HATCH-WAXMAN PATENT LITIGATION AND INTER PARTES REVIEW: A NEW SORT OF COMPETITION

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ABSTRACT

In FTC v. Actavis, *the Supreme Court declined to adopt a rule making reverse payment settlements per se unlawful under the antitrust laws. Instead, the Court concluded that such settlements could be unlawful under the rule of reason. The Court's decision further fueled an already-existing debate about the proper treatment of various elements of reverse payment settlements under the antitrust laws. This debate suggests that the* Actavis *decision has not fully resolved the "turducken" problem presented by these sorts of cases. Difficult questions of antitrust law remain contained within what ultimately began as a patent lawsuit. In addition, the debate suggests that settlements will not necessarily become any less likely, but instead may become more complex in order to obfuscate the purpose and value of the settlement. As a result, the public will continue to be deprived of the benefit of having a determination as to the validity of the underlying patent claims. And consumers will continue to be harmed by sustained and illegitimate monopoly prices.*

This Article finds hope in the new inter partes review (IPR) procedure before the Patent Trial and Appeal Board (PTAB) introduced as a part of the America Invents Act (AIA). The IPR procedure offers a few benefits. It can deliver a faster determination; the procedure can proceed in parallel to district court litigation, which can effect competition among tribunals as well as competition among generic drug manufacturers seeking FDA approval; it discourages settlement; and it applies a more favorable standard for interpreting patent claims.

But these features alone are not enough to deter settlement and effect earlier generic entry, so this Article proposes a few additional changes. First, I propose that the PTO issue a rule requiring that, whenever the patent claims at issue are also the subject of district court litigation precipitated by a generic drug manufacturer's application for marketing approval by the FDA, the PTAB be required to proceed to a final written decision, regardless of whether the parties settle. Second, I propose that the Hatch-Waxman Act be amended to make the 180-day exclusivity period contestable, such that it may be awarded to the applicant for FDA approval that first obtains a determination, whether before a federal district court or the PTAB. Third, and finally, I propose that the Hatch-Waxman Act be amended so that determinations by the PTAB invalidating patent claims effect the same consequences as a federal district court determination invalidating patent claims.

INTRODUCTION

In 2015, spending on pharmaceutical drugs rose to more than $420 billion, a 12.2% increase over 2014 spending.[1] One of the primary causes of growth was the price of patent-protected brands, coupled with the fact that relatively fewer brand-name drugs lost patent protection, which translated into fewer generic drug alternatives.[2] At the same time, those drugs that did lose patent protection resulted in reduced spending by $14.2 billion over the prior year.[3]

Generic competition yields significant savings for consumers. Indeed, a recent study comparing brand-name and generic drug prices between 2002 and 2014 reveals that the entry of generic drugs reduced the price of the brand-name version of a drug by fifty-one percent in the first year after entry and by fifty-seven percent in the second year, followed by continued savings in subsequent years.[4] These savings have the potential to be particularly significant for low- and middle-income households, which spend a greater portion of their income than do high-income households on health care, which includes pharmaceutical drugs.[5]

The Hatch-Waxman Act was enacted to make it easier for generic drug manufacturers to enter the market and compete with brand-name drugs.[6] It

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1. IMS INSTITUTE FOR HEALTHCARE INFORMATICS, MEDICINES USE AND SPENDING IN THE U.S.: A REVIEW OF 2015 AND OUTLOOK TO 2020 6 (2016) [hereinafter MEDICINES USE AND SPENDING], https://morningconsult.com/wp-content/uploads/2016/04/IMS-Institute-US-Drug-Spending-2015.pdf. It should be noted that in the report authors use "spending on medicines" to

> refer to the amounts paid to distributors by their pharmacy or hospital customers. It does not relate directly to either the out-of-pocket costs paid by a patient or the amount health plans pay for the medicines, and does not include mark-ups and additional costs associated with dispensing or other services associated with medicines reaching patients.

Id. at 1.

2. *Id.* at 6 ("The biggest drivers of growth in 2014—the uptake of innovative brands, the prices of protected brands, and a lack of major patent expiries—continued to drive growth in 2015.").

3. *Id.* at 9.

4. IMS INSTITUTE FOR HEALTHCARE INFORMATICS, PRICE DECLINES AFTER BRANDED MEDICINES LOSE EXCLUSIVITY IN THE U.S. 2–3 (2016), https://www.imshealth.com/files/web/IMSH%20Institute/Healthcare%20Briefs/PhRMA%20Generic%20Price%20Brief%20January%202016.pdf.

5. *See* DIANE WHITMORE SCHANZENBACH ET AL., WHERE DOES ALL THE MONEY GO: SHIFTS IN HOUSEHOLD SPENDING OVER THE PAST 30 YEARS 2 fig.1, 4 (2016), https://www.brookings.edu/wp-content/uploads/2016/08/thp_household_expenditures_ea_0602.pdf (reporting that "[h]igh-income households spend a smaller share of their budget on each basic need," which includes health care, which the authors define as including "out-of-pocket expenditures on health insurance, medical services, drugs, and medical supplies . . . ."); *cf.* Jonathan B. Baker & Steven C. Salop, *Antitrust, Competition Policy, and Inequality*, 104 GEO. L.J. ONLINE 1, 4, 18 (2015), http://scholarship.law.georgetown.edu/cgi/viewcontent.cgi?article=2474&context=facpub (noting that "[m]arket power . . . contributes to growing inequality" and proposing a number of ways in which antitrust law can be modified to account for effects on inequality, including by having the Federal Trade Commission and Department of Justice devote greater resources to "investigating concerns in markets such as food manufacturing and retailing, fuel, and healthcare products").

6. H.R. REP. NO. 98-857(I) (1984), *as reprinted in* 1984 U.S.C.C.A.N. 2647, 2647.

attempted to do this, in part, by incentivizing generic drug manufacturers to challenge weak patents covering brand-name drugs. The incentive created by the Act is a limited-time award of market exclusivity for the first generic drug manufacturer that seeks approval for marketing by the Food and Drug Administration (FDA) and that certifies to the FDA that the brand-name drug manufacturer's patent claims covering the drug are either invalid or not infringed.[7] If the first filer is successful in securing a determination that the patent claims are invalid or not infringed, the first filer is entitled to 180 days of exclusive competition with the brand-name drug manufacturer; during that time, no other generic drug manufacturer seeking FDA approval on similar grounds may enter the market.[8]

But in many cases, the first generic drug manufacturer to seek FDA approval does not see its challenge all the way through. Instead, it settles the patent litigation with the brand-name drug manufacturer.[9] Settlement is valuable to both brand-name and generic drug manufacturers. Settlement enables the brand-name drug manufacturer to avoid the risk of having its patent claims invalidated and to continue earning supracompetitive profits. The brand-name drug manufacturer's supracompetitive profits are sufficiently large, such that it can compensate the first filer for the profits it would have earned during the 180-day exclusivity period that it would have been awarded if it had not settled the dispute and agreed not to enter the market. Indeed, the brand-name drug manufacturer can sweeten the deal for the first filer by granting the generic drug manufacturer a license that permits the generic to enter the market at some point later down the road—closer to when the brand-name drug manufacturer's patents expire—and only then triggering the exclusivity period. Both the large payment from the brand-name drug manufacturer to the generic and the delayed, but eventual, market entry come without the risk of litigation. In short, settlement benefits both generic and brand-name drug manufacturers alike.

Consumers, however, lose out. Settlement not only prevents the invalidation of weak patents. The persistence of weak patents additionally prevents the first generic applicant from entering the market and competing with the brand-name drug manufacturer sooner. Moreover, a feature of the

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7. This is known as a "Paragraph IV" certification, discussed *infra* Part I.0

8. 21 U.S.C. § 355(j)(5)(B)(iv)(I). The recently enacted FDA Reauthorization Act of 2017 further incentivizes generic drug entry by prioritizing FDA review of certain generic drug applications, especially if the FDA determines that there is "inadequate generic competition." FDA Reauthorization Act of 2017, Pub. L. No. 11-52, §§ 801, 803(b)(3), (e)(2), 131 Stat. 1005 (2017). These recent amendments, however, do not address instances in which the generic drug applicant seeks to challenge the validity of the name-brand drug manufacturer's patent claims or argue that the patent claims are not infringed. Therefore, the FDA Reauthorization Act of 2017, while complementary to the ideas expressed in this article, is nonetheless beyond the scope of this article.

9. *See, e.g.*, C. Scott Hemphill & Mark A. Lemley, *Earning Exclusivity: Generic Drug Incentives and the Hatch-Waxman Act*, 77 ANTITRUST L.J. 947, 948 (2011).

180-day exclusivity period, discussed further below, prevents subsequent generic drug manufacturers seeking FDA approval on the same grounds from entering the market. Such settlements are particularly pernicious when accompanied by a payment from the brand-name to the generic because they delay generic entry and competition even longer: in return for the large payment, the generic drug manufacturer is willing to accept a license with a later entry date.[10] The end result is that high prices persist.

The Federal Trade Commission (FTC) and private litigants challenged such settlements as anticompetitive.[11] The lower courts, however, could not agree on the proper treatment under the antitrust laws. Some concluded such settlements were per se unlawful. Others, however, refrained from adopting the per se rule, concluding that as long as the anticompetitive effects fell "within the scope of the patent"—i.e., within the lawful exclusionary power—the settlement was immune from antitrust liability.[12] At the same time, an extensive literature developed considering the proper treatment of these sorts of settlements and various settlement terms.[13]

In 2013, the Supreme Court's *FTC v. Actavis* decision considered whether such settlements are unlawful under the antitrust laws.[14] The Court concluded that such agreements, evaluated under the rule of reason,[15] "sometimes violate the antitrust laws," depending on the amount of the payment and its purpose.[16] The Court's decision has further fueled the

10. *See infra* notes 122–27 and accompanying text.

11. *See, e.g.*, *In re* Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 212–13 (2d Cir. 2006), *abrogated by* FTC v. Actavis, Inc., 133 S. Ct. 2223 (2013); Schering-Plough Corp. v. Fed. Trade Comm'n, 402 F.3d 1056, 1076 (11th Cir. 2005); Valley Drug Co. v. Geneva Pharms., Inc., 344 F.3d 1294, 1308 (11th Cir. 2003); *In re* Ciproflaxacin Hydrochloride Antitrust Litig., 544 F.3d 1323, 1333 (Fed. Cir. 2008), *abrogated by* FTC. v. Actavis, Inc., 133 S. Ct. 2223 (2013); King Drug Co. v. Cephalon, Inc., 702 F. Supp. 2d 514, 528–29 (E.D. Pa. 2010), *abrogated by In re* K-Dur Antitrust Litig., 686 F.3d 197 (3d Cir. 2012).

12. *In re Ciproflaxacin Hydrochloride Antitrust Litig.*, 544 F.3d at 1333; *see also In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d at 212–13; *Schering-Plough Corp.*, 402 F.3d at 1076; *Valley Drug Co.*, 344 F.3d at 1308; *King Drug Co.*, 702 F. Supp. 2d at 528–29.

13. *See, e.g.*, HERBERT HOVENKAMP ET AL., IP AND ANTITRUST: AN ANALYSIS OF ANTITRUST PRINCIPLES APPLIED TO INTELLECTUAL PROPERTY LAW § 15.3c1 (2d ed. 2010); Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 MICH. L. REV. 37 (2009); C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553 (2006); Mark A. Lemley & Carl Shapiro, *Probabilistic Patents*, 19 J. ECON. PERSPS. 75 (2005); Maureen A. O'Rourke & Joseph F. Brodley, *An Incentives Approach to Patent Settlements: A Commentary on Hovenkamp, Janis & Lemley*, 87 MINN. L. REV. 1767 (2003); Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND J. ECON. 391 (2003).

14. 133 S. Ct. 2223 (2013).

15. *Id.* at 2237–38.

16. *Id.* at 2227; *see also id.* at 2236–37 ("The reverse payment, for example, may amount to no more than a rough approximation of the litigation expenses saved through the settlement. That payment may reflect compensation for other services that the generic has promised to perform—such as distributing the patented item or helping to develop a market for that item. There may be other justifications. Where a reverse payment reflects traditional settlement considerations, such as avoided

debate about how to evaluate reverse payment settlements for purposes of determining antitrust liability.[17] This debate suggests that difficult questions of antitrust law remain contained within what ultimately began as a patent lawsuit. In addition, it suggests that settlements will not necessarily become any less likely, but instead may only become more complex in order to obfuscate the purpose, value, and effect of the settlement. As a result, the public will continue to be deprived of the benefit of having a determination as to the validity of the underlying patent claims. And consumers will continue to be harmed by sustained and illegitimate monopoly prices.

Rather than add to the debate on the appropriate treatment of reverse payment settlements under the antitrust laws, this Article finds hope in recent changes to the patent laws incorporated into the America Invents Act (AIA).[18] The recently created inter partes review (IPR)[19] procedure before the Patent Trial and Appeal Board (PTAB)[20] enables a third-party petitioner to challenge the patentability of one or more patent claims on limited grounds beginning nine months after the patent has been issued.[21] The IPR procedure offers four primary benefits to generic drug manufacturers seeking FDA approval. First, the IPR procedure can yield a determination on the validity of the patents in as little as eighteen months,[22] which is sufficiently faster than the thirty or more months the Hatch-Waxman regulatory scheme allows for a pharmaceutical patent challenge to be completed in the federal district courts.[23] Second, the IPR procedure can

litigation costs or fair value for services, there is not the same concern that a patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement.").

17. *See, e.g.*, Aaron Edlin et al., *The* Actavis *Inference: Theory and Practice*, 67 RUTGERS U. L. REV. 585 (2015); Aaron Edlin et al., Actavis *and Error Costs: A Reply to Critics*, THE ANTITRUST SOURCE 1 (2014) (arguing against an antitrust rule that accounts for risk aversion because it would be practically difficult for a plaintiff to prove that a settlement was anticompetitive—i.e., "that the settlement entry date came later than the expected date . . . ."); Aaron Edlin, et. al., *Activating* Actavis, 28 ANTITRUST 16 (2013) (suggesting reverse payments in excess of litigation costs plus the cost of any goods and services provided by the alleged infringer are anticompetitive, proposing a method for evaluating reverse payments, and arguing that risk aversion should not be a justification for the size of the reverse payment); Barry C. Harris et al., *Activating* Actavis*: A More Complete Story*, 28 ANTITRUST 83 (2014) (arguing that reverse payments in excess of litigation costs plus the costs of goods and services provided may be justified by a number of things, including the risk tolerance of the parties and the parties' subjective views about the likely outcome of the litigation); Glynn S. Lunney, Jr., FTC v. Actavis*: The Patent-Antitrust Intersection Revisited*, 93 N.C. L. REV. 375 (2015).

18. Leahy-Smith America Invents Act (AIA), Pub. L. No. 112-29, 125 Stat. 284 (2011) (codified in scattered sections of 35 U.S.C.).

19. 35 U.S.C. § 311 (2012).

20. *Id.* § 6.

21. *Id.* § 311(a)–(c)

22. *See infra* note 150 and accompanying text.

23. 21 U.S.C. § 355(j)(5)(B)(iii) (2012), *amended by* FDA Reauthorization Act of 2017, Pub. L. No. 11-52, 131 Stat. 1005 (2017).

proceed in parallel to a challenge in federal district court.[24] This has the potential to enable competition among tribunals as well as competition among generic drug manufacturers seeking FDA approval. Third, the statutory scheme discourages settlement insofar as it grants the PTAB the authority to continue the proceedings and issue a final written decision, even if the petitioner and patent owner settle.[25] The threat of the PTAB issuing a final written decision—that may and can find the challenged patent claims invalid—even after the parties have settled, discourages settlement by reducing the patent owner's incentive to settle. Fourth, it applies a different evidentiary presumption and standard of proof, along with a different claim construction standard, such that it makes it more likely that a patentholder's patent claims will be found not patentable.[26] And because the Federal Circuit applies a more deferential standard of review when reviewing decisions of the PTAB, that determination is more likely to be upheld on appeal.[27]

But these features alone are not enough to deter settlement and effect earlier generic entry. A brand-name and a generic drug manufacturer can still settle, and the 180 days of exclusivity is still vulnerable to manipulation. I therefore propose a few additional changes. First, I propose that the Patent and Trademark Office (PTO) issue a rule requiring the PTAB to continue the proceedings and issue a final written decision once an IPR is initiated, regardless of whether the parties settle, whenever the patent claims at issue are also the subject of district court litigation precipitated by a generic drug manufacturer's application under the Hatch-Waxman Act. Under the statutory framework, the PTAB already has the discretion to do so. My proposal would simply require the PTAB to act within its discretion in clearly defined cases.

Second, I propose that the Hatch-Waxman Act be amended to make the 180-day exclusivity period contestable. Under my proposal, the Act would not simply reward the first filer, regardless of whether it settled or saw its case all the way through to a favorable determination. Rather, it would reward the applicant that first obtains a determination, whether before a federal district court or the PTAB, that the challenged patent claims are invalid (or not infringed).[28] Because the PTAB route is generally faster than

24. *See* 35 U.S.C. § 315.

25. 35 U.S.C. § 317(a) ("If no petitioner remains in the inter partes review, the Office may terminate the review or proceed to a final written decision under section 318(a).").

26. *See* discussion *infra* Part III.B.4.

27. *See id.* ("We review the Board's claim construction de novo except for subsidiary fact findings, which we review for substantial evidence.").

28. A federal district court's jurisdiction permits it to conclude patent claims are invalid *or* not infringed. In contrast, the PTAB's jurisdiction is confined solely to issues of patent validity. 35 U.S.C. § 6. As a result, when speaking of both the federal district court *and* the PTAB, I will refer to their

going through the federal district courts, this may incentivize the first filer to choose adjudication before the PTAB, and almost definitely would incentivize subsequent applicants to do so, particularly if the first filer chose the traditional route through the federal district courts.

Finally, to harmonize the recent changes to the patent laws with the Hatch-Waxman regulatory scheme, I propose that the Hatch-Waxman Act be amended so that determinations by the PTAB invalidating patent claims effect the same consequences as a federal district court determination invalidating a patent. Under the Act, a first filer that is successful in its challenge against a brand-name drug manufacturer may enter the market immediately after the district court enters an order finding the patent claims invalid or not infringed; otherwise, the generic drug manufacturer must wait for a statutorily-imposed stay to expire.[29] But the Hatch-Waxman regulatory scheme predates the creation of the new IPR procedure and the PTAB. The Hatch-Waxman Act therefore does not similarly enable a generic drug manufacturer that is successful before the PTAB to immediately enter the market. The Hatch-Waxman Act should be amended so that, regardless of whether a patent claim is invalidated by a federal district court or the PTAB, the effect is the same.

This Article proceeds in five Parts. Part I provides background, describing the relevant features of the Hatch-Waxman Act. Part II describes the various incentives to settling, including those created by the Hatch-Waxman Act, as well as the problems with settlement. Part III then describes the new IPR procedure and its benefits to generic drug manufacturers seeking FDA approval. Part IV explains the mechanics of how the IPR procedure can work in tandem with federal district court litigation. Part V describes the components of my proposals.

I. THE HATCH-WAXMAN ACT

A. New Drug Applications

Before marketing a drug and entering the market, a drug manufacturer must seek and obtain approval by the FDA.[30] The marketing of drugs in the

mutual power to find a patent claim invalid and refer to the federal district court's power to find the patent claims not infringed only parenthetically.

29. 21 U.S.C. § 355(c)(3)(C)(i)(I) (2012), *amended by* FDA Reauthorization Act of 2017, Pub. L. No. 11-52, 131 Stat. 1005 (2017).

30. *See id.* § 355(a) ("No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) [new drugs] or (j) [abbreviated new drugs] . . . is effective with respect to such drug.").

United States is regulated by the Hatch-Waxman Act, formerly known as the Drug Price Competition and Patent Term Restoration Act.[31]

Under the Hatch-Waxman Act, innovators, or brand-name drug manufacturers, must submit an application commonly referred to as a "new drug application," or NDA, which includes, among other things, evidence establishing that the drug is safe and effective.[32] The drug's safety and efficacy is demonstrated through clinical trials, which generally include human test subjects[33] and are therefore incredibly time-consuming and expensive.

Once the FDA approves a drug, it must list the drug in a publicly available publication,[34] the "Approved Drug Products with Therapeutic Equivalence Evaluations" or, as it is commonly known, the "Orange Book."[35] Along with the proprietary name of the drug, the FDA must publish the number and expiration date of any patent that claims the drug for which approval by the FDA was sought and granted.[36] The Orange Book, therefore, puts generic drug manufacturers on notice of patents that could serve as the basis for a patent infringement claim and which would have to be successfully challenged in order for the generic drug manufacturer to enter the market without risking liability.[37]

B. Abbreviated New Drug Applications

A generic drug manufacturer wishing to obtain FDA approval may submit to an expedited application process. The Hatch-Waxman Act was enacted primarily to streamline and make less costly the process by which generic drug manufacturers challenge patent claims[38] covering

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31. Drug Price Competition and Patent Term Restoration Act of 1981, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. §§ 355, 360cc (2000), 35 U.S.C. §§ 156, 271, 282 (2000)), *amended by* Medicare, Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003).

32. 21 U.S.C. § 355(a)–(b), (d).

33. *See id.* § 355(d) (granting FDA authority to refuse a new drug application if there is a lack of "substantial evidence"—i.e., "evidence consisting of adequate and well-controlled investigations, including clinical investigations").

34. *Id.* § 355(j)(7)(A).

35. *See* U.S. FOOD AND DRUG ADMIN. CENTER FOR DRUG EVALUATION AND RESEARCH, APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS (2017), https://www.fda.gov/downloads/drugs/developmentapprovalprocess/ucm071436.pdf (Orange Book, 37th ed.).

36. 21 U.S.C.§ 355(j)(7)(A)(i), (iii), (b)(1). The FDA is required to publish a revised Orange Book every thirty days. *See id.* § 355(j)(7)(A)(ii).

37. *See id.* § 355(b)(1).

38. The Hatch-Waxman Act speaks in terms of a "patent" being found invalid, not a "patent claim." *See, e.g.*, *id.* § 355(j)(2)(A)(vii) ("An abbreviated application for a new drug shall contain . . . a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the listed drug . . . that such patent is invalid . . . ."). Patent infringement and validity,

pharmaceutical drugs and obtain approval by the FDA.[39] One of the ways in which the Act achieves these goals is by providing for an abbreviated version of the application the brand-name drug manufacturer must submit—i.e., an Abbreviated New Drug Application (ANDA). Through an ANDA, a generic drug manufacturer must show that the drug it seeks to market is effectively the same as an already-approved, brand-name drug, what the statute refers to as a "listed drug"[40]—i.e., a drug listed in the FDA publication, the Orange Book. Specifically, the generic drug manufacturer must show that the drug to be marketed has the same active ingredient(s),[41] route of administration, dosage form, and strength as the listed drug.[42] In addition, the generic drug manufacturer must show that the drug to be marketed is "bioequivalent" to the listed drug[43]—i.e., that the drug delivers the same amount of active ingredient to the patient at the same rate as the listed drug.[44] Note, however, that the generic drug manufacturer need not demonstrate the drug's safety and efficacy by independently conducting clinical trials.

Prior to the enactment of the Hatch-Waxman Act, generic drug manufacturers could only obtain approval by the FDA if they submitted the same sort of data supporting the drug's safety and efficacy that brand-name drug manufacturers were required to submit. Safety and efficacy data covering the brand-name version of the drug were considered proprietary and protected by trade secret; the FDA was not permitted to release the data to the public or to rely on such data when considering another company's application.[45] In order to comply with the FDA's requirements, generic

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however, are determined on a claim-by-claim basis. *See, e.g.*, Amazon.com, Inc. v. Barnesandnoble.com, Inc., 239 F.3d 1343, 1351 (Fed. Cir. 2001). Therefore, when discussing patent infringement and validity, it is more accurate to speak in terms of a "patent claim." The recently enacted AIA reflects this point. *See, e.g.*, 35 U.S.C. § 311(b) (2012) ("A petitioner in an inter partes review may request to cancel as unpatentable 1 or more claims of a patent . . . ."); *id.* § 321(b) ("A petitioner in a post-grant review may request to cancel as unpatentable 1 or more claims of a patent . . . ."). Therefore, for clarity and precision, this Article will refer to "patent claim" or "patent claims," even when discussing parts of Hatch-Waxman that refer simply to a "patent."

39. *See, e.g.*, Hemphill & Lemley, *supra* note 9.

40. 21 U.S.C. § 355(j)(2)(A)(i); *see id.* § 355(j)(7).

41. *Id.* § 355(j)(2)(A)(ii).

42. *Id.* § 355(j)(2)(A)(iii).

43. *Id.* § 355(j)(2)(A)(iv).

44. *Id.* § 355(j)(8)(B). However, generic drugs do not need to contain the same inactive ingredients as the brand-name product. *See Generic Drug Facts*, U.S. FOOD & DRUG ADMIN. (Sept. 13, 2017), https://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/ucm167991.htm.

45. *See, e.g.*, Ellen Flannery & Peter Hutt, *Balancing Competition and Patent Protection in the Drug Industry: The Drug Price Competition and Patent Term Restoration Act of 1984*, 40 FOOD DRUG COSM. L.J. 269, 276 (1985); Bruce N. Kuhlik, *The Assault on Pharmaceutical Intellectual Property*, 71 U. CHI. L. REV. 93, 97–98 (2004); *see also* Public Information, 39 Fed. Reg. 44634, ¶ 252 (Dec. 24, 1974) ("[T]he most persistent issue raised in the comments relates to the disclosure of safety and effectiveness data in . . . NDA [New Drug Application] files. . . . The Commissioner concludes that

drug manufacturers had to duplicate clinical trials, "which could take several years and millions of dollars to complete."[46] This was so even if the patent(s) underlying the brand-name drug had long expired. "As a result, it was estimated that in 1983 only 35 percent of the best-selling off-patent drugs faced generic competition."[47] In addition, in the pre-Hatch-Waxman era, a generic drug manufacturer could not do any testing or investigation of a drug covered by an unexpired patent without exposing itself to the risk of liability for patent infringement.[48] Enabling a generic drug manufacturer to submit an ANDA addresses these issues.

C. Paragraph IV Certification and the Thirty-Month Stay

At first blush, it may seem that the statute unfairly enables generic drug manufacturers to free ride on the listed drug's investment in the research, development, and testing of the listed drug. However, an ANDA filer ultimately cannot market its drugs unless it additionally establishes that the listed drug's supracompetitive profits, which flow in large part from the exclusionary effects of the underlying patent claims, are no longer justified.[49] Providing for a systematic and efficient manner to address any patent rights covering listed drugs is the second significant contribution of the Hatch-Waxman regulatory scheme.[50] As part of an ANDA, a generic drug manufacturer must make one of four certifications addressing any patent claims relating to the listed drug.[51] The first three types of certifications address what could be described as technical issues relating to

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there can be no question, under present law, about the tremendous economic value of the full reports of the safety and effectiveness data contained in a[ ] . . . NDA . . . . Present law contains no provision that would permit the Food and Drug Administration to refuse to approve a 'me-too' product on the basis of information obtained from the first manufacturer, once that information from the first manufacturer is disclosed. The Commissioner recognizes the important public policy issues that would be raised by disclosure of such trade secret data. The public is dependent upon private pharmaceutical manufacturers for development of drugs. . . . If a manufacturer's safety and effectiveness data are to be released upon request, thus permitting 'me-too' drugs to be marketed immediately, it is entirely possible that the incentive for private pharmaceutical research will be adversely affected.").

46. Henry G. Grabowski et al., *Evolving Brand-Name and Generic Drug Competition May Warrant a Revision of the Hatch-Waxman Act*, 30 HEALTH AFFAIRS 2157, 2157 (Nov. 2011), http://content.healthaffairs.org/content/30/11/2157.

47. *Id.*

48. *See* Roche Prods., Inc. v. Bolar Pharm. Co., 733 F.2d 858, 861, 863–65 (Fed. Cir. 1984) (holding that use of patented drug, prior to patent's expiration, by generic manufacturer for testing and investigation related to FDA drug approval constitutes "use" in violation of the patent laws), *superseded by* 35 U.S.C. § 271, *as recognized in* Warner-Lambert Co. v. Apotex Corp., 316 F.3d 1348 (Fed. Cir. 2003).

49. 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (2012), *amended by* FDA Reauthorization Act of 2017, Pub. L. No. 11-52, 131 Stat. 1005 (2017).

50. *See, e.g.*, FTC v. Actavis, Inc., 133 S. Ct. 2223, 2228 (2013) ("[T]he Hatch-Waxman Act sets forth special procedures for identifying, and resolving, related patent disputes.").

51. *See* 21 U.S.C. §355(j)(2)(A)(vii).

the patent—i.e., that the patent information has not been filed, that the patent has expired, or that the patent will expire on a given date.[52] However, the fourth type of certification—known as a "Paragraph IV certification"—is a substantive challenge that the patent claims are either invalid or will not be infringed.[53]

Paragraph IV certifications are becoming increasingly more popular.[54] One of the interesting features of a Paragraph IV certification is that it serves as a statutorily defined act of infringement.[55] In other words, in making a Paragraph IV certification, a generic drug manufacturer infringes a listed drug's patent claims as a matter of law, not as a matter of fact. This then enables the patent owner to bring suit against the ANDA filer for patent infringement.[56] The primary virtue of a statutorily created patent infringement claim is that it enables the parties to sort out the underlying patent rights without the generic drug manufacturer literally infringing the listed drug manufacturer's patent claims and risking treble damages if it is later determined that the generic manufacturer's infringement was "willful."[57]

Upon the patent owner's filing of a patent infringement lawsuit,[58] a statutorily imposed stay is triggered, which prevents the FDA from approving the ANDA for up to thirty months.[59] The rationale for the thirty-month stay is that it will provide sufficient time for the patent litigation to conclude. However, if the thirty-month stay expires before the conclusion

52. *See id*. § 355(j)(2)(A)(vii)(I)–(III).

53. *See id.* § 355(j)(2)(A)(vii)(IV).

54. *See* C. Scott Hemphill & Bhaven N. Sampat, *When Do Generics Challenge Drug Patents?*, 8 J. EMPIRICAL LEGAL STUD. 613, 624–25 (2011) (reporting an increase in the number of Paragraph IV certifications and that fifty-five percent of drugs approved from 2000 to 2002 were subject to such a challenge); FED. TRADE COMM'N, AUTHORIZED GENERIC DRUGS: SHORT-TERM EFFECTS AND LONG-TERM IMPACT 127–28 (Aug. 2011), https://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission.pdf (reporting that first ANDA filers with Paragraph IV certifications increased from 2003 to 2008, despite the likelihood that the brand-name drug manufacturer would market its own, authorized generic).

55. 35 U.S.C. § 271(e)(2)(A) (2012).

56. Once an ANDA filer makes a Paragraph IV certification, it is required to give notice to the holder of the approved NDA and the patentee. *See* 21 U.S.C. § 355(b)(3)(C).

57. *See* 35 U.S.C. § 284 ("[T]he court may increase the damages up to three times the amount found or assessed.").

58. The ANDA filer must give the patentee notice of the Paragraph IV certification within twenty days of making such certification. *See* 21 U.S.C. § 355(j)(2)(B). If the patentee does not file a patent infringement suit within forty-five days of receiving notice, FDA approval of the generic drug is immediately effective, *see id.* § 355(j)(5)(B)(iii), and the ANDA filer may seek a declaratory judgment that the patent is invalid or not infringed, *see* 35 U.S.C. § 271(e)(5).

59. 21 U.S.C. § 355(j)(5)(B)(iii). The district court may extend the thirty-month stay if "either party to the action failed to reasonably cooperate in expediting the action." *Id.* However, if prior to the expiration of the thirty-month stay the court determines that the patent claims are invalid or not infringed, the ANDA is made immediately effective. *See id.* § 355(j)(5)(B)(iii)(I).

of the patent lawsuit, FDA approval becomes immediately effective,[60] in which case, if the ANDA filer is the first such filer, then it is permitted to begin marketing its product while the listed drug manufacturer's patent rights are still being resolved.[61] Marketing the generic drug prior to the conclusion of the patent lawsuit is referred to as an "at risk launch" because the ANDA filer is at risk of being held liable for treble damages for willful infringement if the court later determines that the listed drug's patents are not invalid or are infringed.[62] Alternatively, if the trial proceeds and a court makes a final determination that the patent claims at issue are invalid or not infringed, the first filer can immediately begin selling its generic version of the drug.[63]

D. 180-Day Exclusivity Period

Preparing an ANDA is expensive, costing between $300,000 and $1 million.[64] In addition, the first generic challenger, if successful in securing a determination of invalidity,[65] faces a free-rider problem. A determination that the patent claims are invalid will collaterally estop the patent owner from enforcing its patent claims against *any* subsequent filer.[66] Thus, the first challenger's success clears the way for subsequent challengers to enter the market as well without having to incur any of the cost or risk of a patent lawsuit.[67] The end result would very likely be a

60. *Id.* § 355(j)(5)(B)(iii) ("[A]pproval shall be made effective upon the expiration of the thirty-month period . . . ."). It should be noted that, in practice, the ANDA applicant has to ask for the tentative approval to be converted to final approval. It is not automatic; the agency must determine nothing has changed in the interim. *See id.* § 355(j)(5)(B)(iv)(II)(dd); 21 C.F.R. 314.107(b)(3) (2017). Therefore, in practice, approval may not be quite as immediate as the statute might suggest.

61. 21 U.S.C. § 355(j)(5)(B)(iii).

62. *See, e.g.*, *In re* Nexium (Esomeprazole) Antitrust Litig., 42 F. Supp. 3d 231, 245 (D. Mass. 2014); *In re* Niaspan Antitrust Litig., 42 F. Supp. 3d 735, 743 (E.D. Pa. 2014); *see also* Sciele Pharma, Inc. v. Lupin Ltd., 684 F.3d 1253, 1256 (Fed. Cir. 2012).

63. *See* 21 U.S.C. §355(j)(5)(B)(iii)(I)(aa).

64. Requirements for Submission of In Vivo Bioequivalence Data; Proposed Rule, 68 Fed. Reg. 61640, 61645 (Oct. 29, 2003) (*cited in* Hemphill & Lemley, *supra* note 9, at 951 n.13).

65. If a first ANDA filer has devised an alternative, noninfringing means of achieving bioequivalence, a district court could additionally conclude that the ANDA filer will not infringe the brand-name drug manufacturer's patents. *See* Hemphill, *supra* note 13, at 1606–07. But in this case, the first ANDA filer's expertise may very well itself be protected by patent. *Id.* at 1607. As a result, it is very unlikely that a finding of "noninfringement" will result in a free-rider problem.

66. *See* Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found., 402 U.S. 313, 332–34 (1971). In *Blonder-Tongue*, the Supreme Court abrogated the requirement of mutuality, thereby extending the principle of collateral estoppel. *Id.* at 349–50.

67. Specifically, once the first challenger secures a determination that the patent claims are invalid, consistent with *Blonder-Tongue*, the patent owner would be estopped from enforcing those patent claims against others. *See id.* at 332–34. And under the Hatch-Waxman Act, a federal district court presiding over a patent infringement suit involving the same patent claims and precipitated by a subsequent challenger could therefore enter a judgment finding the patent claims invalid, thereby making the patent challenger's ANDA immediately effective. *See* 21 U.S.C. § 355(j)(5)(B)(iii)(I)(aa).

crowded market with a number of generic drugs in addition to the brand-name drug; competition would ensue, drastically reducing prices and profits.[68] A market with many generic competitors would be very good for consumers. However, the reward for successfully challenging the brand-name drug manufacturer's patents would very likely be insufficiently large to incentivize the first challenger to incur the cost and risk of challenging the brand-name drug manufacturer's patent claims in the first place.

To overcome the free-rider problem and incentivize generic drug manufacturers to challenge and invalidate weak patents, Hatch-Waxman rewards the first filer of an ANDA with a "180-day exclusivity period"—i.e., a 180 day period, during which time FDA approval of other, subsequently filed ANDAs containing a Paragraph IV certification and relying on the same listed drug cannot be made effective.[69] The 180-day exclusivity period protects the first ANDA filer from competition from other generic entrants[70] and effectively creates a duopoly between the listed drug and the generic drug during that time period.[71] Prices during the duopoly period are only slightly lower than they are during the monopoly period.[72] The period of exclusivity is therefore quite valuable and can be "worth several hundred million dollars" to the first filer,[73] yielding more than half of the first ANDA filer's total profits for any one product.[74] And

68. *See Generic Competition and Drug Prices*, U.S. FOOD & DRUG ADMIN. (May 13, 2015), https://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cder/ucm129385.htm [hereinafter *Generic Competition and Drug Prices*] (analyzing and comparing prices for brand-name and generic drug products and concluding that prices continuously fall as more generic drug manufacturers enter the market); MEDICINES USE AND SPENDING, *supra* note 1, at 6.

69. *See* 21 U.S.C. § 355(j)(5)(B)(iv)(I) (explaining that an ANDA "shall be made effective on the date that is 180 days after the date of the first commercial marketing of the drug . . . by any first [filer]").

70. *See* FTC v. Actavis, Inc., 133 S. Ct. 2223, 2228–29 (2013).

71. It should be noted that it is possible for more than one generic drug manufacturer to file an ANDA on the same day. This is most likely the case when the patent underlying the brand-name drug at issue covers a new chemical entity because ANDAs seeking to challenge such patents may not be submitted until after four years from the date of approval of the brand-name drug's NDA. *See* 21 U.S.C. § 355(j)(5)(F)(ii). As a result, there may be a number of generic drug manufacturers waiting for the expiration of the waiting period to file their ANDA on the first day possible. *See id.*

72. *Generic Competition and Drug Prices*, *supra* note 68. The FDA examined data for brand-name and generic drug products sold in the United States from 1999 to 2004. *Id.* The FDA's analysis revealed that the introduction of one generic drug manufacturer reduced prices by only six percent, while the introduction of two generic drug manufacturers reduced prices by forty-eight percent. *Id.* Moreover, "[a]s additional generic manufacturers market the product, the prices continue to fall, but more slowly. For products that attract a large number of generic manufacturers, the average generic price falls to 20% of the branded price and lower." *Id.*

73. Hemphill, *supra* note 13, at 1579.

74. *See* Hemphill & Lemley, *supra* note 9, at 948 n.3 (quoting Daniel F. Coughlin & Rochelle A. Dede, *Hatch-Waxman Game-Playing from a Generic Manufacturer Perspective*, 25 BIOTECH. L. REP. 525, 525–26 (2006)) ("In general, most generic drug companies estimate that 60% to 80% of their potential profit for any one product is made during this exclusivity period."); *see also id.* at 953 ("For many drugs, the exclusivity period offers the majority of the profits available to the generic firm, since profits fall sharply once other generic firms enter the market.").

although other generic drug manufacturers may enter the market after the period of exclusivity expires, the first ANDA filer's market advantage usually persists even after others enter the market.[75]

The statute outlines a number of events that can cause the first ANDA filer to forfeit the 180-day exclusivity period.[76] In general, the first ANDA filer forfeits the exclusivity period when it fails to market the drug within a designated time period after a triggering event.[77] For example, a first ANDA filer forfeits the exclusivity period if it fails to market the drug within seventy-five days from the time it is determined and upheld on appeal that the patent claims at issue are invalid or not infringed, where the appellate court's final decision serves as the triggering event. [78]

Settlement between the first ANDA filer and the brand-name drug manufacturer, however, generally does not constitute a forfeiture event or a triggering event.[79] Indeed, the 180-day exclusivity period of a first ANDA filer that settles is not triggered unless *another* ANDA filer secures a final decision that the patent claims are invalid or not infringed[80] or the court presiding over the subsequent ANDA filer's suit enters a settlement order or consent decree to the same effect;[81] the first ANDA filer does not forfeit the exclusivity period unless it fails to market the drug within seventy-five days from the triggering event.[82] In other words, the Hatch-Waxman Act rewards the first ANDA filer for its competitor's efforts. Worse yet, this feature of the Hatch-Waxman Act enables a settling first ANDA filer to reap the benefits of settling while preserving the award of the exclusivity period for some time in the future. Moreover, because a subsequent ANDA filer cannot enter the market until the first ANDA filer's exclusivity period expires, the 180-day exclusivity period effectively delays entry by subsequent ANDA filers. This creates a "bottleneck," preventing market entry by other generic drug manufacturers.[83] Finally, it is worth noting that, if the first filer forfeits the 180-day exclusivity period for failing to market its drug, the exclusivity period does not pass on to subsequent ANDA filers.[84] As will be discussed further below in Part II, these features together encourage settlement and make the consequences of settlement harmful to consumers.

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75. *See* MARTIN VOET, THE GENERIC CHALLENGE: UNDERSTANDING PATENTS, FDA AND PHARMACEUTICAL LIFE-CYCLE MANAGEMENT 123 (5th ed. 2016).

76. 21 U.S.C. § 355(j)(5)(D).

77. *See id.* § 355(j)(5)(D)(i)(I).

78. *See id.* § 355(j)(5)(D)(i)(I)(bb)(AA).

79. *See id.* § 355(j)(5)(D)(i).

80. *See id.* § 355(j)(5)(D)(i)(I)(bb)(AA).

81. *See id.* § 355(j)(5)(D)(i)(I)(bb)(BB).

82. *See id.* § 355(j)(5)(D)(i)(I)(bb).

83. *See infra* notes 86–95 and accompanying text.

84. 21 U.S.C. § 355(j)(5)(D)(iii)(II); 21 C.F.R. § 314.107(c)(1)–(2) (2017).

II. THE PROBLEM OF SETTLEMENT OF PARAGRAPH IV LITIGATION

One of the objectives of the Hatch-Waxman Act was to facilitate generic drug entry. As discussed above, the Act attempts to achieve this goal by making it easier for generic drug manufacturers to challenge and invalidate weak patents and incentivizing them to do so.

But a 2011 study by Scott Hemphill and Mark Lemley reveals that, despite the quite substantial incentive provided to first ANDA filers by the Hatch-Waxman regulatory scheme, the system is not effecting the intended consequences. They determined that the exclusivity period does not encourage the invalidation of many patents nor does it generally lead to earlier generic entry.[85] Furthermore, they determined that the exclusivity period, when awarded to settling first filers, impedes entry by other generic drug manufacturers, confirming the bottleneck effect.[86]

Hemphill and Lemley examined every instance in which a generic drug manufacturer received the 180-day exclusivity period between 2005 and 2009.[87] Importantly, their methodology only enabled them to observe instances in which the 180-day exclusivity period was actually triggered.[88] Their data and analysis therefore cannot reflect instances in which the parties settled but, at the time of the study, the first ANDA filer was preserving its 180-day exclusivity period, as is the case when the settlement terms provide for delayed entry.

They identified forty-nine drugs between 2005 and 2009 for which the 180-day exclusivity period was awarded by the FDA.[89] They found that in only nine out of forty-nine cases did the generic "win" with an invalidation or unenforceability determination.[90] In contrast, twenty-three of the forty-nine awards, which is almost half, were "no suit" awards—i.e., the brand-name drug manufacturer did not sue the first ANDA filer, likely because it knew its patent claims were weak,[91] which enables the first filer to enter the market immediately.[92] In addition, they found that in nine of forty-nine cases, the parties settled.[93] No suits and settlements, together, make up

85. Hemphill & Lemley, *supra* note 9, at 956–58.

86. *Id.* at 958.

87. *Id.* at 956.

88. *Id.* at 957–58.

89. *Id.* at 956.

90. *Id.* at 957.

91. Hemphill and Lemley explain, "[a] 'no suit' outcome is one in which the patentee did not file a lawsuit in response to a Paragraph IV ANDA filing on that patent, in effect conceding the right of the generic to enter." *Id.* at 956 n.39.

92. *Id.* at 956; *see also* 21 U.S.C. § 355(j)(5)(B)(iii) (2012), *amended by* FDA Reauthorization Act of 2017, Pub. L. No. 11-52, 131 Stat. 1005 (2017). The listed drug manufacturer has forty-five days to bring a suit for an infringement; if the listed drug manufacturer does not do so, the first filer's ANDA becomes "effective immediately"—i.e., after forty-five days. *Id.*

93. Hemphill & Lemley, *supra* note 9, at 957.

thirty-two of forty-nine cases—sixty-five percent of cases—in which the generic drug manufacturer was awarded the exclusivity period without invalidating the underlying patent claims. And because Hemphill and Lemley's methodology did not enable them to capture instances in which the generic drug manufacturer had settled but had not yet triggered the 180-day exclusivity period, the number of settlements and of cases not leading to an invalidation of weak patents is very likely understated.

No suits and settlements are concerning. Both prevent the invalidation of weak patents, and the persistence of weak patents can retard innovation. Settlements are particularly problematic because they also delay entry by generic drug manufacturers. The incentives motivating settlement are discussed further below in Part II.A.

A. Incentives To Settle

The economics of the pharmaceutical drug market, together with characteristics of the Hatch-Waxman regulatory scheme, make it attractive to brand-name drug manufacturers and first ANDA filers alike to settle any patent litigation arising from the generic drug manufacturer's ANDA with a Paragraph IV certification.

1. The Economics of the Pharmaceutical Industry

The simple economics of the pharmaceutical drug market incentivize brand-name drug manufacturers to settle. Brand-name drug companies spend an enormous amount of money on researching and developing new drugs,[94] and face a significant amount of risk that the drug will fail. Once a drug is developed, the brand-name manufacturer must seek FDA approval. This involves, among other things, multiple phases of testing and clinical trials with human test subjects.[95] One recent study concludes that only 7.1% of drugs initially identified for investigation receive FDA approval.[96] In addition, the study estimates that total capitalized research and development costs, per approved drug, including the cost of failed drugs, are $2.558 billion.[97] But this is not the end of it. Once a drug is approved, the testing is not over; the drug manufacturer must conduct what is known

94. *See generally* Joseph A. DiMasi et al., *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. HEALTH ECON. 20, 31 (2016). The authors conclude that the total capitalized research and development costs per approved drug, including the cost of failed drugs and post-approval research and development spending, is about $2.87 billion in 2013 dollars. *Id.* at 27 fig. 4. This figure is based on confidential surveys of ten multinational pharmaceutical companies as well as information gathered from various commercial databases and the federal government. *Id.* at 22.

95. *See* 21 U.S.C. § 355(d); 21 C.F.R. § 312.2 (2017).

96. DiMasi et al., *supra* note 94, at 22.

97. *Id.* at 26–27.

as post-marketing studies.[98] This same study estimates that the post-approval phase costs $466 million.[99] The entire process can therefore cost approximately $2.87 billion[100] and take approximately ten years.[101]

Brand-name drug manufacturers undertake this incredibly expensive and time-consuming process in the hope that the new drug they have developed will turn out to be a "blockbuster"—what has been described as a drug yielding more than $1 billion in annual sales.[102] A blockbuster drug is the ultimate reward to a brand-name drug manufacturer. Blockbuster drugs pay not only for their own research, development, and approval, but also for all the drug manufacturer's failed efforts at developing and bringing to market a new drug.[103] In sum, profits from a blockbuster drug fuel much, if not all, of the brand-name drug manufacturer's operations—the "winners" and the "losers."[104]

An ANDA with a Paragraph IV certification challenging the validity of patent claims protecting the blockbuster drug from competition presents a significant financial risk to the brand-name drug manufacturer. If the patent claims are invalidated, the listed drug manufacturer will be precluded from enforcing those patent claims against the first ANDA filer, as well as any other ANDA filers.[105] Invalidation would consequently clear the way for multiple generic drugs to enter the market. The protection of the blockbuster drug's substantial profits is therefore a considerable incentive for the brand-name drug manufacturer to settle the dispute and avoid having the patent claims invalidated.

Indeed, it is a blockbuster drug's significant profits that attract a challenge by a generic drug manufacturer, including the first ANDA filer, in the first place. If the first ANDA filer's challenge is successful, it will be the exclusive competitor of the brand-name drug manufacturer for 180 days, sharing in the blockbuster drug's significant profits. And during this period of duopoly, prices will be reduced only modestly.[106] At the same time, the profits yielded by a blockbuster drug are sufficiently large enough that a listed drug manufacturer can afford to pay the generic drug manufacturer a settlement amount that is more than the generic drug manufacturer would earn during the 180-day exclusivity period, discounted

98. 21 C.F.R. § 312.85 (2017).

99. DiMasi et al., *supra* note 94, at 27 fig. 4.

100. *See id.* at 31.

101. *See id.* at 26 (noting that ten years is "the approximate time between median pre-approval development costs and median post-approval costs.").

102. Pierre Jacquet et al., *The New Face of Blockbuster Drugs*, 29 IN VIVO 2, 2 (May 2011).

103. *See generally* DiMasi et al., *supra* note 94, at 21.

104. Jacquet et al., *supra* note 102, at 3–4 (showing that the top ten pharmaceuticals companies rely on "blockbusters" for over sixty percent of their revenue on average).

105. *See* Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found., 402 U.S. 313, 349–50 (1971).

106. *See supra* note 72 and accompanying text.

by the probability that the generic drug manufacturer would lose its suit. And settling eliminates the risk associated with litigation. Therefore, settling may very well be more profitable for a first ANDA filer than pursuing its challenge to the brand-name drug manufacturer's patent claims through to a judgment.

2. Preserved Exclusivity

Features of the 180-day exclusivity period magnify the incentive for the first ANDA filer to settle. The Hatch-Waxman Act rewards a first ANDA filer with a 180-day exclusivity period for incurring the cost and taking the risk of challenging the listed drug manufacturer's patent claims. However, if the first ANDA filer settles, it suffers virtually no consequence. As discussed above in Part I.D, settlement alone does not constitute a forfeiture event. Indeed, the first filer can preserve its 180-day exclusivity period for quite some time. Recall that, under the statutory scheme, a first ANDA filer that settles can retain the exclusivity period without the risk of losing it until a triggering event.[107] One such triggering event is when a subsequent ANDA filer pursues its case against the listed drug manufacturer, secures a determination that the patent claims are invalid or not infringed, *and* succeeds in having that determination upheld on appeal.[108] This is a time-consuming and expensive process, which ultimately prolongs the time that the first ANDA filer may retain the exclusivity period without actually using it. And all the while, no other generic drug manufacturer making a similar challenge may enter the market.

The end result of this complicated aspect of the statute is that the first ANDA filer may benefit from whatever consideration it received from the brand-name drug manufacturer in return for settling the dispute—frequently a large payment[109]—while at the same time preserving its period of exclusivity, which, if triggered, will enable the first ANDA filer to share duopoly profits with the listed drug manufacturer. The first filer is almost certainly better off settling than pursuing its case to a judgment.[110]

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107. *See supra* text accompanying note 82.

108. *See* 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(AA).

109. *See generally* Lemley & Shapiro, *supra* note 13, at 92–93.

110. A simple comparison of the first ANDA filer's expected outcome from settling, on the one hand, with its expected outcome from pursuing its case to a judgment, on the other, makes clear that settling very likely will make the first ANDA filer better off. If a first ANDA filer settles, it can expect consideration for the settlement with certainty. In addition, a first ANDA filer that settles can expect to receive the 180-day exclusivity period, at some point in the future, with some probability, and duopoly profits during that time. Recall that the 180-day exclusivity period will be triggered if a subsequent ANDA filer pursues its case to a judgment and invalidates the relevant patents. *See* 21 U.S.C. §355(j)(5)(D)(i)(I)(bb)(AA). The probability of the first ANDA filer receiving the 180-day exclusivity

3. Delayed but Certain Entry

In general, whether a first ANDA filer pursues its case to a determination or settles and waits for a subsequent ANDA filer to secure a determination, the first ANDA filer faces only the *possibility* of entering the market and enjoying the 180-day exclusivity period, depending on whether it or the subsequent ANDA filer, respectively, is successful in its suit against the listed drug manufacturer.[111] However, in many cases, the settlement agreement between the first ANDA filer and the listed drug manufacturer provides for "delayed entry"—i.e., that the first ANDA filer may enter the market at some later date, but at a time prior to the expiration of the patent claims at issue. Delayed entry is essentially a license, which transforms the mere possibility of the first ANDA filer enjoying the exclusivity period into a near certainty.[112] This makes settling more valuable than litigating.

B. The Problem with Settlement

In general, the law favors the settlement of litigation.[113] The rationale for this general policy is that settlement fosters judicial economy and compromise.[114]

But the general policy does not justify favoring a settlement in all circumstances. Moreover, a general policy favoring *settlement* should not be read as a general policy favoring *all settlement terms*. And settlement

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period is therefore the probability of a subsequent ANDA filer winning its suit against the brand-name drug manufacturer. (The flipside is that a first ANDA filer can expect to *not* receive the 180-day exclusivity period with some probability, namely 1 minus the probability that it will receive it.)

In comparison, if a first ANDA filer pursues its case to a judgment, it cannot expect any benefits with certainty. It can, however, expect to win—i.e., to invalidate the patent owner's patent claims—with some probability, which will result in the 180-day exclusivity period and duopoly profits during that time. It can also expect to lose and get nothing with some probability (1 minus the probability that it will win). However, regardless of whether it wins or loses, it will incur litigation costs. Thus, regardless of whether the first ANDA filer settles, it faces some risk of not receiving the 180-day exclusivity period. But when it settles, it additionally receives consideration for settling with certainty. It should be noted that this may be an over-simplification of the settlement terms between the first ANDA filer and the patent owner. Other, more complicated settlement terms are possible that make the settlement payment to the first ANDA filer contingent on future events. Nonetheless, it illustrates that the generic drug manufacturer is very likely better off from settling.

111. 21 U.S.C. §355(j)(5)(D)(i)(I)(bb)(AA).

112. The first ANDA filer will not be able to enjoy the exclusivity period if a subsequent ANDA filer triggers the 180-day exclusivity period prior to the first ANDA filer receiving approval by the FDA. *Id.* § 355(j)(5)(B)(iv)(I).

113. *See, e.g.*, FTC v. Actavis, Inc., 133 S. Ct. 2223, 2234 (2013) (noting "a general legal policy favoring the settlement of disputes").

114. *See, e.g.*, Flex-Foot, Inc. v. CRP, Inc., 238 F.3d 1362, 1369 (Fed. Cir. 2001) ("'[T]here is a compelling public interest and policy in upholding and enforcing settlement agreements voluntarily entered into' because enforcement of settlement agreements encourages parties to enter into them—thus fostering judicial economy." (quoting Hemstreet v. Spiegel, Inc., 851 F.2d 348, 349 (Fed. Cir. 1988))).

terms that violate the law or offend public policy should not be approved or otherwise sanctioned by the federal courts.[115]

So what's the problem with settlement? In the context of the Hatch-Waxman regulatory scheme, depending on the terms, settlement agreements between a brand-name and a generic drug manufacturer are pernicious for at least two reasons. First, as mentioned above, settlement and the preservation of the 180-day exclusivity period not only delay market entry by the first ANDA filer, but also prevent all subsequent ANDA filers from entering the market until the exclusivity period has expired.[116] Settlement therefore acts as a bottleneck, preventing entry into the market by generic drug manufacturers other than the first ANDA filer and delaying competition.

Second, settlements prevent the invalidation of weak patents. And these are not merely weak patents; they are weak patents that enable their holders to charge supracompetitive prices.[117] The persistence of these weak patents, in turn, encumbers follow-on innovation. In addition, it prevents generic drugs from entering the market and competing with the brand-name drug manufacturer. Settlement therefore prevents competition in a second respect. The end result is that supracompetitive prices persist and follow-on innovation is retarded. Furthermore, settlement effects consequences inconsistent with the objectives of the Hatch-Waxman Act and harmful to consumers.

This latter form of harm to competition can amount to a violation of the antitrust laws. Although a full exploration of reverse payment settlements from an antitrust perspective is beyond the scope of this article, this point needs some additional explanation. Section 1 of the Sherman Act prohibits unreasonable agreements—i.e., agreements that harm consumers or the competitive process—especially when those agreements are among competitors.[118] Settlements are effectively agreements. They harm

115. *Cf.* Owen M. Fiss, *Against Settlement*, 93 YALE L.J. 1073, 1085 (1984) (arguing that settlement as a general practice is not preferable to a judgment, in part because settlement prevents justice from being done) (The job of judges "is not to maximize the ends of private parties, nor simply to secure the peace, but to explicate and give force to the values embodied in authoritative texts such as the Constitution and statutes: to interpret those values and to bring reality into accord with them. This duty is not discharged when the parties settle. . . . To be against settlement is not to urge that parties be 'forced' to litigate, since that would interfere with their autonomy and distort the adjudicative process . . . . To be against settlement is only to suggest that when the parties settle, society gets less than what appears, and for a price it does not know it is paying.").

116. *See* 21 U.S.C. § 355(j)(5)(B)(iv)(I).

117. If the patents were weak and the claimed invention had very little value in the market, we would be less concerned if the patents persisted. If the claimed invention had very little value, it would be less likely that the patents would be the subject of a settlement in the first place. Such patents do not pose the same harm to consumers that weak patents covering blockbuster drugs do because they do not similarly enable their holders to charge supracompetitive prices while they persist. *See generally* Mark A. Lemley, *Rational Ignorance at the Patent Office*, 95 NW. U. L. REV. 1495 (2001).

118. 15 U.S.C. § 1 (2012).

competition by causing generic drugs to enter the market after the date that reflects the risk of the patent being found valid.[119]

As Mark Lemley and Carl Shapiro have explained, patents are "probabilistic."[120] A patent is not an absolute right to exclude others; it is merely "a right to *try* to exclude by asserting the patent in court."[121] Accordingly, there is some probability that a generic drug manufacturer will win and the patent will be found invalid and some probability that the generic will lose and the patent will be found not invalid. A brand-name and generic drug manufacturer that wish to avoid the cost and trouble of litigating could agree to generic drug entry on a date that reflects the probability of the generic drug manufacturer winning—i.e., the probability of the patent being found invalid. Such a settlement agreement would achieve the same outcome the parties expect from litigation, and accordingly, the agreement would be unproblematic under the antitrust laws.

A problem arises when the terms of the settlement agreement additionally provide for a large cash payment from the plaintiff, brand-name drug manufacturer, to the defendant, generic drug manufacturer. This is a so-called "reverse payment settlement"—i.e., a settlement in which the plaintiff, patent owner, pays the defendant, ANDA filer and alleged infringer, to not enter the market for a designated period of time and to settle the dispute.[122] Such settlements are referred to as "reverse" payment settlements because the money flows from the plaintiff, and there is no other justification for the payment except to settle the dispute.[123] These sorts of settlements are problematic because a payment from the brand-name to the generic drug manufacturer suggests delayed generic entry beyond the date that reflects the risk of the patent being found invalid—i.e., the generic drug manufacturer is willing to accept a later entry date in exchange for a payment that at least covers the profits lost as a result of the later entry date.

A simple example illustrates the point. Assume that a patent has ten years remaining until it expires. The generic and brand-name drug

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119. *See* FED. TRADE COMM'N, *supra* note 54, at ii.

120. Lemley & Shapiro, *supra* note 13, at 75.

121. *Id.*

122. The Supreme Court in *Actavis* described a reverse payment settlement as follows:

> Company A sues Company B for patent infringement. The two companies settle under terms that require (1) Company B, the claimed infringer, not to produce the patented product until the patent's term expires, and (2) Company A, the patentee, to pay B many millions of dollars. Because the settlement requires the patentee to pay the alleged infringer, rather than the other way around, this kind of settlement agreement is often called a "reverse payment" settlement agreement.

FTC v. Actavis, Inc., 133 S. Ct. 2223, 2227 (2013).

123. *See id.*

manufacturer agree that the probability of the patent being found invalid is fifty percent. A settlement agreement in which the parties agree that the generic drug can enter the market after five years—fifty percent of the time remaining on the patent—would achieve the same outcome expected from litigation and would therefore not be anticompetitive. A payment from the brand-name drug manufacturer to the generic, however, enables the brand-name drug manufacturer to offer a later entry date—say, for example, in six years instead of in five years—by compensating the generic for the one year of profits lost because of the later entry date. During the additional year without competition, consumers will be harmed by supracompetitive prices that can no longer be justified.

To be sure, not all settlements between brand-name and generic drug manufacturers are anticompetitive. It is possible for a first ANDA filer and a brand-name drug manufacturer to settle under terms that provide for the immediate entry of the generic drug manufacturer. In that case, the settlement would have the same effect of a no suit. The generic can enter the market and competition will ensue. It should be noted, however, that the weak patent claims will persist without invalidation, which can harm innovation.

Prior to the Supreme Court's 2013 decision in *FTC v. Actavis*, the FTC took the position that reverse payment settlement agreements were presumptively unlawful under Section 5 of the FTC Act.[124] And while at least one appellate court agreed, [125] other courts rejected the per se rule.[126] At the same time, an extensive literature emerged debating the proper treatment under the antitrust laws of such settlements, depending on the particular terms of the settlement agreement.[127]

FTC v. Actavis attempted to resolve at least some of the debate. The Supreme Court considered whether reverse payment settlements are

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124. *See* Schering-Plough Corp., 136 F.T.C. 956, 970 (2003), *order vacated by* Schering-Plough Corp. v. FTC, 402 F.2d 1056 (11th Cir. 2005); *see also Actavis*, 133 S. Ct. at 2237 ("The FTC urges us to hold that reverse payment settlement agreements are presumptively unlawful and that courts reviewing such agreements should proceed via a 'quick look' approach, rather than applying a 'rule of reason.'").

125. *See In re* Cardizem CD Antitrust Litig., 332 F.3d 896 (6th Cir. 2003) (holding reverse payment settlement agreements per se illegal).

126. *In re* Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323, 1333 (Fed. Cir. 2008) (adopting rule of reason to evaluate reverse payment settlements and concluding reverse payment settlement is within scope of the patent and therefore lawful), *abrogated by Actavis*, 133 S. Ct. 2223; *In re* Tamoxifen Citrate Antitrust Litig., 466 F.3d 187 (2d Cir. 2006) (rejecting per se rule and upholding district court's granting of brand-name manufacturer's motion to dismiss), *abrogated by Actavis*, 133 S. Ct. 2223; *Schering-Plough Corp*., 402 F.3d 1056 (holding that reverse payment settlement that provided for generic entry prior to expiration of patent was not unlawful); Valley Drug Co. v. Geneva Pharms., Inc., 344 F.3d 1294, 1312 (11th Cir. 2003) (rejecting rule that reverse payment settlements are per se unlawful); King Drug Co. v. Cephalon, Inc., 702 F. Supp. 2d 514, 528–29 (E.D. Pa. 2010) (rejecting rule that reverse payment settlements are per se unlawful).

127. *See supra* note 13.

unlawful under the antitrust laws.[128] The Court refused to adopt a per se rule of illegality, noting that this approach was consistent with its precedent that refused to adopt per se rules.[129] But the Court's decision could also be seen as reflecting the view that normatively, antitrust law does not trump patent law and vice versa.[130] Ultimately, the Court concluded that such settlements *may* be unlawful under the rule of reason.[131] Importantly, the Court concluded that it was normally "not necessary to litigate patent validity to answer the antitrust question";[132] it is enough for purposes of determining antitrust liability that the payment seeks to "prevent the risk of competition."[133] The Court's decision recognizes that the mere elimination of the possibility of competition can harm consumers.

A recent FTC report indicates that drug manufacturers entered into substantially fewer reverse payment settlements in the year following the *Actavis* decision.[134] But questions as to the application of the Court's decision remain. For example, the Court explained that the size of the reverse payment, if otherwise unexplained, can "provide a workable surrogate for a patent's weakness."[135] It is not clear from this statement whether the Court meant to create a sort of safe harbor for relatively strong patents—i.e., for small payments, from which a court can infer the purpose of the reverse payment is to reduce only a small risk of patent claim invalidation. In addition, lower courts have struggled to apply the Court's decision in instances where the consideration given from the brand-name drug manufacturer to the generic is something other than money.[136]

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128. *Actavis*, 133 S. Ct. at 2227.

129. *Id*. at 2237.

130. *See id*. at 2238.

131. *Id*. at 2237 ("We decline to [hold that reverse payment settlement agreements are presumptively unlawful]. In *California Dental*, we held (unanimously) that abandonment of the 'rule of reason' in favor of presumptive rules . . . is appropriate only where 'an observer with even a rudimentary understanding of economics could conclude that the arrangements in question would have an anticompetitive effect on customers and markets.' We do not believe that reverse payment settlements . . . meet this criterion." (internal citations omitted)).

132. *Id.* at 2236.

133. *Id.*

134. *See generally* FED. TRADE COMM'N, AGREEMENTS FILED WITH THE FEDERAL TRADE COMMISSION UNDER THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003: OVERVIEW OF AGREEMENTS FILED IN FY 2014: A REPORT BY THE BUREAU OF COMPETITION (Jan. 2016), https://www.ftc.gov/system/files/documents/reports/agreements-filled-federal-trade-commission-under-medicare-prescription-drug-improvement/160113mmafy14rpt.pdf.

135. *Actavis*, 133 S. Ct. at 2226.

136. For example, in some instances, the settling listed drug manufacturer commits to refrain from marketing an "authorized generic"—i.e., its own, lower-priced, unbranded but otherwise equivalent product—in competition with the first ANDA filer. *See* 21 U.S.C. § 355(j)(5)(B) (2012), *amended by* FDA Reauthorization Act of 2017, Pub. L. No. 11-52, 131 Stat. 1005 (2017). Absent the agreement, the listed drug manufacturer would be permitted to market an authorized generic in competition with the first ANDA filer during the 180-day exclusivity period because, unlike subsequent ANDA filers, the listed drug manufacturer already has FDA approval, which it received to sell its

Evaluating such agreements is challenging. As one district court noted, "it is impractical (if not impossible)" to assess the true value of non-cash consideration paid by the brand manufacturer.[137] Thus, while *FTC v. Actavis* may have relieved the lower courts of conducting a mini-patent trial relating to patent validity to resolve a question of antitrust law—i.e., to determine whether a reverse payment settlement agreement is anticompetitive—it has not entirely resolved the "turducken"[138] problem presented by these sorts of cases. Difficult issues of antitrust law remain contained within what ultimately began as a patent lawsuit. In addition, it suggests that it is not necessarily anticompetitive settlements that will become any less likely, only certain types of settlement *terms*—i.e., large cash payments. Indeed, settlements may become more complex in order to obfuscate the purpose, value, and effect of the settlement. These difficulties

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brand-name drug. *See* 21 U.S.C. § 355(j)(5)(B)(iv). This enables the listed drug manufacturer to recoup some of the monopoly profits that it will necessarily lose when the first filer enters the market. The lower courts are in disagreement as to whether a commitment to refrain from selling an authorized generic, standing alone, constitutes a "reverse payment." In *In re Nexium Antitrust Litig.*, the United States District Court for the District of Massachusetts concluded that an agreement to not market an authorized generic constituted a "reverse payment" for purposes of evaluating whether the agreement was anticompetitive. 968 F. Supp. 2d 367, 391–92 (D. Mass. 2013); *see also In re* Lipitor Antitrust Litig., 46 F. Supp. 3d 523, 543 (D. N.J. 2014) ("Although *Actavis* addressed cash payments, reading the opinion as a whole, it is clear that the Supreme Court focuses on the antitrust intent of the settling parties rather than the manner of payment."); *In re* Niaspan (Esomeprazole) Antitrust Litig., 42 F. Supp. 3d 735, 751 (E.D. Pa. 2014) (concluding that "the term 'reverse payment' is not limited to a cash payment" and does not require cash consideration). Other courts, however, have come to a contrary conclusion. *See, e.g.*, *In re* Loestrin 24 Fe Antitrust Litig., 45 F. Supp. 3d 180, 190, 192–93 (D. R.I. 2014) (concluding that a commitment to refrain from marketing an authorized generic does not constitute a "payment"), *vacated by In re* Loestrin 24 Fe Antitrust Litig., 814 F.3d 538 (1st Cir. 2016); *In re* Lamictal Direct Purchaser Antitrust Litig., 18 F. Supp. 3d 560, 568 (D. N.J. 2014) (concluding "that the Supreme Court [in *Actavis*] considered a reverse payment to involve an exchange of money"), *vacated by* King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp., 791 F.3d 388 (3d Cir. 2015); *see also* Edlin, *Activating Actavis*, *supra* note 17, at 18 (noting that valuing the payment from the patent holder to the claimed infringer "is sometimes an intricate proposition. . . . The parties to a payment for delay have ample reason to pack complexities into the deal (such as relatively unimportant services) to conceal its genuine nature.").

137. *In re Loestrin 24 Fe Antitrust Litig*., 45 F. Supp. 3d at 193; *see also In re Lipitor Antitrust Litig.*, 46 F. Supp. 3d at 544–45 (concluding that "reverse payment" included non-cash consideration, but nonetheless finding plaintiffs' complaint insufficient because they failed to attempt to convert the non-cash payment to a monetary value, which is an "intricate" exercise).

138. A turducken is a food item in which a boned chicken is stuffed inside of a boned duck, which is further stuffed inside of a partially boned turkey. This term was used by the Eleventh Circuit Court of Appeals in the *Actavis* decision to describe the relationship between the patent and antitrust issues. FTC v. Watson Pharms., Inc., 677 F.3d 1298, 1315 (11th Cir. 2012). Specifically, the court of appeals declined to decide the validity of the underlying patent claims in the antitrust suit brought by the FTC challenging the reverse payment settlement. *Id.* at 1312–14. And in doing so, the court stated,

> [I]t is worth emphasizing that what the FTC proposes is that we attempt to decide how some other court in some other case at some other time was likely to have resolved some other claim if it had been pursued to judgment. If we did that we would be deciding a patent case within an antitrust case about the settlement of the patent case, a turducken task.

Id. at 1315.

have only further fueled the debate among scholars as to the proper treatment under the antitrust laws of reverse payments.[139]

I do not enter the fray, offering an antitrust solution to what originated as a patent problem and evolved into a regulatory design problem.[140] Rather, my proposal addresses these problems directly by more closely aligning incentives and rewards in a way that weeds out weak patents. My proposal relies in great part on the newly created adjudicatory procedure, the IPR procedure, before the PTAB, which is discussed below in Part III.

III. INTER PARTES REVIEW: A NEW PROCEDURE

Recent changes to the patent laws present an opportunity to deter anticompetitive settlements and encourage a determination of the validity of weak patents by creating competition among ANDA filers. Part III.A first describes the IPR procedure, a new mechanism that was recently introduced as a part of the AIA. Part III.B then highlights features of the IPR procedure that make it an especially attractive procedure to ANDA filers.

A. The IPR Procedure

IPR is a trial proceeding conducted before an administrative court, the PTAB,[141] to review the patentability of one or more claims of a patent.[142] Unlike a patent challenge before a federal court or other proceedings before the PTAB, an IPR may only be pursued on two grounds under the Patent Act: lack of novelty or obviousness.[143] The IPR procedure became available for all patents beginning September 16, 2012.[144]

Unlike the Hatch-Waxman regulatory scheme, the basic statutory framework and mechanics of initiating an IPR are fairly simple and straightforward. A third-party petitioner may initiate an IPR beginning as early as nine months after the underlying patent is granted.[145] The patent

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139. *See supra* note 13.

140. *See generally* Hemphill, *supra* note 13 (arguing that reverse payment settlements are a problem in regulatory design).

141. *See* 35 U.S.C. §§ 6, 311(a) (2012).

142. *See id*. § 311.

143. *See id.*; *see also id.* §§ 102 (novelty), 103 (obviousness).

144. Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 6(f)(2)(A), 125 Stat. 284, 311 (2011).

145. 35 U.S.C. § 311(c)(1). Before nine months, the petitioner may initiate an alternative procedure, known as post-grant review (PGR). *See* 35 U.S.C. §§ 321–329. The PGR procedure is very similar to the IPR procedure and provides the same benefits—namely, a quicker determination and the ability to take advantage of concurrent and competing proceedings, discussed *infra* note 152. In addition to when they may be initiated, there are a couple of differences between the PGR procedure and the IPR procedure. Perhaps the most significant difference is the grounds upon which a petitioner

owner is permitted to file a response.[146] If, based on the petition, the PTAB determines that "there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition," then it may authorize an IPR.[147]

In general, a petitioner is precluded from initiating an IPR if it has already initiated a challenge to the validity of the patent claims in federal district court.[148] However, a petitioner is not precluded from initiating an IPR if the challenge to the validity of the patent claims in federal district court arose as counterclaims.[149] For example, a defendant accused of patent infringement may first counterclaim that the patent claims are invalid and may subsequently initiate an IPR.

B. The Benefits of the IPR Procedure

There are at least a few features of the IPR procedure that make it appealing to patent challengers and can make consumers better off. Specifically, the IPR procedure can yield a faster determination and therefore may yield earlier generic entry. In addition, the new procedure has the potential to create competition between tribunals and ANDA filers; with some modifications, this can deter settlement, yield earlier generic entry, and improve patent adjudication. Furthermore, the IPR procedure, as

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may challenge a patent claim under each. While an IPR may only be pursued on grounds that the patent claims are not novel or are obvious, *see supra* note 143 and accompanying text, a PGR petitioner may challenge a patent claim on any grounds. Specifically, a petitioner may initiate a PGR and challenge a patent based on prior art patents and printed publications, non-statutory subject matter, lack of utility, lack of enablement, lack of written description, prior public use, prior sale or offer for sale, claim indefiniteness, and lack of structure for a claim. *See* 35 U.S.C. § 321(b). In addition, in order for the PTO to initiate an IPR, the petitioner must establish that "there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition," *id.* § 314(a), whereas a PGR petitioner must "demonstrate that it is more likely than not that at least 1 of the claims challenged in the petition is unpatentable." *Id.* § 324(a).

For simplicity, this article discusses only the IPR procedure. In addition, as a practical matter, generic drug manufacturers are more likely to use the IPR procedure than they are to use the PGR procedure because whether a patent claim covering a pharmaceutical drug is valuable and worth challenging will likely not be apparent within the first nine months after it has issued. *See* Doug Lichtman & Mark A. Lemley, *Rethinking Patent Law's Presumption of Validity*, 60 STAN. L. REV. 45, 64 n.61 (2007) (questioning the value of proposals to enable patent challenges within the first nine months after a patent issues because the value of the patent is unclear) ("[O]ther proposals would allow post-grant opposition only within the first nine months after a patent issues. That would render the procedure largely useless, because in many situations the firms that would challenge a given patent are not even going to be in business at the nine-month mark, let alone know that the relevant patent is important enough to warrant the expense and investment associated with post-grant opposition.").

146. 35 U.S.C. § 313; 37 C.F.R. § 42.107(a) (2017).

147. *See* 35 U.S.C. § 314(a). The authority granted to the Director has been delegated to the PTAB pursuant to 37 C.F.R. § 42.108(c).

148. 35 U.S.C. § 315(a)(1) ("An inter partes review may not be instituted if, before the date on which the petition for such a review is filed, the petitioner . . . filed a civil action challenging the validity of a claim of the patent.").

149. *See* 35 U.S.C. § 325(a)(3).

it already exists, has the potential to discourage settlement. Moreover, there are procedural aspects, discussed further below, which make it a more hospitable tribunal to patent challengers.

1. Faster Determination

The entire IPR procedure can be completed in as little as eighteen months.[150] This is sufficiently faster than the thirty months the Hatch-Waxman regulatory scheme allows for a pharmaceutical patent challenge to be completed in the federal district courts.[151]

The faster IPR procedure could, in turn, enable a federal district court in a concurrent action to enter a judgment sooner, which can ultimately enable earlier generic entry. The mechanics of how an ANDA filer could use a proceeding before the PTAB in tandem with a federal district court action is discussed further below in Part IV.[152]

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150. The patent owner has three months to file a preliminary response to a petitioner's petition, *see* 37 C.F.R. § 42.107(b), and the Director has three months from the time the patent owner files a preliminary response to determine whether to institute an IPR. *See* 35 U.S.C. § 314(b)(1). Once instituted, the PTAB has one year to issue a final determination, although the Director may, "for good cause shown," extend the time by as much as six months. *See id.* § 316(a)(11); 37 C.F.R. § 42.100(c).

151. *See* 21 U.S.C. § 355(j)(5)(B)(iii) (2012), *amended by* FDA Reauthorization Act of 2017, Pub. L. No. 11-52, 131 Stat. 1005 (2017). The district court may order a shorter or longer stay if either party fails to cooperate in expediting the action. *See id.*

152. It is worth noting at this point that how much faster the IPR procedure turns out to be will depend on whether changes, like the one I propose in Part V.C, are adopted so that determinations by the PTAB have the same effect as determinations by a federal district court. As I discuss further below, under the present statutory scheme, a determination by the PTAB that a patent claim is invalid does not have the same effect as a similar determination by a federal district court that a patent claim is invalid. For example, a federal district court's order finding a patent claim invalid enables FDA approval of the generic drug manufacturer's ANDA to be immediately effective. *See* 21 U.S.C. § 355(j)(5)(B)(iii)(I). Importantly, FDA approval does *not* hinge on the federal district court's decision being upheld on appeal. In contrast, a determination by the PTAB that a patent claim is invalid does not have the same effect. The generic drug manufacturer can only effect FDA approval if a district court similarly enters an order finding the patent claims invalid. *See id*. § 355(j)(5)(B)(iii). This requires the federal district court to take judicial notice of the PTAB's determination. *See infra* note 210 and accompanying text. The issue that then arises is whether a federal district court will take judicial notice of the PTAB's initial determination—occurring approximately eighteen months after the IPR petition is initiated—or whether instead the district court will wait to see if the initial determination is upheld on appeal by the Federal Circuit. Recent data compiled by the Federal Circuit indicates that it can take the court as many as ten months to dispose of an appeal originating from the PTO. U.S. CT. OF APPEALS FOR THE FED. CIR., MEDIAN TIME TO DISPOSITION IN CASES TERMINATED AFTER HEARING OR SUBMISSION (2015), http://www.cafc.uscourts.gov/sites/default/files/Median%20Disposition%20Time%20for%20Cases%20Terminated%20after%20Hearing%20or%20Submission%20%28Detailed%20table%20of%20data%202006-2015%29.pdf.. If the federal district court chooses to wait and see if the Federal Circuit upholds the PTAB's determination—resulting in the cancelation of the patent claims—that will add an additional ten months on to the process, for a total of approximately twenty-eight months. This is still faster than the thirty months or more it could take for a federal district court to reach a determination, but less significantly so.

2. Concurrent and Competing Proceedings

A second attractive feature of the new IPR procedure is that it can proceed in parallel to a challenge in federal district court. As discussed above, a defendant in a patent infringement lawsuit in federal district court may initiate an IPR;[153] this is one way in which there can be concurrent proceedings that both consider the validity of the same patent claims. However, there is another way in which there can be concurrent proceedings: under the new IPR procedure, a petitioner is not prevented from initiating an IPR simply because *another* party is already challenging the patent owner's patent claims in federal district court, and neither the PTAB nor the federal district court is required to stay the proceeding.[154] Therefore, it is possible for an IPR before the PTAB to occur at the same time a federal district court is considering a challenge to the very same patent claims. And because an IPR is a proceeding before an Article I administrative court, while a patent trial is before an Article III court, the two are not amenable to consolidation, as they might be if they were both proceeding in federal district court.

There are at least a couple of benefits of concurrent proceedings to ANDA filers. First, concurrent jurisdiction creates the same sort of competition between tribunals—in this case, the PTAB and the federal district courts—as there is between state and federal courts[155] and among sister state courts. As with competition among those courts, competition between the PTAB and the federal district courts can improve the competency of both, but especially the patent law competency of the federal district courts. As Rochelle Dreyfuss has observed, "PTAB decisions could be . . . helpful to district court judges." [156] The proceedings before the PTAB will produce a wealth of cases that will add to, and improve upon, the knowledge base from which the Federal Circuit may draw when deciding cases. Dreyfuss explains, "the availability of detailed instruction from the PTAB could change the nature of Federal Circuit jurisprudence."[157]

153. 35 U.S.C. § 325(a)(3).

154. The PTAB is, however, permitted to stay the IPR if there is another proceeding involving the same patent before the PTO. *See* 35 U.S.C. § 315(d); 37 C.F.R. § 42.122(a). In addition, if a petitioner first files an IPR and then files a civil action in federal district court, the federal district court action is automatically stayed. *See* 35 U.S.C. § 315(a)(2).

155. *See, e.g.*, Ann Althouse, *How to Build a Separate Sphere: Federal Courts and State Power*, 100 HARV. L. REV. 1485, 1525–26 (1987); Erwin Chemerinsky, *Parity Reconsidered: Defining a Role for the Federal Judiciary*, 36 UCLA L. REV. 233, 309–10 (1988).

156. Rochelle Cooper Dreyfuss, *Giving the Federal Circuit a Run for Its Money: Challenging Patents in the PTAB*, 91 NOTRE DAME L. REV. 235, 266 (2015).

157. *Id.*

Second, in the context of the Hatch-Waxman regulatory scheme and the new IPR procedure, concurrent jurisdiction could also enable competition among ANDA filers—i.e., first filers and subsequent filers—to be the first to secure a judgment invalidating weak patent claims.

For example, consider the case where a first ANDA filer with a Paragraph IV certification chooses not to initiate an IPR, but instead pursues its challenge to the brand-name drug manufacturer's patent claims solely in federal district court. Sometime after the first filer's ANDA is submitted, a subsequent filer submits an ANDA with a Paragraph IV certification, triggering the same events under Hatch-Waxman that were triggered with respect to the first filer—i.e., the filing of an ANDA with a Paragraph IV certification amounts to statutory infringement and enables the brand-name drug manufacturer to file a patent infringement suit in federal district court. After the brand-name drug manufacturer initiates a patent infringement suit, the subsequent ANDA filer may initiate an IPR before the PTAB. There would then be three concurrent proceedings: (1) the patent infringement suit by the brand-name drug manufacturer against the first filer; (2) the patent infringement suit by the brand-name drug manufacturer against the subsequent filer; and (3) the IPR initiated by the subsequent filer before the PTAB. There would then be competition not only between the PTAB and the federal district court, but also between the first filer and the subsequent filer for a determination.

As the regulatory scheme currently stands, a subsequent ANDA filer who secures a determination that the brand-name drug manufacturer's patent claims are invalid stands to gain very little. As mentioned above, only the first ANDA filer is rewarded with the 180-day exclusivity period.[158] If a subsequent ANDA filer secures a determination before the PTAB that the patent claims are invalid, and the PTO accordingly cancels the claims, then the first ANDA filer will very likely be able to free ride on that determination. As discussed further below in Part IV.B, assuming difficult issues of mootness can be navigated, the first ANDA filer may then have the federal district court take judicial notice of the invalidation and cancelation of the patent claims and enter a judgment finding the patent claims invalid.[159] It is then the first filer—not the subsequent filer—that may be rewarded, *and rewarded earlier*, with the 180-day exclusivity period.[160] However, rewarding the filer that first secures a determination that the underlying patent claims are invalid—regardless of whether the filer was the "first filer"—with the exclusivity period would eliminate this

158. *See* 21 U.S.C. § 355(j)(5)(B)(iv) (2012), *amended by* FDA Reauthorization Act of 2017, Pub. L. No. 11-52, 131 Stat. 1005 (2017).

159. *See generally* Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found., 402 U.S. 313 (1971).

160. *Id*.

problem. A proposal to amend provisions of the Hatch-Waxman Act relating to the 180-day exclusivity period is discussed further below.

3. Discourages Settlement

Another significant benefit of an IPR procedure over litigation in federal district court is that, once an IPR is initiated, the statutory scheme, at least theoretically, discourages settlement. Settling an IPR is not prohibited.[161] However, the statute grants the PTAB the authority to continue the proceedings and issue a final written decision, even if the petitioner and patent owner settle.[162] The threat of the PTAB issuing a final written decision even after the parties have settled discourages settlement by reducing the patent owner's incentive to settle.

One of the primary incentives for a patent owner to settle a patent dispute is to prevent a tribunal from determining that the patent owner's patent claims are invalid. This stems primarily from the preclusive effect of a determination relating to a patent claim's validity. If a tribunal determines that a patent claim is "not invalid," a subsequent challenger is not precluded from challenging the very same patent claims on different grounds[163] or, indeed, on the very same grounds.[164] Although the doctrine of non-mutual collateral estoppel prevents a patent owner from enforcing patent claims that have previously been found invalid against other defendants,[165] the doctrine does not prevent an accused infringer from defending that patent claims previously held "not invalid" are, in fact, invalid.[166]

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161. *See* 35 U.S.C. § 317 (2012) (addressing settlements in the context of inter partes review).

162. *Id.* ("If no petitioner remains in the inter partes review, the Office may terminate the review or proceed to a final written decision under section 318(a).").

163. It is for this reason that a patent claim cannot be held "valid," but only "not invalid." *See, e.g.*, Shelcore, Inc. v. Durham Indus., Inc., 745 F.2d 621, 627 (Fed. Cir. 1984) ("A patent is not held valid for all purposes but, rather, not invalid on the record before the court."); Stevenson v. Sears, Roebuck & Co., 713 F.2d 705, 711 (Fed. Cir. 1983) ("[P]atents cannot be held 'valid' under all circumstances. Rather, a court merely decides in a particular case that the one attacking validity has not overcome the statutory presumption of validity.").

164. The Federal Circuit has explained that "the doctrine of stare decisis is generally an inappropriate one in patent litigation. . . . [P]atents cannot be held 'valid' under all circumstances. Rather, a court merely decides in a particular case that the one attacking validity has not overcome the statutory presumption of validity. . . . 'Because of the intrinsic nature of the subject, the first decision can be quite wrong, or derived from an insufficient record or presentation.'" *Stevenson*, 713 F.2d at 711 (quoting Technograph Printed Circuits, Ltd. v. U.S., 372 F.2d 969 (Ct. Cl. 1967).

165. Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found., 402 U.S. 313, 330–34 (1971).

166. *See Stevenson*, 713 F.2d at 710-11; Boutell v. Volk, 449 F.2d 673, 678 (10th Cir. 1971) ("Neither the actual decision of the Supreme Court [in *Blonder-Tongue*] nor the language of the opinion suggests that the mutuality requirement is relaxed as to a new infringer following an adjudication of validity. To so hold would deprive the alleged infringer of a trial.").

This puts the patent owner in the position of potentially having to defend a validity challenge over and over again. However, if a tribunal determines that a patent claim is "invalid," the patent owner cannot enforce that claim forever afterward.[167] Thus, there is very little upside to winning for the patent owner, but significant downside to losing. In the case of a blockbuster drug, that downside could be worth tens of billions of dollars. In the typical case before a federal district court, settling enables the patent owner to pay an amount certain to avoid this significant downside risk.

But the same cannot be said about IPR proceedings before the PTAB. As a result of the PTAB's statutory authority to continue the proceedings even after the original petitioner settles,[168] settling does not similarly enable the patent owner to avoid the risk of having its patent claims declared invalid. Therefore, the mere threat of the PTAB exercising its authority to continue the proceedings discourages settling.

Because continuation of the IPR proceeding is a matter of PTAB discretion—as opposed to being mandatory—the extent to which it discourages settlement, and reverse payment settlements in particular, may be tempered. A recent study by Erik Hovenkamp and Jorge Lemus suggests exactly that. Hovenkamp and Lemus examined all settlements before the PTAB from the PTAB's inception to the present that involved patents listed in the Orange Book.[169] They concluded that they could infer a reverse payment[170] in seventy-two percent of settled PTAB petitions.[171]

One potential explanation for the high rate of settlement is that, thus far, the PTAB has rarely exercised its discretion to issue a final written decision after the parties have settled, and the PTAB has accordingly acquired a reputation consistent with its practice. The PTAB's reputation, in turn, has muted the threat of the PTAB actually exercising its discretion. In other words, it is possible that the theoretical threat has not borne out in practice, which has resulted in a much lower threat in reality. This can be

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167. *See generally Stevenson*, 713 F.2d 705.

168. 35 U.S.C. § 317 (2012).

169. Erik Hovenkamp & Jorge Lemus, *Reverse Settlement and Holdup at the Patent Office* 20 (July 26, 2016) (working paper), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2814532. A petitioner can file multiple petitions relating to the same patent, so Hovenkamp and Lemus restricted their analysis to settlements involving unique patent–petitioner combinations. *Id.*

170. Hovenkamp and Lemus explain that, because the terms of settlements before the PTAB are confidential, they cannot be certain whether the terms of the settlement amount to a reverse payment settlement. *Id.* at 3. They therefore infer a reverse payment in cases where the parties settle but the generic drug manufacturer/petitioner is not subsequently listed in the Orange Book and therefore most likely did not receive a license as part of the settlement. *See id.* at 3–4.

171. The seventy-two percent figure represents the percentage of all settlements in which a reverse payment settlement could be inferred from the inauguration of the PTAB to the present. *Id.* at 21. To account for the time required for the FDA to approve a generic drug manufacturer's application, Hovenkamp and Lemus restricted their analysis further to settlements occurring prior to May 2015, and they concluded that the settlement rate was actually higher—seventy-eight percent. *Id.*

evaluated empirically and should be investigated further. A proposal for managing this potential effect is discussed further below.

4. More Favorable Evidentiary Presumption, Evidentiary Standard of Proof, Interpretive Standard, and Standard of Review

Other significant differences between proceedings before the PTAB and the federal district court are the more favorable evidentiary presumption, evidentiary standard of proof, interpretive standard for construing patent claims, and appellate standard of review that apply to PTAB proceedings.

Federal district courts are statutorily required to presume patents are valid.[172] Well-developed precedent construes this statutory requirement in such a way that a party challenging the validity of a patent claim must therefore establish that the patent claims are invalid by "clear and convincing evidence."[173] In contrast, in proceedings before the PTAB there is no presumption of validity, and accordingly, the applicable standard of proof a challenger must meet is only the "preponderance of the evidence" standard.[174] The preponderance of the evidence standard is substantially lower than the clear and convincing evidence standard.[175] What this means, as a practical matter, is that it is much easier for a challenger before the PTAB to establish that a patent claim is invalid than it is for a challenger before a federal district court.

In addition, federal district courts and the PTAB apply a different standard when interpreting patent claims. A federal district court interprets claims by giving them their "ordinary and customary meaning as understood by a person of ordinary skill in the art."[176] In contrast, the PTAB applies the "broadest reasonable construction" standard.[177] The ordinary and customary meaning standard is generally narrower than the broadest reasonable construction standard.

From a patent challenger's perspective, a broader interpretation is preferred. Dreyfuss notes, "The broader the claim, the more likely the challenger can find prior art to invalidate it on novelty or obviousness

172. 35 U.S.C. § 282(a).

173. *See, e.g.*, *In re* Baxter Int'l, 678 F.3d 1357, 1364 (Fed. Cir. 2012).

174. *Id.*

175. *Id.*

176. *See, e.g.*, Laryngeal Mask Co. v. Ambu, 618 F.3d 1367, 1369 (Fed. Cir. 2010) ("The words of a claim are generally given their ordinary and customary meaning as understood by a person of ordinary skill in the art in question at the time of the invention when read in the context of the specification and prosecution history."); Int'l Rectifier Corp. v. IXYS Corp., 361 F.3d 1363, 1370 (Fed. Cir. 2004) ("Absent an express intent to impart a novel meaning to a claim term, the words take on the ordinary and customary meanings attributed to them by those of ordinary skill in the art.").

177. *See generally* Cuozzo Speed Techs., LLC v. Lee, 136 S. Ct. 2131 (2016).

grounds, the more abstract it is likely to read, and the less likely it is to be fully supported by the written description, adequately enabled, and distinctly claimed."[178] The PTAB standard is therefore more likely to result in the patent claims being invalidated. Accordingly, the broadest reasonable construction standard and the IPR procedure favors patent challengers, such as ANDA filers.

Finally, both patent-related decisions by the federal district courts and decisions by the PTAB are appealed to the Federal Circuit. The Federal Circuit, however, applies a different standard of review, depending on the tribunal under review. When reviewing determinations by a federal district court, the Federal Circuit reviews issues of law de novo and issues of fact for clear error.[179] However, when reviewing determinations by the PTAB, although it similarly reviews issues of law de novo, it reviews issues of fact for "substantial evidence"—a more deferential standard of review than clear error.[180] This standard of review, in combination with the applicable evidentiary standard and standard for construing patent claims, means that not only is the PTAB more likely to find a patent claim invalid, that determination is more likely to be upheld on appeal to the Federal Circuit. All of these things taken together make the PTAB a more hospitable tribunal to patent challengers than a federal district court.

IV. THE MECHANICS: MAKING IT WORK

So how would an ANDA filer use the two proceedings together? There are at least a couple of things an ANDA filer should consider when trying to use an IPR procedure in tandem with district court litigation: the timing of initiating each and the collateral effects of a determination by the PTAB in the federal district court litigation.

A. Timing

One consideration of a potential ANDA filer should be when to initiate an IPR relative to filing an ANDA. A generic drug manufacturer wishing to file an ANDA and take advantage of the IPR procedure should first file an ANDA with a Paragraph IV certification with the FDA and then initiate an IPR with the PTAB. Filing an ANDA first is advisable for one primary reason. To the extent that only the first filer is entitled to the 180-day exclusivity period, as is provided for under the current statutory

178. Dreyfuss, *supra* note 156, at 254–55.

179. *See, e.g.*, Fresenius USA, Inc. v. Baxter Int'l, 582 F.3d 1288, 1294–95 (Fed. Cir. 2009).

180. *See In re* Baxter Int'l, 678 F.3d 1357, 1361 (Fed. Cir. 2010).

framework,[181] filing an ANDA first with the FDA would enable the applicant to secure the earliest possible filing date in the race to be first. In Part V below, I propose revising the Hatch-Waxman Act so that the 180-day exclusivity period is contestable and awarded, not to the first filer, but rather to the ANDA filer that first secures a determination that the patent claims are invalid (or not infringed).[182] Should the proposed revision (or one like it) be adopted, the filing date of an ANDA could nonetheless serve the important function of establishing priority in the event that two competing tribunals reached a determination on the same day.

Once the IPR is initiated, the generic drug manufacturer can benefit from the patent expertise of the PTAB, the narrow scope of IPR proceedings on issues of patent law,[183] and the one-year time limit for a determination by the PTAB,[184] all of which should yield a relatively speedy determination by the PTAB and almost definitely a better quality one.[185]

B. Collateral Effect of the PTAB's Determination

Assuming that the PTAB concludes that the patent claims are invalid, what is the collateral effect in the federal district court action?

Recall how the district court action arose. The brand-name drug manufacturer's patent infringement suit was precipitated by the generic drug manufacturer's ANDA containing a Paragraph IV certification.[186] An ANDA with a Paragraph IV certification entitles the patent owner to bring suit for patent infringement in federal district court. The ANDA filer is therefore a defendant in the district court action. The ANDA filer typically

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181. 21 U.S.C. § 355(j)(5)(B)(iv) (2012), *amended by* FDA Reauthorization Act of 2017, Pub. L. No. 11-52, 131 Stat. 1005 (2017).

182. *See infra* notes 219–238 and accompanying text.

183. For example, antitrust counterclaims are beyond the scope of the PTAB's jurisdiction. *See* 35 U.S.C. § 6(b) (defining the PTAB's duties).

184. *See id*. § 316(a)(11).

185. *See, e.g.*, *Judge Chen Stresses Importance of AIA*, AIPLA DAILY REP. (Oct. 25, 2014), http://www.managingip.com/pdfs/03-AIPLA-WashingtonDC-2014-sat.pdf ("Chen hopes that the PTAB proceedings will also be a tool to help improve USPTO practice overall."). Federal Circuit Judge Raymond Chen has explained:

> I foresee an opportunity for these board decisions to assist in a forward-looking way to improve patent quality. The patent board will be developing a large body of data that can perhaps yield patterns or insights for what went right, or what went wrong during the initial examination process. And the agency can use those lessons learned to improve patent examination. In the next few years, the patent board will have created a rich source of in-house generated material the agency can potentially use to further improve the quality of patent examination.

Dreyfuss, *supra* note 156, at 266 (quoting Tamlin Bason, *Judge Chen: Board Could Develop Rich Data Source That Will Help Improve Patent Quality*, 88 PAT. TRADEMARK & COPYRIGHT J. (BNA) 1676, 1676 (2014) (quoting Federal Circuit Judge Raymond T. Chen)).

186. 35 U.S.C. § 271(e)(2) (2012).

counterclaims, seeking declaratory relief that the patent claims are invalid.[187] There is therefore both a claim of infringement and a counterclaim of patent invalidity.

First, consider the patent owner's patent infringement suit against the ANDA filer. It is well established that, when a federal court makes a determination that a patent claim is invalid, non-mutual collateral estoppel prevents the patent owner from trying to enforce the same patent claims against another defendant.[188] There are differences, however, between a federal court's powers and the PTAB's powers that ultimately make non-mutual collateral estoppel inapplicable in this particular context.[189] Unlike a federal court, the PTAB has the authority to cancel patent claims that have been found invalid.[190] Once the PTAB cancels the claims, they no longer exist. Or, in the words of the Federal Circuit, canceled claims are "dead."[191]

Under Federal Circuit precedent, the patent owner likely no longer has a cause of action and any pending claims should be dismissed as moot.[192] At the time of this writing, the Federal Circuit has not directly addressed the collateral effects, in a pending district court action, of the PTO canceling patent claims after finding the claims invalid during an IPR procedure. However, in *Fresenius USA, Inc. v. Baxter International, Inc.*, the Federal Circuit considered a closely related issue.[193] Specifically, it considered the collateral effects on pending litigation of the PTO canceling patent claims after they were found invalid during a reexamination proceeding, another special procedure before the PTO.[194] Ultimately the

187. *See id.* § 355(c)(3)(D)(ii).

188. Blonder-Tongue Labs., Inc. v. Univ. of Illinois Found., 402 U.S. 313 (1971); *see also supra* notes 66–67, discussing *Blonder-Tongue*.

189. It should be noted that if the first ANDA filer seeks to have the district court take judicial notice after the PTAB determines that a patent claim is invalid but before that determination is upheld by the Federal Circuit resulting in the cancelation of the claims, *see supra* notes 153–160, then the doctrine of non-mutual collateral estoppel should preclude the brand-name drug manufacturer, plaintiff, from pursuing its infringement suit.

190. 35 U.S.C. § 318(b) (2012) ("If the Patent Trial and Appeal Board issues a final written decision under subsection (a) and the time for appeal has expired or any appeal has terminated, the Director shall issue and publish a certificate canceling any claim of the patent finally determined to be unpatentable . . . .").

191. *See* Fresenius USA, Inc. v. Baxter Int'l, Inc., 721 F.3d 1330, 1338 (Fed. Cir. 2013) (quoting Kaufman Co. v. Lantech, Inc., 807 F.2d 970, 976 (Fed. Cir. 1986)). The Federal Circuit's language, as initially used, related to patent claims that were canceled as a result of reexamination. *See id.* at 1336–38.

192. *See id.* at 1340, 1347 (concluding that a patent claim canceled as the result of a reexamination proceeding moots pending litigation).

193. *See id*. at 1332.

194. *See id.* The procedural posture of *Fresenius* was somewhat complicated. The federal district court had concluded that a patent owner's patent claims were not invalid and infringed, and accordingly, it awarded the patent owner millions of dollars in damages. *Id.* at 1332–33. The Federal Circuit affirmed the district court's determination that some of the patent claims were not invalid, but it

court concluded that the patent owner "no longer [had] a viable cause of action" and therefore the pending litigation was moot.[195] Nothing in the language or the legislative history of the statute relating to the IPR procedure suggests that claim cancelation during an IPR should not similarly moot any pending district court litigation.

Assuming the patent owner's claim for patent infringement becomes moot, the issue that arises is what happens to the ANDA filer's invalidity counterclaim. This question is not simply an interesting, hypothetical inquiry; the answer has important, practical consequences. As with the patent owner's claim for patent infringement, if the counterclaim is moot, the federal district court is divested of jurisdiction over the counterclaim.[196] The court then is powerless to enter an order finding the patent claims invalid.

Whether the court can enter such a judgment will determine whether the generic drug manufacturer can enter the market before the thirty-month stay expires. Again, recall that the brand-name drug manufacturer's patent infringement suit was precipitated by the generic drug manufacturer's ANDA containing a Paragraph IV certification.[197] In response to a patent owner's lawsuit, the FDA's approval of an ANDA is generally stayed for thirty months *or* until the district court enters a judgment that the patent claims are invalid or not infringed.[198] If the district court enters a judgment that the patent claims are invalid, FDA approval of the ANDA is effective upon final approval.[199] Thus, whether the generic drug manufacturer may enter the market sooner, rather than later; whether there is competition in the market sooner, rather than later; and whether consumers ultimately will benefit from lower prices sooner, rather than later, turns on whether the district court enters a judgment recognizing that the patent claims are invalid.

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remanded the case to the district court to reconsider a permanent injunction it had in place, as well as post-verdict damages. *Id.* at 1333. While the litigation was pending, the accused infringer requested ex parte reexamination of the patent claims that had not been invalidated, and "[t]he reexamination proceeded in parallel with the district court litigation." *Id.* at 1334. The PTO determined during the procedure that all the patent claims were invalid. *Id.* at 1334–35. The Federal Circuit affirmed the PTO's determination, which ultimately resulted in the cancelation of the patent claims. *See id.* at 1335. While this was going on, the federal district court entered a judgment against the accused infringer. *See id.* at 1336. Both parties appealed. *See id.* The issue presented to the Federal Circuit was whether the federal district court's judgment was sufficiently final, such that the intervening decision and cancelation of the patent claims by the PTO could not disturb the judgment, or whether instead it required the Federal Circuit to dismiss the cause of action. *See id.* at 1332, 1340–46.

195. *Id.* at 1347.

196. *See* Gen. Protecht Grp., Inc. v. Leviton Mfg. Co., Inc., No. CIV 10-1020 JB/LFG, 2012 WL 1684573, at *1 (D. N.M. May 12, 2012).

197. *See supra* notes 49–63 and accompanying text; 35 U.S.C. § 271(e)(2) (2012).

198. *See supra* notes 59–63 and accompanying text; 21 U.S.C. § 355(j)(5)(B)(iii) (2012), *amended by* FDA Reauthorization Act of 2017, Pub. L. No. 11-52, 131 Stat. 1005 (2017).

199. *See* 21 U.S.C. § 355(j)(5)(B)(iv)(II)(dd); 21 C.F.R. 314.107(b)(3)(v) (2017).

It is not entirely clear whether a counterclaim seeking declaratory relief that certain patent claims are invalid becomes moot upon the cancelation of those very same patent claims. At the time of this writing, no court has considered this specific issue, and a few considerations point in opposing directions. On the one hand, it would seem that if the patent claims are dead, then a federal court is without power to offer any relief to an ANDA filer seeking a declaration that the patent claims are invalid. As a matter of simple logic, it would seem that patent claims that do not exist cannot be declared invalid. There is nothing for the court to invalidate. Therefore, the argument would go, upon the cancelation of the patent claims, the federal court is divested of jurisdiction.[200]

On the other hand, this may be an oversimplification that does not account for practical realities. The PTO's cancelation of the patent claims does not automatically extinguish the rights attendant with those patent claims. While the Patent Act grants patent owners certain exclusive rights, the Hatch-Waxman Act grants innovators other exclusive rights. For example, under the Hatch-Waxman Act, if an already-approved drug is a new chemical entity—i.e., a drug that contains no active ingredient previously approved by the FDA—then a generic drug manufacturer is not permitted to submit an ANDA with a Paragraph IV certification before four years after the brand-name drug manufacturer's application has been approved.[201] Because a generic drug manufacturer cannot market a generic version without filing an ANDA and receiving FDA approval, this waiting period grants a period of market exclusivity to the patent owner that the Patent Act alone does not. To be sure, not all ANDAs will reference a new chemical entity. But the example underscores the fact that the need to seek and obtain FDA approval serves as a barrier to generic entry which ultimately can supplement the brand-name drug manufacturer's period of exclusivity. Thus, although the patent claims themselves may be "dead," the ability of others to be excluded from the market does not die with the claims.

Mootness doctrine accounts for such realities. Supreme Court precedent suggests that a case does not become moot when the collateral effects of a dispute will continue to affect the parties and their relationship.[202] If the parties retain "a concrete interest in the outcome of

200. *See, e.g.*, Super Sack Mfg. Corp. v. Chase Packaging Corp., 57 F.3d 1054, 1060 (Fed. Cir. 1995) (noting that subsequent events can divest the court of jurisdiction), *abrogation recognized by* Cat Tech LLC v. Tubemaster, Inc., 528 F.3d 871 (Fed. Cir. 2008).

201. *See* 21 U.S.C. § 355(j)(5)(F)(ii).

202. *See, e.g.*, Sosna v. Iowa, 419 U.S. 393, 402 (1975) (describing the constitutional mootness question as whether "a live controversy [remains] at the time this Court reviews the case"); Super Tire Eng'g Co. v. McCorkle, 416 U.S. 115, 122 (1974) ("[T]he parties to the principal controversy . . . may still retain sufficient interests and injury as to justify the award of declaratory relief."); *see also* Firefighters Local Union No. 1784 v. Stotts, 467 U.S. 561, 585 (1984) (O'Connor, J., concurring)

the litigation," then the federal court can maintain jurisdiction and resolve the matter.[203] With respect to the patent owner's patent infringement claim, there are no collateral effects of the litigation that turn on whether the court continues to maintain jurisdiction over, and make determinations relating to, the claim. In contrast, whether the ANDA filer can enter the market before the expiration of the thirty-month stay hinges on whether the court can enter a judgment that the patent claims are invalid.[204]

The Supreme Court has not specifically considered whether cancelation of patent claims moots a counterclaim seeking a declaration that those very same patent claims are invalid. It has, however, considered a somewhat related issue. In *Cardinal Chemical Co. v. Morton International, Inc.*, the Court considered the Federal Circuit's routine practice of vacating as moot declaratory judgments invalidating patent claims if the district court had additionally determined that the underlying patent claims were not infringed.[205] As the Court explained, the issue before the Court was therefore related to the appellate court's jurisdiction:

> Under its current practice, the Federal Circuit uniformly declares that the issue of patent validity is "moot" if it affirms the District Court's finding of noninfringement and if, as in the usual case, the dispute between the parties does not extend beyond the patentee's particular claim of infringement. That practice, and the issue before us, therefore concern the jurisdiction of an intermediate appellate court—not the jurisdiction of either a trial court or this Court.[206]

Ultimately, the Court concluded that although the Federal Circuit might have valid reasons for its practice, it was not compelled by the "case or controversy" requirement of Article III of the Constitution.[207] In reaching its decision about the appellate court's jurisdiction, the Court also discussed the trial court's jurisdiction over the declaratory judgment action in the first instance. The Court noted that "a party seeking a declaratory judgment has the burden of establishing the existence of an actual case or controversy" and that "a party may satisfy that burden . . . even if the patentee has not filed an infringement action."[208] *Cardinal Chemical* therefore supports the

("When collateral effects of a dispute remain and continue to affect the relationship of litigants, the case is not moot." (footnote omitted)).

203. *Firefighters Local Union No. 1784*, 467 U.S. at 571.

204. *See* 21 U.S.C. § 355(c)(3)(C).

205. 508 U.S. 83, 86 (1993).

206. *Id.* at 95.

207. *Id.* at 99; *see also id.* at 98 ("[I]t is clear that the Federal Circuit had jurisdiction to review the declaratory judgment of invalidity. The case did not become moot when that court affirmed the finding of noninfringement.").

208. *Id.* at 95.

proposition that whether a claim seeking declaratory relief that a patent claim is invalid presents an actual case or controversy is independent from whether a claim for patent infringement presents a case or controversy.[209] And as discussed above, because a generic drug manufacturer's FDA approval and ability to enter the market turns on whether the federal district court enters a judgment, it would seem that the district court can, consistent with Article III of the Constitution, continue to maintain jurisdiction.

Assuming, then, that the ANDA filer's counterclaim is not moot and the federal district court continues to maintain jurisdiction, the court can then take judicial notice[210] of the PTAB's determination and enter a judgment that the patent claims are invalid, thereby making a full-blown, costly, and time-consuming patent infringement suit before the federal district court unnecessary. If the generic drug manufacturer was the first ANDA filer, the speedier federal district court determination will result in earlier effective approval by the FDA,[211] earlier triggering of the 180-day exclusivity period, and earlier entry by the generic drug manufacturer.[212]

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209. The Supreme Court's recent decision in *Commil USA, LLC v. Cisco Sys., Inc.*, 135 S. Ct. 1920 (2014), similarly suggests that whether a patent infringement suit is moot is independent from whether a counterclaim seeking declaratory relief that patent claims are invalid is moot, although it does not squarely consider the effect of canceling patent claims. *Commil* recognized that although patent infringement and patent validity often arise in the same case and seem to be two sides of the same coin, they are separate issues. The plaintiff–appellant in *Commil* brought suit against defendant-appellee claiming defendant–appellee had directly infringed its patent claims and had additionally induced others to infringe. *Id.* at 1924. An essential element of induced infringement is the requisite scienter, specifically knowledge that the induced acts constitute patent infringement. *Id.* at 1928. Defendant–appellee raised the defense that it "had a good-faith belief" that plaintiff–appellant's patent claims were invalid and therefore it did not possess the requisite scienter, but the district court found defendant's supporting evidence inadmissible. *Id.* at 1924. The issue before the Court was whether the district court had erred in excluding defendant's evidence. *Id.* at 1925. The Court concluded that defendant's good-faith belief of invalidity was irrelevant to the question of patent infringement, explaining "because infringement and validity are separate issues under the [Patent] Act, belief regarding validity cannot negate the scienter required . . . . When infringement is the issue, the validity of the patent is not the question to be confronted." *Id.* at 1928. *But see id.* at 1931 (Scalia, J., dissenting) (stating that "only valid patents can be infringed" and concluding that "anyone with a good-faith belief in a patent's *in*validity necessarily believes the patent *cannot* be infringed"). *Commil* could therefore be read as lending support to the idea that whether the PTAB's cancelation of patent claims moots a patent infringement claim is a separate issue from whether it moots a counterclaim seeking declaratory relief of invalidity.

210. *See* FED. R. EVID. 201(b)(2) ("The court may judicially notice a fact that is not subject to reasonable dispute because . . . it can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned.").

211. FDA approval of an ANDA with a Paragraph IV certification is subject to a thirty-month stay from the time the patent owner receives notice of the ANDA, *see supra* notes 59–63 and accompanying text, unless the district court makes a determination that the patent is invalid or not infringed before the expiration of the thirty-month period. In that case, FDA approval is made effective on the date the court enters judgment. 21 U.S.C. § 355(j)(5)(B)(iii)(I)(aa).

212. *See* 21 U.S.C. § 355(j)(5)(B)(iv). To be sure, there are some cases that are exceptions and are treated differently under the regulatory framework. The Hatch-Waxman Act provides for extra-patent exclusivity when a drug covers a new chemical entity. It does this by making an ANDA filer with a Paragraph IV certification that seeks to challenge a patent covering a new chemical entity wait four years from the date the brand-named drug manufacturer's NDA is approved. *See id.*

If the district court determines that it cannot maintain jurisdiction over the counterclaim, the ANDA filer may have other options. One possibility is that, assuming the federal district court dismisses the case on mootness grounds, the FDA could treat the thirty-month stay as dissolved,[213] thereby enabling the generic drug manufacturer's ANDA to become immediately effective. Another possibility is that the ANDA filer could seek to have the district court dissolve the thirty-month stay on the grounds that the underlying patent infringement suit is moot. It is questionable, however, whether the district court actually possesses the authority to do so. The text of the statute only permits the district court to shorten the thirty-month stay if one of the parties "fail[s] to reasonably cooperate in expediting the action."[214] And although district courts always possess the inherent power to manage their own cases and affairs,[215] the thirty-month stay is not actually a "stay" imposed by the district court, despite the fact that it is commonly referenced as such. It may be more appropriate to refer to it as a statutorily-imposed "waiting period" for approval of an ANDA, and the

§ 355(j)(5)(F)(ii). In addition, regardless of how speedy the district court makes a determination, FDA approval cannot be made effective before seven-and-a-half years from the date the brand-name drug manufacturer's NDA was approved. *See id.* In these instances, the IPR procedure may have little effect on the timing of generic entry.

Consider the scenario in which a hopeful ANDA filer with a Paragraph IV certification seeks to challenge a patent covering a new chemical entity: During the four-year waiting period, the generic drug manufacturer can initiate an IPR. Based on the statutorily defined deadlines, the IPR can be completed within eighteen months. *See supra* note 150. Assuming the generic drug manufacturer obtains a determination from the PTAB that the patent claims are invalid, the brand-name drug manufacturer would then be entitled to appeal the PTAB's decision to the Federal Circuit. *See* 35 U.S.C. §§ 141, 144, 319 (2012). The median time for the Federal Circuit to dispose of a case originating from the PTO is ten months. U.S. CT. OF APPEALS FOR THE FED. CIR., MEDIAN TIME TO DISPOSITION IN CASES TERMINATED AFTER HEARING OR SUBMISSION (2015), http://www.cafc.uscourts.gov/sites/default/files/the-court/statistics/FY16_Median_Disposition_Time_for_Cases_Terminated_after_Hearing_or_Submission_Detailed_Table_of_Data_2.pdf. Assuming the Federal Circuit upholds the PTAB's determination, the PTAB would be authorized to cancel the invalid patent claims approximately twenty-eight months after the IPR was initiated. Whether the generic drug manufacturer would be permitted immediately to file an ANDA would depend on how much time had passed since the brand-name drug manufacturer's NDA had been approved. If four years had not passed—for example, because the generic drug manufacturer initiated an IPR nine months after the underlying patent had been issued, so that only thirty-seven months total had passed since the NDA had been approved—the generic drug manufacturer would have to wait. But even if it did not have to wait, having a determination from the PTAB can only short-circuit the thirty-month stay insofar as the statutory stay would delay FDA approval beyond the seven and one-half years of extra-patent exclusivity the Hatch-Waxman scheme grants to new chemical entities. In other words, a quicker determination can effect quicker FDA approval only if it was otherwise going to take longer than seven and one-half years. *See* 21 U.S.C. § 355(j)(5)(F)(ii).

213. *See, e.g.*, Merck & Co., Inc. v. Apotex, Inc., 287 Fed. App'x 884, 888 (Fed. Cir. 2008).

214. 21 U.S.C. § 355(j)(5)(B)(iii).

215. *See, e.g.*, Dietz v. Bouldin, 136 S. Ct. 1885, 1891 (2016) ("[T]his Court has long recognized that a district court possesses inherent powers that are 'governed not by rule or statute but by the control necessarily vested in courts to manage their own affairs so as to achieve the orderly and expeditious disposition of cases.'" (quoting Link v. Wabash R.R. Co., 370 U.S. 626, 630–31 (1962)).

district court may be without authority to circumvent the plain language of the statute.

The above discussion assumes that the ANDA filer that initiated the IPR procedure before the PTAB and the defendant in the parallel district court patent litigation are the same party. But what if that is not the case, or at least, does not fully describe the case? What if there are two patent infringement suits in federal district court, one against a first ANDA filer and a second against the subsequent ANDA filer, and the IPR procedure is initiated by the subsequent ANDA filer? The collateral effects in the parallel litigation are generally the same, but the practical consequences may be very different. If the subsequent ANDA filer secures a determination by the PTAB that the patent owner's patent claims are invalid and the PTO accordingly cancels the claims, both patent infringement suits—i.e., both the suit against the first ANDA filer and the suit against the subsequent ANDA filer—become moot.[216] Likewise, the counterclaims seeking a declaration that the patent claims are invalid should be similarly resolved (barring any material factual differences or differences in the lower courts' resolution of the mootness issue). Assuming that both lower courts determine that the counterclaim is not moot, both may take judicial notice of the PTAB's determination and the cancelation of the claims, and both can enter a judgment finding the patent claims invalid.

Where the difference lies is in which ANDA filer may enter the market first. Under the present version of the Hatch-Waxman Act, although the subsequent ANDA filer may secure a determination invalidating the patent claims before the first ANDA filer, the 180-day exclusivity period is nonetheless reserved only for the first ANDA filer. In Part V.B, I propose that the Hatch-Waxman Act be revised so that the 180-day exclusivity period is reserved for the ANDA filer that first secures a determination that the patent claims are invalid.

V. PROPOSAL FOR A NEW SORT OF COMPETITION

To better discourage settlement and to harmonize the changes to the patent laws with the Hatch-Waxman regulatory scheme, I make three proposals.

A. A New PTO Rule

First, because of the anticompetitive effects of settling, the PTO should seize the opportunity and issue a rule that interprets its authority to

216. *See* Morton Int'l, Inc. v. Cardinal Chem. Co., 967 F.2d 1571, 1575 (Fed. Cir. 1992).

continue the proceedings in such a way that will discourage settling. One possibility is for the PTO to issue a rule that requires the PTAB to issue a final written decision whenever the patent claims at issue are also the subject of district court litigation precipitated by an ANDA.

The relevant statute unequivocally grants the PTO the authority to proceed to a final written decision, even if the parties settle.[217] And the PTO has the authority to specify that it always do so in a specific subset of cases.[218]

Unlike federal courts, administrative tribunals are not bound by the Article III requirement of a case or controversy.[219] Agencies have both rule-making and adjudicatory powers.[220] While an agency's rule-making authority enables it to make new law prospectively, this does not preclude an agency from formulating new law through ad hoc adjudication.[221] Therefore, the AIA's statutory grant of authority to the PTO to issue a final written decision even if the parties have settled[222] presents no constitutional difficulty.

There are a few potential criticisms of this proposal. First, requiring the PTAB to issue a final written decision regardless of whether the parties settle may have the unintended consequence of discouraging the use of the IPR procedure. ANDA filers and brand-name manufacturers both benefit from settlement. If the proposed rule has the intended consequence of discouraging a brand-name drug manufacturer from settling, the ANDA filer, knowing it faces a lower likelihood of settlement, may be discouraged from initiating the IPR proceeding in the first place. The proposal discussed in Part V.B, below, aims to counteract this possible effect and maintain an ANDA filer's incentives to challenge weak patents.

Second, it is possible for petitioners and patent owners to avoid the impact of my proposal by settling an IPR after a petitioner files a petition but *before* the Director institutes an IPR. The statute granting the PTAB the authority to continue the proceedings and issue a final written decision, even if the parties settle, only grants such authority "[i]f an inter partes review is *instituted*."[223] To avoid having the PTAB exercise its authority, the parties could essentially accelerate their settlement so it occurs before an IPR is ever instituted. Making the 180-day exclusivity period contestable, as my proposal in Part V.B suggests, should deter this

217. 35 U.S.C. § 317(a) (2012).

218. *See* Heckler v. Campbell, 461 U.S. 458, 467 (1983) (holding that the Secretary of Health and Human Services may rely on rulemaking to resolve a certain class of issues).

219. *See* U.S. CONST. art. III, § 1.

220. 5 U.S.C. §§ 553, 554 (2012).

221. *See* SEC v. Chenery Corp., 332 U.S. 194, 202–03 (1947).

222. 35 U.S.C. § 317(a) (inter partes review); 35 U.S.C. § 327(a) (post-grant review).

223. 35 U.S.C. § 318(a) (emphasis added).

gamesmanship. If the 180-day exclusivity period can be awarded to *any* ANDA filer—not just the first—then there is nothing stopping a second, third, fourth, and so on filer from challenging the brand-name drug manufacturer's patent claims in hope of receiving the exclusivity period. A patent owner that settles early sends a signal to other ANDA filers and petitioners about both the patent owner's belief about the strength of its patent claims (or the strength of its determination to avoid the risk of invalidation), and its willingness to offer a settlement. This will only further encourage challenges to its patent claims. The patent owner may therefore be presented with a long line of challengers, all of with whom the patent owner will have to settle, and settle early, in order to avoid the risk of patent claim invalidation. At some point, it simply will not be worth it for the brand-name drug manufacturer to settle. The location of that point is an empirical question that will depend, at least in part, on how deep the brand-name drug manufacturer's pockets are.

Third, a rule requiring the PTAB to continue the proceedings and issue a final written decision—especially in cases that will ultimately result in the cancelation of patent claims—may only reinforce the PTAB's reputation as the "death squad."[224] But the primary purpose of the AIA is to "improve patent quality,"[225] and one obvious way for the PTO to achieve this purpose is to cancel weak patents that should not have been granted in the first place. Moreover, canceling such patents would be in the public interest for a number of reasons discussed above. The moniker, though perhaps not good for public relations, may be a small price for the PTO to pay for improving patent quality and consumer welfare.

B. Enable the 180-Day Exclusivity Period To Be Contestable

To further encourage the invalidation of weak patents, and as a complement to the proposal discussed in Part V.A, I propose that the 180-day exclusivity period be contestable, such that it be awarded to the ANDA filer that first secures a determination that the patent claims are invalid (or not infringed). Making the 180-day exclusivity period contestable should incentivize ANDA filers to secure a determination in two respects. First, a contestable 180-day period encourages both first ANDA filers and subsequent ANDA filers alike to secure a determination that the patent

224. The PTAB's characterization as a "death squad" originates from a remark made by Chief Judge Randall Rader before the American Intellectual Property Law Association in October 2013. *See* Mike Masnick, *Chief Judge of Patent Court Compares Killing Bad Patents to Genocide*, TECH DIRT (Oct. 31, 2013, 1:35 P.M.), https://www.techdirt.com/articles/20131029/16462825058/chief-judge-patent-court-compares-killing-bad-patents-to-genocide.shtml.

225. H.R. REP. NO. 112-98, pt. 1, at 39-40 (2011). *See* Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 6, 125 Stat. 284 (2011).

claims are invalid (or not infringed). A contestable exclusivity period means that a first filer cannot, by settling, simply preserve the exclusivity period for some later, undefined time. If a first ANDA filer does not secure a determination that the patent claims are invalid (or not infringed), it has no right to the exclusivity period. And unlike the present statutory scheme, which enables a first ANDA filer that settles to prevent others from being awarded the exclusivity period,[226] a contestable period deprives a first filer of this "blocking" power.

Indeed, a contestable period actually encourages subsequent ANDA filers by overcoming the free-rider problem such a filer faces. The present version of the statute rewards only the first filer with the 180-day exclusivity period.[227] A subsequent ANDA filer that secures a determination that the patent owner's patent claims are invalid (or not infringed) receives no similar incentive. It must first wait for the expiration of the first filer's 180-day exclusivity period before it can enter the market.[228] This is so even if the first ANDA filer settled, because in that case, the forfeiture provisions are not "triggered" until the subsequent filer secures a determination.[229] Once the 180-day period expires, the subsequent ANDA filer can enter the market.[230] But so too can all other subsequent ANDA filers. A determination that the patent claims are invalid will collaterally estop the patent owner from enforcing its patents against *any* subsequent filer. Therefore, any federal district court presiding over a patent infringement suit involving the same patent claims and precipitated by a subsequent ANDA filer can enter a judgment finding the patent claims invalid, thereby making the patent challenger's ANDA immediately effective.[231] As a result, a number of generic drug manufacturers may be permitted to enter the market at about the same time—i.e., when the first ANDA filer's 180-day exclusivity period expires. The subsequent ANDA filer that first secured the invalidity (or noninfringement) determination that then enters the market may very well be presented with a very crowded market. Its expected profits will undoubtedly be significantly smaller than a first ANDA filer competing during the 180-day exclusivity period. The reward for successfully challenging the brand-name drug manufacturer's patent claims may therefore not be sufficiently large to incentivize the subsequent ANDA filer to take the risk of litigating its case to a judgment.

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226. 21 U.S.C. § 355(j)(5)(B)(iv) (2012), *amended by* FDA Reauthorization Act of 2017, Pub. L. No. 11-52, 131 Stat. 1005 (2017).

227. *See id*.

228. *See id*.

229. *See id*. § 355(j)(5)(A).

230. *Id*. § 355(j)(5)(D)(iii); *see also id*. § 355(j)(5)(D)(i)(VI).

231. *See, e.g.*, Abbott Labs. v. Mylan Pharms., Inc., 37 F. Supp. 2d 1076, 1078 (N.D. Ill. 1999), *aff'd*, 217 F.3d 853 (Fed. Cir. 1999).

Making a subsequent ANDA filer eligible for the exclusivity period, as my proposal does, provides a considerable incentive—the same incentive a first filer has under the present version of the law—and overcomes this free-rider problem.

By making the exclusivity period awardable to the ANDA filer that first secures a determination, it encourages an ANDA filer to use the faster IPR procedure before the PTAB. If the proposal outlined in Part V.A works as intended, an ANDA filer that initiates an IPR procedure will be less likely to extract a settlement bounty from the brand-name drug manufacturer. The ANDA filer may, in turn, be discouraged from initiating an IPR procedure at all. It may prefer instead to challenge the brand-name drug manufacturer's patent claims solely in federal district court. Enabling the 180-day exclusivity period to be contestable is intended to offset this effect and maintain the ANDA filer's incentive to use the IPR procedure.

It is worth noting that even if Congress were to adopt my proposal and make the 180-day exclusivity period contestable, without more, the 180-day period is still vulnerable to manipulation. A generic drug manufacturer could invalidate the brand-name drug manufacturer's patent claims and settle afterwards, agreeing not to enter the market in exchange for a payment. A refinement to the proposal would make clear that the 180-day period would expire 180 days after the generic drug manufacturer entered the market, as long as the manufacturer entered within a designated amount of time, for example, seventy-five days. If the manufacturer did not enter the market within the designated time, then the 180-day exclusivity period would expire immediately upon the expiration of the seventy-five-day period.

Prior to the Supreme Court's decision in *Actavis* and the creation of the new procedures before the PTAB, Hemphill and Lemley proposed a similar change. They proposed that the first generic drug manufacturer be entitled to the 180-day exclusivity period only if it "earned it" by defeating the patent owner, whether by invaliding the patent claims or proving it did not infringe; obtaining a settlement that permitted immediate entry; or being otherwise immediately able to enter the market because the patent holder did not sue for infringement.[232] Hemphill and Lemley's rationale for designing the reward of the exclusivity period in this way is that "legal exclusivity ought to be doled out only where it can be expected to induce desirable behavior."[233]

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232. Hemphill & Lemley, *supra* note 9, at 949. Hemphill and Lemley suggested that their proposal could be easily implemented by the FDA interpreting the Hatch-Waxman Act in a manner similar to the way it interpreted the Act under different statutory language, by the FTC exercising its enforcement powers, or by statutory amendment. *See id.* at 950.

233. *Id.* at 954.

Hemphill and Lemley's proposal goes far in discouraging settlement between brand-name drug manufacturers and first ANDA filers and encouraging generic entry. Their proposal achieves the objective of *not* rewarding a first ANDA filer with a period of exclusivity unless its challenge effectively enables immediate entry. In this respect, my contestability proposal is similar—it too does not reward a first filer with a period of exclusivity unless its challenge effectively enables immediate entry. My contestability proposal goes further, however, requiring both entry *and* a determination of invalidity or noninfringement. In the case where a patent claim is invalidated, this has the additional benefit of clearing out bad patents and preventing them from deterring future innovation.

One effect of their proposal that is not entirely clear is the extent to which it would incentivize first filers to actually pursue their case to a determination. Under the Hatch-Waxman regulatory scheme as it presently stands, a first ANDA filer can receive both a settlement award *and* the 180-day exclusivity period. Hemphill and Lemley's proposal addresses only the exclusivity period. It is possible, however, that the settlement award alone is sufficient to encourage many to settle. This may be so where the brand-name drug manufacturer's supracompetitive profits are sufficiently large, such that the brand-name drug manufacturer can offer the first ANDA filer a settlement amount equal to the duopoly profits the first filer would have received during the 180-day exclusivity period, discounted by the probability the first filer would have lost its suit.[234]

Since Hemphill and Lemley offered their proposal, the Supreme Court decided *Actavis*, which makes such settlement agreements suspicious under the antitrust laws. But as discussed above, one of the consequences of *Actavis* may be that settlement agreements are now more complicated. As a result, it can be difficult to value the consideration flowing from the brand-name drug manufacturer to the first filer; anticompetitive settlements are therefore still possible. In short, Hemphill and Lemley's proposal removes one carrot motivating settlement, but another, potentially larger one remains.

My two proposals are meant to work together to take advantage of the opportunities presented by the recent changes to the patent laws and to minimize both carrots motivating settlement—both the settlement award, by making settlement less valuable to the patent owner whose patent claims

234. Hemphill & Lemley, *supra* note 9. Hemphill and Lemley recognize the fact that a brand-name drug manufacturer may simply pay a generic drug manufacturer more to settle. They contend, however, that their proposal narrows the range of feasible settlements, which should result in fewer settled cases. *Id.* at 977 ("And while some patentees may simply pay the generic more to compensate for the loss of exclusivity, in equilibrium the narrowed range of feasible settlements means that fewer cases will settle." (internal footnote omitted)).

can still be invalidated, and the prospect of the 180-day exclusivity period, by making it contestable and therefore potentially losable.

C. Harmonize Changes to the Patent Laws with the Hatch-Waxman Act

My third proposal is to harmonize the recent changes to the patent laws with the Hatch-Waxman regulatory scheme. A number of events outlined in the statute rely on conduct of the "district court." For example, "if before the expiration of [the thirty-month stay] the district court decides that the patent is invalid or not infringed," then FDA "approval shall be made effective on . . . the date on which the court enters judgment reflecting the decision."[235] It is the district court entering a judgment that triggers the ANDA filer's FDA approval.

The AIA created new procedures, including the IPR procedure, that enable the PTO to invalidate and cancel patent claims. As discussed above, the IPR procedure is faster and therefore has the potential to enable faster generic entry.[236] However, because the PTO is not a "district court," under a plain reading of the statute, invalidation and cancelation by the PTO does not similarly enable immediate FDA approval of a generic drug manufacturer's ANDA. Therefore, assuming the ANDA filer is also engaged in parallel litigation before the district court, if it is successful before the PTO, it must go back to the district court, ask the district court to take judicial notice of the PTO's decision, and have the district court enter a judgment that will enable the ANDA filer's FDA approval to be immediately effective. The ANDA filer may additionally have to defend against an argument that its counterclaim before the district court is moot.[237] Requiring an ANDA filer to navigate these maneuvers is terribly inefficient. Moreover, it is contrary to the purposes of both the Hatch-Waxman Act and the AIA—the former of which was to make it easier for generics to challenge weak patent claims and enter the market, the latter of which was to improve patent quality.[238] Requiring the ANDA filer to engage in these tactics only delays entry by generic drug manufacturers or, worse yet, risks preventing entry altogether if the federal suit is dismissed as moot even after the patent claims have been invalidated. This risk, in turn, may deter use of the procedure. Generic drug manufacturers, as well as the public, would consequently be deprived of the chance to have the PTAB, with all its expertise, consider the validity of the underlying patent

235. 21 U.S.C. § 355(j)(5)(B)(iii)(I) (2012), *amended by* FDA Reauthorization Act of 2017, Pub. L. No. 11-52, 131 Stat. 1005 (2017).

236. *See supra* notes 150–152 and accompanying text.

237. *See* Morton Int'l, Inc. v. Cardinal Chem. Co., 967 F.2d 1571, 1575 (Fed. Cir. 1992).

238. *See supra* note 225 and accompanying text.

claims. To better align the purposes of both the Hatch-Waxman Act and the AIA, the Hatch-Waxman Act should be amended so that, regardless of whether a patent claim is invalidated by a federal district court or the PTAB, the effect is the same—the FDA is no longer precluded from granting final approval. This will clear the way for the generic drug manufacturers to enter the market.

CONCLUSION

The IPR procedure is only in the early stages of use by litigants. One of the purposes of this Article is to outline how the IPR procedure could be used strategically in tandem with district court litigation to effect earlier entry by generic drug manufacturers. I also aimed to go further and propose improvements so that the Hatch-Waxman Act and the provisions of the AIA dealing with the IPR procedure could better work together and fully achieve their purposes. My proposals, if adopted, have the potential to discourage reverse payment settlements, as well as to better incentivize generic drug manufacturers to invalidate weak patents and to do so more expeditiously. In sum, my proposals aim to bring forth a new sort of competition.

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