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## Patent Punting: How FDA and Antitrust Courts Undermine the Hatch-Waxman Act to Avoid Dealing with Patents


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# PATENT PUNTING: HOW FDA AND ANTITRUST COURTS UNDERMINE THE HATCH-WAXMAN ACT TO AVOID DEALING WITH PATENTS

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## ABSTRACT

*Under the Hatch-Waxman Act, patent law and FDA regulation work together to determine the timing of generic entry in the market for drugs. But FDA has sought to avoid any responsibility for reading patents, insisting that its role in administering the patent provisions of the Hatch-Waxman Act is purely ministerial. This gap in regulatory oversight has allowed innovators to use irrelevant patents to defer generic competition. Meanwhile, patent litigation has set the stage for anticompetitive settlements rather than adjudication of the patent issues in the courts. As these settlements have provoked antitrust litigation, antitrust courts have proven no more willing than FDA to address the merits of the underlying patent infringement actions, preferring to rely on misleading proxies such as the existence of a “reverse payment” in the settlement agreement.*

*Antitrust litigation is, at best, a belated and awkward mechanism for correcting the effects of improperly delayed generic entry. But FDA is well-positioned to make timely determinations of which patents meet the statutory criteria for deferring generic entry. With proper staffing and resources, FDA could use its expertise in drug regulation to make rough assessments of the relationship between particular patents and the scope of FDA approval in NDAs and ANDAs quickly and cheaply, while leaving patent infringement remedies intact. Only those patents*

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that FDA decides could reasonably be asserted against an unauthorized generic would lead FDA to stay approval of the generic pending litigation of the infringement action. The result would be a reduction in incentives to pursue dubious patent infringement claims, with a corresponding reduction in opportunities for anti-competitive settlements.

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## INTRODUCTION

A major challenge for any patent system is the difficulty of determining the validity and scope of patent rights. Within the core of the patent system, it may be possible to use skilled experts to examine patent applications and to adjudicate disputes.<sup>1</sup> But ideally, the patent system should also convey

1. Many legal systems throughout the world use specialized tribunals for patent cases. See INT'L INTELLECTUAL PROP. INST. & U.S. PATENT & TRADEMARK OFFICE, STUDY ON SPECIALIZED INTELLECTUAL PROPERTY COURTS (2012), available at <http://iipi.org/wp-content/uploads/2012/05/Study-on-Specialized-IPR-Courts.pdf> (last visited Jan. 25, 2015). In the U.S., intermediate appellate jurisdiction over patent disputes has been consolidated since 1983 in the semi-specialized Court of Appeals for the Federal Circuit ("the Federal Circuit"), created by Congress under the Federal Courts Improvement Act of 1982, Pub. L. No. 97-164, 96 Stat. 25 (codified as amended in scattered sections of 28 U.S.C.). The Federal Circuit has jurisdiction over appeals from decisions of the U.S. Patent & Trademark Office, appeals from decisions of U.S. District Courts in patent cases, and appeals from decisions in the U.S. Court of Claims. The substantial patent docket of the Federal Circuit gives its judges considerable experience with patent cases and familiarity with patent law. Many disputed patent issues turn on case-specific technological questions that might be more effectively handled by providing expertise at the trial court level. See John B. Pegram, *Should There Be a U.S. Trial Court with Speciali-*

information about what it protects to a larger universe of people and institutions that create, disseminate, purchase, utilize, invest in, and regulate new technologies.<sup>2</sup> When these actors make decisions in ignorance, error, or uncertainty about the protections and limitations of patents, the balance between patent protection and free access to unpatented and unpatentable technology is distorted. The more complex the rules and the more uncertain their application, the less effectively they can guide decisions and motivate behavior.

Uncertainty about the scope of patent protection may create challenges in other parts of the legal system. How do regulators and tribunals charged with administering other legal regimes that interact with the patent system handle the complexities of patent law? Are they able to summon the resources and expertise they need to make informed and timely decisions?

In at least one context—regulation of the entry of generic versions of patented drugs—regulators and judges have unapologetically punted on patent issues, relying on broad default rules, deference to interested parties, and other flawed proxies to avoid engaging patent issues on the merits. The validity and scope of drug patents have an important bearing on two types of recurring legal decisions: the timing of U.S. Food and Drug Administration (FDA) approval of generic drug products and the antitrust treatment of settlements of related patent infringement litigation between patent holders and generic competitors. Neither FDA nor the antitrust courts want any part of the job of evaluating patents and comparing them to the scope of regulatory approval to determine whether they are relevant to the issues before them and whether the patents are valid and infringed. The result has been costly delays and obfuscation of the legal issues.

FDA has long sought to minimize its responsibility to administer the patent provisions of the Drug Price Competition and Patent Term Restora-

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*zation in Patent Litigation?*, 82 J. PAT. & TRADEMARK OFF. SOC'Y 765, 788–89 (2000). Some District Courts see more patent litigation than others, giving their judges more experience handling patent cases over time. Kimberly A. Moore, *Forum Shopping in Patent Cases: Does Geographic Choice Affect Innovation?* 83 J. PAT. & TRADEMARK OFF. SOC'Y 558 (2001) (finding that 44% of all patent cases are concentrated in 10 out of 94 U.S. District Courts); cf. Jeanne C. Fromer, *Patentography*, 85 N.Y.U. L. REV. 1444 (2010) (arguing that restricting venue in patent infringement litigation to the place of business of a defendant would improve judicial decision-making in patent cases). Recently Congress established a ten-year pilot program to allow certain judges within 14 U.S. District Courts to hear patent cases that other judges on the same bench decline. Patent Cases Pilot Program, Pub. L. No. 111-349, 124 Stat. 3674 (2011). These measures make it less likely that the judges who preside over patent litigation will be averse to that task or inexperienced in patent cases. For an example of such aversion, see *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013) (Scalia, J., concurring).

2. For a critique of the patent system as failing to provide effective notice of the boundaries of the rights it creates, see JAMES BESSEN & MICHAEL J. MEURER, *PATENT FAILURE: HOW JUDGES, BUREAUCRATS AND LAWYERS PUT INNOVATORS AT RISK* (2009).

tion Act of 1984, commonly known as the Hatch-Waxman Act.<sup>3</sup> The Hatch-Waxman Act is a complex piece of legislation that yokes together patent protection and drug regulation in an effort to balance the competing goals of (1) protecting innovators' incentives to develop new drugs and (2) facilitating the timely entry of cheaper generic versions of older drugs. The legislation uses the timing of FDA product approvals to fortify the exclusionary effects of patents by deferring approval of competing generic products during the patent term. FDA relies on the innovators to specify which patents meet the statutory standards for deferring generic approval, insisting that it lacks the expertise and resources to second-guess these assertions. It interprets the Hatch-Waxman Act as assigning the job of sorting out the merits of patent disputes exclusively to the courts,<sup>4</sup> leaving FDA with only the "purely ministerial" tasks of publishing information that the innovators supply<sup>5</sup> and staying approval of generic products for thirty months after the filing of an infringement action pending instructions from the courts.<sup>6</sup> This very strong default rule gives all patent holders the power to defer generic competition during an automatic stay, even if the merits of their assertions are too dubious to allow them to persuade a court to enter a preliminary injunction.

Punting patent disputes to the courts might in some cases lead to thorough (if costly) resolution of the merits through adjudication, perhaps before an experienced District Court judge who has heard other patent cases,<sup>7</sup> and perhaps with review in the Court of Appeals for the Federal Circuit (Federal Circuit), an appellate court with considerable experience in patent appeals. But as with most litigation, a more common outcome is settlement. In many infringement action settlements between pharmaceutical innovators and generics, the innovator (who has much more to lose than the generic has to gain from the litigation) has agreed to make payments to the generic in exchange for agreement by the generic to defer entry.<sup>8</sup> The Federal Trade Commission (FTC) and drug purchasers have repeatedly sued the settling

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3. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended in scattered sections of titles 15, 21, 35, and 42 of the U.S.C.); *see infra* Part II.

4. Applications for FDA Approval to Market a New Drug: Patent Submission and Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying That a Patent Claiming a Drug Is Invalid or will Not Be Infringed, 68 Fed. Reg. 36,676, 36,681 (June 18, 2003); Abbreviated New Drug Application Regulations; Patent and Exclusivity Provisions, 59 Fed. Reg. 50,338 (Oct. 3, 1994) (codified at 21 C.F.R. pt. 314), *available at* <http://gpo.gov/fdsys/pkg/FR-1994-10-03/html/94-24052.htm> (last visited Jan. 26, 2015).

5. 21 U.S.C. §§ 355(b), (c)(2) (2012).

6. *Id.* § 355(j)(5)(B)(iii).

7. Hatch-Waxman infringement actions tend to cluster in a small number of district courts. *See* Fromer, *supra* note 1, at 1500–02; *cf.* Moore, *supra* note 1, at 558.

8. For a review of the terms of these agreements, *see* C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data to Preserve Drug Competition*, 109 COLUM. L. REV. 629, 647–57 (2009).

firms, arguing that these “reverse payments” or “pay for delay” agreements restrain competition in violation of the antitrust laws.<sup>9</sup>

The antitrust courts have responded with two divergent patent punting strategies. Prior to the Supreme Court’s 2013 decision in *Federal Trade Commission v. Actavis*,<sup>10</sup> the lower courts were divided on whether the agreements were presumptively lawful (due to the existence of an unexpired patent)<sup>11</sup> or presumptively unlawful (due to the payment in exchange for a promise not to compete).<sup>12</sup> The Supreme Court majority in *Actavis* formally held that these cases call for rule of reason analysis<sup>13</sup> that balances “traditional antitrust factors such as likely anticompetitive effects, redeeming virtues, market power, and potentially offsetting legal considerations present in the circumstances, such as here those related to patents.”<sup>14</sup> But the majority denied that this analysis would require analyzing the merits of the underlying patent disputes, instead inviting the courts to infer from the reverse payment that the innovator’s patent infringement claim must have been weak, and the settlement must therefore have been anti-competitive.<sup>15</sup> Three dissenting Justices would have held that an antitrust court should ask whether the settlement gives the patent holder monopoly power beyond that conferred by the patent, since a patent provides an exception to antitrust law.<sup>16</sup> The dissent and the majority agreed on one thing: it was not the job of the antitrust courts to analyze the merits of the underlying patent infringement action.<sup>17</sup>

The reluctance of both FDA and antitrust courts to engage the merits of patent disputes is understandable. Analyzing patent validity and infringement is hard work. Validity analysis requires comparing the invention as defined in the patent claims to the prior art at a particular moment in the past

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9. See *infra* Part III.

10. 133 S. Ct. 2223 (2013).

11. E.g., *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294 (11th Cir. 2003), *cert. denied*, 543 U.S. 939 (2004); *Schering-Plough Corp. v. Fed. Trade Comm’n*, 402 F.3d 1056 (11th Cir. 2005), *cert. denied*, 548 U.S. 919 (2006); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 190 (2d Cir. 2006), *cert. denied*, 551 U.S. 1144 (2007); *Ark. Carpenters Health & Welfare Fund v. Bayer AG*, 604 F.3d 98 (2d Cir. 2010), *cert. denied*, 131 S. Ct. 1606 (2011); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323 (Fed. Cir. 2008), *cert. denied*, 557 U.S. 920 (2009).

12. E.g., *Andrx Pharm., Inc. v. Biovail Corp. Int’l*, 256 F.3d 799 (D.C. Cir. 2001), *cert. denied*, 535 U.S. 931 (2002); *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003), *cert. denied*, 543 U.S. 939 (2004); *In re K-Dur Antitrust Litig.*, 686 F.3d 197 (3d Cir. 2012).

13. *Fed. Trade Comm’n v. Actavis, Inc.*, 133 S. Ct. 2223, 2237 (2013) (rejecting the FTC’s proposed “quick look” analysis that would shift the burden to antitrust defendants to show empirical evidence of “procompetitive effects”).

14. *Id.* at 2231.

15. *Id.* at 2236–37.

16. *Id.* at 2239–40 (viewing uncertainty concerning patent validity as irrelevant to whether a settlement violates the antitrust laws).

17. See *infra* notes 199–200 and accompanying text.

from the perspective of a person having ordinary skill in the art.<sup>18</sup> Infringement analysis requires interpreting patent claims and comparing them to the product or method of treatment for which the defendant seeks FDA approval as set forth in an Abbreviated New Drug Application (ANDA).<sup>19</sup> These determinations require reading patent documents in light of the past understandings of practitioners in the relevant technological community,<sup>20</sup> a perspective that may be difficult to access, particularly for generalist judges with no training in the field of the invention, as well as reading and interpreting documents submitted to FDA seeking regulatory approval to market drugs. The legal rules are complex and likely to be contested by highly motivated parties. There is considerable room for error. In the antitrust context, the challenge of evaluating the merits of the patent case is aggravated by the lack of current conflict between the patent owner and the alleged infringer since both are now defending the settlement. At this stage only the antitrust plaintiff has an interest in establishing that the underlying infringement claim was weak in order to establish that the settlement violated the antitrust laws.

But the merits of the patent dispute matter. Owners of valid patents have a legal right to exclude competitors from the market for the patented invention until the end of the patent term. On the other hand, invalid patents should not defer generic entry, and even valid patents should not prevent the entry of products that do not infringe. Settlements of patent infringement actions may be camouflage for anticompetitive behavior that is not authorized by the patent laws, but they may also legitimately resolve plausible but contested assertions of infringement. The difference turns on the merits.

The mechanisms used by FDA and the courts to avoid having to analyze the merits themselves are highly flawed. FDA's reliance on pharmaceutical innovators to decide which patents call for deferring generic entry effectively assigns the fox to guard the henhouse. Innovators have a strong interest in making dubious assertions of patent infringement. But generics also

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18. Since March 16, 2013, U.S. law has conformed to the approach in most other patent systems, see Rochelle Cooper Dreyfuss, *The Leahy-Smith America Invents Act: A New Paradigm for International Harmonization?*, 24 SING. ACAD. L.J. 669 (2012), by determining prior art as of the filing date of a patent application, with some limited exceptions for prior art within one year of the application filing date. See 35 U.S.C. §§ 102, 103 (2012); Leahy-Smith America Invents Act, Pub. L. 112-29, § 3(n), 125 Stat. 284, 293 (2011). For U.S. patent applications filed prior to March 16, 2013, prior art is measured as of two different dates: the invention date and one year prior to the filing date. See 35 U.S.C. §§ 102, 103 (2006); Leahy-Smith America Invents Act, Pub. L. 112-29, § 3(n), 125 Stat. 284, 293 (2011). For a comparison of statutory language before and after the Leahy-Smith America Invents Act, see *U.S. Patent Act After the America Invents Act*, BITLAW, <http://www.bitlaw.com/source/35usc/index.html> (last visited Jan. 18, 2015).

19. *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc); *Abbott Labs. v. Sandoz, Inc.*, 566 F.3d 1282 (Fed. Cir. 2009) (en banc).

20. *Phillips*, 403 F.3d at 1313.



have a strong interest in raising dubious challenges to validity and infringement. Someone without a stake in the matter needs to analyze the merits.

Punting patent issues to the courts has often led not to adjudication on the merits, but rather to settlements on terms that provoke later antitrust challenges. The shortcuts deployed by antitrust courts to determine whether litigation settlements violate the antitrust laws rely on poor proxies for consideration of the merits and invite subterfuge in the framing of agreements, as more fully explained in Part III.<sup>21</sup>

Even if the antitrust courts were willing to look to the merits of the settled patent dispute, after-the-fact antitrust litigation over patent settlements is a tardy, costly, and error-prone mechanism for determining when an innovator's exclusive rights should end and generic entry should begin. Time is of the essence in making these determinations. A better system would resolve more disputes at an earlier stage, with more technological expertise, and at lower cost, while minimizing opportunities for strategic gaming. At a minimum, rather than punting all disputes to the courts, and thereby setting the stage for a maximum number of settlements, the system should filter out the easiest cases, thereby limiting the opportunity to enter into possibly collusive agreements to those cases in which the need for full adjudication justifies the risks of anticompetitive settlements. If the easy cases never get to litigation, settlements of the remaining cases are more likely to reflect compromise of genuine disputes rather than camouflage for anticompetitive agreements.

The obvious candidate for filtering out the easiest disputes, although a most reluctant one, is FDA. FDA has avoided this job so far by insisting that it lacks expertise in patent matters, while ignoring the considerable advantages that it has over the courts in the unique context of infringement litigation under the Hatch-Waxman Act. Rather than the usual infringement analysis, which compares the claims of a patent to an actual infringing product or process, the Hatch-Waxman Act requires a comparison between the scope of a patent and the scope of FDA approval documents at two different stages. First, to figure out whether a particular patent is properly submitted to FDA for listing, it is necessary to determine whether the patent claims a drug or a method of using a drug that is within the scope of an approved or pending New Drug Application (NDA). If not, then the patent is irrelevant to the timing of generic approval. Second, when an Abbreviated New Drug Application (ANDA) is filed for a generic version of the product, it is necessary to compare the claims of properly listed patents to the scope of approval sought in a pending ANDA to determine whether the patent is relevant to the particular ANDA. If not, then the ANDA need not address that patent in a certification, and FDA need not defer approval of the ANDA.

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21. See *infra* notes 213–218.



Whatever the limits of its patent expertise, FDA has a decisive advantage over any other institution in reading NDAs and ANDAs to determine what drugs and methods of use they cover. Its technical expertise in the field of drug development may also give it a significant advantage over generalist courts in reading and understanding drug patent claims from the perspective of a person having ordinary skill in the art of drug development.

FDA also has the advantage of being in the right place at the right time to make timely decisions. Congress has given FDA a central role in tracking and enforcing the pharmaceutical patents covered by the Hatch-Waxman Act. FDA receives prompt notice of the issuance of relevant patents, the filing of ANDAs, and the filing of infringement actions, giving it an early opportunity to address issues before they get attention from the courts. As the regulatory gatekeeper to the pharmaceutical marketplace, FDA must ultimately determine when generic entry may begin. So far, FDA has taken its marching orders in the first instance from the innovators, erring on the side of deferring generic entry. But it is by no means clear that this is what Congress intended in the Hatch-Waxman Act. We argue below that FDA could and should take a larger role in determining which patents should defer generic entry without overstepping the limits of its statutory authorities and without displacing the role assigned to the courts in the Hatch-Waxman Act and under the patent laws. But further Congressional action may be necessary to get FDA to exercise regulatory oversight and to provide it with resources to do the job expeditiously.

### I. THE HATCH-WAXMAN ACT

Two statutes dominate the legal environment for new drug development: the Patent Act<sup>22</sup> and the Federal Food, Drug and Cosmetic Act.<sup>23</sup> Although these legal regimes were once separate, Congress yoked them together in passing the Hatch-Waxman Act of 1984. Congress attempted to strike a balance between promoting price-lowering competition in older drugs by encouraging generic entry in the market after the expiration of all relevant patents and promoting innovation in new drug development by deferring generic entry prior to that time. This Part describes how the Hatch-Waxman Act adjusted both patent and drug regulation in an effort to balance these competing goals.

To promote competition, the Hatch-Waxman Act substantially lowered the regulatory entry barrier for generic versions (generics) of previously approved products (listed products) by allowing the use of an Abbreviated New Drug Application (ANDA)<sup>24</sup> rather than the more costly New Drug

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22. Set forth as amended in title 35 of the U.S. Code.

23. Set forth as amended in title 21 of the U.S. Code.

24. The requirements for an ANDA are codified as amended at 21 U.S.C. § 355(j)(2)(A) (2012).

Application (NDA) required for a new chemical entity.<sup>25</sup> Prior to the Hatch-Waxman Act, FDA treated generic versions of previously approved products as new drugs, and therefore required that the sponsor of the generic product submit full reports of data from clinical trials to make the same showing of safety and efficacy required for approval of an NDA.<sup>26</sup> This regulatory entry barrier was usually sufficient to defer generic entry long after relevant patents had expired because the costs of full clinical trials were prohibitive for generic products that would be sold at competitive prices.<sup>27</sup> The Hatch-Waxman Act lowered this barrier considerably by allowing approval of an ANDA based on a much less costly showing that a generic product is “bioequivalent” to a previously approved listed product, without requiring duplication of safety and efficacy trials.<sup>28</sup> The result was a substantial increase in approvals of generic drugs. But pharmaceutical innovators saw ANDAs as a form of unfair free-riding that would allow competitors to share in the regulatory benefits of valuable proprietary data that the innovators bore the cost and risk of generating. This free-riding, they argued, would undermine incentives for innovation.

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25. The requirements for an NDA include submissions of “full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use.” 21 U.S.C. § 355(b)(1)(A).

26. Prior to the Hatch-Waxman Act, generic products were sometimes approved without new trials on the basis of published literature under a “paper NDA.” 45 Fed. Reg. 82,060 (Dec. 12, 1980). Questions about the legality and reach of this mechanism were part of impetus for the Hatch-Waxman Act. Alfred B. Engelberg, *Special Patent Provisions for Pharmaceuticals: Have They Outlived Their Usefulness? A Political, Legislative and Legal History of U.S. Law and Observations for the Future*, 39 IDEA J. L. & TECH. 389–428 (1999). Although the Federal Food, Drug, and Cosmetic Act (the “FDCA”) now provides for approval of paper NDAs, 21 U.S.C. § 505(b)(2), this approval pathway has until recently been largely eclipsed by ANDAs. The language of the provision is quite broad, however, and FDA interprets it to allow approval of a drug that is similar but not identical to a previously approved product based in part on previous unpublished studies that the applicant neither conducted nor obtained the right to use. Tam Q. Dinh, *Potential Pathways for Abbreviated Approval of Generic Biologics under Existing Law and Proposed Reforms in the Law*, 62 FOOD & DRUG L.J. 77–137 (2007).

27. Gerald J. Mossinghoff, *Overview of the Hatch-Waxman Act and its Impact on the Drug Development Process*, 54 FOOD & DRUG L. J. 187–94 (1999).

28. An ANDA does not require full reports of clinical trials to show safety and efficacy, so long as the conditions of use, active ingredients, route of administration and strength are the same as a previously approved “listed product,” the ANDA product is “bioequivalent” to the listed product, and the labeling of the two products is the same. 21 U.S.C. § 355(j)(2)(A). FDA regulations define bioequivalence as follows:

*Bioequivalence* means the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study. . . .

21 C.F.R. § 320.1(e) (2014).

To promote innovation, the Hatch-Waxman Act deferred generic entry in two ways. First, it amended the Patent Act to give innovators patent term extensions of up to five years to compensate for some of the time lost while their products were in clinical trials and awaiting FDA approval.<sup>29</sup> Second, it provided head-start periods following approval of an NDA before a generic could submit an ANDA<sup>30</sup> or before FDA could approve an ANDA,<sup>31</sup> sometimes called “data exclusivity” or “regulatory exclusivity.” These regulatory exclusivity periods function somewhat like patents, in that they defer entry of competing generic products, but the patent holder need not bring a costly patent infringement action and take the risk that a court would hold the patent invalid. FDA enforces these exclusivity periods by deferring the submission or approval of ANDAs until specified dates, with the effect of keeping generic products off the market.

The Hatch-Waxman Act also included complex provisions governing the timing of ANDA approval during the term of certain patents—specifically, “any patent which claims the drug for which [an NDA is filed] or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.”<sup>32</sup> These provisions give FDA a role as *de facto* enforcer of certain drug patents by directing it to look to those patents to determine the timing of ANDA approvals. The provisions offer valuable benefits both for innovators and for generics, but not all patents have these effects.

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29. 35 U.S.C. § 156 (2012). The period of extension includes one-half of the time spent in clinical trials and all of the time between submission and approval of the NDA. *Id.* § 156(c)(2). The relevant dates are determined by FDA, and on the basis of those dates the PTO extends the term of the patent. *Astra v. Lehman*, 71 F.3d 1578, 1581 (Fed. Cir. 1995). Both periods are reduced by any time attributable to an applicant’s lack of diligence. 35 U.S.C. § 156(c)(1). The remaining patent life after extension may not exceed fourteen years beyond the date of FDA approval. *Id.* § 156(c)(3). Only the first approval of a new active ingredient qualifies for a patent term extension, and only one patent may be extended per new active ingredient. *Fisons PLC v. Quigg*, 876 F.2d 99 (Fed. Cir. 1989). The patent to be extended must be in force on the date of approval, 35 U.S.C. § 156(a)(1), and it must cover either the product, a method of using the product, or a method of manufacturing the product. *Id.* § 156(a).

30. No ANDA may be submitted for five years following the first approval of an NDA for a new chemical entity, except that an ANDA that includes a challenge to validity or infringement of a patent may be submitted after four years, subject to an extended stay of regulatory approval if an infringement action is commenced during the following year. 21 U.S.C. § 355(j)(5)(F)(ii).

31. FDA may not approve an ANDA that covers an approved supplement to an NDA (such as a supplemental approval for a new indication or for a switch from prescription only to over-the-counter sales) that required further clinical trials for three years from the date of approval of the supplement. *Id.* § 355(j)(5)(F)(iii), (iv).

32. *Id.* § 355(b)(1).

A. *The Orange Book*

The Hatch-Waxman Act created a system within FDA for tracking those patents “with respect to which a claim of patent infringement could reasonably be asserted” against the unauthorized sale of copies of previously approved products, and for deferring the submission and approval of ANDAs during the term of those patents. An NDA applicant must disclose in its NDA the patent number and expiration date of any such patent,<sup>33</sup> and must update this information to include later-issued patents.<sup>34</sup> Upon approval of the NDA, FDA publishes this information in a publication called *Approved Drug Products with Therapeutic Equivalence Evaluations* (known as “the Orange Book”), which FDA updates every thirty days.<sup>35</sup>

When a generic submits an ANDA, it must include a certification or statement about the relevance to its ANDA of each patent in the Orange Book for the previously approved “listed” product. If the patent claims the drug or a method of use for which the ANDA seeks approval, the ANDA must include one of three statutory “certifications”: a “paragraph II certification” indicating that the patent has expired; a “paragraph III certification” indicating the date on which the patent will expire; or a “paragraph IV certification” indicating “that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted.”<sup>36</sup> If the patent claims a method of use for which the ANDA does not seek approval, the ANDA may instead include a “section viii statement” indicating that the patent “does not claim a use for which the applicant is seeking approval.”<sup>37</sup>

The effect of these provisions is to direct FDA to defer ANDA approval during the term of a relevant patent, but not during the term of an irrelevant patent. If the patent does not claim a drug or method of use that is covered by an NDA, or if the patent could not reasonably be asserted against an unauthorized version of the drug, or if the patent only claims a method of use for which the ANDA does not seek approval, the patent is not relevant to approval of the ANDA. If no relevant patents remain in force, the ANDA may be approved without further delay (assuming it is otherwise approva-

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33. *Id.*

34. *Id.* § 355(c)(2).

35. U.S. FOOD & DRUG ADMIN., APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS (34th ed. 2014), available at <http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm>. The Hatch-Waxman Act requires FDA to publish this information and to update it every thirty days, including newly submitted patent information in the updates. 21 U.S.C. § 355(j)(7)(A).

36. 21 U.S.C. §§ 355(j)(2)(A)(7)(vii)(2)–(4). If there are no patents for the listed drug in the Orange Book, the ANDA applicant may use a “paragraph I certification,” indicating that no patent information has been filed. *Id.* § 355(j)(2)(A)(7)(vii)(1).

37. *Id.* § 355(j)(2)(A)(viii).

ble).<sup>38</sup> If a relevant patent is still in force, the ANDA may be approved upon the expiration date of that patent.<sup>39</sup>

### B. ANDA Infringement Litigation

Further provisions permit the parties to litigate disputes about patent validity and infringement in the courts prior to generic entry. Because these provisions are central to FDA's view of its role in patent disputes as "purely ministerial," and because they have had considerable unintended consequences, we consider them here in some detail. These provisions apply when an ANDA applicant makes a paragraph IV certification that a relevant patent is invalid or will not be infringed by the ANDA product. The ANDA applicant must give notice within 20 days to the patent owner and to the holder of the approved NDA including "a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed."<sup>40</sup> The ANDA may then be approved immediately, unless a patent infringement action is brought within forty-five days.<sup>41</sup> The filing of a patent infringement action triggers an automatic thirty-month stay of FDA approval of the ANDA, which may be adjusted by the court if either party fails to cooperate in expediting the action.<sup>42</sup> To allow litigation of these claims prior to generic entry, the Hatch-Waxman Act amended the Patent Act to make it an act of infringement to submit an ANDA "for a drug claimed in a patent or the use of which is claimed in a patent" for the purpose of obtaining approval for commercial marketing prior to patent expiration.<sup>43</sup> A prevailing plaintiff—the innovator—may obtain a court order deferring the effective date of approval of the ANDA until the end of the patent term and an injunction against commercial manufacture, use, offer to sell, or sale by the generic manufacturer but may not recover damages unless commercial acts have occurred.<sup>44</sup> On the other hand, if a court determines that the patent is invalid or not infringed, approval of the ANDA may be made effective immediately, even if the 30-month stay has not yet expired.<sup>45</sup>

These provisions fortify in several ways the exclusionary power of those patents "with respect to which a claim of patent infringement could reasona-

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38. *Id.* §§ 355(j)(2)(A)(vii)(I), (II), 355(j)(5)(B)(i). A section viii statement has no effect on the date on which ANDA approval may be made effective. *Id.* § 355(j)(2)(A)(viii).

39. *Id.* §§ 355(j)(2)(A)(vii)(III), 355(j)(5)(B)(ii).

40. *Id.* §§ 355(j)(2)(B)(iv)(II), 355(j)(5)(B)(iii). The twenty-day period for giving notice is measured from "the date of the postmark on the notice with which the Secretary informs the applicant that the application has been filed." *Id.* § 355(j)(2)(B)(ii)(I). If the notice is made as part of an amendment or supplement to an application, notice must be given at the time of the amendment or supplement. *Id.* § 355(j)(2)(B)(ii)(II).

41. *Id.* § 355(j)(5)(B)(iii).

42. *Id.* § 355(j)(5)(B)(iii).

43. 35 U.S.C. § 271(e)(2)(A) (2012).

44. *Id.* § 271(e)(4).

45. 21 U.S.C. § 355(j)(5)(B)(iii)(I).

bly be asserted” against an ANDA product. They provide notice to generics of the existence of relevant patents and require that generics include patent certifications for each relevant patent in their ANDAs. If a generic asserts through a paragraph IV certification that a relevant patent is invalid or not infringed, it must agree to give notice to the patent holder and NDA holder. If a patent is irrelevant to the ANDA because it covers only methods of use for which the ANDA does not seek approval, the ANDA must include a section viii statement to that effect. Unless an ANDA includes a paragraph IV certification or a section viii statement, FDA will use its regulatory gatekeeper role to defer the effective date of ANDA approval until the patents listed in the Orange Book expire, thereby excluding competitors from the market without the need for infringement litigation. Patent owners need not monitor the market to spot infringing activity: they can wait for infringers to step forward and reveal their plans, along with “a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed” that they may consider as they contemplate whether to bring an infringement action. They may sue for infringement before commercial activity has begun, giving them an opportunity to secure injunctive relief before they suffer any loss of revenue from generic entry. And if they choose to sue, they may secure an automatic thirty-month stay against generic entry, providing preliminary relief without the usual showing<sup>46</sup> required to get a preliminary injunction from a court. These regulatory consequences—which we call the “Hatch-Waxman boost”—reach beyond the ordinary remedies that courts award for patent infringement. The Hatch-Waxman boost uses regulatory consequences to fortify the exclusionary effects of patents. These advantages may motivate innovators to include in the Orange Book patents of dubious validity or narrow scope, even if an impartial observer would disagree that “a claim of patent infringement could reasonably be asserted” against a bioequivalent product on the basis of those patents.

The statute also offers benefits to generics that may encourage them to use paragraph IV certifications to challenge validity or infringement even when the merits of the challenge are uncertain. The most valuable of these benefits is “generic exclusivity,” which gives the first generic to submit an ANDA with a paragraph IV certification a 180-day head start period following first commercial marketing of the ANDA product before FDA will approve another ANDA with a paragraph IV certification for the same drug.<sup>47</sup> Because the first generic competitor in the market for a drug typically charges higher prices and captures a larger market share until a second generic competitor enters the market, this period of generic exclusivity has

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46. See *Amazon.com v. Barnesandnoble.com*, 239 F.3d 1343 (Fed. Cir. 2001).

47. 21 U.S.C. § 355(j)(5)(B)(iv)(I).



significant value.<sup>48</sup> Even if an applicant does not qualify for generic exclusivity, an ANDA with a paragraph IV certification may be submitted a full year before an ANDA without such a certification, as early as four years after approval of the NDA for the listed drug.<sup>49</sup> If the innovator does not bring an infringement action, the ANDA may be approved effective immediately,<sup>50</sup> but if an infringement action is commenced during the fifth year following approval of the NDA, the thirty-month stay is extended to expire seven and a half years after approval of the NDA.<sup>51</sup> A generic firm might welcome an opportunity to probe the willingness of a patent holder to litigate validity and infringement at this early stage, prior to market entry and without having to risk liability for damages if it loses.<sup>52</sup> Finally, filing an ANDA with a paragraph IV certification starts the meter ticking on the thirty-month stay of FDA approval of the ANDA, while precluding (under 2003 amendments) the entry of additional stays based on later patents submitted after the filing date of the ANDA.<sup>53</sup>

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48. CONGRESSIONAL BUDGET OFFICE, HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES IN THE PHARMACEUTICAL INDUSTRY (1998). The value of generic exclusivity is diminished if multiple ANDA filers share the exclusivity. Multiple ANDA filers may share the 180-day period of generic exclusivity if each files a complete application with a paragraph IV certification on the same date and no previously filed ANDA for the same drug included a paragraph IV certification. 21 U.S.C. §§ 355(j)(5)(B)(iv)(I), (II)(bb) (2012). For blockbuster products, such multiple filings are common on the first date that they are allowed, four years after approval of the NDA. *Id.* § 355(j)(5)(F)(ii). See CENTER FOR DRUG EVALUATION, FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY 180-DAY EXCLUSIVITY WHEN MULTIPLE ANDAs ARE SUBMITTED ON THE SAME DAY, 4 (2003), available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm072851.pdf> (last visited Jan. 21, 2015). The value of generic exclusivity may also be diminished if the NDA holder decides to launch its own competing “authorized generic” during the generic exclusivity period. An “authorized generic” is a product that is marketed and priced as a generic but sold under the authority of the holder of the NDA rather than under an ANDA. The courts have sustained the legality of authorized generics. See *Teva Pharma. Indus. Ltd. v. Crawford*, 410 F.3d 51, 54 (D.C. Cir. 2005). Authorized generics increase competition during the period of generic exclusivity and thereby reduce prices to consumers, but the long term effects may be more ambiguous if authorized generics undermine incentives to challenge drug patents by filing paragraph IV certifications. FEDERAL TRADE COMM’N, AUTHORIZED GENERICS: AN INTERIM REPORT (2009), available at <http://www.ftc.gov/os/2009/06/P062105authorizedgenericsreport.pdf> (last visited Jan. 21, 2013). See also JOHN R. THOMAS, CONG. RESEARCH SERV., RL33605, AUTHORIZED GENERIC PHARMACEUTICALS: EFFECTS ON INNOVATION (2006), available at <http://research.policyarchive.org/2955.pdf> (last visited May 1, 2015). The FTC report on authorized generics estimates that on average, expenditures at wholesale prices of a generic during the 180-day exclusivity period equal 61% of expenditures on the brand name product during a comparable period prior to generic entry. Once the generic exclusivity period expires and more generic competitors enter, price competition is likely to reduce profits considerably.

49. 21 U.S.C. § 355(j)(5)(F)(ii) (2012).

50. *Id.* § 355(j)(5)(B)(iii).

51. *Id.* § 355(j)(5)(F)(ii).

52. See *supra* notes 42–45 and accompanying text.

53. 21 U.S.C. § 355(j)(5)(B)(iii).



In short, the rules of the Hatch-Waxman Act alter the exclusionary effects of patents in ways that are potentially valuable to both innovators and generics. Each side has reasons to litigate disputes that might appear risky to an impartial observer. It therefore makes good sense to question the assertions of both innovators and generics as to whether “a claim of patent infringement could reasonably be asserted” against an ANDA product on the basis of particular patents. Otherwise, these interested parties might impose unjustified restrictions on competition in purported reliance on irrelevant patents.

## II. PATENT PUNTING AT FDA

From the start, FDA has taken a narrow view of its role in administering the patent provisions of the Hatch-Waxman Act, insisting that it has no obligation to police the accuracy or appropriateness of the patent information submitted to it by innovators or the relevance of particular patents to particular NDAs or ANDAs.<sup>54</sup> FDA has repeatedly engaged in rule-making to interpret the patent provisions of the Hatch-Waxman Act to specify the kinds of patents that are to be disclosed by NDA applicants and to devise administrative mechanisms to implement those provisions, but it has structured its regulations to keep the agency free of any burden to oversee compliance, or even to read patents to check if the information submitted is accurate.

Some features of the statutory scheme are consistent with a limited FDA role in resolving patent disputes under the Hatch-Waxman regime. For example, the statutory obligation on innovators to disclose patent information to FDA mentions only patent numbers and expiration dates,<sup>55</sup> without explicitly requiring that applicants provide FDA with copies of patents or otherwise specify what they cover.<sup>56</sup> Nor is the statutory obligation on FDA to

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54. Abbreviated New Drug Applications, Proposed Rule, 54 Fed. Reg. 28,872 (proposed July 10, 1989) [hereinafter 1989 Proposal]; Abbreviated New Drug Application Regulations; Patent and Exclusivity Provisions, 59 Fed. Reg. 50,338 (Oct. 3, 1994) [hereinafter 1994 Final] (codified at 21 C.F.R. pt. 314); Applications for FDA Approval to Market a New Drug: Patent Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying That a Patent Claiming a Drug is Invalid or Will Not be Infringed, 67 Fed. Reg. 65,448 (proposed Oct. 24, 2002) [hereinafter 2002 Proposal]; Applications for FDA Approval to Market a New Drug: Patent Submission and Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying That a Patent Claiming a Drug is Invalid or Will Not be Infringed, 68 Fed. Reg. 36,676 (June 18, 2003) [hereinafter 2003 Final] (codified at 21 C.F.R. pt. 314).

55. 15 U.S.C. § 355(b)(1) (2012) (“The applicant shall file with the application the patent number and the expiration date of any patent which claims the drug for the which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.”). *But cf.* 21 C.F.R. § 314.53(b) (2014) (administrative regulation requiring that applicant submit additional information for patents claiming polymorphs and methods of use).

56. FDA regulations, however, require more extensive disclosure. *See id.* § 314.53(b).

publish patent information explicitly limited to information that is relevant or accurate.<sup>57</sup> If an ANDA includes a paragraph IV certification, the statute does not include FDA among the parties to whom the applicant must give “a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed.”<sup>58</sup> The statute specifies an accelerated time frame for ANDA applicants to give the required notice (twenty days after FDA informs the applicant that the ANDA has been filed)<sup>59</sup> and for patent holders to respond by bringing infringement actions (forty-five days after receiving the notice),<sup>60</sup> leaving limited time for administrative review before litigation begins. And if the patent holder decides to sue the applicant for infringement, the statute directs FDA to stay approval of the ANDA for thirty months pending litigation of the patent dispute in the district court,<sup>61</sup> while giving the court authority to modify the stay if the parties are dilatory in pursuing the litigation. These provisions are consistent with a limited function for FDA as a clearinghouse for patent information, leaving to the courts any substantive determinations on the merits.<sup>62</sup>

But the role of the courts is also limited, inviting a larger regulatory role to fill important gaps in the statutory scheme. The considerable commercial values at stake in the cascade of regulatory consequences that follow from listing patents in the Orange Book—what we call the Hatch-Waxman boost—makes it treacherous to leave firms with unfettered discretion over patent listing decisions. Determinations of which patents are entitled to the Hatch-Waxman boost have great economic significance not only to the firms that file NDAs and ANDAs, but also to patients who need drugs and to those who pay for their care.

The statute sets a standard that restricts the Hatch-Waxman boost to certain qualifying patents, specifically:

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57. 21 U.S.C. § 355(b)(1) (2012) (“Upon approval of the application, the Secretary shall publish information submitted under the two preceding sentences.”).

58. The language quoted in text appears at 21 U.S.C. § 355(j)(2)(B)(iv)(II). The statute specifies that notice must be given to “each owner of the patent that is the subject of the certification,” *id.* § 355(j)(2)(B)(iii)(I), and to “the holder of the approved application . . . for the drug that is claimed by the patent or a use of which is claimed by the patent,” *id.* § 355(j)(2)(B)(iii)(II), but does not require that this notice be given to “the Secretary” or to FDA, so long as the applicant includes with its ANDA a statement that it will give notice to the specified parties as required by the statute. *Id.* § 355(j)(2)(B)(i).

59. *Id.* § 355(j)(2)(B)(ii).

60. *Id.* § 355(j)(5)(B)(iii).

61. *Id.* If an infringement action is commenced during the final year of regulatory exclusivity (*i.e.*, between four and five years after approval of the NDA), the 30-month stay shall be extended to give a total of seven and one-half years between NDA approval and expiration of the stay. *Id.* § 355(j)(5)(F)(ii).

62. Indeed, Congress went to some trouble to clarify that the courts could hear these disputes before market entry by the generics, amending the Patent Act to define the filing of an ANDA for a drug claimed in a patent or the use of which is claimed in a patent as an act of patent infringement. 35 U.S.C. § 271(e)(2)(A).

[A]ny patent which claims the drug for which the applicant submitted the application [i.e., the NDA] or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.<sup>63</sup>

This standard imposes at least three limitations: (1) the patent must claim a drug or a method of using a drug;<sup>64</sup> (2) the claimed drug or method of use must be within the scope of the NDA in connection with which the patent is submitted;<sup>65</sup> and (3) the patent must support a reasonable assertion of infringement against unauthorized manufacture, use or sale of the drug. Patents that do not meet these criteria should not trigger the Hatch-Waxman boost.

The statute further limits the Hatch-Waxman boost by relieving ANDA filers from the obligation to submit a certification for certain listed method of use patents. An applicant may instead submit a “section viii statement” if the patent is “a method of use patent which does not claim a method of use for which the applicant is seeking approval.”<sup>66</sup> The use of a section viii statement allows a generic to avoid the requirement to give notice of the basis for the patent challenge and to avoid the automatic thirty-month stay of approval of the ANDA. On the other hand, use of a section viii statement does not allow the generic to claim a right to generic exclusivity. These are significant consequences that turn on the relationship between certain patents on methods of use and the scope of approval sought in an ANDA. Yet nothing in the Hatch-Waxman Act gives District Courts the opportunity or authority to determine whether a particular ANDA is entitled to bypass the Hatch-Waxman boost in this fashion.

As originally enacted, the Hatch-Waxman Act provided no mechanism for judicial review of the propriety of patent listings at all, leaving only FDA in a position to withhold the Hatch-Waxman boost from patents that did not meet the statutory criteria.<sup>67</sup> In 2003, Congress amended the statute to allow an ANDA applicant that has been sued for infringement to “assert a counterclaim seeking an order requiring the holder [of the NDA] to correct or delete

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63. *Id.* § 355(b)(1). The “application” in this context is the NDA submitted by the innovator for the listed drug.

64. For FDA’s interpretation of this statutory language, *see* 21 C.F.R. § 314.53(b) (2014) (language does not extend to patents on manufacturing processes, packaging, metabolites, and chemical intermediates).

65. FDA reasonably interprets the statute as limiting both patents on the drug and method of use. *Id.*

66. 21 U.S.C. § 355(j)(2)(A)(viii) (2012).

67. *Mylan Pharm., Inc. v. Thompson*, 268 F.3d 1323, 1332–33 (Fed. Cir. 2001) (finding no private cause of action to delist a patent from the Orange Book, and improper listing of a patent is not a defense to a patent infringement action); *Apotex, Inc. v. Thompson*, 347 F.3d 1335, 1352 (Fed. Cir. 2003).

the patent information submitted by the holder . . . on the ground that the patent does not claim either—(aa) the drug for which the application was approved, or (bb) an approved method of using the drug.”<sup>68</sup> No damage remedy is available for such a counterclaim, and a counterclaim may only be asserted if an infringement action is filed.<sup>69</sup>

This belated provision for a statutory counterclaim does little to address the problem of improper patent listings. By the time such a counterclaim is asserted, it is already too late to undo the effects of the Hatch-Waxman boost. The listing of the patent has already made it necessary for the ANDA applicant to submit a certification for the patent and to give notice to the NDA holder and patent holder of the basis for any challenge to validity or infringement of the patent, the first ANDA with a paragraph IV certification has already established its entitlement to 180 days of generic exclusivity, and the thirty-month stay has been triggered. The stay may well have run its full course by the time a district court orders the NDA holder to correct the information in the Orange Book.

Although the Hatch-Waxman Act plainly contemplated that the courts would adjudicate disputes about infringement and validity involving “any patent which claims the drug for which the applicant submitted the [NDA] or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug,”<sup>70</sup> there is no reason to think that Congress intended to confer the Hatch-Waxman boost on patents that do not meet the statutory criteria for listing in the Orange Book. It is even less plausible that Congress intended to defer approval of an ANDA based on a method of use patent which does not claim a method of use for which the ANDA is seeking approval. Congress, however, failed to provide an explicit mechanism for determining which patents should trigger the Hatch-Waxman boost, leaving FDA to address this gap in the regulatory scheme through rulemaking.

#### *A. Rulemaking Without Oversight*

FDA has used rulemaking to minimize its ongoing role in administering the patent provisions of the Hatch-Waxman Act. At the same time it has revealed considerable sophistication about how firms have exploited imprecision and gaps in the statute and willingness to take liberties with the statutory text. It took FDA a full decade after passage of the Hatch-Waxman Act

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68. Medicare Prescription Drug, Improvement and Modernization Act of 2003, Pub. L. No. 108-173 117 Stat. 2452 [hereinafter MMA 2003] (codified in pertinent part at 21 U.S.C. § 355(j)(5)(C)(ii)(I)).

69. See 21 U.S.C. § 355(j)(5)(C)(ii)(II) (2012) (“Subclause (I) does not authorize the assertion of a claim described in subclause (I) in any civil action or proceeding other than a counterclaim . . .”).

70. 21 U.S.C. § 355(b)(G) (2012).

to promulgate a final rule in 1994 interpreting its patent provisions.<sup>71</sup> By then FDA had become familiar with many strategic moves made by firms seeking to claim or avoid the Hatch-Waxman boost. The regulations<sup>72</sup> set specific limits on the types of patents to be listed in the Orange Book, calling for the listing of patents on drug substances, drug products and methods of use that are the subject of a pending or approved NDA, and explicitly excluding patents on manufacturing processes,<sup>73</sup> packaging, metabolites, and intermediates.<sup>74</sup> Although the statute mentioned only patent number and expiration date, FDA's regulations further required disclosure of the type of patent and the identity of the patent owner.<sup>75</sup> FDA also required NDA holders "to notify FDA of the patented uses that appear in the approved labeling for their products" so that FDA could provide guidance to ANDA filers about whether to submit a section vii—i.e., a Paragraph II, III, or IV—certification or a section viii statement.<sup>76</sup> The regulations filled other gaps in the statute that had come to light. For example, they extended the use of paragraph IV certifications to patents that are unenforceable (as distinguished from the explicit statutory categories of "invalid" and "not infringed")<sup>77</sup> and specified that late submissions of patents would be included in the Orange Book but do not require further certifications from ANDA applicants who previously submitted a certification for other listed patents.<sup>78</sup> In a provision subsequently struck down by the courts,<sup>79</sup> FDA added to the statutory requirements for generic exclusivity a further requirement that the generic must have successfully defended a patent infringement action.<sup>80</sup>

In contrast to this active role in interpreting the patent provisions of the statute, FDA repeatedly and emphatically rejected suggestions that it monitor compliance with these provisions and regulations in individual cases, citing its lack of patent expertise, lack of resources, and the higher priority it assigned to other tasks. The following response to a proposal that it establish a mechanism "for review of submitted patent information to determine, at

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71. See 1994 Final, *supra* note 54.

72. See 21 C.F.R. § 314.53(b) (2014). The regulations were amended in 2003 in response to an FTC investigation of abuses. See 2002 Proposal, *supra* note 54; 2003 Final, *supra* note 54.

73. The Hatch-Waxman Act included patents on manufacturing methods in designating patents eligible for patent term extension. 35 U.S.C. § 156(a) (2012).

74. The original version of these regulations as promulgated in 1994 are set forth at the end of 1994 Final, *supra* note 54.

75. 1994 Final, *supra* note 54, § III.A.25; 21 C.F.R. §§ 314.53(b), (c).

76. 1994 Final, *supra* note 54, § III.A.1; 21 C.F.R. § 314.53(c).

77. See 1994 Final, *supra* note 54, § III.A.5; 21 C.F.R. §§ 314.50(h)(1)(A)(4), 314.94(a)(12)(i)(A)(4).

78. 1994 Final, *supra* note 54, § III.A.7; 21 C.F.R. § 314.50(i)(B)(4).

79. *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1069 (D.C. Cir. 1998).

80. See 21 C.F.R. § 314.107(c)(1). The 1994 version of 21 C.F.R. § 314.107(c)(1) is set forth at the end of 1994 Final, *supra* note 54.

least on a very general basis, applicability to the particular NDA in question” is typical:

As stated elsewhere in this final rule, FDA does not have the expertise to review patent information. The agency believes that its scarce resources would be better utilized in reviewing applications rather than reviewing patent claims.<sup>81</sup>

FDA sometimes went so far as to cite its own professed ignorance of patent law as a canon of interpretation, invoking it as a reason to choose an interpretation that it could administer without having to understand patent law over an alternative interpretation that would require patent expertise to administer. For example, FDA rejected a suggestion that it should limit the scope of generic exclusivity by deferring only those later-filed ANDAs that actually benefited from the previous paragraph IV challenge by the firm holding generic exclusivity. Under this rejected approach, FDA would not defer approval of an ANDA with a paragraph IV certification that raised a different infringement issue than was raised in the original challenge, because in that situation the subsequent ANDA filer was not free-riding on the efforts of the first challenger. FDA rejected this interpretation of the statute because it would require FDA to determine whether the two paragraph IV certifications raised the same or different patent issues:

FDA lacks the expertise in patent law that would allow it to determine whether a subsequent applicant raised issues of noninfringement in common with the previous applicant. Therefore, the 180-day period is available to the applicant who resolves an issue of patent coverage, regardless of the judgment’s applicability to subsequent ANDA applicants.<sup>82</sup>

Here, FDA prioritized its wish to avoid patent issues over the policy of limiting generic exclusivity to circumstances that would otherwise present a free rider problem. Yet this same policy led FDA to take great liberties with the statutory language in limiting the scope of generic exclusivity when it did not require FDA to engage with patent issues. As previously noted,<sup>83</sup> FDA added a regulatory requirement (subsequently overturned by the courts) that the challenger must be sued for infringement and successfully defend the action in order to claim generic exclusivity. FDA justified this regulatory gloss on the statutory scheme as following from the underlying rationale of encouraging meritorious patent challenges by protecting suc-

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81. 1994 Final, *supra* note 54, § III.C.22. *See also id.* §§ III.C.26, III.C.38, III.F.41, III.G.54, III.G.61.

82. 1989 Proposal, *supra* note 54, § V.K.2.

83. *See supra* notes 79–80 and accompanying text.

cessful challengers from competition from free riders.<sup>84</sup> But the same rationale for generic exclusivity would also seem to support limiting generic exclusivity to defer only those subsequent ANDAs that raise the same infringement issue. After all, ANDAs with patent challenges that do not raise the same issues are not free-riding on the efforts of the first generic challenger. FDA was unwilling to consider this argument only because it meant having to evaluate the relevance of patent infringement litigation to particular ANDAs. Put differently, patent punting functioned as a canon of interpretation that led FDA to choose some meanings and reject others according to the resulting burden on FDA to engage with patents.

Sometimes FDA justified its patent punting moves as preserving the statutory role of the courts in resolving patent disputes. But even for frequently contested matters on which the Hatch-Waxman Act provided no recourse to the courts, such as whether an ANDA applicant could use a section viii statement rather than a paragraph IV certification, FDA insisted that Congress could not possibly have intended for FDA to exercise oversight given its ignorance of patents:

FDA's experience implementing the patent certification provisions suggests that where the patent owner and generic applicant disagree as to the applicability of a use patent, the patent owner may seek to have FDA intervene, by alleging that the generic applicant has not complied with the patent certification and notification provisions of the act. Because FDA has no expertise in the field of patents, the agency has no basis for determining whether a use patent covers the use sought by the generic applicant. Nor does FDA believe that Congress intended the patent provisions of Title I of the 1984 Amendments to require the agency to make such determinations. On the contrary, the 1984 Amendments are plainly structured to allow any patent disputes to be litigated in federal court.<sup>85</sup>

This analysis of Congressional intent ignores significant features of the statute. The only patent disputes that the Hatch-Waxman Act directed to the courts were patent infringement actions based on the filing of an ANDA. Congress did nothing to provide for litigation of disputes about the applicability of particular use patents to particular ANDAs. Indeed, quite the contrary, by allowing section viii statements rather than paragraph IV certifications for irrelevant method of use patents, the Hatch-Waxman Act seems if anything to divert these disputes away from litigation. If an ANDA applicant may use a section viii statement to avoid a method of use patent, it need not include a paragraph IV certification for that patent nor give notice

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84. 1994 Final, *supra* note 54, §§ III.I.72, III.I.76.

85. 1989 Final, *supra* note 54, § III.Q.3.



of the basis for its argument that the patent is invalid or not infringed.<sup>86</sup> The patent will not cause FDA to enter a thirty-month stay against approval of the ANDA, and the section viii statement will not provide a basis for an award of generic exclusivity. If Congress intended for the courts to resolve disputes about whether particular method of use patents should trigger these consequences, they might have extended to section viii statements the same provisions that promote patent infringement litigation following paragraph IV certifications.

The boundaries that FDA sets on its role in administering the patent provisions of the Hatch-Waxman Act cannot be fully explained as a matter of necessary inference from the structure of the statute. A more plausible explanation is its own preference to avoid engaging the merits of any dispute involving patents. Either way, its bottom line has been consistent and clear: FDA will not read patents.

### B. Deference to Innovators

If FDA is unwilling to provide administrative oversight, and if judicial review is unavailable (or untimely), who determines which patents get the Hatch-Waxman boost? For the most part FDA defers to the innovators that submit the patent information. If FDA receives a complaint that a patent is improperly listed, it forwards it to the NDA holder and asks if they want to make any changes:

[I]f an applicant disputes the accuracy or relevance of patent information, it should first notify FDA in writing and state the reasons for the disagreement. FDA will then request that the relevant NDA holder confirm the validity of the patent information, but will not change the patent information itself unless the NDA holder withdraws or amends the patent information. The agency believes that these procedures for determining the validity of patent information are sufficient.<sup>87</sup>

The insufficiency of these procedures soon became manifest as firms took advantage of the lack of administrative oversight to gain the Hatch-

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86. *Caraco Pharm. Labs, Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1676–77 (2012). See 21 U.S.C. § 355(j)(2)(A)(vii)–(viii) (2012).

87. 1994 Final, *supra* note 54, § III.I.64; 21 C.F.R. § 314.53(f) (2014). FDA has recently proposed a modest change in this rule that would allow it instead to defer to the ANDA applicant’s interpretation of the scope of the patent if the NDA holder “fails to timely respond to FDA’s request . . . or submits a revision to the use code that does not provide adequate clarity for FDA to determine whether [a section viii statement] would be appropriate based on the NDA holder’s use code and approved labeling.” Abbreviated New Drug Applications and 505(b)(2) Applications; Proposed Rule, 80 Fed. Reg. 6802, 6827–28 (Feb. 6, 2015) [hereinafter 2015 Proposed]. See *infra* notes 146–56 and accompanying text.

Waxman boost for dubious patent listings.<sup>88</sup> Frustrated ANDA applicants were unable to persuade the courts to compel FDA or NDA holders to remove improperly listed patents from the Orange Book. One obstacle was a pre-Hatch-Waxman provision in the Food, Drug, and Cosmetic Act (FDCA) that limits enforcement to proceedings “by and in the name of the United States.”<sup>89</sup> The Federal Circuit relied on this provision in *Mylan Pharmaceuticals v. Thompson* to reject a private action brought by an ANDA applicant against an innovator and FDA to compel “delisting” of a patent added to the Orange Book eleven hours before an ANDA was to become effective.<sup>90</sup> The Federal Circuit concluded that the action was in essence an impermissible attempt to assert a private right of action for delisting a patent under the FDCA.<sup>91</sup>

ANDA applicants had no more success suing FDA under the Administrative Procedure Act<sup>92</sup> to compel it to delist patents that do not satisfy the requirements for listing.<sup>93</sup> The Federal Circuit in *Apotex v. Thompson*<sup>94</sup> and the Fourth Circuit in *aaiPharma v. Thompson*<sup>95</sup> both concluded that the text of the Hatch-Waxman Act leaves it unclear whether Congress intended for FDA to review patents proffered for listing in the Orange Book,<sup>96</sup> and that FDA’s interpretation of the ambiguous statute was entitled to deference.<sup>97</sup> Both courts, however, noted that FDA’s interpretation left an enforcement gap that Congress or FDA might wish to close.<sup>98</sup> In a concurring opinion in *Apotex v. Thompson*, Judge Plager observed that FDA’s practice was a

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88. Some of these controversies are reviewed in JOHN R. THOMAS, PHARMACEUTICAL PATENT LAW 327–47 (2d ed. 2010). See also Colleen Kelly, *The Balance Between Innovation and Competition: The Hatch-Waxman Act, the 2003 Amendments, and Beyond*, 66 FOOD & DRUG L.J. 417 (2011).

89. 21 U.S.C. § 337(a) (2012). Some provisions may also be enforced by the states. *Id.* § 337(b).

90. 268 F.3d 1323, 1329–30 (Fed. Cir. 2001). The Federal Circuit reversed a District Court decision granting a preliminary injunction against the innovator in a declaratory judgment action based on its assessment that the ANDA applicant was likely to succeed in proving that the patent (which covered a metabolite of the drug) was not properly listed in the Orange Book because it did not claim the approved drug or a method of using the approved drug. 139 F. Supp. 2d 1 (D.D.C. 2001), *rev’d*, 268 F.3d 1323 (Fed. Cir. 2001).

91. 268 F.3d at 1330–32.

92. 5 U.S.C. §§ 701–06 (2012).

93. *Apotex, Inc. v. Thompson*, 347 F.3d 1335 (Fed. Cir. 2003).

94. *Id.* at 1348.

95. 296 F.3d 227, 238 (4th Cir. 2002). The facts of *aaiPharma Inc. v. Thompson* are unusual in that the plaintiff, *aaiPharma*, was not an ANDA applicant seeking to delist an improperly listed patent, but rather a patent holder complaining that the NDA holder, Lilly, refused to submit its patent for listing. The court noted that it was unclear why *aaiPharma*, which did not have its own product ready for market, was interested in securing a 30-month stay, *id.* at 233 n.3, nor why Lilly, which might benefit from the stay, refused to list *aaiPharma*’s patent. *Id.* at 234 n.4.

96. *aaiPharma*, 296 F.2d at 238; *Apotex*, 347 F.3d at 1348.

97. 347 F.3d at 1349.

98. 296 F.3d at 242–43.

“poorly conceived administration of the laws.”<sup>99</sup> Judge Plager thought it reasonable to expect FDA to “have on its staff a handful of competent patent analysts, who, at a minimum, could make an initial judgment about the propriety of a listing,” and concluded, “[i]f neither the Administration nor the courts see fit to make clear FDA’s obligation to administer the Act in a responsible way, Congress should consider doing so.”<sup>100</sup>

### C. FTC Investigation and FDA Response

FDA’s refusal to take a larger role in administering the patent provisions of the Hatch-Waxman Act enabled firms to claim the Hatch-Waxman boost for their patents free of effective oversight. In a 2002 report, FTC made a number of recommendations to address anticompetitive abuses of the Hatch-Waxman Act.<sup>101</sup> Several recommendations specifically addressed improper listing of patents in the Orange Book. The report recommended that only one thirty-month stay be allowed per ANDA, that the requirements for listing patents in the Orange Book should be clarified, and that generics should be able to challenge patent listings in counterclaims to infringement actions. The FTC followed up with a Citizen Petition<sup>102</sup> to FDA asking it to clarify Orange Book listing requirements.<sup>103</sup> FDA responded by amending its regulations<sup>104</sup> to limit the kinds of patents that could be listed in the Orange Book<sup>105</sup> and to limit an NDA holder to a single opportunity for a thirty-month stay against an ANDA.<sup>106</sup> But FDA held firm in its refusal to create

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99. 347 F.3d at 1353 (Plager, J., concurring).

100. *Id.* at 1353–54.

101. FED. TRADE COMM’N, *GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY* (2002).

102. FDA regulations permit any person to submit a citizen petition to FDA asking the Commissioner to issue, amend, or revoke any order or to take or refrain from taking any other form of administrative action. 21 C.F.R. § 10.30.

103. FTC Staff’s Citizen Petition on the Listability of Certain Patents in the Orange Book (May 16, 2001), set forth in Appendix F to FTC Study, *id.* at 108.

104. See 2002 Proposal, *supra* note 54; 2003 Final, *supra* note 54.

105. The revised regulations specify that patents claiming packaging, metabolites, and intermediates do not qualify for listing in the Orange Book and may not be submitted, but that patents with “product by process” claims on a drug substance (*i.e.*, product claims that define the patented product by reciting the process used to create that product) and patents “that claim a drug substance that is the same as the active ingredient that is the subject of the [NDA]” are properly listed. 2003 Final, *supra* note 54, at 36,678–79; 21 C.F.R. § 314.53(b)(1)–(2) (2014). In the case of patents on polymorphs of an approved drug that the NDA holder asserts are “the same as the active ingredient that is the subject of the [NDA],” FDA requires that the applicant certify that it has test data “demonstrating that a drug product containing the polymorph will perform the same as the drug product described in the new drug application,” 21 C.F.R. § 314.53(b)(1), but the rule does not require submission of the test data to FDA.

106. 2003 Final, *supra* note 54, at 36,688–94; 2002 Proposal, *supra* note 54, at 65,454–56. This interpretation of the Hatch-Waxman provisions was superseded by amendments enacted as part of MMA 2003, *supra* note 68, that achieve a similar effect by limiting the 30-month stay to patents that were submitted to FDA prior to the date on which a substantially complete ANDA was submitted. 21 U.S.C. § 355(j)(5)(B)(iii) (2012).

an administrative process to challenge patent listings or to remove improperly listed patents from the Orange Book.

Rather than taking administrative responsibility for monitoring patent submissions, FDA sought to bring about voluntary compliance by requiring that patent submissions be accompanied by detailed “declaration forms” addressing specific questions about the patent claims and attesting to the accuracy of the submitted information under penalty of perjury.<sup>107</sup> The FDA forms warn that a willfully and knowingly false statement is a criminal offense. For method of use patents, submitters must identify specific patent claims that relate to specific sections of the drug label corresponding to the claimed method of use.<sup>108</sup> FDA also added a requirement for applicants to include on the form a description of the method of use in 240 characters or less that would serve as a “use code” for publication in the Orange Book. FDA relies on use codes rather than reading patents to determine whether a method of use patent is relevant to a particular ANDA. If the use code drafted by the NDA holder suggests that the patent covers a method of use for which the ANDA seeks approval, then the applicant must submit a section vii certification for the patent, triggering the Hatch-Waxman boost.<sup>109</sup> If the use code indicates that the patent is not relevant to a particular ANDA, the ANDA applicant may avoid the Hatch-Waxman boost by instead submitting a section viii statement that the patent “does not claim a use for which the applicant is seeking approval” in the ANDA,<sup>110</sup> and the ANDA may be approved without delay.

Assigning the task of drafting use code descriptions to NDA holders introduced new opportunities for strategic behavior and represented a further retreat from oversight of the Orange Book on the part of FDA. FDA had previously drafted use code descriptions itself on the basis of information submitted by NDA applicants.<sup>111</sup> But in 2003, FDA concluded that it was “most consistent with the general balance adopted in Hatch-Waxman” to leave it to innovators to characterize the scope of their patent rights, subject to resolution of infringement disputes in the courts.<sup>112</sup> This new form of patent punting by FDA allowed patent holders to paraphrase their claims so as to maximize the Hatch-Waxman boost.

FDA rejected calls for an administrative process for challenging patent listings, noting that courts had upheld its determination that its role with

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107. 2003 Final, *supra* note 54, at 36, 685–86; 21 C.F.R. § 314.53(b) (2014). The current forms are available at <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM048345.pdf> and <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM048352.pdf>.

108. 21 C.F.R. § 314.53(c)(2)(i)(O)(1)–(2) (2014).

109. See *supra* notes 41–45 and accompanying text.

110. 2003 Final, *supra* note 54, at 36,682–85; 21 C.F.R. § 314.53(c)(2)(i)(O) (2014).

111. 2003 Final, *supra* note 54, at 36,683.

112. *Id.* at 36,682.

respect to patent listings is ministerial,<sup>113</sup> and insisted that “it would be inappropriate and impractical for us to create regulatory mechanisms for reviewing patent listings” because “[w]e lack both the resources and the expertise to resolve such matters.”<sup>114</sup> FDA worried that if it took a larger role, its “decisions on patent listing matters would inevitably lead to disputes and increased litigation against us,” with no assurance that ANDAs would be approved sooner.<sup>115</sup>

#### D. *The Inadequate Counterclaim Remedy*

Shortly after FDA came out with its 2003 Final Rule, Congress amended the Hatch-Waxman provisions as part of the Medicare Prescription Drug, Improvement and Modernization Act (MMA) of 2003<sup>116</sup> to address past abuses highlighted in the FTC report.<sup>117</sup> The MMA provided that an ANDA applicant sued for patent infringement “may assert a counterclaim seeking an order requiring the holder to correct or delete the patent information [in the Orange Book] on the ground that the patent does not claim either—(aa) the drug for which the application was approved; or (bb) an approved method of using the drug.”<sup>118</sup> As soon became apparent, this limited counterclaim remedy was inadequate to correct the problems created by FDA’s failure to exercise timely oversight of patent listings.

This provision has not been extensively used, perhaps because it does not offer effective relief against the harm caused by inappropriate patent listings. A counterclaim is only available to an infringement defendant that has already been sued, providing no help to an ANDA submitter who would prefer to avoid triggering litigation by submitting a section viii statement (that the patent is irrelevant) rather than a paragraph IV certification (that the patent is invalid or not infringed). Moreover, the only remedy available for the counterclaim—a court order<sup>119</sup> to correct the information in the Orange

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113. *Id.* at 36,683.

114. *Id.*

115. *Id.*

116. MMA 2003, *supra* note 68.

117. For a review and analysis of these statutory changes and a comparison to FDA’s regulatory approach, see Colleen Kelly, *The Balance Between Innovation and Competition: The Hatch-Waxman Act, the 2003 Amendments and Beyond*, 66 FOOD & DRUG L.J. 417, 432–45 (2011). The most significant legislative changes limited the availability of a 30-month stay to those patents listed in the Orange Book before submission of a substantially complete ANDA, 21 U.S.C. § 355(j)(5)(B)(iii) (2012); the addition of forfeiture provisions that would cause an ANDA applicant to forfeit its right to claim 180-day exclusivity upon the occurrence of one of a list of “forfeiture events,” *id.* § 355(j)(5)(D); provisions for filing declaratory judgment actions and counterclaims to correct or delete patent information submitted to FDA, *id.* § 355(j)(5)(C); and a requirement that certain patent settlement agreements be filed with the Justice Department or the Federal Trade Commission, MMA 2003, *supra* note 68, § 1112(a)(1).

118. 21 U.S.C. § 355(j)(5)(c)(ii) (2012).

119. The statute explicitly prohibits a damage award. *Id.* § 355(j)(5)(c)(iii).

Book—cannot undo the harm to an ANDA filer who asserts that the patent should not have triggered the Hatch-Waxman boost in the first place.<sup>120</sup> Prior to 2012, some infringement defendants may also have been deterred from using the counterclaim by a restrictive reading of its terms by the Federal Circuit in *Novo Nordisk v. Caraco Pharmaceutical Laboratories*,<sup>121</sup> later reversed by the Supreme Court.

The facts of *Novo Nordisk v. Caraco* illustrate how little the courts can do to correct a problem arising from patent punting by FDA in the face of an NDA holder's strategic behavior. Novo Nordisk held an approved NDA on the drug repaglanide, authorizing it to market the drug for use in three different ways: (1) repaglanide monotherapy (i.e., repaglanide alone); (2) repaglanide in combination with metformin; and (3) repaglanide in combination with thiazolidinediones. Novo Nordisk had a method of use patent (the '358 patent)<sup>122</sup> that claimed:

a method for treating non-insulin dependent diabetes mellitus (NIDDM) comprising administering to a patient in need of such treatment repaglanide in combination with metformin.<sup>123</sup>

When it submitted the '358 patent for listing in the Orange Book, Novo Nordisk provided the following straightforward use code narrative on the FDA form:

Use of repaglanide in combination with metformin to lower blood glucose.

Caraco initially included a paragraph IV certification for the '358 patent in its ANDA for repaglanide in 2005, and Novo Nordisk sued Caraco for infringement. Following a suggestion from FDA, Caraco later amended its ANDA to submit a section viii statement declaring that it did not seek approval for the use of repaglanide in combination with metformin.<sup>124</sup> Novo Nordisk then changed its use code narrative for the patent to the following broader language, which greatly exceeded the scope of the actual claim:

A method for improving glycemic control in adults with type 2 diabetes mellitus.

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120. See *supra* notes 67–69 and accompanying text.

121. *Novo Nordisk A/S v. Caraco Pharm. Labs., Ltd.*, 656 F. Supp. 2d 729 (E.D. Mich. 2009), *rev'd*, 601 F.3d 1359 (Fed. Cir. 2010), *rev'd sub nom. Caraco v. Novo Nordisk*, 132 S. Ct. 1670 (2012).

122. U.S. Patent No. 6,677,358 (filed Dec. 13, 1999).

123. *Id.* col. 10, l. 35. The '358 Patent also included product claims to a combination of repaglanide and metformin.

124. *Novo Nordisk*, 601 F.3d 1367, 1379 n. 16 (Fed. Cir. 2010) (Dyk, J., dissenting).

In light of this change, FDA disallowed Caraco's section viii statement, because the revised use code obscured the fact that the patent was limited to a use (replaglinide in combination with metformin) for which the ANDA did not seek approval. Having previously suggested (on the basis of the prior use code narrative) that Caraco could use a section viii statement, FDA was surely aware of the possibility that the broadened use code narrative misrepresented the claims of the underlying patent, in violation of its regulations.<sup>125</sup> But FDA would not police compliance with its own patent regulations and would not read the patent claims. Instead, it simply deferred to the NDA holder's characterization of what its patent covers.<sup>126</sup>

Unable to get relief from FDA, Caraco filed a counterclaim to compel Novo Nordisk to change back to the original use code. The District Court found that the revised use code narrative "seriously misrepresents the approved method of use covered by [the patent claim]"<sup>127</sup> and concluded that Caraco was entitled to an order requiring Novo to correct the patent information it had submitted to FDA.<sup>128</sup> A divided Federal Circuit panel reversed.<sup>129</sup> The panel majority held that the statutory counterclaim is available only if the patent fails to claim either the drug or *any* approved method of using the drug, and therefore provided no remedy against listing the '358 patent.<sup>130</sup> The majority also held that the only "patent information" that may be deleted or corrected by counterclaim is the "patent number and expiration date" that the statute explicitly requires NDA holders to disclose,<sup>131</sup> not the use code narratives that FDA regulations require.<sup>132</sup>

A unanimous Supreme Court reversed on both grounds, interpreting the statute to permit a counterclaim for correction of an overly broad use code.<sup>133</sup> This interpretation allows the courts to order correction of listings, but judicial attention will likely come too late to correct the damage that could have been averted through timely FDA oversight. In a concurring opinion, Justice Sotomayor lamented that the statutory counterclaim was an

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125. 21 C.F.R. § 314.53(b)(1) (2014) ("The applicant shall separately identify each pending or approved method of use and related patent claim. For approved applications, the applicant submitting the method-of-use patent shall identify with specificity the section of the approved labeling that corresponds to the method of use claimed by the patent submitted.").

126. *Id.* § 314.53(f).

127. *Novo Nordisk A/S v. Caraco Pharm. Labs., Ltd.*, 656 F. Supp. 2d 729, 730 (E.D. Mich. 2009).

128. *Id.*

129. *Novo Nordisk A/S v. Caraco Pharm. Labs., Ltd.*, 601 F.3d 1359 (Fed. Cir. 2010) (Rader, J., majority opinion); 601 F.3d at 1367 (Clevenger, J., concurring); 601 F.3d at 1368 (Dyk, J., dissenting).

130. *Id.* at 1364–66. The majority thought that an infringement defendant that does not seek approval for the patented use can assert as much in a paragraph IV certification and prove it in an infringement action. *Id.* at 1365.

131. 21 U.S.C. § 355(b)(1)(G) (2012).

132. *Novo Nordisk*, 601 F.3d at 1366–67.

133. *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670 (2012).



imperfect solution to the problem created by the overly broad use code, requiring expensive and time-consuming litigation, and called upon Congress or FDA to come up with a better solution.<sup>134</sup> The majority observed in a footnote that the propriety of “FDA’s view of its ministerial role” was not before it,<sup>135</sup> leaving open the possibility of requiring FDA to take a more active role in the future.

The use code system that allowed Novo Nordisk to misrepresent the scope of its patent claims to defer generic competition is not required by the Hatch-Waxman Act, but rather is an administrative innovation designed by FDA to spare itself from having to read patent claims to determine what they cover. As FDA explained in the Preamble to its 2003 rule changes, use codes are designed to clarify “whether an ANDA applicant can ‘carve out’ the method of use [i.e., use a section viii statement] rather than certify to the listed patent.”<sup>136</sup> The statute requires an ANDA to include a certification only “with respect to each patent which claims the listed drug . . . or which claims a use for such listed drug for which the applicant is seeking approval.”<sup>137</sup> If a listed patent only claims a use for which the applicant is *not* seeking approval, the applicant may say so in a section viii statement,<sup>138</sup> without triggering the Hatch-Waxman boost.<sup>139</sup>

This is a crucial distinction. When an ANDA includes a paragraph IV certification, the Hatch-Waxman Act diverts disputes about validity and infringement to litigation.<sup>140</sup> But when FDA implemented the use code system, nothing in the Hatch-Waxman Act diverted disputes about the proper use of a section viii statement to the courts for litigation, and it is unlikely that the courts would have recognized such a claim.<sup>141</sup> A patent holder could sue an ANDA applicant who has used a section viii statement for patent infringement (although it would lose on the merits if the patent in fact does not claim

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134. *Id.* at 1688–89 (Sotomayor, J., concurring).

135. *Id.* at 1677 n.2.

136. 2003 Final, *supra* note 54, at 36,682.

137. 21 U.S.C. § 355(j)(2)(A)(vii) (2012) (emphasis added).

138. *Id.* § 355(j)(2)(A)(viii).

139. 2003 Final, *supra* note 54, at 36,682.

140. FDA relies on these provisions to support its position that the Hatch-Waxman Act does not contemplate anything beyond a “ministerial” role for FDA with respect to patents. *See, e.g.*, 2003 Final, *supra* note 54, at 36,683 (“A fundamental assumption of the Hatch-Waxman Amendments is that the courts are the appropriate mechanism for the resolution of disputes about the scope and validity of patents. The courts have the experience, expertise, and authority to address complex and important issues of patent law.”).

141. Prior to the 2003 amendments, courts repeatedly held that neither the FFDCA nor the Patent Act provides a private cause of action for delisting patents from the Orange Book, *see supra* notes 89–98 and accompanying text. But in one particularly egregious case an ANDA applicant brought a successful claim against FDA under the Administrative Procedure Act alleging that FDA’s refusal to accept a section viii statement rather than a paragraph IV certification was “arbitrary and capricious.” *Purepac Pharm. Co. v. Thompson*, 354 F.3d 877, 883–84 (D.C. Cir. 2004).

a use for which the ANDA seeks approval).<sup>142</sup> But such an infringement action would not give the courts an occasion to address whether the parties were entitled to the Hatch-Waxman boost. The statute makes these benefits (notice, thirty-month stay, generic exclusivity) available without the need for judicial action, but only when an ANDA includes a paragraph IV certification that the patent is invalid or not infringed. And the statute requires such a certification only “with respect to each patent which claims the listed drug . . . or which claims a use for such listed drug for which the applicant is seeking approval” in the ANDA.<sup>143</sup> If FDA allows a patent holder to claim the Hatch-Waxman boost for a patent that is not entitled to those benefits, there is little that courts can do to fix the problem by the time it gets to their attention. Only FDA can exercise effective oversight.

In 2015, twelve years after passage of the MMA, FDA published a proposed rule to revise its ANDA regulations once again.<sup>144</sup> The proposed rule continues to exempt FDA from any obligation to read submitted patents to determine what they claim. But FDA also took note of the Supreme Court’s observation in *Caraco* that “an overbroad use code . . . throws a wrench into the FDA’s ability to approve generic drugs as the statute contemplates.”<sup>145</sup>

To address this problem, the 2015 Proposed Rule would make several changes. First, it would “codify our longstanding requirement that the NDA applicant’s [use code] . . . must contain adequate information to assist FDA and . . . ANDA applicants in determining whether [the patent] claims a use for which the . . . ANDA applicant is not seeking approval.”<sup>146</sup> In particular, it would require that if the patent claim does not cover every use of the drug, “the applicant must only identify the specific portion(s) of the indication or other condition of use claimed by the patent.”<sup>147</sup> Second, in the event that a third party disputes the accuracy or relevance of the submitted patent information, the proposed rule would give the NDA holder thirty days to confirm the correctness of the patent information and to provide information on the specific approved use claimed by the patent that enables FDA to make a determination of whether the patent may be avoided through use of a section

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142. Under 35 U.S.C. § 271(e)(2)(A), added as part of the Hatch-Waxman Act, submitting an ANDA “for a drug claimed in a patent or the use of which is claimed in a patent” counts as an act of infringement. The Federal Circuit has clarified that submission of an ANDA that does not seek approval for the patented use does not count as an act of infringement under this provision. *Bayer Schering Pharma. AG v. Lupin*, 676 F.3d 1316 (Fed. Cir. 2012); *Astrazeneca Pharma. LP v. Apotex Corp.*, 669 F.3d 1370 (Fed. Cir. 2012).

143. *See, e.g., Purepac Pharm. Co. v. Thompson*, 354 F.3d 877 (D.C. Cir. 2004) (NDA holder listed a patent in the Orange Book for an unapproved method of use of listed drug; two competing generics submitted ANDAs, one with a paragraph IV certification for that patent and the other with a section viii statement for the same patent).

144. *See* 2015 Proposed, *supra* note 87.

145. *Id.* at 6820–21, citing *Caraco*, 132 S. Ct. at 1684.

146. *Id.* at 6820.

147. *Id.* *See* text of proposed § 314.53(c)(2)(i)(O)(2) and § 314.53(c)(2)(ii)(P)(2), *id.* at 6882–84.

viii statement.<sup>148</sup> Third, and potentially the most significant of the proposed changes, if the NDA holder either fails to submit a timely response or responds in a way that fails to provide adequate clarity for FDA to determine whether a section viii statement is appropriate, FDA would review the ANDA with deference to the ANDA applicant's interpretation of the scope of the patent.<sup>149</sup> This represents a marked turnaround from FDA's current policy of deference to NDA holders.<sup>150</sup> In 2002, when it proposed the current version of the rule, FDA rejected the possibility of deference to ANDA applicants in the belief that they could not resist the temptation to cheat:

If ANDA . . . applicants could always avoid the possibility of a 30-month stay by asserting in a section viii statement that certain labeling for which the applicant is seeking approval is not protected by a listed method-of-use patent—despite the NDA holder's assertion to the contrary—there would be little reason for any applicant to submit a paragraph IV certification for a method-of-use patent. This approach would essentially eliminate the certification, notice, and litigation process as to any listed method-of-use patent, producing an outcome that is inconsistent with the [Hatch-Waxman] act.<sup>151</sup>

In justifying its 2015 proposal, FDA tells a very different story in which an ANDA applicant “has a strong incentive to interpret the scope of the patent correctly to avoid being subject to patent infringement litigation following ANDA approval and potentially enjoined from marketing its product.”<sup>152</sup> ANDA applicants have another reason to avoid improper use of section viii statements in lieu of paragraph IV certifications: generic exclusivity is only available for an ANDA that includes a paragraph IV certification.<sup>153</sup> Perhaps FDA also recognizes that NDA holders have a strong incentive to submit broad use codes in order to trigger the Hatch-Waxman boost, as suggested by the reference to the *Caraco* case in the Proposed Rule.

The proposed shift from deference to NDA holders to deference to ANDA applicants will surely provoke opposition from NDA holders and may not be implemented. FDA suggests that NDA holders can make deference to ANDA holders unnecessary by avoiding the use of overbroad use codes:

FDA believes that enhancing the mechanism for challenging overbroad use codes listed in the Orange Book may cause NDA holders

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148. *Id.* at 6827; text of proposed § 314.53(f)(1), *id.* at 6885.

149. *Id.* at 6827.

150. 2003 Final, *supra* note 54, at 36,682.

151. *Id.*

152. 2015 Proposed, *supra* note 87, at 6828.

153. *See supra* notes 47–53 and accompanying text.

to be more circumspect in their original submission of patent information to FDA. Accordingly, we expect that there will rarely be a need for the Agency to review the proposed labeling for the . . . ANDA with deference to the . . . ANDA applicant's interpretation of the scope of the patent. However, we invite comment on this proposed approach to enhancing FDA's response to challenges to the accuracy or relevance of submissions of patent information to the Agency, while maintaining the Agency's ministerial role in patent filing.<sup>154</sup>

In other words, FDA is open to considering any approach that does not require it to read patents. But so long as FDA is unwilling to read patent claims to determine their relevance to NDAs and ANDAs, whichever default rule it chooses will empower one side or the other to take advantage of FDA's deference. In 2002 and 2015, FDA made different proposals based on its belief about which party had a better incentive to characterize the coverage of the patent accurately. Given FDA's own interest in maintaining its "purely ministerial role" in patent matters, it is surely tempted to underestimate the likely errors from a rule of deference, whichever side it defers to.

Another factor to consider in picking a rule of deference is which approach makes it easier to correct the inevitable errors. The errors arising from deference to overly broad use codes are effectively uncorrectable. Even though the Supreme Court eventually interpreted the 2003 statutory counterclaim provision to permit judicial orders to correct use codes, it provides a limited remedy that comes too late to undo the effects of the Hatch-Waxman boost. On the other hand, errors arising from deference to improper use of section viii statements can be corrected in patent infringement litigation against the ANDA applicant.<sup>155</sup> If the patent holder is correct that the ANDA seeks approval for a patented use of the drug, the courts have jurisdiction to resolve the matter.<sup>156</sup> The proposed change may thus reduce the incidence of irremediable harms in comparison to the current rule. But FDA could do a better job of distinguishing which patents are relevant to which NDAs and ANDAs if it were willing to read the patents itself instead of deferring to the assessments of interested parties.

### III. SETTLEMENTS AND PATENT PUNTING BY ANTITRUST COURTS

Many litigated cases never reach adjudication on the merits and are instead resolved by settlements on terms that defer competition. Some of these cases have provoked scrutiny under antitrust laws, presenting antitrust courts

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154. 2015 Proposed, *supra* note 87, at 6828.

155. 35 U.S.C. § 271(e)(2).

156. *See infra* notes 261–271 and accompanying text.

with the question of whether and how far the patent rights at stake in the litigation protect the parties from antitrust liability for settling the dispute. These antitrust cases could provide another opportunity to consider whether the settlement reflects a fair compromise of the underlying patent dispute, but instead they have become another arena for patent punting.

#### A. Incentives for Collusive Settlements

Pharmaceutical firms quickly realized that patent infringement litigation against the backdrop of the Hatch-Waxman boost did not have to be a zero-sum game. Rather than pursuing costly and risky litigation to final judgment for one side or the other, the innovator and generic firms could settle and split the rents. The terms of these settlements have differed from case to case—and may be increasingly variable as a result of recent antitrust developments—but in a recurring pattern the generic gives up its challenge to the patent and agrees to defer pursuit of its ANDA, perhaps until the end of the patent term, in exchange for a payment from the innovator to the generic.

These arrangements, sometimes called “reverse payment” or “pay-for-delay” agreements,<sup>157</sup> have drawn extensive antitrust scrutiny, as detailed in the next Part. It is not difficult to understand why such settlements would be of interest to antitrust enforcers. If, but for the settlement, the defendant would have entered the market in competition with the plaintiff, a payment by a market incumbent to keep a potential entrant off the market looks like ordinary collusion to avoid competition. But the existence of patents complicates the story, because the patent holder is asserting a legal right to exclude competitors from the market in the infringement action. If the patent is valid, and if the generic product would infringe, the patent holder has a right to exclude the generic until the patent expires. On the other hand, if the patent is invalid, or if the generic product would not infringe the patent, the patent holder should lose the infringement action. Uncertainty about how these is-

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157. A sampling of the voluminous literature on patent settlements includes Joseph F. Brodley and Maureen A. O'Rourke, *Preliminary Views: Patent Settlement Agreements*, 16 ANTITRUST 53 (2002); Jeremy I. Bulow, *The Gaming of Pharmaceutical Patents*, (Stanford Graduate Sch. of Bus., Research Paper No. 1804, 2003), available at <http://www.gsb.stanford.edu/faculty-research/working-papers/gaming-pharmaceutical-patents>; Thomas F. Cotter, *Refining the “Presumptive Illegality” Approach to Settlements of Patent Disputes Involving Reverse Payments: A Commentary on Hovenkamp, Janis and Lemley*, 87 MINN. L. REV. 1789 (2003); Daniel A. Crane, *Exit Payments in Settlement of Patent Infringement Lawsuits: Antitrust Rules and Economic Implications*, 54 FLA. L. REV. 747 (2002); C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553 (2006); Herbert Hovenkamp et al., *Anticompetitive Settlement of Intellectual Property Disputes*, 87 MINN. L. REV. 1719 (2003); Jonathon M. Lace, *Responding to Patent Litigation Settlements: Does the FTC Have it Right Yet?*, 64 U. PITT. L. REV. 201 (2002); James Langenfeld & Wenqing Li, *Intellectual Property and Agreements to Settle Patent Disputes: The Case of Settlement Agreements with Payments from Branded to Generic Drug Manufacturers*, 70 ANTITRUST L. J. 777 (2003); Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND J. ECON. 391 (2003).

sues will be resolved may lead risk-averse parties to settle the litigation—on terms that are likely to include a reverse payment—even if both sides think the patent holder is likely to prevail.

Consider a simplified example. Suppose an innovator has brought a patent infringement suit against a generic that is the first applicant to file an ANDA with a paragraph IV certification for that product. If the innovator prevails in the lawsuit and gets an injunction against generic entry, it will remain the sole source of the drug and can continue to sell at a monopoly price. Let's say that is worth \$1 billion to the innovator. On the other hand, if the generic prevails, it could enter the market right away,<sup>158</sup> and FDA could not approve another ANDA with a paragraph IV certification for the same product for 180 days.<sup>159</sup> After that period expires, other generics could be approved right away, and the drug would promptly become available at competitive prices. Let's say that the generic challenger assesses the value to it of a complete victory, including the 180-day period of generic exclusivity, at \$100 million. No money will change hands if the case is litigated to final judgment no matter who wins. There is no infringing product on the market, so the innovator cannot recover damages even if it proves that the ANDA product would infringe the patent.<sup>160</sup> What is at stake is injunctive relief and the timing of FDA approval of ANDAs.<sup>161</sup> The parties are unsure what the courts will do, and they are risk averse, so they want to settle.

Suppose the plaintiff has a strong legal case on the merits, and both parties assess the likelihood of a win by the innovator at 80% and the likelihood of a win by the generic at 20%. Even for such a strong case, one would expect risk-averse parties to be willing to compromise and settle on terms that leave each of them somewhat less happy than they would be with a total victory. Given that the innovator has much more at stake financially than the generic, one might expect the bargain to favor the generic if it plays its hand well. If the parties settle for the expected value of the lawsuit to the generic, one would see a reverse payment of \$20 million (20% of \$100 million); but the innovator might be willing to pay as much as \$200 million to avoid a 20% risk of losing \$1 billion. What figure they settle on depends on relative risk aversion and bargaining skills, but a reverse payment is to be expected

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158. 21 U.S.C. § 355(j)(5)(B)(iii)(I) (2012) (“if before the expiration of [the 30-month stay entered upon filing of an infringement action against the ANDA filer] the district court decides that the patent is invalid or not infringed . . . the approval shall be made effective on – (aa) the date on which the court enters judgment reflecting the decision”).

159. *Id.*

160. 35 U.S.C. § 271(e)(4)(C) (2012) (“damages or other monetary relief may be awarded against an infringer only if there has been commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug”).

161. *Id.* § 271(e)(4)(B) (“injunctive relief may be granted against an infringer to prevent the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug”).



in any case. This is not because the patent case is weak, but because the patent is valuable.

Nonetheless, antitrust litigation, sometimes initiated by private plaintiffs and sometimes by FTC, followed quickly on the heels of the reverse payments. Antitrust plaintiffs have seen the reverse payment from the patent holder to the alleged wrongdoer as a smoking gun that calls into question the merits of the asserted patent rights, arguing that the underlying infringement claims must have been frivolous and that the purported settlements are a thin camouflage for improper collusion to delay competition by sharing the rents from invalid patents.

### B. *The Response of Antitrust Courts*

Antitrust courts quickly fell into a circuit split, with some applying a *per se* rule of illegality for reverse payment agreements and others applying a form of rule of reason analysis that approached *per se* legality. In no case, however, did the court inquire into the merits of the underlying patent infringement case. Like FDA, courts punted on the substantive patent issues. Indeed, patent punting was the one point on which all courts agreed.

The Sixth Circuit spoke first, finding reverse payments *per se* illegal in *In re Cardizem CD Antitrust Litigation*.<sup>162</sup> That case grew out of a patent infringement action brought by Hoechst Marion Roussel, Inc., the manufacturer of the branded heart medication Cardizem CD, against Andrx Pharmaceuticals, Inc., a generic firm that had filed an ANDA seeking approval for a generic version of the drug. The parties reached a settlement *pendent lite* in which Andrx agreed not to market its generic version of Cardizem CD pending a final adjudication in the infringement action, and not to waive any of its rights under the Hatch-Waxman Act to a period of generic exclusivity for filing the first ANDA for the product that included a paragraph IV certification challenging the patent.<sup>163</sup> In return, Hoechst agreed to make periodic payments to Andrx while the lawsuit remained pending and to grant it licensing rights in the future. The Sixth Circuit saw the arrangement as “a horizontal agreement to eliminate competition in the market” and “a classic example of a *per se* illegal restraint of trade.”<sup>164</sup> It pointed to the reverse payment and the agreement to retain generic exclusivity in rejecting the argument that the agreement was merely an attempt to

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162. *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003).

163. 21 U.S.C. § 355(j)(5)(B)(iv). Under the version of the statute in effect at the time, FDA could not approve another ANDA with a paragraph IV certification for the same product until 180 days after the earlier of the date of first commercial marketing of the generic drug or the date of a court ruling that the patent is invalid or not infringed. *See Kelly, supra* note 117, at 430–32.

164. *In re Cardizem*, 332 F.3d at 908.



enforce patent rights or to settle patent litigation, noting that Hoechst paid its “only potential competitor \$40 million per year to stay out of the market.”<sup>165</sup>

Shortly thereafter, the Eleventh Circuit called for “rule of reason” analysis in a case involving similar facts, *Valley Drug v. Geneva Pharmaceuticals*.<sup>166</sup> Abbott Laboratories had filed patent infringement lawsuits against two companies that submitted ANDAs seeking FDA approval to market generic versions of Abbott’s drug Hytrin. Under the terms of settlement agreements, each defendant agreed not to begin marketing a generic version of Hytrin until another party did so first, Abbott’s patent expired, or a court declared the patent invalid, and Abbott agreed to make payments to the generics.<sup>167</sup> A district court later held Abbott’s patent invalid.<sup>168</sup> Pharmaceutical wholesalers then sued Abbott and the settling defendants, alleging that their settlement agreements were *per se* violations of § 1 of the Sherman Act. The Eleventh Circuit ultimately held that the arrangement should be evaluated under the rule of reason. The court held that that the reasonableness of the agreements should not be condemned because the patent was subsequently declared invalid, so long as the “exclusionary effects of a settlement” were “reasonably within the scope of the patent.”<sup>169</sup> The provision for reverse payments from the patent holder to the infringers did not call for *per se* liability under the antitrust laws.<sup>170</sup> The court was unable to conclude on the record that the exclusionary effects of the settlement agreements were greater than the exclusionary effects of the patents, and directed the lower court on remand to consider such factors as the magnitude of the reverse payments in relation to the lost profits that would occur if the patent were declared invalid, the costs the parties expected to save from not litigating, and the parties’ expectations with respect to the outcome of the patent infringement case.<sup>171</sup>

After the *Cardizem* and *Valley Drug* decisions, the FTC condemned a reverse payment settlement of a patent infringement action as unlawful under the FTC Act in *In re Schering Plough*.<sup>172</sup> Under the settlement at issue in that case, Schering agreed to make payments totaling \$60 million to the infringement defendant Upsher, and Upsher agreed not to market any ge-

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165. *Id.*

166. *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294 (11th Cir. 2003).

167. *Id.* at 1300–01.

168. *Abbott Labs. v. Geneva Pharm., Inc.*, 51 U.S.P.Q.2d (BNA) 1301 (N.D. Ill. Aug. 28, 1998).

169. *Valley Drug*, 344 F.3d at 1306–08.

170. *Id.* at 1309–10.

171. *Id.* The Federal Circuit, applying the law of the Second Circuit, reached a similar result in *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 544 F. 3d 1323 (Fed. Cir. 2008). See also *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2d Cir. 2005).

172. *Schering-Plough Corp.*, 136 F.T.C. 956, 1060–61 (2003), available at <http://www.ftc.gov/enforcement/cases-proceedings/9910256/schering-plough-corporation-upsher-smith-laboratories-american>.

neric version of Schering's product before September 2001. Upsher also licensed Schering to market six Upsher products in specified territories. Although the FTC declined to apply a rule of *per se* illegality, it refused to inquire into the merits of the patent infringement claim in finding the settlement unlawful. It held that "it is possible to envision special hypothetical cases where some payments from pioneers to generics could be efficient and beneficial to consumers" but found insufficient evidence to support such a claim in that case.

Schering-Plough appealed the FTC's order to the Eleventh Circuit, which vacated the Commission's order.<sup>173</sup> The Supreme Court denied *certiorari* in 2006<sup>174</sup> after the Solicitor General surprisingly broke with the FTC position, arguing that the Eleventh Circuit's opinion did not create a direct conflict with any other Circuit and that the patent settlements issue was not well-presented in that case.<sup>175</sup> The Solicitor General again reversed course in the Obama administration, arguing that "reverse payment" agreements are presumptively unlawful.<sup>176</sup> The Eleventh Circuit held firm throughout these changes in administration, rejecting FTC's position yet again in its 2012 decision in *FTC v. Watson Pharmaceuticals*, which held reverse payment settlements lawful so long as they fall within the patent's exclusionary potential.<sup>177</sup>

In that case Solvay Pharmaceuticals, the patent holder, brought an infringement action against two generic companies that had filed ANDAs for generic versions of the pioneer product AndroGel. The patent litigation was still pending when the Hatch-Waxman thirty-month stay expired, allowing FDA approval of the ANDAs to become effective. Solvay then entered into settlement agreements with the generics. The generics agreed not to market generic versions of AndroGel under their ANDAs until 2015 (five years before the expiration of the patent). Meanwhile, the generics agreed to market branded AndroGel on behalf of Solvay and to serve as back-up manufacturers for Solvay, and Solvay agreed to make millions of dollars a year in payments to the generics.

FTC found the settlement unlawful. On appeal, the Eleventh Circuit held that an allegation that the patentee was unlikely to win its infringement lawsuit could not establish the illegality of a settlement and reiterated its holding that "absent sham litigation or fraud in obtaining the patent, a re-

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173. *Schering-Plough Corp. v. Fed. Trade Comm'n*, 402 F.3d 1056, 1071 (11th Cir. 2005).

174. *Fed. Trade Comm'n v. Schering-Plough Corp.*, 548 U.S. 919 (2006).

175. Brief of United States as *amicus curiae*, *Schering-Plough*, 548 U.S. 919 (No. 05-273), at \*33-35, available at <http://www.justice.gov/atr/cases/f216300/216358.htm>.

176. Brief of the United States in Response to the Court's Invitation, *Arkansas Carpenters Health & Welfare Fund v. Bayer, AG*, 625 F.3d 779 (2d Cir. 2010) (Nos. 05-2851-cv(L), 05-2852-cv (CON), 05-2863-cv (CON)), 2009 WL 8385027, at \*11.

177. *Fed. Trade Comm'n v. Watson Pharm., Inc.*, 677 F.3d 1298 (11th Cir. 2012).

verse payment settlement is immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent.”<sup>178</sup>

In subsequent cases, the Second Circuit analyzed reverse payment settlements in much the same way as the Eleventh Circuit,<sup>179</sup> while the Third Circuit held reverse payment settlements presumptively illegal.<sup>180</sup>

Finally the Supreme Court agreed to review the issue in the AndroGel case, which became known as *FTC v. Actavis*,<sup>181</sup> and reversed the Eleventh Circuit. In an opinion by Justice Breyer, a five Justice majority held that a reverse payment settlement agreement *might* violate the antitrust laws under rule of reason analysis and that the Eleventh Circuit should therefore have allowed the FTC’s lawsuit to proceed.<sup>182</sup> But the majority made clear that rule of reason analysis is not likely to require determining whether the underlying patent action was meritorious in order to decide whether a settlement with a reverse payment was reasonable. Instead, the Court invited the antitrust courts to continue to punt on patent analysis, at least when the settlement involves a payment from the plaintiff to the defendants.

The majority opinion appears to acknowledge the rights conferred by a patent as conferring immunity under the antitrust laws, but it nonetheless steered the courts away from analyzing the merits of the underlying patent dispute in a number of ways. For one thing, it called for a balance of the policies of the patent laws with the policies of the antitrust laws in deciding whether the settlement agreement is within the scope of the patent,<sup>183</sup> leaving open the possibility that a pay-for-delay settlement might still violate the antitrust laws even if the patent were valid and infringed. In rejecting the Eleventh Circuit’s approach, however, the majority noted that an invalid patent confers no right to exclude competitors and that “even a valid patent confers no right to exclude products or processes that do not actually infringe,”<sup>184</sup> suggesting that perhaps the validity and scope of the patent matter and should therefore be considered. Yet the majority did not fault the Eleventh Circuit for failing to consider whether the ANDA product would have infringed the patent. Instead, the majority acknowledged the circuit court’s concern that antitrust litigation should not require costly and complex re-litigation of the settled patent infringement action within the antitrust ac-

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178. *Id.* at 1312.

179. *In re Tamoxifen Citrate Antitrust Litig.*, 429 F.3d 370, 396–97 (2d Cir. 2005).

180. *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 218 (3d Cir. 2012).

181. 133 S. Ct. 2223 (2013).

182. *Id.* at 2225; *see also id.* at 2233 (characterizing prior cases as seeking “to accommodate patent and antitrust policies, finding challenged terms and conditions unlawful unless patent law policy offsets the antitrust law policy strongly favoring competition.”).

183. *Id.* at 2231 (“[T]his Court has indicated that patent and antitrust policies are both relevant in determining the ‘scope of the patent monopoly’—and consequently antitrust law immunity—that is conferred by a patent.”).

184. *Id.*

tion,<sup>185</sup> but concluded that “it is normally not necessary to litigate patent validity to answer the antitrust question.”<sup>186</sup> The Eleventh Circuit’s approach of immunizing reverse payment settlements from antitrust attack to avoid having to address the patent issues thus “throws out the baby with the bath water.”<sup>187</sup> Instead, the Court suggested as an administratively feasible alternative that courts look to the size of the reverse payment as an indication that the patent case lacked merit: “An unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent’s survival,” and the size of the reverse payment thus “can provide a workable surrogate for a patent’s weakness, all without forcing a court to conduct a detailed exploration of the validity of the patent itself.”<sup>188</sup>

The Court presented its own approach as an application of the rule of reason, in contrast to the Eleventh Circuit’s approach of near-automatic antitrust immunity to reverse payment settlements.<sup>189</sup> But if the reverse payment alone will support an inference that the patent was weak without the need for “detailed exploration,” the majority’s approach treads close to a *per se* rule against reverse payment settlements. The Court put forth the possibility that reverse payments may sometimes be justified, notwithstanding their anticompetitive effects. A reverse payment, for example, may amount to no more than a rough approximation of the litigation expenses saved through the settlement, or it may reflect compensation for other services that the generic has promised to perform—such as distributing the patented product or helping to develop a market for it.<sup>190</sup>

Notably absent from the Court’s list of justifications for a reverse payment is a patent holder’s wish to avoid the risk that a valuable patent will be held invalid, with a resulting loss of expected revenues. Indeed, the Court said that if the reason for the reverse payment is “a desire to maintain and to share patent-generated monopoly profits, then, in the absence of some other justification, the antitrust laws are likely to forbid the arrangement.”<sup>191</sup> Nor does the Court suggest that the parties might call into question the “workable surrogate” for a determination of the patent’s weakness by showing that the underlying patent infringement case was, in fact, strong. In other words, a

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185. *Id.* at 2234 (“The [Eleventh] Circuit’s . . . underlying practical concern consists of its fear that antitrust scrutiny of a reverse payment agreement would require the parties to litigate the validity of the patent in order to demonstrate what would have happened to competition in the absence of the settlement. Any such litigation will prove time consuming, complex, and expensive.”).

186. *Id.* at 2236.

187. *Id.*

188. *Id.* at 2236–37; *cf. supra* notes 169–171 and accompanying text, suggesting that settlement of even a strong patent infringement case might be expected to include a reverse payment.

189. *Actavis*, 133 S. Ct. at 2237.

190. *See id.* at 2236.

191. *Id.* at 2237.

plaintiff's willingness to share the rents from a patent with a defendant who challenges validity and infringement is enough to permit a court to find an antitrust violation without further assessment of the merits of the patent infringement case.

Three dissenting justices (Roberts, Scalia, and Thomas) apparently would have punted the patent issues in the opposite direction, protecting the settlement from antitrust liability on the assumption that it "did not exceed the scope of the patent."<sup>192</sup> The dissenters explained that "[a] patent carves out an exception to the applicability of antitrust laws. The correct approach should therefore be to ask whether the settlement gives [the patent holder] monopoly power beyond what the patent already gave it."<sup>193</sup>

Although the dissenters asserted that "the scope of the patent—i.e., the rights conferred by the patent—forms the zone within which the patent holder may operate without facing antitrust liability,"<sup>194</sup> they did not indicate how antitrust courts should ascertain what the scope of the patent is, beyond noting that it "should be determined by reference to *patent law*" rather than antitrust law.<sup>195</sup> In particular, they did not indicate that the *Actavis* case should be remanded for a determination of the scope of the patent at issue under patent law. Instead, they simply assumed that the settlement agreement was within the scope of the patent, evidently based on a belief that the majority accepted that characterization.<sup>196</sup> But both validity and infringement were contested in the patent infringement action and remained unresolved at the time of settlement, and no findings were made on these issues in the antitrust action. The dissent agreed with the majority that "we're not quite certain if the patent is actually valid, or if the competitor is infringing it."<sup>197</sup> Yet somehow this uncertainty as to validity and infringement did not cast doubt on the dissenters' conviction that the settlement agreement was within the scope of the monopoly power conferred by the patent. On the other hand, the dissent warned that the majority's approach will inevitably lead defendants to raise their patent rights as a defense in antitrust actions, casting doubt on the majority's assertion that it will not normally be necessary to litigate patent validity to resolve the antitrust case.<sup>198</sup> The dissent concluded by announcing a preference to "keep things as they were."<sup>199</sup> Perhaps this is an endorsement of the Eleventh Circuit's approach, in which settlement of a patent infringement action is immune from antitrust attack "absent sham liti-

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192. *Id.* at 2239 (Roberts, J., dissenting).

193. *Id.* at 2238.

194. *Id.*

195. *Id.* at 2240 (emphasis in original).

196. The dissent states that "the Court . . . is willing to accept that Solvay's actions did not exceed the scope of its patent." *Id.* (citation omitted).

197. *Id.*

198. *See id.* at 2244.

199. *Id.* at 2247.

gation or fraud in obtaining the patent . . . so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent.”<sup>200</sup>

In sum, although they disagreed about which side should prevail and although there is considerable ambiguity in both opinions, both the majority and the dissent in *Actavis* left considerable room for antitrust courts to continue to punt on patent issues in reviewing settlement agreements.

### C. Patent Punting Leads Antitrust Courts Astray

It is remarkable that across the wide range of views on reverse payment settlements expressed in the Circuit split, *Actavis* opinions, and FTC, nobody has made any effort to engage with the merits of the underlying patent infringement actions. Even opinions that purport to protect only those settlements falling within the “scope of the patent” show no willingness to assess whether, but for the reverse payment settlement, the patentee would actually have obtained an injunction excluding the generic, or the generic would have been permitted to enter the market. In a particularly apt metaphor, the Eleventh Circuit called merits review within the antitrust case “a turducken task”<sup>201</sup>—a turducken being a chicken stuffed inside a duck stuffed inside a turkey. Everybody seems to agree that reviewing the merits is too much for the courts to swallow—they disagree only over whether the default position should be antitrust immunity or liability.

While it is easy to understand the aversion of antitrust agencies and courts to analyzing the merits of settled patent infringement actions, it is not clear how they can avoid that inquiry if the rights conferred by patents have any relevance to antitrust analysis. Even if the *Actavis* decision makes both patent and antitrust policies “relevant in determining the ‘scope of the patent monopoly’—and consequently antitrust law immunity—that is conferred by a patent,”<sup>202</sup> analysis of the patent infringement case forms at least one part of the inquiry. And even under the Eleventh Circuit approach that the *Actavis* dissent would have approved, in order to determine whether a settlement falls within the “exclusionary potential” of the patent, it would seem necessary to at least interpret the patent and compare it to the product and the scope of approval sought by the defendant. Yet neither opinion directs the lower courts to undertake that analysis, instead inviting continued patent punting through reliance on flawed proxies for consideration of the merits of the patent case.

#### 1. Limited Signal Value of the Direction of Payment

The information communicated by the direction of payment in a settlement has limited value to a court making an antitrust determination. Though

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200. Fed. Trade Comm’n v. Watson Pharm., Inc., 677 F.3d 1298, 1312 (11th Cir. 2012).

201. *Id.* at 1315.

202. *Actavis*, 133 S. Ct. at 2231.

the *Actavis* majority saw something unnatural and inherently suspect in reverse payments, observing that the reverse payment “form of settlement is unusual,”<sup>203</sup> other unusual features of litigation under the Hatch-Waxman Act make reverse payments likely in this context, whether the plaintiff’s case is strong or weak.<sup>204</sup> Although it is possible, as the *Actavis* majority assumes, that a patent holder that agrees to make such a payment thinks it has a weak case, it is also possible that the patent holder considers the patent so valuable that it is willing to pay a significant premium to avoid even a small risk of invalidity.<sup>205</sup>

The Hatch-Waxman Act promotes resolution of infringement disputes prior to generic entry. Thus the statute provides for an automatic thirty-month stay of FDA approval of an ANDA with a paragraph IV certification, so long as the innovator files an infringement action within forty-five days.<sup>206</sup> This provides an opportunity for the parties to litigate disputes about patent validity and infringement before the generic product enters the market,<sup>207</sup> and therefore before the innovator has incurred any compensable damages. This is an important design feature that protects both parties. Generic entry typically causes a sharp drop in the price of the product, with resulting revenue loss for the patent holder far in excess of revenue gains for the generic. If infringement litigation had to await generic entry, the patent holder could quickly incur damages that exceed the generic’s ability to satisfy a judgment. For this reason, a generic may be reluctant to enter the market prior to resolution of the infringement action even after the Hatch-Waxman stay expires and its ANDA becomes effective.

Indeed, the term “reverse payment” is something of a misnomer, falsely implying that payment would ordinarily flow in the opposite direction. The Hatch-Waxman Act explicitly prohibits the courts from awarding damages against a defendant who has merely filed an ANDA.<sup>208</sup> At most, a prevailing plaintiff can get an injunction against entry of the generic product and an extension of the stay of FDA approval until the end of the patent term. A prevailing defendant can, at most, get a judgment that the patent is invalid or

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203. *Id.*; see also *id.* at 2233 (“In the traditional examples cited above, a party with a claim (or counterclaim) for damages receives a sum equal to or less than the value of its claim. In reverse payment settlements, in contrast, a party with no claim for damages (something that is usually true of a paragraph IV litigation defendant) walks away with money simply so it will stay away from the patentee’s market.”).

204. See, e.g., Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 MICH. L. REV. 37, 51 (2009) (describing the increasing use of reverse payment settlements under the Act).

205. See *Schering-Plough Corp. v. Fed. Trade Comm’n*, 402 F.3d 1056, 1075; see also, *supra*, text accompanying notes 172–176.

206. 21 U.S.C. § 355(j)(5)(B)(iii) (2012).

207. See Gregory Dolin, *Reverse Settlements As Patent Invalidity Signals*, 24 HARV. J. L. & TECH. 281, 293–94 (2011).

208. 35 U.S.C. § 271(e)(4)(C)(2012).



not infringed (and, if the defendant was the first to file an ANDA with a paragraph IV certification for the product, a six-month period of generic exclusivity before FDA will approve another ANDA with a paragraph IV certification for the same product). The financial value of a win to the plaintiff is much higher than the financial value of a win to the defendant.<sup>209</sup> Due to this disparity in the stakes of the parties, a transfer from the patent holder to the alleged infringer is likely a settlement that reflects a compromise on each side.

To be sure, the underlying patent infringement action may well be weak on the merits. For reasons explained above,<sup>210</sup> the combination of the Hatch-Waxman boost and FDA patent punting makes it advantageous for innovators to pursue weak ANDA infringement actions that they are unlikely to win on the merits. These weak cases may also lead to settlement agreements that call for payments from patent holders to asserted infringers. The *Actavis* majority was understandably concerned that settlements of weak patent infringement cases that would otherwise likely have been resolved in favor of the generic will leave consumers worse off than they would have been if the parties had pursued the litigation to final judgment.<sup>211</sup> But the presence of a reverse payment term is not a reliable indicator of a weak case, and the assertion that such a payment may serve as a “workable surrogate” for consideration of the merits of the infringement action suggests a misunderstanding of the peculiar context of infringement litigation prior to market entry under the Hatch-Waxman Act.

Because the majority believed that a reverse payment is a reliable indication of a weak case, it did not address the possibility that the patent holder might otherwise have prevailed. But if the underlying lawsuit would otherwise have ended in an injunction against the generic, it is not clear how consumers are worse off as a result of the settlement, even if the settlement includes a reverse payment. What matters to consumers is not the direction of payment in the settlement, but the timing of generic entry that brings price-lowering competition.<sup>212</sup>

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209. Indeed, even after the 30-month stay has lifted, the generic may be reluctant to enter the market because the risk of liability would substantially exceed the profits the generic could earn by selling a competing generic product over the same period. This is because prices for generics are substantially lower than the prices that an innovator can charge as the sole source of a patent-protected product. See Dolin, *supra* note 207, at 292 n.59; see also Crane, *supra* note 157, at 762–65.

210. See *supra* notes 206–208 and accompanying text.

211. *Fed. Trade Comm’n v. Actavis, Inc.*, 133 S. Ct. 2223, 2234–35 (2013).

212. The analysis in text considers only the interest of consumers in price-lowering competition, and not their interest in promoting innovation through the incentive of patent-protected monopoly pricing. The latter interest is presumably better served by allowing the holders of valid patents to exclude competitors until the end of the patent term, and may be harmed by reverse payments that divert a portion of the patent rents away from innovators and towards generics, thereby undermining the value of patent incentives.

By focusing antitrust scrutiny on the false indicator of reverse payments, the Court ignored the fact that equally or more anticompetitive patent settlements can be constructed with no reverse payment at all, as discussed next.

## 2. Easy Anticompetitive Work-Arounds

One justification that the *Actavis* majority identified as supporting the legality of some reverse payments is that the “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.”<sup>213</sup> In one type of patent settlement case, the generic agrees to distribute either the innovator’s drug or an “authorized generic” and receives a promise of payment for its services as part of the settlement. A second type of case arises when a generic and innovator want to avoid the scrutiny triggered by a reverse payment altogether. In such a case, they reverse the apparent direction of payment by having the generic promise to pay the patentee for the right to be a distributor.<sup>214</sup> In the first model, the generic becomes an agent selling on behalf of the innovator and receives compensation for its efforts, while in the second the generic is a licensee that remits some share of revenues to the innovator as a royalty.<sup>215</sup> In that case, we have both the absence of a reverse payment and the fact of early generic entry, which should easily satisfy the *Actavis* rule of reason standard.

From the perspective of the consumer, however, such agreements may be worse than the reverse payments at issue in *Actavis*.<sup>216</sup> Suppose, for example, that prior to generic entry, the monopoly mark-up per unit is equal to \$1. Now suppose that the innovator brings a patent infringement lawsuit with a low probability of success. Prior to adjudication of that lawsuit, the patent holder settles with the generic, making the generic its authorized generic distributor until the end of the patent term. The generic agrees to remit to the patent holder a royalty of \$1 per unit of sales. Unless the generic’s marginal costs of production or distribution are lower than those of the innovator, we now have (1) early generic entry, (2) no reverse payment, and (3) a

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213. *Actavis*, 133 S. Ct. at 2236.

214. See Crane, *supra* note 157, at 765.

215. See *id.* In two post-*Actavis* decisions involving complex settlement structures, the District of New Jersey dismissed the plaintiffs’ complaints, finding that the settlements did not involve “reverse payments” within the meaning of *Actavis*, even though they involved some cessation of competition between the innovator and the generic. *In re Lipitor Antitrust Litig.*, 2014 WL 4543502 (No. 3:12-cv-02389 (PGS) D.N.J. Sept. 12, 2014); *In re Effexor XR Antitrust Litig.*, 2014 WL 4988410 (No. 11-5479 (PGS)(LHG) D.N.J. Oct. 6, 2014). In *Lipitor*, the generic agreed to settle Pfizer’s patent infringement challenge by agreeing to a later entry date in the U.S. market in exchange for Pfizer dropping other patent litigation for damages for a token \$1 million payment and allowing the generic to launch generic Lipitor in 11 foreign markets prior to the patent expiration date. In *Effexor*, Wyeth and Teva settled without cash payment from Wyeth to Teva but with Wyeth’s promise not to market an authorized generic version of Effexor during Teva’s 180-day exclusivity period.

216. See *id.* at 765–66.

continuation of the same monopoly pricing. Indeed, because the licensing agreement continues until the expiration of the patent, it may leave consumers paying monopoly prices for longer than some reverse payment settlements that permit generic entry before the expiration of the patent.

It is not necessary to set the royalty equal to the full monopoly overcharge in order to produce anticompetitive results relative to a judgment for the generic. Suppose the royalty is set at 90 percent of the monopoly overcharge, leading to immediate price reductions. But since the first generic to market ordinarily sets its price around 70–80 percent of the brand,<sup>217</sup> this settlement deprives consumers of a much larger price decrease they might have received in the but-for world.

This example is not fanciful: FDA currently lists 673 authorized generics on the market.<sup>218</sup> As long as the agreements authorizing distribution of these products do not involve reverse payments, they will not show up on courts' post-*Actavis* radar screen. Antitrust lawyers are therefore likely to push clients toward settlements of this nature that avoid the red flag of reverse payments. Circumvention of the reverse payment rule established in *Actavis* is not difficult and need not diminish anticompetitive effects.

The direction in which payment flows in a settlement agreement is not what drives anticompetitive effects. What drives these effects is the probability that but for the settlement, the generic and innovator would have entered into price competition. There are ample means other than reverse payments to soften competition between branded and generic drug firms. *Actavis* does not merely ignore this possibility. By crediting licensing agreements as a robustly procompetitive defense, it compounds the error of the decision by appearing to grant categorical immunity to other forms of anticompetitive agreement.

### 3. Limited Relevance of Anticompetitive Motivations

Some language in the *Actavis* majority opinion goes beyond treating reverse payments as a signal of a weak patent case, suggesting that antitrust

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217. See Richard E. Caves et al., *Patent Expiration, Entry, and Competition in the U.S. Pharmaceutical Industry*, in BROOKINGS PAPERS ON ECONOMIC ACTIVITY, MICROECONOMICS, 1, 35 (Martin Neil Baily & Clifford Winston eds. 1991) (“[G]eneric drugs sell for a substantial discount from the price of the branded drug; the estimates suggest that with a single generic entrant, the generic price is roughly 60 percent of the branded drug price.”); David Reiffen & Michael R. Ward, *Generic Drug Industry Dynamics*, 87 REV. ECON. & STAT. 37, 44 (2005) (explaining that their study showed a single generic entrant would set its price at 88% of the branded price); see also Caves et al., *supra*, at 44–45 (finding that generic producers depress the branded drug’s price and “enter the market quoting prices much lower than those of their branded competitors”).

218. *FDA Listing of Authorized Generics as of Jan 9, 2015*, FOOD & DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES (Jan. 9, 2015) <http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/UCM183605.pdf>.

liability is appropriate if the motivation for the agreement is to avoid the risk of generic competition by maintaining and sharing the rents from the patent, even if the risk of invalidity is small:

The owner of a particularly valuable patent might contend, of course, that even a small risk of invalidity justifies a large payment. But, be that as it may, the payment (if otherwise unexplained) likely seeks to prevent the risk of competition. And, as we have said, that consequence constitutes the relevant anticompetitive harm. . . . Although the parties may have reasons to prefer settlements that include reverse payments, the relevant antitrust question is: What are those reasons? If the basic reason [for a reverse payment] is a desire to maintain and to share patent-generated monopoly profits, then, in the absence of some other justification, the antitrust laws are likely to forbid the arrangement.<sup>219</sup>

It is not clear why the Court regarded the intent of the parties in entering into a reverse payment agreement as “the relevant antitrust question,” nor why an intent to maintain and to share patent-generated profits would indicate an antitrust violation. Incentives to recover patent-generated monopoly profits are a feature, not a bug, in the patent system, serving to motivate and reward innovators for making new inventions. Patents can only serve this purpose if their owners affirmatively seek such profits, and the maintenance of monopoly profits often requires asserting patent rights against infringers in litigation. If the point of patents is to motivate innovation in pursuit of monopoly profits, it makes little sense to hold that patent holders run afoul of the antitrust laws when the same motivation leads them to settle meritorious infringement actions rather than take a small risk of losing. Moreover, it is hard to see how a wish to maintain monopoly profits can distinguish plaintiffs with weak claims from those with strong claims. A wish to maintain profits is ubiquitous in litigation over valuable patents.

What matters to consumers is not the anticompetitive intent of the parties in entering into the agreement, but the anticompetitive effects of such an agreement. The presence of a reverse payment in the agreement may indicate that the patent holder is concerned about the possibility of an adverse judgment, but such concern is to be expected from a risk-averse holder of a valuable patent and does not necessarily indicate that the plaintiff is otherwise likely to lose. The terms of the settlement may reveal *something* about the parties’ assessment of litigation risks, but they are a very noisy signal, hardly a substitute for direct consideration of the merits.

In focusing on the subjective motivation for the settlement, the *Actavis* majority seemed to suggest that any motivation by the patent holder to elimi-

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219. Fed. Trade Comm’n v. Actavis, Inc., 133 S. Ct. 2223, 2236–37 (2013).

nate litigation risks is inherently anticompetitive.<sup>220</sup> This strange assumption is at odds with the ordinary operation of the rule of reason. The motivation to suppress competition is present in many business arrangements that easily satisfy the rule of reason.<sup>221</sup> Moreover, the motivation for litigation settlements typically includes a wish to insure against the possibility of an adverse outcome, and in the case of patent settlements, an adverse outcome for the patentee typically means more competition. Yet the *Actavis* majority suggested that such a motivation likely renders the settlement anticompetitive, at least in the absence of some other justification.

Perhaps this approach leaves room for future courts to recognize that the pro-competitive benefits of a settlement outweigh the risk that a settlement will defer price-lowering competition. It is well-documented that these benefits are not limited to the elimination of direct litigation costs, as the majority acknowledged.<sup>222</sup> Indirect litigation costs often exceed attorneys' and expert witness fees.<sup>223</sup> Early elimination of uncertainty around generic entry can allow for better planning by both innovators and generics, as well as invention around the patent.<sup>224</sup> The settlement option increases the generic's flexibility in challenging the innovator's patent and hence decreases the costs of generic challenges.<sup>225</sup> Many settlements allow for generic entry years before the expiration of the patent, a possibility that would be eliminated by the innovator's victory in the patent litigation.<sup>226</sup> In ordinary rule of reason analysis, one would analyze and weigh these factors against the possibility of earlier generic entry in the absence of settlement as a result of a judgment in favor of the generic. But if antitrust courts and agencies continue to punt on determining the likely outcome of the litigation, it is unclear how they can properly assess these possibilities to determine the net anticompetitive effects of settlements. There is no substitute for direct engagement with the

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220. *Actavis*, 133 S.Ct. at 2234.

221. See Crane, *supra* note 157, at 778 ("A patentee's intentions are virtually always explicitly 'anticompetitive' in the precise sense in which antitrust lawyers mean those words—the patentee wishes to suppress the competition for its patented good in order to preserve a stream of monopoly rents from that good.").

222. *Actavis*, 133 S. Ct. at 2236.

223. See Crane, *supra* note 157, at 757–59.

224. *Id.* at 762–65.

225. *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188, 256 (E.D.N.Y. 2003) (citing expert declaration of Dr. Jerry Hausman for the proposition that "[t]o maximize these incentives [for generics to challenge branded patents], a generic company should be permitted to choose not only when to commence patent litigation, but also when to terminate it").

226. See Michael A. Carrier, *Provigil: A Case Study of Anticompetitive Behavior*, 3 HAST. SCI. & TECH. L.J. 441, 442–44 (2011) (discussing early entry provisions in agreements between pioneer and generic companies regarding the medication Provigil, wherein the generic companies agreed in 2006 to delay market entry until 2012, when the patents were set to expire in 2015).

strength of the patent infringement claim, including both validity and infringement issues.

Like the patent punting strategies deployed by FDA, the patent punting strategies deployed by the antitrust courts threaten to upset the balance struck in the Hatch-Waxman Act. This balance both protects innovators from infringing generic competition and encourages generics to compete, as long as they do not infringe any valid patents. The FDA strategy of deference to innovators errs on one side of the balance, while the *Actavis* strategy of presuming anticompetitive effects for reverse payment settlements errs on the other side. FDA's patent punting strategy leads to too much infringement litigation, including weak cases, while the *Actavis* patent punting strategy makes it more difficult to settle that litigation, including strong cases. The Hatch-Waxman Act is a complex compromise between the interests of innovators and generics, leaving room for patent punters to find support for their moves in those provisions that favor one side or the other.<sup>227</sup> But the net result has been unnecessary costs, delays, and harm to consumers.

Antitrust courts would do a better job of determining which settlements harmed consumers if they were willing to examine the merits of the settled infringement actions rather than relying on misleading proxies such as reverse payments and inferences about intent to avoid litigation risks. But the best antitrust courts can do is award damages long after consumers have suffered the consequences of improper delays in generic entry. Under the misleading guidance of *Actavis*, a more likely outcome is that patent litigants will change the way they write their settlement agreements to avoid raising red flags (such as reverse payments), while using equivalent provisions to take advantage of the inability of patent-punting courts to tell which settlements have actually harmed consumers.

#### IV. RECONSIDERING THE RESPECTIVE ROLES OF FDA AND THE COURTS

FDA is in a much better position than antitrust courts to minimize harm to consumers. Through timely regulatory oversight of which patents get the Hatch-Waxman boost, FDA could limit the attractiveness to patent holders of pursuing weak infringement actions, and thus limit the opportunities for deferring generic entry through anticompetitive settlements.

FDA oversight has significant advantages over litigation in minimizing abuses of the Hatch-Waxman scheme. First, FDA is in a position to detect abuses at a much earlier stage than the courts, and thus to minimize improper delays in generic entry. Litigation, at best, leads to deferred decisions on the merits, and may instead lead to collusive settlements of weak claims that could have been avoided through active administrative oversight at an earlier stage. Second, FDA is better able than the courts to make certain

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227. *Actavis*, 133 S. Ct. at 2234; 1989 Proposal, *supra* note 54, § V.Q.3, at 28,909.

statutory determinations that play a central role in the Hatch-Waxman scheme. More specifically, FDA's technological and regulatory expertise give it an advantage over the courts in examining the relationship between patent claims and the scope of regulatory approval under NDAs and ANDAs to determine which patents are entitled to the Hatch-Waxman boost. Prior administrative review would not displace litigation but could determine whether a patent is entitled to cause an automatic thirty-month stay of approval of an ANDA. It could exclude from the Orange Book those patents that could not reasonably be asserted against an ANDA and give courts the benefit of FDA's assessment of the relationship between patents and FDA approval documents. We consider each of these advantages below. We then consider how best to address FDA's reluctance to take on a larger role in administrative oversight of patent matters.

#### A. Timing

The Hatch-Waxman Act reflects a clear plan for the timing of generic entry. It replaced a system in which the costs of regulatory approval maintained a *de facto* entry barrier that excluded generics long after patent expiration with a new set of rules that lowered regulatory entry barriers to accelerate generic entry once relevant patents had expired. After an initial five-year period of regulatory exclusivity, a generic may be approved at lower cost by using an ANDA rather than a more costly NDA. But the timing of ANDA approvals also depends on the duration of patents that meet certain statutory criteria. The effect is to exclude generics during the term of the specified patents if they are valid and would be infringed by the ANDA product, while allowing ANDA approvals to take effect immediately thereafter.

Many features of the Hatch-Waxman Act reveal a clear goal of permitting generic entry as soon as possible once previously approved products and uses are no longer covered by any valid patents that meet the statutory criteria. One important change under the Hatch-Waxman Act was to modify the definition of patent infringement to allow for the completion of all prerequisites to regulatory approval during the patent term. Overturning a judicial decision that held the use of a patented drug in clinical trials to be an act of infringement,<sup>228</sup> Congress created a new statutory infringement exemption for acts "solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs."<sup>229</sup> This change paved the way for prompt generic entry by making it possible to carry out any necessary clinical trials during the patent term. The Hatch-Waxman Act also explicitly provides for the submission of ANDAs during the patent term that would become effective on the

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228. Roche Prods., Inc. v. Bolar Pharm. Co., 733 F.2d 858, 861 (Fed. Cir. 1984).

229. 35 U.S.C. § 271(e)(1) (2012).



patent expiration date.<sup>230</sup> This eliminated the previous *de facto* extension in the duration of market exclusivity beyond the term of the patent to cover the time necessary to test products and gain regulatory approval.

Other statutory provisions show an effort to minimize delays in generic entry as a result of patents that are invalid or not infringed and to accelerate any infringement litigation. For example, the Hatch-Waxman Act ordinarily provides innovators with a five-year period of regulatory exclusivity before a competitor may submit an ANDA, but it permits submission as much as one year earlier if the ANDA includes a paragraph IV certification challenging patent validity or infringement.<sup>231</sup> The Hatch-Waxman Act further encourages prompt patent challenges by rewarding the first generic to submit an ANDA with a paragraph IV certification with 180 days of generic exclusivity before FDA may approve another ANDA with a paragraph IV certification for the same product.<sup>232</sup> The statute accelerates litigation by requiring the challenger to provide notice of the basis for the patent challenge within twenty days.<sup>233</sup> It further encourages patent holders to assert any infringement claims promptly by providing that unless the patent holder responds by filing an infringement action within forty-five days, approval of the ANDA shall be made effective immediately.<sup>234</sup> To ensure the dispute is ripe for judicial resolution, Congress modified the definition of infringement to include submitting an ANDA “for a drug claimed in a patent or the use of which is claimed in a patent.”<sup>235</sup> The statute mandates that “each of the parties shall reasonably cooperate in expediting the action,” and authorizes the court to adjust the duration of the thirty-month stay if either party fails to do so.<sup>236</sup> Even the thirty-month stay, although it defers generic entry temporarily, sets a limit on how long patent litigation may delay regulatory approval of ANDAs. Litigation may continue thereafter, but prolonged litigation cannot defer regulatory approval beyond the stay period without a court order to that effect.<sup>237</sup>

Finally, Congress set limits on the kinds of patents that are relevant to the timing of ANDA approval.<sup>238</sup> The statute requires that innovators identify in their NDAs:

any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasona-

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230. 21 U.S.C. §§ 355(j)(2)(B)(vii)(III), 355(j)(5)(B)(ii) (2012).

231. *Id.* § 355(j)(5)(F)(ii).

232. *Id.* § 355(j)(5)(B)(iv).

233. *Id.* § 355(j)(2)(B).

234. *Id.* at § 355(j)(5)(B)(iii).

235. 35 U.S.C. § 271(e)(2) (2012).

236. 21 U.S.C. § 355(j)(5)(B)(iii).

237. 35 U.S.C. § 271(e)(4)(A); 21 U.S.C. § 355(j)(5)(B)(iii).

238. *See supra* text accompanying notes 66–68.

bly be asserted if a person not licensed by the owner engaged in the manufacture use, or sale of the drug.<sup>239</sup>

In parallel language, the statute requires that ANDAs include a certification “with respect to each patent which claims the listed drug . . . or which claims a use for such listed drug for which the applicant is seeking approval.”<sup>240</sup> Other patents that might be infringed by a generic, such as patents on other methods of use or on manufacturing methods, may not be used to delay the submission or approval of an ANDA, although they might still be asserted in an infringement action. Moreover, the Hatch-Waxman Act does not require that an ANDA include a certification for a method of use patent that does not claim a use for which the ANDA seeks approval, instead permitting a statement “that the method of use patent does not claim such a use.”<sup>241</sup> By limiting the kinds of patents that will automatically defer the use of ANDAs, Congress limited regulatory delays on generic entry without disturbing patent infringement remedies.

These provisions recognize that time is of the essence in determining when generic competition may begin. The Hatch-Waxman Act provides an opportunity for litigating disputes about patent validity and infringement and for a temporary stay of regulatory approval during litigation, but it also accelerates the time frame for litigation and sets statutory limits on the kinds of patents that can delay regulatory approval of ANDAs. It gave FDA a significant role in administering these patent provisions, although FDA has sought to minimize that role. When innovators submit patent information as part of their NDAs, they submit that information to FDA.<sup>242</sup> It is FDA that the statute directs to publish the information.<sup>243</sup> And when generics address these patents in their ANDAs, whether through a section vii certification or a section viii statement, the submission goes directly to FDA.

FDA thus stands at the front door of the Hatch-Waxman patent provisions. It is the first to learn which patents innovators believe are relevant to their NDAs, and the first to learn how generics plan to address those patents in their ANDAs. This position gives FDA—and only FDA—a timely opportunity to determine whether particular patents are properly disclosed as part of a particular NDA, and whether they are properly addressed through a section vii certification or a section viii statement in a particular ANDA. These determinations are critical in determining when FDA approval of ANDAs may become effective. Yet because it would have to read patents in order to make these determinations, FDA refuses to take administrative responsibility and insists that this must be a job for the courts.

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239. 21 U.S.C. § 355(b)(1).

240. *Id.* § 355(j)(2)(A)(vii).

241. *Id.* § 355(j)(2)(A)(viii).

242. *See id.* §§ 355(b)(1), 355(c)(2).

243. *Id.*

To justify its preferred course of patent punting, FDA has ignored the manifest legislative purpose to resolve disputes in a timely fashion, while giving a very broad reading to the Hatch-Waxman litigation provisions. Because Congress provided for litigation in the district courts of certain disputes about patent validity and infringement, FDA has concluded that it is exempt from any obligation of administrative oversight of the Hatch-Waxman patent provisions in individual cases. The result has been a failure of effective enforcement of the statutory limitations on which patents can defer regulatory approval of ANDAs.

In the absence of administrative oversight, innovators can decide which of their patents qualifies for a thirty-month stay of regulatory approval. The 2003 statutory provision for counterclaims to correct improper patent listings does not undo the delays these listings cause. By the time a counterclaim is filed, the improper listing (or improper use code) has already compelled the generic to take steps that it might otherwise have avoided, including submitting a paragraph IV certification for the patent and giving notice to the patent holder, thus triggering an infringement action and thirty-month stay of ANDA approval. Much of that stay is likely to have run its course before the court can grant the only remedy that the statute permits: an order requiring the NDA holder to correct or delete the previously submitted patent information.<sup>244</sup> A court cannot turn back the clock and allow the ANDA to become effective at an earlier point. Even if the patent holder loses on the counterclaim, it will likely have recovered much of the value of the Hatch-Waxman boost, and consumers will have paid the price. FDA's insistence on punting all patent issues to the courts thus frustrates Congress' efforts to replace de facto regulatory entry barriers with a more deliberate and carefully timed approach with statutory rules about which patents can defer generic entry. Only FDA is in a position to take timely steps to prevent irrelevant patents from deferring its own ANDA approvals.

### B. Expertise

Another significant advantage of FDA in determining which patents should defer ANDA approval arises from its expertise as a regulatory agency charged with overseeing approvals of NDAs and ANDAs. This expertise is particularly important to determinations of which patents are appropriate for listing in the Orange Book and which patents may be addressed in a section viii statement rather than a section vii certification. These determinations are

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244. Indeed, it is not clear whether the district court could even direct FDA to terminate the 30-month stay without first determining that the patent is invalid or not infringed. See Kurt A. Karst, *Does a Hatch-Waxman Patent Delisting Counterclaim Terminate a 30-Month Litigation Stay?*, FDA L. BLOG (Nov. 8, 2012, 6:58 PM), [http://www.fdalawblog.net/fda\\_law\\_blog\\_hyman\\_phelps/2012/11/does-a-hatch-waxman-patent-delisting-counterclaim-terminate-a-30-month-litigation-stay.html](http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2012/11/does-a-hatch-waxman-patent-delisting-counterclaim-terminate-a-30-month-litigation-stay.html).

unique to the Hatch-Waxman Act, and require understanding the meaning of NDAs and ANDAs.

The Hatch-Waxman Act limits the patents that innovators are required to disclose to those that claim the drug or a method of using the drug “with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.” FDA has engaged in rulemaking to interpret these provisions.<sup>245</sup> Partly in response to the recommendations of FTC, FDA has specified in detail what kinds of patents are appropriate for listing, addressing patents on polymorphs, intermediates, metabolites, and formulations. FDA has further clarified that whether a patent is appropriate for listing depends upon its relationship to the scope of approval in an approved or pending NDA.<sup>246</sup> Only those patents that claim either a drug or a method of using the drug that is the subject of a pending or approved NDA (or an amendment or supplement to an NDA) may be submitted for listing.<sup>247</sup> Application of this rule thus requires a comparison between patent claims and the scope of approval sought or approved in the NDA. FDA, of course, is the agency that reviews NDAs and has considerable expertise in understanding what they mean.

Similarly, FDA has an expertise advantage over the courts in determining whether an ANDA should address a particular method of use patent through a section vii certification or a section viii statement. The statute requires that an ANDA include a section vii certification “with respect to each patent which claims the listed drug . . . or which claims a use for such listed drug for which the applicant is seeking approval.”<sup>248</sup> Conversely, in the case of “. . . a method of use patent which does not claim a use for which the applicant is seeking approval under this section,” the applicant need not submit a section vii certification. Instead, the statute requires that the ANDA include “a [section viii] statement that the method of use patent does not claim such a use.”<sup>249</sup> FDA regulations confirm that the certification and notice requirements do not apply “to a use patent that claims no uses for which the applicant is seeking approval.”<sup>250</sup> The choice between a section vii certification (such as a Paragraph IV certification that the patent is invalid or not infringed)<sup>251</sup> and a section viii statement (that the patent is a method of use patent that does not claim a use for which the applicant is seeking approval) thus requires a comparison of the patent claims to the scope of approval sought in the ANDA. FDA, as the agency charged with reviewing ANDAs

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245. See *supra* Part II.

246. See 21 C.F.R. § 314.53(b) (2014).

247. *Id.*

248. 21 U.S.C. § 355(j)(2)(A)(vii) (2012).

249. *Id.* § 355(j)(2)(A)(viii).

250. 21 C.F.R. §§ 314.95(a)(3), 314.94(a)(12)(iii)(A).

251. 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

and determining the appropriate scope of approval, has a clear expertise advantage over the courts in understanding what methods of use are covered by an ANDA.

Resolution of these issues in *Caraco v. Novo Nordisk* forced the courts on an unguided march through the weeds of FDA administrative practice without the benefit of the views of the agency responsible for creating the use code system as to how its regulations applied to the facts of that particular case.<sup>252</sup> The patent claims in *Caraco* were not ambiguous, although Novo-Nordisk's misleading use code created an illusion of uncertainty about which uses they covered.<sup>253</sup> The regulatory artifact of use codes, devised by FDA to avoid having to read patents, provided an opportunity to distort claim coverage and mislead FDA. The real dispute was not about the meaning of the claims, but about whether the use code narrative accurately tracks the claims and their relationship to approved uses. FDA surely understood use codes and their relationship to approved uses better than the courts.<sup>254</sup> By punting the entire matter to the courts, FDA thus required a less expert resolution of issues that it could have resolved more authoritatively, and certainly more quickly and cheaply, on its own.

The scope of approval sought in an ANDA is not only relevant to the choice between a section vii certification and a section viii statement. It is also central to the ability of the courts to grant relief prior to market entry under the Hatch-Waxman Act, which provides for early litigation of an infringement claim against a firm that submits an ANDA "for a drug claimed in a patent or the use of which is claimed in a patent." Resolution of these lawsuits requires not only determining what the patents claim, but also what the ANDAs seek approval for. Although sometimes the scope of approval is undisputed,<sup>255</sup> when the scope is contested, judicial decisions reveal considerable confusion about how to make sense of these documents. For example, in *Bayer Schering v. Lupin*,<sup>256</sup> a divided Federal Circuit panel affirmed dis-

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252. See *supra* notes 121–142 and accompanying text.

253. On remand, the Federal Circuit noted that although FDA had found that Novo Nordisk's revised use code for the '358 patent covered all three approved uses of repaglinide, it was undisputed that the patent claim at issue covered only one of those uses. *Novo Nordisk A/S v. Caraco Pharm. Labs.*, 688 F.3d 766, 768–69 (Fed. Cir. 2013) ("[I]n light of the admitted facts in this case, . . . the Supreme Court decision forecloses any argument that Novo's use code is 'correct.' . . . The Food and Drug Administration ('FDA') has found Novo's current use code covers all three FDA-approved methods of using repaglinide. It is undisputed that [the '358 patent] claims only one of those three approved methods of use.") (internal citations omitted).

254. Indeed, the Federal Circuit deferred to FDA on this issue in *Caraco. Id.* at 768.

255. *E.g.*, *Astrazeneca Pharm. LP v. Apotex Corp.*, 669 F.3d 1370 (Fed. Cir. 2012) (affirming dismissal of infringement action against ANDA applicants who had used section viii statements for asserted patents that claimed methods of use for which they did not seek approval in their ANDAs on the ground that the complaints failed to state a claim under 35 U.S.C. § 271(e)(2)).

256. 676 F.3d 1316 (Fed. Cir. 2012).

missal of infringement actions against ANDA applicants who sought approval to market generic versions of the drug Yasmin “for oral contraception,” when the asserted patents claimed a method of using the drug for achieving simultaneously “a contraceptive effect, an anti-androgenic effect, and an anti-aldosterone effect.”<sup>257</sup> Two panel members rejected the argument that FDA had in fact approved use of the drug to achieve the combination of these three effects, but the third panel member dissented on the basis of a different interpretation of the scope of FDA approval.<sup>258</sup> The disagreement was over the significance of a highly technical disclosure in the “Pharmacodynamics” subsection of the “Clinical Pharmacology” section of the FDA-approved label that one of the two active ingredients exhibits anti-mineralocorticoid activity and that animal studies suggest it may have anti-androgenic activity. The panel majority, after reviewing FDA regulations, concluded that this was a disclosure of side effects that did not indicate FDA approval of the use of the drug to achieve these effects, but the dissenting panel member disagreed, citing expert testimony of a former FDA employee and a physician as to how they understood the label.<sup>259</sup> The only contested issue was the scope of FDA approval, not the scope of the patent. Surely it would have been helpful for the courts to have the benefit of FDA’s own interpretation of what methods of use were covered by the approval documents.<sup>260</sup> Yet because FDA would have had to read the patent claims to determine their relationship to the scope of approval, the entire matter went directly to litigation without prior administrative review.

Even on issues of claim interpretation, FDA has significant technological expertise. Patent claims are directed to those who are skilled in the field of the invention; if they fail to inform such persons with reasonable certainty about the scope of the invention, the claims are invalid for lack of definiteness.<sup>261</sup> FDA, as the agency charged with regulating new drug development, surely is closer to the perspective of those skilled in the drug development field than generalist trial courts. At a minimum, a trial court charged with interpreting the language of a claim to a drug or method of use might benefit from knowing how FDA understood the claim.

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257. *Id.* at 1319–20.

258. *Id.* at 1322; *id.* at 1326, 1328–29 (Newman, J., dissenting).

259. *Id.* at 1326, 1328–29 (Newman, J., dissenting).

260. *See also* Braintree Labs. Inc. v. Novel Labs. Inc., 749 F.3d 1349 (Fed. Cir. 2014) and *id.* at 1360–65 (Dyk, J., dissenting) (disagreement between panel majority and dissent over whether dosage specified in ANDA meets particular claim limitation rather than over claim interpretation).

261. 35 U.S.C. § 112(b) (2012) (“The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.”); *see* Nautilus, Inc. v. Biosig Instruments, Inc., 134 S. Ct. 2120 (2014) (rejecting the Federal Circuit’s interpretation that only “insolubly ambiguous” claims are invalid for lack of definiteness in favor of a “reasonable *certainty*” standard).

Claim interpretation is often contested in litigation, and the courts have developed elaborate procedures for resolving disputes over the meaning of claims that FDA cannot and should not attempt to duplicate. When the meaning of a claim can be determined solely on the basis of the patent and its prosecution history,<sup>262</sup> claim interpretation presents a pure question of law, subject to plenary review on appeal.<sup>263</sup> But sometimes it is necessary to consider additional extrinsic evidence such as expert testimony concerning the meaning of terms of art to a person of ordinary skill in the art in the relevant time period, and District Courts need to make subsidiary factual determinations on these matters that are entitled to deferential review on appeal.<sup>264</sup> Under current practice, district courts rule on disputed issues of claim interpretation following a proceeding known as a *Markman* hearing that may include expert testimony and dictionary definitions of claim terms as well as evidence from the patent's prosecution history. Reversals on appeal are common, and many observers believe that the process has failed to produce certainty and predictability as to the meaning of claim language.<sup>265</sup> But in some cases that perplex the courts, claim interpretation might pose little difficulty for an impartial reader who has ordinary skill in the field.

Moreover, it may not be necessary to resolve every ambiguity in a claim that includes limitations that make it clear that an ANDA does not infringe.<sup>266</sup> Consider the recent case of *Braintree Laboratories v. Novel Laboratories*.<sup>267</sup> In that case, a divided Federal Circuit panel reversed, vacated, and remanded a summary judgment of infringement against an ANDA for a generic version of a bowel prep kit for use prior to colonoscopy. Claim 15 of the patent at issue recites:

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262. The prosecution history of a patent is the PTO's complete record of the application process for a patent, including the original application itself, responses made by the examiner, and any amendments made by the applicant. *See Festo Corp. v. Shoketsu Kinzoku Kabushiki*, 535 U.S. 722 (2002).

263. *Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1454–55 (Fed. Cir. 1998) (en banc); *Teva Pharmaceuticals USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831 (2015).

264. *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831 (2015).

265. There is an extensive literature on the topic. *See, e.g.*, Dan L. Burk & Mark A. Lemley, *Fence Posts or Sign Posts: Rethinking Patent Claim Construction*, 157 U. PENN. L. REV. 1743 (2009); Peter S. Menell, et al., *Patent Claim Construction: A Modern Synthesis and Structured Framework*, 25 BERKELEY TECH. L.J. 711 (2010); David L. Schwartz, *Practice Makes Perfect? An Empirical Study of Claim Construction Reversal Rates in Patent Cases*, 107 MICH. L. REV. 223 (2008).

266. In order to infringe a patent claim, a defendant's product or process must meet every element of the patent, either literally or by equivalence, and thus each element limits the scope of the claim. *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 41 (1997); *Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1247 (Fed. Cir. 2000). If the defendant's product or process fails to meet any one limitation of the claim, there is no infringement, and therefore no need to consider whether additional claim elements are present. *Fin Control Sys. Pty. Ltd. v. OAM, Inc.*, 265 F.3d 1311, 1320 (Fed. Cir. 2001).

267. 749 F.3d 1349 (Fed. Cir. 2014).



A composition for inducing purgation of the colon of a patient, the composition comprising from about 100 mL to about 500 mL of an aqueous hypertonic solution comprising an effective amount of  $\text{Na}_2\text{SO}_4$ , an effective amount of  $\text{MgSO}_4$ , and an effective amount of  $\text{K}_2\text{SO}_4$ , wherein the composition does not produce any clinically significant electrolyte shifts and does not include phosphate.<sup>268</sup>

Each member of the three judge panel wrote separately, primarily about the interpretation of the claim terms “purgation,” “a patient,” and “clinically significant electrolyte shifts.” One panel member, Judge Dyk, would have held that the meaning of these claim terms was beside the point because the ANDA product would not infringe the dosage limitation set forth in the claim.<sup>269</sup> The claims called for 100–500 mL of the composition, while the ANDA sought approval for a dose of two sixteen-ounce bottles, or a total of 946 mL.<sup>270</sup> The district court rejected this argument, reasoning that each single bottle satisfied the volume limitation and a single bottle was sufficient to achieve “purgation” as the court interpreted that term in the claim,<sup>271</sup> but FDA had not approved administering a single bottle dose of the product, and the ANDA did not and could not seek approval for an infringing dose. The courts might have understood the issue better with the benefit of FDA’s expertise in comparing an unambiguous dosage term in the patent claim to the scope of approval sought in the ANDA.

In its scrupulous avoidance of engagement with any issues of patent law, FDA is thus leaving the courts to resolve disputes concerning the scope of FDA approval—issues that are squarely within the scope of FDA’s expertise—without giving them the benefit of FDA’s analysis of those issues. It may take a long time for the courts to sort it out, and they may get it wrong. Meanwhile, regardless of the merits, plaintiffs benefit from the protection of a thirty-month stay without having to persuade a court to enter a preliminary injunction.

### *C. Relationship of Administrative Determinations to Litigation Over Validity and Infringement*

Proper administration of the Hatch-Waxman Act requires timely and impartial determinations of which patents are entitled to the Hatch-Waxman boost. Deference to innovators fails the test of impartiality. Experience has shown that in the absence of administrative oversight, innovators will submit

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268. *Id.* at 1353.

269. *Id.* at 1360, 1361–63 (Dyk, J., concurring in part, dissenting in part, and concurring in the result).

270. *Id.* at 1362.

271. *Braintree Labs., Inc. v. Novel Labs., Inc.*, No. 11-1341 (PGS), 2013 U.S. Dist. LEXIS 7698, at \*26–28, 2013 WL 211252, at \*10–11 (D.N.J. Jan. 18, 2013), vacated, 749 F.3d 1349 (Fed. Cir. 2014).

patents that do not meet the statutory criteria for disclosure and could not reasonably be asserted against ANDA applicants in order to use the Hatch-Waxman boost to defer generic entry.<sup>272</sup> Resort to counterclaims in infringement actions to correct improper patent listings fails the test of timeliness. The courts cannot determine which patents should get the Hatch-Waxman boost in a time frame that avoids the cascade of regulatory consequences triggered by listing a patent in the Orange Book and cannot undo the delays caused by allowing the patents to be improperly listed in the first place. Other patents come with remedies under the Patent Act, but they are not entitled to the Hatch-Waxman boost. Only FDA is in a position to tell the difference in a timely fashion. Moreover, punting these disputes to the courts without prior administrative oversight deprives the courts of the benefit of FDA's expertise in understanding the scope of approval in an NDA or an ANDA.

Application of the statutory standards does not require FDA to consider challenges to the validity of a patent, nor does it require a full analysis of infringement. But it does require that FDA read patents at two distinct points. First, when an innovator submits a patent for listing, FDA must determine whether the patent claims an approved drug or an approved method of use and "could reasonably be asserted" against an unauthorized generic. Those drug patents and method of use patents that survive the "reasonable assertion" test may be listed in the Orange Book; those that fail the test are not entitled to the Hatch-Waxman boost. Second, if there is a dispute about whether an ANDA may use a section viii statement for a method of use patent, FDA must determine whether the ANDA seeks approval for any methods of use claimed in a listed patent. If FDA concludes that the ANDA does not seek approval for a patented method of use, the patent holder is not entitled to a thirty-month stay, and the generic may not claim regulatory exclusivity unless the ANDA also includes a paragraph IV certification (perhaps for another patent or claim).

Each of these determinations requires comparing the patent claims to the scope of approval under the NDA or ANDA. If the patent holder sues the generic for patent infringement for filing the ANDA, the court will again need to compare the patent claims to the ANDA to rule on infringement.<sup>273</sup> But FDA administrative determinations of the relationship between patent claims and the scope of approval are by no means redundant to the work to be done by the courts in cases that proceed to litigation.

First, administrative determinations of which patents are entitled to the Hatch-Waxman boost will come much earlier and at considerably lower

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272. See *supra* Part II.

273. 35 U.S.C. § 271(e)(2) (2012). See *Astrazeneca Pharm. LP v. Apotex Corp.*, 669 F.3d 1370, 1377–78 (Fed. Cir. 2012) (“[I]nfringement of method claims under § 271(e)(2) requires filing an ANDA wherein at least one ‘use’ listed in the ANDA is claimed in a patent.”).

cost. They will neither displace litigation nor determine its outcome. They will, however, determine whether the patent holder may get an automatic stay of ANDA approval without a court order.

Second, the issues to be resolved by FDA and the courts are not identical, although they overlap somewhat. FDA will not consider challenges to patent validity.<sup>274</sup> Administrative and judicial determinations will overlap more if there is a dispute about infringement. FDA must determine whether a patent meets the statutory criteria for listing in the Orange Book, including whether it covers an approved drug or method of use and whether it “could reasonably be asserted” against unauthorized manufacture, use, or sale of the drug. Because ANDAs seek approval only for previously approved products and previously approved uses, a patent that meets these criteria may well be infringed by the ANDA, unless the ANDA uses a section viii statement to carve out a patented method of use. But while FDA need only determine whether assertion of the patent would be reasonable, in cases that proceed to litigation the court must go further and decide whether the ANDA product (or its use) would infringe the patent. The “reasonable assertion” standard is a coarser filter that need not exclude every patent that a court might ultimately decide would not be infringed by the generic. FDA need not engage in the same thorough claim interpretation and infringement analysis required of district courts. But it must do more than simply defer to the patent holder to determine whether its assertions are reasonable.

Third, administrative oversight is particularly important for cases that never reach a judicial determination on the merits. Even if the patent holder

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274. The PTO is in a better position than FDA to provide administrative review of patent validity and has new statutory authority to perform that function in a timely and cost-effective way under the Leahy-Smith America Invents Act of 2011, *supra* note 18. For the first nine months after a patent is issued, any person other than the owner may petition the PTO to institute a post-grant review (PGR) of the patent seeking to cancel one or more claims for invalidity on any basis that could be raised in an infringement action. 35 U.S.C. §§ 321–329. After the nine-month window for initiating PGR is closed, it is still possible to challenge the patent by filing a petition for inter partes review (IPR), 35 U.S.C. §§ 311–319, but only on the basis of prior art consisting of patents or printed publications, 35 U.S.C. § 311, and only if the PTO determines that there is a reasonable likelihood that the petitioner would prevail with respect to at least one of the challenged claims, 35 U.S.C. § 314(a). Initial experience suggests that IPR is a powerful tool for challenging invalid patents while avoiding litigation costs. See Brian J. Love & Shawn Ambwani, *Inter Partes Review: An Early Look at the Numbers*, 81 U. CHI. L. REV. 93 (2014) (finding that when a petition was filed the PTO instituted IPR 84% of the time, that in cases that had reached a final decision all claims had been invalidated or disclaimed more than 77% of the time, and that litigation proceeding in parallel had been stayed 82% of the time). Although so far only a small number of IPRs have involved challenges to drug patents, the availability of this new tool for challenging patent validity before an expert agency weakens the case for assigning a similar job to FDA. For analysis of the advantages of IPR in the context of Hatch-Waxman disputes, see Gurpreet Singh Walia, *Inter Partes Review an Option as a Substitute for Hatch-Waxman litigation* (Nov. 7, 2014), available at <http://www.insidecounsel.com/2014/11/07/inter-partes-review-an-option-as-a-substitute-for> (last visited Mar. 9, 2015).

brings an infringement action, the parties may enter into a settlement, perhaps agreeing to defer generic competition without any judicial findings. Prior administrative review will filter out some of these cases by limiting the Hatch-Waxman boost to those patents that could reasonably be asserted, i.e., patents that present a plausible case for deferring generic entry. Although the patent holder could still pursue an infringement action even if its patent is not listed,<sup>275</sup> it may decide not to bother if it does not thereby gain an automatic thirty-month stay of regulatory approval. On the other hand, if the listing of a patent means that FDA agrees that it covers an approved drug or method of use, the position of the patent holder in litigation might be stronger than it is in the current regime of administrative deference to innovators. If generics expect the courts to defer to FDA's determinations, they might file fewer paragraph IV certifications, further limiting litigation.

Finally, in cases that proceed to litigation, prior administrative review would give courts the benefit of FDA's expert reading of NDAs and ANDAs, which should improve the quality of judicial decisions. Courts may also benefit from learning how FDA understood the claim language, given its technical expertise in drug development. Although courts will engage in a more elaborate process of claim interpretation in an infringement action, FDA's assessment prior to litigation of whether a claim could reasonably be asserted against an unauthorized generic could be useful evidence of what the claim language means to a person having ordinary skill in the field to consider alongside other evidence presented by the parties.

#### D. Addressing FDA's Concerns

We expect that the courts would acquiesce in more active administrative oversight along the lines sketched out above, just as they have acquiesced, albeit sometimes reluctantly, in FDA's interpretation of the Hatch-Waxman Act to limit its involvement in patent disputes to the "purely ministerial" function of doing what the NDA holders tell them to do.<sup>276</sup> For the reasons

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275. Some judicial decisions have erroneously stated that a paragraph IV certification is necessary to allow a patent holder to bring an action against an ANDA filer. *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990) ("§ 271(e)(2) [creates] a highly artificial act of infringement that consists of submitting an ANDA or a paper NDA containing [a paragraph IV] certification . . ."); *Bristol Myers Squibb v. Royce Laboratories*, 69 F.3d 1130, 1131 (Fed. Cir. 1995) ("Inclusion of a paragraph IV certification in an ANDA, however, is deemed an act of infringement."). That is not, however, what the statute says. Under 35 U.S.C. § 271(e)(2), it is an act of infringement "to submit [an ANDA] for a drug claimed in a patent or the use of which is claimed in a patent . . . if the purpose of such submission is to obtain approval . . . to engage in the commercial manufacture, use, or sale of a drug . . . claimed in a patent or the use of which is claimed in a patent before the expiration of such patent." See *AstraZeneca Pharmaceuticals v. Apotex Corp.*, 669 F.3d 1370 (Fed Cir. 2012) (upholding jurisdiction over infringement action brought under 35 U.S.C. § 271(e)(2) even though ANDA used a section viii statement rather than a paragraph IV certification for the patent at issue).

276. See *supra* notes 92–100 and accompanying text.

explained above we think a more active role for FDA is necessary to prevent firms from improperly claiming the Hatch-Waxman boost for patents that do not meet the statutory criteria for deferring ANDA approvals. But FDA plainly does not want a more active role in administering the Hatch-Waxman patent provisions and is not likely to assume such a role unless Congress compels it to do so. If Congress wants FDA to oversee the determination of which patents get the Hatch-Waxman boost, it may need to say so. At the same time, it should consider how best to address the objections that FDA has raised to taking on a larger role in the process.

FDA's first justification for patent punting is that it lacks patent expertise. The expanded role we contemplate for FDA in overseeing Orange Book listings and the use of section viii statements would require comparing the claims of patents to the scope of approval under NDAs and ANDAs. The interpretation of patent claims is one part of this analysis; the rest of the job consists of determining whether the patent covers a drug product or method of use that has been approved in an NDA and, in the case of disputes about the adequacy of a section viii statement to address method of use claims, whether the ANDA seeks approval for the patented method of use. We have already argued that FDA has much greater expertise than the courts in understanding the meaning of NDAs and ANDAs. NDAs and ANDAs are drafted according to the requirements of the FDCA<sup>277</sup> as interpreted by FDA.<sup>278</sup> FDA may, however, need to hire patent lawyers or agents to interpret patent claims. These FDA employees will not need to replicate the proceedings that a district court would follow in a full adjudication. FDA's job is to make an initial determination of whether a patent claims a drug product or method of use and could reasonably be asserted against an unauthorized generic. This task requires staff who are familiar with general principles of claim interpretation and the ability to read claim language in light of the specification, the prosecution history, and the meaning of claim language to persons of ordinary skill in the field.

FDA also claims that it lacks the resources to address patent issues. It stands to reason that FDA may need to hire additional personnel to carry out a task that FDA is currently not performing. FDA may well need further resources to allow it to hire skilled personnel to oversee the listing of patents in the Orange Book and determine whether method of use patents can be carved out of ANDA approvals. Time is of the essence in determining when

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277. 21 U.S.C. §§ 355(b)(1), 355(j)(2)(A).

278. A list of FDA resources and Guidance Documents for the preparation of NDAs may be found at [www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/newdrugapplicationnda/default.htm](http://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/newdrugapplicationnda/default.htm) (last visited July 29, 2014). A list of FDA resources and Guidance Documents for the preparation of ANDAs may be found at <http://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/abbreviatednewdrugapplicationandgenerics/default.htm> (last visited July 29, 2014).

generic products may be approved, and inadequate staffing will cause delays. Congress could address resource needs at the same time that it clarifies FDA's oversight role. The cost of additional personnel could be covered by assessing user fees on firms submitting patents for listing in the Orange Book. User fees, in combination with regulatory oversight, might discourage the submission of inappropriate patents more effectively than the current requirement that such submissions be accompanied by declarations under penalty of perjury attesting to their accuracy. User fees could also be assessed to cover the costs of reviewing section viii statements when the patent holder argues that a paragraph IV certification is necessary.

FDA also worries that if it takes a more active role, it will be sued by firms that are unhappy with its decisions. Over the years FDA has defended many lawsuits brought by firms that have been unhappy with its regulatory moves, particularly when it sets a new course.<sup>279</sup> FDA has certainly been sued over its refusal to oversee the Orange Book.<sup>280</sup> Given the commercial significance of the Hatch-Waxman boost, some patent holders can be expected to argue that the statute limits FDA to the "purely ministerial" role it has taken so far, especially if FDA were to change its interpretation without prodding from Congress. Although the courts have so far deferred to FDA's interpretation of the current statute, they have also expressed criticisms, and we think it is likely that they would also defer to a revised interpretation of the existing statute that gives FDA a larger oversight role. But Congress could surely protect FDA from such lawsuits in any new legislation to provide for more active FDA oversight.

Congress could also take steps to shield FDA from lawsuits challenging its decisions in individual cases about the proper listing of patents in the Orange Book or appropriate carve-out in an ANDA of particular patents, although whether it *should* do so presents a closer question than whether it *could* do so. FDA could certainly make erroneous determinations, with costly consequences either way. On the other hand, judicial review could add costs and delays that would cancel the benefits of timely and cost-effective administrative oversight. Moreover, the expanded FDA role we advocate would not prevent patent holders from enforcing their rights under the Patent Act through infringement actions in the courts. FDA would not rule on the validity of patents, nor would it undertake comprehensive infringement analysis. It would simply determine which patents should cause delays

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279. See, e.g., *Edison Pharmaceutical Co. v. FDA*, 600 F.2d 831 (D.C. Cir. 1979) (challenging requirement for double-blind testing and exclusion of physician testimonials to establish safety and efficacy); *E.R. Squibb & Sons, Inc. v. Bowen*, 870 F.2d 678 (D.C. Cir. 1989) (challenging withdrawal of approval of combination product following change in statute for lack of showing that effects of one of the ingredients had medical significance); *Food & Drug Admin. v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000) (challenging initiative to regulate cigarettes as drug-device combination products).

280. See *supra* Part II.B.



in ANDA approvals. A patent holder who believes its patent was improperly excluded from the Orange Book could still sue for infringement based on the filing of the ANDA and seek a preliminary injunction against the generic.<sup>281</sup> Current law provides authority for the court to order that the effective date of approval of the ANDA be deferred until the expiration of the patent.<sup>282</sup> The availability of a preliminary injunction in an infringement action is an adequate judicial safeguard against harm to patent holders from erroneous FDA determinations that a patent could not reasonably be asserted against an unauthorized generic, without the need for a separate lawsuit to contest the administrative decision itself.

Congress might also wish to address the timing of FDA decisions about the proper listing of patents. NDA applicants currently file patent information along with their NDAs, and amend their filings to include patents filed after that date but before NDA approval. The statute requires FDA to publish this information upon approval of the application. The statute further requires NDA holders to file information for patents issued after NDA approval within thirty days, and for FDA to publish the information upon its submission. The statute makes no provision for a review period to determine whether a patent qualifies for listing in the Orange Book.<sup>283</sup> For patents disclosed early enough in the initial term of regulatory exclusivity, FDA could publish the patent information when it is submitted and later remove it from the Orange Book if it determines following review that the patent did not meet the statutory criteria for listing. But for later-issued patents, there may not be time for FDA to review the patent and determine whether it qualifies for listing before the date when an ANDA could be filed or even approved if the patent were not listed. If such patents are initially listed, they may get at least a portion of the Hatch-Waxman boost before FDA can conduct its review and determine that they should be delisted. Under current law, ANDAs filed in the interim would need to include either a section vii certification or a section viii statement for such patents, and the generic would have to give notice in case of a paragraph IV certification, likely triggering an infringement action and a thirty-month stay of approval. But FDA could terminate the stay if it later determines that the patent should not have been listed or that the ANDA does not seek approval for the patented method of use, leaving the patent holder to seek relief from the District Court. An alternative would be to defer the listing of patents in the Orange Book until after FDA determines that they qualify for listing. This approach would withhold the Hatch-Waxman boost from later-issued patents during the lag time between

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281. See 21 U.S.C. § 355(j)(5)(B)(iii)(III)–(IV) (addressing effective date of ANDA approval when district court has granted a preliminary injunction).

282. 35 U.S.C. § 271(e)(4)(A) (2012).

283. Indeed, this time frame arguably provides textual support for FDA's "purely ministerial" understanding of its role in administering these provisions. See *supra* notes 59–62 and accompanying text.



disclosure of the patent and FDA's determination of its relevance to the NDA or ANDA. Some ANDA approvals might become effective during this period, leaving patent holders to pursue their patent infringement remedies to prevent generic entry without the benefit of a stay of regulatory approval. Either way, the statute should specify a finite but reasonable period of time for FDA to make its determination. The one hundred and eighty day period currently specified in the statute for reviewing an ANDA seems like a reasonable period of time for deciding whether a patent is entitled to the Hatch-Waxman boost. Prompt determinations will allow the parties to plan for generic entry and will make FDA's assessment of the relevance of patents to its approval documents available to the courts in cases that proceed to litigation.

Our proposal would replace FDA's current practice of patent punting with a rough administrative assessment of the merits of patent issues that determine the timing of regulatory approval. It would not displace other institutional mechanisms within the heart of the patent system for reviewing the same issues, including review of patent validity in the U.S. Patent and Trademark Office (PTO) and litigation of patent infringement actions in the courts. But it would require some engagement with patents and patent law outside of those institutional mechanisms.

This proposal would not eliminate the problem of anticompetitive settlements of patent infringement actions, but we expect it would reduce the amount of litigation that leads to such settlement by reducing incentives to litigate the weakest cases. We do not propose to limit the right of patent holders to pursue remedies for patent infringement in the courts, but we expect that fewer patent holders would pursue infringement actions if they did not thereby gain the benefits of the Hatch-Waxman boost for cases with little merit. By withholding the Hatch-Waxman boost for patents that are not relevant to particular NDAs and ANDAs, FDA would make infringement litigation less attractive to patent holders in these cases, and the remaining cases would be more likely to have merit. Presumably parties will continue to settle those cases that are filed, but the problem of anticompetitive settlements should diminish with a reduction in the benefits of filing weak cases.

#### CONCLUSION

Under the Hatch-Waxman Act, patent law and FDA regulation work together to determine the timing of generic entry in the market for drugs. But FDA has sought to avoid any responsibility for reading patents, preferring to defer to drug developing firms' assessments of which patents should defer approval of competing generic versions of their products. This gap in regulatory oversight has allowed innovators to defer competition through the listing of irrelevant patents. Provisions for litigation of patent disputes have failed to provide a timely corrective for abuses made possible by the lack of

administrative oversight. Meanwhile, patent litigation has led to anticompetitive settlements, forestalling adjudication of the patent issues and provoking antitrust litigation. Antitrust courts have proven no more willing than FDA to address the merits of the underlying patent infringement actions, preferring to rely on misleading proxies such as the existence of a “reverse payment” in the settlement agreement.

We propose to increase the role of FDA in making timely determinations of which patents meet the statutory criteria for deferring generic entry, while leaving the patent system and its remedies intact. With proper staffing and resources, FDA could use its expertise in drug regulation to make rough assessments of the relationship between particular patents and the scope of FDA approval in NDAs and ANDAs more quickly and cheaply than the courts could rule on related infringement actions. Only those patents that FDA decides could reasonably be asserted against an unauthorized generic would lead FDA to stay approval of the ANDA pending litigation of the infringement action, but litigation would still be available even if FDA decides the patent does not meet the criteria for listing, and the court could enter a preliminary injunction with the same effect as a stay of approval. We expect that without the stay of regulatory approval, patent holders will decide not to pursue some actions that lack merit, limiting opportunities for anticompetitive settlements.

But perhaps we are addressing this problem from the wrong angle. Maybe the problem is not with the Hatch-Waxman Act, but with patent law. We have known for many years that patent issues are challenging and aversive for non-experts. Congress has tried to manage this problem by ghettoizing patent disputes into expert tribunals. Thirty years ago, Congress created the specialized Court of Appeals for the Federal Circuit to hear appeals in patent cases. More recently, Congress started experimenting with mechanisms to bring more expertise into the resolution of patent cases at the trial court level and creating more opportunities for administrative review of patentability within the PTO. But these strategies break down when patent law spills over into other legal regimes.

One lesson we might learn from this case study of patent punting is that the complexity and opacity of the patent system makes it problematic to use patents as a benchmark for determining the scope of legal rights outside the patent system. Under the Hatch-Waxman Act, the timing of regulatory approvals depends on patents, but it is difficult to implement that regime appropriately when regulators are loath to look at patents. Application of the antitrust laws similarly turns, in part, on the validity and scope of patents, but it is difficult to work out what that means when antitrust courts do not evaluate patents. The law is a seamless web, and a regime as important as the patent system has an appropriate bearing on other laws. But if decision-makers are reluctant to analyze patent issues that properly have a bearing on their analysis, the impact of the patent system will inevitably be distorted.

Perhaps the trend toward ghettoizing patent disputes within expert tribunals has allowed complexity and opacity to flourish. Greater reliance on generalists to apply patent law might create pressure to simplify and clarify, making it easier for everyone to understand patents and the rights they confer, and limiting opportunities for strategic abuse of ambiguities. Perhaps the patent system could be more effective in achieving its goals if it were less complex and opaque. To some extent, the complexity of the patent system is a function of technological complexity. But when even a technologically expert agency like FDA shies away from engaging with patent issues, the problem goes beyond technological complexity. Perhaps the ghettoizing of patent law has made it seem more daunting to the uninitiated than it is or needs to be. Perhaps in those areas where patent law necessarily interacts with non-patent law, we would do better to direct those who administer the adjacent non-patent legal regimes to roll up their sleeves and start dealing with patents.