THE JOHN MARSHALL
REVIEW OF INTELLECTUAL PROPERTY LAW

PULLING THE 'TRIGGER' ON THE HATCH-WAXMAN ACT'S 180-DAY EXCLUSIVITY USING *INTER PARTES* REVIEW

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ABSTRACT

The America Invents Act has put in place quick and efficient mechanisms for challenging granted patents in an Article I adversarial setting. And the Hatch-Waxman Act has been the roadmap for generic drug approval-related patent infringement action in Article III courts. An interesting, heretofore unaddressed question lurks at an intersection of the two pieces of enterprising legislation: What impact should a final decision canceling patent claims under the AIA setting have on the forfeiture of 180-day exclusivity under the Hatch-Waxman Act? The 180-day exclusivity is an important piece in the Hatch-Waxman game of chess. This comment presents both the case for and against pulling the forfeiture trigger on the 180-day exclusivity via the new AIA setting. Going further, the comment highlights pragmatic and policy justifications for pulling the trigger, thereby proposing grounds for a conformant legislative action.

Cite as Jaimin Shah, *Pulling the 'Trigger' on the Hatch-Waxman Act's 180-Day Exclusivity Using Inter Partes Review*, 14 J. MARSHALL REV. INTELL. PROP. L. 453 (2015).

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I. INTRODUCTION

The United States healthcare system has enjoyed enormous savings in the last three decades due to reduced drug costs,[1] thanks to the Drug Price Competition and Patent Term Restoration Act of 1984 (commonly known as the Hatch-Waxman Act).[2] The Hatch-Waxman Act is the reason American consumers have had greater access to lower-cost generic drugs.[3] At the same time, the Act is also the force behind pioneer drug companies' continued incentive to research and develop new drugs.[4] The Act finely balances the competing interests of pharmaceutical companies in manifold ways. Among the balancing mechanisms of the Act is one that effectuates resolution of patent issues.[5]

A generic drug manufacturer can initiate challenges to unexpired patents covering a pioneer drug even while the manufacturer's application for regulatory approval is pending review.[6] The first generic company to file such a patent challenge (hereinafter, "first filer") is awarded a 180-day market exclusivity.[7] The 180-day exclusivity sticks out as a carrot. The idea is to incentivize early patent challenges and thereby accelerate the market entry of lower-cost generic drugs.[8] The incentive, however, is counterbalanced by the Act's forfeiture provision.

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[1] *See, e.g.*, John E. Dicken, U.S. Gov't Accountability Office, GAO-12-371R, Drug Pricing: Research on Savings from Generic Drug Use 4 (2012) (estimating that between 1999 and 2010, generic substitution accounted for more than $ 1 trillion in savings).

[2] Pub. L. No. 98–417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. §§ 355, 360cc (2000), 35 U.S.C. §§ 156, 271, 282 (2000)), as amended by the Medicare, Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. N. 108-173, 117 Stat. 2066 (2003)).

[3] GAO-12-371R at 1 (reporting that the on the average, the retail price of a generic drug is 75 per cent lower).

[4] Christopher Ohly & Sailesh K. Patel, *The Hatch-Waxman Act: Prescriptions for Innovative and Inexpensive Medicines*, 19 U. BALT. INTELL. PROP. L.J. 107, 107-08, 113-15, 127 (2011) (imputing "gains in research intensity of the pharmaceutical industry" to the Act's provisions that extend patent terms lost due to delay in FDA approval of branded drugs and that confer non-patent data exclusivities such as the New Chemical Entity exclusivity).

[5] *See* 21 U.S.C. § 355(j)(2)(B) (2012); *id.* §§ 355 (j)(5)(B)-(D).

[6] *See id*. § 355(j)(2) (setting forth in the same subsection regulatory as well as certification and notice letter requirements, the latter of which is a predicate to patent infringement litigation under § 355(j)(5)(B)(iii)); *see also* Ohly & Patel, *supra* note 4, at 116-17 (explaining generally the paragraph-IV certification process as part of an ANDA application that typically triggers a patent infringement action).

[7] *See* 21 U.S.C. § 355 (j)(5)(B)(iv) (2012) (requiring that during the 180-day exclusivity period, no subsequent generic applicant can be given regulatory approval).

[8] *See* Ohly & Patel, *supra* note 4, at 117-18; David E. Korn et. al., *A New History and Discussion of 180-Day Exclusivity*, 64 FOOD & DRUG L.J. 335 (2009).

A first filer's 180-day exclusivity is not iron-clad; it is susceptible to being triggered and even forfeited by certain events.[9] For example, a generic manufacturer with a subsequently initiated patent challenge (hereinafter, "second filer") may win its challenge and force the first filer to launch its product quickly or forfeit its exclusivity.[10] Again, such forfeiture would be consistent with the goal of accelerating generic drug commercialization. A question of first impression is what impact, if any, administrative adjudication of patent validity should have in this exclusivity forfeiture scheme.

The relatively recent America Invents Act (hereinafter, "AIA")[11] affords to patent challengers various new mechanisms for challenging patent validity.[12] The challenges are adjudicated by the specially created Patent and Trial Appeal Board (hereinafter, "PTAB").[13] A goal of the AIA is to weed out weak patents from the system and reduce the litigation burden on district courts.[14] This comment focuses on whether, and under what circumstances, a successful patent challenge under the Article I setting may trigger a first filer's 180-day exclusivity under the Hatch-Waxman Act.

The comment's Background section sets forth the relevant aspects of the Hatch-Waxman Act, the America Invents Act, principles of collateral estoppel, and the trending PTAB action. The Analysis section develops both the case for and against allowing PTAB litigation to activate the Hatch-Waxman Act's 180-day exclusivity scheme. Lastly, the Proposal section makes a pitch for allowing PTAB litigation to activate the exclusivity scheme to further the socio-economic policy behind the Hatch-Waxman Act.

II. BACKGROUND

This comment identifies an interesting, unexplored intersection between the Hatch-Waxman Act and the AIA. Before the intersection is analyzed in depth, a detailed understanding of both pieces of enterprising legislation is warranted. The Hatch-Waxman Act sets forth an elaborate roadmap for generic drug approval-related patent litigation; whereas, the AIA provides efficient mechanisms for adjudication of patent validity at the PTAB. The former is effectuated via Article III courts and the latter through an Article I agency. So, it is also useful to examine the pertinent

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[9] *See* 21 U.S.C. § 355 (j)(5)(D) (2012).

[10] *Id.* § 355 (j)(5)(D)(i)(I)(bb)(AA) (triggering – per a final court decision about the patent challenge - a 75-day clock period within which the first filer must go to market or lose its 180-day exclusivity).

[11] Leahy-Smith America Invents Act (AIA), Pub. L. No. 112-29, 125 Stat. 284 (2011) (codified in 35 U.S.C.).

[12] *See, e.g.*, 35 U.S.C. §§ 321-29 (2012) (post grant review); *id.* §§ 311-19 (2012) (*inter partes* review).

[13] *See* 35 U.S.C. §§ 6, 141 (2012); *see also* Joe Matal, *A Guide to the Legislative History of the America Invents Act: Part II of II*, 21 FED. CIRCUIT B.J. 539, 541 (2012).

[14] *See* Mark Consilvio & Jonathan R.K. Stroud, *Unraveling the USPTO's Tangled Web: An Empirical Analysis of the Complex World of Post-Issuance Patent Proceedings*, 5821 J. INTELL. PROP. L. 33, 43-44 (2013); The White House, *President Obama Signs America Invents Act, Overhauling the Patent System to Stimulate Economic Growth, and Announces New Steps to Help Entrepreneurs Create Jobs* (Sept. 16, 2011), http://www.whitehouse.gov/the-press-office/2011/09/16/president-obama-signs-america-invents-act-overhauling-patent-system-stim.

principles of collateral estoppel. Lastly, highlighting the current trend of settlement of the relevant PTAB action will set the stage for the analysis.

A. The Hatch-Waxman Act

Under the Hatch-Waxman Act, a generic drug manufacturer typically files an Abbreviated New Drug Application (hereinafter, "ANDA") with a paragraph-IV certification.[15] The paragraph-IV certification is a challenge to one or more listed patents pertaining to the branded drug.[16] The certification sets the ball rolling on the patent challenge under the litigation-related provisions the Act.[17]

Egged on by a paragraph-IV certification, when a brand company brings infringement suit, there is a thirty-month stay on approval of the respective ANDA (hereinafter, "30-month stay").[18] The 30-month stay can end prematurely if a district court enters judgment in the generic company's favor,[19] unless a first filer's 180-day exclusivity is blocking the second filer's final approval.[20]

As an incentive to the first filer who races to the Food and Drug Administration (hereinafter, "FDA"), the Hatch-Waxman Act affords to the filer a 180-day exclusivity during which no other subsequently filed paragraph-IV ANDA may be approved.[21] But while the Act provides the economic incentive, the Act provides for its forfeiture too.[22] The Act's forfeiture by failure-to-market provision, in particular, is quite formulaic.[23]

The formulaic provision sets forth in a timing-driven schematic the trigger events that could lead to forfeiture of the first filer's 180-day exclusivity.[24] One of the trigger

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[15] 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (2012).

[16] *See id.* (providing for a certification "that [a] patent [covering the brand drug] is invalid or will not be infringed by the [ANDA] product."); *see also* Shashank Upadhye, *There's A Hole in My Bucket Dear Liza, Dear Liza: The 30-Year Anniversary of the Hatch-Waxman Act: Resolved and Unresolved Gaps and Court-Driven Policy Gap Filling*, 40 WM. MITCHELL L. REV. 1307, 1313-14 (2014) (("When the brand company's new drug application (NDA) is approved, the brand company is obligated to list certain patents in [what is commonly known as] the Orange Book."))

[17] Upadhye, *supra* note 16, at 1316-17 (("Once the ANDA containing a Paragraph IV certification is filed, the generic drug company then will send a so-called Paragraph IV notice letter to the brand company informing it that the generic company has filed an ANDA against the brand drug version and explaining in great detail the basis why the patent certified against is not an obstacle to final approval. That is, the notice letter will explain the bases for non-infringement and/or invalidity of the patent. Upon receipt of the notice letter, the brand company can evaluate the allegations contained therein and may choose to sue the generic company.")

[18] Upadhye, *supra* note 16, at 1316-17.

[19] 21 U.S.C. § 355(j)(5)(B)(iii)(I)-(IV) (2012).

[20] *Id.* § 355(j)(5)(B)(iv)(I).

[21] *Id.*; Upadhye, *supra* note 16, at 1318-19 (explaining using an apt hypothetical why "the economics of the 180-day exclusivity makes a good deal of sense").

[22] *See* 21 U.S.C. § 355 (j)(5)(D) (2012).

[23] *See id.* § 355 (j)(5)(D)(i)(I).

[24] *Id.* The forfeiture-due-to-failure-to-market provision stipulates that the first filer forfeits its 180-day exclusivity when the filer fails to launch upon the occurrence of event (aa) or event (bb), whichever occurs *later*. Two types of events fall under the (aa) umbrella:

(AA), which is 75 days after ANDA approval, and

(BB), which is 30 months from the date of ANDA submission.

events of interest is patent delisting.[25] A first filer may forfeit its 180-day exclusivity if the patent information in the Orange Book is "withdrawn by the [NDA] holder" (hereinafter, "delisting trigger").[26] In Teva's Hatch-Waxman case pertaining to Merck's anti-hypertension drugs Cozaar and Hyzaar, Merck voluntarily withdrew its Orange Book patent, and the FDA, going by the plain text of the delisting provision, determined that Teva forfeited its exclusivity.[27] The District of Columbia Court of Appeals reversed, reasoning that the FDA's interpretation was inconsistent with the *structure* of the Hatch-Waxman Act, particularly its 180-day exclusivity provision.[28] Thus, a brand company cannot voluntarily delist an exclusivity-conferring Orange Book-listed patent.[29]

A second trigger event of interest is a final, favorable court decision as to each patent against which an ANDA filer has made a paragraph-IV certification (hereinafter, "court decision trigger").[30] Accordingly, a second filer may attempt to win its patent litigation and cause the first filer to forfeit its exclusivity using the court decision trigger.[31] In fact, Teva Pharmaceuticals, Inc., tried to do so through its declaratory judgment suit in relation to its ANDA for the drug Aricept®.[32] In the Aricept case, the brand company tried to get rid of Teva's declaratory suit by providing to Teva covenants not to sue on two Orange Book-listed patents and by submitting statutory disclaimers for the other two listed patents.[33] But the Court of Appeals for the Federal Circuit held that Teva's suit must go forward because, as long as the patents continue to be listed in the Orange Book, final approval of Teva's ANDA will

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Either (AA) or (BB) suffices to constitute (aa); both are not required. But neither (AA) nor (BB) can trigger forfeiture as long (bb) can still occur. This is because of the "later of" prong separating (aa) and (bb).

Three types of events fall under the (bb) umbrella:

(AA), which is a final, non-appealable decision as to the patent;

(BB), which is settlement of the case a court enters judgment including a finding that the patent is deemed invalid or not infringed; and

(CC), which is delisting of the patent from the Orange Book by the brand company.

Further, each event under (bb) must meet two requirements. First, 75 days must pass from the occurrence of (AA), (BB), or (CC) to become a (bb) event. Second, to become a (bb) event, each of (AA), (BB), and (CC) must occur with respect to each patent in the suit.

Any one of (AA), (BB), and (CC) suffices to amount to (bb); all three are not required. Again, the occurrence of any event under (bb) would not trigger forfeiture as long as an event under (aa) can potentially occur. This is because of the "later of" predicate between (aa) and (bb).

[25] 21 U.S.C. § 355 (j)(5)(D)(i)(I)(bb)(CC) (2012).

[26] *Id.*; *see generally* Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations, U.S. FOOD & DRUG ADMINISTRATION, available at www.fda.gov/cder/ob/default.htm (last updated May 17, 2013).

[27] Teva Pharm. USA, Inc. v. Sebelius, 595 F.3d 1303, 1304-08 (D.C. Cir. 2010).

[28] *Id.* at 1316-18 ("We see nothing in the . . . *structure of the statute* such that brand companies should be newly able to delist challenged patents, thereby triggering a forfeiture event that deprives generic companies of the period of marketing exclusivity they otherwise deserve." (emphasis added)).

[29] *Id.* at 1317-18.

[30] *See* 21 U.S.C. § 355 (j)(5)(D)(i)(I)(bb)(AA) (2012).

[31] *Id.*

[32] *See* Teva Pharm. USA, Inc. v. EISAI Co., 620 F.3d 1341, 1342-1345 (Fed. Cir. 2011). Teva was the second filer in this case. Eisai filed an infringement suit against Teva only with respect to one of the five Orange Book-listed patents. So Teva sought declaratory judgment of non-infringement of the other four patents.

[33] *Id.* at 1346-48 (relying on *Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278, 1291-92 (Fed. Cir. 2008)).

remain blocked by the first filer's 180-day exclusivity.[34] Exclusion of a generic from the market is a cognizable injury-in-fact, and such an "FDA-approval-blocking injury" creates an "actual controversy."[35]

Thus, generally speaking, brand companies' unilateral actions such as statutory disclaimers, covenants not to sue, and patent delisting cannot cause exclusivity forfeiture; by contrast, litigation involving adverse parties has the potential to cause forfeiture.[36] Sitting somewhere in the middle of this spectrum are the litigation-type patent validity challenge mechanisms recently created under the America Invents Act.

B. The America Invents Act

The AIA aims to overhaul the patent system by, among other things, weeding out weak patents.[37] To that end, the Act affords post-issuance adversarial mechanisms that a patent challenger may initiate at the PTO.[38] This comment will focus on the *inter partes* review (hereinafter, "IPR") mechanism.[39]

An IPR can be used to mount invalidity challenges against any patent after nine months of the patent's issuance.[40] Anyone not a patent owner may petition for an

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[34] Teva Pharm. USA, Inc. v. EISAI Co., 620 F.3d 1341, 1346-48 (Fed. Cir. 2011).

[35] *Id.* Teva's case never actually went forward. The case was dismissed as moot and the judgment was vacated because when Eisai's writ of certiorari was pending at the Supreme Court, the first filer commercially launched its ANDA product triggering its own 180-day exclusivity period. *See Teva Pharm. USA, Inc. ex rel. Gate Pharm. Div. v. EISAI Co.*, 426 F. App'x 904 (Fed. Cir. 2011).

[36] *See also* 21 U.S.C. § 355(j)(5)(C)(ii)(I) (allowing a generic company to assert a counterclaim seeking an order requiring the holder to correct or delete the patent information submitted by the holder . . . on the ground that the patent does not claim either the drug for which the application was approved or an approved method of using the drug"). While a brand company's act of voluntarily delisting a patent would be unilateral in nature, a deletion of the patent pursuant to this counterclaim certainly has an adversarial flavor.

[37] Consilvio & Stroud, *supra* note 14.

[38] *See* 35 U.S.C. §§ 311-19 (2012) (inter partes review); *id.* §§ 321-29 (post grant review); Pub. L. 112-29, § 18, 125 Stat. 284, 328 (2011); Changes to Implement Inter Partes Review Proceedings, Post-Grant Review Proceedings, and Transitional Program for Covered Business Method Patents, 77 Fed. Reg. 48680 (Aug. 14, 2012) (codified at 37 C.F.R. pt. 42).

[39] Generic pharmaceutical companies are likely to take advantage of the IPR mechanism of the AIA more frequently than the post-grant review (hereinafter, "PGR") and covered business method patent review (hereinafter, "CBM") mechanisms. PGR can be used to challenge any granted patent but only within nine months of the patent's issuance. *See* 35 U.S.C. § 321(c) (2012). This timing restriction may cause generic companies to invalidate some Orange Book patents too early in the game, preventing the later filing of a paragraph-IV certification to secure 180-day exclusivity. Concededly, later-listed patents can certainly be challenged through a PGR. *See Accord Healthcare, Inc. v. Helsinn Healthcare S.A. et. al.*, PGR2014-00010, Paper 1 (P.T.A.B. Sept. 2, 2014) (requesting post-grant review of a patent listed in the Orange Book for the drug Aloxi®, where the patent issued after the drug's NDA was approved). But this comment's author wishes to restrict the discussion to IPRs for the sake of simplicity and convenience. Also, covered business method patent review is for financial products or services-related patents. And very few patents in the pharmaceutical area are related to financial products or services.

[40] *See* 35 U.S.C. § 311 (2012); *see also id.* § 311(b) (limiting the challenge to "a ground that could be raised under section 102 or 103 and only on the basis of prior art consisting of patents or printed publications").

IPR.[41] The petition must be filed within one year of any complaint alleging patent infringement.[42]

IPR proceedings are adjudicative, not merely examinational.[43] A provision indicative of the adversarial nature of the proceeding is that the patent owner may respond to the petition with "reasons why no *inter partes* review should be instituted."[44] The standard for instituting the review, however, is low.[45] After an IPR is instituted, the patent owner may move to cancel any challenged patent claim.[46] A patent owner may also propose substitute claims.[47]

Fact discovery is allowed, but it is quite limited.[48] Where IPR proceedings depart significantly from district court litigation is the former's lower burden of proof for claim cancellation.[49]

As to timing, IPR proceedings call for an accelerated timeline. The decision to institute a proceeding must be made within six months of the filing of a petition.[50] And within one year of institution, a final written decision must be made.[51] Therefore, a petitioner is guaranteed a decision on the merits no later than 1.5 years from the filing of the petition. A dissatisfied party has a right to appeal.[52]

Thus, IPR proceedings retain district court litigation's adversarial flavor but shed its procedurally laborious aspects. In other words, efficiency is the hallmark.[53] The efficiency effectively spills over into any corresponding parallel district court litigation in at least three ways.[54]

First, cancellation of a patent claim generally extinguishes any cause of action that may arise out of or be pending under the patent claim.[55] In *Fresenius*, for example, the Federal Circuit held that cancellation of certain patent claims after *ex parte*

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[41] *See* 35 U.S.C. § 311(a) (2012); 37 C.F.R. § 42.101 (2013).

[42] *See* 37 C.F.R. § 42.101(b) (2013).

[43] *See* Abbott Labs. v. Cordis Corp., 710 F.3d 1318, 1326 (Fed. Cir. 2013) (emphasizing – based in part on legislative history of the AIA – this distinction between *inter partes* review and *inter partes* reexamination when presented with the question of whether parties may take depositions during *inter partes* reexaminations).

[44] *See* 35 U.S.C. § 313 (2012); 37 C.F.R. § 42.107(a) (2013).

[45] *See* 35 U.S.C. § 314 (2012); 37 C.F.R. § 42.108(c) (2013) (providing that as long as the petition raises a "reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims," review will be instituted).

[46] *See* 35 U.S.C. § 316(d) (2012); 37 C.F.R. § 42.121 (2013).

[47] *See* 35 U.S.C. § 316(d) (2012).

[48] *Id.* § 316(a)(5) (limiting discovery to "deposition of witnesses submitting affidavits or declarations" and "what is otherwise necessary in the interest of justice").

[49] *Id.* § 316(e) (requiring that unpatentability be proved by a preponderance of evidence as opposed to proving invalidity by clear and convincing evidence, which is a higher burden of proof required in district court litigation).

[50] *See id.* § 314(b).

[51] *See* 37 C.F.R. § 42.100(c) (2013).

[52] *See* 35 U.S.C. § 319 (2012).

[53] *See* Consilvio & Stroud, *supra* note 14, at 43-44.

[54] A fourth mechanism by which efficiency may spill over is AIA's provision pertaining to stay of parallel district court litigation, *see* 35 U.S.C. § 315(a)(2), but that aspect is not pertinent to the analysis of the issue addressed by this comment.

[55] *See* Fresenius USA, Inc. v. Baxter Int'l, Inc., 721 F.3d 1330, 1340 (Fed. Cir. 2013), *cert. denied*, 134 S. Ct. 2295 (U.S. 2014).

reexamination mooted the co-pending district court litigation because the district court's judgment had not yet reached finality.[56]

Second, a petitioner may not assert in a civil action the same grounds of invalidity that the petitioner "raised or reasonably could have raised" during the IPR.[57] The statutory estoppel is broader than common law collateral estoppel because of it's "reasonably could have raised" language.[58] Thus, the line of invalidity attack used in an IPR is not available in district court litigation once a final written decision issues in the IPR.

Third, certain timing restrictions are imposed on the institution of IPRs, which further contribute to the efficiency spillover.[59] For example, if IPR was available at the time the *Fresenius* case was litigated, Fresenius could not have used IPR in the same way as *ex parte* reexamination due to the timing restrictions.[60]

Thus, claim cancellation at the PTO moots an Article III case or controversy,[61] reducing a court's litigation backlog; but to take advantage of the efficiency mechanism, an IPR challenge must be brought efficiently. Efficiency gains notwithstanding, application of estoppel as here must conform to common law principles of collateral estoppel.

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[56] *Id.* at 1341-42. In *Fresenius*, the district court found invalid certain claims of Baxter's hemodialysis machine patents. *Id.* at 1332-33. The Federal Circuit reversed, holding that the claims were not invalid. *Id.* at 1333. The Court then remanded on the issues of damages calculations and injunctive relief. *Id.* Meanwhile, the PTO cancelled the remaining asserted claims during *ex parte* reexamination, a decision that the Board of Patent Appeals and Interferences subsequently affirmed. *Id.* at 1334-35. Baxter appealed the BPAI decision, but the Federal Circuit affirmed. *Id.* at 1335.

Baxter next appealed to the Federal Circuit arguing that the district court's judgment was final and therefore it must be given preclusive effect. *Id.* at 1340. But the Federal Circuit held that the district court's judgment was not "sufficiently final" to have preclusive effect because "several aspects of the district court's original judgment [were left] unresolved." *Id.* at 1341.

[57] *See* 35 U.S.C. § 315(e)(2). The legislative purpose behind the statutory estoppel provision is to prevent harassment of patent owners by repeated challenges. *See* Robert L. Stoll, *Maintaining Post-Grant Review Estoppel in the America Invents Act: A Call for Legislative Restraint*, 2012 PATENTLY-O PAT. L.J. 1, 5-11 (2012).

[58] *See* Monica Grewal & Richard Crudo, *Estoppel as Applied to and from Patent Office Post-Grant Proceedings*, 88 PTCJ 1020 (Issue No. 2175, Aug. 15, 2014).

[59] *See* 35 U.S.C. § 315(a)(1) (2012) (barring institution of an IPR if petitioner has already filed a "civil action challenging the validity of a claim of the patent"); *Id.* § 315(a)(3) (further setting forth in the subsection that "[a] counterclaim challenging the validity of a claim of a patent does not constitute a civil action challenging the validity of a claim"); *Id.* § 315(d) (barring institution of an IPR "more than 1 year after the date on which the petitioner . . . is served with a complaint alleging infringement").

[60] *See id.* § 315(a)(1). In *Fresenius*, Fresenius had initiated *ex parte* reexamination of the Baxter patent in 2005, which was *after* the start in 2003 of its suit seeking declaratory judgment of non-infringement and invalidity of the Baxter patents. 721 F.3d at 1332-34.

[61] In *ePlus, Inc. v. Lawson Software, Inc.*, 760 F.3d 1350, 1359-60 (Fed. Cir. 2014), the Federal Circuit again set aside a district court's award of injunction and civil contempt remedies, which was pending appeal, after the PTO cancelled in *ex parte* reexamination the claims asserted in the district court.

C. General Principles of Collateral Estoppel

A court may apply collateral estoppel based on an administrative agency's decision if the agency, acting in judicial capacity, properly resolves the issues before it, which the parties had sufficient opportunity to litigate.[62] Collateral estoppel is generally a procedural issue and is therefore governed by the law of the regional circuit.[63] Under the Federal Circuit, the following four requirements must be met for application of collateral estoppel: (i) the issues in the two proceedings must be identical; (ii) the issue in the first proceeding must have been actually litigated; (iii) the resolution of the issue in the first proceeding must have been necessary for a final adjudication of the dispute; and (iv) the party against whom estoppel is asserted must have had a full and fair opportunity to litigate the issue in the first proceeding.[64]

Given the similarities and differences in the procedural nuts and bolts of IPR and district court litigation, the fourth element concerning full and fair opportunity to litigate will be the most important. This element stems from the Due Process Clause of the Fourteenth Amendment of the United States Constitution.[65] To meet the constitutional standard, courts have considered the following procedural nuances of agency proceedings to determine collateral estoppel effect on an Article III court: opportunity to cross-examine the adverse party's witnesses;[66] availability of a record adequately supporting the findings;[67] right to judicial review;[68] similarity of burden of proof;[69] extent of representation of the party sought to be precluded;[70] scope of pre-trial discovery afforded;[71] and existence of evidentiary opportunities or restrictions.[72]

At the intersection of the Hatch-Waxman Act and the AIA lies the question of whether a paragraph-IV ANDA applicant can seek a determination recognizing a final, favorable IPR decision as a forfeiture trigger event. The recent IPR settlement trend is indicative of the uncertainty of the answer.

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[62] United States v. Utah Const. & Min. Co., 384 U.S. 394, 422 (1966); *see also* Astoria Fed. Sav. & Loan Ass'n v. Solimino, 501 U.S. 104, 107 (1991) (("[w]e have long favored application of the common-law doctrines of collateral estoppel (as to issues) and res judicata (as to claims) to those determinations of administrative bodies that have attained finality.")).

[63] *See* Ohio Willow Wood Co. v. Alps S., LLC, 735 F.3d 1333, 1342 (Fed. Cir. 2013).

[64] *See generally* Innovad Inc. v. Microsoft Corp., 260 F.3d 1326, 1334 (Fed. Cir. 2001); 89 Am. Jur. Proof of Facts 3d 1 (Originally published in 2006) (compiling cases pertaining to each of the four elements of collateral estoppel as applied *between district courts* in patent infringement actions).

[65] *See* U.S. CONST. amend. XIV § 1; Kremer v. Chem. Const. Corp., 456 U.S. 461, 481-82(1982).

[66] *See* Brown v. Plaut, 131 F.3d 163, 168 (D.C. Cir. 1997).

[67] *See* Moore v. Chater, 97 F.3d 1460 (9th Cir. 1996).

[68] United States v. Utah Const. & Min. Co., 384 U.S. 394, 422 (1966).

[69] City of Cleveland v. Cleveland Elec. Illuminating Co., 734 F.2d 1157, 1165-66 (6th Cir. 1984).

[70] Thomas v. Gen. Servs. Admin., 794 F.2d 661, 664 (Fed. Cir. 1986).

[71] Buckhalter v. Pepsi-Cola Gen. Bottlers, Inc., 820 F.2d 892, 895-97 (7th Cir. 1987).

[72] United States v. Karlen, 645 F.2d 635, 640 (8th Cir. 1981).

D. Orange Book Patent IPR Settlement Trend

The generic drug industry has responded relatively slowly to the introduction of the post-grant review processes under AIA.[73] But two trends seem to be emerging. One, IPR seems to be mainly a second filer's game.[74] And two, these IPR challenges tend to settle.[75]

For example, Ranbaxy initiated an IPR challenge against a patent listed in the Orange Book for the anti-HIV drug Lexiva®.[76] Here, because there was no co-pending lawsuit, Ranbaxy had either not filed a paragraph-IV ANDA application or was not sued.[77] Rather, another generic company, Mylan, had already filed an ANDA and was litigating against the same patent in district court.[78] Anyway, the PTAB instituted

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[73] *See* Christopher R. Noyes et al., *When Inter Partes Review Meets Hatch-Waxman Patents, Law360,* Sept. 9, 2014 (reporting that, of a total of 1,562 IPR petitions filed through July 2014, only 32 petitions were against Orange Book-listed patents and that of those 32, three petitions were filed in 2012, seven were filed in 2013, and 22 have been filed this year through July 2014).

[74] *See id.* ("Only one IPR petition has been filed by the first ANDA filer to be sued for infringement in related Hatch-Waxman litigation. Twenty-one petitions have been filed by subsequent ANDA defendants; and 10 have been filed by petitioners that were not — as of the date of filing the petition — defendants in related Hatch-Waxman litigation. These petitioners may be prospective ANDA filers, ANDA filers that have not yet been sued for patent infringement, or interested third parties."). Similarly situated to Teva in the Aricept case, these second filers are likely interested in creating a forfeiture trigger event based on a favorable IPR decision. *See* Teva Pharm. *supra* note 32.

[75] IPRs against three Orange Book-listed patents have reached a final written decision. *See* Amneal Pharmaceuticals, LLC v. Supernus Pharmaceuticals, Inc., IPR2013-00368, Paper No. 94 (P.T.A.B. Dec. 9, 2014) (Oracea®); Amneal Pharmaceuticals, LLC v. Supernus Pharmaceuticals, Inc., IPR2013-00371, Paper No. 96 (P.T.A.B. Dec. 9, 2014) (Oracea®); Amneal Pharmaceuticals, LLC v. Supernus Pharmaceuticals, Inc., IPR2013-00372, Paper No. 92 (P.T.A.B. Dec. 9, 2014) (Oracea®). By contrast, IPRs against eight Orange Book-listed patents have been settled so far. *See* Apotex Inc. v. Alcon Pharmaceuticals, Ltd. IPR2013-00012, Paper No. 73 (P.T.A.B. Nov. 15, 2013) (Vigamox®); Apotex Inc. v. Alcon Pharmaceuticals, Ltd. IPR2013-00015, Paper No. 61 (P.T.A.B. Nov. 15, 2013) (Vigamox®); Ranbaxy Laboratories, Ltd. et al. v. Vertex Pharmaceuticals, Inc., IPR2013-00024, Paper No. 71 (P.T.A.B. Nov. 15, 2013) (Lexiva®); Apotex Corp. v. Alcon Research, Ltd, IPR2013-00428, Paper No. 60 (P.T.A.B July 21, 2014) (Travatan Z®); Apotex Corp. v. Alcon Research, Ltd, IPR2013-00429, Paper No. 58 (P.T.A.B July 21, 2014) (Travatan Z®); Apotex Corp. v. Alcon Research, Ltd, IPR2013-00430, Paper No. 58 (P.T.A.B July 21, 2014) (Travatan Z®); Impax Laboratories, Inc. v. Meda Pharmaceuticals Inc., IPR2014-00731, Paper No. 12 (P.T.A.B. Aug. 4, 2014) (Astepro®); Pack Pharmaceuticals v. Alza Corporation, IPR2014-00868, Paper No. 10 (P.T.A.B. Sept. 8, 2014) (Glucotrol XL); *see generally* Anna J. Smith, *Inter Partes Review -- Parties Favor Settlement Over Board Decisions*, Foley & Lardner LLP, http://www.pharmapatentsblog.com/2014/09/25/inter-partes-review-parties-favor-settlement-over-board-decisions/ (Sept. 25, 2014) (observing that parties "choos[e] certainty" by settling their IPRs).

[76] *See* Ranbaxy Laboratories Ltd. et al. v. Vertex Pharmaceuticals, Inc., IPR2013-00024, Paper No. 1 (P.T.A.B. Oct. 18, 2012).

[77] *See* Charles H. Chevalier, *A Rare Inter Partes Review for an Orange Book Listed Patent*, Gibbons P.C., http://www.iplawalert.com/2013/12/articles/patent/a-rare-inter-partes-review-for-an-orange-book-listed-patent/ (Dec. 3, 2013) (discussing the possibility that either "Ranbaxy did not file a paragraph IV certification or Vertex chose not to file suit" in the context of Lexiva® patents).

[78] *See* ViiV Healthcare Co. et al. v. Mylan Inc. et al., No. 12-1065-RGA (D. Del.) (filed Aug. 22, 2012).

Ranbaxy's IPR,[79] and six months later, Ranbaxy settled the IPR "and any potential Hatch-Waxman litigation on th[e] patent."[80]

Some industry observers view brand-generic settlements as thwarting the Hatch-Waxman Act's goal of earlier generic drug commercialization.[81] The IPR settlement trend is likely due to the uncertainty about the legal question of how, if at all, an IPR decision would impact a first filer's 180-day exclusivity.

III. ANALYSIS

A question of first impression is whether a paragraph-IV ANDA applicant can seek a determination recognizing a favorable IPR decision, affirmed on appeal,[82] as an event triggering forfeiture of a first filer's 180-day exclusivity.[83] For example, let us assume that in the IPR case discussed in the previous sub-section, Ranbaxy had filed its own paragraph-IV ANDA for generic Lexiva while its IPR challenge was pending. The filing would most likely have triggered a lawsuit for Ranbaxy.[84] Further assume that Mylan was the first filer and had maintained its 180-day exclusivity.[85] While both

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[79] *See* Ranbaxy Laboratories Ltd. et al v. Vertex Pharmaceuticals, Inc., IPR2013-00024, Paper No. 16 (P.T.A.B. March 5, 2013).

[80] *See* Ranbaxy Laboratories Ltd. et al v. Vertex Pharmaceuticals, Inc., IPR2013-00024, Paper No. 69 (P.T.A.B. Oct. 31, 2013). Subsequently, Mylan also settled its district court litigation against the patent. *See* Stipulation of Dismissal with Prejudice at 120, ViiV Healthcare Co. et al. v. Mylan Inc. et al., No. 12-1065-RGA (D. Del. dismissed July 2, 2014).

[81] *See* Fed. Trade Comm'n, Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions 8 (2010) (approximating the annual cost to consumers at $ 3.5 billion due to delayed generic entry that, in turn, results from a type of settlement between brand and generic companies); *see also* C. Scott Hemphill & Mark A. Lemley, *Earning Exclusivity: Generic Drug Incentives and the Hatch-Waxman Act*, 77 ANTITRUST L.J. 947, 949 (2011) ("Society doesn't benefit from a private deal to drop a challenge that has the effect of limiting competition."); *see generally* Megan M. La Belle, *Against Settlement of (Some) Patent Cases,* 67 VAND. L. REV. 375, 397-410 (2014) (arguing that patent litigation settlements are against public interest). Interestingly, a University of Washington professor-founded Initiative for Responsibility in Drug Pricing LLC piggybacked on a generic company's IPR challenge against a patent relating the drug Tygacil® – hoping to take the challenge forward in the event the brand and the generic settle. *See* Initiative for Responsibility in Drug Pricing LLC v. Wyeth LLC, IPR2014-01259, Paper No. 1 (P.T.A.B. Aug. 8, 2014). The petition, however, was denied. *Id.* at Paper No. 8 (P.T.A.B. Feb. 13, 2015).

[82] *See* 21 U.S.C. § 355 (j)(5)(D)(i)(I)(bb)(AA) (2012) ((("a court enters a final decision from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the patent is invalid or not infringed")); 35 U.S.C. § 319 (granting any party to the IPR proceeding the right to appeal the final written decision of the PTAB to the Federal Circuit); *see also* 28 U.S.C. § 1295(a)(1) (2012) (granting to the Federal Circuit exclusive jurisdiction over appeals of district court decisions in patent cases).

[83] *See* 21 U.S.C. § 355 (j)(5)(D)(i)(I)(bb); *supra* text accompanying note 24; *see also* H. Keeto Sabharwal et al., *How Inter Partes Review Impacts Hatch-Waxman Exclusivity*, Law360, Feb. 27, 2013 (reflecting upon the legal uncertainty as to "whether, and to what extent, a successful IPR challenge by a subsequent [ANDA] filer may impact the 'failure to market' trigger for forfeiture of 180-day Hatch-Waxman exclusivity held by a first-to-file ANDA applicant").

[84] *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (2012); Upadhye, *supra* note 16, at 1316-17.

[85] This is a fair assumption given that Mylan was in its paragraph-IV litigation much before Ranbaxy initiated its IPR. Moreover, Ranbaxy's IPR settlement contemplates "potential Hatch-Waxman litigation" on the patent, which indicates that Ranbaxy may have had a plan to

Ranbaxy and Mylan had their district court cases pending, Ranbaxy may have received a favorable IPR decision. After winning on appeal, Ranbaxy would certainly have been interested in seeking a determination recognizing the final IPR decision as an event triggering Mylan's exclusivity forfeiture.[86]

Two forfeiture trigger events are implicated by a favorable, final decision from an IPR proceeding.[87] The first one is the court decision trigger.[88] And the second event is the delisting trigger.[89] As with most legal questions, there is a case for and there is a case against.

A. The Case Against Pulling the Trigger

The first question is whether a paragraph-IV ANDA filer can seek a determination recognizing a final, favorable IPR decision as a court decision trigger. Brand companies (and possibly, first filers as well) will proffer several reasons why the court decision trigger should not apply.

First, textualist and other interpretive considerations preclude such a decision. The Hatch-Waxman Act expressly provides for the trigger when a court enters a final decision in "an infringement action" pertaining to the patent.[90] By contrast, the 30-month stay provision in the same statute contemplates that a district court decision "including any substantive determination that there is no cause of action for patent infringement or invalidity" may terminate the 30-month stay.[91] By implication, therefore, the absence of such language in the court decision trigger provision is a strong indication that, for a first filer to lose its prize, Congress intended to set a high bar.

The high congressional bar operates (or should operate) in the form of a higher burden of proof for invalidity in district court litigation, thereby stemming any preclusive effect of an IPR decision.[92] A patent is presumed valid, and the presumption can be overthrown only by clear and convincing evidence of invalidity.[93] The higher burden of proof is a procedural advantage for a brand company in a Hatch-Waxman infringement action. Absence of this advantage in an IPR proceeding should preclude

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paragraph-IV challenge the patent in the future. *See* Ranbaxy Laboratories Ltd. et al v. Vertex Pharmaceuticals, Inc., IPR2013-00024, Paper No. 69 (P.T.A.B. Oct. 31, 2013).

[86] *See* 21 U.S.C. § 355 (j)(5)(D)(i)(I) (2012).

[87] *Id.*

[88] *See* 21 U.S.C. § 355 (j)(5)(D)(i)(I)(bb)(AA) (2012); *supra* text accompanying note 24.

[89] *See* 21 U.S.C. § 355 (j)(5)(D)(i)(I)(bb)(CC); *supra* text accompanying note 24.

[90] *See* 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(AA) (2012).

[91] *Id.* § 355(j)(5)(B)(iii)(I).

[92] *Cf.* Freedom Sav. & Loan Ass'n v. Way, 757 F.2d 1176, 1180 (11th Cir. 1985) ("Congress limited the res judicata or collateral estoppel effect to be given the decisions of the TTAB because the Lanham Act provides for extensive judicial involvement in the registration and protection of trademarks. . . . [T]he ability of courts to hear appeals on a de novo basis reflects a Congressional intent not to invoke the immunizing doctrines of res judicata or collateral estoppel with regard to TTAB proceedings. In this Circuit, a court hearing an infringement claim is not legally and conclusively bound by a prior decision of the TTAB regarding the same trademark dispute.").

[93] *See* Microsoft Corp. v. i4i Ltd. P'ship, 131 S. Ct. 2238, 2246 (2011) (reasoning to the conclusion that absent an express burden of proof requirement in the Patent Act, common law principles govern, and under common law, a presumption of validity can be overcome only by clear and convincing evidence).

collateral application of an affirmed IPR decision.[94] Matter-of-factly, in trademark infringement actions, district courts often deny collateral application of decisions made by the Trademark Trial and Appellate Board (hereinafter, "TTAB").[95]

The high congressional bar effectuates an important policy. An Orange Book patent – when it confers 180-day exclusivity to a first filer – is crucial to the incentive regime of the Hatch-Waxman Act.[96] Incentivized by the 180-day exclusivity, first filers act as trailblazers in Hatch-Waxman patent litigation. But if second filers can easily tinker with the incentive for their own benefit, it will frustrate the first filer's endgame. Thus, recognizing an affirmed IPR decision as a forfeiture trigger under either trigger provision would impair the important policy objective of safeguarding the first filer's exclusivity.

Similar considerations apply to the second question of whether an ANDA filer in district court litigation can move to compel an NDA holder to delist a patent based on a final, favorable IPR decision. A generic company may consider using the Hatch-Waxman statute's delisting counterclaim to trigger forfeiture.[97] But, textualist and other interpretive considerations again compel a negative conclusion.

An ANDA filer can assert the delisting counterclaim only in response to an "infringement action."[98] Read in context, the counterclaim provision's very next sub-section underscores that such a counterclaim cannot be the basis for an

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[94] *See* RESTATEMENT (SECOND) OF JUDGMENTS § 28(4) (advising against preclusion when "the adversary has a significantly heavier burden than he had in the first action"); *see also* 18 Wright, Miller, and Cooper, Federal Practice and Procedure § 4422 (2d ed. 2002)) (explaining in the context of a civil proceeding followed by a criminal proceeding that "a party who has carried the burden of establishing an issue by a preponderance of the evidence is not entitled to assert preclusion in a later action that requires proof of the same issue by a higher standard"); *cf.* State of N.C. v. Charles Pfizer & Co., 537 F.2d 67, 74 (4th Cir. 1976) (denying collateral estoppel based on a Federal Trade Commission finding in antitrust litigation in district court because "[t]he Commission did not require that the alleged fraud on the Patent Office be demonstrated by *clear and convincing evidence* and employed evidentiary and procedural rules much more lenient than those incident to a judicial trial" (emphasis added)).

[95] *See* Way, 757 F.2d at 1186 (affirming district court's refusal to collaterally apply TTAB's determination of likelihood of confusion to the district court's infringement inquiry mainly because evidence of actual confusion was not considered in the former but important for the latter); *accord* Levy v. Kosher Overseers Ass'n of Am., Inc., 104 F.3d 38, 41-43 (2d Cir. 1997) (reversing district court's grant of collateral estoppel because "the standards governing 'likelihood of confusion' in registration cancellation or opposition proceedings before the TTAB and Federal Circuit can be different than the 'likelihood of confusion' standard applicable in trademark infringement actions in a district court"); Jim Beam Brands Co. v. Beamish & Crawford Ltd., 937 F.2d 729, 735-36 (2d Cir. 1991) (holding that collateral estoppel was incorrectly applied because the TTAB's decision of no likelihood of confusion even when the Federal Circuit had affirmed the agency's decision).

[96] *See* Teva Pharm. USA, Inc. v. Sebelius, 595 F.3d 1303, 1316-18 (D.C. Cir. 2010); Ohly & Patel, *supra* note 4, at 117-18; Korn, *supra* note 8, at 335; Upadhye, *supra* note 16, at 1318-19.

[97] *See* 21 U.S.C. § 355(j)(5)(C)(ii)(I) (2012). Note that under a plain reading of the delisting trigger provision, only an NDA holder can voluntarily withdraw an Orange Book-listed patent. *See* 21 U.S.C. § 355 (j)(5)(D)(i)(I)(bb)(CC) (2012) (providing for forfeiture of the 180-day exclusivity seventy-five days after "[t]he patent . . . is withdrawn *by the holder of the application* approved under subsection (b) of this section" (emphasis added)). That ability of the NDA holder, however, is circumscribed if the patent is a 180-day exclusivity-conferring patent. *See* Teva Pharm. USA, Inc. v. Sebelius, 595 F.3d 1303, 1316-18 (D.C. Cir. 2010). Also note that the suggestion about an ANDA filer invoking the counterclaim provision presupposes the existence of a patent infringement action, which is a prerequisite to the assertion of the counterclaim. *See id.* § 355(j)(5)(C)(ii)(II).

[98] *See* 21 U.S.C. § 355(j)(5)(C)(ii)(I) (2012).

independent cause of action.[99] So, Congress could have contemplated only district court litigation as the ANDA filer's avenue here.[100] Congress could not have intended an IPR proceeding to be subsumed within the counterclaim provision, which was introduced in the Hatch-Waxman Act about eight years before the AIA was signed into law in 2011.[101]

Moreover, the counterclaim provision is a generic company's countermeasure against erroneous or frivolous patent listings.[102] So, absent erroneous or frivolous conduct on the brand company's part, the company should not be compelled to delist its patents.

Pragmatic concerns also militate against applying the delisting trigger. Listing relevant patents in the Orange Book is an affirmative obligation for a brand company.[103] The listing serves as a notice to ANDA filers who, in turn, have the obligation to provide one of four patent-specific certifications in the ANDA.[104] But an IPR petitioner may challenge, and the PTAB may cancel, only some of the claims in an IPR proceeding.[105] The brand company, the FDA, or even a court cannot prophesize if the remaining claims will be relevant against future ANDA filers. As a practical

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[99] *See id.* § 355(j)(5)(C)(ii)(II).

[100] *See* Texas Instruments Inc. v. Cypress Semiconductor Corp., 90 F.3d 1558, 1568 (Fed. Cir. 1996) (explaining the general rule that "an administrative agency decision, issued pursuant to a statute, cannot have preclusive effect when Congress, either expressly or impliedly, indicated that it intended otherwise," citing Astoria Fed. Sav. & Loan Ass'n v. Solimino, 501 U.S. 104, 110 (1991)).

[101] *See* Pub. L. No. 108–173, 117 Stat.2066 (2003) (introducing amendments to the Hatch-Waxman Act, including the counterclaim provision); Pub. L. No. 112-29, 125 Stat. 284 (2011) (bringing into effect the America Invents Act).

[102] *See* 21 U.S.C. § 355 (j)(5)(C)(ii)(I) (2012) (enabling an ANDA applicant to "assert a counterclaim seeking an order requiring the [NDA] holder to *correct or delete* the patent information submitted by the holder" (emphasis added)); Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S, 132 S. Ct. 1670, 1687 (2012) (holding that by providing for the counterclaim, Congress addressed "a broader problem—that generic companies generally had no avenue to challenge the accuracy of brands' patent listings, and that the FDA therefore could not approve proper applications to bring inexpensive drugs to market."). In *Caraco*, a generic company certified to the FDA through its product's label that the company did not seek to market only for one use that was patented. *Id.* at 1679. In response to the generic company's carved-out label, the brand company broadened its Orange Book use code description (brand companies are required to provide to the FDA a method of use description pertaining to any listed method patent). *See id.* The broadened use code signaled to the FDA that the generic company's product was within the patent scope, which, in turn, prevented the FDA from approving the generic product. *Id.* Eventually, the Court held that the Act's counterclaim provision was the appropriate tool to counter such brand company shenanigans. *See id.* at 1687.

[103] *See* Upadhye, *supra* note 16, at 1338 ("Section 355(b)(1)(G) creates the affirmative obligation to list into the Orange Book the patents that can be implicated by the approval of an ANDA or § 505(b)(2) application. Once patents are listed in the Orange Book, the FDA cannot approve any ANDA or § 505(b)(2) application until all listed patents have been certified against using one or more of the relevant patent certifications. Because the ANDA sponsor must certify to one or more patents, it is only when the sponsor notifies the brand company through the Paragraph IV notice letter that the brand company even becomes aware of the generic drug application. If an ANDA sponsor certifies under either Paragraphs I, II, or III, it is not required to notify the brand company at all.").

[104] *See id.*

[105] *See* 35 U.S.C. § 311 (2012) ("[a] petitioner in an inter partes review may request to cancel as unpatentable *1 or more* claims of a patent) (emphasis added); *see, e.g.*, Ariosa Diagnostics v. Isis Innovation Limited, IPR2012-00022, Paper 166, at 56 (P.T.A.B. Sept. 2, 2014) (cancelling claims 1, 2, 4, 5, 8, 19, 20, 24, and 25 but upholding claims 3, 12, 13, 15, 18, 21, and 22 against the petitioner's IPR challenge).

matter, therefore, delisting the entire patent when only some of its claims have been cancelled may not be a viable option.

All of the above may be compelling reasons to maintain the Hatch-Waxman *status quo* despite the AIA. But the flipside cannot be ignored. Second filers also have legitimate stake in the game.

B. The Case For Pulling the Trigger

Second filers will countercharge with several arguments as to why a final, favorable IPR decision should collaterally apply either as a court decision or delisting trigger. First, the AIA regime calls for a new perspective. And the textualist argument that Congress envisioned only an infringement action to work its way to exclusivity forfeiture cannot be harmonized with the AIA.[106]

As a threshold matter, the Hatch-Waxman Act antedates the AIA; therefore, the Hatch-Waxman Act is not controlling on the issue of whether Congress intended a PTAB decision to have a preclusive effect sufficient to trigger exclusivity forfeiture.[107] Next, according to the Supreme Court in *Microsoft v. i4i*, a patent holder's procedural advantage in district court litigation existed by virtue of the common law.[108] But, tellingly, the AIA's lower burden of proof requirement for claim cancellation effectively overrides *Microsoft v. i4i*.[109] The AIA has created litigation-type adversarial mechanisms and has authorized the PTAB to cancel patent claims.[110] The authorization effectuates statutory estoppel, replacing common law collateral estoppel, and the statutory estoppel kicks in whenever the PTAB removes the very basis underlying a cause of action in infringement.[111]

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[106] *See* Astoria Fed. Sav. & Loan Ass'n v. Solimino, 501 U.S. 104, 109 (1991) (explaining that the value in "harmonizing different statutes . . . prompts the kindred rule that legislative repeals by implication will not be recognized, insofar as two statutes are capable of coexistence, 'absent a clearly expressed congressional intention to the contrary.'" (citing Morton v. Mancari, 417 U.S. 535, 551 (1974)).

[107] *See* Univ. of Tennessee v. Elliott, 478 U.S. 788, 794-95, (1986) (reasoning that "[a]lthough [28 U.S.C.] § 1738 is a governing statute with regard to the judgments and records of state courts, because § 1738 antedates the development of administrative agencies it clearly does not represent a congressional determination that the decisions of state administrative agencies should not be given preclusive effect").

[108] *See* Microsoft Corp. v. i4i Ltd. P'ship, 131 S. Ct. 2238, 2246 (2011) (holding that absent an express burden of proof requirement in the Patent Act, common law principles govern, and under common law, a presumption of validity can be overcome only by *clear and convincing evidence*).

[109] *See* 35 U.S.C. § 316(e) (2012) (expressly setting forth that "[i]n an inter partes review . . . . the petitioner shall have the burden of proving a proposition of unpatentability by a *preponderance of the evidence*." (emphasis added)); *see also* H.R. REP. 112-98, at 48 (2011) ("This new . . . post-grant review procedure will provide a meaningful opportunity to improve patent quality and restore confidence in the presumption of validity that comes with issued patents in court.").

[110] *See* 35 U.S.C. § 318(b) (2012); *accord* Abbott Labs. v. Cordis Corp., 710 F.3d 1318, 1326 (Fed. Cir. 2013). Moreover, the IPR proceeding otherwise provides substantially similar procedural advantages in an adversarial setting. *See supra* Background section, subsection B.

[111] *Cf.* Fresenius USA, Inc. v. Baxter Int'l, Inc., 721 F.3d 1330, 1344 (Fed. Cir. 2013) (holding that the re-examination statute authorizes the PTO to cancel patent claims and that cancellation extinguishes the basis for a suit); *contra* Texas Instruments Inc. v. Cypress Semiconductor Corp., 90 F.3d 1558, 1568-69 (Fed. Cir. 1996) (pointing to direct evidence of congressional intent of disallowing decisions of the International Trade Commission to have preclusive effect on district courts); State of

The AIA regime also raises a pragmatic concern and, therefore, an interpretive revelation. Alarmingly, the IPR statute's "raised or reasonably could have raised" estoppel would create a deadlock for second filers.[112] Under the estoppel provision, "the petitioner, may not assert [] in civil action . . . that the claim is invalid on any ground that the petitioner *raised or reasonably could have raised* during that inter partes review" after the PTAB has reached a final written decision on the merits.[113] Therefore, a second filer that succeeds in an IPR will be subsequently prohibited from using the same invalidity challenge – no matter how strong it is – to trigger forfeiture via district court litigation. Consequently, the second filer will continue to be stuck behind the first filer's 180-day exclusivity.[114] Such an absurd result could not have been intended by Congress.[115]

Second, as to the delisting trigger, the notice function of listing a patent in the Orange Book is irrelevant if all the claims of the patent stand cancelled. Concededly, however, an IPR petitioner may succeed in challenging at the PTAB only those patent claims that are asserted against the petitioner in district court.[116] Under that scenario, a court may not consider it wise to order delisting the entire patent. That is because while the counterclaim provision authorizes a court to order the NDA holder to correct or delete patent information in the Orange Book, the provision does not expressly authorize a court to do so on a claim-by-claim basis.[117] Nonetheless, the court should order delisting whenever a situation allows.[118] Moreover, even under a narrow reading of *Caraco v. Novo* as applicable only to erroneous or frivolous listings, a brand company's continued listing of a patent after its claims have been cancelled would still be erroneous, if not frivolous.[119]

The analogy to trademark cases is inapposite because TTAB proceedings are fundamentally different.[120] The TTAB decides in an *inter partes* proceeding the registration eligibility of a mark in light of another already registered mark.[121] After

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N.C. v. Chas. Pfizer & Co., 537 F.2d 67, 74 (4th Cir. 1976) (denying collateral estoppel based on a Federal Trade Commission finding by citing to an express provision of the Federal Trade Commission Act as inconsistent with the very doctrine of collateral estoppel). Moreover, the Supreme Court recently noted that "[p]rocedural differences, by themselves . . . do not defeat issue preclusion." B & B Hardware, Inc. v. Hargis Indus., Inc., No. 13-352, 2015 WL 1291915, at *13 (U.S. Mar. 24, 2015).

[112] *See* 35 U.S.C. § 315(e)(2) (2012).

[113] *Id.* (emphasis added).

[114] *Contra* Teva Pharm. USA, Inc. v. EISAI Co., 620 F.3d 1341, 1345, 1347 (Fed. Cir. 2011) (holding that because an exclusivity-conferring Orange Book patent blocks FDA approval, the second filer has a legitimate cause of action to challenge the patent).

[115] *Cf.* Brief for Petitioner at 33-34, B&B Hardware, Inc. v. Hargis Indus., Inc., 134 S. Ct. 2899 (2014) (No. 13-352), 2014 WL 4404693 at *33-34 (arguing in the context of the Lanham Act that if a district court were to follow one standard of likelihood of confusion to *register* a trademark and another standard of likelihood of confusion to determine *infringement* of a trademark, then the interplay between the TTAB and a district court would lead to counterintuitive results).

[116] *See* discussion *supra* Analysis subsection I.

[117] *See* 21 U.S.C. § 355(j)(5)(C)(ii)(I) (2012).

[118] For example, in a particular case, a court may find that the while some other claims remain unchallenged, the claims pertaining to the approved brand drug are cancelled.

[119] *See* Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S, 132 S. Ct. 1670, 1687 (2012); *supra* text accompanying note 102.

[120] *Compare* 15 U.S.C. §§ 1063-64 (2012) (trademark opposition and cancellation proceedings), *with* 35 U.S.C. § 311 (2012) (inter partes review proceedings).

[121] *See* 15 U.S.C. §§ 1063-64 (2012).

the TTAB decides the eligibility question, the question of infringement of the mark often comes up in district courts.[122] In resolving the infringement question, a district court may or may not apply the TTAB's finding of likelihood of confusion because trademark registration and infringement could be separate inquiries.[123] But the Supreme Court recently held that a court must give preclusive effect to a TTAB decision in a case where the ordinary elements of issue preclusion are met, thereby creating a strong presumption in favor of recognizing the agency's decision as collaterally applicable.[124] Thus, the original trademark – which is not extinguished in a TTAB proceeding – may form the basis for an infringement action in district court. By contrast, the PTO's cancellation of a patent claim extinguishes any cause of action associated with the patent.[125]

Lastly, from a policy perspective, not recognizing a final, favorable IPR decision as a trigger event will deny to second filers the advantages of the efficiency spillover from PTAB litigation.[126] And generic companies would be dissuaded from taking advantage of the AIA-prompted cleanliness campaign against weak patents and from considering the PTAB as part of their endgame.[127] To say that incentivizing the first

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[122] *See id.* § 1141(1) (creating a civil cause of action for trademark infringement); *see, e.g.*, B & B Hardware, Inc. v. Hargis Indus., Inc., 569 F.3d 383, 385-87 (8th Cir. 2009) (reviewing district court's decision in B & B's infringement action against Hargis after the TTAB denied registration of Hargis' mark "Sealtite" due to its confusing similarity with B & B's "Sealtight"). Also, for a review the TTAB's decision, a losing party may ask either the Federal Circuit or may file a civil action in a federal district court. *See id.* § 1071.

[123] *See* Freedom Sav. & Loan Ass'n v. Way, 757 F.2d 1176, 1185-86 (11th Cir. 1985) (holding that the TTAB's finding that the defendant's purported mark "Freedom Realty Company" was likely to be confusingly similar to the plaintiff's already registered marks "Freedom Federal" and "Freedom Account" did not necessarily apply to the district court's analysis as to whether "Freedom Realty Company" infringed the plaintiff's marks – because the latter required evidence of actual confusion, which the TTAB did not consider); *but see* EZ Loader Boat Trailers, Inc. v. Cox Trailers, Inc., 746 F.2d 375, 378-79 (7th Cir. 1984) (applying collateral estoppel based on TTAB's decision of no likelihood of confusion between "Super Loader" and "EZ Loader" and other trademarks owned by the plaintiff); Flavor Corp. of Am. v. Kemin Indus., Inc., 493 F.2d 275, 278, 281 (8th Cir. 1974) (giving collateral estoppel effect to an agency decision of no likelihood of confusion between plaintiff's "PESTLUR" and defendant's "LURE"); Jean Alexander Cosmetics, Inc. v. L'Oreal USA, Inc., 458 F.3d 244, 256 (3d Cir. 2006) (affirming district court's dismissal based on preclusive effect of the TTAB's decision of no likelihood of confusion between plaintiff's "EQ System" and defendant's "Shades EQ" marks); *see also* 6 J. Thomas McCarthy, *McCarthy on Trademarks and Unfair Competition* § 32:101 (4th ed.) ("[A]n inter partes decision of the Trademark Board, whether reviewed by the Federal Circuit or not, must be carefully examined to determine exactly what was decided and on what evidentiary basis. Many such oppositions and cancellations are decided only upon a limited comparison of the registered or applied-for format and goods without regard for their marketplace manner of use. For this reason . . . such decisions have no later preclusive effect in a suit where actual usage in the marketplace is the paramount issue."). Moreover, registration of a trademark does not confer a procedural advantage to the trademark owner in an infringement action. *See* DeCosta v. Viacom Int'l, Inc., 981 F.2d 602, 606-07 (1st Cir. 1992) (affirming refusal to relitigate likelihood of confusion simply because the mark was registered later - based on the rationale that registration of a trademark does not make proving the trademark's infringement easier); EZ Loader Boat Trailers, Inc., 746 F.2d at 379 (deciding that lack of registration of the trademark did not confer a procedural advantage to an adversary challenging a mark in an infringement action).

[124] *See* B & B Hardware, 2015 WL 1291915, at *14.

[125] *See* Fresenius USA, Inc. v. Baxter Int'l, Inc., 721 F.3d 1330, 1344 (Fed. Cir. 2013).

[126] *Supra* Background section, subsection B.

[127] Given the structure of the generic drug industry, IPR might be the right tool for second filers given the cost-effectiveness and efficiency of IPR proceedings. *See, e.g.*, Brian Murphy et al., *A New*

filer is the only goal of the 180-day exclusivity provision is missing the forest for the trees. The provision also incentivizes second filers to attempt to pull the rug from under the first filer's feet.[128] The ultimate objective is early commercialization of less expensive generic drugs for the benefit of American consumers.

IV. PROPOSAL

Having considered both sides of the coin, the final step would be to choose a result that is fully consistent with the objectives of the Hatch-Waxman Act. The case for pulling the trigger wins when two things are considered in tandem: (i) the practical consequences of pulling the trigger; and (ii) the public policy purpose of enhancing access to affordable healthcare.

First filers are not uninvited to the IPR game, and they may incidentally benefit from the game even after choosing not to play. So, the practical consequences of an IPR-based exclusivity trigger are not out of line with the Hatch-Waxman Act's incentive regime. And commonsensically (as well as under the public rights doctrine), a weak patent, which should not have passed the PTO's muster in the first place, should not stand in the way of consumer access to generic drugs. Thus, a conformant amendment to the Hatch-Waxman Act would best serve the Act's policy objectives.

A. Practical Consequences of Pulling the Trigger

The IPR-based exclusivity trigger makes practical sense for several reasons. As a threshold matter, no generic company or public interest organization will be able to trigger a first filer's 180-day exclusivity forfeiture *solely* based on a favorable IPR decision. For a court decision trigger, the Hatch-Waxman Act requires district court litigation.[129] To initiate district court litigation, a generic company must file a paragraph-IV ANDA.[130] And the filing of a paragraph-IV ANDA signifies the likelihood of a generic drug on the market before patent expiration. On the other hand, a public interest group will likely not have standing for appellate review to obtain a

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Weapon In Generic Drug Companies' Arsenal, Law360, Apr. 19, 2013 (explaining why "[f]or generic competitors that are not first to file an ANDA with a Paragraph IV patent challenge, the strategy is quite different").

[128] *See* 21 U.S.C. § 355 (j)(5)(D)(i)(I)(bb)(AA) (2012); Teva Pharm. USA, Inc. v. EISAI Co., 620 F.3d 1341, 1343-47 (Fed. Cir. 2011); *see also* Upadhye, *supra* note 16, at 1324-25 (explaining why "Congress legislated to extinguish the 180-day exclusivity").

[129] *See* 21 U.S.C. § 355 (j)(5)(D)(i)(I)(bb)(AA) (2012) (setting forth a trigger event when "[i]n an *infringement action* brought against that applicant with respect to the patent or in a *declaratory judgment action* brought by that applicant with respect to the patent, a *court* enters a final decision" (emphasis added)).

[130] *See* 21 U.S.C. § 355 (j)(2)(A)(vii)(IV) (2012); Upadhye, *supra* note 16, at 1316-17. Moreover, the declaratory judgment action provision requires that a paragraph-IV ANDA applicant wait forty-five days after the NDA holder fails to initiate infringement action based on a paragraph-IV challenge. *See id.* § 355(j)(5)(C)(i). So, a generic company that is not sued still cannot seek a court decision trigger through the IPR route without having an ANDA in the waiting.

final decision.[131] This result is not counterintuitive to the purpose of the Hatch-Waxman Act.

Next, a generic company in a paragraph IV lawsuit can ask the FDA to recognize the Federal Circuit's affirmance of an IPR decision as a forfeiture trigger, and in the event of a denial, the company can challenge the denial in a federal court. Recognizing the final, favorable decision as a court decision trigger will be in line with the purpose of the Hatch-Waxman Act.[132] And at the same time, it will not diminish the first filer's incentive. Consider the following hypothetical.

A brand drug company (hereinafter, "B") has listed one patent in the Orange Book for its pioneer drug. The patent is set to expire in 2020. A first filer (hereinafter, "F1") files a paragraph IV ANDA seeking approval of a generic version and is in early stages of district court litigation. A second filer (hereinafter, "F2) is still preparing to submit its own ANDA. But, in the meantime, F2 petitions for an IPR of the patent.

Next, F2 files its own paragraph-IV ANDA, and B initiates an infringement action against F2 in district court. While F1 and F2 are litigating their infringement actions, the PTAB cancels the asserted claims. Promptly, B appeals the PTAB's decision to the Federal Circuit.[133] Next, the Federal Circuit affirms the IPR decision, and F2 moves the court to enter judgment in its favor.[134] At this point, F1's ANDA is either awaiting approval or is already approved.

Assume F1's ANDA is still awaiting approval. If the court enters judgment in F2's favor and if the FDA recognizes F2's win as a court decision trigger, it will not lead up to F1's exclusivity forfeiture because F1's ANDA is still awaiting approval.[135]

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[131] *See* Consumer Watchdog v. Wisconsin Alumni Research Found., 753 F.3d 1258, 1263 (Fed. Cir. 2014), *cert. denied*, No. 14-516, 2015 WL 731871 (U.S. Feb. 23, 2015). For example, Coalition for Affordable Drugs (ADROCA) LLC recently filed an IPR challenge against a patent relating to the drug Ampyra®. *See* Coalition for Affordable Drugs (ADROCA) LLC v. Acorda Therapeutics, Inc., IPR2015-00720, Paper No. 1 (P.T.A.B. Feb. 10, 2015). Whatever the outcome of this IPR at the PTAB, the Federal Circuit will likely dismiss any appeal due to lack of Article III standing. *See Consumer Watchdog*, 753 F.3d at 1263.

[132] *See* discussion *supra* Analysis subsection B. For the reasons provided in the subsection, a final, favorable IPR decision should not constitute delisting trigger unless Congress empowers courts to order delisting on a claim-by-claim basis. For the same reason, a court will not be inclined to deem the continued listing of a patent as erroneous or frivolous even after claim cancellation by PTAB.

[133] *See* 35 U.S.C. § 319 (2012). Because the PTAB's decision is not final at this stage, the district court will likely not be inclined to either dismiss the infringement case or recognize it as a court decision trigger under the Hatch-Waxman Act. *See generally* Fresenius USA, Inc. v. Baxter Int'l, Inc., 721 F.3d 1330, 1340-42 (Fed. Cir. 2013) (discussing the element of finality of a decision that is necessary to give effect to principles of res judicata), *cert. denied*, 134 S. Ct. 2295 (U.S. 2014). In the hypothetical, if B chooses not to appeal the PTAB decision, F2 can most likely seek appellate review even after having received a favorable decision. *See* 35 U.S.C. § 319 (providing that "[a]ny party to the inter partes review shall have the right to be a party to the appeal"); *see generally* Jean Alexander Cosmetics, Inc. v. L'Oreal USA, Inc., 458 F.3d 244, 256 (3d Cir. 2006) (explaining based on several authorities why a party that prevails at the TTAB may still appeal the decision).

[134] Here, as a prerequisite, F2 must have received "tentative approval" of its ANDA at this time. *See* 21 U.S.C. § 355 (j)(5)(D)(i)(I)(bb) (2012).

[135] *See* 21 U.S.C. § 355 (j)(5)(D)(i)(I) (2012); *supra* text accompanying note 24. In this hypothetical, while a (bb) event has occurred, an (aa) event has not. The "later of" predicate between (aa) and (bb) in the provision implies that if an (aa) event could occur, forfeiture is not triggered until the event actually occurs. In other words, F2 is still stuck behind F1's 180-day exclusivity. But there is a caveat. Here, F1 would be ill-advised to prepare an ANDA application that is so qualitatively deficient that FDA approval takes more than 30 months from the ANDA' submission. *See id.* § 355 (j)(5)(D)(i)(IV)

Consequently, F1 must market its generic within seventy-five days of receiving ANDA approval to avoid exclusivity forfeiture. Of course, this result is in conformity with the Hatch-Waxman Act's goals.

Alternatively, assume F1's ANDA has received approval by the time F2 obtains the entry of a favorable judgment. If the FDA recognizes F2's win as a court decision trigger, it will not lead up to F1's exclusivity forfeiture if F1 goes to market within seventy-five days.[136] Again, forcing a generic to enter the market in this manner is consistent with the Hatch-Waxman Act's aspirations.

Similar situations can be contemplated with multiple generic players, a plurality of patents, and differentially timed events.[137] The end result in most, if not all, such situations will be acceleration of generic drug commercialization in congruity with the legislative scheme. Thus, pulling the trigger has practical value, and it is consistent with the overall structure of the Hatch-Waxman Act.[138] Pulling the trigger will also be consistent with the modern-day rise of administrative agencies and their acknowledged role in resolving matters pertaining to public rights.

B. Patent as a Public Right

An improperly granted patent should not preclude consumer access to cheaper versions of a drug. This conclusion is supported by the public rights doctrine. Under the public rights doctrine, controversies involving public rights "may be removed from Art. III courts and delegated to legislative courts or administrative agencies."[139] A

(setting forth that a first filer's failure to obtain tentative approval in 30 months from the date of the ANDA submission will constitute exclusivity forfeiture).

[136] *See* 21 U.S.C. § 355 (j)(5)(D)(i)(I)(bb)(AA) (2012); *supra* text accompanying note 24. F1 will have 75 days from the entry of favorable judgment to prepare for commercialization, but as long as F1 enters the market within that time-frame, F1 will not forfeit its exclusivity.

[137] Where multiple patents are listed for a single branded drug, a favorable, final decision is required for each patent. *See* 21 U.S.C. § 355 (j)(5)(D)(i)(I)(bb) (2012) (requiring the court decision trigger "as to *each* of the patents" that an ANDA applicant challenges) (emphasis added)). So, a second filer will not be able to tinker with a first filer's exclusivity by choosing one weak patent from the list and winning on an IPR.

[138] *See* Teva Pharm. USA, Inc. v. Sebelius, 595 F.3d 1303, 1316-18 (D.C. Cir. 2010) (considering the overall "structure" of the Hatch-Waxman Act instead of placing emphasis on plain text meaning of the delisting provision in deciding that a brand company cannot voluntarily delist an exclusivity-conferring patent); *see also* Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S, 132 S. Ct. 1670, 1687 (looking at the "broader problem" addressed by the Hatch-Waxman Act in deciding that a generic company may assert the counterclaim provision of the Act when a brand company impermissibly expands the scope of a use code accompanying a listed method patent). At least partially, Senator Hatch's original vision of rewarding a "successful challenger" instead of a "mere first filer" will come alive if a final, favorable IPR decision is recognized as a court decision trigger. *See generally Examining the Senate and House Versions of the "Greater Access to Affordable Pharmaceuticals Act," Hearing Before the S. Comm. on the Judiciary*, 108th Cong., at 2-3 (Aug. 1, 2003) (Statement of Senator Orrin G. Hatch).

[139] *See* N. Pipeline Const. Co. v. Marathon Pipe Line Co., 458 U.S. 50, 67-70 (1982) ("This doctrine may be explained in part by reference to the traditional principle of sovereign immunity, which recognizes that the Government may attach conditions to its consent to be sued. (citations omitted). But the public-rights doctrine also draws upon the principle of separation of powers, and a historical understanding that certain prerogatives were reserved to the political Branches of Government. . . . The understanding of these cases is that the Framers expected that Congress would be free to commit

patent right is a matter of public concern.[140] That is especially true where a patent confers a marketing exclusivity in such an area of public health.[141] By corollary, therefore, a court must recognize and give full effect to an Article I adjudication of a pharmaceutical patent's validity, a task historically conducted by the judicial branch under the Hatch-Waxman Act.

The reasoning in *Thomas* is illuminating.[142] The case involved a federal statute regulating "follow-on" pesticide registration.[143] The challenge pertained to the constitutionality of a provision in the statute that required binding arbitration of certain disputes.[144] The Court held that the matter fell under the public rights exception because "[u]se of a registrant's data to support a follow-on [pesticide] registration serves a public purpose as an integral part of a program safeguarding the public health."[145] Thus, Article I adjudication was deemed to be proper.[146]

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such matters completely to non-judicial executive determination, and that as a result there can be no constitutional objection to Congress' employing the less drastic expedient of committing their determination to a legislative court or an administrative agency.") In this case, the Court adopted a limited definition of public right that was sufficient to resolve the case. *Id.* Accordingly, the Court held that public right is the one that "at a minimum" arises between the government and others. *Id.* Subsequent cases, however, have expanded on that definition by eliminating the requirement that the government be a party in the dispute. *See, e.g.*, Thomas v. Union Carbide Agr. Products Co., 473 U.S. 568, 586 (1985) ("Insofar as appellees interpret [*Northern Pipeline*] and *Crowell* [*v. Benson*, 285 U.S. 22 (1932)] as establishing that the right to an Article III forum is absolute unless the Federal Government is a party of record, we cannot agree.").

[140] *See* Patlex Corp. v. Mossinghoff, 758 F.2d 594, 604 (Fed. Cir. 1985) ("[T]he grant of a valid patent is primarily a public concern. Validity often is brought into question in disputes between private parties, but the threshold question usually is whether the PTO, under the authority assigned to it by Congress, properly granted the patent. At issue is a right that can only be conferred by the government." (citing Crowell v. Benson, 285 U.S. 22, 50, 52 (1932)), *on reh'g*, 771 F.2d 480 (Fed. Cir. 1985)); *see also* Blonder-Tongue Labs., Inc. v. Univ. of Illinois Found., 402 U.S. 313, 343 (1971) ("A patent by its very nature is affected with a public interest. . . . [It] is an exception to the general rule against monopolies and to the right to access to a free and open market. The far-reaching social and economic consequences of a patent, therefore, give the public a paramount interest in seeing that patent monopolies spring from backgrounds free from fraud or other inequitable conduct and that such monopolies are kept within their legitimate scope." (quoting *Precision Instrument Mfg. Co. v. Automotive Maintenance Machinery Co.*, 324 U.S. 806, 816 (1945)); *see generally* Amelia Smith Rinehart, *Patent Cases and Public Controversies*, 89 NOTRE DAME L. REV. 361 (2013) ("A patent could be described as a private solution to a public problem--the government grants to an inventor a private exclusive right to his invention for a limited time in order to encourage the promotion of progress to benefit the public as a whole. . . . Some members of the public might like to practice the invention without consequence--this group could include competitors, hopeful market entrants, patent licensees, or even strangers to the patent owner. Other people might believe that the patent harms them and others (including the government sovereign itself) by restricting competition and limiting innovation or by offending on moral or ethical grounds.") By contrast, a debtor's state common law counterclaim is not a matter of public right, and its adjudication in bankruptcy court is unconstitutional. *See* Stern v. Marshall, 131 S. Ct. 2594, 2611 (2011).

[141] *Cf.* Rinehart, *supra* note 140, at 387-90 (2013) (recognizing the "public health concerns" in invalidity cases involving patents covering genetic subject matter, therapeutic food, and genetically modified food).

[142] Thomas v. Union Carbide Agr. Products Co., 473 U.S. at 589-90.

[143] *Id.* at 571-75.

[144] *Id.* at 576.

[145] *Id.* at 589.

[146] *Id.*

Thomas is the closest analogy here.[147] Under *Thomas*'s reasoning, Congress would have the authority to remove from the Hatch-Waxman scheme the task of adjudicating patent validity and assigning it to PTAB.[148] To deem otherwise would be to quarantine patent validity disputes under the Hatch-Waxman Act to the four walls of an Article III court and thereby defeat the efficiency and housekeeping goals of AIA.[149]

Relatedly, in *Patlex Corp.*, the patent owner challenged the constitutionality of the retroactively operating reexamination statute, asserting that he had made significant business investments in reliance on the grant of the patent under the previous statute.[150] But the Federal Circuit upheld the statute.[151] Significantly, the court held that that statute was "curative" and that "a defectively examined and therefore erroneously granted patent must yield to the reasonable Congressional purpose of facilitating the correction of governmental mistakes."[152]

In the Hatch-Waxman context, an exclusivity-conferring patent is important in the big-picture scheme of incentivizing and heralding generic drugs before patent expiration.[153] And the first filer may have some legitimate investment-backed expectations.[154] Nonetheless, the AIA could be viewed as curative of 180-day exclusivities that may exist due to governmental mistakes.

Finally, pulling the trigger as proposed here will have to be accomplished through the barrel of the Federal Circuit, an Article III court. While public rights adjudication does not require judicial review,[155] the schematic explained in subsection A above entails an Article III nod. That further legitimizes giving a final, favorable IPR decision the status of a court decision trigger.

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[147] *Id.* at 589-90.

[148] *See id.* at 589 ("Congress has the power, under Article I, to authorize an agency administering a complex regulatory scheme to allocate costs and benefits among voluntary participants in the program without providing an Article III adjudication.")

[149] *See id.* at 590 ("'To hold otherwise would be to defeat the obvious purpose of the legislation to furnish a prompt, continuous, expert and inexpensive method for dealing with a class of questions of fact which are peculiarly suited to examination and determination by an administrative agency specially assigned to that task.'" (citing Crowell v. Benson, 285 U.S. 22, 46 (1932)).

[150] *See* Patlex Corp. v. Mossinghoff, 758 F.2d 594, 600 (Fed. Cir. 1985) ("The grant of [the] patents in 1977 and 1979 triggered activities by [the patent owner], such as the negotiation of licenses and the suing of accused infringers, in accordance with and in reliance on the patent statute then in existence. Relying on what he viewed as the bundle of rights and attributes encompassed by Title 35 as it stood in 1977 and 1979, [the patent owner] acted in accordance with the existing law. [The patent owner] asserts that the retroactive application of Public Law 96-517 deprived him of the rights that he was actively proceeding to enforce," *on reh'g*, 771 F.2d 480 (Fed. Cir. 1985)).

[151] *Id.* at 603-04.

[152] *Id.*

[153] *See* Ohly & Patel, *supra* note 4, at 117-18.

[154] *See* Upadhye, *supra* note 16, at 1318-19.

[155] *See generally* Mila Sohoni, *Agency Adjudication and Judicial Nondelegation: An Article III Canon*, 107 Nw. U. L. Rev. 1569, 1589-94 (2013) (distinguishing cases involving private rights from those involving public rights).

C. Legislative Amendment

Such compelling practical and policy rationales notwithstanding, an court may decline to recognize a final, favorable IPR decision as a court decision trigger because of lack of express congressional authorization. In that event, Congress should consider an amendment to the 180-day exclusivity forfeiture provision empowering courts and instructing the FDA to recognize a final, favorable PTAB decision as a forfeiture trigger in an ANDA case.