LITIGATING PATENTED MEDICINES: COURTS AND THE PTO

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INTRODUCTION

In patent litigation, parallel proceedings before federal courts and the PTO are seemingly routine.[1] Recent data suggest that as much as 75% of all post-issuance proceedings before the PTO are involved in concurrent district court litigation.[2] Drug patent litigation under the Hatch-Waxman Act, however, has long remained the exception. During the same time period, only roughly 10% of *all* traditional drug patent lawsuits were challenged in parallel before the PTO,[3] making up a scant 11.3% of post-issuance proceedings.[4] In contrast to other technologies, pharmaceutical patent litigation has therefore been primarily siloed in the federal courts.

Recent changes to patent law—namely, the expansion of administrative proceedings at the PTO after the America Invents Act (AIA)[5]—may change this calculus. In particular, the institution of inter partes review—and challengers' astonishing success in invalidating their competitors' patents' claims[6]—appear to invite an era of increasing parallel challenges in drug

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[1] Rebecca D. Hess & Angela Y. Dai, *Effect of New PTO Patent Review Proceedings on Concurrent Patent Disputes in U.S. District Court or The ITC: Have The Chances of a Stay Increased?*, 25 INTELL. PROP. & TECH. L.J. 3, 3 (2013) ("In high-stakes patent disputes, corporate counsel often find themselves engaged in concurrent proceedings before the U.S. Patent and Trademark Office (PTO), a U.S. District Court, and/or the U.S. International Trade Commission (ITC).").

[2] Brian J. Love & Shawn Ambwani, *Inter Partes Review: An Early Look at the Numbers*, 81 U. CHI. L. REV. DIALOGUE 93, 107 (2014) (Appendix B).

[3] (Data forthcoming.)

[4] *See* Love & Ambwani, *supra* note 2, at 107 (Appendix B).

[5] *See generally* Andrei Iancu & Ben Haber, Post-Issuance Proceedings in the America Invents Act, 93 J. PAT. & TRADEMARK OFF. SOC'Y 476 (2012).

[6] *See* Love & Ambwani, *supra* note 2, at 107 (Appendix B).

patent litigation. Furthermore, the FDA's recent watershed approval of a "biosimilar" drug,[7] in combination with the virtually impenetrable patent litigation structures surrounding biologics,[8] may similarly encourage a rise in biologic patent challenges before the PTO. The future of litigating patented medicines is therefore likely to take place before both the federal courts *and* the PTO.

This Essay briefly explores this shift in four parts. First, it analyzes the historical relationship between Hatch-Waxman Act patent litigation and the PTO prior to the AIA. Second, it examines some preliminary qualitative data regarding Hatch-Waxman Act patent litigation after the AIA. And third, it prospectively applies this analysis to biosimilar patent litigation under the Biologics Price Competition and Innovation Act. This Essay concludes with a number of thoughts on how this shift in one subject area of patent litigation informs—and changes—the relationships among federal courts, the PTO, and the patent bar.

I. HATCH-WAXMAN ACT LITIGATION AND THE PTO BEFORE THE AIA

In order to obtain Food and Drug Administration (FDA) approval to market a new drug, a brand drug manufacturer must submit a New Drug Application (NDA) to the agency. In addition to a host of information concerning the drug's composition, manufacture, safety, and efficacy, the NDA must also contain a list of patents "to which a claim of patent infringement could reasonably be asserted."[9] The FDA dutifully lists this patent information "in a fat, brightly hued volume called the Orange Book (less colorfully but more officially denominated Approved Drug Products with Therapeutic Equivalence Evaluations)."[10]

The legal effect of this listing is to delay the FDA from approving any generic application based on a patented brand drug until all of the Orange Book-listed patents are expired, declared invalid, or found to be not infringed by the proposed generic drug. To that end, all generic applications—formally known as Abbreviated New Drug Applications (ANDAs)—must include one of four certifications for each patent listed in the Orange Book covering the brand drug. Importantly, a "paragraph IV certification"—the ultimate type of patent certification—declares that although a brand manufacturer has listed a patent in the Orange Book, the generic manufacturer believes the patent to be invalid, or that the patent will not be infringed by the generic's proposed product.[11]

A generic's filing of a paragraph IV certification begins a complex procedural litigation scheme designed to simultaneously protect innovative brand manufacturers from generic competition and encourage aggressive generic manufacturers to weed out invalid drug patents.[12] To begin with: The filing of a paragraph IV certification is, by statute, an act of patent

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[7] Kevin E. Noonan, *FDA Approves Sandoz Filgrastim Biosimilar*, PATENT DOCS, Mar. 8, 2015, http://www.patentdocs.org/2015/03/fda-approves-sandoz-filgrastim-biosimilar.html.

[8] *See generally* Janet Freilich, *Patent Infringement in the Context of Follow-On Biologics*, 16 STAN. TECH. L. REV. 9 (2012).

[9] 21 U.S.C. § 355(b)(1).

[10] Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S, 132 S. Ct. 1670, 1676 (2012).

[11] 21 U.S.C. § 355(j)(2)(A)(vii)(IV); *see Caraco*, 132 S. Ct. at 1677 (referring to this filing as a "paragraph IV certification").

[12] *See Caraco*, 132 S. Ct. at 1676.

infringement, thus allowing the brand drug manufacturer to bring suit against its generic rival, even though no act of direct patent infringement had yet occurred.[13] The brand manufacturer then has forty-five days to sue to the generic manufacturer for infringement.[14] The lawsuit, in turn, precludes the FDA from approving the generic application for at least thirty months, or until the patent is found to be invalid or not infringed in a final, nonappealable judgment.[15] If the brand manufacturer fails to file suit within the forty-five days, the generic manufacturer may file a declaratory action against the brand.[16] In addition, to entice generic manufacturers to engage in this scheme, the Hatch-Waxman Act awards the first generic manufacturer to file an ANDA containing a paragraph IV certification with 180 days of "generic exclusivity," during which the FDA will further delay approval of any following ANDAs.[17]

The upshot of this "incredibly complicated gauntlet"[18] is that it takes the median brand-generic patent dispute over two years to go to trial—if it goes to trial at all. Indeed, of the approximately 2,776 ANDA cases filed since January 1, 2000, only 146—just over 5%—have gone to trial. An even smaller portion—80 cases or 2.9%—have been resolved through summary judgment. And the vast bulk of the remainder—1,386 cases or 49.9%—have been disposed of by consent.[19] Costing each party roughly $6 million through trial,[20] the Hatch-Waxman Act's statutory system designed to encourage generic litigants to fight invalid drug patents to the merits, appears, instead, to be an extraordinarily expensive exercise in alternative dispute resolution.

This is not altogether surprising. Prior to the Supreme Court's recent decision in *FTC v. Actavis, Inc.*,[21] brand manufacturers routinely settled patent disputes with generic manufacturers by paying them to delay entry into the marketplace.[22] In 2006, for example, Cephalon paid

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[13] *Compare* 35 U.S.C. § 271(e)(2) ("It shall be an act of infringement to submit—(A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act . . . for a drug claimed in a patent or the use of which is claimed in a patent . . . .") *with* 35 U.S.C. § 271(a) ("[W]hoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States . . . during the term of the patent therefor, infringes the patent.").

[14] 21 U.S.C. § 355(c)(3)(C).

[15] *Id.* § 355(j)(5)(B)(iii).

[16] *Id.* § 355(j)(5)(C).

[17] *Id.* § 355(j)(5)(B)(iv).

[18] John Richards et al., *Panel I: Do Overly Broad Patents Lead to Restrictions on Innovation and Competition?*, 15 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 947, 970 (2005) (remarks of David Balto).

[19] Data obtained from LexMachina on Apr. 2, 2015, by searching for all "ANDA" and "patent"-tagged cases filed. An automatically generated report of the data can be found at https://www.scribd.com/doc/260732646/2-776-Cases.

[20] INTELLECTUAL PROPERTY INSURANCE SERVICES CORPORATION, AIPLA 2013 REPORT OF THE ECONOMIC SURVEY (2014), *available at* http://www.patentinsurance.com/custdocs/2013aipla%20survey.pdf (listing patent cases worth more than $25 million in damages—pedestrian by ANDA litigation standards—to cost each side, on average, $5.9 million).

[21] 133 S. Ct. 2223 (2013).

[22] FEDERAL TRADE COMMISSION, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY (2002), *available at* http://perma.cc/JNA3-3M48; *see also* Michael A. Carrier, *Payment After* Actavis, 100 IOWA L. REV. 7, 18-19 (2014) (discussing *FTC v. Actavis*); C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 NYU L. REV. 1553, 1567-73 (2005) (summarizing the FTC study and several cases from it).

several generic competitors $200 million, in total, to cease contesting Cephalon's patents covering its sleep disorder drug, Provigil.[23] Those settlements, according to Cephalon's CEO, gave the company an additional $4 billion in sales.[24] In *FTC v. Actavis*, however—decided only months after the AIA became effective—the Court forbid such payments to the extent they raised several antitrust concerns unique to the Hatch-Waxman Act's litigation scheme.[25] As a consequence, the decline of such "reverse payment" settlements has coincided with the implementation of the AIA.

The combination of all of these quirks of therefore seem to explain a curious facet of ANDA litigation: that, prior to the AIA, many drug patent disputes were rarely litigated in parallel proceedings before the PTO, namely, in inter partes or ex parte reexaminations. Of the roughly 1,920 ANDA cases filed in district court from January 1, 2000 to September, 30, 2012—before the effective date of the AIA—only 10% were litigated on patents subject to a reexamination.[26] This contrasts markedly with earlier evidence suggesting that 75% of all patent infringement suits are based on patents subject to petitions for reexamination.[27] In addition, reports from several attorneys suggest that these were instituted, by and large, by "follow on" generics, i.e., generic manufacturers not entitled to the 180 day generic exclusivity period.[28]

This disconnect between Hatch-Waxman Act litigation and parallel administrative proceedings—that is, between the courts and the PTO—could be explained for several reasons. First, reexamination proceedings tended to last, on average, 36 months—almost a year longer than merits litigation in Hatch-Waxman Act cases,[29] and in any event, six months longer than the statutory thirty month stay. Reexamination was therefore unlikely to provide any additional speed in resolving brand-generic drug disputes. Relatedly, the narrow window of timing set in motion by paragraph IV filings—the requirement that generics provide patent certifications with their ANDA, and the 45-day window for brands to bring suit after certification—simply encouraged federal court, as opposed to the PTO, as the primary forum for such disputes.

Second, the 180-day generic exclusivity period strongly encouraged generic manufacturers to file paragraph IV certifications as soon as practicable. In many instances, the profitably of the generic exclusivity period far eclipsed the costs of full blown litigation—providing little incentive to engage in cheaper, concurrent proceedings before the PTO. This strongly counseled against a wait-and-see approach to filing reexaminations petitions before the PTO on Orange Book listed patents prior to filing litigation-triggering paragraph IV certifications.

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[23] *See* Michael A. Carrier, *Provigil: A Case Study of Anticompetitive Behavior*, 3 HAST. SCI. & TECH. L.J. 441, 444 (2011).

[24] *Id.*

[25] *See* Carrier, *supra* note 22, at 18-19.

[26] (Data forthcoming.)

[27] Eric J. Rogers, *Ten Years of Inter partes Patent Reexamination Appeals: An Empirical View*, 29 SANTA CLARA HIGH TECH. L.J 305, 320 (2013) (citing Jack B. Blumenfeld & Leslie A. Polizoti, *Stays Pending Reexamination*, 908 PLI/PAT 91, 97-98 (2007)).

[28] Jonathan E. Singer, *Paragraph IVs And IPRs—Never the Twain Shall Meet? A Case Challenges ANDA Applicants' Ability To File IPRs*, LEXOLOGY, Nov. 20, 2014, http://www.lexology.com/library/detail.aspx?g=db631a1a-563c-4469-95c0-5a095c43b6da.

[29] (Data forthcoming.)

Third, because the stakes for such disputes were—and continue to be—tremendously high, pharmaceutical clients, both brands and generics, tend to be less cost-sensitive than their counterparts in other technology areas. To that end, the cost-savings often associated with reexamination do little to encourage pharmaceutical manufacturers to resolve their disputes before the PTO rather than full bore patent litigation in federal court. Or, more concretely: few generic manufacturers are willing to save a few million dollars in attorneys' fees if it means risking hundreds of millions dollars in revenues. Trial, especially in the pharmaceutical context, may, in fact, be optimal.[30] Using reexamination as an *alternative* to district court litigation may be penny-wise and pound-foolish.

Fourth, reexamination proceedings—both inter and ex parte—operated as much as original examinations: letter writing campaigns before one or multiple examiners, with heavy restrictions on the type of documents (and arguments) that could be proffered by the petitioners. This sort of proceeding is far removed from traditional, adversarial federal litigation. Therefore, to the degree that generic manufacturers are receiving legal counsel from litigators as to whether to challenge patents through reexamination, concurrently or otherwise, those attorneys may be uneasy about making such recommendations.

Fifth, and significantly, reexamination proceedings were mostly unsuccessful from a challenger's perspective. Since inter partes reexamination was instituted in 1999, until its replacement by the AIA in 2012, only 31.5% of inter partes reexaminations resulted in the cancellation of all of the challenged patent's claims at-issue.[31] This invalidation rate was approximately the same as that in district court. Of the 220 Hatch-Waxman Act cases litigated to the merits—either trial or summary judgment—from 2000 until 2012, 47, or 21.3%, resulted in an invalidity finding.[32] Inter partes reexaminations, therefore, provided only a marginal benefit to generic litigants.

Lastly, inter partes reexaminations could not be settled—even by agreement among the petitioner and the patent holder. This almost certainly discouraged generic manufacturers from instituting concurrent proceedings before the PTO that they could not terminate by settlement. Indeed, petitions for concurrent proceedings by generic manufacturers may have had the effect of poisoning the well from which the water of large reverse payment settlements may have been drawn, at least prior to *Actavis*.[33]

These hypotheses concerning generic litigants' preference for litigation in federal court over concurrent proceedings before the PTO also highlighted the potential for change. Quicker, more robust, trial-like proceedings at the PTO—even at higher cost—may have proved enticing to generic manufacturers. This combined with *Actavis*'s prohibition on large reverse payment settlements also suggests a more attractive avenue within the PTO for generic litigants. Enter the AIA's new system of inter partes review.

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[30] James Bessen & Michael J. Meurer, *Lessons for Patent Policy from Empirical Research on Patent Litigation*, 9 Lewis & Clark L. Rev. 1, 5 (2005) ("Settlement costs arise implicitly in this example and lead to equilibrium trial under certain conditions. Settlement is attractive to the parties in this example because it avoids trial costs.18 But settlement is costly because it sacrifices some of the monopoly profit available in the new product market (we assume industry profit is $150 million rather than $200 million following settlement).").

[31] *See* Love & Ambwani, *supra* note 2, at 107.

[32] (Data forthcoming.)

[33] 35 U.S.C. § 305 (2010).

II. HATCH-WAXMAN ACT LITIGATION AND THE PTO AFTER THE AIA

The AIA wrought profound changes on post-issuance proceedings before the PTO. The old system of reexamination was replaced with a menagerie of new, administrative proceedings: inter partes review, post-grant review, covered business method review, supplemental examination, and third-party citation of prior art.[34] These proceedings were designed to benefit "potential infringers and other patent challengers. . . . [so they can] have tools to drastically increase the transaction costs associated with procuring patents, and can affirmatively act to minimize any downsides."[35]

Inter-partes review, in particular, was designed to be much more friendly to challengers than the old inter partes reexamination system. First, unlike the old inter partes reexamination system—a letter writing campaign before a new patent examiner—inter partes review proceeds in a substantially trial-like fashion, before an Administrative Law Judge, and including "discovery, a hearing, witnesses, joinder, and settlement."[36] Second, by statute, inter partes review must be completed within twelve months, although the PTO may effectively grant itself a six month extension. By and large, this has meant that inter partes review petitions have been completed within fifteen months[37]—less than half of the time it took to complete inter partes reexaminations. Third, unlike inter partes reexaminations, inter partes review are amenable to settlement—making them a far more attractive option to risk-averse litigants in high-stakes cases. And fourth—and perhaps most importantly—inter partes review has so far been *wildly* successful to patent challengers, invalidating 78.8% of the claims challenged, almost triple the invalidation rate of its predecessor statute. In comparison to inter partes reexam, inter partes review now truly provides an alternative avenue for patent challengers, even if they are litigation-focused, time-sensitive, and risk-averse.

These changes to post-issuance proceedings suggest that generic manufacturers—litigation-focused, time-sensitive, and risk-averse—may find new purchase in post-issuance proceedings as concurrent litigation avenues. And, indeed, some recent data suggest that this is so. As of March 26, 2015, 68 inter partes review challenges were filed on patents concurrently pending in traditional Hatch-Waxman litigation.[38] This appears to represent a slight uptick in the number of reexaminations filed against Hatch-Waxman litigated patents during a similar time frame prior to the AIA. But numbers aside, there may be more substantive (or procedural) reasons why the new system of inter partes review may become into its own avenue for Hatch-Waxman litigation.

First, inter partes review's timeframe of fifteen months is importantly shorter than the statutory thirty-month stay imposed by brand manufacturers' lawsuits in response to paragraph IV certifications. A generic manufacturer may, therefore, concurrently file a paragraph IV certification and a petition for inter partes review, with the hope of invalidating the brand manufacturer's Orange Book-listed patents before the subsequent district court proceedings are even completed. Recently, this strategy was explicitly upheld by both the PTO and a federal

[34] *See generally* Iancu & Haber, *supra* note 5, at 476.

[35] *Id.* at 490.

[36] *Id.* at 480.

[37] Love & Ambwani, *supra* note 2, at 107 (Appendix B).

[38] (Data from Chris Noyes, WilmerHale.)

district court, with each adjudicator declaring that paragraph IV certifications did not constitute prior "civil actions" barring the filing of a subsequent inter partes petition.[39] This strategy, if successful, allows generic manufacturers to enter the market as soon as the FDA approved their ANDA, without having to wait for further proceedings before the district court. In addition, the first generic to deploy this strategy and include a paragraph IV certification would still be entitled to 180-days of generic exclusivity—a carrot potentially worth tens of millions dollars alone.

Second, unlike the old system of inter partes reexamination, inter partes reviews are fully resolvable by settlement. This is especially important for generic manufacturers looking to expeditiously resolve any litigation with brand manufacturers—and even more so after the Supreme Court ended large reverse payments as Hatch-Waxman settlements in *Actavis*. This seems especially important in the brand-generic context, where the risks of failure—losing patent protection or being forced to wait until lengthy patents expire—can be catastrophic. To that end, of the fifteen inter partes reviews with a concurrent Hatch-Waxman Act case that have been thus far resolved on the merits, a full eight have been resolved by settlement.[40]

Lastly, generic manufacturers may be swayed enough by the general aptitude of the inter partes review process in invalidating claims—more so than under the previous system of reexamination. In traditional, district court litigation, generic manufacturers were largely successful, claiming victory in 48% of paragraph IV cases according PwC's most recent annual study on patent litigation. This eclipsed general defendant win rates under the old inter partes reexamination system by roughly 17%. Thus, there was little to prefer at the PTO compared to district court. Under, the new system of inter partes review, however, patent challengers are successful, on average, 78.8% of the time—a 62% increase in odds relative to district court litigation. All things being equal, generic manufacturers should therefore prefer to resolve their patent disputes before the PTO, rather than federal court.

Whether this remains a viable avenue for generic manufacturers to litigate their rival brands' patents, of course, remains to be seen. Notably, inter partes review's hard bars on estoppel may make some generic manufacturers concerned about taking such large business risks at the PTO. Nonetheless, several recent cases demonstrate that generic manufacturers are slowly coming around. Ranbaxy, for example, recently petitioned the PTO to institute an inter partes review concerning Vertex's HIV antiviral, Lexiva, for which Vertex was already engaged in Hatch-Waxman litigation against Mylan.[41] This strategy was deployed to stretch Vertex thinly between Hatch-Waxman litigation in federal court against one party, and PTO proceedings against another. Those cases are still ongoing.

At the same time, smaller generic manufacturers may find inter partes review as an ideal "follow on" strategy—to file such petitions after larger generic manufacturers have already fought their cases in district court and lost. Because the follow on generic will not be estopped

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[39] Senju Pharmaceutical Co. v. Metrics, Inc., 1:14-cv-03962 (D.N.J. Mar. 31, 2015) (Order) (Simandle, J.); Noven Pharma., Inc. v. Novartis AG, IPR2014-00550 (P.T.O. Oct. 14, 2014).

[40] Apotex, Inc. v. Alcon, IPR2013-00012 (P.T.O. Oct. 4, 2012); Apotex, Inc. v. Alcon, IPR2013-00015 (P.T.O. Oct. 12, 2012); Ranbaxy Labs Ltd. v. Vertex Pharma. Inc., IPR2013-00024 (P.T.O. Oct. 18, 2012); Apotex, Inc. v. Alcon, IPR2013-00428 (P.T.O. July 5, 2013); Apotex, Inc. v. Alcon, IPR2013-00429 (P.T.O. July 5, 2013); Apotex, Inc. v. Alcon, IPR2013-00430 (P.T.O. July 5, 2013); Amneal v. Endo Pharma., IPR2014-00160 (P.T.O. Oct. 18, 2013); Impax v. Meda Pharma., IPR2014-00731 (P.T.O. May 7, 2014).

[41] Ranbaxy Lab., Ltd. v. Vertex Pharm., Inc., IPR2013-00024 (P.T.O.).

from taking their cases to the PTO—so long as their petitions present a "reasonable likelihood" of success in invalidating the previously upheld patents—this may open a broad avenue for "second wave" generic challengers. These challenges, in turn, may be successful on their own—either because of the PTO's forgiving metrics for invalidating claims, or because such challenges will bring their own opportunities for settlement.

All in all, post-issuances proceedings—and inter partes review in particular—appear to be a new avenue for Hatch-Waxman litigation. The 68 current PTO challenges to Hatch-Waxman litigated patents appear to be increasing, and continue to be instituted by a broad and diverse set of challengers: larger, established generic manufacturers such as Actavis, Apotex, Mylan; smaller generic companies, such as Metrics, Inc., Torrent Pharmaceuticals, and Actelion; and even some *brand* manufacturers, such as Purdue. Whether such trends continue in the near future remains to be seen. But, for now, the incentives are finally aligned to make post-issuance proceedings attractive options for generic challengers.

III. BIOSIMILARS: A NEW AVENUE?

These same incentives may affect another form of patent medicine litigation: "biosimilars." Analogous to the Hatch-Waxman Act's separation of brand and generic manufacturers, the Biologics Price Competition and Innovation Act (BPCIA) allows FDA approval of follow on biologic drugs that, for technical reasons, cannot be guaranteed to be molecularly identical to their reference drugs. To receive approval, "biosimilar" manufacturers need only show that the biosimilar is chemically "highly similar" to the brand biologic, and that there are no "clinically meaningful differences" regarding safety, purity, or potency. Recently, on March 6, 2015, the FDA approved its first biosimilar—filgrastim, a relatively simply biologic useful in stimulating white blood cell count.

Unlike ANDA approval, however, there is no streamlined process to clear the patents surrounding a particular drug; there is no Orange Book for biologics.[42] Rather the BPCIA sets forth a complicated litigation scheme to resolve patent disputes that some commentators have referred to as the "patent dance." First, the biosimilar manufacturer must inform the brand biologic that it intends to market a competing drug; this triggers a pre-filing information exchange process that includes the biosimilar providing, to the brand, some manufacturing details. The brand biologic then provides a list of all of the patents it believes it can assert against the biosimilar manufacturer, on the basis of the prior information disclosure. The parties then must negotiate as to which patents the biologic will assert in a first round of litigation. After suit is filed, the biosimilar may not file a declaratory judgment action on the remaining patents until either that first round of litigation is complete or the biosimilar gives the brand manufacturer a 180-day notice that the biosimilar intends to market at risk.

This "patent dance" has obvious downsides for biosimilar manufacturers. Because biologics manufacturers get to select which patents against the biosimilar's proposed product, the process tends to favor biologic manufacturers over biosimilars. But the process also seems almost designed to simply delay litigation. Further, the statute contemplates multiple rounds of litigation among parties—a requirement which, if faithfully followed, may take years. Indeed, to date, no company has successfully survived this tango.[43] Indeed, the FDA's recent approval of

[42] There is a Purple Book, but it does not—yet—list patent information concerning each biologic approval.

[43] Yaniv Heled, *Five Years After the BPCIA: A Stocktaking* (manuscript on file with the author).

biosimilar filigrastim was helped because of the thin intellectual property protection attached to the original biologic—a single U.S. patent, No. 6,162,427. That patent expires in December 2015. The biosimilar manufacturer, Sandoz, must now contemplate, simply, whether it should launch "at risk" or wait until the patent expires later this year.

This complex patent litigation scheme, and the high stakes involved, suggest that inter partes review should be similarly attractive to biosimilar manufacturers. Indeed, without an Orange Book to serve as a clearing house, freeing or encumbering a particular drug against a set list of patents, there is little other way to cut a path to biosimilar approval than Götterdämmerung-style litigation against the biologic manufacturer. Furthermore, inter partes review should be quicker than the multiple rounds of litigation contemplated by the BPCIA, let alone the initial information disclosure and patent selection procedures. The invalidation rate, too, is similarly higher than what biosimilars could expect from district court litigation.

Thus far, only one biosimilar applicant has challenged its biologic-manufacturing rival through inter partes review: Hospira against Janssen concerning Eprex, a red blood cell-growth stimulant useful in challenging anemia.[44] After some litigation before the PTO, Janssen ultimately disclaimed all of its patent's claims, thus leaving its biologic unprotected by intellectual property. Whether Hospira will ultimately be able to receive biosimilar approval is likely to be known by this year. But in the meantime, Hospira's strategy augurs well for future biosimilar manufacturers.

IV. CONCLUSIONS

The relationship between courts and the PTO, long an odd marriage, has been particularly strange concerning drugs and biologics. Prior to the AIA, the incentives for concurrent proceedings before both tribunals were simply not aligned, and litigants only engaged in both in what seemed like quite specific circumstances. Post-issuance proceedings after the AIA, however, have greatly normalized this relationship: aligning incentives, synchronizing litigation timelines, and providing results in ways beneficial to patent challengers.

This "normalizing" of the relationship between courts and the PTO in litigating patented medicines may provide several insights into drug-and-biologic litigation, specifically, but also to patent litigation more generally. First, and most specifically, the upshot of the AIA's new administrative proceedings may simply create a sea change in litigating medical patents. Generics and biosimilars may largely begin their fights at the PTO, rather than federal courts, and only choose to enter the crucible of federal court litigation if absolutely necessary. This will surely bring clarity to litigation much sooner than otherwise expected. But, without knowing whether and how generics and biosimilars will be successful in this new strategy—and whether it will dampen innovation if ultimately *too* successful—it is unclear whether it bring any positive change to consumers.

Relatedly, this increase in interaction between courts and PTO under the banner of the pharmaceutical patent bar may bring Hatch-Waxman Act and BPCIA litigation, much at the periphery of policy disputes concerning the PTO, back into the fold. Increasingly, patent litigation has been experiencing a split between high-tech patent litigators and those who practice in the pharmaceutical and biologic fields. Policy debates concerning PTO practices, such as

[44] Hospira, Inc. v. Janssen Pharm., Inc., IPR2013-00365 (P.T.O.).

guidances on patentable subject matter, have largely left out such players. Routine practice before the PTO may help "wetware" patent litigators reengage with the agency.

Separately, this change in relationship between courts and the PTO highlights the relative unimportance of the FDA in these matters. While, in other areas, the FDA has recently taken a more muscular approach to regulation—new guidances on laboratory developed tests, genetic data, and biosimilars—the agency has, once again, left its expertise over the patent aspect of these cases unutilized. Patents, it is fair to say, have become a practically leprous area of the FDA's jurisdiction. And yet, more guidance is needed regarding how the agency will interpret the BPCIA and how to square that will the ultimate intellectual property difficulties in effecting approval.

More generally, these larger changes to PTO procedure, combined with smaller changes in antitrust law, litigation costs, and drug exceptionalism, paint a textured portrait of multiple institutional actors working in synchronicity if not in concert. It would be wholly unclear whether generic and biosimilar manufacturers would have reason to view concurrent proceedings before the PTO positively, were it not for the simultaneous development of the AIA, the BPCIA, *Actavis,* the rise in litigation costs, the rise in drug pricing, and the general zeitgeist in favor of invalidating patents. The story told here is complex, and one, ultimately, about how relationships, such as that between the courts and the PTO, are often ones of unintended consequence.