system.”).

³⁰ See NARD, *supra* note 20, at 435–36. See generally Jeanne C. Fromer, *Claiming Intellectual Property*, 76 U. CHI. L. REV. 719, 796 (2009) (exploring intellectual property claiming practice in light of “taxonomical, descriptive, and normative features,” and suggesting ways to optimize the patent claiming system); Joshua D. Sarnoff, *The Historic and Modern Doctrine of Equivalents and Claiming the Future, (1790–1870)* (pt. 1), 87 J. PAT. & TRADEMARK OFF. SOC’Y 371 (2005) (summarizing the early history of the doctrine of equivalents).

³¹ See, e.g., NARD, *supra* note 20, at 435.

³² See John F. Duffy, *The Festo Decision and the Return of the Supreme Court to the Bar of Patents*, 2002 SUP. CT. REV. 273, 308–10 (describing the patent claim as “an innovation of patent attorneys . . . formulated to protect and to expand the rights of patentees”). Patents are granted for the sole purpose of promoting discovery and invention. See U.S. CONST. art. I, § 8, cl. 8. This goal is furthered by a patent system that encourages specificity in the disclosure of patented inventions. See *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1351–52 (Fed. Cir. 2005) (stating that claims should “reasonably apprise those skilled in the art of the scope of the invention” (quoting *Amgen Inc. v. Hoechst Marion Roussel*, 314 F.3d 1313, 1342 (Fed. Cir. 2003)) (internal quotation mark omitted)).

³³ See Duffy, *supra* note 32 at 306–16; Sarnoff, *supra* note 30, at 399.

clearly been copied, but without any literal infringement of its patent claims.³⁴ To rectify such perceived injustices, courts turned to the doctrine of equivalents.³⁵

Interestingly, Congress has never officially sanctioned the doctrine of equivalents; the Patent Act, read literally, limits patent protection to the scope of the patent claims.³⁶ Accordingly, prior to 1950, the Supreme Court “consistently limited the doctrine of equivalents under the 1870 Patent Act to the scope of application of constructed claim language.”³⁷ However, all of this changed following the Supreme Court’s decision in *Graver Tank & Manufacturing Co. v. Linde Air Products Co.*³⁸ In that case, the Court upheld the lower court’s ruling that, under the doctrine of equivalents, a welding composition containing manganese infringed a patent claiming welding compositions containing magnesium.³⁹ Stating that “[i]t is difficult to conceive of a case more appropriate for application of the doctrine of equivalents,” the Court ruled that although “infringement was not literal, the changes which avoid literal infringement are colorable only.”⁴⁰ The Court in *Graver Tank* also stood by the “function-way-result” test developed in prior decisions, holding that infringement could be established under the doctrine of equivalents when an infringing device copied a patented invention so as to “perform[] substantially the same function in substantially the same way to obtain the same result.”⁴¹ This decision is famous not only as the Court’s most significant pronouncement to date regarding the doctrine of equivalents, but also for the vigorous dissent authored by Justice Black, in which he argued

³⁴ Donald S. Chisum, *The Scope of Protection for Patents After the Supreme Court’s Warner-Jenkinson Decision: The Fair Protection-Certainty Conundrum*, 14 SANTA CLARA COMPUTER & HIGH TECH. L.J. 1, 6–7 (1998). This tension between the need for specificity in patent claiming to satisfy the “public notice” function of patents and the desire to protect patent holders from inequities due to overly stringent claim interpretations has been termed the “Fair Protection-Certainty Conundrum.” *Id.* (internal quotation marks omitted).

³⁵ Indeed, as Judge Learned Hand observed, courts “resort to the ‘doctrine of equivalents’ to temper unsparing logic and prevent an infringer from stealing the benefit of the invention.” *Royal Typewriter Co. v. Remington Rand, Inc.*, 168 F.2d 691, 692 (2d Cir. 1948).

³⁶ Sarnoff, *supra* note 30, at 373.

³⁷ *Id.*; see also Joshua D. Sarnoff, *The Historic and Modern Doctrines of Equivalents and Claiming the Future: (1870–1952)* (pt. 2), 87 J. PAT. & TRADEMARK OFF. SOC’Y 441 (2005) (providing continued discussion of the history of the modern doctrine of equivalents).

³⁸ 339 U.S. 605 (1950).

³⁹ *Id.*

⁴⁰ *Id.* at 612.

⁴¹ *Id.* at 608; see also *Sanitary Refrigerator Co. v. Winters*, 280 U.S. 30, 42 (1929); *Machine Co. v. Murphy*, 97 U.S. 120, 125 (1877).

against the doctrine of equivalents, emphasizing the importance of the notice function of patent claims.⁴²

Nearly fifty years later, the Supreme Court outlined the modern doctrine of equivalents in *Warner-Jenkinson Co. v. Hilton Davis Chemical Co.*, affirming its decision in *Graver Tank* by holding that “a product or process that does not literally infringe upon the express terms of a patent claim may nonetheless be found to infringe if there is ‘equivalence’ between the elements of the accused product or process and the claimed elements of the patented invention.”⁴³ However, the Supreme Court recognized that after *Graver Tank*, courts had perhaps been too eager in applying the doctrine of equivalents in patent cases, and that this to some extent could defeat the notice function of patents.⁴⁴ To guard against this, the Court limited the application of the doctrine by outlining the “all-elements” rule, mandating that equivalence be determined by comparing the claimed invention with the accused infringing device on an element-by-element basis, rather than by comparing the claimed invention to the accused device as a whole.⁴⁵ Additionally, the Court held that the doctrine was not limited to equivalents disclosed in the patent specification, and that infringement analysis under the doctrine of equivalents is measured at the time of the alleged infringement rather than, as is the case with literal infringement, at the time the patent was issued.⁴⁶

The Supreme Court most recently addressed the question of the doctrine of equivalents in *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*⁴⁷ In *Festo*, the Court again affirmed its support for the doctrine of equivalents by rejecting an en banc Federal Circuit ruling that made prosecution history estoppel a complete bar to the doctrine’s application.⁴⁸ Prosecution history estoppel arises when, during patent prosecution, the patentee makes a narrowing amendment to the patent claims to avoid rejection by the patent

⁴² *Graver Tank*, 339 U.S. at 612 (Black, J., dissenting). Arguing that “[w]hat is not specifically claimed is dedicated to the public,” *id.* at 614, Justice Black’s criticisms have echoed through the years, outlining the heart of the continued debate over application of the doctrine of equivalents.

⁴³ *Warner-Jenkinson*, 520 U.S. 17, 21 (1997).

⁴⁴ The Court stated that it “share[d] the concern . . . that the doctrine of equivalents, as it has come to be applied since *Graver Tank*, has taken on a life of its own, unbounded by . . . patent claims,” and also observed that “[t]here can be no denying that the doctrine of equivalents, when applied broadly, conflicts with the definitional and public-notice functions of the statutory claiming requirement.” *Id.* at 28–29.

⁴⁵ *Id.* at 29.

⁴⁶ *Id.* at 37.

⁴⁷ 535 U.S. 722 (2002).

⁴⁸ *Id.*

examiner.⁴⁹ In such a situation, courts often will not allow the patentee to later claim the surrendered subject matter through the use of the doctrine of equivalents.⁵⁰ Over time, the Federal Circuit began to view prosecution history estoppel as an increasingly inflexible barrier to the application of the doctrine of equivalents, culminating in its *Festo* decision, in which the court held that a patentee who surrendered subject matter during patent prosecution was completely barred from later using the doctrine of equivalents to claim that same subject matter.⁵¹ However, the Supreme Court rejected this approach, holding that prosecution history instead created a rebuttable presumption against application of the doctrine of equivalents that could be overcome by the patentee in certain situations.⁵²

II. BIOLOGICS AND THE DOCTRINE OF EQUIVALENTS: TWO ILLUSTRATIVE CASES

As discussed in the previous Part, the doctrine of equivalents evolved to prevent “unscrupulous copyists,”⁵³ from avoiding patent infringement by making insubstantial changes to a patented invention that take it outside the literal scope of the patent’s claims. 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.”⁵⁴ 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.⁵⁵ However, as Professor Donald Chisum has noted,

⁴⁹ “The process of applying for a patent is called *patent prosecution*, and the record of the prosecution proceedings before the PTO is called the *prosecution history* (sometimes referred to as file history).” NARD, *supra* note 20, at 37. Narrowing amendments are modifications to the patent application that narrow the scope of the claims, often to overcome an examiner’s rejection. *Id.* at 38.

⁵⁰ See, e.g., *Festo*, 535 U.S. at 733–34 (“When . . . the patentee originally claimed the subject matter alleged to infringe but then narrowed the claim in response to a rejection, he may not argue that the surrendered territory comprised unforeseen subject matter that should be deemed equivalent to the literal claims of the issued patent.”).

⁵¹ *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 234 F.3d 558 (Fed. Cir. 2000), *vacated*, 535 U.S. 722 (2002).

⁵² *Festo*, 535 U.S. at 737–41. “When the patentee has chosen to narrow a claim, courts may presume . . . that the territory surrendered is not an equivalent of the territory claimed. In those instances, however, the patentee still might rebut the presumption that estoppel bars a claim of equivalence.” *Id.* at 741.

⁵³ See *supra* note 29.

⁵⁴ JANICE M. MUELLER, *PATENT LAW 352* (3d ed. 2009); see also Chisum, *supra* note 34, at 7 (“Claims are often written by people with limited resources and time, imperfect expression skills, and incomplete understandings of the invention, the prior art that determines its patentability, and the forms in which it may later be cast.”).

⁵⁵ See *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 607 (1950).

the desire to provide patentees a “fair scope of protection” comes at the price of creating at least some uncertainty as to the scope of patent protection “that may deter legitimate investment and business activities.”⁵⁶ This Part argues that the doctrine of equivalents is particularly difficult to apply in cases involving complex technologies like biologics and discusses two cases that illustrate these difficulties.

In many patent disputes, application of the doctrine of equivalents can be relatively straightforward. For example, consider a simple hypothetical patent claiming a metal hook designed as a coat hanger. If another party subsequently began producing a coat hanger that was exactly like the claimed metal coat hanger in every respect, save that it was made of some different material (that nevertheless performed substantially the same function in the same way to achieve the same result as metal), it is easy to say that the original patent’s claim scope should be broadened by the doctrine of equivalents to cover the copy, which differed only in the substance used in its manufacture. Indeed, the Supreme Court in *Graver Tank* confronted a similar problem of material substitution, where the accused infringer developed a welding flux that substituted manganese for the magnesium used in the original, patented flux.⁵⁷ Although the patent at issue claimed “alkaline earth metal silicates,” a group of elements that includes magnesium but not manganese, the Court upheld the trial court’s determination that manganese and magnesium were equivalent, and that the accused welding flux composition therefore infringed under the doctrine of equivalents.⁵⁸

Application of the doctrine to patents involving biologics often proves more challenging. To understand why this is so, one must only consider the simplest of biologic examples, a DNA nucleotide⁵⁹ sequence:

Outright and forthright duplication is a dull and very rare type of infringement. To prohibit no other would place the inventor at the mercy of verbalism and would be subordinating substance to form. It would deprive him of the benefit of his invention and would foster concealment rather than disclosure of inventions, which is one of the primary purposes of the patent system.

Id.

⁵⁶ See Chisum, *supra* note 34, at 62 (describing the “Fair Protection-Certainty Conundrum”).

⁵⁷ 339 U.S. at 610.

⁵⁸ *Id.* at 612. In its decision, the Court noted that “[s]pecialists familiar with the problems of welding compositions understood that manganese was equivalent to and could be substituted for magnesium . . . their observations were confirmed by the literature of chemistry. . . . Though infringement was not literal, the changes which avoid literal infringement are colorable only.” *Id.*

⁵⁹ DNA (deoxyribonucleic acid) is the genetic storage material. DNA exists as sequences of nucleotides (adenine, guanine, thymine, and cytosine) that encode for genes. Genes are transcribed into RNA (ribonucleic

[C]onsider a claim reciting a purified, isolated DNA molecule comprising the nucleotide sequence AAGGTCAGGTCA. What are the pertinent limitations of this claim? Is a single nucleotide, A (the base adenine), the relevant limitation to be met . . . ? Or is the pertinent limitation . . . a codon of three nucleotides, AAG (which together form the amino acid lysine)? Or is it an even longer stretch of the recited nucleotide sequence (perhaps the [entire sequence])? Federal Circuit decisions have not yet clearly answered these questions; the answers are likely to be case-specific.⁶⁰

If applying the doctrine of equivalents to the example of changing a single nucleotide in a simple DNA sequence (like the one shown above) makes for difficult academic analysis, one must sympathize with attorneys, judges, and juries that are forced to apply the doctrine to the complex panoply of nucleotide sequences, proteins, antibodies, engineered cell lines, vaccines, and viruses that constitute the current array of biologic pharmaceuticals, a class of therapies that will almost certainly become more numerous and complex in the future. The analysis is further complicated by the fact that simple changes, even single changes at the DNA or protein level, can lead to drastic consequences for the biologic in question.⁶¹

Two recent cases, *Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp.*⁶² and *Goldenberg v. Cytogen, Inc.*,⁶³ illustrate the difficulties postulated above. In *Boehringer*, the Federal Circuit affirmed the lower court's ruling of infringement under the doctrine of equivalents.⁶⁴ The case involved attenuated viruses that had been developed as vaccines against a disease known as Porcine Reproductive Respiratory Syndrome (PRRS), which devastated commercial pig herds in the 1980s.⁶⁵ The accused infringers

acid) sequences that are subsequently translated into amino acid polypeptides, which then fold into structures called proteins, which comprise the body's molecular machinery. See generally BENJAMIN LEWIN, GENES X (10th ed. 2011) (providing a detailed description of the structure and function of DNA, and the processes of transcription and translation).

⁶⁰ MUELLER, *supra* note 54, at 355–56.

⁶¹ In extreme cases, these changes may not only interfere with the normal function of a protein, but can even render it toxic. See D. Alan White et al., *Increased Sensitivity to Light-Induced Damage in a Mouse Model of Autosomal Dominant Retinal Disease*, 48 INVESTIGATIVE OPHTHALMOLOGY & VISUAL SCI. 1942 (2007) (describing how a single nucleotide change in the rhodopsin gene (which encodes an ocular protein that is essential for vision) results in the production of a mutant protein that is responsible not only for a progressive, degenerative form of blindness, but also an acute sensitivity to retinal damage from bright light).

⁶² 320 F.3d 1339 (Fed. Cir. 2003).

⁶³ 373 F.3d 1158 (Fed. Cir. 2004).

⁶⁴ 320 F.3d at 1354.

⁶⁵ *Id.* at 1343. Attenuated viruses are viruses that have been grown in tissue culture for several generations. These viruses develop mutations that allow them to better survive in tissue culture, but that

introduced evidence showing that the two viruses differed by at least seventy-three nucleotides, and that the accused infringing virus exhibited substantial differences from the original, including the fact that it did not make pigs sick upon inoculation, and exhibited poor growth in porcine lung macrophages.⁶⁶ In spite of these arguments, the Federal Circuit upheld the lower court's judgment of infringement, ruling that a reasonable jury could have found infringement under the doctrine of equivalents and stating, "While it may be reasonable to assume that genetic similarity is a relevant comparison between the viruses[,] . . . the jury was presented with expert testimony that the two viral genomes are highly similar overall and that any differences between the two are insignificant."⁶⁷

This case provides a wonderful illustration of the difficulties inherent in applying the doctrine of equivalents in a biologics context. The fact that the two viruses were so different in their nucleotide sequences, yet were still found to be equivalent, leads one to wonder how many nucleotide changes would be required to convince a fact-finder that an accused virus was not performing substantially the same function in substantially the same way to achieve the same result. If seventy-three nucleotide differences were not enough to demonstrate that the two viruses were not equivalent, would one hundred differences have been enough? Half of the genome?⁶⁸

Perhaps instead of highlighting nucleotide sequence differences, attorneys for a similarly accused infringer should rather point out nucleotide substitutions that change the structure of the proteins they encode in ways that alter the proteins' functionality, thus undermining the "function" leg of the "function-way-result" triumvirate. However, highlighting differences between two viruses at a functional level may not prove any more enlightening to a fact-finder undertaking a doctrine of equivalents analysis than pointing out differences in DNA sequence, as is illustrated by the fact that the two viruses in *Boehringer* indeed exhibited differing efficacy as vaccines.⁶⁹ Although the

reduce their virulence in a native host. Attenuated viruses that still elicit a host immune response are often useful as vaccines. *Id.* at 1343–44.

⁶⁶ *Id.* at 1351–52.

⁶⁷ *Id.* at 1352.

⁶⁸ A genome is an organism's entire set of DNA. See MATT RIDLEY, *GENOME: THE AUTOBIOGRAPHY OF A SPECIES IN 23 CHAPTERS* (2001) (providing a chromosome-by-chromosome examination of the human genome).

⁶⁹ See 320 F.3d at 1351. In fact Schering–Plough, the accused infringer in this case, relied heavily upon this fact in trying to prove noninfringement, arguing that its virus generated "a protective immune response when administered to pigs, while a pig inoculated with [plaintiff's virus] develops PRRS." *Id.*

Boehringer court avoided this question by focusing upon the activity of the viruses in their production phase, ruling that vaccine efficacy was irrelevant to the question of whether the two viruses lacked substantial differences in their ability to be grown and propagated in a specific cell type,⁷⁰ the case nevertheless provides an illustration of the difficulties inherent in determining equivalence in a biologics context.

Goldenberg v. Cytogen involved patents claiming radiolabeled antibodies that could be used as markers for detecting cancer cells.⁷¹ The accused infringing product, ProstaScint, was designed to screen for prostate tumors,⁷² and consisted of a radiolabeled antibody that targeted the intracellular portion of a transmembrane antigen.⁷³ The plaintiff's patent claimed cancer detection methods using labeled antibodies targeting "intracellular antigens."⁷⁴ The U.S. District Court for the District of New Jersey granted summary judgment in favor of the accused infringer.⁷⁵ In its decision, that court construed the phrase "intracellular marker substance" as defining "an antigen existing *within* a body cell."⁷⁶ It held that this distinguished the patentee's claims from the accused infringer's product, which targeted markers that were "integral to the plasma membrane and . . . cell surface antigen[s]."⁷⁷ The district court refused to accede to the plaintiff's request to define "intracellular marker substance" as including "sub-units of antigens," which would have strengthened the plaintiff's case under the doctrine of equivalents because ProstaScint's binding site, while localized to the cell membrane, was nevertheless intracellular.⁷⁸

⁷⁰ *Id.* ("[W]hat happens when the virus is administered to a pig is irrelevant to the assessment of whether the two viral strains are equivalent The fact that, in other contexts, [accused infringer's virus] can perform other functions in different ways to yield a different result is not relevant.")

⁷¹ 373 F.3d 1158 (Fed. Cir. 2004). Antibodies are specialized proteins created by the immune system to identify foreign objects, including proteins, bacteria, and viruses. Immunologists refer to such foreign objects as antigens. Antibodies bind specifically to antigens at target sites called epitopes. See HARVEY LODISH ET AL., *MOLECULAR CELL BIOLOGY* (6th ed. 2007) (providing a basic treatment of these and other molecular biology concepts). Radiolabeled antibodies are antibodies that have been conjugated to radioactive tracer materials. The tracers enable such antibodies to be used for localizing targets, such as tumor cells, within a living body. See A. Bischof Delaloye & B. Delaloye, *Tumor Imaging with Monoclonal Antibodies*, 25 *SEMINARS NUCLEAR MED.* 144 (1995) (reviewing the history of tumor localization using radiolabeled antibodies).

⁷² *Goldenberg*, 373 F.3d at 1162.

⁷³ *Id.*

⁷⁴ *Id.* at 1160–63.

⁷⁵ *Goldenberg v. Cytogen, Inc.*, No. 00-763 (AET), 2003 U.S. Dist. LEXIS 26075 (D.N.J. Apr. 29, 2003), *aff'd in part, rev'd in part*, 373 F.3d at 1158.

⁷⁶ *Id.* at *4 (emphasis added).

⁷⁷ *Id.* at *9.

⁷⁸ *Id.* at *4.

The district court paid significant attention to the prosecution history of the patents in question,⁷⁹ as well as the testimony of experts for both parties.⁸⁰ In announcing its decision, the court stated:

Defendants argue that ProstaScint does not bind to an antigen located within a tumor cell. Instead, ProstaScint targets PSMA. The Court has determined that PSMA is a cell surface antigen not an intracellular marker substance. Furthermore, plaintiff's discussion of "function" and "way" ignores the distinction . . . between antibodies that bind to intracellular antigens and those that bind to cell surface ones. In sum, plaintiffs have not met the requirements of the "function-way-result" test.⁸¹

The Federal Circuit reversed the lower court's grant of summary judgment under the doctrine of equivalents, and remanded for consideration as to whether an antibody targeting an *intracellular domain* of a *transmembrane* antigen is the equivalent of an antibody targeting an *intracellular* antigen.⁸² In its ruling, the Federal Circuit rejected the district court's classification of transmembrane epitopes as being distinct from intracellular epitopes, holding that "[t]ransmembrane antigens . . . appear to be a category of their own, and are not susceptible to the black and white categorization made by the district court."⁸³ Accordingly, the Federal Circuit ruled that the plaintiff had presented a sufficient factual dispute under the doctrine of equivalents to avoid summary judgment.⁸⁴

The disconnect between the rulings of the district court and the Federal Circuit in *Goldenberg v. Cytogen* provides another example of the difficulties inherent in applying the doctrine of equivalents to cases involving biologics. Whereas the district court was obviously persuaded by the defendant's argument that the intracellular domain of a transmembrane antigen was not equivalent to an intracellular antigen, the Federal Circuit found there to be a factual dispute as to the equivalency of the two. The fact that disagreement could exist between the two courts suggests that a jury facing similar questions

⁷⁹ See *supra* note 49.

⁸⁰ *Goldenberg*, 2003 U.S. Dist. LEXIS 26075, at *5–18.

⁸¹ *Id.* at *17 (citation omitted).

⁸² *Goldenberg*, 373 F.3d at 1168–69. In other words, the question was whether an antibody targeting an antigen that was completely within a target cell (an *intracellular* antigen) was the equivalent of an antibody targeted to the intracellular part of an antigen that was embedded within the membrane of a target cell (the intracellular portion of a *transmembrane* antigen). See *supra* note 71.

⁸³ *Goldenberg*, 373 F.3d at 1168.

⁸⁴ *Id.* at 1169.

would be similarly conflicted, if not more so. It must also be considered that a jury confronting the already difficult scientific issues at hand would, unlike the judges of the district court and the Federal Circuit, presumably also be unfamiliar with the legal niceties involved in applying the doctrine of equivalents.

Among other things, this jury would have to be educated as to the meaning of such scientific concepts as the difference between the “intracellular” and “extracellular” portions of a cell, membrane biology (including the definition of “transmembrane”), the workings of the immune system, by which “antibodies” interact with “epitopes,” which are in turn simply portions of “antigens,” and the process by which such “antibodies” can be “radiolabeled” with radioactive tracers and used to localize certain “epitopes” associated with cancers. In the end, any jury considering the question would be subjected to the conflicting testimony of various scientific experts hired by the opposing parties, each providing complex evidence to support her view, and further obscuring the central issues of the case with technical details.⁸⁵ After this crash course in graduate-level molecular and cell biology, the jury would finally be expected to render a decision concerning a dispute about which both scientific and judicial experts were unable to reach a consensus. One sympathizes.

III. FURTHER ANALYZING THE DIFFICULTIES INHERENT IN APPLYING THE DOCTRINE OF EQUIVALENTS TO BIOLOGICS CASES

Part II illustrated the difficulties inherent in applying the doctrine of equivalents to cases involving biologics. The discussions of *Boehringer* and *Goldenberg* highlighted the complex nature of the issues confronting attorneys, judges, and juries dealing with biologics patents.⁸⁶ This Part discusses additional factors that must be addressed when considering the doctrine of equivalents in a biologics context. First, this Part further explores the difficulties, alluded to above, that typical juries have in deciding cases involving complex scientific or technical concepts. Next, it examines more

⁸⁵ See Stephen Daniels, *The Question of Jury Competence and the Politics of Civil Justice Reform: Symbols, Rhetoric, and Agenda-Building*, 52 LAW & CONTEMP. PROBS. 269, 280 (1989) (“[J]uries are likely to be misled or confused in [complex] cases by the ‘battle of experts’ over the technical evidence, thereby eliminating any chance for a fair, rational decision.”).

⁸⁶ Of course, this is just the beginning. Given the increasing popularity of biologics, see *supra* notes 8–14 and accompanying text, novel biologics of increasing complexity can be expected to be developed apace, presenting even greater challenges for discerning equivalency.

fully the “Fair Protection-Certainty Conundrum” mentioned above,⁸⁷ and argues that the inherent uncertainty created by the doctrine of equivalents in broadening patent scope has a particularly chilling effect upon biologics innovation. Finally, this Part argues that licensing, which can often provide at least a partial remedy against the potential of the doctrine of equivalents to chill innovation, is generally not an acceptable alternative in the field of biologics.

A. Juries Are Likely to Have Difficulty Resolving Cases Dealing with Biologics

One of the biggest drawbacks of the doctrine of equivalents in biologics cases is that, in the absence of summary judgment, disputed matters of fact fall to a jury decision. In *Boehringer*, the court ruled on an appeal of a renewed motion for summary judgment filed by the accused infringing party.⁸⁸ As such, the court was limited in its review, and could overturn the lower court’s denial of the motion “only if the jury’s factual findings are not supported by substantial evidence, or if the legal conclusions implied in the jury’s verdict cannot be supported by that evidence.”⁸⁹ Unfortunately, there is substantial evidence that juries have difficulty resolving cases involving complex scientific issues of the sort common to biologics patent disputes.⁹⁰ The typical juror has achieved a high school education or its equivalent, often has difficulty understanding complex jury instructions, and is easily misled by expert testimony.⁹¹

The limitations of the typical jury present a huge problem for parties to biologics patent disputes, which involve technologies at the forefront of

⁸⁷ See *supra* note 34 (describing the “Fair Protection-Certainty Conundrum”).

⁸⁸ *Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp.*, 320 F.3d 1339, 1350 (Fed. Cir. 2003).

⁸⁹ *Id.* (citing *Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1454 (Fed. Cir. 1998)).

⁹⁰ See generally Alan Feigenbaum, *Special Juries: Deterring Spurious Medical Malpractice Litigation in State Courts*, 24 CARDOZO L. REV. 1361, 1389–96 (2003) (concluding that the average juror lacks the educational background necessary to understand the “testimony . . . concerning complex scientific and technical evidence” that is often presented in medical malpractice cases); Jody Weisberg Menon, *Adversarial Medical and Scientific Testimony and Lay Jurors: A Proposal for Medical Malpractice Reform*, 21 AM. J.L. & MED. 281, 281 (1995) (examining the “special problems” confronted by jurors attempting to understand expert testimony involving “medical and scientific issues” in medical malpractice cases).

⁹¹ Feigenbaum, *supra* note 90; Menon, *supra* note 90; see also Janet C. Hoeffel, *The Dark Side of DNA Profiling: Unreliable Scientific Evidence Meets the Criminal Defendant*, 42 STAN. L. REV. 465, 510 (1990) (highlighting potential drawbacks to the use of DNA profiling in criminal trials, and noting the potential for expert witnesses to mislead lay juries with complex scientific evidence).

innovation, and where issues may hinge upon legal and scientific concepts that even experts can have difficulty understanding.⁹² The possibility that juries can be fooled by the clever use of complicated scientific testimony is especially troubling in biologics cases involving the doctrine of equivalents, as both the Supreme Court and the Federal Circuit have stressed the importance of expert testimony in such cases.⁹³ It was presumably with these issues of jury qualification in mind that the Supreme Court ruled in *Markman v. Westview Instruments, Inc.* that in patent disputes, questions of claim construction were matters for the court, rather than the jury, to decide.⁹⁴ However, reserving claim construction for the courts does not change the fact that in cases involving the doctrine of equivalents, ultimate questions of fact are often decided by juries⁹⁵ that are poorly equipped to deal with complex scientific issues.⁹⁶

Several solutions have been proposed to deal with this problem. Some commentators have suggested that the federal jury selection procedures should be amended to create “special juries” that consist of jurors meeting a certain threshold of education, such as a college degree.⁹⁷ However, it could be argued that this might not provide an adequate solution to the problem, as possession of a college degree is not necessarily a sinecure for ensuring a

⁹² See Gregory D. Leibold, *In Juries We Do Not Trust: Appellate Review of Patent-Infringement Litigation*, 67 U. COLO. L. REV. 623, 623 (1996) (noting that “[t]he rapid increase in the complexity of technology being patented (especially in the computer-related and biological fields) has made patent trials extremely difficult for average jurors to understand,” and recommending the use of special juries to address these concerns); see also Feigenbaum, *supra* note 90, at 1364–65 (also advocating the use of special juries in medical malpractice cases involving complicated scientific testimony).

⁹³ *AquaTex Indus. v. Techniche Solutions*, 479 F.3d 1320, 1329 (Fed. Cir. 2007) (“Both the Supreme Court and this court have made clear that the evidence of equivalents must be from the perspective of someone skilled in the art, for example through testimony of experts or others versed in the technology.” (quoting *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 609 (1950)) (internal quotation mark omitted)).

⁹⁴ 517 U.S. 370, 388 (1996).

⁹⁵ See *Hilton Davis Chem. Co. v. Warner-Jenkinson Co.*, 62 F.3d 1512, 1522 (Fed. Cir. 1995) (holding that determination of infringement under the doctrine of equivalents is a question of fact for the jury), *rev'd*, 520 U.S. 17 (1997).

⁹⁶ Potential issues affecting the ability of jurors to process scientific evidence may even arise from such mundane sources as popular television programs. Evidence of this can be found in a study documenting the “CSI effect,” in which “juror expectations and demands about scientific evidence” were shown to have been increased by the popularity of the hit television series *CSI: Crime Scene Investigation*, with the result being that jurors “have high expectations that the prosecutor will present some scientific evidence in virtually every criminal case.” Donald E. Shelton et al., *A Study of Juror Expectations and Demands Concerning Scientific Evidence: Does the “CSI Effect” Exist?*, 9 VAND. J. ENT. & TECH. L. 331, 333, 336, 367 (2006).

⁹⁷ See *supra* note 92 (citing articles that describe the issue of juror confusion and recommending the use of expert juries).

juror's understanding of complicated scientific issues. Others have advocated the use of alternative dispute resolution as a means for parties in commercial intellectual property disputes to avoid the perils of ordinary litigation through the use of skilled mediators or arbitrators, or even by "creat[ing] their own trial with an expert judge and even a panel of expert jurors."⁹⁸ However, in cases involving biologics, and especially follow-on biologics, parties may be unlikely to turn to alternative dispute resolution. This is because the patent holder, not wanting to lose its limited monopoly, may have little or no incentive to negotiate with a follow-on manufacturer, while conversely the follow-on manufacturer wins nothing unless it is successful in challenging the patent or proving that its product does not infringe.

In the absence of better options, courts may choose to keep biologics cases from the jury whenever possible by ruling summarily on infringement under the doctrine of equivalents, exercising their traditional judicial prerogatives over claim construction and, in appropriate situations, applying limits upon the doctrine such as the all-limitations rule or prosecution history estoppel.⁹⁹ However, as biologic pharmaceuticals become increasingly successful and more products are brought to market, the number of disputes over ownership of biologics patents will only increase.¹⁰⁰ This will inevitably result in more biologics cases involving the doctrine of equivalents, presenting difficult questions of fact that are not amenable to summary judgment.¹⁰¹ These cases will be decided by juries that in many cases simply are not well prepared to handle them.

⁹⁸ Scott H. Blackman & Rebecca M. McNeill, *Alternative Dispute Resolution in Commercial Intellectual Property Disputes*, 47 AM. U. L. REV. 1709, 1716 (1998); see also *infra* Part III.B (discussing the merits of expert juries for deciding technologically complex cases).

⁹⁹ In fact, the Supreme Court in *Warner-Jenkinson Co. v. Hilton Davis Chemical Co.* indirectly addressed these same concerns over the ability of the common jury to handle complicated patent issues. 520 U.S. 17, 39 n.8 (1997). Interestingly, the Court did not directly rule upon whether the doctrine of equivalents is even a question for the jury. *Id.* at 39; see also David R. Todd, *How Modern Treatment of 35 U.S.C. § 112(6) Has Caused Confusion: Hilton Davis v. Warner-Jenkinson and the Right to a Jury on the Issue of Patent Infringement Under the "Equitable" Doctrine of Equivalents*, 1996 BYU L. REV. 141 (outlining the historical controversy over the jury's role in decisions involving the doctrine of equivalents). *But cf. infra* note 202 and accompanying text (cautioning against underestimating the capacity of lay jurors to participate meaningfully in complex litigation).

¹⁰⁰ See *supra* notes 8–14, 160 and accompanying text (describing the increasing popularity of biologic pharmaceuticals).

¹⁰¹ See *supra* Part II.

B. *The Doctrine of Equivalents Chills Innovation in the Biologics Arena*

Commentators aptly describe patent law as “a utilitarian set of property rules that derives legitimacy to the extent it promotes innovation and welfare.”¹⁰² As has been discussed, patents are basically compromises between the government and the patent holder in which the former grants the latter a limited monopoly over the invention in question in return for the latter’s disclosure to the public the methods for creating the invention.¹⁰³ Patent law is very specific about the requirements for such disclosures, in that they must be enabling or, in other words, must teach a “person skilled in the art to which it pertains” how to practice the invention.¹⁰⁴ The requirement for enabling disclosures is thought to be a key for promoting innovation, as later inventors can examine the methods of creating the patented invention, and thus learn how to improve upon it.¹⁰⁵ However, as long as the original patent is in effect, subsequent innovators cannot practice improved inventions that would infringe upon the original; therefore, to encourage innovation, the ideal patent would very clearly delineate exactly what its claims protect. This is sometimes referred to as the “notice” function of patents.¹⁰⁶ The doctrine of equivalents by its very nature allows the scope of protection to be enlarged beyond the literal claims of the patent, thus defeating, to a certain extent, the notice function of patents.¹⁰⁷ This can have a stifling effect upon innovation,¹⁰⁸ particularly in the field of biologics.

¹⁰² Alden F. Abbott & Suzanne T. Michel, *The Right Balance of Competition Policy and Intellectual Property Law: A Perspective on Settlements of Pharmaceutical Litigation*, 46 IDEA 1, 8 (2005).

¹⁰³ See, e.g., *Graham v. John Deere Co.*, 383 U.S. 1, 5–6 (1966) (describing the Constitution’s Patent Clause as “both a grant of power and a limitation,” and observing that Congress “may [not] enlarge the patent monopoly without regard to the innovation, advancement or social benefit gained thereby”); see also *supra* notes 15, 17 (discussing the incentive structure of the patent system).

¹⁰⁴ 35 U.S.C. § 112 (2006). “The enablement requirement ensures that the public knowledge is enriched by the patent specification to a degree at least commensurate with the scope of the claims.” *Nat’l Recovery Techs., Inc. v. Magnetic Separation Sys., Inc.*, 166 F.3d 1190, 1195–96 (1999).

¹⁰⁵ “The scope of enablement . . . is that which is disclosed in the specification plus the scope of what would be known to one of ordinary skill in the art without undue experimentation.” *Nat’l Recovery Techs.*, at 1196. *But see* Holbrook, *supra* note 17, at 136–39 (arguing that disclosure requirements are actually more important for demonstrating possession of an invention (and therefore the right to a patent) than for teaching the public about the invention).

¹⁰⁶ See Karen Millane Whitney, *Sources of Patent Prosecution History Must Not Violate Public Notice Requirement*, 32 SETON HALL L. REV. 266, 271 (2001) (“Patents primarily function to give the public notice.”); see also *supra* notes 15, 17 (discussing notice and the incentive structure of the patent system).

¹⁰⁷ See Holbrook, *supra* note 17 (describing notice as the primary purpose of disclosure); Nicole S. Robbins, Note, *The Curtailment of the Doctrine of Equivalents: Courts Emphasize the Public Notice Function of Patent Claims*, 35 SUFFOLK U. L. REV. 323 (2001) (describing conflict between the doctrine of equivalents and the notice function of patents); *supra* notes 34, 44 (describing Professor Chisum’s “Fair Protection-

Courts, judges, and scholars have struggled with and quarreled over this drawback of the doctrine of equivalents since its creation.¹⁰⁹ Some of the strongest criticism of the modern doctrine of equivalents has come from within the Supreme Court itself.¹¹⁰ In his dissent in *Graver Tank*, Justice Black lamented the Court's expansion of the doctrine beyond its traditional limits as a "sterilization of Acts of Congress and prior decisions," and went on to conclude that the Court's decision

treat[s] a patent claim "like a nose of wax, which may be turned and twisted in any direction . . . so as to make it include something more than, or something different from, what its words express. . . . The claim is a statutory requirement, prescribed for the very purpose of making the patentee define precisely what his invention is; and it is unjust to the public, as well as an evasion of the law, to construe it in a manner different from the plain import of its terms." Giving [a] patentee the benefit of a grant that it did not precisely claim is no less "unjust to the public" and no less an evasion of [statutory requirements] merely because done in the name of the "doctrine of equivalents."¹¹¹

Striving for clarity and a bright-line interpretation of patent law, the Court of Appeals for the Federal Circuit began severely limiting the application of the doctrine of equivalents in its decisions.¹¹² As discussed in Part I, however, the

Certainty Conundrum" and observing that the Supreme Court has recognized the tension between the doctrine of equivalents and the notice function of patents).

¹⁰⁸ See, e.g., Joshua D. Sarnoff, *Abolishing the Doctrine of Equivalents and Claiming the Future After Festo*, 19 BERKELEY TECH. L.J. 1157 (2004) (arguing that the doctrine of equivalents impedes innovation).

¹⁰⁹ See *id.*

¹¹⁰ *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 612–18 (1950) (Black, J., dissenting).

¹¹¹ *Id.* at 613–14 (third alteration in original) (quoting *White v. Dunbar*, 119 U.S. 47, 51 (1886)).

¹¹² See Timothy R. Holbrook, *The Supreme Court's Complicity in Federal Circuit Formalism*, 20 SANTA CLARA COMPUTER & HIGH TECH. L.J. 1, 1 (2003) ("The Federal Circuit increasingly has articulated rules of law to promote certainty, at the expense of fairness. The root of this bias likely derives from the court's Congressional mandate to promote uniformity and certainty in patent law."); Michael J. Meurer & Craig Allen Nard, *Invention, Refinement, and Patent Claim Scope: A New Perspective on the Doctrine of Equivalents*, 93 GEO. L.J. 1947, 1951–53 (2005) (sympathizing with the Federal Circuit's concerns over the uncertainty engendered by the doctrine of equivalents, but noting that "the [doctrine of equivalents] creates a social benefit by allowing patent applicants to avoid certain refinement costs during patent prosecution"). But see Doug Lichtman, *Substitutes for the Doctrine of Equivalents: A Response to Meurer and Nard*, 93 GEO. L.J. 2013, 2032 (2005) (arguing that the doctrine of equivalents is necessary to protect patentees from unforeseen technological developments, to prevent "wasteful efforts to perfect claim language," and to allow the patent system to make good decisions "by bringing into the process information that is for various reasons unavailable early in the life of the patent").

Supreme Court in *Warner-Jenkinson*¹¹³ and *Festo*¹¹⁴ rejected these stringent limitations, and articulated the current, more flexible limits of the doctrine.¹¹⁵

The conflicts highlighted above are at the heart of the “Fair Protection-Certainty Conundrum,” coined by Professor Chisum in 1998.¹¹⁶ Professor Chisum argued that patent law involved constant tension between “Certainty” and “Fairness”:

There is clearly an interest in providing a clear definition of the scope of the patent right; lack of clarity can impede legitimate investment in technology-based products and services. On the other hand, strict and literal adherence to the written claim in determining the scope of protection can invite subversion of a valuable right and substantially diminish the economic value of patents.¹¹⁷

The doctrine of equivalents is the perfect embodiment of this conundrum. While on the one hand, it provides patentees with a remedy to guard against the inequitable conduct of copyists who could skirt patent protection by making “unimportant and insubstantial changes” to patented devices,¹¹⁸ this comes at the expense of a broadening of the scope of patent protection that can substantially increase uncertainty.¹¹⁹

¹¹³ *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17 (1997). Here, the Court stated, in perhaps the most convincing (and final) pronouncement concerning its support for the doctrine, “Congress can legislate the doctrine of equivalents out of existence any time it chooses. The various policy arguments now made by both sides are thus best addressed to Congress, not this Court.” *Id.* at 28. The Court later repeated this argument verbatim in its *Festo* decision. *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 733 (2002).

¹¹⁴ 535 U.S. at 722.

¹¹⁵ See Sarnoff, *supra* note 108 (criticizing the Court’s articulation of the modern doctrine of equivalents).

¹¹⁶ Chisum, *supra* note 34.

¹¹⁷ *Id.* at 7.

¹¹⁸ See *Graver Tank & Mfg. Co. v. Linde Air Products Co.*, 339 U.S. 605, 607 (1950) (noting that the doctrine of equivalents exists to prevent the “unscrupulous copyist” from “mak[ing] unimportant and insubstantial changes and substitutions to the patent which, though adding nothing, would be enough to take the copied matter outside the claim, and hence outside the reach of law”).

¹¹⁹ Timothy R. Holbrook, *Equivalency and Patent Law’s Possession Paradox*, 23 HARV. J.L. & TECH. 1, 46 (2009) (“[A]ssessing the literal scope of a patent is rife with uncertainty. The use of the doctrine of equivalents to expand patent scope compounds this uncertainty, creating high transaction costs for third parties in assessing the scope of the patentee’s right to exclude.” (footnote omitted)); see also Sarnoff, *supra* note 108, at 1167 (“Whatever equivalency standard is applied, the modern doctrine necessarily expands patent scope and renders it more uncertain than direct application of construed claim language. The modern doctrine adds to the scope of application of construed claims.”).

This broadening of patent scope can have a particularly chilling effect upon innovation in the field of biologics.¹²⁰ As Part II illustrated, the complexity of biologics technology can make patent boundaries inherently uncertain in the first place; the doctrine of equivalents increases this uncertainty.¹²¹ This is illustrated in *Boehringer*, where the court's decision ultimately gave the patentee rights to an amorphous class of viruses grown in a specific cell type, regardless of the properties that those viruses later exhibited as therapeutic agents, with the limits of the class being defined only by the ephemeral constraints of the doctrine of equivalents.¹²² In effect, the *Boehringer* decision provides a template to creators of vaccines for crafting patents in a way that would stifle innovation by keeping improved versions of the vaccine off the market.¹²³

Unpredictability in patent rights leads to increased transaction costs with respect to licensing of potential blocking patents,¹²⁴ as well as increased operating costs due to the possibility of unexpected litigation.¹²⁵ These increased operating costs are a significant barrier to follow-on innovators in the field of biologics that already face high operating costs due to difficulties and risks that are not shared by typical generic drug manufacturers.¹²⁶ This could prevent many potential innovators from entering the biologics market altogether, with the resultant lack of innovation hurting consumers that would otherwise benefit from the wider selection of less costly and more effective biologics that increased competition in the industry would provide.¹²⁷ It is important for courts to recognize the drawbacks of such uncertainty, and exercise restraint over the application of the doctrine of equivalents in

¹²⁰ Arti K. Rai, *Fostering Cumulative Innovation in the Pharmaceutical Industry: The Role of Patents and Antitrust*, 16 BERKELEY TECH. L.J. 813, 813 (2001) ("In the context of the biopharmaceutical industry, broad patents, particularly on upstream invention, represent the main threat to competition.").

¹²¹ See *supra* note 119.

¹²² See *supra* Part II.

¹²³ See *supra* Part II.

¹²⁴ See *infra* Part III.C.

¹²⁵ See *infra* note 144.

¹²⁶ See Henry Grabowski et al., *The Market for Follow-On Biologics: How Will It Evolve?*, 25 HEALTH AFF. 1291, 1300 (2006) ("[I]ncreased uncertainty and IP litigation in biotech also would have major significant negative-incentive effects on capital market decisions for developing private and public biotech firms with promising pipelines."); Sahr, *supra* note 14, at 47–54 (citing special challenges that future manufacturers of biologic follow-ons are likely to face, including more stringent equivalency rules under FDA guidelines, higher fixed development costs associated with more onerous regulatory barriers, and the overall complexity of biologic therapeutics).

¹²⁷ See Sahr, *supra* note 14, at 41–56.

biologics cases to avoid unnecessarily broadening basic patents in a way that chills innovation in a field that is vital to public health.

C. *Licensing Is Not an Acceptable Solution*

The doctrine of equivalents creates uncertainty regarding patent scope and, as discussed above, this is perhaps even more true for biologics patents.¹²⁸ In many situations, patent disputes involving truly valuable technologies are resolved through the use of licensing agreements, with the owner of the patent licensing its use to another party.¹²⁹ However, while licensing agreements may provide an acceptable solution to patent conflicts in many industries, there is evidence that they are of limited use in the field of biologics,¹³⁰ especially in cases where the doctrine of equivalents is involved.¹³¹

Licensing can be expected to occur when patents are distributed evenly among firms participating in a particular industry.¹³² Such firms have a strong incentive to cross-license intellectual property when “their interests are symmetrical: they need their competitors’ patents just as much as the

¹²⁸ See *supra* Part II.B.

¹²⁹ See Joseph C. Cianfrani, *An Economic Analysis of the Doctrine of Equivalents*, 1 VA. J.L. & TECH. 1 (1997) (noting that in many instances such problems may be resolved through licensing or outright purchase of the patent in question). *But see* Abbott, *supra* note 102 (examining the antitrust issues inherent in the controversial practice of “reverse payments” by pioneer drug firms to follow-on competitors). Some commentators have even suggested that patent law could be modified to allow for compulsory licensing in certain instances, noting that the German Patent Act in section 24 provides for “compulsory license in cases in which a patentee is not willing to license for reasonable compensation.” Rochelle Cooper Dreyfuss, *Collaborative Research: Conflicts on Authorship, Ownership, and Accountability*, 53 VAND. L. REV. 1161, 1230 n.263 (2000). *But see* Symposium, *Panel I: Do Overly Broad Patents Lead to Restrictions on Innovation and Competition?*, 15 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 947, 992 (2005) (“[P]eople, especially in the pharmaceutical industry, are very much opposed to compulsory licensing[;] . . . they believe that would be the death knell of innovation.”).

¹³⁰ See Rai, *supra* note 120, at 831–34 (arguing that historically, in industries relying on cumulative innovation, broad patents on initial inventions are not effectively licensed, and that “there are indications in the biopharmaceutical industry that development through tailored licensing will be difficult to achieve”).

¹³¹ See M. Aminthe Broussard, *Ambivalence in Equivalents: Problems and Solutions for Patent Law’s Doctrine of Equivalents*, 64 LA. L. REV. 119, 131 (2003) (arguing that restricting the application of the doctrine of equivalents would provide “clarity and certainty for potential infringers,” who then “could better make long-term decisions, such as whether to attempt to buy a license”); Qing Lin, *A Proposed Test for Applying the Doctrine of Equivalents to Biotechnology Inventions: The Nonobviousness Test*, 74 WASH. L. REV. 885, 898 (1999) (observing that the “function-way-result” and “known interchangeability” tests that have traditionally been used to resolve questions involving the doctrine of equivalents are “not applicable to certain infringement disputes in biotechnology”).

¹³² See Mark A. Lemley, *Patenting Nanotechnology*, 58 STAN. L. REV. 601, 623–27 (2005) (describing licensing as a solution to over-patenting in the burgeoning field of nanotechnology).

competitors need their patents.”¹³³ However, this ideal situation rarely exists in the real world, especially in fields in which basic technologies have become so heavily patented as to create a “patent thicket.”¹³⁴ Patent owners in such fields may be reluctant to license valuable technologies, especially to potential competitors in the same industry.¹³⁵ Accordingly, a patent holder like the one in *Boehringer*¹³⁶ might be reluctant to license its virus production methods to an accused infringer that is a potential competitor within the patent holder’s own industry.¹³⁷

Additionally, transaction costs associated with licensing agreements are exacerbated when there is uncertainty as to the value of the patent to be licensed.¹³⁸ The simple reason for this is that the interested parties have difficulty determining what subject matter is actually protected by the patent, and are thus unsure of its value.¹³⁹ The doctrine of equivalents leads to uncertainty regarding the scope of patent coverage,¹⁴⁰ particularly with respect to biologics patents.¹⁴¹ This increase in uncertainty leads to high transaction costs, making it less likely that conflicts over patent infringement in the field of biologics arising under the doctrine of equivalents will be resolved through licensing agreements.¹⁴² Accordingly, even if a patent holder such as the one in *Boehringer* was willing to license its technology to a competitor, the fact that the doctrine of equivalents makes the limits of the patent itself uncertain could prevent the parties from reaching an agreement. For instance, the patent

¹³³ *Id.* at 623.

¹³⁴ A “patent thicket” is “an overlapping set of patent rights requiring that those seeking to commercialize new technology obtain licenses from multiple patentees.” Carl Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard Setting*, in 1 INNOVATION POL’Y & ECON. 119, 119–22 (Adam B. Jaffe, Josh Lerner & Scott Stern eds., 2001).

¹³⁵ See Lemley, *supra* note 132, at 625 (describing the breakdown of “efficient licensing” when a “patent thicket” develops).

¹³⁶ See *supra* Part II.

¹³⁷ See Natasha N. Aljalian, *The Role of Patent Scope in Biopharmaceutical Patents*, 11 B.U. J. SCI. & TECH. L. 1, 23 n.88 (2005) (describing biotech patent thickets created when the “sheer number of gene patents essentially precludes the use of any of the disclosed information by researchers unless multiple licenses and permissions are obtained”); see also *infra* notes 195–96 and accompanying text (describing another situation where licensing did not provide the solution to a biotech patent dispute).

¹³⁸ See Cianfrani, *supra* note 129, at para. 2 n.2 (observing that disputes over a patent’s value may be “exacerbated by any uncertainty in the patent system, especially by the doctrine of equivalents as the parties can have widely divergent views on whether the patent is infringed”).

¹³⁹ *Id.*

¹⁴⁰ See Lichtman, *supra* note 112, at 2031 (“The doctrine makes patent scope less certain and through that stands in the way of negotiation and compliance efforts.”)

¹⁴¹ Lin, *supra* note 131; see also *supra* Part II (providing case study examples of the uncertainty engendered by the doctrine of equivalents in a biologics context).

¹⁴² See Cianfrani, *supra* note 129.

holder may believe that its patent covers more subject matter under the doctrine of equivalents than it truly does, leading it to charge a prohibitively high licensing fee.¹⁴³ Conversely, the potential licensee might feel that it could modify its own invention in order to escape the doctrine's penumbra.¹⁴⁴ In any event, the inherent uncertainty of patent rights is clouded by the doctrine of equivalents, and this is especially pronounced in such cutting-edge fields as biologics. Such uncertainty makes licensing decisions risky for the interested parties, driving up transaction costs and stifling innovation. This is especially troubling for biologics, where innovation through both direct competition and follow-on products is necessary to make the public health benefits of these miracle breakthroughs widely available at the most reasonable cost.¹⁴⁵ The failure of licensing to provide an effective outlet for innovation underscores the need for courts to prevent biotechnology patent rights from becoming overly broadened through the use of the doctrine of equivalents.¹⁴⁶

IV. ENSURING PROPER APPLICATION OF THE DOCTRINE OF EQUIVALENTS IN BIOLOGICS CASES

As the Supreme Court noted in *Warner-Jenkinson*, "Congress can legislate the doctrine of equivalents out of existence any time it chooses."¹⁴⁷ At first glance this solution may appear attractive, considering the difficulties inherent in applying the doctrine in a biologics context.¹⁴⁸ However, while legislative

¹⁴³ See Broussard, *supra* note 131, at 133 (noting situations involving the doctrine of equivalents where "some patentees were seeking greater coverage than their patents allowed[,] . . . blackmailing competitors into paying licensing fees"); Rai, *supra* note 120, at 834 (arguing that such disagreements over patent worth are "particularly likely in the context of upstream molecular biology research because the negotiating parties are often scientists who may overestimate the value of their scientific contribution").

¹⁴⁴ But the wise innovator will exercise caution when doing so, keeping in mind Justice Black's warning that an innovator "cannot rely on what the language of a patent claims. He must be able, at the peril of heavy infringement damages, to forecast how far a court relatively unversed in a particular technological field will expand the [patent's] language . . ." *Graver Tank & Mfg. Co. v. Linde Air Products Co.*, 339 U.S. 605, 617 (1950) (Black, J., dissenting).

¹⁴⁵ See *supra* notes 8–13; see also Sahr, *supra* note 14, at 47–48 ("Price competition among multiple follow-on manufacturers is essential to substantially lower the cost of biologics to consumers. Prices will not be significantly lowered until several interchangeable products reach the market.").

¹⁴⁶ See Rai, *supra* note 120, at 813 ("In the context of the biopharmaceutical industry, broad patents, particularly on upstream invention, represent the main threat to competition. Thus patent law needs to take the lead in preserving competition, primarily by limiting the scope of patents on upstream invention."); Broussard, *supra* note 131, at 131 (observing that costs arising because of the uncertainties engendered by the doctrine of equivalents are "passed along to consumers in the form of higher prices").

¹⁴⁷ *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 28 (1997).

¹⁴⁸ Alternatively, one could limit the abolishment of the doctrine of equivalents to cases involving biologics. Although this limitation would be a less drastic solution than totally abolishing the doctrine in all

abolishment of the doctrine would certainly tilt the “Fair Protection-Certainty” balance in the direction of greater certainty, this shift would of course be accompanied by the sacrifice of a certain amount of fairness to patentees. Patents exist to promote innovation.¹⁴⁹ As discussed previously, in a biologics context the application of the doctrine of equivalents can unduly dampen the incentives for follow-on innovators to create new and improved versions of pioneer biologics.¹⁵⁰ However, abolishing the doctrine altogether would tilt the balance too far in the other direction, narrowing the scope of patent protection and reducing the incentives for firms to develop pioneer biologics in the first place.¹⁵¹

The best solution to the problem of applying the doctrine of equivalents in biologics cases is therefore not to abolish the doctrine completely, but rather to carefully limit its application through a variety of means. This Part first discusses two legal limitations on the doctrine of equivalents (prosecution history estoppel and the all limitations rule), provides examples of biologics patent cases where these limitations were correctly brought into play, and prefaces the discussion with an argument that judges should apply these limitations with an eye toward protecting the public interest in biologics innovation. Next, this Part discusses the benefits of impaneling expert juries to resolve cases involving biologics patents. Finally, this Part argues that in cases where the doctrine of equivalents is applied in a biologics context, the patent holder should be denied injunctive relief—in effect limiting its remedy to a compulsory license. This would provide fair compensation to the patentee while still allowing the accused infringer to bring its product to market.

cases, it still leaves the not insignificant problem of defining what a biologic actually is. *See* Rader, *supra* note 8, at 743 (discussing the “Babel-like situation with terminological chaos and anarchy” that applies to defining biologics as a class).

¹⁴⁹ *See supra* note 19 and accompanying text.

¹⁵⁰ *See supra* Part III.B.

¹⁵¹ *See* Ryan Thomas Grace, *Losing the Forest Among the Trees in the Festo Saga—Rationalizing the Doctrine of Equivalents and Prosecution History Estoppel in View of the Historical Justifications for Patent Protection*, 11 J. INTELL. PROP. L. 275 (2004) (arguing that expansion of prosecution history estoppel following *Festo* unduly limits application of the doctrine of equivalents, reducing incentives for inventors to disclose inventions). *But see* Meurer & Nard, *supra* note 112, at 1998 (arguing that while the doctrine of equivalents is important to the patent system, it must nevertheless be restricted to maintain balance, and characterizing concerns that restricting the doctrine of equivalents will reduce incentives for innovation as “probably overstated”).

A. *Legal Limitations on the Doctrine of Equivalents*

An effective way to prevent misuse of the doctrine of equivalents to overly broaden biotechnology patent rights can be found in the power of the courts themselves to limit the doctrine's application. The Supreme Court in *Warner-Jenkinson* was fully cognizant of the danger that the doctrine of equivalents could acquire "a life of its own, unbounded by . . . patent claims."¹⁵² To guard against this, the Court specifically discussed various judicial limits that could be applied by the lower courts to militate against this threat.¹⁵³ In the years following *Warner-Jenkinson*, courts, striving for certainty in the field of patent law, began to rely heavily upon these judicial limitations to limit application of the doctrine of equivalents.¹⁵⁴ This culminated in the Federal Circuit's ruling that one of the limitations, prosecution history estoppel, provided a complete bar to the doctrine's application.¹⁵⁵ This holding was overruled by the Supreme Court's *Festo* decision, which held prosecution history estoppel to be, rather, an incomplete bar.¹⁵⁶ However, so long as the lower courts respect the Supreme Court's clear desire to preserve the doctrine as a means of protecting patent holders from the "unscrupulous copyist,"¹⁵⁷ these legal limitations can provide important means for limiting the doctrine's application to biologics cases. Moreover, these limitations are at the court's discretion, allowing issues involving the doctrine of equivalents in biologics cases to be resolved by summary judgment, avoiding altogether the problems associated with jury decisions in technologically complex cases.¹⁵⁸ A review of the caselaw reveals numerous instances where the courts have limited the reach of the doctrine in biologics cases.¹⁵⁹

¹⁵² 520 U.S. at 28–29; *see also supra* note 44.

¹⁵³ *See Warner-Jenkinson*, 520 U.S. at 39 n.8 (describing some of these limitations and noting that, "[o]f course, the various legal limitations on the application of the doctrine of equivalents are to be determined by the court, either on a pretrial motion for partial summary judgment or on a motion for judgment as a matter of law").

¹⁵⁴ *See supra* note 44 and accompanying text.

¹⁵⁵ *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 234 F.3d 558 (Fed. Cir. 2000), *vacated*, 535 U.S. 722 (2002).

¹⁵⁶ *Festo*, 535 U.S. at 737. The Court acknowledged concerns that the doctrine of equivalents led to inherent uncertainty in the field of patent law, but argued, "[t]hese concerns . . . are not new. Each time the Court has considered the doctrine it has acknowledged this uncertainty as the price of ensuring the appropriate incentives for innovation, and it has affirmed the doctrine over dissents that urged a more certain rule." *Id.* at 732; *see also supra* notes 47–52 and accompanying text.

¹⁵⁷ *See supra* note 29.

¹⁵⁸ *See supra* Part III.A.

¹⁵⁹ *See infra* Part IV.A.1.

Before discussing the legal limitations on the doctrine of equivalents, it is important to point out that innovation in the field of biologic pharmaceuticals is of great public interest, as these therapies have the potential to cure a variety of diseases that in the prebiologics era were untreatable.¹⁶⁰ Courts already factor the public interest into infringement analysis, particularly when considering permanent injunctions as a remedy for patent infringement.¹⁶¹ For example, in *Hybritech Inc. v. Abbot Laboratories*, the Federal Circuit upheld a lower court's refusal to grant a permanent injunction that would have prevented the distribution of cancer and hepatitis test kits.¹⁶² The field of biologics is particularly susceptible to the chilling effect that can occur when patent rights are overly broad or ambiguous.¹⁶³ Given the substantial public interest in continued innovation in the field of biologics, courts should apply the following limitations on the doctrine of equivalents (and indeed, should apply the doctrine of equivalents in general) to biologics cases, especially with respect to technologies that directly impact human health and safety, so as to increase the certainty of patent scope, thus preserving incentives for innovation in the field.

1. Prosecution History Estoppel

Prosecution history estoppel prevents a patentee from claiming as equivalents limitations that were surrendered during the patent application

¹⁶⁰ See, e.g., WENDY H. SCHACHT & JOHN R. THOMAS, CONG. RESEARCH SERV., RL 33901, FOLLOW-ON BIOLOGICS: INTELLECTUAL PROPERTY AND INNOVATION ISSUES 1 (2009) (“[T]he biologics market is rapidly expanding by any number of measures, including the quantity of approved products, the size of the market, and the importance of these drugs to the health of U.S. citizens.”); Ingrid Kaldre, *The Future of Generic Biologics: Should the United States “Follow-On” the European Pathway?*, 2008 DUKE L. & TECH. REV. 0009, <http://www.law.duke.edu/journals/dltr/articles/pdf/2008dltr0009.pdf> (discussing the “unique” promise these drugs hold for treating life-threatening diseases and discussing the obstacles facing generic versions of pioneer biologics); Caroline Lochhead, *Huge Boon for Biotech in Measure*, S.F. CHRON., Dec. 6, 2009, at A1 (describing biologics as “miracle breakthrough therapies” that may one day cure diseases like “AIDS, Parkinson’s, multiple sclerosis . . . and many others”); Karen Tumulty & Michael Scherer, *How Drug-Industry Lobbyists Won on Health-Care*, TIME (Oct. 22, 2009), <http://www.time.com/time/politics/article/0,8599,1931595-1,00.html> (“These miraculous drugs . . . are widely regarded as the future of the pharmaceutical industry and, indeed, of medicine itself. . . . As policymakers look for ways to control health-care costs, the price of biologics is drawing more and more scrutiny.”).

¹⁶¹ See *eBay Inc. v. Mercexchange, L.L.C.*, 547 U.S. 388, 391 (2006) (describing the four factors used to determine whether a permanent injunction should be granted, including whether “the public interest would not be disserved by a permanent injunction”).

¹⁶² 849 F.2d 1446, 1458 (Fed. Cir. 1988); see also *Datascope Corp. v. Kontron, Inc.*, 611 F. Supp. 889, 895 (D. Mass. 1985) (refusing to grant preliminary injunction on the sale of intra-aortic inflatable balloon catheters (IABs) in part because “the public will be harmed by an injunction [because] some physicians prefer defendant’s dual lumen IABs”), *aff’d*, 786 F.2d 398 (Fed. Cir. 1986).

¹⁶³ See *supra* Part III.B.

process.¹⁶⁴ The Supreme Court in *Festo* held that when a patentee makes an amendment to a patent application that narrows the scope of its claims without somehow explaining that the amendment was unrelated to patentability, this amendment creates a rebuttable presumption against subsequent assertion of the doctrine of equivalents to “reclaim” what was surrendered.¹⁶⁵ The Court went on to explain that this presumption could be rebutted when a narrowing amendment could not “reasonably be viewed as surrendering a particular equivalent,” and noted that such situations could arise when the surrendered equivalent was unforeseeable at the time of the amendment, when the rationale behind the amendment bore only a tangential relationship to patentability, or if for any other reason the patentee should not have reasonably been expected to have described the equivalent in question.¹⁶⁶ In addition to this “amendment-based estoppel,” courts also recognize “argument-based estoppel,” in which claim scope is surrendered by statements made to the patent examiner during patent prosecution.¹⁶⁷

Examples from recent caselaw illustrate instances in which courts have used prosecution history estoppel to prevent the use of the doctrine of equivalents to unduly broaden the scope of pharmaceutical and biologics patents. In *Schwarz Pharma, Inc. v. Paddock Laboratories, Inc.*, the Federal Circuit upheld a lower court’s decision to bar a patentee from using the doctrine of equivalents because of prosecution history estoppel.¹⁶⁸ The patentee, in response to an obviousness rejection by a patent examiner, had modified its claims regarding a generic version of an ACE inhibitor¹⁶⁹ so as to

¹⁶⁴ See *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 733–34 (2002) (describing how claim surrender triggers prosecution history estoppel).

¹⁶⁵ *Id.* at 740 (“When the patentee is unable to explain the reason for amendment, estoppel not only applies but also ‘bar[s] the application of the doctrine of equivalents as to that element.’ These words do not mandate a complete bar; they are limited to the circumstance where ‘no explanation is established.’” (alteration in original) (citation omitted) (quoting *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 33 (1997))).

¹⁶⁶ *Id.* at 740–41.

¹⁶⁷ See *Conoco, Inc. v. Energy & Envtl. Int’l, L.C.*, 460 F.3d 1349, 1363 (Fed. Cir. 2006) (“[P]rosecution history estoppel can occur during prosecution in one of two ways, either (1) by making a narrowing amendment to the claim (‘amendment-based estoppel’) or (2) by surrendering claim scope through argument to the patent examiner (‘argument-based estoppel’).”).

¹⁶⁸ 504 F.3d 1371 (Fed. Cir. 2007).

¹⁶⁹ ACE (Angiotensin Converting Enzyme) inhibitors are a class of drugs that mediate the renin-angiotensin-aldosterone system, which is responsible for regulating blood pressure, water balance, kidney function, and inflammation. The drug is widely used to treat hypertension, cardiovascular disease, and kidney disease. See, e.g., Michael W. Tempelhof, *Comparative Role of Angiotensin Receptor Blockers Versus Other Agents in the Management of Hypertension, Cardiovascular Disease and Nephropathy*, 102 S. MED. J. 1201 (2009) (comparing ACE inhibitors with other hypertension treatment agents).

remove certain types of metal-containing stabilizers.¹⁷⁰ This narrowing amendment was not sufficient to constitute argument-based estoppel;¹⁷¹ however, the courts nevertheless determined that amendment-based estoppel prevented the patentee from later claiming as an equivalent a drug that used magnesium oxide as a stabilizer.¹⁷²

Although not a true biologics case, *Schwarz Pharma* is nevertheless relevant to this discussion because the accused infringer was a follow-on drug company that had developed a generic version of a pioneer drug through the abbreviated new drug application (ANDA) process delineated by the Hatch–Waxman Act.¹⁷³ Like the drug in *Schwarz Pharma*, most follow-on drugs can be expected to differ from their pioneer drug cousins only in minor ways.¹⁷⁴ Allowing the doctrine of equivalents unrestrained coverage of such follow-on drugs would arguably usurp the whole function of Hatch–Waxman, which is to encourage the development of low-cost versions of popular pioneer drugs; accordingly, prosecution history estoppel becomes an important tool for preventing this.¹⁷⁵ With the passage of the Biologics Price Competition and Innovation Act,¹⁷⁶ application of the doctrine of equivalents will likely become even more problematic, and the use of prosecution history estoppel to temper the reach of the doctrine of equivalents all the more necessary.¹⁷⁷

Prosecution history estoppel also prevented a patentee from claiming infringement under the doctrine of equivalents in *Mycogen Plant Science, Inc. v. Monsanto Co.*¹⁷⁸ This case involved a patent for synthetic pesticide genes designed to be expressed in plants, which would then secrete the gene products

¹⁷⁰ *Schwarz Pharma*, 504 F.3d at 1373.

¹⁷¹ *Id.*

¹⁷² *Id.* at 1375–78.

¹⁷³ *Id.* at 1372.

¹⁷⁴ See Sahr, *supra* note 14, at 45–47 (discussing “design-around” biologics).

¹⁷⁵ See *supra* notes 10–13 and accompanying text; see also Meurer & Nard, *supra* note 112, at 1954 (arguing that the doctrine of equivalents undermines the notice function of patents, with the result that “[p]otential competitors have a difficult time competing aggressively by using technology that is adjacent to the technology controlled by the patent owner”).

¹⁷⁶ See *supra* notes 10–13.

¹⁷⁷ See *supra* Parts II, III.

¹⁷⁸ 91 F. App’x 666 (Fed. Cir. 2004). In this unpublished decision, the Court of Appeals for the Federal Circuit affirmed its previous holding in *Mycogen Plant Sci., Inc. v. Monsanto Co.*, 252 F.3d 1306 (Fed. Cir. 2001), where it rejected Mycogen’s claims of infringement under the doctrine of equivalents because of prosecution history estoppel. The court was forced to reexamine this previous holding in light of the Supreme Court’s ruling in *Festo*, which held that prosecution history estoppel created a rebuttable presumption against the use of the doctrine of equivalents, rather than a complete bar. *Mycogen Plant Sci.*, 91 F. App’x at 668–69.

as a sort of continuous insecticide.¹⁷⁹ Monsanto developed its own versions of the patented genes, which contained significantly different genetic sequences than Mycogen's.¹⁸⁰ The Federal Circuit held that claim cancellations made by Mycogen during prosecution that replaced a broad DNA sequence claim with a narrower sequence claim prevented it from asserting that Monsanto's versions infringed under the doctrine of equivalents.¹⁸¹ The court rejected Mycogen's argument that although it abandoned claims that covered certain similar gene sequences, the possibility of dissimilar gene sequences that still functioned as pesticides was unforeseeable, noting that at one point, "Mycogen originally attempted to claim *all* functionally equivalent genes."¹⁸²

Mycogen is a textbook illustration of the need to dampen the reach of the doctrine of equivalents in some biologics cases. The facts of the case closely parallel the examples given in Part II, above, illustrating the difficulty of determining the appropriate scope of the doctrine when applied to DNA sequences.¹⁸³ Prosecution history estoppel spared the *Mycogen* court the difficulty of making such a determination because of clear evidence that the patentee had failed during prosecution to obtain coverage for all functional equivalents of its patented gene.¹⁸⁴ Although prosecution history estoppel will not prove applicable to every case involving patented gene sequences, in similar situations it should prove a valuable method for preventing the use of the doctrine of equivalents to unduly broaden the scope of biologics patents.¹⁸⁵

2. *The All Limitations Rule*

In *Warner-Jenkinson*, the Supreme Court was careful to explain that when applying the doctrine of equivalents, courts should be careful not to allow "such broad play as to effectively eliminate [an] element in its entirety."¹⁸⁶ In other words, although it may sometimes be appropriate for the doctrine to broaden the scope of patent claims, the doctrine should not be applied if the

¹⁷⁹ *Id.* at 666–67.

¹⁸⁰ *Id.* at 667.

¹⁸¹ *Mycogen Plant Sci.*, 252 F.3d 1306, 1319–20 (Fed. Cir. 2001).

¹⁸² *Mycogen Plant Sci.*, 91 F. App'x at 667–69. The court similarly rejected arguments by Mycogen that the claim cancellations were merely "tangential" to patentability and that, in the alternative, it should not have "reasonably be[en] expected" to have described the equivalent in question. *Id.* at 669.

¹⁸³ See *supra* Part II.

¹⁸⁴ *Mycogen Plant Sci.*, 91 F. App'x at 668.

¹⁸⁵ Although the *Mycogen* case dealt with DNA sequences, one can easily imagine a similar application of prosecution history estoppel in cases involving RNA or protein sequences.

¹⁸⁶ *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 29 (1997).

result would be simply to write out a claim in its entirety. Although this limitation on the doctrine of equivalents can be difficult to apply in practice,¹⁸⁷ the Federal Circuit has used it in recent cases to limit application of the doctrine of equivalents in a biologics context.

For example, in *Cook Biotech Inc. v. ACell, Inc.*, owners of a patent covering tissue compositions used as scaffolding for tissue reconstruction argued that a competitor's composition infringed under the doctrine of equivalents.¹⁸⁸ The patentee cited evidence showing that the accused infringing composition was equivalent to its patented composition, even though the infringing composition included two additional tissue layer types.¹⁸⁹ The Federal Circuit, however, refused to apply the doctrine because the plaintiff-patentee's claims had specifically mentioned a delamination step, which necessarily removed the tissue types in question.¹⁹⁰ Accordingly, application of the doctrine of equivalents in this case violated the all limitations rule because it would have completely vitiated the requirement that the composition be delaminated.¹⁹¹

In *Carnegie Mellon University v. Hoffmann-La Roche Inc.*, another case applying the all elements rule in a biologics context, the issue was a patent describing recombinant plasmids designed to express enzymes known as DNA polymerases.¹⁹² Specifically, the patent in question covered a DNA polymerase produced from a DNA coding sequence derived from the *E. coli* bacterium, while the accused infringing sequence was derived from the *T. aquaticus* bacterium.¹⁹³ Rejecting the patentee's arguments that the accused infringing sequence infringed under the doctrine of equivalents, the court held that "[t]o find otherwise would require this Court to eliminate the *E. coli* limitations from the '745 patent, which under Warner-Jenkinson, this Court cannot do."¹⁹⁴

¹⁸⁷ See, e.g., MUELLER, *supra* note 54, at 380–82 (describing the all limitations rule as lacking “workable limits” and positing that, “taken to an extreme, application of the vitiation doctrine itself vitiates the doctrine of equivalents”).

¹⁸⁸ 460 F.3d 1365 (Fed. Cir. 2006).

¹⁸⁹ *Id.* at 1379.

¹⁹⁰ *Id.*

¹⁹¹ *Id.*

¹⁹² No. C 01-0415 SI, 2004 U.S. Dist. LEXIS 4975 (N.D. Cal. Feb. 25, 2004), *aff'd*, 541 F.3d 1115 (Fed. Cir. 2008).

¹⁹³ *Id.* at *13–14.

¹⁹⁴ *Id.* at *21.

As with prosecution history estoppel, the all limitations rule allowed the courts in the above instances to prevent biologics patents from becoming overly broadened by the doctrine of equivalents. Although, when considered in the abstract, the two cases may seem to be rather dry exercises in legal semantics, in reality the rulings helped to preserve vital biologics innovation that would otherwise have been stifled. In *Cook Biotech*, the accused infringer attempted to license technology from the patent holder but was unsuccessful,¹⁹⁵ further illustrating the inadequacy of licensing as a remedy for patent disputes in the field of biologics;¹⁹⁶ the court's use of the all limitations rule to constrain the reach of the doctrine of equivalents thus resulted in preservation of the defendant's avenue of research. Similarly, although the court in *Carnegie Mellon* was on the surface confronted with simple distinctions between DNA polymerases produced by two different bacterial sources, the ultimate issue in the case was ownership of the rights to *Taq* polymerase, which is the key enzymatic ingredient in the polymerase chain reaction (PCR), a biologics tool that has found almost ubiquitous application in science, medicine, and law enforcement over the past few decades.¹⁹⁷ Accordingly, using the all limitations rule, the courts prevented the holder of a distantly related patent from tying up the rights to one of the most important biologics discoveries of the past twenty-five years.

B. Breaking the “Black Box”—Expert Juries

The preceding suggestions have focused solely upon judicial remedies. Given the difficulties that juries often have in dealing with cases involving complex technologies, such as those found in the biologics arena,¹⁹⁸ it is perhaps unsurprising that many potential solutions to the issue of applying the doctrine of equivalents to an increasingly complicated world of biologics

¹⁹⁵ *Cook Biotech*, 460 F.3d at 1369.

¹⁹⁶ See *supra* Part III.C.

¹⁹⁷ Indeed, as the Federal Circuit noted:

[A]s Roche states in its briefs, that *Taq* DNA polymerase was and continues to be integral to the success of polymerase chain reaction (“PCR”), a widely used technique in molecular biology that was invented by Kary Mullis in 1983. Indeed, in 1993, Mullis won the Nobel Prize in Chemistry for his development of PCR and the journal *Science* named *Taq* DNA polymerase the “Molecule of the Year.” While we reach our decision irrespective of those facts, *we readily can see why appellants have attempted to broaden the scope of their claims beyond the E. coli species disclosed.*

Carnegie Mellon Univ. v. Hoffmann-La Roche Inc., 541 F.3d 1115, 1129 n.4 (Fed. Cir. 2008) (emphasis added).

¹⁹⁸ See *supra* Part III.A.

patents would focus on taking such questions *out* of the hands of the jury. Indeed, the Supreme Court in *Warner-Jenkinson* specifically acknowledged the problems posed by “black-box jury verdicts,” and suggested that these issues could be at least partially alleviated by summary judgment with respect to the previously outlined judicial limitations on the doctrine of equivalents, leaving “no further *material* issue for the jury to resolve.”¹⁹⁹ Defendants in patent litigation may be particularly reluctant to try a case in front of a jury, as juries tend to favor patent holders in such disputes.²⁰⁰ However, to limit any analysis of legal issues to judicial remedies is to ignore the jury half of the equation, and in any event many disputes involving the doctrine of equivalents in the biologics arena will not prove amenable to judicial “quick fixes.”²⁰¹

And perhaps patent professionals should not be so intent upon finding a summary judgment quick fix in the first place. For one thing, the attitude that jurors simply do not have the capacity to participate in complex litigation could be considered arrogant and paternalistic at best, naive and misinformed at worst.²⁰² Additionally, although summary judgment is now the most likely method of disposition for patent cases,²⁰³ it was once considered inappropriate for patent cases precisely because of the complexity inherent in most patent disputes.²⁰⁴ As more and more patent litigators attempt to avoid the jury “black box” by filing for summary judgment, courts have become flooded with lengthy and detailed motions.²⁰⁵ As a result, summary judgment motions, which were once thought to alleviate judicial strain, end up tying up the courts in protracted motions practice.²⁰⁶ In any event, as the ultimate finders of fact,

¹⁹⁹ *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 39 n.8 (1997).

²⁰⁰ See Kimberly A. Moore, *Judges, Juries, and Patent Cases—An Empirical Peek Inside the Black Box*, 99 MICH. L. REV. 365, 408 (2000). After a statistical analysis of all patent cases from 1983 to 1999, then-Professor Moore concluded that “[p]atent holders have been more successful in jury trials than in bench trials. Juries find for the patent holder more often on validity, infringement, and willfulness issues and they do award higher damages.” *Id.*

²⁰¹ For example, 2.2% of the 13.5% of 2006 patent cases reaching adjudication were decided by jury verdict, the second highest subset after summary judgment, which decided 7.0% of cases reaching adjudication. Paul M. Janicke, *Patent Jury Verdicts: Myths and Realities*, INTELL. PROP. TODAY, July 2007, at 18, 18 tbl.1.

²⁰² One patent practitioner opines: “The hubris of lawyers is remarkable. We see examples of human skill and intelligence every day, but we still think that the ordinary person is too dumb to figure out what we lawyers can understand because of our education and special intelligence.” Joseph N. Hosteny, *About Summary Judgments*, INTELL. PROP. TODAY, Apr. 2003, at 20, 20.

²⁰³ See *supra* note 201.

²⁰⁴ Joseph N. Hosteny, *My Wishes for 2007* (pt. 1), INTELL. PROP. TODAY, Feb. 2007, at 22, 22.

²⁰⁵ See *id.*

²⁰⁶ *Id.* It is also important to remember that judges are human, and the overwhelming amount of data that is presented to the courts through protracted summary judgment proceedings makes it even more difficult for

juries are the final arbiters in many questions involving the doctrine of equivalents. Accordingly, solutions to the problem of jury confusion hinge upon impaneling juries that are more capable of rendering decisions in areas of patent law that, like the biologics arena, involve complex, difficult-to-understand technologies.

A solution can be found in the use of expert juries to decide technically challenging cases such as biologics patent disputes.²⁰⁷ The use of expert juries is rooted in English common law. Originally, juries in England were often selected for their special knowledge of the issues at trial.²⁰⁸ However, over time the use of expert juries in England declined, until the practice was largely abolished in 1949.²⁰⁹ In the United States, expert juries were provided for by

judges to properly resolve patent disputes. As one judge noted, “You can file a brief of whatever length you want, but I have to tell you, I begin to lose interest after fifteen pages or so.” Hosteny, *supra* note 202, at 21 (quoting Judge Hubert Will of the Northern District of Illinois) (internal quotation marks omitted).

²⁰⁷ It should be noted that proposals also exist to bring the experience of expert *courts* to bear upon the problems of complex litigation. Indeed, the Court of Appeals for the Federal Circuit, the only appeals court with jurisdiction that is defined by specific subject matter (namely, patent disputes), was established by the Federal Courts Improvements Act of 1982, with the explicit hopes that it would be an expert court that could bring uniformity and order to the field of patent law. See John B. Pegram, *Should the U.S. Court of International Trade Be Given Patent Jurisdiction Concurrent with That of the District Courts?*, 32 HOUS. L. REV. 67, 85–87 (1995) (describing the reasons behind the creation of the Federal Circuit and arguing that the U.S. Court of International Trade also be given patent jurisdiction). Patent litigators are extremely selective with respect to venue choice, and although the motivation behind choosing a particular venue is often based upon whether plaintiffs or defendants are typically thought to be favored in that jurisdiction, patent litigators often choose venues that are presided over by judges with experience in trying patent cases. See Anat Hakim et al., *Western District of Wisconsin Court Proves a Speedy and Affordable Venue for Patent Litigation*, INTEL. PROP. TODAY, Oct. 2001, at 34, 34 (citing “the speed of the [court’s] docket,” reasonable expenses, and proximity to a highly educated jury pool as reasons for the U.S. District Court for the Western District of Wisconsin’s popularity among patent litigators). Finally, an ongoing pilot program has been developed to allow patent cases to be swapped from courts that would rather not entertain them with those that would. Although the program is still in its early stages, it is hoped that this particular program will lead to increased unity and predictability in complex patent cases. See Donna M. Gitter, *Should the United States Designate Specialist Patent Trial Judges? An Empirical Analysis of H.R. 628 in Light of the English Experience and the Work of Professor Moore*, 10 COLUM. SCI. & TECH. L. REV. 169, 172–73 (2009) (expressing the hope that the proposed plan will “reduce the appellate claim construction reversal rate, thereby affording needed certainty to U.S. inventors and investors who require stability in the U.S. patent litigation process”). But see Nancy Olson, *Does Practice Make Perfect? An Examination of Congress’s Proposed District Court Patent Pilot Program*, 55 UCLA L. REV. 745 (2008) (citing statistical data regarding reversal rates following claim construction at the district court level as demonstrating no link between judicial experience with patent cases and affirmance of claim construction rulings).

²⁰⁸ See James C. Oldham, *The Origins of the Special Jury*, 50 U. CHI. L. REV. 137, 139 (1983) (“[I]n cases of national importance, grand juries often consisted of leading citizens. . . . [Meanwhile,] juries of experts ranged from panels of cooks and fishmongers to the all-female jury impaneled to ascertain whether a female defendant was pregnant.” (footnote omitted)).

²⁰⁹ *Id.* at 210.

statute in many states by the first part of the twentieth century.²¹⁰ However, as in England, the use of such juries declined in the latter half of that century,²¹¹ and currently only Delaware has statutory provisions for impaneling special juries.²¹²

Other commentators have advocated the use of such juries in litigation involving complex medical and technological issues.²¹³ Rules allowing courts to impanel expert juries for patent cases that, like those involving biologics, deal with scientifically demanding subject matter could alleviate concerns of the “black box” jury. Such expert juries would be screened during the selection process for the educational background²¹⁴ or technical experience²¹⁵ sufficient for understanding the issues at trial.²¹⁶

The use of expert juries would help alleviate the fears of patentees and defendants alike. Parties to complex biologics litigation could be reassured that such juries would not decide cases on a whim or predilection after listening to hours of detailed expert testimony that jurors never understood in the first place.²¹⁷ These juries would be less likely to simply identify with the

²¹⁰ See Feigenbaum, *supra* note 90 (discussing the history of expert juries in the United States).

²¹¹ *Id.* at 1399.

²¹² DEL. CODE ANN. tit. 10, § 4506 (2010) (“The Court may order a special jury upon application of any party in a complex civil case. The party applying for a special jury shall pay the expense incurred by having a special jury, which may be allowed as part of the costs of the case.”).

²¹³ Feigenbaum, *supra* note 90 (discussing the history of expert juries in the United States and advocating the use of special juries as a way to deter spurious medical malpractice claims).

²¹⁴ See William V. Luneburg & Mark A. Nordenberg, *Specially Qualified Juries and Expert Nonjury Tribunals: Alternatives for Coping with the Complexities of Modern Litigation*, 67 VA. L. REV. 887, 900 (1981) (arguing for modified jury selection procedures that are “keyed to educational background” for technically complex civil cases).

²¹⁵ See Kristy Lee Bertelsen, *From Specialized Courts to Specialized Juries: Calling for Professional Juries in Complex Civil Litigation*, 3 SUFFOLK J. TRIAL & APP. ADVOC. 1, 15 (1998) (arguing that for complex litigation, impaneling “professional juries would alleviate poor decision making and erratic verdicts by ensuring that competent individuals, who are familiar with the subject matter of the litigation, render decisions”).

²¹⁶ See Beth Z. Shaw, *Judging Juries: Evaluating Renewed Proposals for Specialized Juries from a Public Choice Perspective*, 2006 UCLA J.L. & TECH. 3, 6 (analyzing the use of specialized juries through public choice theory and concluding that such juries enjoy streamlined deliberations due to “uniformity of information and comprehension”); see also Tony Caliendo, *A Proposed Solution to Jury Confusion in Patent Infringement Cases Involving Means-Plus-Function Claims*, 2004 BYU L. REV. 209 (proposing simpler and more effective jury instructions to aid juries in deciding cases involving the doctrine of equivalents and means-plus-functions claims); Menon, *supra* note 90, at 298 (arguing that technical issues should be communicated to juries by persons skilled at relaying complex information to laypersons).

²¹⁷ Similar to the use of expert juries, some commentators have proposed the use of neutral, court-appointed experts to assist both judge and jury with understanding complex scientific testimony. See, e.g., Samuel H. Jackson, *Technical Advisors Deserve Equal Billing with Court Appointed Experts in Novel and*

patent holder in cases involving the doctrine of equivalents²¹⁸ and as a result would be more likely to apply the doctrine of equivalents in ways that would at least somewhat alleviate concerns related to unjustified broadening of patent protections in the field of biologics.

C. Denying Preliminary Injunctions as a Remedy in Biologics Cases Involving the Doctrine of Equivalents

Licensing can provide an attractive solution to patent disputes. If the terms of a suitable license can be negotiated between the patentee and the accused infringer, both parties can end up with a net gain, as the accused infringer is able to practice the disputed invention without further concerns over legal consequences, and the patentee is justly compensated for the use of its intellectual property.²¹⁹ Unfortunately, for a variety of reasons, parties are often unable to agree on a licensing option to resolve disputes involving biologics patents, especially when the doctrine of equivalents is involved.²²⁰ Absent options to license, a biologics innovator that is uncertain as to whether its invention infringes an existing biologics patent under the doctrine of equivalents faces the difficult choice between either abandoning its invention or subjecting itself to the possibility of an infringement suit. One way of avoiding this dilemma is for courts to refuse to award permanent injunctions in biologics disputes involving the doctrine of equivalents. This would essentially limit the patentee's remedy to damages, reasonable royalties, or some combination of both. The accused infringer, upon paying the remedy, would be free to make, use, sell, or offer to sell the infringing biologic.²²¹ In other words, this solution would effectively make licensing compulsory in such cases.

Patents are ownership rights. Such rights can be enforced through property rules (injunctions) or liability rules (damages).²²² Assuming a goal of

Complex Scientific Cases: Does the Federal Judicial Center Agree?, 28 ENVTL. L. 431, 465, 443 (1998) (arguing that such experts would be "valuable tools for deciphering novel, complex scientific theories" and would help resolve the issue of the "battle of the experts").

²¹⁸ See Moore, *supra* note 200, at 385–90 (providing a statistical analysis comparing patent litigation outcomes decided by judges to those decided by juries).

²¹⁹ See *supra* Part III.C.

²²⁰ *Id.*

²²¹ All other remedies, such as lost profits and other damages, including enhanced damages in cases of willful infringement, would still be available to the patentee. See discussion *infra* note 241.

²²² See RICHARD A. POSNER, *ECONOMIC ANALYSIS OF LAW* 68–69 (7th ed. 2007) (discussing property versus liability rules).

allocating these rights in such a way as to maximize the value of their use, when transaction costs are high the most efficient way to protect such rights is through a denial of injunctive relief, which limits the owners of the rights to damages.²²³ In cases involving biologics, transaction costs involved in licensing technology are typically high, and are often insurmountable.²²⁴ The doctrine of equivalents, which creates uncertainty regarding the scope of patent rights, further exacerbates these transaction costs.²²⁵ Accordingly, to ensure that the public's interest in lifesaving biologics innovation is served, injunctive relief should be denied in cases involving the doctrine of equivalents in a biologics context.

This can be a troubling idea. People are conditioned to take it for granted that ownership should be enforced through property rules—after all, if a party owns property, most would feel that other parties should be enjoined from using that property without the owner's permission. In actuality, this is not (and should not be) always the case, as is illustrated, for example, by the textbook cases involving industrial polluters versus residential homeowners.²²⁶ Of course, the government itself has the ability to appropriate through compulsory licenses real property (through eminent domain),²²⁷ intellectual property,²²⁸ emergency foodstuffs,²²⁹ nuclear technology,²³⁰ weapon systems,²³¹ and pollution control measures.²³² Additionally, courts have long

²²³ *Id.* (“In conflicting-use situations in which transaction costs are high, the allocation of resources to their most valuable uses is facilitated by denying owners of property an injunctive remedy against invasions of their rights and instead limiting them to a remedy in damages”); see also Guido Calabresi & A. Douglas Melamed, *Property Rules, Liability Rules, and Inalienability: One View of the Cathedral*, 85 HARV. L. REV. 1089 (1972) (discussing further the differences between property and liability rules).

²²⁴ This is one reason for the failure of voluntary licensing to address ownership issues in the field of biologics. See *supra* Part III.C.

²²⁵ See *supra* note 119.

²²⁶ See James E. Krier & Stewart J. Schwab, *Property Rules and Liability Rules: The Cathedral in Another Light*, 70 N.Y.U. L. REV. 440, 442 (1995) (discussing the property and liability rule theories advanced by Calabresi and Melamed and noting that “[t]he problem of environmental pollution is the stock example”).

²²⁷ Perhaps the most famous recent Supreme Court case dealing with the question of eminent domain is *Kelo v. City of New London*, 545 U.S. 469 (2005), a decision that generated a firestorm of controversy and prompted a Los Angeles businessman to attempt to convince the town of Weare, New Hampshire, to use eminent domain to acquire property owned by Justice Souter for development of a new hotel. See Dan Glaister, *Activists Take Campaign to Top Judge's Elegant Domain*, GUARDIAN (London), Jan. 23, 2006, at 18.

²²⁸ Federal law grants the federal government the right to use or manufacture any patented invention, or license such use of manufacture to a third party, with the remedy to the patentee limited to “reasonable and entire compensation for such use and manufacture.” 28 U.S.C. § 1498 (2006).

²²⁹ Plant Variety Protection Act, 7 U.S.C. § 2404 (2006).

²³⁰ 42 U.S.C. § 2181 (2006).

²³¹ 35 U.S.C. §§ 181–183 (2006).

²³² Clean Air Act, 42 U.S.C. § 7608 (2006).

held equitable discretion over the granting or denial of injunctive relief (and thus the choice between property and liability rules) in civil cases, and the Supreme Court in *eBay Inc. v. MercExchange, L.L.C.*, recently stressed this fact.²³³ Finally, much of the research in the biologics and pharmaceutical fields originates in public universities that receive significant federal funding, which further validates the public's interest in receiving the benefits of lifesaving technologies that are often made possible through its tax dollars.²³⁴

Denial of injunctive relief in patent disputes has been proposed as a solution for maximizing the public benefit of medical technologies in an age of global terrorism,²³⁵ improving global access to medications for addressing serious public health needs including AIDS, tuberculosis, malaria, cancer, and heart disease,²³⁶ and preventing an "anticommons" with respect to patents on human DNA sequences.²³⁷ Other commentators have argued for a less drastic use of compulsory licenses. One attractive modification to the general compulsory license strategy is the use of "time-varying compulsory licenses," which are compulsory licenses with rates that increase over time.²³⁸ Use of these types of licenses would prevent a patentee from stifling valuable innovations while also encouraging the infringing party to quickly develop non-infringing versions of its infringing products.²³⁹ Other proposals have limited denials of injunctive relief to patent disputes involving the doctrine of equivalents, and even in those instances on a case-by-case basis.²⁴⁰ At the very

²³³ See 547 U.S. 388, 392–93 (2006) ("[T]his Court has consistently rejected invitations to replace traditional equitable considerations with a rule that an injunction automatically follows a determination that a copyright has been infringed."). But see Michael C. Brandt, *Compulsory Licenses in the Aftermath of eBay Inc. v. MercExchange, L.L.C.: The Courts' Authority to Impose Prospective Compensatory Relief for Patent Infringement*, 17 FED. CIR. B.J. 699 (2008) (arguing that the *eBay* decision should not be read as altering available patent remedies and that policy concerns mediate against compulsory licenses).

²³⁴ See, e.g., Eileen M. Kane, *Molecules and Conflict: Cancer, Patients, and Women's Health*, 15 AM. U. J. GENDER SOC. POL'Y & L. 305, 317–18 (2007) (arguing that the public interest should be a key factor in questions of ownership of federally funded technologies).

²³⁵ Grace K. Avedissian, *Global Implications of a Potential U.S. Policy Shift Toward Compulsory Licensing of Medical Inventions in a New Era of "Super-Terrorism"*, 18 AM. U. INT'L L. REV. 237 (2002).

²³⁶ Kevin Outterson, *Pharmaceutical Arbitrage: Balancing Access and Innovation in International Prescription Drug Markets*, 5 YALE J. HEALTH POL'Y L. & ETHICS 193 (2005).

²³⁷ Donna M. Gitter, *International Conflicts over Patenting Human DNA Sequences in the United States and the European Union: An Argument for Compulsory Licensing and a Fair-Use Exemption*, 76 N.Y.U. L. REV. 1623 (2001).

²³⁸ Eric Keller, *Time-Varying Compulsory License: Facilitating License Negotiation for Efficient Post-Verdict Patent Infringement*, 16 TEX. INTELL. PROP. L.J. 427, 441 (2008).

²³⁹ *Id.*

²⁴⁰ See Holbrook, *supra* note 119 (arguing that preclusion of injunctive relief for infringement under the doctrine of equivalents would in many instances ameliorate the resultant uncertainty in claim scope).

least, injunctive relief should certainly be denied in biologics cases involving the doctrine of equivalents for all of the reasons discussed previously: the difficulties inherent in applying the doctrine in a biologics context; the highly technical nature of the issues involved, which may be confusing for lay jurors; the potential for the doctrine to stifle biologics innovation (and the concomitant failure of voluntary licensing to remedy this); and the overriding public interest in furthering innovation and access to lifesaving and life-changing biologic pharmaceuticals.²⁴¹

It could be argued that a weakness in such a proposal would be the difficulty in determining a fair licensing fee for the patentee. However, “courts routinely are involved in assessing royalty rates and remedies in patent cases,”²⁴² and caselaw provides substantial guidance as to what actually constitutes a reasonable royalty.²⁴³ It could also prove difficult to determine just what qualifies as a biologic in the first place;²⁴⁴ a (perhaps too) simple remedy to this definitional quandary would be to limit the “biologics” class to those products that are so defined by the FDA,²⁴⁵ or in future “pathways to biologics” legislation.²⁴⁶ This proposal would also have the added benefit of reducing the amount of complicated patent litigation pending before courts, as biologics patentees whose infringement cases depended upon the doctrine of equivalents would be more likely to negotiate licenses if denied injunctive relief, while both patentees and accused infringers would have an incentive to avoid litigation costs and reach licensing agreements without facing the uncertainty of court-mandated licensing terms.²⁴⁷ The reduction in litigation would benefit the public by both freeing up expensive, publicly funded judicial

²⁴¹ It is important to emphasize that this proposal would echo Professor Holbrook’s in preserving “[t]he full panoply of remedies for literal infringement,” while “[l]ost profits and other damages would remain available” for both literal infringement and cases involving the doctrine of equivalents. *Id.* at 46.

²⁴² *Id.* at 47–48.

²⁴³ For example, many courts, including the Federal Circuit, ascribe to the four-factor *Panduit* test for determining reasonable royalties, which analyzes (1) the demand for the patented good, (2) the absence in the market of acceptable non-infringing substitutes, (3) the ability of the patentee to exploit such demand through manufacturing and marketing capabilities, and (4) the profit the patentee would otherwise have made. *Panduit Corp. v. Stahlin Bros. Fibre Works, Inc.*, 575 F.2d 1152, 1156 (6th Cir. 1978).

²⁴⁴ See Rader, *supra* note 8 (observing that defining biologics as a class of pharmaceuticals can be a difficult proposition).

²⁴⁵ See *supra* note 8 and accompanying text.

²⁴⁶ See *supra* note 10 and accompanying text.

²⁴⁷ This addresses one of the biggest arguments in favor of property rules over liability rules, namely that interested parties “can establish the relevant values by bargaining more cheaply and more accurately than can the judge weighing the evidence.” James E. Krier & Stewart J. Schwab, *Property Rules and Liability Rules: The Cathedral in Another Light*, 70 N.Y.U. L. REV. 440, 450 (1995).

resources and also, hopefully, contributing to lower prices for biologic pharmaceuticals, as less money would be wasted in litigation by biologics firms. To prevent follow-on innovators from attempting to “game” the system by willfully infringing and counting on the courts to set a better royalty rate than could otherwise have been negotiated, damages for willful infringement in cases involving the doctrine of equivalents in a biologics context, currently at the court’s discretion, could be set by statute at triple base damages. All remedies other than injunctive relief would remain available to a patent holder, including damages, lost profits, and costs.²⁴⁸

This proposal results in more desirable outcomes when applied to cases like *Boehringer* and *Cook Biotech*. In *Boehringer*, the lack of an injunctive remedy would deny the patentee the ability to keep the infringer from producing and selling its improved vaccine, thus improving the health of commercial pig herds and providing substantial public benefit. The patentee would still be left with reasonable royalty revenues secured by a license, which under this proposal would in all likelihood have been negotiated without the need for the interested parties to waste time and resources on a trial. In *Cook Biotech*, the parties wound up in litigation after the accused infringer tried and failed to license scaffolding technology from the patentee.²⁴⁹ Under this proposal, such litigation would never have taken place, because without the possibility of winning injunctive relief, the patentee would have no incentive to deny granting a (reasonable) license in the first place.

This proposal is superior to judicial limitations on the doctrine of equivalents or the impaneling of expert juries to hear complex biologics cases. Unlike those remedies, this proposal would come into play after a verdict has been rendered, meaning that it is available even when judicial restraints on the doctrine of equivalents, like prosecution history estoppel or the all limitations rule, do not apply, and would somewhat ameliorate the fallout of poor verdicts delivered by overwhelmed juries. Additionally, the denial of a permanent injunction would provide a meaningful threat that would deter litigation and encourage licensing in the first place. Denying injunctive relief in cases involving the doctrine of equivalents in a biologics context strikes an appropriate balance between providing compensation to patentees for the use of valuable intellectual property rights while still allowing innovator firms to

²⁴⁸ See *supra* note 241.

²⁴⁹ See *supra* note 195 and accompanying text.

bring less costly and more effective versions of biologic pharmaceuticals to market.

CONCLUSION

The rapidly evolving arena of biologic pharmaceuticals will revolutionize medicine and enhance the quality of life for millions of persons. However, the exquisite complexity that makes biologic treatments so amenable to previously untreatable disorders also creates difficulties in the field of patent law, particularly with respect to such ephemeral concepts as the doctrine of equivalents, difficulties that are highlighted by cases such as *Boehringer* and *Goldenberg*. There is considerable evidence that juries have difficulty dealing with cases involving technologically advanced subject matter of the type that is often at issue in biologics cases. These factors lead to uncertainty as to the limits of biologic patents, which carries with it the potential to chill vital biologics innovation in a way that cannot be overcome by such remedies as cross-licensing.

To address these problems, courts should be prepared to exert their legal prerogatives over the doctrine of equivalents in biologics cases, including rigorous application of both prosecution history estoppel and the all limitations rule. Additionally, the impaneling of expert juries that are better able to understand the complex, far-reaching issues involved in such cases, which often have policy ramifications that go well beyond the resolution of the particular case at bar, can also provide more certainty and predictability in cases involving the doctrine of equivalents in a biologics context. Finally, the denial of injunctive relief in biologics cases where infringement is found under the doctrine of equivalents provides fairness and a preservation of incentives for biologics patent holders while preventing the development of a “patent thicket” in the biologics arena, allowing follow-on innovators to bring vital new biologic therapeutics to the public. In any event, courts should exercise caution when applying the doctrine of equivalents in a biologics context to

ensure that its legitimate function of protecting patent holders from “unscrupulous copyists” can be reconciled with the preservation of innovation in the field of biologic pharmaceuticals.

D. ALAN WHITE*

* Executive Notes and Comments Editor, *Emory Law Journal*; J.D. Candidate, Emory University School of Law (2011); Ph.D., University of Florida (2005) (Medical Sciences-Genetics); B.S., University of Georgia (1996) (Genetics). I thank my advisor, Professor Timothy Holbrook, for his generous assistance with the development and writing of this Comment. I would also like to thank the students, faculty, and staff of Emory University School of Law, and especially my colleagues on the *Emory Law Journal*, for their contributions to the development of this Comment, and to my legal education in general. Finally, I thank my family and friends, and especially my wife, Tracey, for their constant support and encouragement. This Comment is dedicated to my good friend and mentor, Professor Alfred S. Lewin.