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# The Paradox of Legal Equivalents and Scientific Equivalence: Reconciling Patent Law's Doctrine of Equivalents with the FDA's Bioequivalence Requirement

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# THE PARADOX OF LEGAL EQUIVALENTS AND SCIENTIFIC EQUIVALENCE: RECONCILING PATENT LAW'S DOCTRINE OF EQUIVALENTS WITH THE FDA'S BIOEQUIVALENCE REQUIREMENT

Janet Freilich\*

## ABSTRACT

*Contrary to popular perception, generic drugs often enter the market before the patents covering their brand name counterparts have expired by making slight changes to the drug to avoid the brand name patent. These generics face a paradox: the U.S. Food and Drug Administration (FDA) requires that the generic “not show a significant difference” from the reference product, while patent law requires that the generic have “substantial differences” as compared to the reference product. The generic must be bioequivalent, but not legally equivalent, to the brand name drug. This paradox occurs frequently in the courts but has never been discussed in the literature. This Article analyzes every case to date involving this equivalence paradox to create a normative theory explaining and predicting courts’ treatment of these cases. It then explains the implications for patent law. Namely, it demonstrates how courts use these cases as an opportunity to tailor the scope of the patent based on its ability to provide ex post incentives for commercialization and development. Finally, this Article discusses the broader implications of the paradox on FDA law and concludes that these cases demonstrate that, while courts are increasingly skeptical of evergreening, the paradox impedes progress towards cheaper, safer medicine.*

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## I. INTRODUCTION

“**T**RULY then, I fear you are damned both by father and mother. Thus when I shun Scylla, your father, I fall into Charybdis, your mother. Well, you are gone both ways.”<sup>1</sup>

Generic drug manufacturers face a paradox. First, they must create a product that is bioequivalent to a brand name drug to obtain approval from the FDA.<sup>2</sup> Second, they must create a product that does not infringe, either literally or by equivalents, on the brand name drug’s patent.<sup>3</sup> A generic drug is bioequivalent if it does “not show a significant difference” from the reference product.<sup>4</sup> However, a generic drug infringes by equivalents if it is not “substantially different” from the reference drug’s patent.<sup>5</sup> Thus, the law requires generic drug manufacturers to be bioequivalent but not legally equivalent.<sup>6</sup> This paradox appears frequently in litigation but has never been addressed by the literature.<sup>7</sup>

1. WILLIAM SHAKESPEARE, *THE MERCHANT OF VENICE* act 3, sc. 5.

2. See 21 U.S.C. § 355(j)(2)(A)(iv) (2006).

3. See *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 21 (1997) (“[A] product or process that does not literally infringe . . . 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.”).

4. 21 U.S.C. § 355(j)(8)(B)(i).

5. *Warner-Jenkinson Co.*, 520 U.S. at 40.

6. See discussion *infra* Part III (discussing the paradox existing between the bioequivalence requirement and the doctrine of equivalents).

7. See *infra* Part III (detailing presence of this paradox in numerous cases).

This Article conducts a comprehensive analysis of every case that deals with bioequivalent drugs that are alleged to be legally equivalent. I document both manufacturing and patenting strategies that are more or less successful at navigating the equivalence paradox and the implications for patent law, evergreening, and drug availability and safety. In doing so, I seek to answer two questions: first, what principle explains and predicts the outcome of these cases, and second, whether there is a theoretical grounding for the courts' decisions in either patent law or FDA law. The answers to these questions are important to scholars studying legal theory and policy makers seeking to craft a coherent set of laws regulating the pharmaceutical industry.

Our society has placed a bet on generic drugs as an answer to our rapidly increasing healthcare finance woes. Generic drugs do not have the same market monopoly possessed by brand name innovator drugs<sup>8</sup> and can get FDA approval with fewer costly studies.<sup>9</sup> Consequently, they are significantly less expensive than brand name products.<sup>10</sup> Generic drugs are supposed to be completely interchangeable with their brand name counterparts, and pharmacists are permitted to substitute a generic drug when a doctor prescribes a brand name medication.<sup>11</sup> To encourage companies to create generic drugs, Congress provided the statutory incentive of temporary market exclusivity.<sup>12</sup>

Generic drugs do not have to be identical to the brand name product.<sup>13</sup> Despite popular perception, they rarely are. This is because generic drug manufacturers must account for brand name patents.<sup>14</sup> Even once brand name drugs are off-patent, they are usually off-patent only with respect to the portion of their patent portfolio that covered the drug's active ingredients.<sup>15</sup> The brand name drug is still protected by weaker patents cover-

8. See Eric L. Cramer & Daniel Berger, *The Superiority of Direct Proof of Monopoly Power and Anticompetitive Effects in Antitrust Cases Involving Delayed Entry of Generic Drugs*, 39 U.S.F. L. REV. 81, 91 (2004) (discussing the monopoly power brand name drug manufacturers enjoy over their generic counterparts).

9. Therapeutically Equivalent Drugs; Availability of List, 45 Fed. Reg. 72,590 (Oct. 31, 1980) (to be codified at 21 C.F.R. pt. 20) (“[The] FDA believes it is neither in the interest of the public health nor a productive use of the nation’s scarce research resources to require costly duplication of tests. A regulatory system that requires such duplicative testing is wasteful, anticompetitive, scientifically unsound, and ethically dubious.”).

10. See *Facts About Generic Drugs*, FDA, <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/ucm167991.htm> (last visited Sept. 15, 2012) (“On average, the cost of a generic drug is 80 to 85 percent lower than the brand name product.”).

11. See *infra* notes 87–89 and accompanying text (discussing state laws that provide for generic drug substitution).

12. See *infra* note 109 and accompanying text (discussing the 180-day exclusivity provision of the Hatch-Waxman Act).

13. See *infra* notes 74–82 and accompanying text (discussing the bioequivalence requirement for generic drugs).

14. *Meijer, Inc. v. Biovail Corp.*, 533 F.3d 857, 859 (D.C. Cir. 2008) (“The would-be manufacturer of a generic bioequivalent to a previously approved branded drug may file an abbreviated new drug application (ANDA) with the [FDA] while the branded drug is purportedly protected by a patent.”).

15. See FTC, *GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTS STUDY* 39–40 (2002), available at <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf> (noting that

ing different dosage forms or formulations.<sup>16</sup> Generic companies must create a product that does not infringe on those patents.<sup>17</sup> This results in generic drugs that differ in some respect from their brand name counterparts.

While designing around a brand name patent, the generic companies must stay within the FDA's guidelines. The FDA requires "bioequivalence"—meaning that generic drugs must show that they have an activity level that falls within 80% to 125% of the brand name drug's activity level.<sup>18</sup> This creates a challenge for generic companies who must satisfy the bioequivalence requirement but must still avoid infringing on the brand name drug's patents.

Further complicating the situation, the brand name drug is protected not only by the literal language of the patent, but also by the judicially-created "doctrine of equivalents." The doctrine of equivalents broadens the scope of a patent beyond its literal meaning to encompass products that perform "substantially the same function in substantially the same way to obtain the same result."<sup>19</sup> The intent is to prevent a competitor from committing a "fraud on a patent" by changing an insignificant detail such that their product is outside the literal scope of the language but should, equitably, still fall within the patent's protection.<sup>20</sup>

Yet this is precisely what Congress encourages generic companies to do: create a product that is almost identical to the brand name product so that it can be sold at a lower price.<sup>21</sup> On one hand, generic companies face bioequivalency regulations, which restrict how different the generic may be from the brand name product,<sup>22</sup> and, on the other, the doctrine of equivalents, which restricts how similar the generic may be to the brand name product.<sup>23</sup> Generic companies face the paradox of creating a product that is bioequivalent but not legally equivalent.<sup>24</sup>

In Part II of this Article, I provide a general overview of patent law, including the doctrine of equivalents, and discuss the role of the Hatch-Watchman Act in this analysis. In Part III, I conduct a comprehensive study of every case to-date and patent involving the doctrine of

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brand-name drug companies are often suing for three or more patent infringement claims for each high-earning drug); Lisa Larrimore Ouellette, *How Many Patents Does It Take to Make A Drug? Follow-On Pharmaceutical Patents and University Licensing*, 17 MICH. TELECOMM. & TECH. L. REV. 299, 316 (2010) (noting that "the average number of patents per drug is 2.97; the median number is two. Sixty-seven percent of drugs have more than one patent").

16. See *infra* notes 136–40 and accompanying text.

17. See 35 U.S.C. § 271 (2006).

18. See *infra* note 83 and accompanying text (discussing the pharmacokinetic parameters for generic drugs).

19. *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 608 (1950).

20. See *id.*

21. See discussion *infra* Part II.B (discussing the Hatch-Waxman Act and its underlying goal of lowering prices of drugs through the creation of an ANDA pathway).

22. See, e.g., 21 C.F.R. § 314.92(a)(1) (2012).

23. See *Graver Tank*, 339 U.S. at 607.

24. See discussion *infra* Part IV (discussing the paradox existing between the bioequivalence requirement and the doctrine of equivalents).

equivalents and generic products to explore the response of generic companies and the courts to this paradox. I conclude that the cases are rarely aimed at the core patent protecting the drug but instead focus on downstream commercialization and development efforts. The results suggest that courts are skeptical of these downstream patents, perhaps because they are often a consequence of evergreening.

In Part IV, I seek a theory to explain and predict the outcomes of equivalence paradox cases. I conclude that courts (perhaps unconsciously) base their decision on whether the generic work-around adds commercial value to the product, an approach consistent with the Federal Circuit's use of commercial success as a secondary consideration in determining obviousness. In Part V, I reconcile the treatment of these cases with patent theory. I find that courts are primarily concerned with creating optimal *ex post* incentives and use the cases to help address the challenge of determining the proper patent scope toward this goal.

Under the prospect theory, patents are intended to encourage downstream innovation by giving the patentee a monopoly to coordinate innovative efforts;<sup>25</sup> however, there comes a point where the patent's *ex post* incentives are no longer sufficient to incentivize innovation. As a theoretical matter, the patent should end at that point. As a practical matter, it is essentially impossible to correctly determine the precise patent scope and length necessary to maximize the patentee's downstream innovative potential without granting an excessive monopoly and incurring deadweight loss.<sup>26</sup> Equivalence paradox cases give the legal system a second bite at the patent-scope apple. Courts have a chance to view the competitive landscape after the patent has been granted and adjust the scope of the patent based on whether its prospective function is succeeding.

In Part VI, I address questions of FDA law. In particular, I suggest that courts may use the commercial value of the generic product as a proxy to test whether the brand name patent is adopted solely for evergreening or if it actually adds social value. I also address the aim of the Hatch-Waxman Act: safer, cheaper medicine. I find that patent law hinders the goals of the Hatch-Waxman Act and that equivalence cases highlight an area where two separate legal doctrines overlap to create perverse incentives. This emphasizes the need to create a more coherent body of law governing the pharmaceutical industry.

## II. BACKGROUND

### A. PATENT BOUNDARIES AND THE DOCTRINE OF EQUIVALENTS

The American patent system is designed to promote innovation.<sup>27</sup> It

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25. See discussion *infra* Part V.A (discussing Edmund Kitch's prospect theory and other *ex post* incentives of patent law).

26. See discussion *infra* Part V.A (discussing the issue of determining sufficient patent scope to incentivize downstream innovation).

27. *Graham v. John Deere Co.*, 383 U.S. 1, 9 (1996) ("The patent monopoly was not designed to secure to the inventor his natural right to his discoveries. Rather, it was a

does so by offering inventors a tradeoff: they are awarded exclusive rights in their inventions for a limited period of time while the public receives a disclosure of the details of their inventions.<sup>28</sup> This disclosure allows other inventors to create follow-on products based on the original technology and, after the patent term expires, allows competitors to use the disclosure to make their original inventions.<sup>29</sup> Patentees describe their inventions using “claims,” as required by statute.<sup>30</sup> These claims define the subject matter covered by the patent.<sup>31</sup>

A patent gives its holder the right to exclude others from making, us-

reward, an inducement, to bring forth new knowledge.”); *Mazer v. Stein*, 347 U.S. 201, 219 (1954) (“The economic philosophy behind the clause empowering Congress to grant patents and copyrights is the conviction that encouragement of individual effort by personal gain is the best way to advance public welfare through the talents of authors and inventors in ‘Science and useful Arts.’”); see also Mark A. Lemley & David McGowan, *Legal Implications of Network Economic Effects*, 86 CAL. L. REV. 479, 526 (1998); Lawrence Lessig, *Intellectual Property and Code*, 11 ST. JOHN’S J. LEGAL COMMENT. 635, 638 (1996).

28. D. Alan White, *The Doctrine of Equivalents: Fairness and Uncertainty in an Era of Biologic Pharmaceuticals*, 60 EMORY L. J. 751, 756 (2011).

29. *Id.* Note that the efficiency of our patent system and whether it actually incentivizes innovation is a matter of great controversy. Compare Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839, 843–44 (1990) (explaining that the goal of the patent system should be to maximize the innovative incentives of multiple parties over time and that patent rights can reduce innovation by blocking competitors from participating in the innovative process), with Edmund W. Kitch, *The Nature and Function of the Patent System*, 20 J.L. & ECON. 265, 266 (1977) (arguing that patents reward innovators and encourage innovation). For an overview of many theories of patent incentives, see Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1596–1615 (2003) (summarizing the major models).

30. 35 U.S.C. § 112 (2006) (The patent specification must “conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.”).

31. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005). It is widely acknowledged that while claims are important in defining the scope of the patent, they do not always do so effectively. See, e.g., Gretchen Ann Bender, *Uncertainty and Unpredictability in Patent Litigation: The Time is Ripe for a Consistent Claim Construction Methodology*, 8 J. INTEL. PROP. L. 175, 209–17 (2001) (describing the problems that result from inconsistent claim construction); Christopher A. Cotropia, *Patent Claim Interpretation Methodologies and Their Claim Scope Paradigms*, 47 WM. & MARY L. REV. 49, 58 (2005) (providing an overview of claim construction practices); Russell B. Hill & Frank P. Cote, *Ending the Federal Circuit Crapshoot: Emphasizing Plain Meaning in Patent Claim Interpretation*, 42 IDEA 1, 2 (2002) (explaining that inconsistent claim construction practices waste judicial resources); Kimberly A. Moore, Markman *Eight Years Later: Is Claim Construction More Predictable?*, 9 LEWIS & CLARK L. REV. 231, 239 (2005) (showing that district courts’ claim construction findings are reversed by the Federal Circuit 34.5% of the time); Kelly Casey Mullally, *Patent Hermeneutics: Form and Substance in Claim Construction*, 59 FLA. L. REV. 333, 343 (2007) (describing scholar’s criticism of the unpredictability of claim construction). In addition to the problems of claim construction, patentees can often amend their claims after the patent has been granted, which creates additional problems with relying on claims’ definitional function. See Tun-Jen Chiang, *Fixing Patent Boundaries*, 108 MICH. L. REV. 523, 525 (2010) (exploring the ways in which patentees can change claims after a patent has been granted, and arguing that these changing claims create problems in the patent system); William R. Hubbard, *Efficient Definition and Communication of Patent Rights: The Importance of Ex Post Delineation*, 25 SANTA CLARA COMPUTER & HIGH TECH. L.J. 327, 358–59 (2009); Paul M. Janicke, *When Patents are Broadened Midstream: A Compromise Solution to Protect Competitors and Existing Users*, 66 U. CIN. L. REV. 7, 25–29 (1997).

ing, selling, offering for sale, or importing the invention.<sup>32</sup> It does not, however, give the holder an affirmative right to practice the invention.<sup>33</sup> Literal infringement requires that the accused invention replicate every detail of the patent.<sup>34</sup> Courts have long recognized that restricting patent infringement to literal infringement would “convert the protection of the patent grant into a hollow and useless thing.”<sup>35</sup> It would be simple for an “unscrupulous copyist to make unimportant and insubstantial changes and substitutions in the patent” and replicate the product while leaving the patentee without a legal remedy.<sup>36</sup>

To avoid the problem of the “unscrupulous copyist,” courts developed the equitable doctrine of equivalents. The doctrine, which first appeared in case law in 1853,<sup>37</sup> states that an accused product that does not infringe literally may still infringe if it does “the same work in substantially the same way, and accomplish[es] substantially the same result” as the patented product, “even though [it] differ[s] in name, form or shape.”<sup>38</sup> The

32. 35 U.S.C. § 154(a)(1) (“Every patent shall contain . . . a grant to the patentee, . . . of the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States.”).

33. See 35 U.S.C. § 271(a).

34. See, e.g., *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 609 (1950).

35. *Id.* at 607. Other courts and scholars support this view. See, e.g., *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 731 (2002) (“If patents were always interpreted by their literal terms, their value would be greatly diminished.”); Tun-Jen Chiang, *The Levels of Abstraction Problem in Patent Law*, 105 Nw. U. L. REV. 1097, 1138 (2011) (arguing that if the patent’s scope were “confined to precise replication . . . then pirates would quickly learn to copy the principle or the heart of the patent without replicating the precise embodiment . . . . Protection limited to literal reproduction is worthless and easily circumvented.”). But see Lee Petherbridge, *On the Decline of the Doctrine of Equivalents*, 31 CARDOZO L. REV. 1371, 1404 (2010) (arguing that the recent trend towards de-emphasizing the doctrine of equivalents means that “courts have challenged the legitimacy of the premise that the doctrine of equivalents is necessary to protect the incentive structure of the patent system. And, the idea that the doctrine of equivalents is necessary to encourage inventors to invent and to disclose inventions may have been found wanting. Ample evidence suggests that all the while the courts were killing the doctrine of equivalents, patent applicants were increasing the rate at which they filed applications for new inventions.”); Timothy R. Holbrook, *Equivalency and Patent Law’s Possession Paradox*, 23 HARV. J.L. & TECH. 1, 39 (2009) (arguing that the doctrine of equivalents may actually reduce the incentive to innovate because a rule preventing a patentee from claiming downstream inventions as equivalents would “creat[e] an incentive for the patentee to continue to innovate and improve upon her invention because others also [would] have an opportunity to invent and patent improvements on it”).

36. *Graver Tank*, 339 U.S. at 607. Note that the characterization of a copyist as “unscrupulous” conflicts with later Federal Circuit jurisprudence encouraging copyists. See, e.g., *Read Corp. v. Portec, Inc.*, 970 F.2d 816, 828 (Fed. Cir. 1992) (“We have often noted that one of the benefits of the patent system is the incentive it provides for ‘designing around’ patented inventions, thus creating new innovation.”); *Slimfold Mfg. v. Kinkead Indus.*, 932 F.2d 1453, 1457 (Fed. Cir. 1991) (“Designing around patents is, in fact, one of the ways in which the patent system works to the advantage of the public in promoting progress in the useful arts, its constitutional purpose.”); *State Indus. v. A.O. Smith Corp.*, 751 F.2d 1226, 1236 (Fed. Cir. 1985) (“One of the benefits of a patent system is its so-called ‘negative incentive’ to ‘design around’ a competitor’s products, even when they are patented, thus bringing a steady flow of innovations to the marketplace. It should not be discouraged . . . .”).

37. *Winans v. Denmead*, 56 U.S. 330, 341 (1853).

38. *Union Paper-Bag Mach. Co. v. Murphy*, 97 U.S. 120, 125 (1877).



purpose of the doctrine is to prevent “fraud on a patent” by preventing instances where a patentee does not get the full benefit of his patent because a copyist changed a minor detail of the invention.<sup>39</sup>

There are two tests courts use to determine if a product has infringed by equivalents. The first test is the “tripartite” or “function-way-result” test.<sup>40</sup> Under this test, the court asks “whether the accused device . . . performs substantially the same function in substantially the same way to achieve substantially the same result.”<sup>41</sup> The second test is the “insubstantial differences” test. Under this test the court looks at the substantiality of the differences between the two products.<sup>42</sup> The Supreme Court has expressed no preference between the tests, stating that “the particular linguistic framework used [to determine equivalence] is less important than whether the test is probative of the essential inquiry.”<sup>43</sup>

The key to applying the doctrine of equivalents is that it must be used on an element-by-element basis, rather than on the product as a whole.<sup>44</sup> This means that the court must compare one element of the accused product to one element of the patented product, rather than looking at the similarities between the two holistically.<sup>45</sup> The purpose of this requirement is to preserve a meaning for each of the claim’s elements and to avoid unduly enlarging the scope of the patent.<sup>46</sup>

Equivalency is a matter of fact. It “is not an absolute to be considered in a vacuum.”<sup>47</sup> *Graver Tank Manufacturing Co. v. Linde Air Products Co.*, a seminal doctrine of equivalents case, put forward several factors courts should consider in determining equivalence: “the purpose for which an ingredient is used in a patent, the qualities it has when combined with other ingredients, and the function which it is intended to perform.”<sup>48</sup> *Graver-Tank* further instructed courts to consider “whether persons reasonably skilled in the art would have known of the inter-

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39. See *Graver Tank*, 339 U.S. at 608.

40. *Dawn Equip. Co. v. Ky. Farms Inc.*, 140 F.3d 1009, 1015–16 (Fed. Cir. 1998).

41. *Id.* at 1016.

42. *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 35–36 (1997).

43. *Id.* at 40.

44. *Id.*

45. *Id.* This element-by-element approach has both supporters and detractors in the literature. See, e.g., Tun-Jen Chiang, *supra* note 35, at 527 n.17 (supporting the element-by-element analysis because it constricts the doctrine of equivalents and allows claims to “retain[] some boundary-defining role”); Mark A. Lemley, *Point of Novelty*, 105 Nw. U. L. REV. 1253, 1273 (2011) (arguing that the element-by-element approach makes it too easy for competitors to design around a product by making small, non-innovative changes); Harry Surden, *Efficient Uncertainty in Patent Interpretation*, 68 WASH. & LEE L. REV. 1737, 1773–74 (2011) (supporting the element-by-element approach in the context of literal infringement because it helps define claim scope); Esther Steinhauer, *Using the Doctrine of Equivalents to Provide Broad Protection for Pioneer Patents: Limited Protection for Improvement Patents*, 12 PACE L. REV. 491, 492–98 (1992) (suggesting that the element-by-element approach is only suitable for non-pioneering, i.e., improvement, patents, whereas pioneering patents should be assessed as a whole).

46. *Warner-Jenkinson*, 520 U.S. at 40.

47. *Graver Tank & Mfg. Co. v. Linde AirProds. Co.*, 339 U.S. 605, 609 (1950).

48. *Id.*

changeability of an ingredient” at issue.<sup>49</sup>

The range of equivalents that may be claimed under the doctrine depends on the nature of the plaintiff’s invention. A pioneer invention is “commonly understood to denote a patent covering a function never before performed, a wholly novel device, or one of such novelty and importance as to mark a distinct step in the progress of the art, as distinguished from a mere improvement or perfection of what ha[s] gone before.”<sup>50</sup> It is entitled to a greater scope of protection.<sup>51</sup> “Mere improvement” inventions may also use the doctrine of equivalents; however, courts will grant them a narrower scope of equivalents.<sup>52</sup>

Because the doctrine of equivalents is so fact dependent, the Federal Circuit has long been concerned that lower courts would overuse the doctrine.<sup>53</sup> An overbroad doctrine of equivalents would swallow the purpose of claim limitations in patent law.<sup>54</sup> Therefore, the Federal Circuit has imposed several restrictions on the doctrine, including prior art limitation,<sup>55</sup> dedication to the public domain,<sup>56</sup> and prosecution history estop-

49. *Id.*

50. *Boyd Power-Brake Co. v. Westinghouse*, 170 U.S. 537, 561–62 (1898).

51. *Cont’l Paper Bag Co. v. E. Paper Bag Co.*, 210 U.S. 405, 414 (1908); see also John R. Thomas, *The Question Concerning Patent Law and Pioneer Inventions*, 10 HIGH TECH L.J. 35, 37 (1995). The extent to which the pioneer doctrine is still good law is debatable. The Federal Circuit appeared to have overruled it in *Texas Instruments, Inc. v. U.S. International Trade Commission*, 846 F.2d 1369 (Fed. Cir. 1988), writing that a patent’s “‘pioneer’ status does not change the way infringement is determined.” *Id.* at 1370. However, the pioneer doctrine continues to be used by both the Federal Circuit and lower courts. For an extensive survey of the doctrine, see Brian J. Love, *Interring the Pioneer Invention Doctrine*, 90 N.C. L. REV. 379, 389–404 (2012).

52. *Graver Tank*, 339 U.S. at 608 (“The doctrine operates not only in favor of the patentee of a pioneer . . . invention, but also for the patentee of a secondary invention consisting of a combination of old ingredients which produce new and useful results . . .”).

53. See *K-2 Corp. v. Salman S.A.*, 191 F.3d 1356, 1366 (Fed. Cir. 1999); Martin J. Adelman & Gary L. Fancione, *The Doctrine of Equivalents in Patent Law: Questions that Pennwalt Did Not Answer*, 137 U. PA. L. REV. 673, 699 (1988) (“[T]he doctrine of equivalents, once thought to be a narrow doctrine designed to prevent ‘fraud on the patent,’ has become an issue of fact to be resolved in virtually every patent suit.”).

54. See *supra* notes 35–36 and accompanying text (discussing the problems that arise with inconsistent claim construction).

55. The prior art limitation prevents courts from using the doctrine of equivalents to expand a patent’s claims to such an extent that it would include prior art. *K-2 Corp.*, 191 F.3d at 1366–67 (“[T]he doctrine of equivalents cannot allow a patent to encompass subject matter existing in the prior art.”); *Wilson Sporting Goods Co. v. David Geoffrey & Assocs.*, 904 F.2d 677, 684 (Fed. Cir. 1990) (“[Prior art] limits the range of permissible equivalents of a claim.”). For scholarly explanations of and commentary on the prior-art limitation, see Michael A. Carrier, *Cabining Intellectual Property Through a Property Paradigm*, 54 DUKE L. J. 1, 115–16 (2004) (discussing the prior-art limitation and its policy rationale); John Mills, *Three “Non-Obvious” Modifications to Simplify and Rein in the Doctrine of Equivalents*, 14 FED. CIR. B.J. 649, 661 (2005) (explaining the mechanics of the prior-art limitation). The rationale behind the limitation is that a patent that overlapped with the prior art would not have been approved by the PTO during examination; therefore, the patent should not be able to gain that coverage after the fact through the doctrine of equivalents. *Wilson Sporting Goods*, 904 F.2d at 677.

56. If a patent owner discloses an equivalent in the specification of the patent but did not claim it, the patentee cannot claim it under the doctrine of equivalents. *Miller v. Bridgeport Brass Co.*, 104 U.S. 350, 352 (1881) (“[T]he claim of a specific device or combination, and an omission to claim other devices or combinations apparent on the face of the

pel.<sup>57</sup> Courts frequently use these limitations, particularly prosecution history estoppel, as a way to prevent brand name companies from claiming that their generic competitors infringe by equivalents.<sup>58</sup>

The doctrine of equivalents is controversial.<sup>59</sup> Scholars have begun predicting the demise of the doctrine, noting that, in recent years, surpris-

patent are, in law, a dedication to the public of that which is not claimed.”); *Johnson & Johnston Assocs. v. R.E. Serv. Co.*, 285 F.3d 1046, 1054 (Fed. Cir. 2002) (“[W]hen a patent drafter discloses but declines to claim subject matter . . . this action dedicates that unclaimed subject matter to the public.”); *Unique Concepts, Inc. v. Brown*, 939 F.2d 1558, 1562–63 (Fed. Cir. 1991) (“[S]ubject matter disclosed but not claimed in a patent application is dedicated to the public.”). The test for whether a patentee has dedicated material to the public domain is “purely objective.” *Johnson*, 285 F.3d at 1053 n.1. Namely, the “patentee’s subjective intent is irrelevant to determining whether unclaimed subject matter has been disclosed and therefore dedicated to the public.” *Id.* The rationale is that the doctrine of equivalents is designed to protect patent owners against unanticipated uses; therefore, patentees should not be allowed to use the doctrine to broaden their claims to encompass uses they did anticipate. *See SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1346–47 (Fed. Cir. 2001).

57. Prosecution history estoppel arises when the patentee limits the scope of the patent during prosecution. *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 733 (2002). The rationale for prosecution history estoppel is to prevent patentees from behaving strategically by filing narrow claims that easily pass examination and later broadening the claims through application of the doctrine of equivalents. *Maxwell v. J. Baker, Inc.*, 86 F.3d 1098, 1107 (Fed. Cir. 1996) (“A patentee may not narrowly claim his invention and then, in the course of an infringement suit, argue . . . the doctrine of equivalents . . . . Such a result would merely encourage a patent applicant to present a broad disclosure in the specification of the application and file narrow claims.”); *Genentech, Inc. v. Wellcome Found. Ltd.*, 29 F.3d 1555, 1564 (Fed. Cir. 1994) (“An applicant should not be able deliberately to narrow the scope of examination to avoid during prosecution scrutiny by the PTO of subject matter . . . and then, obtain in court . . . a scope of protection which encompasses that subject matter.”).

58. *See Duramed Pharm., Inc. v. Paddock Labs., Inc.*, 644 F.3d 1376, 1380 (Fed. Cir. 2011); *Reckitt Benckiser Inc. v. Watson Labs., Inc.*, 430 F. App’x 871, 878 (Fed. Cir. 2011); *Schwarz Pharma, Inc. v. Paddock Labs., Inc.*, 504 F.3d 1371, 1375 (Fed. Cir. 2007); *SmithKline Beecham Corp. v. Excel Pharm., Inc.*, 356 F.3d 1357, 1365 (Fed. Cir. 2004); *Glaxo Wellcome, Inc. v. Impax Labs., Inc.*, 356 F.3d 1348, 1356 (Fed. Cir. 2004); *Ranbaxy Pharm., Inc. v. Apotex, Inc.*, 350 F.3d 1235, 1241 (Fed. Cir. 2003); *Glaxo Grp. Ltd., v. Ranbaxy Pharm., Inc.*, 262 F.3d 1333, 1338–39 (Fed. Cir. 2001); *Biovail Corp. Int’l v. Andrx Pharm., Inc.*, 239 F.3d 1297, 1302 (Fed. Cir. 2001); *Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1252 (Fed. Cir. 2000); *Merck & Co. v. Mylan Pharm., Inc.*, 190 F.3d 1335, 1341 (Fed. Cir. 1999); *Pharmacia & Upjohn Co. v. Mylan Pharm., Inc.*, 170 F.3d 1373, 1376 (Fed. Cir. 1999); *Duramed Pharm., Inc. v. Paddock Labs., Inc.*, 715 F. Supp. 2d 552, 555 (S.D.N.Y. 2010), *aff’d*, 644 F.3d 1376 (Fed. Cir. 2011); *In re Gabapentin Patent Litig.*, 393 F. Supp. 2d 278, 293 (D.N.J. 2005); *Aventis Pharm., Inc. v. Barr Labs., Inc.*, 335 F. Supp. 2d 558, 569 (D.N.J. 2004); *SmithKline Beecham Corp. v. Excel Pharm., Inc.*, 214 F. Supp. 2d 581, 592 (E.D. Va. 2002), *vacated*, 356 F.3d 1357 (Fed. Cir. 2004); *Bayer AG v. Elan Pharm. Research Corp.*, 64 F. Supp. 2d 1295, 1304 (N.D. Ga. 1999), *aff’d*, 212 F.3d 1241 (Fed. Cir. 2000); *Merck & Co. v. Mylan Pharm., Inc.*, 19 F. Supp. 2d 334, 352 (E.D. Pa. 1998), *aff’d*, 190 F.3d 1297 (Fed. Cir. 2001); *Pharmacia & Upjohn Co. v. Mylan Pharm., Inc.*, 5 F. Supp. 2d 399, 406 (N.D. W. Va. 1998), *aff’d*, 170 F.3d 1373 (Fed. Cir. 1999).

59. *See Adelman & Francione, supra* note 53, at 677; T. Whitley Chandler, *Prosecution History Estoppel, the Doctrine of Equivalents, and the Scope of Patents*, 13 HARV. J.L. & TECH. 465, 466–67 (2000); Joseph S. Cianfrani, *An Economic Analysis of the Doctrine of Equivalents*, 1 VA. J.L. & TECH. 1, 13 (1997); Michael J. Meurer & Craig A. Nard, *Invention, Refinement and Patent Claim Scope: A New Perspective on the Doctrine of Equivalents*, 93 GEO. L.J. 1947, 1948 (2005); Paul R. Michel, *The Role and Responsibility of Patent Attorneys in Improving the Doctrine of Equivalents*, 40 IDEA 123, 124 (2000); Petherbridge, *supra* note 35, at 1372; Joshua D. Sarnoff, *Abolishing the Doctrine of Equivalents and Claiming the Future after Festo*, 19 BERK. TECH. L.J. 1157, 1163 (2004);

ingly few plaintiffs have won their doctrine of equivalents arguments.<sup>60</sup> In particular, a study by John Allison and Mark Lemley found that although plaintiffs win over 50% of patent cases, they won just 24% of doctrine of equivalents cases between 2003 and 2011.<sup>61</sup> Allison and Lemley posit that *Markman's* requirement concerning how courts construe claims caused this decline.<sup>62</sup> They argue that because courts dispose of claim construction issues as a matter of law, courts cannot dispose of the entire case before trial unless they also resolve claims of infringement on summary judgment; therefore, a judge who has found no literal infringement as a matter of law is likely to find the same for infringement by equivalents merely to dispose of the case.<sup>63</sup>

Although this may signal that courts' treatment of the doctrine of equivalents has changed, the doctrine remains important for litigants. For example, ten percent of patent cases raise the doctrine.<sup>64</sup> Although Allison and Lemley point to the low rate of plaintiff wins as evidence of the doctrine's decline,<sup>65</sup> the win rate remains high in the equivalence paradox cases studied in this article—suggesting that the doctrine of equivalence may hold more relevance in this context than in patent litigation generally.<sup>66</sup> In addition, it is well established that different industries innovate differently; thus, conclusions about patents in general or patents within a specific industry do not always apply to another industry.<sup>67</sup> The pharmaceutical and biotechnology industries, as a whole, have a higher-than-average plaintiff win rate,<sup>68</sup> which is consistent with my finding that equivalence paradox cases also have a high plaintiff win rate.<sup>69</sup>

## B. THE HATCH-WAXMAN ACT AND BIOEQUIVALENCE

The Hatch-Waxman Act (formally known as the Drug Price Competition and Patent Term Restoration Act of 1984) sets out the abbreviated

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John R. Thomas, *Claim Re-Construction: The Doctrine of Equivalents in the Post-Markman Era*, 9 LEWIS & CLARK L. REV. 153, 154 (2005).

60. John R. Allison & Mark A. Lemley, *The (Unnoticed) Demise of the Doctrine of Equivalents*, 59 STAN. L. REV. 955, 966 (2007).

61. *Id.*

62. *Id.* at 958.

63. *Id.*

64. A search of Westlaw's ALLFEDS database for "doctrine of equivalents" from 01/01/2011 to 01/01/2012 yielded 191 results compared to a search for "patent infringement" across the same dates which yielded 1403 results.

65. Allison & Lemley, *supra* note 60, at 967.

66. Allison and Lemley found that patentees won 40% of doctrine of equivalents cases prior to *Markman*, but only 24% of cases decided between 1999 and 2007. *Id.* at 978. My research has found that, in cases involving abbreviated new drug application (ANDA) products and the doctrine of equivalents, over a third of the cases were resolved in favor of the plaintiffs, a rate closer to the pre-*Markman* plaintiff win rate than to the post-*Markman* rate.

67. Burk & Lemley, *supra* note 29, at 1588–89.

68. The percentage of plaintiff wins in all pharmaceutical doctrine of equivalents cases is derived by adding the percentage of wins in pharmaceutical and biotechnology doctrine of equivalents cases as listed in the appendix of Allison & Lemley's article, *supra* note 60.

69. Note that the percentage of plaintiff wins in paradox cases is even higher than the percentage of plaintiff wins in pharmaceutical and biotechnology cases as a whole.

new drug application (ANDA) pathway.<sup>70</sup> It was enacted as a compromise between the brand name and generic industries and seeks to make generic drugs available more cheaply while ensuring that brand name companies retain sufficient incentives to invest in the research and development of new drugs.<sup>71</sup>

The Act gives brand name products increased patent life<sup>72</sup> and generic products an abbreviated application pathway.<sup>73</sup> To qualify to use the ANDA pathway, a drug must be the “same as” a listed drug (i.e., a drug approved through an NDA).<sup>74</sup> The term “same as” is defined as “identical in active ingredient(s), dosage form, strength, route of administration, and conditions of use.”<sup>75</sup> If a generic is not the “same as” the listed drug, it cannot be approved through an ANDA unless the applicant submits a suitability petition and the FDA accepts the petition.<sup>76</sup>

Generic companies do not need to provide full safety and efficacy data or conduct clinical trials.<sup>77</sup> They merely need to demonstrate that their product is “bioequivalent,”<sup>78</sup> meaning that the rate and extent of absorption of the drug does “not show a significant difference from the rate and extent of absorption of the listed drug.”<sup>79</sup> The applicant must also show that the drug contains the same active ingredient(s) as the reference drug and has the same route of administration, dosage form, and strength.<sup>80</sup>

70. Pub. L. No. 98-417, § 101, 98 Stat. 1538, 1585 (1984) (codified as amended at 35 U.S.C. § 156).

71. *Abbott Labs. v. Young*, 920 F.2d 984, 991 (D.C. Cir. 1990) (“The Act emerged from Congress’s efforts to balance two conflicting policy objectives: to induce brand name pharmaceutical firms to make the investments necessary to research and develop new drug products, while simultaneously enabling competitors to bring cheaper, generic copies of those drugs to market.”).

72. Patent life is extended by a “time equal to the regulatory review period for the approved product.” 35 U.S.C. § 156(c) (2006). The extension cannot be longer than five years. *Id.* § 156(g)(1)(8). If applicants do not act with “due diligence” to further their drug’s application during this period, that time can be subtracted from the patent life. *Id.* § 156(c)(1).

73. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j) (2006).

74. *See Applications for FDA Approval to Market a New Drug*, 21 C.F.R. § 314.92(a)(1) (2012).

75. *Id.*

76. 21 C.F.R. § 314.93(b).

77. *See* 21 U.S.C. § 355(j)(1).

78. *Id.* § 355(j)(2)(A)(iv) (“An abbreviated application for a new drug shall contain . . . information to show that the new drug is bioequivalent to the listed drug” unless the FDA has approved the applicant’s suitability petition, filed according to 21 U.S.C. § 355(j)(2)(C).).

79. *Id.* § 355(j)(8)(B).

80. *Id.* § 355(j)(2)(A); 21 C.F.R. § 314.94(a)(5). If the generic drug has a different active ingredient, route of administration, dosage form, or strength, the applicant must submit a suitability petition to the FDA, which the FDA will grant only if no additional investigations are necessary to support safety and efficacy. 21 U.S.C. § 355(j)(2)(c); 21 C.F.R. § 314.93. Petitions must follow the rules set out in 21 C.F.R. § 10.20, which in turn requires the use of a citizen’s petition format specified by 21 C.F.R. § 10.30(c). 21 C.F.R. § 314.93(c). If a generic manufacturer does need additional data to support safety and efficacy, it is not eligible to use the ANDA pathway, and must use the application process described in 21 U.S.C. § 355(b) (known as the 505(b)(2) pathway). The 505(b)(2) pathway allows approval of generic drugs for which the investigations relied on were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or

The FDA has interpreted bioequivalence as the “absence of a significant difference in the rate and extent to which the active ingredient . . . becomes available at the site of drug action.”<sup>81</sup> The FDA assesses bioequivalence by looking at pharmacokinetic data, specifically the parameters that measure the cumulative drug concentration in systemic circulation over a period of time and the maximum concentration of the drug in the body during administration.<sup>82</sup> These pharmacokinetic parameters must fall entirely within 80% to 125% of the mean pharmacokinetic parameters of the listed drug.<sup>83</sup>

The FDA’s primary concern is to protect “the patient against approval of products that are not bioequivalent.”<sup>84</sup> The Orange Book states that the use of the described statistical methods means “that there is no more

use. 21 U.S.C. § 355(b)(2). For more information on the 505(b)(2) pathway, see Tam Q. Dinh, *Potential Pathways for Abbreviated Approval of Generic Biologics Under Existing Law and Proposed Reforms to the Law*, 62 FOOD & DRUG L.J. 77 (2007); K. R. Kelleher, *FDA Approval of Generic Biologics: Finding a Regulatory Pathway*, 14 MICH. TELECOMM. & TECH. L. REV. 245, 250–51 (2007).

81. 21 C.F.R. § 320.1(e) (2012). The FDA allows a variety of study protocols, including studies performed *in vivo*, *in vitro*, or both. *Id.* § 320.24(a). Section 320.24(b) lists approaches that are acceptable in descending order of accuracy, sensitivity, and reproducibility. The choice of study type is made in consultation with the FDA and is based on the site of action of the drug in question and the ability of the study design to compare bioavailability at that site between the generic and reference drug. FDA, APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, at viii (2012) [hereinafter ORANGE BOOK], available at <http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm071436.pdf>. The FDA is committed to placing bioequivalence study design guidance documents on its website and has developed almost 900 product-specific bioequivalence guidance documents. CTR. FOR DRUG EVALUATION & RESEARCH, GUIDANCE FOR INDUSTRY: BIOEQUIVALENCE RECOMMENDATIONS FOR SPECIFIC PRODUCTS 1 (2010), available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidance/UCM072872.pdf>.

82. ORANGE BOOK, *supra* note 81, at ix. These parameters are known as Area Under the Curve (AUC) and  $C_{max}$ . AUC is the total area under a graphed curve where the x-axis represents time and the y-axis represents drug concentration. CTR. FOR DRUG EVALUATION & RESEARCH AND CTR. FOR BIOLOGICS EVALUATION & RESEARCH, GUIDANCE FOR INDUSTRY: EXPOSURE-RESPONSE RELATIONSHIPS—STUDY DESIGN, DATA ANALYSIS, & REGULATORY APPLICATIONS 14 (2003), available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm072109.pdf>. The AUC represents the average drug concentration in systemic circulation over a period of time. *Id.*  $C_{max}$  refers to the maximum concentration of a drug in the body during administration and is the highest point on a graph where the x-axis represents time and the y-axis represents drug concentration. *Id.*  $C_{max}$  is significant because it indirectly measures the rate of absorption and relates to the drug’s potential to cause side effects. Barbara M. Davit et al., *Comparing Generic and Innovator Drugs: A Review of 12 Years of Bioequivalence Data from the United States Food and Drug Administration*, 43 ANNALS PHARMACOTHERAPY 1583, 1585 (2009).

83. ORANGE BOOK, *supra* note 81, at ix. The guidelines for statistical analysis are set forth in 21 C.F.R. § 320.23(a)(2). Applicants must analyze their bioequivalence data using a “one-sided test procedure.” *Id.* This requires two tests. *Id.* The first “determines whether a generic product (test), when substituted for a brand name product (reference), is significantly less bioavailable.” *Id.* The second determines “whether a brand-name product when substituted for a generic product is significantly less bioavailable.” *Id.* The applicant must then calculate bioequivalence using an analysis of variance (ANOVA) procedure and must have a 90% confidence interval for certain pharmacokinetic parameters. *Id.* The 90% confidence interval must fall entirely within 80% to 125% of the mean pharmacokinetic parameters of the listed drug. *Id.*

84. *Id.* at x.

than a 5% chance that a generic . . . is not truly equivalent to the reference.”<sup>85</sup> Studies seem to back up this claim.<sup>86</sup>

If a generic drug is “therapeutically equivalent” to the reference product, pharmacists may substitute the generic drug for the brand name drug without special authorization from the physician.<sup>87</sup> Whether pharmacies are allowed to substitute interchangeable drugs is a matter of state law.<sup>88</sup> All fifty states currently have a law that either allows for generic substitution or *mandates* generic substitution.<sup>89</sup>

There is heated debate in the healthcare industry about the validity of the practice of substitution.<sup>90</sup> Certain drugs have absorption rates that vary significantly from patient to patient (“high variability drugs”).<sup>91</sup> The pharmacokinetic parameters of approved generic high variability drugs differ from their brand name counterparts, sometimes by more than ten percent.<sup>92</sup> Even “bioequivalent” drugs that are not classified as highly variable can have poor interchangeability in practice. For example, epilepsy patients who switch to a generic drug occasionally begin to have more frequent seizures.<sup>93</sup> Additionally, one study showed that Israeli pa-

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85. *Id.*

86. A study of 224 generic products approved in the first two years after passage of the Act found that the AUC of generic and brand name products differed by an average of only 3.5%. Stuart L. Nightingale & James C. Morrison, *Generic Drugs and the Prescribing Physician*, 258 JAMA 1200, 1202 (1987). A study of 273 generic drug applications approved in 1997 found that the mean difference between the generic and brand name product was 3.47% for AUC and 4.29% for  $C_{max}$ . FDA, *Review of Generic Bioequivalence Studies*, 282 JAMA 1995, 1995 (1999). A recent study of the 2070 generic applications between 1996 and 2007 found that the mean difference between the generic and brand name drugs was 3.56% for AUC and 4.35% for  $C_{max}$ . Davit et al., *supra* note 82, at 1583. Note that these studies were all conducted by FDA employees and thus have an inherent bias.

87. Henry Grabowski et al., *Implementation of the Biosimilar Pathway: Economic and Policy Issues*, 41 SETON HALL L. REV. 511, 524 (2011). The Orange Book defines “therapeutic equivalents” to mean two products that “are pharmaceutical equivalents [that] can be expected to have the same clinical effect and safety profile when administered to patients . . . .” ORANGE BOOK, *supra* note 81, at vii.

88. See Grabowski et al., *supra* note 87, at 524.

89. David R. Holmes et al., *American College of Cardiology Foundation and American Heart Association 2011 Health Policy Statement on Therapeutic Interchange and Substitution*, 58 J. AM. C. CARDIOLOGY 1287, 1305 (2011).

90. See, e.g., Peter Meredith, *Bioequivalence and Other Unresolved Issues in Generic Drug Substitution*, 25 CLINICAL THERAPEUTICS 2875, 2875–76 (2003); James A. Reiffel, *Formulation Substitution and Other Pharmacokinetic Variability*, 85 AM. J. CARDIOLOGY 46D, 46D (2000); Sandra Sabatini et al., *Drug Substitution in Transplantation*, 33 AM J. KIDNEY DISEASE 389, 389 (1999).

91. These drugs have more trouble meeting bioequivalence requirements. Barbara M. Davit, *Highly Variable Drugs: Observations from Bioequivalence Data Submitted to the FDA for New Generic Drug Applications*, 10 AM. ASS’N PHARMACEUTICAL SCIENTISTS J. 148, 151 (2008). The FDA recommends that ANDA applicants for high variability drugs do bioequivalence studies with a larger number of subjects to compensate for the inconsistency in bioavailability from patient to patient. Leslie Beneet, Professor of Biopharm. Scis., Presentation to FDA Advisory Committee for Pharmaceutical Science: Therapeutic Considerations of Highly Variable Drugs (Oct. 6, 2006), available at <http://www.fda.gov/ohrms/dockets/ac/06/slides/2006-4241s2-index.htm>.

92. Davit et al., *supra* note 82, at 1590.

93. M.J. Berg et al., *Generic Substitution in Treatment of Epilepsy: Case Evidence of Breakthrough Seizures*, 71 NEUROLOGY 525, 525–30 (2008).

tients who switched from brand name warfarin (an anticoagulant) to generic warfarin needed higher doses of the generic product to achieve the same results.<sup>94</sup>

### 1. Provisions for Patent Infringement

A suit for patent infringement cannot be filed unless the defendant has committed an act of infringement.<sup>95</sup> Research and development leading to an FDA application is not an act of infringement.<sup>96</sup> Filing an ANDA is, however, an act of artificial infringement, so brand name companies are allowed to file infringement suits against generic companies as soon as an ANDA has been filed.<sup>97</sup> In addition, the Hatch-Waxman Act encourages generic companies to file invalidity suits against brand name patents, to bring down the cost of drugs.<sup>98</sup> To accomplish these goals, the Act includes a number of provisions governing patent infringement in the context of ANDAs.

For example, when a brand name company files a new drug application (NDA), it submits patent information to the FDA for any patent that claims the relevant drug.<sup>99</sup> The FDA compiles these patents in the *Approved Drug Products with Therapeutic Equivalence Evaluations*, informally called the *Orange Book*.<sup>100</sup> When a generic company files an ANDA, it must provide a certification with respect to each patent listed for the brand name product in the *Orange Book*.<sup>101</sup> The ANDA must

94. Hillel Halkin et al., *Increased Warfarin Doses and Decreased International Normalized Ratio Response After Nationwide Generic Switching*, 74 *CLINICAL PHARMACOLOGY & THERAPEUTICS* 215, 215–20 (2003).

95. 35 U.S.C. § 271(a) (2006).

96. *Id.* § 271(e)(1). The Hatch-Waxman Act inserted this provision into the Patent Act to effectively overrule the Federal Circuit's decision in *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858, 863 (Fed. Cir. 1984) (holding that the experimental use defense did not protect a generic company who used a patented product to prepare an FDA application). The Federal Circuit recognized that *Roche* had been overturned in *Eli Lilly & Co. v. Medtronic, Inc.*, 872 F.2d 402, 406 (Fed. Cir. 1989) (“We can only conclude that Congress intended the enactment of section 271(e)(1) to set aside the *Roche* interpretation of section 271(a).”). This provision of 271(e)(1) has been discussed at length in the scholarly literature. See, e.g., Rebecca S. Eisenberg, *Proprietary Rights and the Norms of Science in Biotechnology Research*, 97 *YALE L. J.* 177, 178–80 (1987) (describing the application of the doctrine in the context of biotechnology); Ned. A. Israelsen, *Making, Using, and Selling Without Infringing: An Examination of 35 U.S.C. Section 271(e) and the Experimental Use Exception to Patent Infringement*, 16 *AIPLA Q.J.* 457, 458–61 (1989) (providing an overview of 271(e) and the cases interpreting it); Jordan P. Karp, *Experimental Use as Patent Infringement: The Impropriety of a Broad Exception*, 100 *YALE L. J.* 2169, 2169–70 (1991) (describing the history of the experimental use exception and arguing that it should not be broadened); E. Joshua Rosenkranz, *The FDA Exemption and Research Tools: The Federal Circuit Gets it Wrong*, 38 *AIPLA Q.J.* 309, 310–11 (2010) (summarizing policy arguments for and against 271(e)).

97. See 35 U.S.C. § 271(e) (2006 & Supp. V 2011).

98. Elizabeth S. Weisswasser & Scott D. Danzis, *The Hatch-Waxman Act: History, Structure, and Legacy*, 71 *ANTITRUST L.J.* 585, 603 (2004).

99. 21 U.S.C. § 355(b)(1) (2006). There is controversy over which patents must be listed in this way. See Weisswasser & Danzis, *supra* note 98, at 596–99.

100. *ORANGE BOOK*, *supra* note 81.

101. 21 U.S.C. § 355(j)(2)(A)(vii).



certify either that no such patents are listed in the *Orange Book*,<sup>102</sup> that the patents have expired,<sup>103</sup> that the manufacturer does not intend to market the generic until the patent has expired,<sup>104</sup> or that the patent is invalid or not infringed.<sup>105</sup>

The last option is called a “Paragraph IV” certification.<sup>106</sup> The brand name company has forty-five days to file a lawsuit asserting that the generic drug infringes,<sup>107</sup> in which case the ANDA approval is automatically stayed for the shorter of thirty months or until a final court decision of non-infringement.<sup>108</sup> As an incentive for the generic company to take on the costly process of a lawsuit, the Act gives 180 days of market exclusivity to the first generic company to sue (meaning that no other generic product based on the same brand name drug can be approved during that time).<sup>109</sup> If the brand name company wins the suit, the ANDA cannot be approved until the patent expires.<sup>110</sup>

These incentives—both the availability of additional market exclusivity and the possibility of additional patent exclusivity—encourage pharmaceutical companies to behave strategically. Much has been written about “evergreening,” the process by which pharmaceutical companies file a

102. *Id.* § 355(j)(2)(A)(i).

103. *Id.* § 355(j)(2)(A)(ii).

104. *Id.* § 355(j)(2)(A)(iii).

105. *Id.* § 355(j)(2)(A)(iv).

106. Julie D. Polovina, Note, *Mutant Biologies: The 2010 Health-Reform Legislation's Potential Impact on Reducing Biologic Research and Development Costs*, 100 GEO. L.J. 2291, 2302 (2012).

107. 21 U.S.C. § 355(j)(2)(B). If the brand name company does not file a suit within forty-five days, the ANDA is effective immediately. 21 U.S.C. § 355(j)(5)(B)(iii).

108. 21 U.S.C. § 355(j)(5)(B)(iv). Note that the thirty-month provision is also highly controversial, because it is the target of strategic behavior on the part of brand name companies to extend their market monopoly. A study by the FTC found that 72% of NDA holders who received a Paragraph IV certification filed a suit against the generic company. FTC, *GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY 14* (2002), available at <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf>. For more information, see Matthew Avery, *Continuing Abuse of the Hatch-Waxman Act by Pharmaceutical Patent Holders and the Failure of the 2003 Amendments*, 60 HASTINGS L.J. 171, 173 (2008); Claire Comfort, *Will the Federal Circuit's Eli Lilly v. Teva Decision Lead to Efforts to Abuse the Modification Provision of the Hatch-Waxman Act?*, 16 RICH. J.L. & TECH. 2, 2–4 (2009); Yuk Fung Hui, *FDA's Proposed Rules on Patent Listing Requirements for New Drug and 30-Month Stays on ANDA Approval (Proposed Oct. 24, 2002)*, 12 ANNALS HEALTH L. 325, 326–31 (2003); Laura J. Robinson, *Analysis of Recent Proposals to Reconfigure Hatch-Waxman*, 11 J. INTELL. PROP. L. 47, 75–78 (2003); Christopher R. Walker, *Deadly Delay / Postponed Pills*, 10 J. MARSHALL REV. INTELL. PROP. L. 255, 262 (2010).

109. See 21 U.S.C. § 355(j)(5)(B)(iv). This is one of the most controversial provisions of the Act. For more information on the 180-day exclusivity provision, see Scott Hemphill & Mark A. Lemley, *Earning Exclusivity: Generic Drug Incentives and the Hatch-Waxman Act*, 77 ANTITRUST L.J. 947, 948–50 (2011); Erika Lietzan et al., *A New History and Discussion of 180-Day Exclusivity*, 64 FOOD & DRUG L.J. 335, 335–37 (2009); Erika Lietzan & David E. Korn, *Issues in the Interpretation of 180-day Exclusivity*, 62 FOOD & DRUG L.J. 49, 49–75 (2007); Christopher S. Ponder, *The Dubious Value of Hatch-Waxman Exclusivity*, 45 Hous. L. REV. 555, 557–58 (2008); John R. McNair, Note, *If Hatch Wins, Make Waxman Pay: One-Way Fee Shifting as a Substitute Incentive to Resolve Abuse of the Hatch-Waxman Act*, 2007 U. ILL. J.L. TECH. & POL'Y 119, 123–26 (2007); Brian Porter, Comment, *Stopping the Practice of Authorized Generics: Mylan's Effort to Close the Gaping Black Hole in the Hatch-Waxman Act*, 22 J. CONTEMP. HEALTH L. & POL'Y 177, 179–82 (2005).

110. 35 U.S.C. § 271(e)(4) (2006).

number of patents on minor improvements to their drugs and then list those patents in the *Orange Book*.<sup>111</sup> These small improvements (such as different excipients, changes in dosage, and different drug-delivery strategies) then protect that form of the drug for an additional patent term.<sup>112</sup>

### III. EXPLORING THE PARADOX

For over two decades, brand name plaintiffs in ANDA patent infringement lawsuits have argued that generic products infringe on their patents under the doctrine of equivalents.<sup>113</sup> District courts recognized early on that an “admission of bioequivalence is not an admission of infringement under the doctrine of equivalents. They are two distinct concepts.”<sup>114</sup> The question was first addressed by the Federal Circuit in 1999.<sup>115</sup> A subsequent decade of Federal Circuit cases addressed the question of infringement by equivalents without any comment on the paradox of the seemingly inconsistent requirements of bioequivalency and the doctrine of equivalents.<sup>116</sup> The Federal Circuit finally commented on the issue in

111. See, e.g., ROBIN FELDMAN, *RETHINKING PATENT LAW* 170–78 (2012); Kate S. Gaudry, *Evergreening: A Common Practice to Protect New Drugs*, 29 *NATURE BIOTECHNOLOGY* 876, 876–78 (2011) (calculating the number of patents covering drugs listed in the *ORANGE BOOK* between 2000 and 2010 and finding that most drugs are covered by multiple patents, many of which are added to the *Orange Book* after the drug has come to market); C. Scott Hemphill & Bhaven N. Sampat, *When Do Generics Challenge Drug Patents?*, 8 *J. EMPIRICAL LEGAL STUD.* 613, 617–24 (2011); Terry G. Mahn, *Patenting Drug Products: Anticipating Hatch-Waxman Issues During the Claims Drafting Process*, 54 *FOOD & DRUG L.J.* 245, 250 (1999); Michael R. Herman, Note, *The Stay Dilemma: Examining Brand and Generic Incentives for Delaying the Resolution of Pharmaceutical Patent Litigation*, 111 *COLUM. L. REV.* 1788, 1799 (2011).

112. Natalie M. Derzko, *The Impact of Recent Reforms of the Hatch-Waxman Scheme on Orange Book Strategic Behavior and Pharmaceutical Innovation*, 45 *IDEA* 165, 258 (2005). However, note that new rules passed by the FDA in 2003 prohibited listing process patents and patents claiming packaging, metabolites, or intermediaries. Applications for FDA Approval to Market a New Drug: Patent Submission and Listing Requirements, 68 *Fed. Reg.* 36,677, 36,677 (June 18, 2003) (to be codified at 21 *C.F.R.* pt. 314).

113. The first court opinion addressing the argument that a bioequivalent generic drug might infringe on a brand name drug by equivalents was published in 1991. *A.H. Robins Co. v. Erbamont Inc.*, No. C2-89-864, 1991 WL 229150, at \*2 (S.D. Ohio Apr. 18, 1991), *vacated*, 944 F.2d 913 (Fed. Cir. 1991).

114. *Upjohn Co. v. Mova Pharma. Co.*, 31 F. Supp. 2d 211, 215 (D. P.R. 1998), *rev'd on other grounds*, 225 F.3d 1306 (Fed. Cir. 2000).

115. *Pharmacia & Upjohn Co. v. Mylan Pharm., Inc.*, 170 F.3d 1373, 1375–76 (Fed. Cir. 1999).

116. Federal circuit cases that addressed both bioequivalency and the doctrine of equivalents in that decade include: *Schwarz Pharma, Inc. v. Paddock Labs., Inc.*, 504 F.3d 1371, 1374–78 (Fed. Cir. 2007); *Ortho-McNeil Pharm., Inc. v. Caraco Pharm. Labs., Ltd.*, 476 F.3d 1321, 1328–29 (Fed. Cir. 2007); *Abbott Labs. v. Andrx Pharm., Inc.*, 473 F.3d 1196, 1207–08 (Fed. Cir. 2007); *Abraxis Bioscience, Inc. v. Mayne Pharma (USA) Inc.*, 467 F.3d 1370, 1379–80 (Fed. Cir. 2006); *Pfizer, Inc. v. Teva Pharm. USA, Inc.*, 429 F.3d 1364, 1376 (Fed. Cir. 2005); *Janssen Pharmaceutica, N.V. v. Eon Labs Mfg.*, 134 F. App'x 425, 429–30 (Fed. Cir. 2005); *SmithKline Beecham Corp. v. Excel Pharm. Inc.*, 356 F.3d 1357, 1363–65 (Fed. Cir. 2004); *Glaxo Wellcome, Inc. v. Impax Labs., Inc.*, 356 F.3d 1348, 1353–56 (Fed. Cir. 2004); *Ranbaxy Pharm., Inc. v. Apotex, Inc.*, 350 F.3d 1235, 1239–41 (Fed. Cir. 2003); *Abbott Labs. v. Novopharm Ltd.*, 323 F.3d 1324, 1328–29 (Fed. Cir. 2003); *Glaxo Grp. Ltd. v. Ranbaxy Pharm., Inc.*, 262 F.3d 1333, 1338 (Fed. Cir. 2001); *Biovail Corp. Int'l v. Andrx Pharm., Inc.*, 239 F.3d 1297, 1303–04 (Fed. Cir. 2001); *Upjohn Co. v. Mova Pharm. Corp.*, 225 F.3d 1306, 1308–10 (Fed. Cir. 2000); *Bayer AG v. Elan Pharm.*

*Johns Hopkins University v. Datascope Corp.*, noting briefly that “FDA equivalence is irrelevant to patent law because it involves fundamentally different inquiries.”<sup>117</sup>

The next year, the Federal Circuit commented more extensively on the question of bioequivalence and legal equivalents in *Abbott Laboratories v. Sandoz, Inc.*<sup>118</sup> Abbott argued that the defendant had “effectively admitted infringement by equivalents when it claimed before the [FDA] that its . . . generic was bioequivalent to Abbott’s . . . product.”<sup>119</sup> The Federal Circuit was not persuaded by Abbott’s argument. Its opinion stated:

While bioequivalency may be relevant to the function prong of the function-way-result test, bioequivalency and equivalent infringement are different inquiries. Bioequivalency is a regulatory and medical concern aimed at establishing that two compounds are effectively the same for pharmaceutical purposes. In contrast, equivalency for purposes of patent infringement requires an element-by-element comparison of the patent claim and the accused product, requiring not only equivalent function but also equivalent way and result.<sup>120</sup>

The court worried that “[i]f bioequivalency meant per se infringement, no alternative to a patented medicine could ever be offered to the public during the life of a patent.”<sup>121</sup> The court thus concluded that “while potentially relevant, the bioequivalency of an accused product with a product produced from the patent at issue is not sufficient to establish infringement by equivalents.”<sup>122</sup>

Although bioequivalence involves a different inquiry than patent equivalence, navigating between the two types of equivalences is nevertheless challenging for industry and courts. In *AstraZeneca Pharmaceuticals LP v. Mayne Pharma (USA) Inc.*, AstraZeneca patented Diprivan, a mixture of injectable anesthetic and EDTA, an antimicrobial compound added to improve the shelf-life of the product.<sup>123</sup> The generic company<sup>124</sup> set out to develop a generic formulation of Diprivan.<sup>125</sup> It settled on a formulation that mixed the anesthetic with DTPA, a compound similar to the EDTA used in Diprivan.<sup>126</sup> An internal memorandum pushed DTPA

Research Corp., 212 F.3d 1241, 1250–54 (Fed. Cir. 2000); *Merck & Co. v. Mylan Pharm., Inc.*, 190 F.3d 1335, 1340–42 (Fed. Cir. 1999); *Pharmacia*, 170 F.3d at 1373, 1378–79.

117. 543 F.3d 1342, 1348 (Fed. Cir. 2008).

118. 566 F.3d 1282, 1296–98 (Fed. Cir. 2009).

119. *Id.* at 1298.

120. *Id.*

121. *Id.* (quoting *Abbott Labs. v. Sandoz, Inc.*, 486 F. Supp. 2d 767, 776 (N.D. Ill. 2007)).

122. *Id.*

123. Nos. 02 Civ.7936 WHP, 03 Civ.6487 WHP, 2005 WL 2864666, at \*2 (S.D.N.Y. Nov. 2, 2005), *aff’d in part, rev’d in part sub nom.*, *Abraxis Bioscience, Inc. v. Mayne Pharma (USA) Inc.*, 467 F.3d 1370 (Fed. Cir. 2006).

124. The company was not the defendant because the product had been licensed before the litigation. *Id.* at \*4.

125. *Id.* at \*5.

126. *Id.*

as a promising substitute because, among other things, the anesthetic mixed with DTPA matched the pharmacokinetic profile of Diprivan, meaning it could be approved without submitting additional studies to the FDA. Moreover, the senior scientist working on the project stated in the memorandum that she believed the new product would not infringe the Diprivan patent.<sup>127</sup> This narrative reveals a very conscious effort to create a product that was bioequivalent but not legally equivalent. The generic company almost got it right. The FDA did approve the product as bioequivalent; however, the court found that the product infringed on Diprivan by equivalents.<sup>128</sup>

#### A. SEARCH STRATEGY

To study how courts, the pharmaceutical industry and the FDA have dealt with the intersection of the doctrine of equivalents and bioequivalence, I analyzed all cases involving ANDAs and the doctrine of equivalents up to the end of 2011. To find all cases involving ANDAs and the doctrine of equivalents, I conducted the following search in Westlaw's ALLFEDS<sup>129</sup> database:

("doctrine of equivalent\*" "substitution of equivalent\*" "function-way-result" (infring! w/3 equivalent\*) "triple identity" "equivalently infringing!" "infring! by equivalent\*" "equivalent infringement" Festo "Graver Tank" "Warner-Jenkinson" 291k237) and (ANDA "abbreviated new drug application" "hatch-waxman" "waxman-hatch" "bioequivalenc!" "FDA equivalence" "505(j)" "355(j)" cmax tmax auc pharmacokinetic\* bioavailable!).

The search, conducted on January 15, 2012, returned 187 cases. I scanned each result, discarding cases that mentioned the doctrine of equivalents only in passing or did not reach the issue. I ended up with sixty-four cases, divided into twenty-one Federal Circuit cases and forty-three district court cases. I read each case and discarded cases that dealt with the doctrine of equivalents only through its limitations (prosecution history estoppel or prior art) rather than reaching the merits of the argument. That left me with eight Federal Circuit cases and twenty-five district court cases that analyzed the substance of whether a generic drug infringed on a brand name drug's patent by equivalents. The earliest case was decided in 1991,<sup>130</sup> the second in 1996,<sup>131</sup> and the bulk of the cases in the twenty-first century.

127. *Id.*

128. *Id.* at \*22. The case was appealed to the Federal Circuit, which upheld the District Court's holding of infringement by equivalents but overturned it on other grounds. *Abraxis Bioscience*, 467 F.3d at 1382-83.

129. ALLFEDS includes all federal cases since 1790. I did not search state cases because both patents and ANDAs are matters of federal law, and thus are unlikely to be dealt with in state court.

130. *A.H. Robins Co. v. Erbamont, Inc.*, No. C2-89-864, 1991 WL 229150, at \*1 (S.D. Ohio Apr. 18, 1991), *vacated*, 944 F.2d 913 (Fed. Cir. 1991).

131. *Marion Merrell Dow Inc. v. Baker Norton Pharm., Inc.*, 948 F. Supp. 1050, 1057 (S.D. Fla. 1996).

The Federal Circuit has been favorable towards district courts' analyses of the doctrine of equivalents. Of the eight cases that were appealed, seven reached the issue of the doctrine of equivalents and only one was reversed on equivalents grounds.<sup>132</sup> Although this is a low rate of reversal relative to claim construction cases, the numbers are too small to draw broad conclusions about the reversal rate.<sup>133</sup> The low reversal rate, however, is interesting in light of the Federal Circuit's general hostility towards the doctrine of equivalents during that period.<sup>134</sup>

The plaintiffs won in one-third of the ANDA doctrine of equivalents cases, which is somewhat higher than the percentage of plaintiff wins in all doctrine of equivalents cases and the percentage of wins in all biotech and pharmaceutical doctrine of equivalents cases.<sup>135</sup>

### B. ANALYSIS OF TYPES OF CHANGES

Equivalence paradox cases are rarely aimed at the central drug patent—the patent covering the active ingredient of the drug. Rather, the generic work-arounds are primarily aimed at the commercialization and development aspects of the drug. This means that the controversy is rarely about the patent on the drug itself, but instead on peripheral patents related to such things as formulation, stability, or packaging of the drug. Of the cases I surveyed, only three cases focused on the active ingredient of the drug.<sup>136</sup> Thirteen cases dealt with formulation (the inactive ingredients used to make the pill, cream, or injection).<sup>137</sup> Four cases

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132. *Bio Tech. Gen. Corp. v. Duramed Pharm., Inc.*, 325 F.3d 1356, 1363–64 (Fed. Cir. 2003). While the Federal Circuit reversed on claim construction grounds, the court still mentions that the district court's doctrine of equivalents analysis was wrong: "Although in its discussion of the doctrine of equivalents the [district] court stated that 'the patent contemplates a particular order of pill ingestion within one package,' . . . we reject the restriction." *Id.* at 1360. *Aventis Pharma Deutschland GMBH v. Lupin Ltd.*, No. 2:05CV421, 2006 WL 1582412, at \*9 (E.D. Va. June 5, 2006), was appealed and reversed because the plaintiff's patent was found invalid; therefore, the Federal Circuit did not reach the issue of equivalents. *See* 499 F.3d 1293, 1303 (Fed. Cir. 2007).

133. District courts' claim construction is overturned at a rate of 34.5%. Moore, *supra* note 31, at 233.

134. Allison & Lemley, *supra* note 60, at 966–67.

135. Although not statistically significant, the percentage of plaintiff wins in all doctrine of equivalents cases is taken from Allison & Lemley, *supra* note 60. The percentage of plaintiff wins in all pharmaceutical doctrine of equivalents cases is derived by adding the percentage of wins of in pharmaceutical and biotechnology doctrine of equivalents cases as listed in the appendix of Allison & Lemley's article. *Id.* at 966–67, 980–82.

136. *Abbott Labs. v. Sandoz, Inc.*, 486 F. Supp. 2d 767, 767–73 (N.D. Ill. 2007) (brand name drug: cefdinir anhydrate; generic drug: cefdinir monohydrate; court found no infringement); *Chiron Corp. v. SourceCF Inc.*, 431 F. Supp. 2d 1019, 1029–31 (N.D. Cal. 2006) (brand name drug: antibiotic concentrations of 60–200mg/mL; generic drug: concentrations of less than 60 mg/mL); court found no infringement); *Marion Merrell Dow*, 948 F. Supp. at 1053–55 (S.D. Fla. 1996) (brand name drug: terfenadine acid metabolite; generic drug: terfenadine pro-drug; court found no infringement).

137. *Acorda Therapeutics Inc. v. Apotex Inc.*, No. 07-4937, 2011 WL 4074116, at \*8 (D.N.J. Sept. 6, 2011), *aff'd*, 476 F. App'x 746 (Fed. Cir. 2012) (brand name drug: tizanidine on beads; generic drug: tizanidine granulation; court found no infringement); *Cephalon, Inc. v. Watson Pharm., Inc.*, 769 F. Supp. 2d 729, 746–50 (D. Del. 2011) (brand name drug: sodium bicarbonate; generic drug: potassium bicarbonate; court found no infringement); *Elan Corp. v. Andrx Pharm., Inc.*, Nos. 98-7164 CIV, 00-7075 CIV, 2008 WL 4709251, at

dealt with chemical synthesis<sup>138</sup> or purity<sup>139</sup> of the drug, and four cases dealt with packaging of the drug.<sup>140</sup>

\*29–34 (S.D. Fla. Aug. 13, 2008) (brand name drug: multi-particulate pellet form surrounded by multi-layer membrane; generic drug: pellet that does not dissolve completely during use, is not completely spherical, and is not completely enclosed by membrane; court found infringement by equivalents); *In re Omeprazole Patent Litig.*, 490 F. Supp. 2d 381, 423–30 (S.D.N.Y. 2007), *aff'd*, 281 F. App'x 974 (Fed. Cir. 2008) (brand name drug: talc and hydroxypropylmethylcellulose to stabilize core; generic drugs: other chemicals used to stabilize core; court found no infringement); *Ranbaxy Labs. Ltd. v. Abbott Labs.*, Nos. 04 C 8078, 05 C 1490, 2005 WL 3050608, at \*19–23 (N.D. Ill. Nov. 10, 2005), *aff'd*, 473 F.3d 1196 (Fed. Cir. 2007) (brand name drug: drug mixed with “a pharmaceutically acceptable polymer”; generic drug: drug mixed with glycerin monostearate; court found infringement by equivalents); *AstraZeneca Pharm. LP v. Mayne Pharma (USA) Inc.*, Nos. 02 Civ.7936 WHP, 03 Civ.6487 WHP 2005 WL 2864666, at \*20–23 (S.D.N.Y. Nov. 2, 2005), *aff'd in part, rev'd in part sub nom.*, *Abraxis Bioscience, Inc. v. Mayne Pharm (USA) Inc.*, 467 F.3d 1370 (Fed. Cir. 2006) (brand name drug: stabilized with disodium edetate; generic drug: stabilized with diethylenetriaminepentaacetate; court found infringement by equivalents); *Janssen Pharm. N.V. v. Eon Labs Mfg.*, 374 F. Supp. 2d 263, 273–75 (E.D.N.Y. 2004), *aff'd*, 134 F. App'x 425 (Fed. Cir. 2005) (brand name drug: beads with diameter of 600–700um; generic drug: beads with diameter of 700–800um; court found no infringement); *Bristol-Myers Squibb Co. v. Andrx Pharm., Inc.*, 343 F. Supp. 2d 1124, 1162–63 (S.D. Fla. 2004) (brand name drug: pregelatinized starch; generic drug: microcrystalline cellulose; court found no infringement); *Bristol-Myers Squibb Co. v. Teva Pharm. USA, Inc.*, 288 F. Supp. 2d 562, 582–84 (S.D.N.Y. 2003) (brand name drug: lubricant selected from stearyl fumarate or hydrogenated vegetable oil; generic drug: lubricants sodium lauryl sulfate and glyceryl behenate; court found no infringement); *Biovail Corp. Int'l v. Andrx Pharm., Inc.*, 158 F. Supp. 2d 1318, 1325–33 (S.D. Fla. 2000), *aff'd*, 239 F.3d 1297 (Fed. Cir. 2001) (brand name drug: drug in admixture with wetting agent; generic drug: drug over core of sucrose and starch; court found no infringement); *Upjohn Co. v. Mova Pharm. Corp.*, 31 F. Supp. 2d 211, 214–16 (D.P.R. 1998), *aff'd*, 225 F.3d 1306 (Fed. Cir. 2000) (brand name drug: spray-dried lactose making up 70% of composition; brand name drug: spray-dried lactose making up 49% of composition; court found no infringement); *Glaxo Wellcome, Inc. v. Pharmadyne Corp.*, 32 F. Supp. 2d 265, 283–84 (D. Md. 1998) (brand name drug: stabilized with ethanol; generic drug: stabilized with propylene glycol; court found infringement by equivalents); *A.H. Robins Co. v. Erbamont, Inc.*, No. C2-89-864, 1991 WL 229150, at \*3–11 (S.D. Ohio Apr. 18, 1991), *vacated*, 944 F.2d 913 (Fed. Cir. 1991) (brand name drug: hydrophilic surfactant external to microcapsule; generic drug: meristic acid in shell wall of microcapsule; court found no infringement).

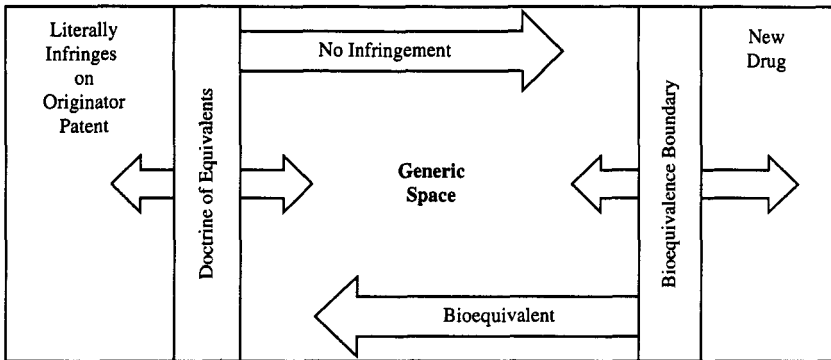
138. *Sanofi-Aventis U.S. LLC v. Sandoz, Inc.*, No. 07-2762 (JAP), 2009 WL 1741571, at \*5 (D.N.J. June 18, 2009), *vacated*, 345 F. App'x 394 (Fed. Cir. 2009) (brand name drug: enantiomers separated using high performance liquid chromatography; generic drug: enantiomers separated using different methods; court found no infringement); *SmithKline Beecham Corp. v. Apotex Corp.*, No. Civ.A.99-CV-4304, 2005 WL 941671, at \*32 (E.D. Pa. Mar. 31, 2005) (brand name drug: process that could not be conducted in ether solvent; generic drug: process that could be conducted in either solvent; court found no infringement).

139. *Pozen Inc. v. Par Pharm., Inc.*, 800 F. Supp. 2d 789, 810–12 (E.D. Tex. 2011) (brand name drug: substantially all sumatriptan in first layer and substantially all naproxen in second layer; generic drug: 100% sumatriptan and 15% naproxen in first layer and 85% naproxen in second layer; court found infringement by equivalents); *Aventus*, 2006 WL 1582412, at \*5–6 (brand name drug: product “substantially free of other isomers”; generic drug: product containing between 0.06% and 0.5% of isomer-1; court found infringement by equivalents).

140. *Abbott Labs. v. Baxter Pharm. Prods., Inc.*, No. 01 C 1876, 2005 WL 2347221, at \*17–20 (N.D. Ill. Sept. 22, 2005), *rev'd*, 471 F.3d 1363 (Fed. Cir. 2006) (brand name drug: mixing drug with water to prevent degradation; generic drug: containers lined with resin to prevent contact with degrading agent; court found no infringement); *EKR Therapeutics, Inc. v. Sun Pharm. Indus.*, 633 F. Supp. 2d 187, 202–04 (D.N.J. 2009) (brand name drug: solution that is isotonic as packaged; generic drug: solution that is hypotonic as packaged and accompanied by instructions for dilution to make it isotonic before delivery; court

The emphasis generic companies place on work-arounds aimed at commercialization and development is no coincidence. Rather, it is an inherent feature of the equivalence paradox. Generic companies have a limited intellectual space in which they can create work-arounds. The intellectual space is bounded on one end by the brand name company's patent and, on the other end, by the FDA's regulations. That is the nature of the paradox: patent law requires generic companies to innovate a certain distance from the bounds of the patent, but FDA regulations require generic companies to remain close to the brand name product.

Figure 1: The intellectual boundaries of "generic space"



This feature of the paradox is described in Figure 1. A generic drug that is identical to or insubstantially different from the brand name drug would fall to the left of the figure—it would infringe either literally or by equivalents. A generic drug that is too different from the brand name drug would fall to the right of the figure and would not be considered bioequivalent by the FDA. Thus, it could not be a generic but would instead be classified as a new drug. Generic drugs thus have a limited "generic space" in which to innovate.

If the generic company seeks to create a work-around for an active ingredient, the intellectual space in which generics can innovate is extremely narrow. A generic drug manufacturer cannot change the active ingredient substantially from the active ingredient in the reference product or else the FDA will not approve the drug.<sup>141</sup> If the generic company changes the active ingredient such that it performs a different *function*, the drug would almost by definition not be bioequivalent because the

found infringement by equivalents); *Bio-Tech. Gen. Corp. v. Duramed Pharm., Inc.*, 174 F. Supp. 2d 229, 236–41 (D.N.J. 2001), *rev'd*, 325 F.3d 1356 (Fed. Cir. 2003) (brand name drug: first four to five pills contain estrogen, rest progestin/estrogen mix; generic drug: first twenty-one pills contain progestin/estrogen mix, last seven pills contain estrogen; court found no infringement); *Mead Johnson & Co. v. Barr Labs., Inc.*, 38 F. Supp. 2d 289, 292–93 (S.D.N.Y. 1999) (brand name drug: pill marked with transverse score notches; generic drug: pill marked with opposing score notches; court found infringement by equivalents).

141. 21 C.F.R. § 314.127 (2012).

patient would experience a different effect. If the generic company changes the active ingredient such that it performs the same function in a different way, it is very unlikely that the generic would still achieve the same bioavailability at a similar concentration, so it is very unlikely that the drug would be bioequivalent. If the generic company changes the active ingredient such that it performs the same function in the same way but achieves a different result, the drug would very likely not be bioequivalent (unless the result was within 80% to 125% of the brand name drug's result, but arguably that would not constitute a substantially different result).<sup>142</sup>

In general, the tests for bioequivalence and legal equivalence are conducted on different levels—the former on the level of the entire drug formulation's activity and the latter on the level of a particular element.<sup>143</sup> For changes to active ingredients, the tests are conflated.<sup>144</sup> Bioequivalence looks at the performance of the active ingredient, and legal equivalence also looks at the performance of the active ingredient.<sup>145</sup> Thus, it is extremely hard to make a change in the active ingredient that both satisfies the FDA and does not infringe by equivalents.

Conversely, a generic company has much wider latitude to make changes to inactive ingredients. The changes in this category include substituting different binding agents, different wetting agents, different lubricants, or different disintegrants or changing the coating around the drug.<sup>146</sup> These sorts of inactive ingredients are generally used to control the way the drug is released once it is in the body.<sup>147</sup> For example, a disintegrant helps the drug break up into small pieces in the digestive system so that it can be more easily dissolved, while a coating around a drug might form a matrix that impedes drug release, so that the drug escapes into the bloodstream slowly and creates an extended-release effect.<sup>148</sup>

The FDA does regulate the types of excipients that may be changed but allows a wide range of substitutes within certain numerical parameters.<sup>149</sup> In addition, the generic must still meet the bioequivalence re-

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142. See *Acorda Therapeutics*, 2011 WL 4074116, at \*8.

143. See *Cephalon, Inc. v. Watson Pharm., Inc.*, 769 F. Supp. 2d 729, 746 (D. Del. 2011) (bioequivalence test conducted on formulation of the drug). But see *Sanofi-Aentis*, 2009 WL 1741571, at \*5 (literal infringement test focused on the element of "optically pure oxaliplatin").

144. See *Merion Merrell Dow Inc. v. Baker Norton Pharm., Inc.*, 948 F. Supp. 1050, 1053 (S.D. Fla. 1996) (both legal equivalence and bioequivalence tests focused on the active ingredient terfenadine).

145. 21 C.F.R. § 320.1.

146. *Id.* § 320.33.

147. *Id.*

148. Michael Bihari, *Extended-release Medication*, ABOUT.COM DRUGS, <http://www.drugs.about.com/od/edrugandmedicalterms/g/ext-release-def.htm> (last visited Sept. 20, 2012).

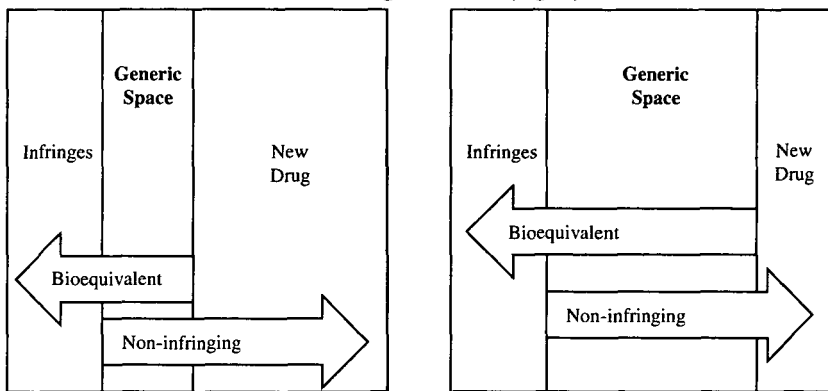
149. See CTR. FOR DRUG EVALUATION & RESEARCH, GUIDANCE FOR INDUSTRY: SUBMISSION OF SUMMARY BIOEQUIVALENCE DATA FOR ANDAS 3-9 (2011), available at [www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM134846.pdf](http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM134846.pdf).



quirements, but there are many possible changes to inactive ingredients that will not affect the pharmacokinetic profile of the drug. Therefore, they have a better chance of avoiding infringement by equivalents. Generic companies won in eighty percent of the cases in this category, evidencing that there is more space for generic companies to create work-arounds when the brand name patent covers inactive ingredients than when the patent covers active ingredients.

The effect of the FDA's aversion to changes to the active ingredient and openness to changes to inactive ingredients is that the equivalence paradox arises primarily in the context of commercialization and development. Conceptually, this is illustrated in Figure 2.

Figure 2: Generic space for changes in active ingredients (left) and inactive ingredients (right)



In Figure 2, the diagram to the left represents the scope of the intellectual space available for generic companies to create work-arounds when the brand name patent covers the active ingredient of the drug. The generic space is narrow because the FDA does not allow a wide range of changes to the active ingredient. The diagram to the right represents the scope of the intellectual space available for generic companies to create work-arounds when the brand name patent covers an inactive ingredient of the drug. The generic space is considerably wider because the FDA allows a wider range of changes to the inactive ingredients of the drug. Thus, the FDA's bioequivalence requirements shift, depending on the type of change in question, to make changes going to commercialization and development more feasible for generic companies.

### C. ANALYSIS OF TYPES OF PATENTS

The type of patent covering a brand name product affects the scope of equivalents that the patentee can claim. In this section, I analyze the patents used to protect the products described in the cases above and draw conclusions about which types of patents offer the most protection to brand name companies under the doctrine of equivalents. Unsurprisingly,

patents on the actual chemical entity are strongest while patents on the method-of-use are the weakest.

The FDA divides patents into seven categories.<sup>150</sup> However, the FDA allows only three types of patents to be listed in the *Orange Book*: (1) patents claiming a drug *substance* (the active ingredient); (2) patents claiming the drug *product* (the formulation or composition); and (3) method-of-use patents.<sup>151</sup> Drug product patents cover “a finished dosage form, for example, tablet, capsule, or solution, that contains a drug substance, generally, but not necessarily, in association with one or more other ingredients.”<sup>152</sup> Method-of-use patents can be listed only if they claim a method of use that is in the labeling of the approved NDA.<sup>153</sup> The FDA also identifies four types of patents that *cannot* be listed in the *Orange Book*. These are: (1) patents claiming packaging;<sup>154</sup> (2) patents claiming metabolites;<sup>155</sup> (3) patents claiming intermediaries;<sup>156</sup> and (4) process patents.<sup>157</sup>

I identified the patents at issue in the doctrine of equivalents cases described above and divided them according to the seven FDA categories. I categorized the patents by reading the text of the patent and by looking at the patent code listed in the *Orange Book*.<sup>158</sup> I also identified patents that claim the actual chemical entity used as the active ingredient in the drug. This sort of patent affords the most protection to brand name com-

150. 21 C.F.R. § 314.53(b).

151. *See id.*

152. *Id.* § 314.3(b).

153. Applications for FDA Approval to Market a New Drug: Patent Submission and Listing Requirements, 68 Fed. Reg. 36,676, 36,681 (June 18, 2003) (to be codified at 21 C.F.R. pt. 314) (“If an NDA applicant or holder or patent owner intends to submit information on a patent that claims a method of use, the patent must claim a use that is described in the NDA. If we have already approved the NDA, the patent must claim a method of use that is in the labeling of the approved NDA.”). The FDA noted that this is a long-standing policy. *Id.* (citing Abbreviated New Drug Application Regulations: Patent & Exclusivity Provisions, 59 Fed. Reg. 50,338, 50,363–64 (Oct. 3, 1994)).

154. Packaging patents include only patents that claim solely packaging (e.g., a bottle or container), and not packaging in combination with the drug product, such as a dosage form (e.g., a tablet, capsule, or gel-form of a drug) or a drug delivery system (e.g., an inhaler or transdermal patch). Applications for FDA Approval to Market a New Drug: Patent Submission and Listing Requirements, 68 Fed. Reg. at 36,680. The rule clarifies the distinction between packaging and dosage forms in response to comments concerned that “patents claiming devices or containers that are ‘integral’ to the drug product or require FDA approval” would not be able to be listed. *Id.*

155. A metabolite patent is one claiming the by-product of a drug produced after the drug has been metabolized by the body. 21 C.F.R. § 314.53(b)(1).

156. An intermediary patent is one claiming “materials that are produced during preparation of the active ingredient and are not present in the finished drug.” Applications for FDA Approval to Market a New Drug: Patent Submission and Listing Requirements, 68 Fed. Reg. at 36,681.

157. *Id.*

158. Listings in the *Orange Book* are accompanied by a patent abbreviation describing the patent (and type of exclusivity). A list of patent codes can be found at ADB1. A list of drugs and their respective patent codes can be found beginning at ADA1. Note that not all of the relevant products are listed in the *Orange Book* (some have been taken off the market) and others are in the *Orange Book* but do not have a patent code (many patents were invalidated in subsequent cases).

panies, both because it is difficult for generic companies to develop a work-around to the patent while maintaining bioequivalency, and because the Hatch-Waxman Act provides new chemical entities with at least a four-year protection from challenges.<sup>159</sup>

Note that as I categorized patents, I did not always follow the patent code listed in the *Orange Book* when the functional use of the patent placed it in a different category. For example, Treximet, the product at issue in *Pozen Inc. v. Par Pharmaceutical, Inc.*,<sup>160</sup> is covered by a patent coded in the *Orange Book* as a drug product;<sup>161</sup> however, I categorized it as a drug *substance* because the patent performs the same protective function as a drug substance patent. Treximet is made up of two active ingredients: naproxen and sumatriptan.<sup>162</sup> These ingredients have long been used for other functions, making the actual chemical entities no longer patentable. However, Treximet combines the two active ingredients to create a novel medical product.<sup>163</sup> Therefore, although Pozen could not patent the active ingredient, it could—and did—patent the combination of active ingredients, which gives it the same protection as a drug substance patent.<sup>164</sup> Thus, it is the functional equivalent of a drug substance patent.

After placing each patent into a category, I counted the number of patents that fell into more than one category. Although each claim can be directed towards only one category, each patent contains multiple claims, and different claims may be directed at different categories. In addition, an individual product was often protected by multiple patents, with different patents falling into different categories. Thus, in addition to the FDA's categories, I also have "combination" categories. For example, if one of the drug's patents claimed methods for making an extended-release formulation of the drug, while another patent claimed a combination of the drug and the excipients needed to get the extended release profile, I categorized the drug as having a combination drug product and process patent. Only product/process and product/method combinations were present in my data set. Although most "drug substance" patents also contained claims directed at formulations, processes, and methods, I did not include drug substance patents in the combination categories because the active ingredient claim is the patent's strongest claim, and the other claims offer less protection and are thus less relevant to a doctrine of equivalents analysis.

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159. The period is four years if the generic firm files a Paragraph IV certification; otherwise, it is five years. This can increase if the brand name company does clinical trials in particular patient populations, such as children. See Laba Karki, *Review of FDA Law Related to Pharmaceuticals: The Hatch-Waxman Act, Regulatory Amendments and Implications for Drug Patent Enforcement*, 87 J. PAT. & TRADEMARK OFF. SOC'Y 602, 612-15 (2005).

160. 800 F. Supp. 2d 789, 796 (E.D. Tex. 2011).

161. ORANGE BOOK, *supra* note 81, at 3-303.

162. *Id.*

163. *Id.*

164. See *supra* Figure 2.

Figure 3: Percentage of Drugs Protected by Each Category of Patent

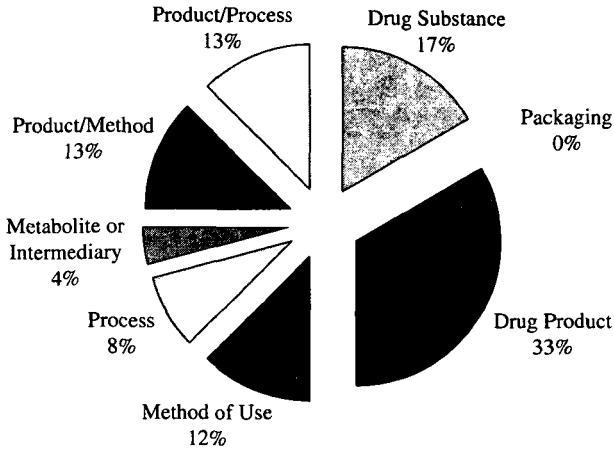


Figure 3 shows the percentage of drugs protected by each category of patent. Most drugs (fifty-nine percent) are protected by a drug product patent (alone or in combination with another category). The second most common type of patent was a method-of-use patent (alone or in combination with a product patent). Seventeen percent of drugs are protected by a drug substance patent. Few drugs were protected by process, metabolite, or intermediary patents, and no drugs were protected by packaging patents, perhaps because these are the types of patents that cannot be listed in the *Orange Book*.

I then determined how many patents in each category were able to protect their drug through the doctrine of equivalents. The results are displayed below:

Figure 4: Likelihood of Winning Doctrine of Equivalents Cases Based on Type of Patent

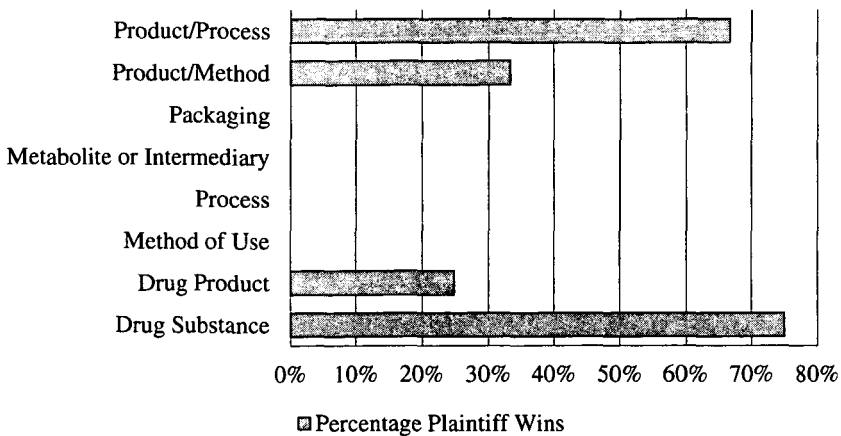


Figure 4 shows the percentage of doctrine of equivalents cases won by the plaintiff, categorized by type of patent. Plaintiffs whose drugs were protected only by a metabolite or intermediary, process, or method-of-use patent never won a doctrine of equivalents case. Plaintiffs whose products were protected by a drug substance patent won frequently (seventy-five percent of cases)—an expected result because patents covering the active ingredient are the strongest type of patent. Plaintiffs whose products were protected by a drug product patent won at a rate of twenty-five percent.<sup>165</sup>

Plaintiffs who protected their product with more than one type of claim increased their level of protection. Products protected by both product and method claims obtained slightly more protection, winning one-third of infringement cases, slightly above average. Products protected by both product and process claims obtained a great deal more protection, winning two-thirds of infringement cases, well above average. A caveat is that these patents afford the strongest protection for patentees arguing the doctrine of equivalents. Stronger patents may not be challenged at all by an ANDA, or may win on literal infringement.

There are two important policy conclusions to be drawn from this data, both of which relate to evergreening.<sup>166</sup> First, scholars have suggested that courts are losing patience with evergreening patents and are treating them with more skepticism.<sup>167</sup> The difference in win-rates based on patent type is empirical evidence of this suggestion. Drug substance patents cover the active ingredient of the drug and are the core patents protecting it. As such, they are almost never evergreening patents. Product, process, packaging, metabolite, and intermediary patents may be evergreening patents. Where a drug is covered by only one patent, courts are strongly favorable to drug substance patents—giving them a wide scope of equivalents and holding that they are infringed at a rate of seventy-five percent. Courts are notably less favorable to drug product patents—giving them a narrow scope of equivalents and holding that they are infringed only at a rate of twenty-five percent.

However, the second conclusion to be drawn from the data is that although courts may be increasingly skeptical of evergreening patents, evergreening is still an effective strategy. One form of evergreening is “stacking patents” by covering a drug with multiple patents or by altering the formulation of a drug and then pulling the old drug from the market.<sup>168</sup> The graph above demonstrates that this multiple-patenting ap-

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165. See *supra* Figure 4.

166. See discussion *infra* Part V.

167. E.g., Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy*, 13 MICH. TELECOMM. & TECH. L. REV. 345, 356 (2007) (“[T]he courts grow more skeptical of evergreening strategies . . .”).

168. Stacey L. Dogan & Mark A. Lemley, *Antitrust Law and Regulatory Gaming*, 87 TEX. L. REV. 685, 711 (2009) (“After Congress corrected that particular [evergreening] problem, crafty firms took a different tack: rather than stacking patents, they stacked products—making trivial changes to their product formulation and pulling the old drug from the market.”).

proach appears to work. While products covered only by drug product patents win only twenty-five percent of the time, drug companies can increase their win rate to sixty-five percent by covering their product with multiple patents.

#### IV. EXPLAINING THE PARADOX

Why do the equivalence cases come out the way they do? What guiding principle explains the differences in courts' decisions? Here, I search for a normative or theoretical basis to explain the outcomes and predict future cases—a micro theory.<sup>169</sup> First, I explain why the mere words of the doctrine of equivalents tests are insufficient to explain and predict courts' decisions. Then I propose that courts look (perhaps unconsciously) at whether the generic work-around adds some commercial value over the brand name company's invention and that this concept of added value can be used to explain and predict the outcomes in equivalence paradox cases.

The mere words of the doctrine of equivalents tests are insufficient to explain and predict courts' decisions. Courts use one of two etymological frameworks.<sup>170</sup> They may use the “function-way-result” test, which asks whether the accused product performed substantially the same function in substantially the same way to obtain substantially the same result.<sup>171</sup> Alternatively, courts may look at whether there are “insubstantial differences” between the two products.<sup>172</sup> To be sure, courts organize their opinions around these linguistic tests.<sup>173</sup> But what is an “insubstantial difference”? What is the difference between “substantially the same function” and “insubstantially the same function”? Mere words unconnected to a concrete concept cannot explain where the line between “substantial” and “insubstantial” falls.

Compare, for example, *Bristol-Myers Squibb Co. v. Teva Pharmaceuticals USA, Inc.*<sup>174</sup> with *Glaxo Wellcome, Inc. v. Pharmadyne Corp.*<sup>175</sup> In *Bristol*, the plaintiff made Monopril, an anti-hypertension drug.<sup>176</sup> Bristol's patent claimed a tablet “comprising of about 0.3% to 4% of a lubricant selected from sodium stearyl fumarate or hydrogenated vegetable

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169. I draw my terminology from A. Samuel Oddi's description of “macro level” theories, which “describe the overall patent system,” and “micro level” theories, which “describe the patent system at a micro level in terms of explaining the outcome of actual patent validity decisions.” A. Samuel Oddi, *Un-Unified Economic Theories of Patents—The Not-Quite-Holy Grail*, 71 NOTRE DAME L. REV. 267, 268–69 (1996).

170. “[T]he particular linguistic framework used to determine ‘equivalence’ . . . is less important than whether the test is probative of the essential inquiry.” *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 19 (1997).

171. *Id.* at 35.

172. *Id.* at 39–40.

173. *Id.* at 39 (“Both the parties and the Federal Circuit spend considerable time arguing [which] approach is better.”).

174. 288 F. Supp. 2d 562 (S.D.N.Y. 2003).

175. 32 F. Supp. 2d 265 (D. Md. 1998).

176. *Bristol*, 288 F. Supp. 2d at 569.

oil."<sup>177</sup> Teva's product used sodium lauryl sulfate and glyceryl behenate as lubricants.<sup>178</sup> Because the lubricants were different, Teva's product did not literally infringe.<sup>179</sup> Bristol-Myers Squibb alleged that Teva infringed by equivalents.<sup>180</sup>

The court held that Teva did not.<sup>181</sup> The lubricants did serve substantially the same function.<sup>182</sup> However, they did so in a substantially different way because (1) Teva used two lubricants, while Bristol-Myers Squibb used one; (2) Teva used a combination of water-insoluble lubricant and water-soluble lubricant, whereas Bristol-Myers Squibb used only water-soluble lubricant; and (3) Teva's lubricant made up 6.4% of the formulation by weight, which was more than the 4% limit in Bristol-Myers Squibb's patent.<sup>183</sup> These are "substantial" differences.

A facially similar case, *Glaxo v. Pharmadyne*,<sup>184</sup> turned out differently. Glaxo manufactured Zantac, a medication used to treat heartburn and ulcers.<sup>185</sup> Zantac combined the active ingredient with ethanol, an antimicrobial placed in the solution to preserve shelf life.<sup>186</sup> Pharmadyne's generic product combined the active ingredient with propylene glycol, which acted as the antimicrobial.<sup>187</sup> Glaxo sued Pharmadyne for patent infringement under the doctrine of equivalents.<sup>188</sup> The court found that Pharmadyne developed its product by copying Glaxo's patent, and did little independent research beyond testing polyol-alcohols to determine which had similar effects to ethanol.<sup>189</sup> The court held that Pharmadyne's product infringed by equivalents because this was an "insubstantial" difference.<sup>190</sup>

Why is substituting two lubricants for one a substantial difference while substituting an alcohol for a polyol-alcohol not? This paper argues that the answer lies in the value of the substitution. The court in *Bristol* finished its opinion by explaining that the generic product did not achieve substantially the same result as the brand name product because the generic product prevented sticking and picking in long tableting runs, whereas the brand-name lubricant could have resulted in sticking, making the generic formulation "superior" and thus precluding infringement.<sup>191</sup> The court's use of the term "superior" is significant. Nothing in doctrine of equivalents jurisprudence requires courts to consider the superiority of

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177. *Id.* at 565.

178. *Id.* at 572.

179. *Id.* at 588.

180. *Id.*

181. *Id.*

182. *Id.* at 589.

183. *Id.* at 582-83.

184. *Glaxo*, 32 F. Supp. 2d at 265.

185. *Id.* at 269.

186. *Id.* at 277-79.

187. *Id.* at 282.

188. *Id.*

189. *Id.* at 283.

190. *Id.* at 291.

191. *Bristol*, 288 F. Supp. 2d at 583.

the defendant's product. Yet the court here did so, and found that the defendant's formulation did not infringe because it improved on the brand name product in a way that made manufacturing more efficient.<sup>192</sup>

Although other courts do not use the language of superiority, the same concept undergirds their opinions. In my analysis of the equivalence paradox cases, I found that the most coherent way to explain the results of the cases was to ask whether the generic product's change added value. "Value" is a difficult term to define, but it correlates with an increase in commercial value, meaning that the product might improve patient safety, make the drug easier to produce, or make the drug more marketable. Changes that did not add value often actually decreased the commercial value of the product by making it less safe, harder to produce, or less marketable.

To analyze my hypothesis, I separated the equivalence cases based on whether the generic product added value.<sup>193</sup> In *all* of the cases where the generic product added value, the court found that the product did not infringe on the brand name patent.<sup>194</sup> In two-thirds of the cases where the generic product did not add value, the court found that the product did infringe on the brand name patent.<sup>195</sup>

The concept of "added value" is best explained by reference to cases.

192. *Id.*

193. I wish to note that my categorization is in no way scientifically replicable. A different researcher may come to a different conclusion about the placement of specific cases. However, I believe that while others may categorize a case or two differently, my overall conclusion would hold.

194. *Arcorda Therapeutics Inc. v. Apotex Inc.*, No. 07-4937, 2011 WL 4074116, at \*8 (D.N.J. Sept. 6, 2011), *aff'd*, No. 2012-1019, 2012 WL 2086719 (Fed. Cir. June 11, 2012); *Sanofi-Aventis U.S. LLC v. Sandoz, Inc.*, No. 07-2762(JAP), 2009 WL 1741571, at \*1 (D.N.J. June 18, 2009); *SmithKline Beecham Corp. v. Apotex Corp.*, No. Civ.A.99-CV-4304, 2005 WL 941671, at \*1 (E.D. Pa. Mar. 31, 2005); *Abbot Labs. v. Baxter Healthcare Corp.*, 660 F. Supp. 2d 882, 884 (N.D. Ill. 2009); *Chiron Corp. v. SourceCF, Inc.*, 431 F. Supp. 2d 1019, 1038 (N.D. Cal. 2006); *Abbot Labs. v. Baxter Pharm. Prods., Inc.*, No. 01C 1876, 2005 WL 2347221, at \*26 (N.D. Ill. Sept. 22, 2005); *Janssen Pharm. N.V. v. Eon Labs. Mfg.*, 374 F. Supp. 2d 263, 263 (E.D.N.Y. 2004), *aff'd*, 134 F. App'x 425 (Fed. Cir. 2005); *Bristol*, 288 F. Supp. 2d at 562; *Biovail Corp. Int'l v. Andrx Pharm., Inc.*, 158 F. Supp. 2d 1381, 1318 (S.D. Fla. 2000), *aff'd*, 239 F.3d 1297 (Fed. Cir. 2001); *Upjohn Co. v. Mova Pharm. Corp.* 311 F. Supp. 2d 211, 214 (D.P.R. 1998), *aff'd*, 225 F.3d 1306 (Fed. Cir. 2000).

195. Cases where the generic did not add value and was found to infringe: *Bio-Tech. Gen. Corp. v. Duramed Pham., Inc.*, 325 F.3d 1356, 1356 (Fed. Cir. 2003); *;* *Pozen Inc. v. Par Pharm., Inc.*, 800 F. Supp. 2d 789, 825 (E.D. Tex. 2011); *EKR Therapeutics, Inc. v. Sun Pharm. Indus.* 633 F. Supp. 2d 187, 207 (D.N.J. 2009); *Elan Corp. v. Andrx Pharm., Inc.*, Nos. 98-7164CIV, 00-7075, 2008 WL 4709251, at \*73 (S.D. Fla. Aug. 13, 2008); *Aventis Pharma Deutschland GMBH v. Lupin Ltd.*, No. 2:05CV421, 2006 WL 1582412, at \*1 (E.D. Va. June 5, 2006); *Ranbaxy Labs. Ltd. v. Abbott Labs.*, Nos. 04 C 8078, 05 C 1490, 2005 WL 3050608, at \*31 (N.D. Ill. Nov. 10, 2005), *aff'd*, 473 F.3d 1196 (Fed. Cir. 2007); *AstraZeneca Pharm. LP v. Mayne Pharma (USA) Inc.*, No. 02 CIV.7936 WHP, 2005 WL 2864666, at \*1 (E.D. Mich. Nov. 2, 2005), *aff'd in part, rev'd in part*, 467 F.3d 1370 (Fed. Cir. 2006); *Mead Johnson & Co. v. Barr Labs., Inc.*, 38 F. Supp. 2d 289, 290 (S.D.N.Y. 1999 *Glaxo*, 32 F. Supp. 2d at 293; *A.H. Robins Co. v. Erbamont, Inc.*, No. C2-89-864, 1991 WL 229150, at \*21 (S.D. Ohio Apr. 19, 1991), *vacated*, 944 F.2d 913 (Fed. Cir. 1991). Cases where the generic did not add value and was not found to infringe include: *Cephalon, Inc. v. Watson Pharm., Inc.*, 769 F. Supp. 2d 729, 761 (D. Del. 2011); *Abbot Labs. v. Sandoz, Inc.*, 486 F. Supp. 2d 767, 768 (N.D. Ill. 2007); *In re Omeprazole Patent Litig.*, 490 F. Supp. 381, 423 (S.D.N.Y. 2007), *aff'd*, 281 F. App'x 974 (Fed. Cir. 2008); *Bristol-Myers Squipp Co. v.*



Take, for example, *Chiron Corp. v. SourceCF Inc.*<sup>196</sup> and *Abbott Laboratories v. Baxter Healthcare Corp.*,<sup>197</sup> both of which demonstrate added value. In *Chiron*, the plaintiff produced TOBI, a nebulizer that can deliver tobramycin (an aerosolized antibiotic) to patients suffering from cystic fibrosis.<sup>198</sup> Chiron obtained a patent to prevent any other companies from making a nebulizer that delivers tobramycin at concentrations between 60–200 mg/ml.<sup>199</sup> Over time, other companies developed more efficient nebulizers, but Chiron used its patent to prevent them from using their improved nebulizers to administer tobramycin at the relevant concentrations.<sup>200</sup> The defendant, SourceCF, developed TOFIN—a method of administering tobramycin at concentrations lower than 60 mg/ml.<sup>201</sup> Chiron sued for patent infringement, both literally and by equivalents.<sup>202</sup>

The court held that TOFIN did not literally infringe because the concentration of tobramycin was lower than 60 mg/ml.<sup>203</sup> On the question of equivalents, although SourceCF's witness testified that TOFIN was designed to deliver a dose "equivalent" to that of TOBI, the court found that the equivalent result did not mean that the result was achieved in the same way.<sup>204</sup> The court reasoned that Chiron never tested lower concentrations of tobramycin, but the defendants found a way to effectively use the lower concentrations; therefore, the two products must be functioning in different ways.<sup>205</sup> Thus, TOFIN did not infringe by equivalents.

Essentially, the court in *Chiron* relied on the added value of the defendant's product. The court could not explain the differences between the two products, which generally leads courts to decide that the plaintiff cannot prove its case based on lack of evidence.<sup>206</sup> However, here the court

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Andrx Pharm., Inc., 343 F. Supp. 2d 1124, 1127 (S.D. Fla. 2004); Marion Merrell Dow Inc. v. Baker Norton Pharm., Inc., 948 F. Supp. 1050, 1057 (S.D. Fla. 1996).

196. *Chiron*, 431 F. Supp. 2d at 1019.

197. *Abbott*, 660 F. Supp. 2d at 882.

198. *Chiron*, 431 F. Supp. 2d at 1020.

199. *Id.* at 1021.

200. *Id.* at 1020–21.

201. *Id.* at 1024.

202. *Id.* at 1025.

203. *Id.* at 1034.

204. *Id.* at 1037–38.

205. *Id.* at 1038.

206. See, e.g., *Cephalon*, 769 F. Supp. 2d at 747–49. Plaintiff's product Fentora, consisting of fentanyl buccal tablets, was used to treat breakthrough pain in cancer. *Id.* at 734. The tablet was given sublingually and evolved gas by means of an effervescent reaction to increase the rate of absorption across the oral mucosa. *Id.* at 736. Cephalon used sodium bicarbonate to create effervescence and alleged that Watson's product used potassium bicarbonate to do the same. *Id.* at 746. However, Cephalon only alleged that Watson's tablets were "bioequivalent to Fentora" and did not provide any evidence about the nature of the chemical reaction that would occur. *Id.* at 747–48. Moreover, Cephalon did not provide any experiments determining the rate or extent of absorption of the drug across the oral mucosa. *Id.* at 747. The court therefore found that there was no evidence of infringement. *Id.* In *In re Omeprazole*, 490 F. Supp. 2d at 381, the plaintiff's product was Prilosec, which was made of omeprazole, a proton pump inhibitor that slowed gastric acid secretion and could be used to treat ulcers. *Id.* at 392. The plaintiff's brand name product was an oral omeprazole formulation that attained resistance from gastric acids and stability through the addition of various alkaline salt mixtures and water soluble coatings. *Id.* at 392–93. The

relied on the defendant's added value—the ability to deliver an equivalent dose at lower concentrations—to conclude that there must be a substantial difference.<sup>207</sup> The court was not relying on the words of the doctrine of equivalence test, because it could not pinpoint why there was a substantial difference in the “way” the drug functions; nevertheless, the court concluded that there was such a difference.<sup>208</sup>

The importance of value is also apparent in *Abbott*. Here, Abbott Laboratories produced an inhalable anesthetic made of sevoflurane.<sup>209</sup> Sevoflurane can degrade when it is exposed to a Lewis acid, creating hydrochloric acid as a by-product.<sup>210</sup> Hydrochloric acid is toxic; therefore, degraded sevoflurane cannot be used in humans.<sup>211</sup> Lewis acids are often found in the containers used to hold sevoflurane during its transportation.<sup>212</sup> Abbott's scientists discovered that adding water to sevoflurane neutralizes the Lewis acid in the container and prevents degradation.<sup>213</sup> Abbott patented “a quantity of sevoflurane and a Lewis acid inhibitor in an amount effective to prevent degradation by a Lewis acid.”<sup>214</sup>

Baxter Healthcare also sold sevoflurane.<sup>215</sup> To get around the problem of degradation, Baxter packaged its sevoflurane in containers lined with epoxy phenolic resin.<sup>216</sup> This lining prevented the sevoflurane from contacting the container (and thus from contacting Lewis acids). Therefore, the sevoflurane did not degrade.<sup>217</sup> Abbott alleged that Baxter's product infringed under the doctrine of equivalents.<sup>218</sup> The court held, however, that the products were not equivalent because the two products did not operate the same way.<sup>219</sup> Baxter's lining physically blocked sevoflurane from contacting Lewis acids, whereas Abbott's product used water to react with the Lewis acids to neutralize them.<sup>220</sup> Therefore Baxter's product did not infringe.<sup>221</sup> Although the court used only the function-way-result language, the value of Baxter's product is apparent.

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generic products used different chemicals to stabilize the omeprazole. *Id.* at 425. The plaintiff argued that this infringed by equivalents. *Id.* The court did not discuss the question in detail, instead finding that the plaintiff had not produced enough evidence to show that the other chemicals performed the same function in substantially the same way to produce the same results. *Id.* at 447–48. The court therefore held for the defendant. *Id.*

207. *Chiron*, 431 F. Supp. 2d at 1038.

208. *Id.*

209. *Abbott*, 2005 WL 2347221, at \*1.

210. *Id.* at \*1–2.

211. *Id.* at \*2.

212. *Id.*

213. *Id.* at \*3.

214. *Id.* at \*4.

215. *Id.* at \*17.

216. *Id.*

217. *Id.* at \*20.

218. *Id.* at \*14.

219. *See id.* at \*19–20.

220. *Id.* at \*20.

221. *Id.*

Conversely, generic companies that make changes that do not increase value are generally found to infringe by equivalents. In *Mead Johnson & Co. v. Barr Laboratories, Inc.*, the plaintiff made tablets of Desyrel Dividose, an antidepressant.<sup>222</sup> The product contained transverse score marks along the tablets to help the patient break the tablet into multiple subdosages.<sup>223</sup> Barr's generic product also contained score markings to facilitate tablet breakage;<sup>224</sup> however, Barr's tablets had two pairs of opposing score notches instead of a transverse score mark.<sup>225</sup> Barr admitted that these score marks were, like Mead's score marks, directed at enabling a patient to break the pill.<sup>226</sup>

The court analyzed the infringing product using the function-way-result test.<sup>227</sup> Both designs had the function of facilitating the fracturing of the tablet into equal dosages.<sup>228</sup> Both products did this through directing pressure applied by the patient to achieve a more uniform fracturing.<sup>229</sup> Both products had the same result: fractured tablets.<sup>230</sup> Thus, Barr infringed under the doctrine of equivalents.<sup>231</sup>

Although the court used the function-way-result language, the language alone does not necessitate the result. The court could have found that the tablets functioned a different way, based on the differences in design that facilitate breakage. But this result would have been absurd. It is evident that while Barr made changes, these changes were not substantial because the change lacked value. The change from score marks to notches did not make the product safer, more efficient, or easier to manufacture. The change was simply designed to evade a patent and added no other redeeming value.<sup>232</sup>

*Aventis Pharma Deutschland GMBH v. Lupin Ltd.* is a similar case.<sup>233</sup> In this case, the plaintiff produced Altace, a medication used to treat high blood pressure.<sup>234</sup> The plaintiff's patent covered the active ingredient "substantially free of other isomers."<sup>235</sup> Isomers are a form of impurity.<sup>236</sup> The defendant's ANDA product was composed of the active ingre-

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222. 38 F. Supp. 2d 289, 291 (S.D.N.Y. 1999).

223. *Id.* A transverse score is defined by the court to mean "two or more notches, lines, grooves or scratches that run continuously and uninterrupted on the same surface from edge to edge." *Id.*

224. *Id.* at 293.

225. *Id.*

226. *Id.*

227. *Id.*

228. *Id.*

229. *Id.*

230. *Id.*

231. *Id.* at 293-94.

232. We task generic companies with designing work-arounds to patents to provide drugs to the public at a lower price; therefore, designing around a patent has significant social benefits.

233. No. 2:05CV421, 2006 WL 1582412, at \*1 (E.D. Va. June 5, 2006).

234. *Id.* at \*1-2.

235. *Id.* at \*2.

236. *Id.* at \*8 n.7.

dient and contained between 0.06% and 0.5% by weight of isomer-1.<sup>237</sup> The court analyzed infringement under the function-way-result test.<sup>238</sup> Because low levels of isomer-1 had no effect on the drug, the products, in the opinion of the court, worked the same way.<sup>239</sup> Additionally, both products treated hypertension; therefore, they had the same result.<sup>240</sup> The court concluded that the generic infringed by equivalents.<sup>241</sup>

As in *Mead*, the language of the doctrine of equivalents test did not require this result. The court could have concluded that the products delivered different results because the plaintiff's product delivered a slightly purer drug than the defendant's product. Yet this is not a substantial difference because reducing the purity of the drug did not add value to the drug; in fact, it slightly diminished its value. Once again, the value of the change helps explain the court's conclusion.

The use of value as a proxy for "substantialness" fits intellectually with the Federal Circuit's use of commercial success as a secondary consideration of obviousness.<sup>242</sup> Courts look at secondary considerations, in part, because it is difficult to determine obviousness during patent prosecution because this necessitates a consideration of the foreseeability of the technology.<sup>243</sup> Obviousness decisions are particularly difficult in pharmaceutical and biotechnology cases because life sciences are more "unpredictable" than other industries.<sup>244</sup>

Similarly, the doctrine of equivalents requires judges or juries<sup>245</sup> to consider, among other things, the purpose of the feature in the overall patent, its qualities when combined with other features, its function, and whether a person reasonably skilled in the art would have known of the interchangeability of the two technologies at issue.<sup>246</sup> Particularly challenging is the question of whether the defendant's technology is an "unanticipated equivalent[ ]."<sup>247</sup> Essentially, the trier of fact must determine whether the defendant's substitution was foreseeable to the patentee.

237. *Id.* at \*2.

238. *Id.* at \*5.

239. *Id.*

240. *Id.*

241. *Id.*

242. See, e.g., *Greenwood v. Hattori Seiko Co.*, 900 F.2d 238, 241 (Fed. Cir. 1990); *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1380 (Fed. Cir. 1986); *Vandenburg v. Dairy Equip. Co.*, 740 F.2d 1560, 1567 (Fed. Cir. 1984); *Kansas Jack, Inc. v. Kuhn*, 719 F.2d 1144, 1150 (Fed. Cir. 1983); see also Rochelle Cooper Dreyfuss, *The Federal Circuit: A Case Study in Specialized Courts*, 64 N.Y.U. L. REV. 1, 9 (1989). This approach, however, is criticized by some scholars. Doug Lichtman & Mark A. Lemley, *Rethinking Patent Law's Presumption of Validity*, 60 STAN. L. REV. 45, 56 (2008); see, e.g., Robert P. Merges, *Commercial Success and Patent Standards: Economic Perspectives on Innovation*, 76 CAL. L. REV. 803, 809 (1988); Gideon Parchomovsky & Peter Siegelman, *Towards an Integrated Theory of Intellectual Property*, 88 VA. L. REV. 1455, 1520 (2002).

243. See Peter Lee, *Patent Law and the Two Cultures*, 120 YALE L.J. 2, 13–15 (2010).

244. Computer science is, for example, "predictable." Dan L. Burk & Mark A. Lemley, *Is Patent Law Technology-Specific?*, 17 BERK. TECH L.J. 1155, 1157 (2002).

245. See *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 609 (1950) (stating that equivalency is a matter of fact).

246. *Id.*

247. *Kinzenbaw v. Deere & Co.*, 741 F.2d 383, 389 (Fed. Cir. 1984).

This is a determination in many ways analogous to a determination of nonobviousness in a suit over patent validity; therefore, the use of a secondary consideration such as value is reasonable.<sup>248</sup>

Although the number of equivalence paradox cases appealed to the Federal Circuit is low, the general trend suggests that the Federal Circuit approves of the district courts' handling of equivalence paradox cases. Eight equivalence paradox cases have been appealed to the Federal Circuit since 2000.<sup>249</sup> Of these, one was vacated on unrelated grounds,<sup>250</sup> one was reversed on doctrine of equivalents grounds,<sup>251</sup> and six were upheld.<sup>252</sup>

The case reversed on doctrine of equivalents grounds supports the theory that courts decide cases based on added value.<sup>253</sup> In *Bio-Technology*, the plaintiff produced Mircette, an oral contraceptive.<sup>254</sup> The contraceptive package was designed such that the first pill would be taken at the onset of menstruation.<sup>255</sup> The first week of pills contained estrogen.<sup>256</sup> The remaining pills contained a mix of estrogen and progestin.<sup>257</sup> After twenty-eight days, the package would be empty, and the woman would take a new package and begin the cycle again.<sup>258</sup> The patent outlined this two-stage system.<sup>259</sup> Duramed's generic oral contraceptive reversed this system.<sup>260</sup> Menstruation would begin on about day twenty-one of the package.<sup>261</sup> For the first three weeks (before menstruation), the woman would take a pill containing a mix of estrogen and progestin.<sup>262</sup> After the onset of menstruation, the woman would take the last pills in the package, which contained only estrogen.<sup>263</sup> She would then take a new package and begin the cycle again.<sup>264</sup> Thus, the two products contained

248. Both require determination of the foreseeability of a technology based on certain prior facts.

249. *Abbott Labs. v. Sandoz, Inc.*, 566 F.3d 1282 (Fed. Cir. 2009); *Abbott Labs. v. Andrx Pharm., Inc.*, 473 F.3d 1196 (Fed. Cir. 2007); *Aventis Pharma Deutschland GmbH v. Lupin, Ltd.*, 499 F.3d 1293 (Fed. Cir. 2007); *Abraxis Bioscience, Inc. v. Mayne Pharma (USA) Inc.*, 467 F.3d 1370 (Fed. Cir. 2006); *Pfizer Inc. v. Teva Pharm. USA Inc.*, 429 F.3d 1364 (Fed. Cir. 2005); *Janssen Pharmaceutica, N.V. v. Eon Labs. Mfg.*, 134 F. App'x 425 (Fed. Cir. 2005); *Bio Tech. Gen. Corp. v. Duramed Pharm., Inc.*, 325 F.3d 1356 (Fed. Cir. 2003); *Upjohn Co. v. Mova Pharm. Corp.*, 225 F.3d 1306 (Fed. Cir. 2000).

250. *Aventis*, 499 F.3d at 1294–95 (reversing because plaintiff's patent was invalid without reaching the issue of equivalence).

251. *Bio Tech.*, 325 F.3d at 1364.

252. *Sandoz*, 566 F.3d at 1299; *Andrx*, 473 F.3d at 1198; *Abraxis*, 467 F.3d at 1373; *Pfizer*, 429 F.3d at 1369; *Janssen*, 134 F. App'x at 427; *Upjohn*, 225 F.3d at 1308.

253. *See Bio Tech.*, 325 F.3d at 1364.

254. *Bio Tech. Gen. Corp. v. Duramed Pharm., Inc.*, 174 F. Supp. 2d 229, 232 (D.N.J. 2001), *rev'd*, 325 F.3d 1356 (Fed. Cir. 2003).

255. *Id.* at 234.

256. *Id.*

257. *Id.*

258. *Id.*

259. *Id.*

260. *Id.* at 238.

261. *Id.*

262. *Id.* at 240.

263. *Id.*

264. *See id.*

exactly the same number of pills of the same chemical composition and were taken in the same order relative to menstruation. The only difference is in the order they were arranged in the package.

The district court held that defendant's product did not infringe by equivalents.<sup>265</sup> The lower court explained that the ordering of the drugs was a limitation of the patent<sup>266</sup> and held that reversing the ordering in the package is a change that "is not insubstantial."<sup>267</sup> Although the district court acknowledged that, over the course of several months, the women using the contraceptive would experience identical effects, it held that the patent covered only one cycle, and thus the "generic version of Mircette does not perform in substantially the same way to achieve substantially the same results as the patented system."<sup>268</sup> This case did not fit with the value theory because a change in the ordering of the pills does not make the drug more marketable or improve methods of manufacturing and it might even make the drug less safe.<sup>269</sup>

On appeal, the Federal Circuit overturned the case.<sup>270</sup> Although it was technically overturned on claim construction grounds,<sup>271</sup> the appeals court explained in dicta that the district court erred in its doctrine of equivalents analysis, writing that "[a]lthough in its discussion of the doctrine of equivalents the court stated that 'the patent contemplates a particular order of pill ingestion within one package,' . . . we reject the restriction."<sup>272</sup> Thus, at the Federal Circuit level, the case fits with the value theory because a change in the ordering of the pills added no value, and therefore the generic should be found to infringe.

## V. IMPLICATIONS FOR PROBLEMS IN PATENT LAW

There are two major debates on the topic of patent efficiency: (1) whether patents provide sufficient incentives to innovate, and (2) whether patents provide sufficient incentives to develop and commercialize the patented invention?<sup>273</sup> The first question tracks the traditional "reward" theory of patent law, which is an economic argument that patent rights are a reward for the innovation disclosed in the patent and an ex ante incentive to innovate.<sup>274</sup> The second question tracks the "pros-

265. *Id.* at 241.

266. *Id.* at 240.

267. *Id.*

268. *Id.*

269. See *infra* notes 351–70 and accompanying text (exploring safety implications of generic drugs).

270. *Bio Tech.*, 325 F.3d at 1356.

271. This case was overturned on the basis that the district court erred in construing the patent to cover only one cycle, because this was "a construction that would allow any potential infringer to avoid liability through any of a number of elementary expedients, such as cutting each of its monthly packages in two." *Id.* at 1362.

272. *Id.* at 1360.

273. Benjamin Roin, *Unpatentable Drugs and the Standards of Patentability*, 87 *TEX. L. REV.* 503, 508–09 (2009).

274. See John F. Duffy, *Rethinking the Prospect Theory of Patents*, 71 *U. CHI. L. REV.* 439, 439 (2004).

pect" theory of patent law, which argues that patents are granted for the ex post purpose of incentivizing a patentee to continue investing in commercializing his product.<sup>275</sup>

In this section, I explain that the courts' "value" approach to the paradox focuses on ex post incentives and bears little relation to ex ante incentives. The emphasis on ex post incentives occurs for two reasons. First, the equivalence paradox cases deal almost exclusively with aspects of a drug aimed at commercialization and development.<sup>276</sup> Second, equivalence paradox cases arise when the prospect function of patents fails. The prospect function of patents is to incentivize the downstream commercialization and development of drugs by giving patentees a monopoly.<sup>277</sup> However, generic companies win equivalence paradox cases when they improve on the commercialization and development efforts of the patent holder.<sup>278</sup> This means that generic companies win when the patent no longer sufficiently incentivizes its holder and outside competitors are able to do a better job of commercialization and development. Thus, courts are in a position to alter patent scope on a case-by-case basis, using the equivalence paradox cases to help answer the timeless question of how big a patent's scope must be to sufficiently incentivize downstream development without adding deadweight loss.

With respect to ex ante incentives, I explain that, facially, the courts' "value" approach to the paradox is an elegant answer to the problem of ensuring that patents provide sufficient ex ante incentives to innovate and disclose. I then argue that although this may be true in the context of individual patents, the pharmaceutical industry functions on the basis of patent portfolios, not individual patents; thus, the courts' calculus, in reality, does not correlate with ex ante incentives. This is important for scholars and policy makers because recognizing that the pharmaceutical industry functions on a patent portfolio basis may enable courts to address ex ante incentives within the framework of current decisions.

I begin my discussion with ex post incentives because they are the focus of the courts' analysis. Then, I conclude with an explanation of why the courts cannot use equivalence paradox cases to perform a similar function for ex ante incentives.

#### A. EX POST INCENTIVES

Ex post incentives are a problem in patent law. The most traditional patent models explain that patents are rewards for the innovation required to produce the patent and for the disclosure in the patent.<sup>279</sup> This conception of patent law "essentially ignore[s] all but the beginning of the

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275. *Id.* at 440.

276. *See supra* Part III.

277. *Graham v. John Deere Co.*, 383 U.S. 1, 9 (1996).

278. *See supra* Part III.

279. *Oddi, supra* note 169, at 274.

[innovation] process.”<sup>280</sup> The most widespread response to this “reward” based theory of patent law is Edmund Kitch’s prospect theory.<sup>281</sup> Kitch recognized that the patent system gives innovators early and broad patents that are actually greater than the reward theory would necessitate.<sup>282</sup> On the basis of this conclusion, Kitch theorized that the foundation for patent law is actually ex post motivation, giving patentees “an incentive to make investments to maximize the value of the patent without fear that the fruits of the investment will produce unpatentable information appropriable by competitors.”<sup>283</sup> Kitch relied on Yoram Barzel’s suggestion that races to invent and commercialize are inefficient,<sup>284</sup> and argued that the patent system could prevent such inefficiency by granting broad patents that placed the patentee “in a position to coordinate the search for technological and market enhancement of the patent’s value.”<sup>285</sup>

Other scholars have also recognized the problem of ex post incentives in patent law, worrying that the current structure of patent law does not sufficiently address post-patenting development and commercialization.<sup>286</sup> Some suggest that competition is the best spur to development of a patent,<sup>287</sup> while others propose specialized “commercialization patents” aimed at post-patenting development.<sup>288</sup> Regardless of the specifics of the proposal, all agree that patent law must address ex post incentives.<sup>289</sup>

Once it has been established that patent law must be concerned with ex post incentives, the next task is to determine the proper patent scope to create optimal incentives.<sup>290</sup> Too broad a patent creates deadweight loss in the form of an extended monopoly that forces higher prices on consumers and stifles competition. Too narrow a patent may prevent useful products from coming to market because the patent holder is insufficiently incentivized to develop them. This problem has been explored in more detail in the context of determining the proper patent scope to cre-

280. Ted Sichelman, *Commercializing Patents*, 62 STAN. L. REV. 341, 348 (2010).

281. Kitch, *supra* note 29, at 268.

282. *Id.* at 267.

283. *Id.* at 276.

284. Yoram Barzel, *Optimal Timing of Innovations*, 50 REV. ECON. & STAT. 348, 352 (1968); *see also* Duffy, *supra* note 274, at 441–45.

285. Kitch, *supra* note 29, at 276.

286. *See, e.g.*, Michael Abramowicz, *Orphan Business Models: Towards a New Form of Intellectual Property*, 124 HARV. L. REV. 1362, 1367–68 (2011); Michael Abramowicz & John F. Duffy, *Intellectual Property for Market Experimentation*, N.Y.U. L. REV. 337, 337–43 (2008); Michael Abramowicz, *The Danger of Underdeveloped Patent Prospects*, 92 CORNELL L. REV. 1065, 1068 (2007); Oren Bar-Gill & Gideon Parchomovsky, *A Marketplace for Ideas?*, 84 TEX. L. REV. 395, 403 (2005); Christopher A. Cotropia, *The Folly of Early Filing in Patent Law*, 61 HASTINGS L.J. 65, 69 (2009); F. Scott Kieff, *Property Rights and Property Rules for Commercializing Inventions*, 85 MINN. L. REV. 697, 707 (2001); F. Scott Kieff, *The Case for Registering Patents and the Law of Economics of Present Patent-Obtaining Rules*, 45 B.C. L. REV. 55, 65 (2003); Sichelman, *supra* note 280, at 343–53.

287. Merges & Nelson, *supra* note 29, at 843–44.

288. Sichelman, *supra* note 280, at 341.

289. *See, e.g., id.*; Merges & Nelson, *supra* note 29, at 843.

290. *See* Roin, *supra* note 273, at 509.



ate optimal ex ante incentives.<sup>291</sup> This is a problem in the ex post context as well.

Before I explain why and how courts' resolution of equivalence paradox cases is primarily aimed at ex post incentives, I will address an issue of context. Traditionally, ex post development and commercialization referred to development and commercialization of the technology described in one patent.<sup>292</sup> This is less obvious in the pharmaceutical industry. Drug companies typically use patent portfolios, meaning that they have many patents protecting one product.<sup>293</sup> A drug may be protected by a patent covering its active ingredient and also by many other patents protecting various aspects of its formulation, synthesis, and packaging.<sup>294</sup> Thus, the importance of ex post commercialization and development is not necessarily apparent in relation to any one patent, but instead is important with respect to the composition of the active ingredient. When I use the term "drug" in this section, I refer to the finished product on the market, which is typically the sum of a patent portfolio.

Equivalence paradox cases are primarily aimed at ex post incentives because the majority of patents at issue in the cases deal with downstream commercialization and development of a drug.<sup>295</sup> As described above,<sup>296</sup> only three of the twenty-five equivalence cases focus on the active ingredient of the drug. The other cases deal with generic work-arounds related to downstream commercialization and development.<sup>297</sup> This is an inherent aspect of equivalence cases because the FDA allows a greater range of work-arounds for downstream changes to a drug, as opposed to changes involving the active ingredient.<sup>298</sup> Thus, courts are more likely to be concerned with downstream development because that is the issue at hand.

Furthermore, equivalence cases arise when there has been a failure in downstream development. For courts to find infringement, two circum-

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291. Louis Kaplow, *The Patent-Antitrust Intersection: A Reappraisal*, 97 HARV. L. REV. 1813, 1882 (1984). For further descriptions of efforts to balance incentives to innovation with costs to society, see WILLIAM D. NORDHAUS, *INVENTION, GROWTH AND WELFARE: A THEORETICAL TREATMENT OF TECHNOLOGICAL CHANGE* 70 (1969); see also Michael Abramowicz, *Perfecting Patent Prizes*, 56 VAND. L. REV. 115, 127-77 (2003); David S. Abrams, *Did TRIPS Spur Innovation? An Analysis of Patent Duration and Incentives to Innovate*, 157 U. PA. L. REV. 1613, 1626-41 (2009); Ian Ayres & Paul Klemperer, *Limiting Patentees' Market Power Without Reducing Innovation Incentives: The Perverse Benefits of Uncertainty and Non-Injunctive Remedies*, 97 MICH. L. REV. 985, 987 (1999); John F. Duffy, *The Marginal Cost Controversy in Intellectual Property*, 71 U. CHI. L. REV. 37, 45-49 (2004); Einer Elhauge, *Defining Better Monopolization Standards*, 56 STAN. L. REV. 253, 300 (2003); Steven Shavell & Tanguy Van Ypersele, *Rewards Versus Intellectual Property Rights*, 44 J.L. & ECON. 525, 525-42 (2001).

292. See Sichelman, *supra* note 280, at 374-76.

293. Gideon Parchomovsky & R. Polk Wagner, *Patent Portfolios*, 154 U. PA. L. REV. 1, 5-6 (2005).

294. See *supra* notes 136-40 and accompanying text.

295. See *supra* Part III.

296. See *supra* Part III.

297. See *supra* Part III.

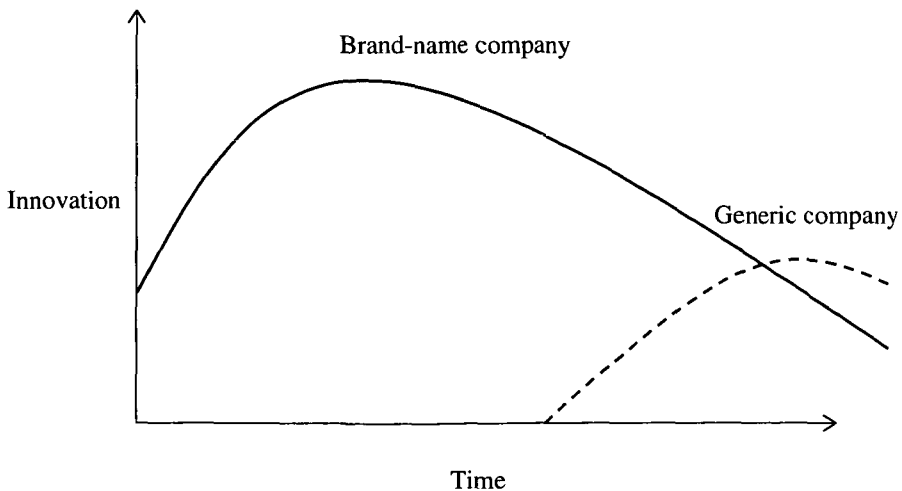
298. See *supra* Part III.

stances must be present. First, the generic company must have created an innovation that improves the drug in some way, generally related to improved commercialization and development.<sup>299</sup> Second, the brand name company must have been unable to make and patent that improvement themselves.<sup>300</sup>

Under prospect theory, patents are intended, in part, to encourage downstream innovation by giving the patentee a monopoly to allow for coordinated innovative efforts.<sup>301</sup> In equivalence paradox cases, the prospect function of patents worked to an extent because the drug had reached the market; however, there comes a point where the patent's ex post incentives are no longer sufficient to incentivize downstream innovation. As a theoretical matter, the patent should end at that point. As a practical matter, it is essentially impossible to correctly determine the precise patent scope and length necessary to maximize the patentee's downstream innovative potential without granting an excessive monopoly and incurring deadweight loss. Thus, we compromise by creating an inflexible patent length and inflexible FDA market exclusivity that estimate optimal patent monopolies.

Equivalence paradox cases essentially give the legal system a second bite at the patent scope apple. Courts have a chance to view the competitive landscape after the patent has been granted and ask whether the patentee or the competitor is the better innovator. For every innovation, there should be a point at which the patentee ceases to be the better innovator and is overtaken by the competitor. I sketch this concept in Figure 5, below.

Figure 5: Innovation over Time



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

300. *Id.*

301. See *supra* text accompanying notes 281–85.

Figure 5 shows how innovation changes over time. Early on, the brand name company that holds a broad “prospect” patent commercializes and develops the product and brings it to market. But gradually, the incentive to innovate fades. At some point, generic companies have a stronger incentive to innovate and begin to improve on the drug in valuable ways.<sup>302</sup> This is the point at which the patent should narrow because disallowing the generic’s improvement creates deadweight loss.

This is what happens in equivalence paradox cases. Generic companies try to create work-arounds. Sometimes, these work-arounds are innovative and improve the product. At other times, they involve little innovation and may even make the product worse.<sup>303</sup> When there is no valuable innovation, the generic company loses. When there is valuable innovation, the generic company wins, and the range of equivalents covered by the brand name patent is narrowed; to do otherwise would allow deadweight loss from a patent that is no longer incentivizing innovation. As a further benefit, this has the effect of incentivizing competition. There is controversy regarding whether broad patents or competition is more effective at increasing downstream development.<sup>304</sup> Equivalence cases expand the scope of patents where broad patents are more effective and narrow than in cases where competition is more effective.

## B. EX ANTE INCENTIVES

Under the utilitarian calculus of standard patent theory, a patent is an incentive to innovate.<sup>305</sup> The “reward” theory explains that a patent is an incentive for ex ante innovation—in other words, it rewards the invention that is disclosed in the patent and seeks to incentivize more such discoveries and disclosures.<sup>306</sup> This model of patent law creates an empirical challenge: how much incentive is sufficient? Louis Kaplow’s “ratio test” requires that the optimal package to be granted to intellectual property owners should be developed by providing “those rights that grant just enough reward to induce . . . inventive or creative activity at the lowest social cost possible.”<sup>307</sup> Too great of a reward to patent holders creates deadweight loss, which is socially undesirable. Too little of a reward reduces the incentive to innovate and creates social loss in the form of

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302. See Kitch, *supra* note 29, at 268–72.

303. See, e.g., *Aventis Pharma Deutschland GMBH v. Lupin Ltd.*, No. 2:05CV421, 2006 WL 1582412, at \*1 (E.D. Va. June 5, 2006).

304. See Michael A. Carrier, *Unraveling the Patent-Antitrust Paradox*, 150 U. PA. L. REV. 761, 788–91, 796–97 (2002).

305. See Kitch, *supra* note 29, at 268–71.

306. Oddi, *supra* note 169, at 275. Oddi suggest that the reward theory is more properly called the “patent-induced” theory to distinguish it from the “natural rights” theory of patent law. *Id.* at 274–75. But as reward theory is commonly applied to Oddi’s “patent-induced” theory, I will use the reward terminology for the purpose of simplicity. The reward theory is criticized for perceiving “little to no need to protect risky and costly post-invention development and commercialization efforts.” Sichelman, *supra* note 280, at 344.

307. Daniel A. Crane, *Intellectual Liability*, 88 TEX. L. REV. 253, 299 (2009).

fewer inventions.<sup>308</sup> Many articles have suggested ways to tailor patent rights to address this problem.<sup>309</sup>

On its face, the “value” approach taken by the courts to equivalence cases seems to dovetail nicely with the reward theory as a way to tailor patent scope based on initial innovative efforts. A patent that required a great deal of innovation should get a greater reward: a broader patent. A patent that required little innovation should get a smaller reward: a narrower patent. More specifically, the patent scope should reflect whether the innovation would have been disclosed to society in the absence of the patent.

In equivalence cases, the courts are faced with two parties, each of whom have put some level of innovating effort into creating a “highly similar” product. In a sense, this faceoff helps answer the question of whether the innovation would have been disclosed but-for the patent. If the generic company did little more than copy the brand name company’s patent, then the court has no evidence that the invention would have been developed but-for the patent. If the generic company improved on the brand name product or, better yet, managed to achieve a level of accomplishment that the brand name company could not, then it is evidence that the innovation would still have been available to the public but-for the brand name patent. Thus, in the latter situation, the brand name company deserves a narrower patent.

Note that, even if a generic company improved on a patent, it does not necessarily follow that the generic company could have created the innovation without the disclosure provided in the patent. Many generic companies use the brand name patent as a starting point for their research.<sup>310</sup> However, some generic work-arounds are quite independent of the brand-name patents.<sup>311</sup>

For example, in *SmithKline Beecham Corp. v. Apotex Corp.*,

308. This is, of course, a simplification. Scholarly work has added many other dimensions onto this calculus. See, e.g., Merges & Nelson, *supra* note 29, at 868–69.

309. See generally Crane, *supra* note 307; sources cited *supra* notes 286–90. Note that the concern over patent scope and monopoly power is related to the widespread debate about property rights (which create a broad patent monopoly) versus liability rights (which create narrower, more easily tailored rules). See e.g., Mark A. Lemley & Philip J. Weiser, *Should Property or Liability Rules Govern Information?*, 85 TEX. L. REV. 783, 786–88 (2007); Henry E. Smith, *Intellectual Property as Property: Delineating Entitlements in Information*, 116 YALE L.J. 1742, 1742–43 (2007). This argument has its basis in the real property law literature. See generally Guido Calabresi & A. Douglas Melamed, *Property Rules, Liability Rules, and Inalienability: One View of the Cathedral*, 85 HARV. L. REV. 1089 (1972); Ian Ayres & J. M. Balkin, *Legal Entitlements as Auctions: Property Rules, Liability Rules, and Beyond*, 106 YALE L.J. 703 (1996); Lucian Bebchuk, *Property Rights and Liability Rules: The Ex Ante View of the Cathedral*, 100 MICH. L. REV. 601 (2001); Louis Kaplow & Steven Shavell, *Property Rules Versus Liability Rules: An Economic Analysis*, 109 HARV. L. REV. 713 (1996); James E. Krier & Stewart J. Schwab, *Property Rules and Liability Rules: The Cathedral in Another Light*, 70 N.Y.U. L. REV. 440 (1995); Carol M. Rose, *The Shadow of the Cathedral*, 106 YALE L.J. 2175 (1997).

310. See Tara Stuart, *Has the Supreme Court Incorrectly Expanded § 271(e)(1) to Risk Regulatory Taking?*, 5 J. MARSHALL REV. INTELL. PROP. L. 216, 222 (2006).

311. See, e.g., *SmithKline Beecham Corp. v. Apotex Corp.*, No. Civ.A.99-CV-4304, 2005 WL 941671, at \*1–3 (E.D. Pa. Mar. 31, 2005).

SmithKline produced Paxil, a blockbuster anti-depression drug.<sup>312</sup> SmithKline scientists conducted experiments to “identify processes suitable for industrial scale production of” Paxil.<sup>313</sup> They settled on a process that could only be conducted in a non-ether solvent and obtained a patent on this process.<sup>314</sup> The defendants produced a similar medication using an ether solvent and, thus, did not literally infringe SmithKline’s patent.<sup>315</sup> Although SmithKline also argued that defendants’ process infringed by equivalents, the court found the doctrine inapplicable because the processes did not perform substantially the same function in substantially the same way.<sup>316</sup>

In *SmithKline*, the generic company developed an entirely different chemical synthesis process.<sup>317</sup> Paxil is a blockbuster drug with an enormous market value. It is clearly socially beneficial to develop a process to produce Paxil on an industrial scale, as the brand-name company did. But would society have received a process for industrial production of Paxil in the absence of the brand name patent? The generic company’s success at developing an alternate patent provides some evidence to suggest that the answer is yes. Thus, perhaps the scope of the brand name patent should be somewhat narrower because society did not need to grant a large monopoly to obtain the innovative effort and, therefore, society should not bear a large deadweight loss.

A narrow patent for an easily worked-around innovation will not entirely discourage innovation. The brand name company will still have a patent on the process, and thus will still hold a monopoly while the generic company develops its work-around. Furthermore, the brand name company will still hold a patent on its version of the process and thus will be able to benefit. By using the “value” method of interpreting equivalence paradox cases, courts can tailor patent scope to ex ante innovative effort.

Although this is an elegant way of addressing the patent scope problem, this approach does not work in the pharmaceutical and biotechnology industries. Tailoring an individual patent in an equivalence case as a way to respond to ex ante incentives fails to address the larger question of ex ante efforts to create the drug itself. This is because the high cost of clinical trials means that pharmaceutical companies do not operate on a one-product-one-patent model, but rather on a patent portfolio model.<sup>318</sup>

Pharmaceutical companies rarely, if ever, have only one patent cover-

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312. *Id.* at \*2, \*15.

313. *Id.* at \*2.

314. *Id.* at \*3–5.

315. *Id.* at \*32.

316. *Id.* at \*5, \*32–33.

317. *Id.* at \*33.

318. The literature is increasingly addressing the issue of patent portfolios. See, e.g., Richard J. Gilbert & Michael L. Katz, *Should Good Patents Come in Small Packages? A Welfare Analysis of Intellectual Property Bundling*, 24 INT’L J. INDUS. ORG. 931, 934 (2006); Parchomovsky & Wagner, *supra* note 293, at 1.

ing a drug.<sup>319</sup> Instead, they will patent the “new chemical entity,” which is the active ingredient in the drug, and will also patent a variety of peripheral patents related to method-of-use, chemical synthesis, packaging, purity, stability, and formulation.<sup>320</sup> The peripheral patents can be essential to getting the drug to market. Namely, a patient generally cannot just swallow the active ingredient—it must be formulated into a pill or injection, purified to ensure reliability and safety, and packaged to ensure stability prior to use.<sup>321</sup> However, the peripheral patents are not the focus of a brand-name pharmaceutical company.<sup>322</sup> That is to say, pharmaceutical companies generally do not develop ways to package a drug if there is no drug to package.<sup>323</sup> The new chemical entity patent forms the core of the patent portfolio and requires the creation of a variety of other peripherally patentable innovations during the commercialization process.<sup>324</sup> Thus, it makes little sense to look at the *ex ante* incentives to create a peripheral patent. It is more coherent to look at whether the portfolio of patents provides sufficient *ex ante* incentives for the pharmaceutical company to bring the drug through clinical trials. In the context of *SmithKline*, the appropriate question is not whether a mass synthesis process for Paxil would have been developed in absence of the brand name patent, but whether Paxil would have made it to the market in the absence of its protective patent portfolio.

As explained above,<sup>325</sup> equivalence paradox trials involve the peripheral patents. Take, for example, a method of packaging: if a court considers the *ex ante* innovative effort required for its development, it will miss the forest for the trees. While the patent protection may have incentivized the development of the packaging, the packaging development was more likely incentivized by the patent on the active ingredient—the core patent. The research that led to the core patent was in turn incentivized by the knowledge that the resulting drug would be protected not merely by a patent on its active ingredient (which frequently expires before the drug gets to market) but by an entire portfolio that would extend the company’s market monopoly. Put another way, the peripheral patent was not only a reward for developing packaging, it was also a reward for developing the drug itself.

Moving from the one-product-one-patent approach to a portfolio approach makes it clear why “value” analysis is much too narrow to fit with the reward theory of patent law. The fact that the generic company developed a work-around for a peripheral patent does not necessarily mean that it could have developed a work-around for the drug itself. Moreover,

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319. See Parchomovsky & Wagner, *supra* note 293, at 5–6, 16–17.

320. Lara J. Glasgow, *Stretching the Limits of Intellectual Property Rights: Has the Pharmaceutical Industry Gone Too Far?*, 41 *IDEA* 227, 232–33 (2001).

321. *Id.* at 231–33.

322. *Id.*

323. *Id.*

324. *Id.*

325. See *supra* Part II.

even if the generic company was capable of the intellectual, innovative effort, the cost of clinical trials for a new drug is extraordinarily high,<sup>326</sup> which is one reason that strong patent protection is vital in the pharmaceutical industry. Thus, the equivalence analysis is ill-suited to consider ex ante incentives. As a theoretical matter, patent law would be more coherent if courts did consider the ex ante incentives for the entire portfolio when analyzing equivalence cases.

## VI. IMPLICATIONS FOR PROBLEMS IN FDA LAW

The courts' analysis of equivalence cases finds a theoretical home in the ex post theories of patent law. However, equivalence cases implicate not only patent law, but also the Hatch-Waxman Act and related FDA regulation. There are two central areas of FDA law affected by these cases: (1) evergreening and (2) the goal of cheaper, safer medicine. In this section, I discuss how the equivalence cases are evidence that courts are becoming increasingly skeptical of evergreening patents. In addition, courts may use their value calculus to differentiate between patents obtained solely for the purpose of evergreening and patents that have some social benefit. Next, I assess the effect of the equivalence paradox on the primary goal of the Hatch-Waxman Act: creating a generic pathway in order to bring safe drugs at a low cost to the market quickly. I conclude that although the paradox may fit with patent theory, it is contrary to the goals of the Hatch-Waxman Act, and both courts and policy makers should consider the conflicting incentives created by the various laws regulating the generic industry.

### A. EVERGREENING

Evergreening, a much-discussed issue in pharmaceutical law,<sup>327</sup> occurs when a pharmaceutical company that has lost both FDA exclusivity and patent protection on the active ingredient of its drug seeks to extend its monopoly by protecting the drug with a series of peripheral patents that allow for additional FDA exclusivity and further patent protection.<sup>328</sup> In particular, this practice allows a brand name company to list additional patents in the FDA's *Orange Book*, which in turn allows the patentee to sue manufacturers of generic versions of their product for infringement and obtain thirty-month stays on the generic product's market entry.<sup>329</sup> Newer statutes, such as the 2003 Medicare Prescription Drug, Improvement, and Modernization Act<sup>330</sup> and the 2009 Biologics Price Competi-

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326. See Glasgow, *supra* note 320, at 255.

327. See sources cited *supra* note 111.

328. Gaudry, *supra* note 111, at 876-78.

329. See, e.g., Glasgow, *supra* note 320, at 233; Mark A. Lemley & Kimberly A. Moore, *Ending Abuse of Patent Continuations*, 84 B.U. L. REV. 63, 82 (2004); Christine S. Paine, *Brand-Name Drug Manufacturers Risk Antitrust Violations By Slowing Generic Production Through Patent Layering*, 33 SETON HALL L. REV. 479, 488 (2003).

330. Pub. L. No. 108-173, 117 Stat. 2066 (2003); 68 Fed. Reg. 36,676 (June 18, 2003) (to be codified 21 C.F.R. at 314). The preamble to the proposed rule acknowledged that the

tion and Innovation Act (BCPIA),<sup>331</sup> attempt to curb evergreening, but abuses continue.<sup>332</sup>

Evergreening is widely considered a negative behavior—an example of pharmaceutical companies exploiting loopholes in legislation to achieve a longer patent term than otherwise entitled.<sup>333</sup> As a practical matter, evergreening is problematic because it delays the market entry of low-cost generic drugs. As a theoretical matter, evergreening is problematic because it gives patent holders a greater reward than Congress determined that they are entitled to and creates deadweight loss by preventing generic companies from entering the market.

However, the practice of patenting peripheral elements of a drug can also be positive. With respect to *ex ante* incentives, Scott Hemphill points out that a defense to pharmaceutical companies' strategic behavior is that such behavior increases the reward for innovation and thus incentivizes development of new drugs.<sup>334</sup> With respect to *ex post* incentives, to commercialize a product, pharmaceutical companies must discover how to synthesize the drug; how to purify it; how to stabilize it to ensure a shelf life long enough for the drug to be shipped and used; how to create packaging that does not react with the product and is safe for consumer use;

change was in response to “NDA holders submit[ting] new patents for listing shortly before other listed patents for the same drug were to expire.” 68 Fed. Reg. at 36,677 (Oct. 24, 2002).

331. 42 U.S.C. § 262 (2006 & Supp. V 2011). The BCPIA includes an “anti-evergreening” provision—a list of improvements in a drug that do not qualify for an exclusivity period—in an effort to reduce the strategic small improvements made by producers of small molecule drugs attempting to extend their market monopoly. *Id.* § 262(j)(7)(c). The anti-evergreening provision provides that the following improvements will not receive exclusivity: “a supplement for the biological product that is the reference product,” an application filed by the sponsor of the original reference product for a change “that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device or strength,” or “a modification in the structure of the biological product that does not result in a change in safety, purity, or potency.” *Id.*

332. See, e.g., Stacey L. Dogan & Mark A. Lemley, *Antitrust Law and Regulatory Gaming*, 87 TEX. L. REV. 685, 711 (2009) (“After Congress corrected that particular [evergreening] problem, crafty firms took a different tack: rather than stacking patents, they stacked products—making trivial changes to their product formulation and pulling the old drug from the market.”); Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy*, 13 MICH. TELECOMM. & TECH. L. REV. 345, 348 (2007) (“In recent years firms have become quite creative about strategies to secure “evergreening” patents in order to defer the date their products go off-patent.”); Robin Feldman, *Rethinking Rights in Biospace*, 79 S. CAL. L. REV. 1, 30 (2005) (describing a form of evergreening); C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553, 1619 (2006) (“Drug makers have displayed a great deal of ingenuity in preserving the profits from an innovative drug. The strategies include . . . new patents on the same drug.”); Mark A. Lemley, *Ignoring Patents*, 2008 MICH. ST. L. REV. 19, 30 (2008) (“Patent owners have strong incentives to extend the life of their patents . . . by “evergreening”—obtaining multiple patents covering the same product.”). For a discussion on the impact of the doctrine of equivalents on biologics, see Janet Freilich, *Patent Infringement in the Context of Follow-on Biologics*, 16 STAN. TECH. L. REV. 9 (2012).

333. See *supra* text accompanying note 111.

334. C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 COLUM. L. REV. 629, 637 (2009) (The most fundamental [defense] is that permitting settlement increases the brand-name firm's profits and hence its expected reward for developing innovating drugs.”).



and how to mix the active ingredient with inactive ingredients to create an injection, cream, or pill that is safe and effective.<sup>335</sup>

Scholars suggest that courts are increasingly skeptical of evergreening strategies,<sup>336</sup> but both courts and regulatory agencies struggle to craft legal strategies to separate useful peripheral patents from evergreening.<sup>337</sup> An examination of the equivalence cases in the context of evergreening provides two related and important observations. First, it is evident that courts are in fact becoming increasingly skeptical of evergreening patents. Second, the cases suggest that courts are using “value” as a shortcut to determine whether peripheral patents are genuinely useful or are merely strategic evergreening. Evergreening the patents on the active ingredient of a drug is essentially never attempted. Patents on other aspects of a drug—such as formulation, packaging, synthesis, purity, or stability—are significantly more likely to be targeted in evergreening. As demonstrated above, plaintiffs holding patents covering the active ingredient of the drug win seventy-five percent of the time.<sup>338</sup> This indicates that courts are willing to give these patents a broad range of equivalents. However, plaintiffs holding patents that do not cover the active ingredient of the drug—patents that are more likely to be evergreening patents—win only twenty-five percent of the time.<sup>339</sup> This suggests that courts give a narrower range of equivalents to patents they suspect are evergreening patents.

The use of value as the key criteria for determining if the generic drug infringes on a patent also aids the courts’ identification of evergreening patents. A patent that cannot be worked-around by a generic company is less likely to be an evergreening patent and more likely to instead produce genuine value for society in the form of an invention that may not have been developed otherwise. Similarly, a patent that can be worked-around by a generic company is more likely to be a weak patent produced merely as a form of evergreening that adds little value to society.

## B. CHEAPER, SAFER MEDICINE

The courts’ approach to the equivalence paradox can be explained as a matter of patent theory and serves a useful role in incentivizing ex post development and identifying evergreening patents. However, this ap-

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335. David Pilling & Richard Wolffe, *Drug Abuses: As Pharmaceutical Companies Go to Extraordinary Lengths to Protect Expiring Patents, Regulators are Starting to Pay Close Attention*, FIN. TIMES (London), Apr. 20, 2000, at 20 (explaining that scientific experts have found that new versions of a drug often improve side effects that were problematic in a prior version of the drug).

336. See Eisenberg, *supra* note 332, at 356 (“[T]he courts grow more skeptical of evergreening strategies . . .”).

337. Glasgow, *supra* note 320, at 251 (suggesting that the FTC and other agencies hesitate to regulate evergreening because “evergreened” drugs have genuine benefits or because it is too difficult for courts to sort through “new patents that are actually beneficial and those that seek to extend a patent monopoly”).

338. See *supra* Part III.

339. See *supra* Part III.

proach does not harmonize with the goals of the Hatch-Waxman Act. A primary goal of the Hatch-Waxman Act is to ensure that generic drugs are available quickly, cheaply, and safely.<sup>340</sup> My analysis of the equivalence paradox cases suggests that patent law works against the Hatch-Waxman Act to delay generic drugs, increase their expense, and sometimes reduce their safety.

The equivalence paradox delays generic entry and increases the expenses of generic drugs.<sup>341</sup> Generics are permitted to enter the market as soon as FDA exclusivity expires.<sup>342</sup> The exclusivity periods are set by the Hatch-Waxman Act as a compromise between the generic and brand name industries.<sup>343</sup> The time frame delineated by the Hatch-Waxman Act suggests that Congress intended generics to enter the market immediately after the expiration of the period set by the Hatch-Waxman Act. In practice, this does not occur if the brand name company retains patent protection, which is often accomplished through evergreening.<sup>344</sup> Patent law thus operates to delineate a space where generic companies cannot enter, despite legislative intent that they do so.<sup>345</sup> The doctrine of equivalents only exacerbates the problem by expanding the fence around the patent. An argument could be made that courts should never apply the doctrine of equivalents in these cases because it results in the courts thwarting clear legislative intent to allow generics into the market. The effect of the doctrine of equivalents is to delay generic entry by forcing generic manufacturers to create broader work-arounds to the patent.

Part of the problem stems from the confused narrative of the proper role of generic companies. In this narrative, brand name companies are the innovators, while generic companies are producers of drugs that are essentially identical to brand name drugs that are created to bring down the price of medicine. Yet, because generic drugs enter the market before the brand-name patents have expired, generic companies are also tasked with innovating. Often, generic companies can create lower cost synthesis and delivery methods that decrease drug cost and improve drug quality.<sup>346</sup> Unfortunately, generic drugs encounter a patent system that does not consistently describe their role, creating problems such as the equivalence paradox. The legal system would do well to recognize generic companies' role in innovation, as well as their role in lowering the cost of medicine.

The equivalence paradox also has problematic safety implications.<sup>347</sup>

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340. *Abbott Labs. v. Young*, 920 F.2d 984, 991 (D.C. Cir. 1990).

341. *Id.*

342. *Id.*

343. *Id.*

344. Gaudry, *supra* note 111, at 876–78.

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

346. *See supra* Part III.

347. The safety of generic drugs is a particular problem in light of the Supreme Court's decision in *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011) (holding that patients injured by a generic drug product could not sue the generic drug manufacturer under state tort claims because federal labeling regulations preempted state tort laws).

Because a generic company must ensure that its product is sufficiently distant from the brand name product, but still close enough to satisfy the FDA, the generic product must be similar to but not quite the same as the brand name product.<sup>348</sup> This may incentivize generic companies to work-around the brand name patent in a way that creates needless safety risks. For example, generic companies may add impurities to their products to avoid infringement.<sup>349</sup>

To understand the possible safety risks, consider the following cases. In *Bio-Technology v. Duramed*, the plaintiff produced Mircette, an oral contraceptive.<sup>350</sup> The contraceptive package was designated such that the first pill would be taken at the onset of menstruation.<sup>351</sup> The first week of pills contained estrogen.<sup>352</sup> The remaining pills contain a mix of estrogen and progestin.<sup>353</sup> Duramed's generic oral contraceptive reversed this system.<sup>354</sup> Menstruation would begin on about day twenty-one of the package.<sup>355</sup> For the first three weeks (before menstruation), the woman would take a pill containing a mix of estrogen and progestin.<sup>356</sup> After the onset of menstruation, the woman would take the last pills in the package, which contained only estrogen.<sup>357</sup>

Imagine a woman whose doctor prescribes her Mircette, explains how and when to take the pills (beginning within a few days of the start of her menstrual cycle), and sends her to the pharmacy with a prescription in hand. The pharmacist, allowed by law to substitute the generic version for a brand name prescription, gives her Duramed's product. The woman, having spoken with her doctor about how to take the product, and perhaps already having years of experience with the brand name product, scans (or does not read) the instructions, assuming she can take the pills the way her doctor told her, or the way she had been doing so in the past. She begins taking the pills the Sunday after her menstrual cycle begins (as is common for most oral contraceptives). Unbeknownst to her, she is taking the pills incorrectly because the generic product requires her to start taking the pills a week later. Her body receives the hormones at the incorrect time, and the woman unexpectedly gets pregnant. This safety risk is a very real problem with making small changes to packaging in a generic product that will be interchangeably supplied by a pharmacy.<sup>358</sup>

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348. See *supra* Part III.

349. E.g., *Pozen Inc. v. Par Pharm., Inc.*, 800 F. Supp. 2d 789, 825 (E.D. Tex. 2011); *Aventis Pharma Deutschland GmbH v. Lupin Ltd.*, No. 2:05CV421, 2006 WL 1582412, at \*1 (E.D. Va. June 5, 2006).

350. 174 F. Supp. 2d 229, 232 (D.N.J. 2001), *rev'd*, 325 F.3d 1356 (Fed. Cir. 2003).

351. *Id.* at 234.

352. *Id.*

353. *Id.*

354. *Id.* at 238.

355. *Id.* at 240.

356. *Id.*

357. *Id.*

358. Note that *Duramed* was appealed to the Federal Circuit where it was overturned on the basis that the district court erred in its claim construction. *Bio Tech. Gen. Corp. v. Duramed Pharm., Inc.*, 325 F.3d 1356, 1356 (Fed. Cir. 2003). The Federal Circuit did not

A second case demonstrating the safety hazard present when a generic company makes packaging changes is *EKR Therapeutics, Inc. v. Sun Pharmaceutical Industries*.<sup>359</sup> In *EKR*, the plaintiff produced Cardene, a drug to treat hypertension.<sup>360</sup> Cardene could not be directly administered into the body because it was not isotonic (meaning that it had a different osmotic pressure than cells in the body).<sup>361</sup> EKR solved this problem by adding sorbitol to the product, and the patent claimed an “isotonic” composition.<sup>362</sup> Sun’s generic drug was identical to EKR’s product except that it contained about 60% less sorbitol, meaning the solution was no longer isotonic.<sup>363</sup> The directions on Sun’s label instructed that the administering physician must mix the solution with dextrose to render the solution isotonic before giving it to a patient.<sup>364</sup>

Sun’s product infringed by equivalents,<sup>365</sup> and thus is not on the market; however, it had the potential to cause serious harm. EKR’s hypertension drug does not need to be diluted.<sup>366</sup> Sun’s hypertension drug did.<sup>367</sup> A physician accustomed to using EKR’s product might not realize that the product was a generic product, and he might administer the generic without dilution. Alternatively, he might know the generic required dilution, but might dilute it incorrectly because he was tired or made some other human error. EKR, the pre-diluted product, removes this dilution requirement and thus removes an opportunity for unintentional mistakes in dosage.

The types of small changes generic companies make to stay bioequivalent while avoiding infringement may result in products with these sorts of safety risks. Fortunately, neither product is on the market. Although courts do not explicitly consider patient safety when ruling on doctrine of equivalents questions, in these cases it seems as if the doctrine of equivalents provides a patient safety benefit. Nevertheless, judges<sup>368</sup>—or worse, juries<sup>369</sup>—are poorly positioned to rule on safety issues, and

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reach the question of infringement by equivalents, but remanded for further consideration. *Id.* at 1364.

359. *See* 633 F. Supp. 2d 187 (D.N.J. 2009).

360. *Id.* at 189.

361. *Id.* at 195.

362. *Id.* at 193.

363. *Id.* at 194.

364. *Id.* at 196.

365. *Id.* at 207.

366. *Id.* at 193.

367. *Id.* at 196.

368. There is ample evidence that judges and juries are ill-equipped to make scientific decisions. *See, e.g.,* Burk & Lemley, *supra* note 244, at 1196 (“Judges are at a rather serious disadvantage in trying to put themselves in the shoes of an ordinarily skilled scientist.”); Kimberly A. Moore, *Are District Court Judges Equipped to Resolve Patent Cases?*, 15 HARV. J. L. TECH. 1, 38 (2002) (concluding that “judges are not, at present, capable of resolving these [scientific patent] issues with sufficient accuracy”); Arti K. Rai, *Engaging Facts and Policy: A Multi-Institutional Approach to Patent System Reform*, 103 COLUM. L. REV. 1035, 1040 (2003) (“Generalist trial judges, and juries empaneled by trial judges, may be overwhelmed by the technology involved in patent cases.”).

369. *See, e.g.,* Scott Brewer, *Scientific Expert Testimony and Intellectual Due Process*, 107 YALE L.J. 1535, 1539 (1998) (arguing that judges and juries do not understand the

safety issues have no relation to the patent law on which courts base their decision. It would be better to craft laws that avoid giving generic companies perverse incentives to make products less safe.

## VII. CONCLUSION

The findings of this article are important to patent theorists and policy makers. Although this paradox does not exist in industries that are less regulated, the commercial value calculus courts use when analyzing infringement questions may translate to other industries. Moreover, my finding that courts adjust the scope of equivalents to improve the correspondence between patent scope and desired patent incentives is applicable across patent law. Because pharmaceuticals operate on a portfolio model, courts in equivalence paradox cases have been unable to tailor patents to fit *ex ante* incentives, but industries where portfolios are less prevalent should not encounter this problem. With respect to the pharmaceutical industry, this Article provides an important data point about patentees' and courts' approaches to evergreening and highlights the conflict created by the multiple legal frameworks that affect the industry.

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technology in scientific cases and thus make arbitrary decisions based upon experts' credentials, reputation, and demeanor); Alan Feigenbaum, *Special Juries: Deterring Spurious Medical Malpractice Litigation in State Courts*, 24 *CARDOZO L. REV.* 1361, 1389-96 (2003); Robert D. Myers et al., *Complex Scientific Evidence and the Jury*, 83 *JUDICATURE* 150, 152 (1991) (suggesting that a jury comprised of lay people will have difficulty being "a competent fact finder and decision-maker in lengthy trials that require comprehension of substantial quantities of complex scientific, technical, or statistical evidence and resolving the testimony of expert witnesses whose opinions conflict"); Joseph Saunders, *Scientifically Complex Cases, Trial by Jury, and the Erosion of Adversarial Processes*, 48 *DEPAUL L. REV.* 355, 356 (1998); Barry S. Wilson, *Patent Invalidity and the Seventh Amendment: Is the Jury Out?*, 34 *SAN DIEGO L. REV.* 1787, 1787 (1997) (arguing that juries favor inventors and are biased against large corporations or foreign defendants). *But see* Markman v. Westview Instruments, Inc., 52 F.3d 967, 993 (Fed. Cir. 1995) (Mayer, C.J., concurring) ("There is simply no reason to believe that judges are any more qualified than juries to resolve the complex technological issues often present in patent cases."); Howard T. Markey, *On Simplifying Patent Trials*, 116 *F.R.D.* 369, 372 (1987) (noting that there is no empirical evidence supporting the contention that judges are more likely to correctly decide patent cases than juries.); Kimberly A. Moore, *Judges, Juries, and Patent Cases—An Empirical Peek Inside the Black Box*, 99 *MICH. L. REV.* 365, 370-74 (2000) (conducting an empirical study of the way that judges and juries decide patent cases and determining that while it is unclear whether judges or juries decide the cases *better*, they do decide them differently).