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Ships in the Night: Resolving Administrative Conflict Between FDA- and Patent-Related Legislation

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Ships in the Night: Resolving Administrative Conflict Between FDA- and Patent-Related Legislation

ARTICLES

SHIPS IN THE NIGHT: RESOLVING ADMINISTRATIVE CONFLICT BETWEEN FDA- AND PATENT-RELATED LEGISLATION

CARLOS A. GARCIA* AND JONATHAN STROUD**

In 2011, the Leahy-Smith America Invents Act altered U.S. patent administrative law, creating three review procedures whereby third parties have means of challenging the patentability of previously-issued patents. Lawmakers established the administrative framework, and policymakers, judges, and executive employees implemented, revised, and altered their procedures to conform. The marketplace and public adjusted their business and personal expectations accordingly.

Unexpected, though, was the Leahy-Smith America Invents Act's profound impact on the carefully balanced administrative schemes involving the approval of biosimilars and generic drugs. The unintended statutory conflicts among three administrative pathways, the Drug Price and Competition and Patent

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Term Restoration Act, the Biologics Price Competition and Innovation Act, and the Leahy-Smith America Invents Act, have increased costs and complexity in unwarranted ways. Senator Orrin Hatch recently sounded a siren of warning as to the conflicts between these dissimilar ships set to crash into one another.

Principles of administrative comity compel accommodation. So does sound and serviceable administration. While a handful of legislative fixes have been proposed, introduced, revised, debated, and abandoned, to date no one in the literature has identified, discussed, and analyzed that conflict, reviewed the full range of potential solutions, and offered a workable, easily-implementable administrative alternative. We do.

In the interests of promoting generic drug competition, reducing needless litigation costs, and restoring the delicate balance Congress struck between the courts and the administrative state with the abbreviated regulatory/litigation pathways for generic and biosimilar medicines, this Article analyzes the Leahy-Smith America Invents Act, the Drug Price and Competition and Patent Term Restoration Act, and the Biologics Price Competition and Innovation Act, and looks to the legislative history and analogous district court practice.

This Article recommends that the United States Patent and Trademark Office adopt guidance and policy directing the Patent Trial and Appeal Board to exercise their statutory discretion to deny institution during parallel statutory Drug Price Competition and Patent Term Restoration Act or Biologics Price Competition and Innovation Act litigation. This is all the more judicious after SAS Institute Inc. v. Iancu, a Supreme Court decision upholding the United States Patent and Trademark Office Director's authority to issue regulations, and it accords with the other provisions and legislative history of the various acts. This Article offers proposed agency guidance and internal policy recommendations that would provide clarity in an area where it is sorely needed; after all, someone must see the ships safely ashore.

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INTRODUCTION

Drug pricing invites controversy. As America's population ages, the AARP's voice resonates all the more loudly, particularly in the era of Donald Trump's presidency. Newsworthy flashpoints like the made-for-TV-villain Martin Shkreli¹ and the EpiPen controversy² are emblematic of Americans' growing concerns about the rising costs of healthcare and prescription drug coverage.³ To wit, President Trump and others have courted voters on the campaign trail with promises of lowering drug prices⁴ and with threats of taking action against pharmaceutical companies. His first (widely admired) Commissioner of the Food and Drug Administration (FDA),⁵ Dr. Scott Gottlieb, unveiled plans to lower drug prices for expensive biologics drugs.⁶ Democratic rivals for the 2020 Presidential election (and others) have introduced further drug policy and pricing reform bills into the 116th Congress.⁷ Among other ideas indicative of this policy fixation on drug pricing, President Trump proposed creating a new international index of drug prices used to benchmark the prices for drugs paid for by Medicare Part B to certain developed nations.⁸

1. See, e.g., Andrew Pollack, *Drug Goes from \$13.50 a Tablet to \$750, Overnight*, N.Y. TIMES (Sept. 20, 2015), <https://www.nytimes.com/2015/09/21/business/a-huge-overnight-increase-in-a-drugs-price-raises-protests.html> (noting that the price increases for some drugs was “unjustifiable for the medically vulnerable patient population” and “unjustifiable for the medically vulnerable patient population”).

2. See, e.g., Olga Khazan, *Have You Ever Tried to Buy an EpiPen?*, ATLANTIC (Aug. 24, 2016), <https://www.theatlantic.com/health/archive/2016/08/epi-pens/497126> (noting that, at the time of this Article, the cost of an EpiPen increased by more than \$500 since 2009).

3. See, e.g., Trent Gillies, *Why Health Care Costs are Making Consumers More Afraid of Medical Bills than an Actual Illness*, CNBC (Apr. 22, 2018, 11:15 AM), <https://www.cnbc.com/2018/04/22/why-health-care-costs-are-making-consumers-more-afraid-of-medical-bills-than-an-actual-illness.html>.

4. See Tami Luhby & Lauren Fox, *Trump Leans into Midterms with a Pitch to Un-Rig Medicare Drug Prices*, CNN (Oct. 25, 2018, 6:18 PM), <https://www.cnn.com/2018/10/25/politics/trump-drug-prices>.

5. *FDA Commissioner*, FDA, <https://www.fda.gov/aboutfda/commissionerspage> (last updated Feb. 19, 2019).

6. Scott Gottlieb, M.D., Comm'r, FDA, Remarks at the Brookings Institution on the Release of the FDA's Biosimilars Action Plan (July 18, 2018), <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm613881.htm>.

7. See *infra* notes 144, 159, 349 (discussing recent legislative proposals originating in the Senate).

8. See Robert Pear, *Trump Proposes to Lower Drug Prices by Basing Them on Other Countries' Costs*, N.Y. TIMES (Oct. 25, 2018), <https://www.nytimes.com/2018/10>

These proposals, while seemingly plain, reflect longstanding concerns over streamlining drug discovery, ensuring appropriate patent protection over new discoveries and innovations, and controlling the cost of the resulting litigation that so often arises from generic or biosimilar entry.

This longstanding concern resulted in Congress first passing the Drug Price Competition and Patent Term Restoration Act (Hatch-Waxman Act) in 1984.⁹ Prior to passing the Hatch-Waxman Act, a new generic drug applicant would have had to submit their own independent New Drug Application (NDA) comprising new clinical data obtained from clinical trials conducted using the generic drug.¹⁰ The Hatch-Waxman Act removed this significant barrier to generic drug entry.¹¹ It did so through compromise, allowing generic drug manufacturers to rely on the innovator's NDA if the generic manufacturer could show that their drug met similar standards as the innovator's drug: identity, strength, quality, purity stability, bioavailability, and bioequivalence.¹² While largely successful in controlling litigation and approval costs and encouraging streamlined generic competition, Hatch-Waxman addressed only small molecule drugs and ignored the then-nascent biologic drug industry (and approval process), made possible by advances in recombinant DNA technology.¹³

By 2009, Congress sought to usher in a new era of U.S. biologic competition with the passage of the Biologics Price Competition and Innovation Act (BPCIA) as part of the Patient Protection and Affordable Care Act (Affordable Care Act).¹⁴ Congress passed this bill against the backdrop of many other first-world governments implementing regulations governing the development of biosimilar therapeutics in the preceding decade amid rapid growth in their

/25/us/politics/medicare-prescription-drug-costs-trump.html (commenting that President Trump's proposal would take effect in late 2019 or early 2020).

9. Pub. L. No. 98-417, 98 Stat. 1585 (1984).

10. See 21 U.S.C. § 355d (2006); see also Allen M. Sokal & Bart A. Gerstenblith, *The Hatch-Waxman Act: Encouraging Innovation and Generic Drug Competition*, FINNEGAN (2010), <https://www.finnegan.com/en/insights/the-hatch-waxman-act-encouraging-innovation-and-generic-drug.html>.

11. PETER BARTON HUTT & RICHARD A. MERRILL, *FOOD AND DRUG LAW: CASES AND MATERIALS* 5 (2d ed. 1991).

12. *Id.*

13. See Ryan Timmis, Comment, *The Biologics Price Competition and Innovation Act: Potential Problems in the Biologic-Drug Regulatory Scheme*, 13 NW. J. TECH. & INTELL. PROP. 215, 217 (2015).

14. See *id.* at 216.

development, marketing, and sales.¹⁵ The law also governed patent disputes between innovative companies that develop the biologicals and would-be biosimilar manufacturers.¹⁶

The BPCIA, in some respects, mirrored the Hatch-Waxman Act, offering an abbreviated pathway to approval for copies of biologics, while also departing from it significantly. At its core, the BPCIA, like the Hatch-Waxman Act, sought to balance the rewards for innovation with the public interest of having access to affordable medicines after the innovator is appropriately compensated for their costly innovation.¹⁷ While the makers of biologics seek marketplace protection and rewards for their innovations and investments, consumers seek competitively priced, affordable medicines, and biosimilar manufacturers seek to fill that need with biosimilar products. Consequentially, both frameworks required and created regulated litigation pathways for patent disputes emerging from the generic-innovator divide.¹⁸

Meanwhile, just two years after Congress passed the BPCIA, it passed the Leahy-Smith America Invents Act of 2011 (AIA).¹⁹ In doing so, Congress addressed growing concerns with patent quality, international harmonization, and the high cost of patent litigation in general.²⁰ Additionally, Congress sought to efficiently and effectively resolve validity and patentability disputes by bringing the United States in line with international systems using post-grant opposition proceedings.²¹ Mostly implemented in bulk by September 2012,²² the

15. See Hannah Koyfman, *Biosimilarity and Interchangeability in the Biologics Price Competition and Innovation Act of 2009 and FDA's 2012 Draft Guidance for Industry*, 32 BIOTECHNOLOGY L. REP. 238, 242–43 (2013).

16. See 42 U.S.C. § 262(k)(6) (2012); see also Timmis, *supra* note 13, at 223.

17. See Holly Soehnge, *The Drug Price Competition and Patent Term Restoration Act of 1984: Fine-Tuning the Balance Between the Interests of Pioneer and Generic Drug Manufacturers*, 58 FOOD & DRUG L.J. 51, 53 (2003).

18. See, e.g., *id.* at 63–64; see also *In re Bupirone Patent Litig.*, 185 F. Supp. 2d 363, 365 (S.D.N.Y. 2002) (resolving a dispute between Bristol-Meyers Squibb and four patent disputes).

19. Pub. L. No. 112-29, 125 Stat. 284 (2011).

20. See Jonas Anderson, *Congress as a Catalyst of Patent Reform at the Federal Circuit*, 63 AM. U. L. REV. 961, 967 (2014) (noting that among Congress's areas of concern were "patent venue, monetary damages, and claim construction").

21. See Filip De Corte et al., *AIA Post-Grant Review & European Oppositions: Will They Work in Tandem, or Rather Pass like Ships in the Night?*, 14 N.C. J.L. & TECH 93, 96–97 (2012).

22. Pub. L. No. 112-29, § 6, 125 Stat. at 306–07 (codified as amended in scattered sections 35 U.S.C., including 35 U.S.C. §§ 321–329 (2012)); see also De Corte et al., *supra* note 21, at 117.

law has been used, *inter alia*, to challenge patents related to pharmaceutical and biological therapeutic products, though such challenges have been met with mixed success.²³

Yet since 2012, the calls for streamlined drug approval, efficient marketplace competition, and reduced prescription drug costs have not abated; if anything, they have been amplified.²⁴ Those calls can be best understood as continued public concern over allegedly anticompetitive litigation practices within the pharmaceutical and generic drug industries, resulting in inquiries from arms of the U.S. government, such as the Federal Trade Commission (FTC), the Department of Justice (DOJ), and the FDA itself.²⁵ It seems plain in hindsight that the BPCIA, passed in 2009, may need to be revisited to further reduce the costs of litigation, streamline legitimate market entry of biosimilar versions of approved biologicals, or support a just application of laws across agencies. Clashes between the policies of federal agencies have also brought unnecessary costs, increased the opportunities for anticompetitive behaviors, and introduced needless corporate and government legal waste.²⁶

One such unintended agency clash has been between the FDA-centric Hatch-Waxman and BPCIA Acts, which created litigation pathways to streamline generic market entry, and the USPTO-centric AIA of 2011, which generally allows any third party to challenge the legitimacy of a patent grant. Today, once the abbreviated New Drug Application (aNDA) or the abbreviated Biologics Licensing Application (aBLA) litigation schemes have been initiated, the *inter partes* review

23. See Corinne E. Atton & April M. Breyer, *Drug Patents May Fare Better Than Other Technologies in IPR Proceedings*, BIOLOGICSHQ 1 (June 12, 2017), <http://www.biologicsHQ.com/wp-content/uploads/2017/06/Drug-Patents-May-Fare-Better-Than-Other-Technologies-In-IPR-Proceedings.pdf>.

24. See *Prescription Drug Prices Rising Despite Trump Pressure on Big Pharma*, CBS NEWS (Sept. 24, 2018, 3:11 PM), <https://www.cbsnews.com/news/prescription-drug-prices-rising-despite-trump-pressure-on-big-pharma> (outlining the Trump administration's goals and the resulting changes).

25. Cf. Rodney J.Y. Ho, *Midyear Commentary on Trends in Drug Delivery and Clinical Translational Medicine: Growth in Biosimilar (Complex Injectable Drug Formulation) Products Within Evolving Collaborative Regulatory Interagency (FDA, FTC, and DOJ) Practices and Enforcement*, 106 J. PHARMACEUTICAL SCI. 471, 475 (2016) (“[O]ver the past 10 years, the DOJ has taken the lead in enforcing the regulations on marketing and product safety. Inter-agency collaborations and concerted efforts have led to settlements as high as \$3 billion.”).

26. See Joanna M. Shepherd, *Biologic Drugs, Biosimilars, and Barriers to Entry*, 25 HEALTH MATRIX 139, 141–42 (2015), <https://scholarlycommons.law.case.edu/cgi/viewcontent.cgi?article=1021&context=healthmatrix>.

(IPR) and post-grant review (PGR) procedures of the AIA have been used regularly to unnecessarily increase these high-stakes litigation costs without a significant resultant benefit to the system;²⁷ they have been used to further anticompetitive behavior;²⁸ they have created true generic hold-up; and they have given way to “side deals” with non-practicing parties, all of which have further muddied the waters and frustrated the goals of the Hatch-Waxman Act and BPCIA.²⁹

Yet ready solutions lie within reach. Congress, the courts, and even the agencies, possess the tools needed to prevent or mitigate the conflict and support the goals of the three Acts.³⁰ For one, the Patent Trial and Appeal Board (PTAB), using authority delegated to it by Congress and the United States Patent and Trademark Office (USPTO) Director, can use the discretion vested in them by the statute and recognized by the Supreme Court of the United States to solve the problem today.³¹ Once the problem is properly framed and explained, it will become clear that the administration, the courts, and Congress can and should act now to help these three important legislative solutions work in harmony to reduce, rather than increase, costs, delay, and anticompetitive behavior in the pharmaceutical and generic industries.

In Part I, this Article lays the groundwork for its argument by reviewing the key provisions of the Hatch-Waxman Act and the BPCIA, outlining the development of parallel proceedings at the USPTO, detailing the law of administrative policy implementation, and stating important principles of administrative comity.

In Part II, this Article then analyzes the conflicts that have arisen over the past seven years, highlighting counterproductive examples of aNDA and aBLA litigation frustrated or burdened by the conflict. In these examples, parallel USPTO proceedings have hampered the efficient resolution of lengthy, large-scale litigation, frustrating the preexisting schemes created by Congress (and championed by the AIA’s co-sponsor, Senator Orrin Hatch). Recent administrative law decisions from the PTAB and the Court of Appeals for the Federal Circuit will factor into our conclusions.

27. See *infra* Sections I.B.1–.2 and accompanying text.

28. See *infra* Sections I.B.1–.2 and accompanying text.

29. See *infra* Sections I.C.1–.2 and accompanying text.

30. See, e.g., *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144 (2016) (affirming substantive rulemaking authority for the PTAB); see also *St. Regis Mohawk Tribe v. Mylan Pharm. Inc.*, 896 F.3d 1322, 1327 (Fed. Cir. 2018) (affirming the USPTO Director’s absolute discretion in allowing IPR to proceed).

31. See *infra* Section III.C.4.

In Part III, we invite the next FDA Commissioner (and his or her successors) to work with USPTO Director Iancu (or his successors) to seek readily available administrative means to reduce or streamline parallel legal proceedings by, among other things, encouraging USPTO Director Iancu's (and his delegated decision-makers') use of his discretion to observe administrative comity and avoid conflict between the agencies and statutory schema and reduce unnecessary legal waste in an area where such waste only antagonizes the goals of all three schemes.

Finally, this Article concludes that, while Congress could act to address the oversight of the conflict generated by the good intentions of the BPCIA, the Hatch-Waxman Act, and the AIA, it is not required to do so. Although it may be politically challenging to do so in the era of hyperpolarized politics and public antagonism to pharmaceutical companies in general, it is wholly within USPTO Director Iancu's and the PTAB's power to carefully consider parallel aNDA and aBLA litigation as an important—and often dispositive—factor in their decisions whether to institute petitions before the PTAB.

I. BACKGROUND

A. *The Reissue, Correction, and Reexamination of Issued Patents*

Patents in the United States seek to balance incentivizing public innovation with the public's right to free markets by offering a period of exclusivity in exchange for public disclosure.³² Specifically, the

32. See U.S. CONST. art. I, § 8, cl. 8. (establishing Congress's power to promote scientific progress by securing limited rights for inventors). Patents as a legal cause of action are generally traced to the Venetian Statute of 1474, which established the state of Venice during the Renaissance, and established the first statutory patent system, i.e., the earliest codified system in the world. It allowed for the grant of a patent for "any new and ingenious device, not previously made," if useful. See Joanna Kostylo, *Commentary on: Venetian Statute on Industrial Brevets (1474)*, in PRIMARY SOURCES ON COPYRIGHT (1450–1900) (L. Bently & M. Kretschmer eds., 2008). There has been some scholarly analysis of the state of early Italian patron-inventors and patron-mathematicians that suggests that competition to be the first to innovate led to secretive parallel inquiries and stymied progress, for instance in the race to solve the cubic equation (and a well-documented case of intellectual property theft, by Girolamo Cardano, who claimed to have solved it). See generally IAN STEWART, WHY BEAUTY IS TRUTH: A HISTORY OF SYMMETRY, ch. 4 (2007). There is some debate as to whether patent-like bequests may have been recognized in ancient Greece, though it seems as if those citations are more in the form of a bounty or prize for any who developed something new and offered it to the sovereign; the English grants of the 14th century are in this vein, as a kind of sub-contract between the sovereign and

U.S. Supreme Court “has consistently held that the primary purpose of our patent laws is not the creation of private fortunes for the owners of patents but is ‘to promote the progress of science and useful arts.’”³³ It does so by appropriately incentivizing private investment in research and innovating new technologies for the good of all, while not unduly restricting free trade or inviting unjust profiteering.³⁴ In this, the USPTO is the primary defender of the public interest and the free market,³⁵ and the party best positioned to strike that “careful balance” between the benefits from incentivizing innovation and the costs imposed by exclusive rights that, if left unchecked or mismanaged, can stifle both competition and further innovation.³⁶ The patentability requirements of novelty and non-

certain specialized industries. CHARLES ANTHON, *A CLASSICAL DICTIONARY: CONTAINING AN ACCOUNT OF THE PRINCIPAL PROPER NAMES MENTIONED IN ANCIENT AUTHORS, AND INTENDED TO ELUCIDATE ALL THE IMPORTANT POINTS CONNECTED WITH THE GEOGRAPHY, HISTORY, BIOGRAPHY, MYTHOLOGY, AND FINE ARTS OF THE GREEKS AND ROMANS. TOGETHER WITH AN ACCOUNT OF COINS, WEIGHTS, AND MEASURES, WITH TABULAR VALUES OF THE SAME* 1273 (1848). For instance, the earliest recorded and verified English grant from the sovereign is generally agreed to have been made to John Kempe and Company in 1331. *See generally* TERRELL *ON THE LAW OF PATENTS* (18th ed. 2018). Other grants of variable time periods, such as a grant from Henry VII in 1449 for two years, have also been recorded and observed. E. Wyndham Hulme, *The History of the Patent System under the Prerogative and at Common Law*, 12 *LAW Q. REV.* 141 (1896).

33. *Motion Picture Patents Co. v. Universal Film Mfg. Co.*, 243 U.S. 502, 511 (1917) (quoting U.S. CONST. art. I, § 8, cl. 8).

34. *See, e.g.*, Letter from James Madison to Congress (Apr. 11, 1816), FOUNDERS ONLINE: NAT’L ARCHIVES, <https://founders.archives.gov/documents/Madison/99-01-02-5064> (“I recommend . . . that further restraints be imposed on the issue of patents to wrongful claimants, and further guards provided against fraudulent exactions of fees by persons possessed of patents.”).

35. *See Motion Picture Patents Co.*, 243 U.S. at 519; *see also* *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 816 (1945) (“A patent by its very nature is affected with a public interest.”). The USPTO has primary responsibility for insuring only warranted patents issue. “Congress has charged the United States Patent and Trademark Office (PTO) with the task of examining patent applications,” and granting patents only if the patent applications satisfy “the prerequisites for issuance of a patent.” *See* *Microsoft Corp. v. i4i Ltd. P’ship*, 564 U.S. 91, 95–96 (2011). The USPTO “has special expertise in evaluating patent applications” for compliance with these patentability requirements. *Kappos v. Hyatt*, 566 U.S. 431, 445 (2012).

36. *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 146 (1989); *see also* *Kimble v. Marvel Entm’t, LLC*, 135 S. Ct. 2401, 2406–07 (2015). Indeed, “[i]t is as important to the public that competition should not be repressed by worthless patents, as that the patentee of a really valuable invention should be protected in his monopoly.” *Pope Mfg. Co. v. Gormully*, 144 U.S. 224, 234 (1892). The Court’s conclusion in *Lear, Inc. v. Adkins* that state law could not bar a licensee from challenging the validity of the licensed patent reflected an affirmative policy

obviousness reflect Congress's judgment that exclusive rights in information that is already publicly available or can be easily determined from publicly available information "would not only serve no socially useful purpose, but would in fact injure the public by removing existing knowledge from public use."³⁷

Patents are federal statutory rights enacted under Article I.³⁸ They spring from the Constitution's prescription that Congress seeks to promote progress in the useful arts and science.³⁹ In outlining the early contours of the U.S. patent system, Congress, in the first patent act under their constitutional authority,⁴⁰ gave themselves the ability to grant patents, but did not create mechanisms for the correction of erroneously issued patents, either those initiated congressionally, by the patent owners, or at the at the request of third parties, even for typographical errors.⁴¹ Later, Congress amended the statute to

judgment that invalidating weak patents served "the important public interest in permitting full and free competition in the use of ideas which are in reality a part of the public domain." 395 U.S. 653, 670–71 (1969); *see also* *Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found.*, 402 U.S. 313, 344 (1971) (noting that the Court's decisions have long "encourage[d] authoritative testing of patent validity").

37. *Bonito Boats*, 489 U.S. at 148, 150.

38. "Under the common law the inventor had no right to exclude others from making and using his invention." *Deepsouth Packing Co. v. Laitram Corp.*, 406 U.S. 518, 525–26 (1972), *supersede by statute*, 35 U.S.C. § 271; *see also* *Wheaton v. Peters*, 33 U.S. 591, 661 (1834) (stating that inventors never had exclusive rights to inventions at common law "either in this country or in England").

39. U.S. CONST. art. I, § 8, cl. 8 (granting Congress the power "[t]o promote the [p]rogress of [s]cience and useful [a]rts, by securing for limited [t]imes to [a]uthors and [i]nventors the exclusive [r]ight to their respective [w]ritings and [d]iscoveries").

40. The Patent Act expressly defines a patent as being "[s]ubject to the provisions of this title." 35 U.S.C. § 261 (2012). Patent rights "must be derived from [the] patent grant, and thus from the patent statute." *Deepsouth*, 406 U.S. at 526. They are created at Congress's discretion, and "Congress may . . . select[] the policy which in its judgment best effectuates the constitutional aim" and "set out conditions and tests for patentability." *Graham v. John Deere Co.*, 383 U.S. 1, 6 (1966); *see also* *Deepsouth*, 406 U.S. at 530 (describing Constitution as "permissive" for patent rights).

41. In *Oil States Energy Services, LLC v. Greene's Energy Group, LLC*, 138 S. Ct. 1365, 1376 (2018), the argument was made that *McCormick Harvesting Machine Co. v. Aultman* stood for the proposition that the USPTO could not, constitutionally, impinge upon Federal Article III invalidity proceedings by reviewing patents post-issuance. *See McCormick*, 169 U.S. 606, 608 (1898) ("It has been settled by repeated decisions of this court that when a patent has received the signature of the Secretary of the Interior, countersigned by the Commissioner of Patents, and has had affixed to it the seal of the Patent Office, it has passed beyond the control and jurisdiction of that office . . .").

Not so. Rather, Congress can authorize or delegate its own administrative adjudication when, as here, the right exists solely because of a federal statute "and

delegate its authority to administer patents, as well as to issue certificates of correction,⁴² to reissue patents,⁴³ and to create other post-grant procedures (such as interferences on patents over which there was a dispute on ownership).⁴⁴ But it did not allow third parties to administratively challenge the propriety of existing patent claims for years after the founding, though many other jurisdictions did, some for over a century—for instance, the English system created in 1883.⁴⁵

In the 1980s, as part of the Patent and Trademark Law Amendments Act (Bayh-Dole Act)⁴⁶ and the patent reforms helping to create a specialized Article III appellate court, the U.S. Court of Appeals for the Federal Circuit,⁴⁷ Congress, at the same time, created

does not depend on or replace a right . . . under state law.” *Stern v. Marshall*, 564 U.S. 462, 491 (2011) (quoting *Thomas v. Union Carbide Agric. Prods. Co.*, 473 U.S. 568, 584 (1985)). Congress can permit USPTO error correction “before [a] particularized tribunal[] created to perform the specialized adjudicative tasks related to that right” as an “incidental extension[] of Congress’[s] power to define rights that it has created.” *N. Pipeline Constr. Co. v. Marathon Pipe Line Co.*, 458 U.S. 50, 83–84 (1982) (plurality opinion); *see also* *United States v. Duell*, 172 U.S. 576, 583 (1899) (“Congress may provide such instrumentalities in respect of securing to inventors the exclusive right to their discoveries as in its judgment will be best calculated to effect that object.”).

42. *See* Act of March 4, 1925, Pub. L. No. 68-610, § 1, 43 Stat. 1268, 1268–69 (1925).

43. *See* Pub. L. No. 106-113, div. B, § 1000(a)(9), 113 Stat. 1501, 1536 (1999).

44. *See* 35 U.S.C. § 135(a) (2006) (showing the Code as it was pre-AIA); *see also* U.S. PAT. & TRADEMARK OFF., MANUAL OF PATENT EXAMINING PROCEDURE (MPEP) § 2301 (9th ed. 2018) [hereinafter MPEP], <https://www.uspto.gov/web/offices/pac/mpep/s2301.html>.

45. *See* B. Zorina Khan, *An Economic History of Patent Institutions*, ECON. HIST. ASS’N (Mar. 16, 2008), <http://eh.net/encyclopedia/an-economic-history-of-patent-institutions>. The Japanese, German, European Union, the BRIC countries (Brazil, India, Russia, and China), and other jurisdictions—like South Africa and Saudi Arabia—all have or have had post-grant review proceedings allowing third-party opposition in various forms. *See, e.g., Opposition and Revocation*, GER. PAT. & TRADEMARK OFF., https://www.dpma.de/english/patents/opposition_and_revocation (last visited May 20, 2019); *Opposition to Grant of Patent*, JAPAN PAT. OFF., https://www.jpo.go.jp/e/system/trial_appeal/shubetu-igi (last visited May 20, 2019); *Oppositions*, EUR. PAT. OFF., <https://www.epo.org/applying/european/oppositions> (last updated Oct. 4, 2017).

46. Patent and Trademark Law Amendments Act, 35 U.S.C. §§ 200–212 (2012).

47. *See* the Federal Courts Improvement Act of 1982, Pub. L. No. 97-164, 96 Stat. 25 (1982) (merging the appellate division of the then-Court of Claims with the Court of Customs and Patent Appeals (CCPA) to form the thirteenth U.S. appellate court). Interestingly, the original proposals included granting the new court with the power to review all tax appeals as well, to promote uniformity across Article I administrative appeals. Prior to the 1980s, appeals from the USPTO were decided by the CCPA, whose progenitor tribunal, the Court of Customs Appeals, was deemed a “mere Article I tribunal” by the Supreme Court on the eve of the Great Depression, in a

ex parte reexamination (EPX) of issued patents.^{48,49} This gave the USPTO the “authority to reexamine—and perhaps cancel—a patent claim that it had previously allowed.”⁵⁰ Patents granted after July 1, 1981 were issued subject to cancellation in EPX, and those granted between November 29, 1999 and September 16, 2012 were issued additionally subject to inter partes reexamination (IPX).⁵¹ Congress modified reexamination by instituting IPR on September 16, 2012, as the latest iteration of its decades-long scheme for post-issuance USPTO error correction.⁵²

dispute over judicial pay. See *Ex parte Bakelite Corp.*, 279 U.S. 438, 451 (1929) (finding the earlier tribunal constitutional and not an Article III court, and finding that Congress may decide “arising between the government and others, which from their nature do not require judicial determination and yet are susceptible of it”); see also 62 GILES S. RICH, A BRIEF HISTORY OF THE UNITED STATES COURT OF CUSTOMS AND PATENT APPEALS 66–67 (1980) (discussing *Ex parte Bakelite* and referring to the CCA as a “mere administrative tribunal” with tongue in cheek). Note that this understanding of the CCA and its successor the CCPA is not entirely settled; the Supreme Court in 1962 in *Glidden* later held that the CCPA, whose powers were not vastly distinct from the earlier CCA, was indeed an Article III court. *Glidden Co. v. Zdanok*, 370 U.S. 530 (1962). All of this is idle historical speculation to satisfy curiosity; the Federal Circuit is unambiguously an Article III Circuit Court.

48. See MPEP, *supra* note 44, § 2201:

Statutory basis for citation of prior art patents or printed publications in patent files and *ex parte* reexamination of patents became available on July 1, 1981, as a result of new sections 301–307 of title 35, United States Code, which were added by Public Law 96–517, enacted on December 12, 1980 On November 29, 1999, . . . Public Law 106–113 was enacted, and expanded reexamination by providing an “*inter partes*” option. [Public Law 106–113] authorized the extension of reexamination proceedings via an optional *inter partes* reexamination procedure in addition to *ex parte* reexamination. 35 U.S.C. 311–318 . . . are directed to the optional *inter partes* reexamination procedures.

49. See Wayne B. Paugh, *The Betrayal of Patent Reexamination: An Alternative to Litigation, Not a Supplement*, 19 FED. CIR. B.J. 177, 180–90 (2009).

50. *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2137 (2016). A patent validity or patentability challenge—whether in litigation or before the office—is an “attempt to prove that the patent never should have issued in the first place” and therefore is integrally related to the expert USPTO’s primary examination function. See *Microsoft Corp. v. i4i Ltd. P’ship*, 564 U.S. 91, 96 (2011). Indeed, the litigation “presumption of validity of patents” exists to reflect deference to the expert [USPTO]’s considered judgment, *not* to protect the patentee or because patents are property rights. See *id.* at 97, 110–12.

51. See MPEP, *supra* note 44, § 2201 (discussing the expansion of reexamination through an “*inter partes*” option, in addition to the existing “*ex partes*” option).

52. 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*, 21 J. INTELL. PROP. L. 33, 36 (2013) (commenting that after September 16, 2012,

As part of reforms urged largely by patent owners to regain control and uniformity over the patent system, EPX permitted patentees to bolster the patentability of an issued patent over prior art that surfaced after examination had concluded.⁵³ Patentees, the USPTO, or third parties could also ask the USPTO to reexamine a patent, providing them a way to challenge the patentability of a patent without district court litigation, and providing patent owners with a means to further amend the claims of already-issued patents.

At passage, EPX offered an alternative to (or streamlined aide-de-camp to) some aspects of litigation. Congress stated in 1980 that:

Reexamination will permit efficient resolution of questions about the validity of issued patents without recourse to expensive and lengthy infringement litigation The reexamination of issued patents could be conducted with a fraction of the time and cost of formal legal proceedings and would help restore confidence in the effectiveness of our patent system It is anticipated that these measures provide a useful and necessary alternative for challengers *and for patent owners* to test the validity of United States patents in an efficient and relatively inexpensive manner.⁵⁴

The legislative history suggests it was meant as a compromise between patent owner and petitioners, and to further balance the interests of both. One congressman urged reexamination would “be of great benefit to small businesses for defending their patents.”⁵⁵ In congressional hearings leading to their creation, then-Commissioner Sidney Diamond thought “[r]eexamination would eliminate or simplify a significant amount of patent litigation. In some cases, the USPTO would conclude as a result of reexamination that a patent should not have issued.”⁵⁶ As an *ex parte* affair, even when requested by third parties, only the USPTO and the patentee participated.⁵⁷

“inventors and practioners had to quickly . . . navigate the many post-grant options they were suddenly confronted with”).

53. See H.R. REP. NO. 112-98, at 45 (2011).

54. H.R. REP. NO. 96-1307(I), at 3–4 (1980) (emphasis added), *reprinted in* 1980 U.S.C.C.A.N. 6460, 6462–63.

55. 126 CONG. REC. 29,901 (1980) (statement of Rep. Hollenbeck).

56. See *Patent Reexamination: Hearing on S. 1679 Before the S. Comm. on the Judiciary*, 96th Cong. 15 (1979) (statement of Sidney Diamond, Comm’r, U.S. Patent and Trademark Office).

57. See *Ex Parte Reexamination: Everything You Need to Know*, UPCOUNSEL, <https://www.upcounsel.com/ex-parte-reexamination> (last visited May 20, 2019).

To further that balance, in 1999, Congress created IPX.⁵⁸ These were filed by third parties (or occasionally ordered by the USPTO).⁵⁹ Both the third party and the patent owner participated in IPX proceedings, if so desired, generally allowing any interested third party to assist the USPTO in making their determination, in the public interest, that a patent claim was or was not erroneously granted.⁶⁰

Both EPX and IPX were avenues for the USPTO to reexamine an issued patent, given any substantial new evidence relevant to patentability, including over prior art and arguments already presented to the USPTO.⁶¹ A Central Reexamination Unit (CRU) handled all requests and conducted both IPXs and EPXs.⁶² Reexaminations are paper exchanges, with no possibility for district-court-style discovery, though in rare cases they allowed for additional discovery or an oral hearing.⁶³

It has been so widely noted that IPX, and to a lesser extent EPX, was used less than anticipated that citation to that fact would be reductive.⁶⁴ Both IPX and EPX proceedings led naturally to stays of related district court litigations (though Congress could not compel them),⁶⁵ as federal district court judges used their inherent docket control power to stay cases likely to be simplified by office

58. Pub. L. No. 106-113, div. B, § 1000(a)(9), 113 Stat. 1501, 1536 (1999).

59. 35 U.S.C. § 311(a) (2006) (showing the Code as it was pre-AIA and stating that a “[r]equest for inter partes reexamination” begins when “[a]ny third-party requester at any time [files] a request for inter partes reexamination by the Office of a patent on the basis of any prior art cited under the provisions of section 301”).

60. *See id.*

61. Greg H. Gardella & Emily A. Berger, *United States Reexamination Procedures: Recent Trends, Strategies and Impact on Patent Practice*, 8 J. MARSHALL REV. INTELL. PROP. L. 381, 382–83 (2009).

62. *Id.* at 382, 391. The FDA Commissioner can also order reexamination sua sponte. Though this practice had fallen out of favor, one reexamination was ordered by the government in 2011.

63. *See Abbott Labs. v. Cordis Corp.*, 710 F.3d 1318, 1320 (Fed. Cir. 2013) (“Since the PTO does not provide for depositions in inter partes reexamination proceedings, such proceedings are not ‘contested cases’ within the meaning of section 24, and subpoenas under section 24 are not available.”).

64. *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*, 21 J. INTELL. PROP. L. 1, 40 (2013) (“The underutilization of the inter partes reexamination procedure is a major reason for the changes made by Congress.”).

65. *See* Saurabh Vishnubhakat et al., *Strategic Decision Making in Dual PTAB and District Court Proceedings*, 31 BERKELEY TECH. L.J. 45, 48 (2016).

proceedings.⁶⁶ Such stay requests were liberally granted, with some sources suggesting 60% of such requests were granted.⁶⁷

During the AIA debates, congressmen noted that in hindsight, reexamination had provided “a less costly way of removing or restricting patents that should not have been granted or that were granted too broadly,” and that it was wise “to permit such challenge even before litigation-inducing controversy has arisen.”⁶⁸

B. *The AIA’s Further Patent Office Proceedings*

In furthering their work on EPX and IPX, Congress meant the AIA’s new statutory post-grant review procedures to be, among other things, further “quick and cost-effective alternatives to litigation.”⁶⁹ The AIA renamed and streamlined post-grant proceedings like PGR and IPR, both of which went into effect on September 16, 2012.⁷⁰

Importantly, as the Supreme Court notes that “[a]lthough Congress changed the name from ‘reexamination’ to ‘review,’ nothing convinces us that, in doing so, Congress wanted to change its basic purposes, namely, to reexamine an earlier agency decision.”⁷¹

66. See, e.g., *Ethicon, Inc. v. Quigg*, 849 F.2d 1422, 1426–27 (Fed. Cir. 1988) (requesting stay pending IPX).

67. See, e.g., Meaghen H. Kent, *Patent Trial and Appeal Board Statistics*, VENABLE (Apr. 23, 2014), <https://www.venable.com/insights/publications/2014/04/patent-trial-and-appeal-board-statistics> (noting that there is a 72% grant rate for stays pending post-grant proceeding results); *Success Rates for Motions to Stay Pending Reexamination*, Docket Navigator (2014) (on file with authors) (showing between 51.2% and 61.3% of district courts granted stays pending reexaminations prior to the AIA).

68. *In re Constr. Equip. Co.*, 665 F.3d 1254, 1261 (Fed. Cir. 2011) (Newman, J., dissenting).

69. See H.R. REP. NO. 112-98, at 48 (2011) (stating that statutory PGR procedures were designed to be “quick and cost effective alternatives to litigation”); 157 CONG. REC. 2710 (Feb. 28, 2011) (statement of Sen. Grassley) (noting that IPR was intended to provide a “faster, less costly alternative[] to civil litigation to challenge patents”).

70. Section 18 of the AIA, titled “Transitional program for covered business method patents,” established a subset of PGR proceedings for “covered business method patents” (CBM). Pub. L. No. 112-29, § 18, 125 Stat. 284 (2011). Because § 18 is scheduled to sunset after eight years in 2020, it is not codified in title 35, but is a floating statute. See *id.* § 18(a)(3)(A). CBM proceedings are, generally irrelevant for the purposes of this article, treated similarly to PGR proceedings; Federal Circuit decisions have sharply curtailed their scope (despite one of us unsuccessfully arguing otherwise. See generally P. Andrew Riley et al., *The Surprising Breadth of Post-Grant Review for Covered Business-Method Patents: A New Way to Challenge Patent Claims*, 15 COLUM. SCI. & TECH. L. REV. 235 (2014). The proceedings are likely to sunset in 2020, and they seem, at this point, destined for the dustbin of history.

71. *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144 (2016).

The rights provided by every patent today are, and always have been, subject to post-issuance USPTO review and cancellation.⁷²

Procedurally, PGR and IPR replaced IPXs with a more streamlined proceeding conducted directly by administrative patent judges (APJs) rather than the CRU; they include limited discovery and oral advocacy, but are primarily paper proceedings and importantly, for the first time, they shifted the burden from the USPTO to the third-party petitioner to demonstrate unpatentability.⁷³

1. *Inter partes* review (IPR)

The IPR procedures—just like the district court’s Federal Rules of Civil Procedure—seek “the just, speedy, and inexpensive resolution of every proceeding.”⁷⁴ The AIA requires that the PTAB finally determine the case in less than a year (extendable by six months for good cause or indefinitely for joinder).⁷⁵ Third parties must first

72. It is “the federal patent scheme [that] creates a limited opportunity to obtain a property right in an idea.” *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 149 (1989). “[T]he Patent Act itself indicates that patents shall have the attributes of personal property ‘[s]ubject to the provisions of this title.’” *eBay Inc. v. MercExchange, LLC*, 547 U.S. 388, 392 (2006) (quoting 35 U.S.C. § 261). USPTO error correction and cancellation have always been permissible, at Congress’s discretion.

73. See 157 CONG. REC. 3386, 3428 (Mar. 8, 2011) (statement of Sen. Kyl) (“One important structural change made by the present bill is that *inter partes* reexamination is converted into an adjudicative proceeding in which the petitioner, rather than the Office, bears the burden of showing unpatentability.”).

74. 37 C.F.R. § 42.1(b) (2017). Compare § 42.1(b), with Fed. R. Civ. P. 1 (“These rules govern the procedure in all civil actions and proceedings in the United States district courts They should be construed, administered, and employed by the court and the parties to secure the *just, speedy, and inexpensive determination of every action and proceeding.*”) (emphasis added).

75. Section 315(c) of the AIA states that “the Director, in his or her discretion, may join as a party to [a previously instituted] *inter partes* review any person who properly files a petition under section 311 that the Director . . . determines warrants the institution of an *inter partes* review” Pub. L. No. 112-29, § 315(c), 125 Stat. 284, 301 (2011). Senator Kyl made the following comments during the AIA debates, which suggest Congress and the PTO contemplated additional parties could join to existing proceedings as a matter of right:

The Office anticipates that joinder will be allowed as of right—if an *inter partes* review is instituted on the basis of a petition, for example, a party that files an identical petition will be joined to that proceeding, and thus allowed to file its own briefs and make its own arguments. If a party seeking joinder also presents additional challenges to validity that satisfy the threshold for instituting a proceeding, the Office will either join that party and its new arguments to the existing proceeding, or institute a second proceeding for the patent.
157 CONG. REC. 3386, 3429 (March 8, 2011) (statement of Sen. Kyl).

petition the PTAB; patent owner may optionally respond with why the petition should not be instituted; the PTAB will preliminarily determine simply if the petition supporting the ground demonstrates “a reasonable likelihood that at least one of the claims challenged in the petition is unpatentable.”⁷⁶ That decision is dedicated to the USPTO Director’s complete discretion.⁷⁷

First, although the Director’s discretion in how he conducts IPR is significantly constrained, he possesses broad discretion in deciding whether to institute review. *Oil States*, 138 S. Ct. at 1371. Although this is only one decision, it embraces the entirety of the proceeding. If the Director decides to institute, review occurs. *If the Director decides not to institute, for whatever reason, there is no review.* In making this decision, *the Director has complete discretion to decide not to institute review.* *Oil States*, 138 S. Ct. at 1371 (“The decision whether to institute inter partes review is committed to the Director’s discretion.”).⁷⁸

IPRs changed the standard for institution of post-grant proceedings: requests for reexamination before the enactment of the AIA were instituted when prior art patents or printed publications presented “a substantial new question of patentability.”⁷⁹ IPR expands the body of challengeable patents⁸⁰ and eliminates a step in the appeals process, appealing directly to the Federal Circuit.⁸¹ They expand estoppel and allow for deposition of expert witnesses and other limited discovery.⁸²

76. 37 C.F.R. § 42.108(c) (2017).

77. *Oil States Energy Servs., LLC v. Greene’s Energy Grp., LLC*, 138 S. Ct. 1365, 1371 (2018) (“The decision whether to institute inter partes review is committed to the Director’s discretion.”). *But see* Saurabh Vishnubhakat, *Disguised Patent Policymaking*, 76 WASH. & LEE L. REV. (forthcoming 2019), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3242146 (noting that “[USPTO] power has grown immensely in this decade” but arguing “the agency is wielding its power in predictably troubling ways,” yet nonetheless positing that “the era of broad [USPTO] power is still in relative infancy,” and thus urging that “[m]eaningful reform is still possible,” as “its new and controversial practices are not yet entrenched”).

78. *See St. Regis Mohawk Tribe v. Mylan Pharm. Inc.*, 896 F.3d 1322, 1327 (Fed. Cir. 2018) (emphasis added) (citing *Oil States*, 138 S. Ct. at 1371).

79. 35 U.S.C. § 303(a) (2012); *see also St. Regis Mohawk Tribe*, 896 F.3d at 1332.

80. The current regime precludes reexamination of patents filed before Nov. 1, 1999. *See* Eric C. Cohen, *A Primer on Inter Partes Review, Covered Business Method Review, and Post-Grant Review before the Patent Trial and Appeal Board*, 24 FED. CIR. B.J. 1, 3 & n.23 (2014).

81. *See* 37 C.F.R. § 1.983(a) (2017).

82. *Id.* § 42.51–.53.

2. *Post-grant review (PGR)*

PGRs (and CBM reviews) are procedurally congruent with IPRs, with some key substantive and timing differences, as well as (oddly) higher fees. Unlike IPRs, parties can only petition for PGR during the first nine months after the USPTO grants (or reissues) a patent, making them ideal for proactive challenges.⁸³ Except for business method patents and pending interferences, PGR only applies to patents with a priority date later than March 15, 2013, i.e., patents that contain a claim with an effective filing date on or after March 16, 2013.⁸⁴ A petition to institute PGR may be filed by anyone other than the owner of the patent.⁸⁵ The petition should state relief sought, list material facts, and include the petitioner's entire argument.⁸⁶ The petitioner may raise any statutory grounds for invalidity—sections 101, 102, 103, and 112 challenges.⁸⁷

C. *The FDA's Generic Competition Regulatory Schemes*

Because of the complicated and thorough approval process the FDA conducts for safety and efficacy, it is often expensive and time-consuming for the initial innovator to innovate and then navigate the FDA approval process to bring a new medicine to the market.⁸⁸

83. 35 U.S.C. § 321(c); 37 C.F.R. § 42.202. More in-depth treatment of both is beyond the scope of this Article. For more, see, for example, P. Andrew Riley, Jonathan R.K. Stroud & Jeff Totten, *The Surprising Breadth of Post-Grant Review for Covered-Business-Method Patents: A New Way to Challenge Patent Claims*, 15 COLUM. SCI. & TECH. L. REV. 235 (2014) (CBMs); Jonathan Stroud, *Patent Post-Grant Review After Alice*, 69 BAYLOR L. REV. 56 (2017) (PGRs).

84. 35 U.S.C. § 321; AIA, Pub. L. No. 112-29, §§ 3(n), 6(f), 125 Stat. 284, 293, 311 (2011).

85. 35 U.S.C. § 321(a); 37 C.F.R. § 42.201. Section 18 of the AIA created a special type of PGR—a transitional program for challenging covered business method patents. Congress intended the product, CBM review, to be an accessible, low-cost procedure for companies to challenge broad, abstract patents of questionable patentability related to the financial industry. See generally Joe Matal, *A Guide to the Legislative History of the America Invents Act: Part II of II*, 21 FED. CIR. B.J. 539, 630–31 (2012). CBM reviews can be filed any time after issue provided they meet other factors. Any party threatened or sued on a covered patent may pursue a CBM review petition.

86. 37 C.F.R. § 42.22.

87. Note that the CBM review proceeding sunsets in 2020 and is unlikely to be renewed by Congress. See *Transitional Program for Covered Business Method Patents*, U.S. PAT. & TRADEMARK OFF., <https://www.uspto.gov/patents-application-process/appealing-patent-decisions/trials/transitional-program-covered-business> (last visited May 20, 2019).

88. *Cost to Develop and Win Marketing Approval for a New Drug Is \$2.6 Billion*, TUFTS CTR. FOR THE STUDY OF DRUG DEV. (Nov. 18, 2014), <https://csdd.tufts.edu/s/pr-coststudy.pdf> (estimating the price of innovation for a new drug at a total cost of \$2,558 million). But see Rohit Malpani, *R&D Cost Estimates: MSF Response to Tufts*

Likewise, it is often prohibitively expensive for a generic or biosimilar follow-on company to bring an analogue to market themselves, even after patent protection has expired, through duplicative and costly reapproval of the analogue, regardless of how similar it is to the innovator product.⁸⁹ Congress sought to streamline the approval process for generic and biosimilar medicines with two important acts discussed below, commonly called the Hatch-Waxman Act and the BPCIA.⁹⁰

1. *The Hatch-Waxman Act*

Streamlined litigation schemes designed to facilitate the market entry of non-biologic (i.e., small-molecule or synthetic) drugs have existed in the United States since 1984.⁹¹ In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984, commonly called the Hatch-Watchman Act.⁹² The Hatch-Waxman Act gave the FDA broad and well-defined authority to issue abbreviated approval to generic drugs after the non-abbreviated approval of a brand-name drug.⁹³ Rather than having to wait for the first innovator's patent(s) to expire and then starting the process for gaining approval, generic companies could now file an aNDA prior to patent expiration of the branded medicine.⁹⁴ This allowed generic

CSDD Study on Cost to Develop a New Drug, DRS. WITHOUT BORDERS (Nov. 18, 2014), <https://www.doctorswithoutborders.org/what-we-do/news-stories/news/rd-cost-estimates-msf-response-tufts-csdd-study-cost-develop-new-drug> (“The cost of developing products is variable, but experience shows that new drugs can be developed for as little as \$50 million, or up to \$186 million if you take failure into account.”).

89. Erwin A. Blackstone & Joseph P. Fuhr, *The Economics of Biosimilars*, 6 AM. HEALTH & DRUG BENEFITS 469, 472 (2013), <http://www.ahdbonline.com/issues/2013/september-october-2013-vol-6-no-8/1596>.

90. See *infra* Sections I.C.1–2 and accompanying text.

91. See Steven Kozlowski et al., *Developing the Nation's Biosimilars Program*, 365 NEW ENG. J. OF MED. 385, 385 (2011), <https://www.nejm.org/doi/full/10.1056/NEJMp1107285>.

92. Hatch-Waxman Act, Pub. L. No. 98-417, 98 Stat. 1585, 1586 (1984) (codified at 21 U.S.C. §§ 321, 355 (2012); 35 U.S.C. §§ 156, 271, 282 (2012)); Jeremiah J. Kelly & Michael David, *No Longer “If,” but “When”: The Coming Abbreviated Approval Pathway for Follow-on Biologics*, 64 FOOD & DRUG L.J. 115, 115 (2009).

93. See Kelly & David, *supra* note 92, at 115–19 (“[B]iological drug products are typically produced *in vivo* (in a biological system) and, as a result, are complex and less well understood.”). Further, the manufacturing process has a serious effect on the final product—purification is required. *Id.* at 115, 119 (“Hatch-Waxman aimed to strike a critical balance in the Food, Drug & Cosmetic Act (FDCA) between incentives for drug innovation and the need for lower drug prices through increased competition.”).

94. Food, Drug & Cosmetic Act, 21 U.S.C. § 355(j) (2012).

companies to lower their cost of entry to the market, increasing competition and effectively lowering drug prices.⁹⁵

The Hatch-Waxman Act also created a highly detailed regulatory approval pathway (the aNDA) that asks generic applicants to demonstrate that their drug is “bioequivalent,” meaning therapeutically equivalent.⁹⁶ The FDA lists innovator and generic drugs in *Approved Drug Products with Therapeutic Equivalence Evaluations* (Orange Book)⁹⁷ with an appropriate “equivalence” grade (generally, an A-type or B-type rating).⁹⁸

Under the statute, patent information (i.e., patent number for each drug for which a reasonable claim of patent infringement could be made) must be submitted about a drug on the list to be published by the Secretary, who must include such information in the Orange Book.⁹⁹ This has an important public notice function; it puts all potential competitors and patent challengers on notice of the innovator applicant’s most valuable patent assets. Process of manufacture patents may not be submitted per regulation,¹⁰⁰ and the Secretary must update the list every thirty days by statute.¹⁰¹

The Orange Book listing has litigation consequences.¹⁰² A potential generic competitor submitting an aNDA for a generic product must

95. See Henry Grabowski et al., *The Market for Follow-On Biologics: How Will It Evolve?*, 25 HEALTH AFF. 1291, 1291 (2006) (discussing the Hatch-Waxman Act’s long-term cost savings as it relates to potential biosimilars savings). Biologics price competition could likewise significantly lower the cost of health care. See Dawn Willow, *The Regulation of Biologic Medicine: Innovators’ Rights and Access to Healthcare*, 6 CHI-KENT J. INTELL. PROP. 32, 34–35 (2006) (estimating cost saving effect of generic competition).

96. Hatch-Waxman Act, sec. 101, § (2)(A)(iv). The applicant must provide “information to show that the new drug is bioequivalent to the listed drug referred to in clause (i) . . .” with the exception that if the applicant admits the drug has a different active ingredient, additional studies are needed. *Id.*

97. See FDA, ORANGE BOOK: APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS (38th ed. 2018) [hereinafter ORANGE BOOK], <https://www.accessdata.fda.gov/scripts/cder/ob>.

98. *Id.* at xiii–xx.

99. 21 U.S.C. § 355(j)(7)(A).

100. 21 C.F.R. § 314.53(b) (2017).

101. 21 U.S.C. § 355(j)(7)(A)(ii).

102. We note that delisting actions exist, where a challenger seeks to have a listed patent dropped from the Orange Book for not in fact listing or reading on the drug approved. The 2003 Medicare Modernization Act (MMA) added provisions that let § 505(b)(2) and aNDA applicants challenge Orange Book listings, where the Federal Circuit had formerly ruled there was no private right of action to delist an allegedly improperly listed patent. See, e.g., *Mylan Pharm., Inc. v. Thompson*, 268 F.3d 1323, 1325 (Fed. Cir. 2001).

certify to the FDA for patents in the Orange Book when the aNDA is filed, but need not certify any other non-listed patents.¹⁰³ If a patent is later listed, the generic applicant is not required to re-certify.¹⁰⁴

The certifications have four flavors, commonly called the “four paragraphs”:

- (I) the patent information has not been filed by patentee (a “paragraph I certification”); or
- (II) the patent has expired (a “paragraph II certification”); or
- (III) when the patent will expire (a “paragraph III certification”); or
- (IV) that the patent is invalid or not be infringed by the manufacture, use, or sale of the new drug (a “paragraph IV certification”).¹⁰⁵

A paragraph IV certification in an aNDA is considered a de facto, if highly artificial, act of infringement in court.¹⁰⁶ If a paragraph IV certification is made, and all other regulatory requirements are complete, the aNDA will “be made effective immediately”¹⁰⁷ unless the patent owner sues for infringement under 35 U.S.C. § 271(e)(2)(A) within forty-five days of receiving the notice letter.¹⁰⁸ Once such an action is brought, the FDA automatically suspends approval of the aNDA for a maximum of thirty months, or until the court rules, whichever is earlier.¹⁰⁹ That process streamlines disputes

103. 21 U.S.C. § 355(b).

104. *Id.*

105. 21 U.S.C. § 355(j)(2)(A)(vii)(I)–(IV) (also known as Section 505(j)(2)(A) of the Food, Drug & Cosmetic Act).

106. 35 U.S.C. § 271(e)(2)(A) (2012).

107. 21 U.S.C. § 355(j)(5)(B)(iii).

108. *Id.*

109. *Id.* See generally Nora Xu, Comment, *AIA Proceedings: A Prescription for Accelerating the Availability of Generic Drugs*, 66 EMORY L.J. 1007 (2017) (summarizing that neither a PTAB decision nor the Federal Circuit’s affirmance terminate the thirty-month stay); Matias Ferrario et al., *The Use of Inter Partes Review Petitions in ANDA Litigation*, KILPATRICK TOWNSEND (Aug. 4, 2014), <https://www.kilpatricktownsend.com/~media/The%20Use%20of%20Inter%20Partes%20Review%20Petitions%20in%20ANDA%20Litigation>; Howard W. Levine et al., *Inter Partes Review in Generic Drug Litigation—Why the USPTO Should Exercise Its Discretion to Deny IPR Petitions in Appropriate Hatch-Waxman Act Disputes*, FINNEGAN (Mar. 7, 2014), <https://www.finnegan.com/en/insights/inter-partes-review-in-generic-drug-litigation-why-the-uspto.html>; Jeffrey Lewis & Niki Ikahihifo-Bender, *When Courts Allow Changes To Hatch-Waxman 30-Month Stay*, LAW360 (Sept. 10, 2018, 12:35 PM), <https://www.law360.com/articles/1080769>. There is a safe harbor for developmental or regulatory acts of infringement, such as testing or clinical trials done to comply with FDA requirements; 35 U.S.C. § 271(e)(1) states generally that “[i]t shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably related to the

between brand and generic by bringing many of the outstanding issues together to be resolved by an incentivized first generic filer and the branded drug originator.

The brass ring at the end of this certification and litigation process for the “first filer” for generic approval is a window of 180 days where the first generic gets market exclusivity over any other potential generic challengers¹¹⁰—creating a two-drug market and giving the first generic a head start over all other competitors, who generally rush in and lower prices dramatically in a sort of “tragedy of the commons” effect.¹¹¹

The Hatch-Waxman Act lowered the price of prescription drugs as intended.¹¹² For instance, “when Eli Lilly lost patent protection for the antidepressant drug Prozac (fluoxetine) in 2001, generic competitors garnered more than 70% of Prozac’s market within 2 months.”¹¹³ In 2010 generic drugs made up about 75% of total prescriptions filled in the United States; it had risen to about 85% by 2016, and is projected to continue to climb.¹¹⁴

2. *Biologics, biosimilars, and the BPCIA*

a. The background of biologics

Compared to the small molecule generic drug competition legislated by the Hatch-Waxman Act, biologics, then in their financial

development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs.”

110. 21 U.S.C. § 355(j)(5)(B)(iv). Note that the 180-day period can be forfeited for many reasons, such as failure to use or violation of antitrust laws. *Id.* § 355(j)(5)(D). It is also possible for simultaneous filers (i.e., filers on the same day) to share the 180 days if both are sufficient applications.

111. *Id.* § 355(j)(5)(B)(iv).

112. See Kozlowski et al., *supra* note 91, at 385; see also Kevin Outterson & Aaron S. Kesselheim, *How Medicare Could Get Better Prices on Prescription Drugs*, 28 HEALTH AFF. w832, w837 (2009), <https://www.healthaffairs.org/doi/full/10.1377/hlthaff.28.5.w832> (predicting large cost savings from follow-on biologic legislation).

113. Richard G. Frank, *Regulation of Follow-On Biologics*, 357 NEW ENG. J. OF MED. 841, 842 (2007), <https://www.nejm.org/doi/full/10.1056/NEJMp078095>.

114. Compare GENERIC PHARMACEUTICAL ASS’N, 2011 ANNUAL REPORT 24 (noting that 73% of prescriptions filled are for generics but they make up only one-eighth of total drug spending), with Murray Aitken, *Medicines Use and Spending in the U.S.: A Review of 2016 and Outlook to 2021*, QUINTILESIMS INSTITUTE 43 (2017), https://structurecms-staging-psyclone.netdna-ssl.com/client_assets/dwcnk/media/attachments/590c/6aa0/6970/2d2d/4182/0000/590c6aa069702d2d41820000.pdf (showing that unbranded generics composed 84.6% of dispensed prescription medications in the U.S. market).

and developmental infancy, escaped lawmaker's notice. The innovative biologics were mostly devoid of direct competition from lower-cost biosimilars even after the expiration of the patents that covered the innovative biologics.¹¹⁵ Sometimes, the lack of direct competition from lower-cost alternatives, among other things, led to prices upwards of \$20,000 per year for biologic drug treatments.¹¹⁶ These higher prices reflect the higher costs associated with developing and manufacturing a biological as compared to small-molecule drugs.¹¹⁷

The higher prices for biologics contributed in part to the rising cost of health care, leading first to a Hatch-Waxman Act-like solution in Europe, and then here.¹¹⁸ In 2003, the European Union enacted the world's first regulatory system for follow-on biologics.¹¹⁹ The European Medicines Evaluation Agency (EMA) Guidance on the Regulation of Biosimilars established a new nomenclature for generic competition: "similar biological medicinal products."¹²⁰ In 2008, Health Canada (HC) followed with Guidance on Regulation of Subsequent Entry Biologics, Canada's framework for the review of abbreviated applications for biologics.¹²¹ The notable success of the

115. Cf. Blackstone & Fuhr, *supra* note 89, at 472.

116. See *id.* at 475 ("[Roche] developed 2 new drugs, Perjeta (pertuzumab) and Kadcyca (ado-trastuzumab emtansine), to replace Herceptin. The typical course of Perjeta costs \$188,000.").

117. See *Biologics and Biosimilars: Balancing Incentives for Innovation: Hearing Before the Subcomm. on Courts and Competition Policy of the H. Comm. on the Judiciary*, 111th Cong. 2 (2009) [hereinafter 2009 Hearing] (statement of Rep. Henry Johnson, Jr., Chairman, Subcomm. on Courts and Competition Policy) ("Estimates put average development costs as much as \$1.37 billion. It is also without a doubt that the cost of pharmaceutical products, and in particular biologics, is huge.").

118. See *id.* ("In 2007, pharmaceutical expenditures accounted for \$231.3 billion in health care costs, and biologics represented \$40.3 billion of this total.").

119. Council Directive 2004/27, art. 10, 2004 O.J. (L 136) 34, 39 (EC).

120. Eur. Medicines Agency, Comm. for Medicinal Products for Human Use, *Annex to Guideline on Similar Biological Medicinal Products Containing Biotechnology-Derived Proteins as Active Substance: Non-Clinical and Clinical Issues; Guidance on Similar Medicinal Products Containing Recombinant Human Soluble Insulin*, European Medicines Agency 3, Doc. No. EMEA/CHMP/BMWP/32775/2005 (Feb. 22, 2006), http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500003957.pdf.

121. Canadian Minister of Health: Health Products and Food Branch, *Guidance Document: Information and Submission Requirements for Biosimilar Biologic Drugs* ii, <https://www.canada.ca/en/health-canada/services/drugs-health-products/biologics-radiopharmaceuticals-genetic-therapies/applications-submissions/guidance-documents/information-submission-requirements-biosimilar-biologic-drugs> (last updated Dec. 2, 2012).

Hatch-Waxman Act, the exponential growth of the biologics industry, and the European and Canadian examples of effective regulatory schemes made the eventual statutory creation of a U.S. biosimilar approval pathway inevitable.¹²²

In 1997, in a first step toward streamlining the ad hoc nature of the biologic license application (BLA) process, Congress passed the FDA Modernization Act, which under § 123(f) required the agency to conform the drug (NDA) and biologic (BLA) approval processes in parallel.¹²³ Among other significant changes,¹²⁴ the FDA Modernization Act also did away with the expensive and cumbersome requirement for biologics to obtain a separate Establishment License Application (ELA) for their manufacturing facilities.¹²⁵

The FDA approves single-molecule drugs and some biologics under the so-called § 505 NDAs,¹²⁶ while most biologics are approved with § 351 BLAs.¹²⁷ For drugs, there are three approval pathways a follow-on applicant can file: (1) a normal NDA,¹²⁸ (2) an NDA which uses

122. As Senator Hatch said: “When we adopted the 1984 Hatch-Waxman law, we were in an era of small molecule medicine and large patient population blockbuster drugs. Times have changed. It appears that we are rapidly entering an era of large molecule medicine and small patient population drugs.” 148 CONG. REC. 15,677 (2002).

123. FDA Modernization Act of 1997, Pub. L. No. 105-115, § 123(f), 111 Stat. 2296, 2323–24 (1997) (codified at 21 U.S.C. § 310 (2012)) (“The Secretary of Health and Human Services shall take measures to minimize differences in the review and approval of products required to have approved [BLAs] . . . and products required to have approved [NDAs] . . .”).

124. See David M. Dudzinski, *Reflections on Historical, Scientific, and Legal Issues Relevant to Designing Approval Pathways for Generic Versions of Recombinant Protein-Based Therapeutics and Monoclonal Antibodies*, 60 FOOD & DRUG L.J. 143, 177 (2005):

FDAMA also completely rewrote 42 U.S.C. § 262(a) by codifying the BLA requirement for all biologics, [and] reaffirmed that all biological products are subject to the FDCA Section 123(g) of FDAMA, which stated that no licensed biologic requires a section 505 application, sparked controversy in that it could possibly be interpreted to mean that biologics could use the ANDA provisions of FDAMA. In response, the House passed a technical amendment clarifying that this section could not be construed to apply ANDA provisions to biologics, although this bill did not reach the Senate for consideration.

125. Elimination of Establishment License Application for Specified Biotechnology and Specified Synthetic Biological Products, 61 Fed. Reg. 24,227, 24,227 (May 14, 1996); Biological Products Regulated Under Section 351 of the Public Health Service Act; Implementation of Biologics License; Elimination of Establishment License and Product License, 64 Fed. Reg. 56,441, 56,441 (Oct. 20, 1999).

126. 21 U.S.C. § 355 (2012).

127. § 351. Devices are approved under § 360.

128. § 355(b)(1); Abbreviated New Drug Application Regulations, 57 Fed. Reg. 17,950, 17,950–52 (Apr. 28, 1992).

publicly available literature (Paper NDA),¹²⁹ or (3) an aNDA (the so-called § 505(b)(2) approval), which uses the FDA's earlier finding of safety and efficacy of the brand-name drug.¹³⁰

Like with single-molecule drugs and Hatch-Waxman, for most biologics,¹³¹ there was, prior to the BPCIA, only one approval path—a biosimilar applicant needed to file a full BLA.¹³² The follow-on applicant then would have needed to repeat the clinical trials that the innovator conducted and could not rely on old approval data to support the abbreviated application, with certain exceptions (i.e., Avonex approval, a rare exception that proves the rule).¹³³

Full biologic approval is a significant and costly regulatory burden,¹³⁴ requiring extensive pharmacology, pharmacokinetics, toxicokinetics, and tissue distribution studies, toxicology studies, and a separate Good Laboratory Practices requirement.¹³⁵ Applicants must repeat the many requirements of Phase I (small trials meant to demonstrate safety only), Phase II (larger trials meant to demonstrate safety and efficacy), and Phase III (large, complex trials meant to

129. Publication of "Paper NDA" Memorandum, 46 Fed. Reg. 27,396, 27,396 (May 19, 1981).

130. 21 U.S.C. § 355(j).

131. Exceptions may be historical accident, although it is worth noting the statutory definitions of biologic and drug overlap (in that the definition for drugs is broad):

Thus, by May 1981, FDA had divided protein-based therapeutics between the Bureaus, with human insulin, human growth hormone (and analogues), thymosin, ACTH, and endorphins under the purview of the Bureau of Drugs, while interferons, vaccines (for hepatitis B and influenza), and serum albumin fell under the jurisdiction of the Bureau of Biologics. There is little evidence of the deliberations and motivations for these distinctions, although one notes that the products in the Bureau of Drugs are physically smaller, and less complex proteins.

Dudzinski, *supra* note 124, at 163.

132. James G. Kenimer & John J. Jessop, *Biologics, in FDA REGULATORY AFFAIRS: A GUIDE FOR PRESCRIPTION DRUGS, MEDICAL DEVICES, AND BIOLOGICS* 129, 136–37 (Douglas J. Pisano & David Mantus, eds., 2004) (discussing clinical requirements in detail).

133. Avonex is a follow-on interferon beta-1b biologic. Biogen used comparability data with the first-to-file product, Betaseron, and received approval under § 505 from the FDA, despite the fact that the two have a different number of amino acids; one is glycosylated while the other is not, and there are two amino acid differences in the chain. *See Berlex Labs., Inc. v. FDA*, 942 F. Supp. 19, 21–22 (D.D.C. 1996) (challenging the abbreviated approval unsuccessfully).

134. *See Grabowski et al., supra* note 95, at 1293 (discussing R&D costs for drugs and biologics in terms of the Hatch-Waxman Act).

135. For an excellent discussion of those requirements, see Kenimer & Jessop, *supra* note 132, at 138–44.

demonstrate how safe and effective the treatment is compared to existing treatments) human clinical trials.¹³⁶

Importantly for our purposes, before the BPCIA, there was no way to resolve complex biologics patent disputes between parties, forcing them to litigate piecemeal their patents increasing expense and delay.¹³⁷ Hence, the FDA needed an abbreviated approval pathway for follow-on biologicals to help alleviate this burden, spur competition, streamline attendant litigation, and improve access to affordable medicines.

b. The BPCIA and biosimilars

The BPCIA was reintroduced in the 111th Congress in 2009 in modified form from earlier failed bills in the 110th, and Congress finally passed it as Title VII of the well-known health care reform bill in 2010.¹³⁸ The BPCIA amends the definition of what a biologic is under § 262(i) of the Public Health Service Act,¹³⁹ grants the FDA statutory authority to issue biosimilar and interchangeable determinations,¹⁴⁰ and bestows upon the agency, broad deference in determining the procedural details of the scheme.¹⁴¹ It also sets up a patent challenge system¹⁴² and offers exclusivity incentives for the first

136. *Id.* at 141–42.

137. Alexej Ladonnikov, Comment, *The Biosimilar Patent Dance—If You Don't Dance, You're No Friend of Mine*, 35 SANTA CLARA HIGH TECH. L.J. 135, 141 (2018) (noting that the BPCIA laid out a mechanism for complex patent dispute resolution that did not previously exist).

138. *See supra* notes 1–6 and accompanying text (discussing the new health care reform act). Senator Edward Kennedy introduced the bill during the 110th Congress it was reintroduced and adopted by the 111th Congress, with many significant changes adopted from Representative Anna Eshoo's competing bill. *Compare* Biologics Price Competition and Innovation Act of 2007, S. 1695, 110th Cong. § 2(b)(3) (2007) (Kennedy bill) (defining “biosimilar” as “no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product”), *with* Pathway for Biosimilars Act, H.R. 5629, 110th Cong. § 101(a)(2), § (k)(2)(A)(i)(I) (2008) (Eshoo bill) (adding that “biosimilar[s]” must be “highly similar”). Notably, Congress largely rejected the bill put forth by Rep. Henry Waxman. *See* Access to Life-Saving Medicines Act, H.R. 1038, 110th Cong. (2007).

139. 42 U.S.C. § 262(i) (2012); Biologics Price Competition and Innovation Act of 2009, Pub. L. No. 111-148, § 7002(b), 124 Stat. 119, 814–15 (2010) (codified at 42 U.S.C. § 262(i)).

140. Biologics Price Competition and Innovation Act of 2009, § 7002(a), 124 Stat. at 804–05.

141. *Id.* at 806.

142. *Id.* at 812–13.

interchangeable product filed and approved,¹⁴³ though notably it does not contain a certification requirement or penalty and thus doesn't demand the creation of a listing of applicable patents like the "Orange Book".¹⁴⁴ It grants the agency ten years to come up with a comprehensive pathway to encourage and expedite follow-on generic applications to drive down the cost of health care.¹⁴⁵ The BPCIA grants biologics innovator applicants twelve years of data exclusivity for using the data obtained from their clinical studies from the product's first FDA approval.¹⁴⁶

The complex patent challenge system defined by the BPCIA is administered through the federal districts courts, involves the FDA, and was intended to reduce costly litigation.¹⁴⁷ It also includes twelve years of data exclusivity designed to prevent the premature approval of biosimilar products.¹⁴⁸

In contrast to the Hatch-Waxman Act, the BPCIA created two statutory determinations for a follow-on biologic product: biosimilar

143. *Id.* at 806.

144. To wit, a bipartisan group of Senators, led by Susan Collins (R-ME) and Tim Kaine (D-VA), recently introduced a co-sponsored a bill that would amend the statute to address this. *See* Biologic Patent Transparency Act, S. 659, 116th Cong. (2019).

145. *Id.* at 808.

146. *Id.* at 807. For more on the regulatory approval aspects of the BPCIA, see Mr. Stroud's 2011 article discussing the administrative law aspects of the regulatory approval framework—itsself borrowed from in the background section here. Jonathan Stroud, Comment, *The Illusion of Interchangeability: The Benefits and Dangers of Guidance-Plus Rulemaking in the FDA's Biosimilar Approval Process*, 63 ADMIN. L. REV. 599 (2011). For the purposes of this article, we focus on the patent challenge aspects of both the Hatch-Waxman Act and BPCIA.

147. *See* Biologics Price Competition and Innovation Act of 2009, § 7002(a)(2), 124 Stat. at 812–13 (laying out the new patent challenge system). For more on the loopholes, quirks, and vagaries the new system presents, see James N. Czaban et al., *Panacea or Poison Pill? Making Sense of the New Biosimilars Law*, 8 BNA LIFE SCI. & INDUSTRY REP. 1, 5–9 (2010), <https://www.bloomberglaw.com/product/blaw/document/XARAJVG5GVG0> (calling the new patent challenge system the "Kabuki Theater of Biologics Patent Litigation").

148. Biologics Price Competition and Innovation Act of 2009, § 7002(a)(2), 124 Stat. at 807. The twelve-year data exclusivity provision, far more than was given for small-molecule drugs, created a strong new form of intellectual property protection for innovator biologics. *See* Interview with Hans Sauer, Assistant Chief Council, Biotechnology Indus. Org., in Washington, D.C. (Jan. 21, 2011) (on file with authors) ("It is a sad commentary on the state of the patent system that biotech firms felt the need to lobby hard for this alternative form of intellectual property to run to."); *see also* Maxwell R. Morgan, *Regulation of Innovation Under Follow-On Biologics Legislation: FDA Exclusivity as an Efficient Incentive Mechanism*, 11 COLUM. SCI. & TECH. L. REV. 93, 100–01 (2010) (supporting the twelve-year provision).

and interchangeable.¹⁴⁹ These can be analogized to the distinction in single-molecule drugs between products that are bioequivalent (i.e., those that receive a B rating in the Orange Book), versus products that are both bioequivalent and interchangeable (i.e., those that receive an A rating).¹⁵⁰ In the former case, bioequivalence generally means the generic drug can only be prescribed for the same indications as the innovator, not substituted for it.¹⁵¹ In the latter, pharmacists can switch a patient's prescription of one for the other without asking the prescribing physician.¹⁵² Further, the legislation gives the FDA the power to decide *not* to allow for either biosimilar or interchangeable determinations for some classes of biologics.¹⁵³ The new law helps create an aBLA, with the two standards resulting in far different, more unpredictable results than the Hatch-Waxman Act.

c. The patent two-step

According to Alexej Ladonnikov, “[t]he BPCIA laid out a mechanism by which the [innovator] and biosimilar applicants could resolve patent disputes,” colloquially known as the “patent dance,” though it could be more appropriately called the patent two-step.¹⁵⁴ As Ladonnikov notes, this mechanism consists first of “several rounds of information exchange.”¹⁵⁵ The patent dance provisions, while seeking similar goals as the Hatch-Waxman Act, differ significantly in practice.¹⁵⁶ They involve an *optional* first patent selection process—an exchange of the patents that both parties view as most beneficial to first litigate, leading then to a first round of district court litigation and a *second* notice/litigation stage involving the selected patents.¹⁵⁷ The complex proceeding including the “patent dance” ensures that all or almost all variegated disputes are decided by a district court

149. Biologics Price Competition and Innovation Act of 2009, § 7002(b)(3), 124 Stat. at 814–15.

150. *See id.*; *see also* ORANGE BOOK, *supra* note 97, at xiii–xx.

151. RICHARD R. ABOOD, PHARMACY PRACTICE AND THE LAW 139–41 (6th ed. 2011) (“For example, if the Orange Book lists four pharmaceutically equivalent drugs, two with a B rating and two with an A rating, the pharmacist may interchange the two drugs with A ratings.”).

152. *Id.*

153. Biologics Price Competition and Innovation Act of 2009, § 7002(a), 124 Stat. at 808.

154. Ladonnikov, *supra* note 137, at 141.

155. *Id.*

156. *See id.* at 142–53.

157. *Id.* at 141–42.

before the commercial marketing of a biosimilar product.¹⁵⁸ Notably, they do not involve any mandatory public notice provisions, though recent legislative efforts seek to remedy this oversight.¹⁵⁹

As Ladonnikov notes (and we will not attempt to improve upon):

The patent dance involves two stages, the first having seven major steps:

Stage 1:

1. Applicant files aBLA with FDA, creating an “artificial” infringement.
2. Within 20 days of the FDA accepting their drug for review, a new drug applicant notifies [the innovator] of their plans to release a biosimilar, confidentially discloses their FDA application for the drug, and confidentially discloses their manufacturing information.
3. Within 60 days of (1), [the innovator] then identifies patents it could reasonably assert against the applicant (based on applicant’s disclosures), as well as [the innovator’s] own willingness to license those patents.¹⁶⁰
4. Within 60 days of (2), applicant responds with explanations of why their product does not infringe upon identified patents, why [the innovator’s] claims are invalid, or why they are unenforceable. Alternatively, applicant may state that it will not begin commercial marketing until the listed patents expire.
5. Within 60 days of (3), [the innovator] provides a rebuttal to applicant’s claims of non-infringement, invalidity, or unenforceability. After applicant’s receipt of the rebuttal, the parties have a period of 15 days to negotiate in good faith as to which patents should [first] be the subject of an infringement suit.
6. If the parties agree on which patents to litigate over, [the innovator] files suit over those patents within 30 days of the agreement. But if parties fail to agree within 15 days of starting negotiations, then they simultaneously exchange a list of patents that each party believes should be the subject of the infringement suit.
 - a. After negotiations fail but before the actual exchange of lists of patents, the applicant has to inform [the innovator] of the number of patents it intends to list. [The innovator’s] list of patents cannot exceed this number, unless applicant lists no patents, in which case [the innovator] may list one.
7. If the parties simultaneously exchange lists, then [the innovator] has 30 days to file infringement claims on each of the

158. *See id.*

159. *See* Biologic Patent Transparency Act, S. 659, 116th Cong. (2019).

160. Note that this is the first instance of required disclosure, and is party-specific— meaning that the disclosures happen between the aBLA sponsor and the innovator, and the public need not see the list.

patents on the exchanged lists. Applicant then notifies FDA of the suit within 30 days of service and provides a copy of the complaint.

Stage 2:

1. Applicant provides [the innovator] a notice of commercial marketing (“NCM”) no later than 180 days before the date it seeks to market their biosimilar.¹⁶¹

As scholars note, “[t]here is no automatic [thirty]-month stay or equivalent period for the FDA approval of biosimilars;” instead, after the first Stage 1 “patent-dance” concludes, there is a second stage of litigation possible, an open-ended preliminary injunction on marketing until a decision on patent validity, enforcement, and infringement is complete.¹⁶²

Once the FDA completes its aBLA proceeding, “[t]he biosimilar applicant has to disclose its intention to market starting 180 days following the grant of approval by the FDA, *regardless of whether the [first stage of the] ‘patent dance’ is followed.*”¹⁶³ (The emphasis highlights the oddly voluntary nature of the dance). Following notice, the innovator may seek a preliminary injunction in US district court until the court decides patent validity, enforcement, and infringement.¹⁶⁴

The Supreme Court recently decided a case related to these provisions, *Sandoz Inc. v. Amgen Inc.*,¹⁶⁵ which, while beyond the scope of this Article, demonstrates the complexity of the scheme created by Congress.¹⁶⁶

d. Summary

The BPCIA granted the FDA broad new authority to create an accelerated premarket approval pathway for generic competition to biologics to drive down the prices of biologicals and reduce the overall costs of health care. The BPCIA balanced the competing interests of

161. *Id.*

162. Kirke M. Hasson & Maria Salgado, *Biosimilars Enter the Courts: How Will Patent Infringement Settlements Be Tested for Validity Under Antitrust Laws?*, 16 ANTITRUST SOURCE 1, 3 (2016).

163. *Id.* “‘Patent dance’ is a name often given to the schedule by which the biosimilar applicant and the reference product sponsor exchange information regarding the patents that may be the subject of litigation.” *Id.* at 3 n.10 (citing *Amgen Inc. v. Apotex Inc.*, 827 F.3d 1052 (Fed. Cir. 2016)).

164. 42 U.S.C. § 262(1)(8)(B) (2012).

165. 137 S. Ct. 1664 (2017).

166. *Id.* at 1669.

innovation and patients. Developers of biologicals seek protection for their costly innovations, and patients seek less costly medicines.¹⁶⁷

Innovators of biologicals (as opposed to biosimilars) sought and earned protections like marketing exclusivity similar to the marketing exclusivity provided to innovators of small molecule drugs in the Hatch-Waxman Act.¹⁶⁸ Passing the BPCIA provided protections by offering, for example, eighteen months of marketing exclusivity for the first “interchangeable” biosimilar approved.¹⁶⁹ The BPCIA sought to create an abbreviated approval pathway for biosimilar biologics by the FDA.¹⁷⁰ While the law that laid the foundation for regulating biosimilars passed in 2010, the FDA did not release regulatory guidelines until 2012.¹⁷¹ Regulating biosimilars brought about new challenges from the original regulations in generic drugs because regulators had to establish scientific criteria for comparing reference products to biosimilars.¹⁷² To address this, the U.S. system takes a stepwise approach to biosimilarity that focuses on the “totality of evidence.”¹⁷³ At bottom, the U.S. approach is three-pronged.

First, analytical studies are performed to show the high level of similarity between the biosimilar product and the reference product.¹⁷⁴ Second, animal studies are performed.¹⁷⁵ The animal studies can include toxicity studies, and immunogenicity studies.¹⁷⁶ Third and finally, human clinical studies are performed, which can include further immunogenicity studies.¹⁷⁷ One of the key factors for determining biosimilarity is the immunogenicity of the biosimilar product.¹⁷⁸ The FDA approach allows for analysis of immunogenicity

167. See Anita Krishnan et al., *Global Regulatory Landscape of Biosimilars: Emerging and Established Market Perspectives*, BIOSIMILARS 19, 20, 29 (2015), https://www.researchgate.net/publication/273501664_Global_regulatory_landscape_of_biosimilars_emerging_and_established_market_perspectives.

168. See Terry G. Mahn & Gauri M. Dhavan, *Biosimilars vs. Generics—Major Differences in the Regulatory Model*, PHARMACEUTICAL COMPLIANCE MONITOR (Mar. 13, 2012), <http://www.pharmacompliancemonitor.com/biosimilars-vs-generics-major-differences-in-the-regulatory-model/1861>.

169. *Id.*; see also § 262(k).

170. See § 262(k)(2)(A).

171. See Krishnan et al., *supra* note 167, at 25.

172. See Kozlowski et al., *supra* note 91, at 385–86.

173. See Krishnan et al., *supra* note 167, at 25.

174. *Id.*

175. *Id.*

176. *Id.*

177. *Id.*

178. See Kozlowski et al., *supra* note 93, at 387.

so it aligns with its aim of eliminating residual uncertainty at each phase of the approval process.¹⁷⁹

The biosimilar patent dance is complex litigation associated with BPCIA approvals, and it involves two primary steps: the first involves an exchange of patent information followed by mandated district court litigation; the second involves a “final” suit involving a preliminary injunction followed by a full trial on validity, infringement, and remedy.¹⁸⁰

D. Patent Protection of FDA-Approved Drug, Biologic, and Device Products

Innovators of medical products including drugs and devices typically obtain patent protection at the USPTO for a (generally) twenty-year exclusive term¹⁸¹ and a trademark for their brand name.¹⁸² In contrast to other innovations, however, innovators of pharmaceutical and biological products rarely enjoy the full breadth of exclusivity for their patented innovations. One reason is the numerous and extensive clinical and pre-clinical studies required for FDA approval and the time necessary for the FDA to evaluate the merits of a submitted new drug application that too often consume several years of patent term exclusivity.¹⁸³ This occurs despite the availability of patent term extensions for FDA-approved biologics and pharmaceuticals as such extensions are not available if the extension would provide more than fourteen-years of exclusivity after FDA approval.¹⁸⁴

The second reason is 35 U.S.C. § 271(e)(1), which provides a safe harbor for acts that would otherwise constitute patent infringement so individuals may engage in activities reasonably related to the

179. On March 6, 2015, the FDA approved its first biosimilar product, Zarxio. *See FDA Approves First Biosimilar Product Zarxio*, FDA (Mar. 6, 2015) (on file with American University Law Review).

180. *See Understanding the Biosimilar “Patent Dance,”* BIOSIMILARS RESOURCE CTR. (Oct. 3, 2016), <https://www.biosimilarsresourcecenter.org/understanding-biosimilar-patent-dance>.

181. *See* 35 U.S.C. § 154(a)(2) (2012) (granting statutory authority to issue twenty-year patents).

182. Lanham Act, 15 U.S.C. § 1051 (2012) (granting statutory authority over trademarks). Thus, despite being codified at different section numbers, drug approvals are commonly referred to as § 505 approvals, biologics as § 355, and devices as § 510(k). Abbreviated approvals under Hatch-Waxman are referred to as § 505(b)(2) approvals.

183. *See* Henry G. Grabowski, *Data Exclusivity for Biologics: What Is the Appropriate Period of Protection?*, AM. ENTERPRISE INST. (Sept. 8, 2009), <http://www.aei.org/publication/data-exclusivity-for-biologics-what-is-the-appropriate-period-of-protection>.

184. *See* 35 U.S.C. § 156(c)(3); 37 C.F.R. § 1.775(d)(2)–(4) (2011).

development and submission of information to the FDA.¹⁸⁵ Said differently, 35 U.S.C. § 217(e)(1) provides protection from patent infringement for a significant period prior to FDA approval to allow for the development of generics and biosimilars. Without § 271(e)(1), developers of generics and biosimilars would be severely impaired in their ability to develop such medicines in the United States during the period of patent exclusivity for the innovative medicine. The act of infringement for generic drugs and biosimilars is separately defined under § 271(e)(2) and generally occurs when an application seeking their marketing approval is submitted to the FDA.¹⁸⁶

At its core, the Hatch-Waxman Act inextricably links the FDA approval process with patent infringement litigation. As mentioned, if a generic manufacturer seeks FDA approval prior to the expiration of Orange Book-listed patents, the generic manufacturer must provide the FDA with a paragraph IV certification stipulating that the patents in question are either invalid or not infringed and must notify the patent owner of the aNDA submission. The patent owner then has forty-five days after the notification to sue alleging patent infringement. In response, the FDA will postpone their approval of the aNDA submission for thirty months to allow patent holder to assert their patent rights in federal court. Under the Hatch-Waxman Act, patent enforcement of approved pharmaceutical drugs is generally not meant to take place absent the regulatory scheme.

Biosimilar applicants, in contrast, do not face a thirty-month stay for FDA approval pending the results of patent litigation following the submission of an aBLA. Instead, biosimilars applicants are only required to provide notice of their aBLA filing and of their intent to commercially market their biosimilar. Either of these notices can lead to litigation to enjoin the launch of the biosimilar product.¹⁸⁷ In many respects, the duration of the resulting litigation is contingent on whether the aBLA applicant discloses their aBLA application to the reference product sponsor, and whether multiple waves of litigation ensue as defined by the BPCIA.¹⁸⁸

185. Shashank Upadhye, *Understanding Patent Infringement Under 35 U.S.C. § 271(e): The Collisions Between Patent, Medical Device and Drug Laws*, 17 SANTA CLARA HIGH-TECH. L.J. 1, 42–43.

186. § 271(e)(2).

187. *Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664, 1669, 1678 (2017).

188. See Sanya Sukduang & Thomas J. Sullivan, *The Patent Dance*, FINNEGAN I (2018), <https://www.finnegan.com/en/insights/the-patent-dance-article.html>.

Yet despite these differences, the BPCIA and Hatch-Waxman schemes couple the drug regulatory approval process with the enforcement of patents covering the branded medicines. In both cases, patent enforcement ensues after the generic or biosimilar applicant files their application, and applicants under both schemes enjoy the benefits provided by the schemes prior to and after their filings.¹⁸⁹ This is not the case for any other patented technology, and a primary reason the AIA has had a disproportionate effect on the biopharma industry as compared to others.

AIA proceedings disrupt the enforcement of patents that cover branded medicines by allowing the generic or biosimilar applicant to challenge the validity of these patents prior to, during, and often after such schemed litigation has commenced. Many have written on how AIA proceedings have resulted in tilting the scales of fairness, altering the careful balance struck by the BPCIA and the Hatch-Waxman Act. In this context:

- (1) the effective loss of the 30-month stay of FDA where the district court action is suspended pending an AIA proceedings;
- (2) the increased burden on the patent holder, who then has to concurrently defend their patents on identical validity arguments in multiple highly complex and fact-intensive disputes;
- (3) the benefit provided to late aNDA filers (and to some extent first aNDA filers who request joinder) who can use the Hatch-Waxman district court litigation as a road map for improving their petitions for inter partes review;
- (4) the chance that parallel AIA and federal validity litigations will cause disparate outcomes;¹⁹⁰ and
- (5) the lack of an ability as a matter of right to extend the 30-month FDA when the district court case is suspended pending the decision of a parallel AIA proceeding.

are just a few notable examples of how AIA proceedings have disrupted the status quo in unintended, unexpected ways that frustrate the goals of the statutes.¹⁹¹ While patent protection is available to innovators of

189. *See id.* at 1–3.

190. For a notable example of this effect, see *Novartis AG v. Noven Pharm. Inc.*, 853 F.3d 1289 (Fed. Cir. 2017), where the district court and the PTAB reached different conclusions, and the Federal Circuit found that the PTAB is not bound by prior judicial decisions.

191. *See Xu, supra* note 109, at 1041–42 (summarizing that neither a PTAB decision nor the Federal Circuit’s affirmance terminate the 30-month stay); *see also Ferrario et al., supra* note 109; A. Antony Pfeffer & Catrina Wanning Wang, *Post-Grant*

medical products, its use and efficiency have been thrown into question by the effects of the conflict between the statutes and the lack of regulatory comity exercised by the two agencies.

E. Administrative Law Mechanisms Available to Implement Policy Goals

When an administrative agency is created, Congress grants the agency certain powers to enact policy in rules, regulations, and orders that can have the force of law to accomplish the goals of the agency.¹⁹² Rulemaking and adjudication are the main avenues that an agency may use to enact its policies.¹⁹³ Rulemaking is a quasi-legislative process, whereas adjudication is more like a court proceeding.¹⁹⁴ The purpose of the agency and the way it was created will generally determine whether it uses rulemaking or adjudication.¹⁹⁵ Each form has its own pros and cons; however, rulemaking can be further divided into three subcategories: formal rulemaking, informal rulemaking, and policy statements.¹⁹⁶ Formal and informal rulemaking are the only recognized forms of rulemaking that create substantive rules, which are binding and have the force of law,¹⁹⁷ policy statements can occasionally have the same effect.¹⁹⁸ While some agencies use rulemaking, others turn to using adjudication to create policy that mimics the form of the common law system.¹⁹⁹ Regardless of the

Proceedings Complicate Pharmaceutical Litigation, N.Y. L.J. ONLINE (Apr. 4, 2016), <https://www.orrick.com/Insights/2016/04/Post-Grant-Proceedings-Complicate-Pharmaceutical-Litigation>; Levine et al., *supra* note 109, at 2; Lewis & Ikahihifo-Bender, *supra* note 109.

192. See Jeffrey Lubbers, *Use of Rulemaking or Adjudication for the Setting of Policy: A Comparison*, in A GUIDE TO FEDERAL AGENCY RULEMAKING 113–14 (5th ed. 2012).

193. Jeffrey J. Rachlinski, *Rulemaking Versus Adjudication: A Psychological Perspective*, 32 FLA. ST. U. L. REV. 529, 529 (2005); David L. Shapiro, *The Choice of Rulemaking or Adjudication in the Development of Administrative Policy*, 78 HARV. L. REV. 921, 924 (1965).

194. See Shapiro, *supra* note 193, at 923–24; see also Rachlinski, *supra* note 193, at 529–30.

195. See Shapiro, *supra* note 193, at 924; see also Rachlinski, *supra* note 193, at 529–30.

196. ANDREW POPPER ET AL., ADMINISTRATIVE LAW: A CONTEMPORARY APPROACH 72 (3d ed. 2010).

197. See *id.*

198. *Compare* Pac. Gas & Elec. Co. v. Fed. Power Comm'n, 506 F.2d 33, 45 (D.C. Cir. 1974) (holding that EPA Order No. 467 was a general statement of policy in part because the stated purpose of the Order was merely to guide [the agency] in other proceedings), *with* Appalachian Power Co. v. EPA, 208 F.3d 1015, 1028 (D.C. Cir. 2000) (holding that an EPA “guidance document” published without notice and comment rulemaking under the auspices of issuing a policy statement was an invalid legislative rule because the document functionally amended the underlying agency rule).

199. See Rachlinski, *supra* note 193, at 529–30.

system that an agency uses, it has a plethora of options at its disposal to create policy, and it will generally use the most efficient form to accomplish its goals.²⁰⁰

1. *Formal rulemaking*

Formal rulemaking, sometimes called legislative rulemaking, is a trial-like process rarely used because of its rigid structure and narrow scope of effect.²⁰¹ It originates from § 553(c) of the Administrative Procedures Act (APA), where the statute provides procedures that these rules are “made on the record after opportunity for an agency hearing, sections 556 and 557 of this title apply instead of this subsection,” and are “required by statute.”²⁰² Effectively, formal rulemaking is only required when express congressional requirement is dictated by statute.²⁰³ Given that formal rulemaking is a difficult, dilatory process, agencies use other forms of rulemaking, such as informal rulemaking.²⁰⁴

2. *Informal rulemaking*

Formal rulemaking is distinguished from informal—or “notice-and-comment”—rulemaking. For any statute not expressly requiring formal rulemaking, the less burdensome notice-and-comment rulemaking suffices. Section 553(b) outlines the procedures of informal rulemaking, essentially requiring that the agency provide public notice of the proposed rule, an opportunity to comment on the rule before it is issued, and a concise statement of basis and purpose of the final rule.²⁰⁵ The final rule need not be identical to the proposed one;

200. See Jeffrey S. Lubbers, *The Transformation of the U.S. Rulemaking Process—For Better or Worse*, 34 OHIO N. U. L. REV. 469, 471–72 (2008) (discussing the ossification of informal rulemaking).

201. See POPPER ET AL., *supra* note 196, at 72; PETER BARTON HUTT ET AL., *FOOD AND DRUG LAW: CASES AND MATERIALS* 49 (4th ed. 2014).

202. 5 U.S.C. § 553(c) (2012); *United States v. Florida East Coast Ry.*, 410 U.S. 224 (1973).

203. *West Chicago v. U.S. Nuclear Regulatory Comm’n*, 701 F.2d 632, 644–45 (7th Cir. 1983).

204. See generally Robert W. Hamilton, *Procedures for the Adoption of Rules of General Applicability: The Need for Procedural Innovation in Administrative Rulemaking*, 60 CAL. L. REV. 1276, 1276–77 (1972).

205. § 553(b) provides:

General notice of proposed rulemaking shall be published in the Federal Register, unless persons subject thereto are named and either personally served or otherwise have actual notice thereof in accordance with law. The notice shall include—

however, there needs to be a logical connection between the two versions or one needs to be the “logical outgrowth” of the other.²⁰⁶ If the final rule is drastically different from the proposed rule, notice is inadequate, and a court may remand the rule for another round of commenting.²⁰⁷ An agency chooses informal rulemaking because it can closely control the process and create a rule that gives the public notice of consequences for violating the new rule.²⁰⁸ While informal rulemaking is more widely used, it too comes with its own barriers that lead agencies to using other forms of rulemaking.²⁰⁹ The procedures of informal rulemaking can create hurdles that the agencies must jump to pass rules, which is why many turn to even less formal rulemaking that might be binding.²¹⁰

3. *Policy statements, memorandums, and internal policies*

Policy statements, somewhat like guidance documents, allow an agency to change a procedure that can affect how a rule is implemented, sometimes effectively giving that policy the force of a law.²¹¹ They do so, however, without the same level of due process protections as notice-and-comment rulemaking would; a subtle but critical difference between guidance documents and internal policy decisions is the procedure that accompanies their implementation, as required by statute.

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- (1) a statement of the time, place, and nature of public rule making proceedings;
 - (2) reference to the legal authority under which the rule is proposed; and
 - (3) either the terms or substance of the proposed rule or a description of the subjects and issues involved.

Except when notice or hearing is required by statute, this subsection does not apply—

- (A) to interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice; or
- (B) when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.

206. *Chocolate Mfrs. Ass'n of the U.S. v. Block*, 755 F.2d 1098, 1103–04 (4th Cir. 1985) (“There is no question that an agency may promulgate a final rule that differs in some particulars from its proposal.”).

207. *Id.* at 1107.

208. *See generally* Lubbers, *supra* note 192, at 123–24.

209. *See* Stroud, *supra* note 146, at 629.

210. *Id.*

211. *Id.* at 629–30.

While guidance documents are “statements of general policy or interpretations of general applicability formulated and adopted by the agency” that are published in the Federal Register,²¹² internal policy decisions are not necessarily published. Depending on the agency, a guidance document can vary from changes in approval procedures to how administrative law judges should interpret a law.²¹³ Internal policy decisions, sometimes confusingly called general policy statements, generally outline decisions that affect how the agency functions day-to-day.²¹⁴ These decisions can affect the information an agency has at its disposal or explain how agency employees will enforce a policy.²¹⁵ While neither guidance nor policy decisions are technically binding authority,²¹⁶ agencies might enforce informal policy decisions through adjudication, effectively creating policies that seem binding through common practice.²¹⁷

Internal policy statements, like memorandums, instructions to the staff, and the like, do not legally have the same authority as formal or informal rules or laws. They can, however, guide the practices and policies of the agency and can—and often do—affect the best practices. These guidelines are somewhat protected from judicial scrutiny by a long-held distinction between “law” and “policy,”²¹⁸ a necessary factor in administrative law driven, not by interpretation of written law, but by practical concerns and political necessity. These guidelines are often excluded from the “legal side of the ledger.”²¹⁹ They are also frequently viewed as a method for agencies to skip over the more formal—and difficult—requirements of notice-and-comment rulemaking.²²⁰

212. 5 U.S.C. § 552(a)(1)(D) (2012).

213. See Stroud, *supra* note 146, at 629–31; see also Connor N. Raso, Note, *Strategic or Sincere? Analyzing Agency Use of Guidance Documents*, 119 YALE L.J. 782, 788 (2010).

214. See John Bashaw, *Regulation of Nanoparticles: Trying to Keep Pace with a Scientific Revolution*, 6 NANOTECH. L. & BUS. 475, 481 (2009) (discussing general policy statements).

215. See Nat'l Mining Ass'n v. McCarthy, 758 F.3d 243, 251–53 (D.C. Cir. 2014) (“In terms of reviewability, legislative rules and sometimes even interpretive rules may be subject to pre-enforcement judicial review, but general statements of policy are not.”).

216. *Id.* at 253 (“[W]hile regulated parties may feel pressure to voluntarily conform their behavior because the writing is on the wall about what will be needed to [comply], there has been no ‘order compelling the regulated entity to do anything.’”).

217. See Stroud, *supra* note 146, at 629–30.

218. See Gillian E. Metzger & Kevin M. Stack, *Internal Administrative Law*, 115 MICH. L. REV. 1239, 1281–83 (2017).

219. *Id.* at 1244.

220. See *id.* at 1277–78 (discussing how the APA promotes the use of internal law).

The difference between “law” and “policy” seems like an academic distinction, but procedurally it is critical. Knowing, for example, how an agency employee is likely to review material will affect how one should present the material. Limited funding and resources means that agencies have to choose what issues to pursue. Changes in policy can affect changes in enforcement, creating hyper-focused attention on a few particular pet-projects of the agency, while allowing other issues to pass-on by.²²¹

Internal statements and guidelines can also be used by Article III courts in reviewing agency decisions. The APA²²² instructs reviewing courts to review the “whole record.”²²³ This “record can consist of whatever influenced the agency’s decision-making.”²²⁴ The APA also requires that “those statements of *policy* and interpretations [that] have been adopted by the agency” shall be published by the agency.²²⁵ Understanding how a court may view these policy guidelines and internal statements against an agency’s decision should inform why a lack of policy guidance should not necessarily be viewed negatively. Agencies understand that a specific policy and record thereof can be “‘litigation risk’ sensitive.”²²⁶ This has, paradoxically, led to a policy by some agencies to limit policy guidelines.²²⁷

4. *Adjudication*

An agency can use adjudication to implement policies decision-by-decision, as issues arise.²²⁸ While rulemaking is “the process leading

221. See *Massachusetts v. EPA*, 549 U.S. 497, 527 (2007) (“As we have repeated time and again, an agency has broad discretion to choose how best to marshal its limited resources and personnel to carry out its delegated responsibilities.”). *But see* Leland E. Beck, *Agency Practices and Judicial Review of Administrative Records in Informal Rulemaking*, ADMIN. CONF. OF THE U.S. 27 (2013), <https://www.acus.gov/sites/default/files/documents/Agency%20Practices%20and%20Judicial%20Review%20of%20Administrative%20Records%20in%20Informal%20Rulemaking.pdf> (“This reinforces a notion expressed several times . . . that agencies generally do not adopt policies (or have the resources necessary to do so) without some animating event.”).

222. Administrative Procedure Act, Pub. L. No. 79-404, 60 Stat. 237 (1946).

223. 5 U.S.C. § 706 (2012).

224. Nicholas Bagley, *Remedial Restraint in Administrative Law*, 117 COLUM. L. REV. 253, 292 (2017) (citing *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 420 (1971)).

225. § 552(a)(2)(B) (emphasis added).

226. See Beck, *supra* note 221, at 28.

227. See *id.* at 26.

228. Compare 5 U.S.C. § 554 (Adjudications), with 5 U.S.C. § 552(a)(1)(D) (applying “substantive rules of general applicability adopted as authorized by law” as

to the issuance of regulations,” adjudication is the process of “determining the legal status of persons who are named as parties, or of the acts or practices of those persons.”²²⁹ Agency adjudications create a sort of common law within the agency, almost the equivalent of a rule,²³⁰ but that only formally applies to the parties involved and any subsequent adjudications.²³¹ When the agency wishes to change its policies, it must do so through formal or informal rulemaking.²³² For there to be a change in agency policy, a panel of administrative judges must deviate from precedent; however, this decision cannot be arbitrary and may be subject to judicial review.²³³ Agencies like the National Labor Relations Board and the Securities and Exchange Commission rely heavily on adjudication because of the frustratingly slow pace of the rulemaking process.²³⁴ While some agencies prefer one form of policymaking, others must use all forms to implement and enforce their policies.²³⁵

Ultimately, it is the agency’s decision whether to use rulemaking, adjudication, or a combination of the two.²³⁶ However, the agency is bound by the limitations of the APA.²³⁷ When an agency uses guidance documents to implement policy, the policy is not technically binding until formally enforced.

F. Administrative Comity

When an area of law or executive administration requires a high level of expertise, Congress can create an administrative agency to regulate, and essentially legislate, in that field. Congress delegates

well as “statements of general policy or interpretations of general applicability formulated and adopted by the agency”).

229. See Shapiro, *supra* note 193, at 924.

230. Rachlinski, *supra* note 193, at 529–30.

231. William D. Araiza, *Judicial and Legislative Checks on Ex Parte OMB Influence over Rulemaking*, 54 ADMIN. L. REV. 611, 616 (2002).

232. Ass’n of Admin. Law Judges, Inc. v. Heckler, 594 F. Supp. 1132, 1133 (D.D.C. 1984); see also Jeffrey Scott Wolfe, *Are You Willing to Make the Commitment in Writing? The APA, ALJs, and SSA*, 55 OKLA. L. REV. 203, 231 (2002).

233. See Araiza, *supra* note 231, at 616–17.

234. See Rachlinski, *supra* note 193, at 531–32.

235. See generally Lubbers, *supra* note 200, at 477–78 (discussing overall trend toward the use of guidance documents).

236. See SEC v. Chenery Corp., 332 U.S. 194, 202–03 (1947) (stating that agencies can generally decide whether to use rulemaking, adjudication, or a mixture of the two).

237. See 5 U.S.C. §§ 553–554 (2012).

agencies a limited scope of their own authority.²³⁸ Often, multiple agencies or executive agents have been delegated overlapping or concurrent jurisdiction—for instance, the FDA and the Alcohol and Tobacco Tax and Trade Bureau (TTB) of the DOJ have overlapping jurisdiction over regulating and enforcing parts of federal tobacco policy and legislation.²³⁹ While agencies or arms of the executive with overlapping jurisdiction generally work to avoid issues,²⁴⁰ when there is a direct conflict between their regulations or enforcement activities, it is not always legally clear which agency's rules should govern.²⁴¹ While there is “no reason, absent an occlusive statutory bar, for an administrative agency to be obtuse to the genuine concerns of other administrative agencies” when both agencies have similar jurisdictions, in practice there may be no practical arbiter over such commonplace conflicts; direct agency disputes rarely (if at all) make it to the judiciary for various reasons (not the least being the prohibition over advisory opinions); as such, most inter-agency conflicts are settled through practical political compromises, and should be guided by principles of administrative comity.²⁴²

Administrative comity is analogous to principles of comity seen in other areas of governmental interactions (such as between countries or courts with overlapping jurisdiction), except it concerns administrative agencies instead of sovereign states or courts.²⁴³ At its

238. Lee Loevinger, *The Administrative Agency as a Paradigm of Government—A Survey of the Administrative Process*, 40 IND. L.J. 287, 293 (1965) (describing Congress's purpose in delegating legislative responsibilities to agencies).

239. This particular overlap has been long-recognized and has resulted in Memorandums of Understanding (MOUs) between the agencies, first in 1974, and later in 1987, which attempt to head off potential agency/enforcement conflicts. *See, e.g.*, Memorandum of Understanding between the Food and Drug Administration and the Bureau of Alcohol, Tobacco, and Firearms (Nov. 20, 1987), <https://www.ttb.gov/pdf/atf-fda-1987.pdf>. The many MOUs between the TTB and other agencies are just one example of efforts by executive authorities to avoid or minimize such conflicts, and demonstrate ongoing comity concerns. *See MOU Search Results*, U.S. DEP'T OF TREASURY TTB, <https://search.ttb.gov/search?utf8=%E2%9C%93&affiliate=ttb&query=mou> (last visited May 20, 2019).

240. *See, e.g.*, *infra* note 247 and accompanying text.

241. Jacob E. Gersen, *Overlapping and Underlapping Jurisdiction in Administrative Law*, 2006 SUP. CT. REV. 201, 206–07 (2007).

242. *Hinfey v. Matawan Reg'l Bd. of Educ.*, 391 A.2d 899, 907 (N.J. 1978).

243. *See* Erwin Chemerinsky, *Parity Reconsidered: Defining a Role for the Federal Judiciary*, 36 UCLA L. REV. 233, 280–83 (1988) (discussing how the principle of comity is used to justify circumscribing federal court jurisdiction to reduce friction with state courts); James C. Rehnquist, *Taking Comity Seriously: How to Neutralize the*

core, the doctrine seeks to avoid conflict between agencies through honoring and enforcing the decisions of others with similar jurisdiction, and exercising prudential discretion to avoid conflicting decision-making where warranted.²⁴⁴ While there are legal scholars, like Justice Rehnquist, who believe comity is a “toothless abstraction” or “not a rule” that does not justify intergovernmental deference, others, like Justice Handler, see comity as a necessity for maintaining practical order.²⁴⁵ Administrative comity is comparable to other legal doctrines such as *res judicata*, collateral estoppel, and justiciability, although it is more of an informal agreement rather than a codified doctrine.²⁴⁶ When there is a conflict between two agencies’ regulations, unless there is a statute directly on point, no binding doctrine informs a court how to settle such dispute.²⁴⁷ Ultimately, whenever an issue arises between agencies, comity counsels that it should “be resolved by the forum or body which, on a comparative scale, is in the best position by virtue of its statutory status, administrative competence and regulatory expertise to adjudicate the matter.”²⁴⁸ (That, of course, requires the cooperation and agreement of those agencies and civil servants).

Abstention Doctrine, 46 STAN. L. REV. 1049, 1067 (1994) (addressing comity and the “notoriously fuzzy business of recognizing foreign judgments”).

244. *Hinfey*, 391 A.2d at 908.

245. Compare Rehnquist, *supra* note 243, at 1066–67, with Howard H. Kestin, *Justice Alan B. Handler: The Jurist as Scholar, Teacher, Craftsman, and Statesman*, 30 SETON HALL L. REV. 715, 719–20 (2000) (noting that comity ensures that a controversy would be resolved by the agency in the best position to resolve the matter).

246. *Hinfey*, 391 A.2d at 908.

247. The issue (and ad hocery of solutions) is longstanding, having been recognized in, for instance, by Albert Abel:

The following are typical: the Railroad Retirement Board’s reliance on Interstate Commerce Commission determinations of carrier status for coverage purposes; the licensing of ship radios and operators by the Bureau of Marine Inspection on the basis of recommendations from the Federal Communications Commission; and the tendency of junior agencies in the field of utility regulation to reproduce procedural techniques of the Interstate Commerce Commission. The other major device, namely, seeking the views of outside agencies whose interests are affected Essentially, it is a branch of diplomacy; the practices involved rest on inter-agency comity. It may lead, where agency powers are contiguous or overlapping, either to joint occupation of a field, to a definition of their respective jurisdictions, or in extreme cases to adoption of some divisional arrangement such as was mentioned earlier.

Albert S. Abel, *Decentralized Administrative Techniques of the Federal Government*, 10 U. CHI. L. REV. 437, 448 (1943); see also Rehnquist, *supra* note 243, at 1066–67.

248. *Hinfey*, 391 A.2d at 908.

Judges may, at their own discretion, also compare statutes based on primacy, valuing one over another based on timing, scope, authority, and other various indicia. For instance, deference can be given to the statute that is more specific and on point for any particular conflict.²⁴⁹ This preference is reflected in other areas of administrative law.²⁵⁰ While the Supreme Court has not explicitly used the term administrative comity to decide any particular interagency dispute, it has used the principle to settle disputes in areas of the law such as labor and anti-trust.²⁵¹ The term was first coined in *Amalgamated Clothing Workers of America v. NLRB*,²⁵² a 1966 dispute about a potential violation of the National Labor Relations Act.²⁵³ There, the court used administrative comity in finding the Regional Director's findings should be used and given "persuasive relevance" upon remand.²⁵⁴

The doctrine has been most explicitly outlined in the New Jersey state courts.²⁵⁵ The state has even codified administrative comity statewide to help minimize conflicts between its state agencies with overlapping jurisdiction.²⁵⁶ Importantly, comity does not preempt one agency from enforcing its regulations; the Supreme Court has held that "the same issues and parties may be proceeded against simultaneously by more than one agency."²⁵⁷ Instead, it counsels an

249. *Id.*

250. Courts have struggled to determine if deference should be given to statutes enacted by multiple federal agencies; however, *Chevron* dictates that deference will generally be given to an agency's interpretation of a statute. See Gersen, *supra* note 241, at 207.

251. See *Ricci v. Chi. Mercantile Exch.*, 409 U.S. 289, 315–16 (1973) (quoting *Carnation Co. v. Pac. Westbound Conference*, 383 U.S. 213, 222 (1996)) ("We have held that principles of administrative comity preclude courts from finding antitrust violations 'only . . . when the defendants' conduct is arguably lawful' under the administrative scheme.").

252. 365 F.2d 898 (D.C. Cir. 1966).

253. See *id.* at 905 ("The findings of the Regional Director may be accorded 'persuasive relevance,' a kind of administrative comity, aiding the Examiner and the Board in reaching just decisions, subject however to power of reconsideration both on the record already made and in the light of any additional evidence that the Examiner finds material and helpful to a proper resolution of the issue.").

254. *Id.*

255. See, e.g., *Balsley v. N. Hunterdon Reg'l Sch. Dist. Bd. of Educ.*, 568 A.2d 895, 898 (N.J. 1990); *Hackensack v. Winner*, 410 A.2d 1146, 1161 (N.J. 1980); *Hinfey v. Matawan Reg'l Bd. of Educ.*, 391 A.2d 899, 907–08 (N.J. 1978).

256. *Hennessey v. Winslow Twp.*, 875 A.2d 240, 245 (N.J. 2005) ("Agency conflicts are minimized by adherence to this Court's instructions on administrative comity, when appropriate, as well as by such developments as the establishment of the [Office of Administrative Law].").

257. *Warner-Lambert Co. v. FTC*, 361 F. Supp. 948, 952 (D.D.C. 1973).

ad hoc approach based on a reasonable recognition of the conflicting statutes, agencies, and executive authority at play.

II. THE ADMINISTRATIVE CONFLICT BETWEEN SCHEMES RENDERS
HATCH-WAXMAN AND BPCIA LITIGATION LENGTHIER, MORE
EXPENSIVE, MORE COMPLEX, DOES NOT END OR STREAMLINE
LITIGATION, AND SERVES NO ACT WELL

Comprehensive, reliable data from multiple sources and analysis of individual disputes demonstrate conclusively there is a costly and counterproductive conflict between the earlier-passed statutory schemes meant to speed generic entrance and the AIA, and that AIA proceedings are unintentionally frustrating Congress's and the Executive's goals of the BPCIA and the Hatch-Waxman Act.²⁵⁸ Rather than being used to efficiently review patent validity or simplify matters, as intended, in this context the IPR and PGR processes have deleteriously interfered with (and increased the cost of) the aNDA and aBLA approval processes in most cases. As a political outcome, the unanticipated conflict between the FDA and the court's approval system and the USPTO's second-look program has, because of statutory and regulatory conflict, decreased fairness, efficiency, and led to unjust outcomes, based primarily on the lack of consideration of how the two variegated agency/court processes are organized and interact. This suggests that, at least case-by-case, it would benefit the American public and the industry if that tension were considered by the USPTO when deciding whether to institute a parallel proceeding before the agency.

A. *Statistics from the Patent Office and Others*

Helpfully, the USPTO has already conducted an internal study examining the outcomes of Orange Book-listed patents in AIA proceedings. To date, the number of challenges was comparatively low (389) compared to other types of challenges (7557 total). Of those 389, 66% were instituted by the PTAB, though it is worth noting that many of those institutions were "me-too" joinder challengers seeking to join preexisting proceedings.²⁵⁹ The low

258. See *infra* Section II.A (describing how various challenges in parallel Hatch-Waxman and BPCIA litigation can be costly, duplicative, and complicated rather than streamlined).

259. David P. Ruschke et al., *Chat with the Chief: New PTAB Studies in AIA Proceedings: Expanding Panels and Trial Outcomes for Orange Book-listed Patents*, U.S. PAT.

numbers mask their import, however; in a field where patent families of Orange Book-listed patents range generally from 1–10 patents, one cancellation or proceeding has an outsize impact on a product, compared to, for instance, some wireless standard portfolios that have thousands of patents covering a particular type of technology.

Yet, despite those instituted proceedings, only about 17% of all petitions resulted in the cancellation of any claims.²⁶⁰ Often, the PTAB instituted the proceedings, reviewed the patent (in parallel with the district court, who could not stay its own validity proceedings), and ultimately concluded the patent challenger failed to demonstrate the claims should not have been granted.²⁶¹

Interestingly, the USPTO also found that about 20% of the challenged Orange Book-listed patents faced three or more petitions, generally, in Mr. Stroud's opinion, by other generics seeking to join

& TRADEMARK OFF. 34, 38 (Mar. 13, 2018), https://www.uspto.gov/sites/default/files/documents/chat_with_the_chief_march_2018.pdf.

260. *Id.* at 46.

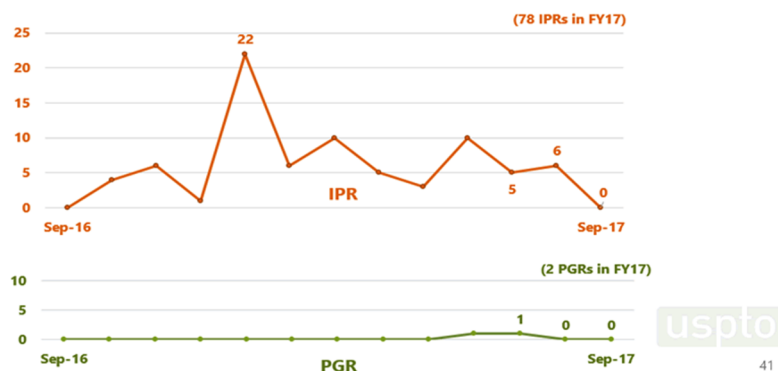
261. One example Mr. Stroud was involved with in private practice, *Metrics, Inc. v. Senju Pharmaceutical, Co.*, involved two IPRs filed by a generic “second filer” against formulation patents, i.e., patents covering formulations of the active drug at work in the marketed product. *See, e.g., Metrics, Inc. v. Senju Pharm., Co.*, IPR2014-01041, Paper No. 1 at 1–2 (P.T.A.B. June 26, 2014).

The case was notable in that Metrics (albeit under the name “Coastal Pharmaceuticals”) filed its 21 U.S.C. § 355(j)(2)(A)(vii)(IV) letter (“Paragraph IV letter”) on all five Orange Book-listed patents. As is common, the letter included invalidity grounds on the two challenged patents; what was notable was that those invalidity grounds were identical (nearly verbatim) to those filed in the two IPR petitions and appeared in the letter on the same day the petition was filed. *Compare Metrics, Inc.*, IPR2014-01041, Paper No. 1 at 2, *with Metrics, Inc.*, IPR2014-01041, Ex. 2001, at 7–8. The USPTO instituted both IPRs; while Metrics quickly settled, Innopharma, another generic second-filer, successfully joined the petition filed by Metric first. *See, e.g., Innopharma Licensing Inc. v. Senju Pharm. Co.*, IPR2015-00902, Paper No. 3 at 7 (P.T.A.B. Mar. 19, 2015). Innopharma continued the challenge; the PTAB found that secondary indicia of nonobviousness overcame the initial showing of obviousness and upheld all challenged claims of patents. *Innopharma*, IPR2015-00902, Paper 90 at 25 (finding evidence of secondary considerations of commercial success and industry acclaim “outweighs Petitioner’s evidence of obviousness based on the prior art”). The district court case settled with the various filers shortly thereafter, but not after forcing Senju to litigate validity in parallel forums on *the exact same grounds*, twice, to no avail. *See Stipulated Consent Judgment and Injunction* at 1–4, *Senju Pharm. Co. v. Innopharma Licensing, Inc.*, No. 1:15-cv-03240 (D.N.J. Oct. 13, 2016). Given the temporary stay of regulatory approval and the complex and ongoing nature of the district court case—where five patents rather than just these two were at issue—it seems unlikely that any judge would have ever stayed any parallel district court proceeding.

the earlier-filed proceedings to prevent favorable settlements with the IPR filer.²⁶² Anecdotally, multiple “me too” joinder petitions are routinely filed by other generic applicants on instituted proceedings.²⁶³ Per the USPTO, while Orange Book-listed patents appear to have an institution rate on par with other areas of technology and are frequently targeted by multiple petitions and parties—and are publically listed by another agency for all to see their value—to date Orange Book-listed patents are, by far, the most likely to withstand AIA proceedings.²⁶⁴

Others have conducted similar studies, with similar results.²⁶⁵ For instance, a study from Drug Patent Watch (along with the USPTO study) demonstrates only 20% of claims challenged are ultimately held to have issued in error (though many settle, as generics jockey for market position). To wit, it notes that seventy-eight IPRs had been filed by September of 2017 on Orange Book-listed patents and that IPR was the predominant means of challenge²⁶⁶:

**Petitions Challenging Orange Book-listed Patents Filed by Month
(September 2017 and Previous 12 Months: 9/1/16 to 9/30/17)**



262. Ruschke et al., *supra* note 259, at 53.

263. See, e.g., Cary Miller, *PTAB Denies Joinder of IPR Petitioner that Won't Take "Silent Understudy" Role*, JONES DAY (July 20, 2017), <https://www.ptablitigationblog.com/ptab-denies-joinder-ipr-petitioner-wont-take-silent-understudy-role>.

264. See Ruschke et al., *supra* note 259, at 34, 46.

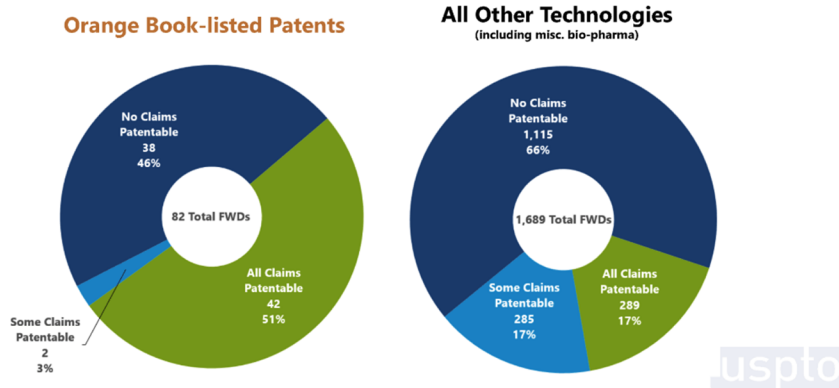
265. See, e.g., *What We Know from 4-Plus Years of Drug Patent Challenges Heard by the PTAB*, DRUG PAT. WATCH, <https://www-drugpatentwatch-com.cdn.ampproject.org/c/s/www.drugpatentwatch.com/blog/what-we-know-from-4-plus-years-of-drug-patent-challenges-heard-by-the-ptab/> (last visited May 20, 2019) (finding that from September 2016 through September 2017, seventy-eight *inter parte* reviews were filed, compared to only two post-grant reviews).

266. Ruschke et al., *supra* note 259, at 41.

This too demonstrates the resiliency of Orange Book-listed patents compared to all other types, showing that, of the 318 petitions that were instituted (less than 50% of the total if settlements and withdrawals are considered) and made it to a final written decision (eighty-two to date; note that some settle or are withdrawn), roughly half of all challenged claims have survived in full, even among this narrow set of patents. And notably, few challenge (and even fewer affect) new chemical entities or all remaining Orange Book-listed patent claims.²⁶⁷

Status of Instituted Claims in Final Written Decisions

(As of End FY17: 9/16/12 to 9/30/17)



45

STATUS OF PETITIONS CHALLENGING ORANGE BOOK-LISTED PATENTS (AS OF END FY17: 9/16/12 TO 9/30/17)		
PETITION STATUS	ORANGE BOOK	ALL OTHER TECHNOLOGIES
Reached Final Written Decision	21% (82)	24% (1,689)
Settled	17% (68)	22% (1,585)
Denied Institution	27% (106)	23% (1,651)
Dismissed	2% (6)	1% (103)
Joined	17% (65)	4% (289)
Open	14% (56)	22% (1,587)
Request for Adverse Judgment	2% (6)	4% (264)
Total Petitions	100% (389)	100% (7,168)

267. See *id.* at 45, 49.

Another important study by Filko Prugo, Scott McKeown, and Jon Tanaka offers further insight.²⁶⁸ They note that 82% of Orange Book-listed patent proceedings see the patent first asserted in district court, almost exclusively as part of Hatch-Waxman litigation.²⁶⁹ And only 26% of Purple Book-associated patents were first asserted in district court, suggesting as others have noted that many potential biosimilar applicants or competitors have turned to post-grant challengers early rather than engage in the cumbersome biosimilars dance.²⁷⁰ They note, too, that invalidity rates in Federal Court are *higher* than those before the PTAB, at least in Orange Book-listed and Purple Book-associated patents.²⁷¹

Captured in these studies are petitions filed by those who seek to exploit the administrative conflict between the AIA and FDA proceedings for financial or political gain. For example, one study showed that the hedge fund petitioners—the now-infamous Coalition for Affordable Drugs (which boasts co-founder Eric Spangenberg, the self-proclaimed “King of the Patent Trolls”), Ferrum Ferro Capital, and Silver Star Capital, LLC (run by the same man, Kevin Barnes)²⁷² have filed more than thirty IPR petitions between them challenging Orange Book-listed patents, for either political or financial gain.²⁷³ Of note, to date, these challenges have been spectacular failures, and Eric Spangenberg and Kyle Bass reportedly were

268. See Filko Prugo et al., *Orange, Purple Book Patentees Hone PTAB Survival Skills*, BNA (June 8, 2018), <https://www.bna.com/insight-orange-purple-n73014476446>.

269. See *id.* (showing only 10% of Orange Book-listed patents challenged at the PTAB are never asserted in district court, at least as of the time their tracking concluded).

270. See *id.* (noting of those patents, 44% are later asserted in district court).

271. *Id.* On an atavistic level, this makes sense; one would expect the excessively valuable and chemically complex drug-related patents would be difficult to understand or properly adjudicate to those not technically trained, such as district court judges; it suggests at least on some level that the PTAB could be preferable given the administrative tribunal’s technical backgrounds. Of course, that only works if PTAB proceedings were being used as a true substitute for validity.

272. See, e.g., Ferrum Ferro Capital, LLC v. Allergan Sales, LLC, IPR2015-00858, Paper No. 1 at 2 (P.T.A.B. Mar. 9, 2016).

273. Jonathan J. Darrow et al., *The Generic Drug Industry Embraces a Faster Cheaper Pathway for Challenging Patents*, APPLIED HEALTH ECON. & HEALTH POL’Y (2018); see also Joseph Herndon, *IPRs Threatened/Filed as Money-Making Strategy*, PATENTDOCS, (Aug. 16, 2016), <https://www.patentdocs.org/2016/08/iprs-threatenedfiled-as-money-making-strategy.html>. The timing of the Spangenberg/Bass petitions’ first filings and the very public nature of their announcements, right before the Senate Judiciary Committee was set to vote on the Innovation Act, suggests that their effort—and the firestorm of criticism of the IPR system from pharmaceutical advocates—was targeted to disrupt the until-then-smooth legislative process for the Innovation Act. Representatives of that entity have later confirmed to one of us (Mr. Stroud) that this was indeed their goal. If you do not have a lobby of your own, why not co-opt a powerful one?

forced in 2016 to return the \$700 million in funding they had secured for the project, and their filings had little impact after the first wave of panic.²⁷⁴

How were these petitioners able to use the administrative conflict between the FDA and the USPTO for political or financial gain? First, the Hatch-Waxman Act requires new drug applicants to list their most valuable patents covering their approved drugs in the Orange Book publicly, making it easy for anyone to identify the crown jewels of an Orange Book-listed patent portfolio. And while a given FDA-approved drug may have a handful of Orange Book-listed patents, oftentimes a single Orange Book-listed patent is responsible for the innovative drug's continued exclusivity.²⁷⁵ When a single Orange Book-listed patent (or even a handful) is the main deterrent preventing generic market entry, motivated financiers could use AIA proceedings to target them, some by seeking to manipulate the innovator's stock price by filing a petition, others by threatening to file the petition and seeking monetary compensation from the innovator in return for not filing. Still others have filed proceedings after other generic competitors would be time-barred, creating an opportunity for them to rejoin the challenge and avoid the bar.²⁷⁶ It would be possible, too, to have major market influence if a motivated financier were to successfully challenge all remaining patent claims covering a company's most profitable (or only) drug product as the eventual cancellation of the patent might sink the company, help a rival, or even open the door to mergers and acquisitions. Said attempts would certainly affect value.²⁷⁷

274. See Stephen Foley & David Crow, *Kyle Bass Returns Funds amid Retreat on Pharma Shorting Campaign*, FIN. TIMES (Feb. 23, 2016), <https://www.ft.com/content/0ffc05d2-d97e-11e5-98fd-06d75973fe09>; see also J. Gregory Sidak & Jeremy O. Skog, *Attack of the Shorting Bass: Does the Inter Partes Review Process Enable Petitioners to Earn Abnormal Returns?*, 63 UCLAL. REV. DISCOURSE 120, 132, 138–40, 147 (2015) (noting that, while the day the first IPR was filed against Acorda its stock dropped 10%, it dropped less than 5% after the second day, actually rose by 2.49% the day the third IPR was filed, and dropped less than 2% after the fourth; and after the first two IPRs were denied, the company's share price leapt substantially).

275. See Kenneth J. Costa, Note, *Patent System Manipulation: Hedge Funds Abusing IPR, Poor Patent Quality & Pharmaceutical Monopolies*, 35 CARDOZO ARTS & ENT. L.J. 177, 178, 184, 186 (2016); Edward A. Meilman et al., *Due Diligence in Transactions Involving Intellectual Property*, IP LITIGATOR 7, 10 (2012); Vishnubhakat et al., *supra* note 65, at 62.

276. See Kevin Penton, *NY Reps Seek to Curb Hedge Funds' Use of AIA Reviews*, LAW360 (Dec. 5, 2016, 8:47 PM), www.law360.com/assetmanagement/articles/869373.

277. Note that recently, the litigation financier Burford Capital has been active, both in its own name and as Neptune Generics, challenging Orange Book-listed patents. See, e.g., *Corcept Therapeutics Inc. (CORT) Q4 2018 Earnings Conference Call Transcript*, MOTLEY FOOL (Feb. 26, 2019, 1:57 PM) [hereinafter *Cort Conference Call*], <https://www.fool.com/earnings/call-transcripts/2019/02/26/corcept-therapeutics-incorporated-cort-q4-2018-ear.aspx> ("Neptune Generics, a subsidiary of the litigation finance

As “any person” not the patent owner can challenge patents via AIA proceedings, and challengers need no reason to file, AIA proceedings have introduced a new, unanticipated, often duplicative cost to bringing innovative medicines to patients, particularly where Congress has already mandated district court proceedings to resolve brand/generic disputes.²⁷⁸

As it relates to biosimilar applicants, while it is still early in that regime’s life, scholar Kevin Noonan, in partnership with his firm MBHB, has written a helpful and comprehensive listing of the biosimilar applicants and the stage of their pursuits to date.²⁷⁹ He updates it regularly; the following is based on the June 2018 report. He notes that since passage, the FDA has had twenty-four biosimilar applicants, and eleven biosimilars have been approved.²⁸⁰

BIOLOGIC DRUG	BIOSIMILAR (PROVIDER)
Neupogen® (filgrastim)	Zarxio® (Sandoz)
Neulasta® (pegfilgrastim)	Fulphila™ (Mylan/Biocon)
Enbrel® (etanercept)	Erelzi® (Sandoz)
Herceptin® (trastuzumab)	Ogivri (Mylan/Biocon)
Remicade® (infliximab)	Inflectra® (Pfizer); Renflexis® (Bioepsis); Ixifi (Pfizer)
Humira® (adalimumab)	Amjetiva® (Amgen), Cyltezo (Boehringer Ingelheim)
Avastin® (bevacizumab)	Mvasi (Amgen/Allergan)
Epogen®/Procrit® (epoetin alfa)	Retacrit (Pfizer/Hospira)

firm, Burford Capital, an entity that does not, to our knowledge, manufacture, sell or distribute any medications, has requested an inter partes review of our ‘348 patent, one of the four we’ve asserted against Teva that concern methods of dosing Korlym. Recently, the Patent Trial and Appeal Board, or PTAB, agreed to let Neptune’s IPR go forward.”).

Burford recently took aim at Opiant Pharmaceuticals and filed fifteen IPRs on all remaining patents covering naloxone (branded as Narcan), a long-known drug that now sells for \$150 in intranasal form and helps reverse opioid overdoses. *See* Richard Lloyd, *Burford Takes Aim at Opioid Overdose Medication in Series of IPRs*, IAM (Feb. 21, 2019), <https://www.iam-media.com/finance/burford-takes-aim-against-opioid-overdose-medication-series-iprs>. So at least some financial firms seem to recognize the value of such proceedings. *See* Katharine Wolanyk, *The PTAB’s Dramatic Effect on Patent Value and Corresponding Disincentives to Capital Allocation*, BURFORD CAP. (Sept. 15, 2017), <http://www.burfordcapital.com/blog/ptab-fifth-anniversary-patent>.

278. Interestingly, if unrelatedly, the Supreme Court recently granted certiorari on the question of whether “person” includes the government for purposes of filing post-grant challenges. *Return Mail, Inc. v. U.S. Postal Serv.*, 868 F.3d 1350 (Fed. Cir. 2017), *cert. granted*, 139 S. Ct. 397 (Oct. 26, 2018) (No. 17-1594).

279. *See* Kevin E. Noonan, *Status of U.S. Biosimilar Approvals and Pending Applications*, PATENTDOCS (June 28, 2018), <https://www.patentdocs.org/2018/06/status-of-us-biosimilar-approvals-and-pending-applications.html>.

280. *Id.*

Noonan notes that approval has been (relatively) rapid, with those granted taking ten to twenty months on average from FDA acceptance to approval, though he notes that Pfizer/Hospira's Retacrit (a biosimilar of Epogen/Procrit) took forty-two months for the FDA to review.²⁸¹ He caveats his findings with the fact that most of the approved U.S. biosimilars had already been approved in Europe, meaning studies, results, and other synergies were available early; he uses the lengthy Retacrit saga to demonstrate the onerous burden a "new" biosimilar applicant might have proving purity, safety, and efficacy, much less addressing patent protection.²⁸²

Noonan also notes that, as of June, fourteen applications are pending²⁸³:

BIOLOGIC DRUG	BIOSIMILAR APPLICANTS
Neulasta®	Apotex, Sandoz, Coherus
Neupogen®	Apotex, Adello Biologics
Lantus®	Samsung Bioeopsis/Merck; Mylan/Biocon
Rituxan®	Teva/Celltrion; Sandoz
Herceptin®	Teva/Celltrion; Amgen/Allergan; Samsung Bioeopsis/Merck; Pfizer
Humera®	Sandoz

He notes that, of those, many are embroiled in complex patent BPCIA litigation²⁸⁴:

281. *Id.*

282. *Id.*

283. *Id.*

284. *Id.* (alterations added).

BIOSIMILAR/COMPANY	RP/RPS	LITIGATION TYPE/VENUE	STATUS/OUTCOME
Pegfilgrastim (Apotex) Filgrastim (Apotex)	Neulasta®/ Neupogen® Amgen	DC: S.D. Fla. CAFC	Preliminary injunction; noninfringement; CAFC affirmed
Pegfilgrastim (Coherus)	Neulasta®/ Amgen	DC: D. Del. CAFC	D. Del.: Dismissed FRCP 12(b)(6); CAFC: Appeal pending
Trastuzumab (Pfizer)	Herceptin®/ Genentech	DC: D. Del.	Pending
Filgrastim (Adello Biologics)	Neupogen®/ Amgen	DC: D. N.J.	Pending
Rituximab (Teva/Celltrion)	Rituxan®/ Genentech	DC: N.D. Cal. (DJ filed); D. N.J.	N.D. Cal: Dismissed FRCP 12(b)(6) D. N.J.: Pending
Trastuzumab (Teva/Celltrion)	Herceptin®/ Genentech	DC: N.D. Cal. (DJ filed); D. Del.	N.D. Cal: Dismissed FRCP 12(b)(6) D. Del.: Pending
Trastuzumab (Amgen/Allergan)	Herceptin®/ Genentech	DC: D. Del.	Pending
Rituximab (Sandoz)	Rituxan®/ Genentech	DC: D. N.J. (DJ filed)	Pending
Adalimumab (Sandoz)	Humira®/ AbbVie	PTAB	IPR petition denied
Trastuzumab (Samsung Bioepsis)	Herceptin®/ Genentech	PTAB	IPR petition denied

Of those, he notes that at least Humira and Herceptin have had patents challenged in IPR (though it is hard to determine which patents would have made it into the dispute); his tracking includes a tranche of five IPRs filed against AbbVie patents covering Humira by Coherus and Boehringer Ingelheim, which resulted in claims of three

patents being cancelled,²⁸⁵ though those are currently on appeal.²⁸⁶ Note that AbbVie reportedly has upwards of 240 patent assets or pending applications covering its Humira product; these three challenged patents are not the only patents preventing biosimilar entrance, not by a longshot;²⁸⁷ the entire cost of the parallel proceedings, pending since 2016, are duplicative and, some might argue, inefficient.

Given this, at least in Orange Book-listed or Purple Book-associated patents undergoing challenges from generic/biosimilar aspirants, rather than provide a faster and more cost-effective means to adjudicate the validity of issued patents, AIA proceedings here add duplicative cost and inject unnecessary complexity into these disputes. The data bears this out; over two-thirds of IPRs filed on Orange Book-listed patents are filed *after* a generic manufacturer has been sued for infringement—a fact that unfortunately lends itself to parallel proceedings unlikely to resolve or simplify each other.²⁸⁸ This is not surprising, given the reward of the 180-day exclusivity for being the first aNDA filer—which serves to incentivize the potential aNDA filer to file an aNDA prior to filing a petition for either inter partes or post-grant review.

We note the number of IPR proceedings challenging Orange Book-listed patents has risen steadily since the procedures were first implemented.²⁸⁹ We provide discrete examples below that further illustrate the deleterious effect that AIA proceedings have had on the delicate balance created by the BPCIA and the Hatch-Waxman Act.

285. *Coherus BioSciences, Inc. v. AbbVie BioTech., Ltd.*, IPR2016-00172, Paper No. 60 at 2 (P.T.A.B. May 16, 2017); IPR2016-00-188, Paper No. 54 at 2 (P.T.A.B. June 9, 2017); IPR2016-00-189, Paper No. 56 at 2 (P.T.A.B. June 9, 2017), -408, Paper No. 46 at 2 (P.T.A.B. July 6, 2017); IPR2016-00-409, Paper No. 46 at 2 (P.T.A.B. July 6, 2017), collectively found some claims of 8,889,135, 9,017,680, and 9,073,987 unpatentable as obvious.

286. *Coherus BioSciences Inc. v. AbbVie Biotech. Ltd.*, No. 17-2304, Paper 61 at 2 (P.T.A.B. July 14, 2017).

287. Sally Turner, *Humira: The Highs and Lows of the World's Best Selling Drug*, PHARMACEUTICAL TECH. (Sept. 5, 2018), <https://www.pharmaceutical-technology.com/features/humira-abbvie-drug>.

288. Jonathan J. Darrow et al., *Will Inter Partes Review Speed US Generic Drug Entry?*, 35 NATURE BIOTECH. 1139, 1140 (2017).

289. Darrow et al., *supra* note 273.

1. Example 1: Novartis Pharmaceuticals Corp. v. Breckenridge Pharmaceutical, Inc.

Generic manufacturers have used the post-grant review process concurrently with federal court litigation as outlined in the Hatch-Waxman Act to increase cost and the likelihood that a patent that covers an approved pharmaceutical drug could be cast into doubt.

On October 22, 2014, Novartis Pharmaceuticals Corp. sued Breckenridge Pharmaceutical, Inc., Roxane Laboratories, Inc., and Par Pharmaceutical, Inc. as result of their aNDA filings seeking authority to market a generic version of Zortress.²⁹⁰ While the district case was ongoing, Par Pharmaceutical, Inc. filed the first of two petitions for IPR on October 21, 2015, challenging several claims of one of three patents asserted by Novartis at the district court.²⁹¹ Par Pharmaceutical filed its second petition on May 17, 2016, directed to a claim inadvertently omitted from the earlier filed petition, over one year after Novartis filed its complaint.²⁹² The PTAB instituted the first of Par Pharmaceutical's petitions on April 29, 2016, and within a month, Breckenridge²⁹³ and Roxane Laboratories²⁹⁴ filed multiple petitions similar to those filed by Par Pharmaceuticals and motioned the PTAB for joinder with the Par petitions. Par also motioned for joinder of its later filed petition with their earlier filed one. The PTAB granted Breckenridge's Motion, granted-in-part Roxane's Motion, and denied Par's Motion for joinder.²⁹⁵ The granted motions for Breckenridge and Roxane involved the same claims with similar arguments to those asserted by Par in their earlier filed petition.²⁹⁶

Here, Breckenridge and Roxane Laboratories took advantage of an exception to 35 U.S.C. § 315(b), also known as the one-year bar.

290. See *Novartis Pharm. Corp. v. Breckenridge Pharm., Inc.*, 248 F. Supp. 3d 578, 600 (D. Del. 2017), *rev'd*, 2018 U.S. App. LEXIS 34462 (Fed. Cir. 2018) (holding for Novartis that Breckenridge Pharmaceutical, Roxane Laboratories, and Par Pharmaceutical induced infringement for generic drug patents).

291. See *Par Pharmaceutical, Inc. v. Novartis AG*, IPR2016-00084, Paper No. 2 at 1 (P.T.A.B. Oct. 26, 2015).

292. *Par Pharmaceutical, Inc. v. Novartis AG*, IPR2016-01059, Paper No. 1 at 1 (P.T.A.B. May 17, 2016).

293. See *Breckenridge Pharm., Inc. v. Novartis AG*, IPR2016-01023, Paper No. 4 at 1 (P.T.A.B. May 10, 2016); *Breckenridge Pharm., Inc. v. Novartis AG*, IPR2016-01103, Paper No. 1 at 1 (P.T.A.B. May 26, 2016).

294. See *Roxane Labs., Inc. v. Novartis AG*, IPR2016-01102, Paper No. 2 at 1 (P.T.A.B. May 26, 2016).

295. *Roxane Labs., Inc.*, IPR2016-01102, Paper No. 16 (P.T.A.B. Oct. 27, 2017).

296. *Id.*

Petitions for IPR may not be instituted if the petition is filed more than one year after the date at which the petitioner is served with a complaint alleging infringement of the patent in question.²⁹⁷ However, § 315(b) explicitly states the one year bar does not apply to joinder under subsection (c).²⁹⁸ The next subsection, § 315(c), empowers the Director, at his or her discretion, to join as a party to an IPR any person who properly filed a petition under § 311 that “the Director . . . determines warrants the institution of an inter partes review under [§] 314.”²⁹⁹ Despite filing petitions one year after having been sued by Novartis, Breckenridge and Roxane Laboratories circumvented the time bar limitation and joined Par’s instituted petition.³⁰⁰

Rather than file merits challenges, generic manufacturers are increasingly requesting joinder onto earlier filed petitions for IPRs. By requesting joinder, the later petitioners can ensure that they are a party to any settlement between the innovator and the earlier petitioner.³⁰¹ And the petitions filed by Par, Breckenridge, and Roxane Laboratories all ran in parallel to the district court Hatch-Waxman Act litigation, further increasing Novartis’ litigation costs and potentially delaying market entry for the first aNDA filer.³⁰² The IPR system, given the joinder rules, can make it more difficult for the pharmaceutical innovator to reach a settlement with the earlier petitioner as the later filers can simply step into the shoes of the earlier filer and continue the IPR.³⁰³ Neither increasing the innovator’s litigation costs nor decreasing the likelihood of settlement are in the public interest.

297. See 35 U.S.C. § 315(b) (2012).

298. See *id.*

299. § 315(c).

300. See *Breckenridge Pharm., Inc. v. Novartis AG*, IPR2016-01023, Paper No. 5 at 1 (P.T.A.B. May 10, 2016); *Breckenridge Pharm., Inc. v. Novartis AG*, IPR2016-01103, Paper No. 4 at 1 (P.T.A.B. May 26, 2016); see also *Roxane Lab., Inc. v. Novartis AG*, IPR2016-01102, Paper No. 3 at 1 (P.T.A.B. May 26, 2016).

301. See Marianne Terrot et al., *Post-Grant Proceedings as a Freedom-to-Operate Tool*, LAW360 (Oct. 30, 2017, 10:19 AM), <https://www.law360.com/articles/974387/post-grant-proceedings-as-a-freedom-to-operate-tool>.

302. See *Novartis Pharm. Corp. v. Breckenridge Pharm., Inc.*, 248 F. Supp. 3d 578, 600 (D. Del. 2017).

303. See Michael Loney, *They Tried to Make Me Go to PTAB . . .*, 244 MANAGING INTELL. PROP. 10, 20 (2014).

2. *Example 2: AstraZeneca AB v. Aurobindo Pharmaceuticals Ltd.*

As another example, on May 23, 2014, AstraZeneca sued Aurobindo Pharma³⁰⁴ and Wockhardt Bio AG because of their submission of an Abbreviated New Drug Application under § 505(j) of the Federal Food, Drug, and Cosmetic Act to the FDA seeking approval to market and sell a generic version of AstraZeneca's saxagliptin prior to the expiration of AstraZeneca's Orange Book-listed patent, RE'186. AstraZeneca sued other generic manufacturers, including Mylan Pharmaceuticals Inc., on June 2, 2014.³⁰⁵ On October 8, 2014, the court consolidated the numerous filed civil actions, and held a three-day bench trial on the matter on September 19 through September 21, 2016, with the sole issue before the court—an obviousness-based invalidity defense.³⁰⁶ On February 2, 2017, the district court found none of the asserted claims invalid for obviousness.³⁰⁷ Mylan filed their appeal to the Federal Circuit on March 9, 2017, but by May 24, 2018, a few weeks before the oral arguments, Mylan and AstraZeneca jointly moved the court to dismiss the appeal.³⁰⁸

While the district court litigation and appeal were ongoing, Mylan petitioned the USPTO to also review the RE'186 patent.³⁰⁹ On June 4, 2015, more than one year after the original complaint was filed, Mylan petitioned for IPR of several claims of the RE'186 patent.³¹⁰ Although the petition was initially denied, Mylan filed and was granted a Request for Rehearing, and the petition was eventually instituted on all challenged claims under an obviousness-theory of unpatentability.³¹¹ Then several other generic manufacturers, including Aurobindo Pharma and Wockhardt Bio AG, filed separate follow-on petitions on the same grounds of unpatentability stated in the Mylan petition, and requested and were granted joinder under 35 U.S.C. § 315(c).³¹² On August 18 2017, the PTAB rendered their

304. *AstraZeneca AB v. Aurobindo Pharm. Ltd.*, 232 F. Supp. 3d 636, 639 (D. Del. 2017).

305. *AstraZeneca AB v. Mylan Pharm., Inc.*, 72 F. Supp. 3d 549, 551 (D. Del. 2014).

306. *AstraZeneca AB*, 232 F. Supp. 3d at 639.

307. *Id.* at 649.

308. *AstraZeneca AB v. Mylan Pharm., Inc.*, Nos. 2017-1777, 2017-1778, 2017-1779, 2017 WL 3951871, at *2 (Fed. Cir. 2017).

309. *Mylan Pharm., Inc. v. AstraZeneca AB*, IPR2015-01340, Paper No. 3 at 1 (P.T.A.B. June 4, 2015).

310. *Id.*

311. *Mylan Pharm., Inc.*, IPR2015-01340, Paper No. 79 at 53 (P.T.A.B. Aug 18, 2017).

312. *Wockhardt Bio AG v. AstraZeneca AB*, IPR2016-01029, Paper No. 15 at 2 (P.T.A.B. Aug. 23, 2016); *Aurobindo Pharma U.S.A., Inc. v. AstraZeneca AB*, IPR2016-01117, Paper No. 3 at 1 (P.T.A.B. June 2, 2016).

Final Written Decision finding all challenged claims to not have been unpatentable by a preponderance of the evidence.³¹³ Mylan filed its notice of appeal at the Court of Appeals for the Federal Circuit on October 19, 2017 and eventually moved to dismiss.³¹⁴

3. *Example 3: Eli Lilly & Co. v. Teva Parenteral Medicines, Inc.*

A particular egregious example of the unforeseen effects introduced by the IPR procedures outlined in the AIA occurred during Eli Lilly's litigation over its patent (U.S. Patent 7,772,209; the '209 patent) covering the co-administration of its chemotherapeutic drug, Alimta, with folic acid and vitamin B12.³¹⁵ Teva Parental Medicines, Inc., Barr Laboratories, Inc., and APP Pharmaceuticals filed separate aNDAs seeking approval to market generic versions of Alimta, with each aNDA including a Paragraph IV certification against the '932 patent.³¹⁶ Eli Lilly sued all three generic manufacturers for which two trials were conducted, one on validity and a second on infringement.³¹⁷ On the first trial, the district court found the patent not invalid on March 31, 2014.³¹⁸ Regarding the second trial, the district court held on August 25, 2015 all three generic manufacturers to indirectly infringe claims of the '209 patent.³¹⁹ All three generic filers appealed both decisions to the Federal Circuit, but the court on January 12, 2017 affirmed the district court's decisions on validity and infringement.³²⁰

While the appeals were pending, Neptune Generics, LLC, although not an aNDA-filer on record and itself an agent of litigation investment firm Gerchen Keller Capital,³²¹ filed multiple petitions at

313. Mylan Pharm., Inc. v. AstraZeneca AB, IPR2015-01340, Paper No. 79 at 53 (P.T.A.B. Aug 18, 2017).

314. Motion to Dismiss at 3, Mylan Pharm., Inc. v. Research Corp. Tech., No. 2017-2088, 2017-2089, 2017-2091 (Fed. Cir. Oct. 19, 2017).

315. Eli Lilly & Co., v. Teva Parenteral Meds., Inc., No. 1:10-cv-01376, 2014 WL 1350129, at *1 (S.D. Ind. Mar. 31, 2014).

316. *Id.* at *2.

317. *Id.* at *1.

318. *Id.* at *16.

319. Eli Lilly & Co. v. Teva Parenteral Meds., Inc., 126 F. Supp. 3d 1037, 1043 (S.D. Ind. 2015).

320. See Eli Lilly & Co. v. Teva Parenteral Meds., Inc., 845 F.3d 1357, 1376 (Fed. Cir. 2017).

321. There have been conflicting reports over who fully controls Neptune—Burford Capital or Gerchen Keller Capital. See, e.g., *Cort Conference Call*, *supra* note 277.

the USPTO challenging the validity of the '209 patent.³²² According to Lilly's Preliminary Response,³²³ "[w]hen Neptune first raised its allegations regarding the '209 patent with Lilly, it indicated a willingness to forget all about them and not challenge the '209 patent if Lilly provided Neptune with some sort of consideration in return."³²⁴ Soon after, a late aNDA filer, Sandoz, Inc. filed its own separate petition asserting the claims of the '209 patent were obvious over the same prior art of record in the 2014 district court litigation.³²⁵ By 2016, all three petitions were instituted and other late aNDA filers, and even the early aNDA filers including Teva, filed their own petitions and joined the Neptune Generics' and Sandoz's petitions.³²⁶ By late 2017, the PTAB issued their Final Written Decision on the Neptune Generics' and Sandoz's petitions, finding the Petitioners failed to demonstrate the claims of the '209 patent are unpatentable.³²⁷ The matters continue as the parties of record filed notices of appeal on the Neptune Generics' and Sandoz's petitions.³²⁸

Eli Lilly is not alone in having to curtail the exploits of financial firms that have used the IPR process for their own financial gain, some spectacularly unsuccessfully,³²⁹ and some under the guise of generic drug companies who act without intent to produce a generic product, further confusing things.³³⁰ However, with Eli Lilly, the facts are still more troubling, in that the early aNDA filers then joined and thus were able, after a time-bar, to attempt to cancel Eli Lilly's patent outside the purviews of the Hatch-Waxman Act, despite presence of otherwise-barred parties and the cost and expense of a completed

322. See *Neptune Generics, LLC v. Eli Lilly & Co.*, IPR2016-00237, Paper No. 84 at 85–86 (P.T.A.B. Oct. 5, 2017); *Neptune Generics, LLC v. Eli Lilly & Co.*, IPR2016-00240, Paper No. 8 at 70–71 (P.T.A.B. Oct. 5, 2017).

323. See *Neptune Generics, LLC*, IPR2016-00237, Paper No. 10 at 4; *Neptune Generics, LLC*, IPR2016-00240, Paper No. 9 at 4.

324. See *Neptune Generics, LLC*, IPR2016-00237, Paper No. 10 at 4.

325. See *Sandoz Inc. v. Eli Lilly & Co.*, IPR2016-00318 Paper No. 2 at 59 (P.T.A.B. Dec. 14, 2017) (objecting to pieces of evidence and claimed Lilly's '209 patent was obvious before its implementation).

326. See *Wockhardt Bio AG v. Eli Lilly & Co.*, IPR2016-01393, Paper No. 9 (P.T.A.B. Nov. 21, 2016).

327. See *id.*

328. Brief for Petitioner at 2, *Neptune Generics, LLC v. Eli Lilly & Co.*, No. 18-1257 (Fed. Cir. Dec. 6, 2017).

329. See Joseph Walker & Rob Copeland, *New Hedge Fund Strategy: Dispute the Patent, Short the Stock*, WALL ST. J. (Apr. 7, 2015, 7:24 PM), <http://www.wsj.com/articles/hedge-fund-manager-kyle-bass-challenges-jazz-pharmaceuticals-patent-1428417408>.

330. *Id.*

earlier Hatch-Waxman trial.³³¹ While the IPRs here may appear as redundant proceedings—themselves an unnecessary complication and expense—they can also provide various generic manufacturers with many opportunities at challenging the innovator’s patent in multiple forums as they jockey for position, with little way to settle generic entrants under Hatch-Waxman, and little likelihood of the generic actually cancelling all patents preventing market entry of generic competition.³³² Parallel proceedings like these were not contemplated when the Hatch-Waxman Act was passed, do not embody the purposes of the AIA itself, and are not an efficient means of litigating disputes like these that are already cabined and complicated by another set of long-implemented statutory schemes. Instead, they harass the patent owner, increase the litigation costs for all parties, and deter settlements with early aNDA filers.

4. *Examples 4 and 5: Biologics: Phigenix, Inc. v. Immunogen, Inc. and Coherus BioSciences, Inc. v. AbbVie BioTechnology, Ltd.*

Biologics IPRs, both those related to and outside of the aBLA context, have been met with mixed results.³³³ Immunogen develops complex biologicals like Kadcyra in partnership with other biopharmaceutical companies.³³⁴ In *Phigenix, Inc. v. Immunogen, Inc.*,³³⁵ Immunogen presented nonobviousness arguments and objective evidence of nonobviousness relating to the claim representing Immunogen’s commercial embodiment of Kadcyra in its

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

332. See *id.* at 947 n.41.

333. For early examples of biologics IPRs, see *Musculoskeletal Transplant Found. v. MiMedx Grp.*, IPR2015-00664, Paper No. 49 at 3 (P.T.A.B. Aug. 16, 2016); *Daiichi Sankyo Co. v. Alethia Biotherapeutics, Inc.*, IPR2015-00291, Paper No. 29 at 2 (P.T.A.B. June 15, 2015); *Baxter Healthcare Corp. v. Millenium Biologix, LLC*, IPR2013-00582, Paper No. 48 at 4 (P.T.A.B. Mar. 18, 2015); *Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, IPR2013-00128, Paper No. 92 at 2–4 (P.T.A.B. July 25, 2014) (granting Patent Owner’s Motion to Amend to the extent it requested to cancel the challenged claims because the request was non-contingent, but denying said Motion to the extent it requested entry of substitute claims); *St. Jude Medical v. Univ. of Mich.*, IPR2013-00041, Paper No. 69 at 3 (P.T.A.B. May 1, 2014); *Illumina, Inc. v. Trs. of Columbia Univ.*, IPR2012-00007, Paper No. 140 at 3 (P.T.A.B. Mar. 6, 2014); *Illumina, Inc. v. Trs. of Columbia Univ.*, IPR2012-00006, Paper No. 128 at 3 (P.T.A.B. Mar. 6, 2014).

334. See *Our History*, IMMUNOGEN, <https://www.immunogen.com/who-we-are/our-history> (last visited May 20, 2019).

335. IPR2014-00676, Paper No. 39 (P.T.A.B. Oct. 27, 2015).

POR.³³⁶ Immunogen submitted evidence of unexpected superior results, fulfilling a long-felt and unmet need, praise in the field, and commercial success.³³⁷ The PTAB found a sufficient nexus between the evidence of commercial success and the claimed invention:

Patent Owner also provides evidence [in the form of expert testimony analyzing sales and prescription data, and marketing and promotional efforts relating to Kadcyła] regarding the commercial success of T-DM1/Kadcyła. In view of the specific components recited in claim 8, i.e., a specific antibody, linker, and toxin, which are the same as those in T-DM1/Kadcyła . . . , we are persuaded that Patent Owner establishes a sufficient nexus in relation to the cited objective evidence of nonobviousness.³³⁸

The PTAB emphasized that it was persuaded because the patent owner had tied the specific disclosure in the specification and claim 8 to the evidence of unexpected results, praise, and commercial success.³³⁹ The PTAB proceeding occurred outside of the scope of any aBLA application, and Phigenix, as a non-practicing entity, lacked standing on appeal.³⁴⁰

Perhaps the first prime biologics example of parallel litigation including a duplicative PTAB component (given how little the BPCIA has been used to date) are the many petitions on various AbbVie patents³⁴¹ directed to Humira, most of which charge that some patents are invalid for obviousness; at least one set of eight IPRs was filed by Sandoz,³⁴² who has filed for an aBLA of Humira in February

336. *Id.* at 23.

337. *Id.* at 23–24.

338. *Id.* at 24.

339. *Id.* at 25.

340. *Phigenix, Inc. v. Immunogen, Inc.*, 845 F.3d 1168, 1170 (Fed. Cir. 2017) (holding that Phigenix lacked standing to seek judicial review of the PTAB's decision).

341. Such petitions include—but are not limited to—IPRs by Sandoz and Coherus BioSciences, which collectively found some claims of 8,889,135, 9,017,680, and 9,073,987 unpatentable but are currently on appeal. *See* *Boehringer Ingelheim Int'l GMBH v. AbbVie Biotechnology Ltd.*, IPR2016-00409, Paper No. 46 at 2 (P.T.A.B. July 6, 2017); *Boehringer Ingelheim Int'l GMBH v. AbbVie Biotechnology Ltd.*, IPR2016-00408, Paper No. 46 at 2 (P.T.A.B. July 6, 2017); *Coherus BioSciences Inc. v. AbbVie Biotechnology Ltd.*, IPR2016-00189, Paper No. 56 at 2 (P.T.A.B. June 9, 2017); *Coherus BioSciences Inc. v. AbbVie Biotechnology Ltd.*, IPR2016-00188, Paper No. 54 at 2 (P.T.A.B. June 9, 2017); *Coherus BioSciences Inc. v. AbbVie Biotechnology Ltd.*, IPR2016-00172, Paper No. 60 at 2 (P.T.A.B. May 16, 2017).

342. For instance, the '559 patent was the subject of one of eight IPRs Sandoz filed since July 2017 on patents relating to adalimumab. Sandoz has appealed the denial of Sandoz's petition on AbbVie's U.S. Patent 9,512,216.

of this year and was sued under the BPCIA, per the patent dance, on just one of the many patents surrounding Humira, on August 10, 2018 in the U.S. District Court in New Jersey.³⁴³ The complaint alleges that the remaining patents (at least 84) may be litigated after the 180-day notice provision is invoked.³⁴⁴ Before the BPCIA litigation against Sandoz even commenced, multiple parallel proceedings had been initiated.³⁴⁵

III. PROPOSALS TO MITIGATE THE CONFLICT

As demonstrated, post-grant review challenges in the biopharmaceutical context, while few and rarely successful, generally occur in parallel with Hatch-Waxman and BPCIA litigation and because of their nature, district court judges are often unable to stay the litigation pending the results of the challenges, resulting in costly, duplicative, and complicated conflicts. Moreover, these AIA proceedings conflict directly with their statutory mandate and run afoul of agency comity principles. This results in conflict between the statutes, a by-product of the unfortunate lack of foresight from the drafters of the AIA vis-à-vis pharmaceutical generic applicant-related litigation. The problem merits addressing immediately; the question is how. What means are fastest, least politically costly, and most likely to succeed?

As with any statutory conflict, there are three means of addressing the problem: legislative, judicial, and executive (i.e., administrative). This Article addresses each. We recommend administrative solutions.

A. *Legislative Solutions*

Given that the statutory conflict arises from the interplay between the FDA's and USPTO's regulatory framework, Congress has two options when considering legislative change in this fraught area: legislative change focused on the USPTO (and the reform measures of the 2011 AIA), or legislative change focused on the FDA (and reform measures directed toward the Hatch-Waxman Act and BPCIA approval pathways).³⁴⁶ Both present significant challenges, and both

343. See Complaint, *AbbVie Inc. v. Sandoz Inc.*, No. 3:18-cv-1266 (D.N.J. Aug. 10, 2018).

344. *Id.* at ¶¶ 4–5.

345. *Id.* at ¶ 2 (noting that numerous biosimilar companies filed IPR proceedings at the PTAB when they were confronted with AbbVie's patents before the BPCIA litigation process began).

346. See Alfred B. Engelberg, *Hatch Amendment Would Delay Generic Competition and Increase Drug Costs*, HEALTH AFF. BLOG (Nov. 9, 2018), <https://www.healthaffairs.org/doi/10.1377/hblog20181106.747590/full> (providing a detailed explanation of

have been floated as possible legislative solutions.³⁴⁷ Neither is easy; legislation is an arduous, unpredictable, and unwieldy process rife with unintended consequences (as should now be self-evident). But as this Article discusses, one of the two approaches—the FDA legislative reform approach—is far more likely, for complex political reasons, to succeed, though neither has much of a chance.

At bottom, the issue is one of scope. A change to the USPTO's rules—one exempting patents embroiled in the Hatch-Waxman Act or BPCIA litigation from post-grant review—would likely be industry-specific unless carefully tailored to address only the conflict between the statute, and even then is likely to meet opposition or become embroiled in further calls for patent reform (or counter-reform).³⁴⁸ Any change, even tangentially affecting drugs or drug pricing, is fraught these days and is unlikely to find a smooth path on the Hill, particularly under a President that has occasionally been critical of drug pricing, and with a Democratic House and White House hopefuls rolling out drug pricing reform bills in the House and Senate.³⁴⁹

A change in the FDA's approval rules would likely be industry-neutral (at least compared to an industry-specific carve out of the USPTO's jurisdiction), cabined to preventing administrative conflict between the two statutes, and (in theory) would largely pass unmolested and unmarred by the ongoing calls for reform at the USPTO by other industry groups, on 35 U.S.C. § 101 subject matter and other contentious issues. It seems more likely to result in the singular goal of streamlining generic approvals by avoiding duplicative costs in the following: parallel litigation that is unlikely to be stayed;

Congress's two options for legislative reform in addressing the statutory conflict and identifying the effects of each one).

347. Compare Philip S. Johnson, *Hatch Amendment Would Preserve Balanced Incentives for Pharmaceutical Innovation and Drug Affordability*, HEALTH AFF. BLOG (Nov. 9, 2018), <https://www.healthaffairs.org/doi/10.1377/hblog20181106.217086/full>

(maintaining that legislative reform aimed at the procedures established by the Hatch-Waxman Act, which balances innovation incentives and drug affordability, would discourage pharmaceutical innovation by “giving would-be generics unnecessary second chances to invalidate important drug patents” after an unsuccessful first challenge), with Engelberg, *supra* note 346 (asserting that legislative reform targeting the IPR proceedings authorized by the AIA would delay generic competition by enabling the owners of non-meritorious patents to profit from their mere existence through the assertion of frivolous patent infringement claims, which IPRs have successfully curtailed).

348. See *infra* Section III.A.I and accompanying text.

349. See, e.g., Prescription Drug Price Relief Act of 2019, S. 102, 116th Cong. (2019) (Sen. Bernie Sanders (I-VT)).

and USPTO proceedings that are not truly intent on questioning patentability, but rather meant to increase costs and complexity for generics not in pole position under the Hatch-Waxman Act.

But even if preferable, and even if politically achievable, FDA legislative change is unlikely to fully address the issue, for multiple reasons. It would not obviate the core of the conflict; that is, a system that encourages parallel proceedings with little to no means of an early resolution, or of a stay or diversion of either's end. Altering either the Hatch-Waxman Act or the BPCIA litigation procedures to delay them for post-grant review seems unlikely, was unintended, and would not mitigate the conflict between the two. Nonetheless, tying a proposal that would affect a parallel post-grant regime—such as making it optional for generic entrants to use either district court or administrative challenges, but not both—holds promise, as long as potential political opponents and Congressional Budget Office (CBO) scoring see it as industry-neutral and as increasing efficiency, rather than negatively affecting drug prices. This Article details past examples of these approaches, USPTO or FDA reform, which hold promise, but in the end, neither seems unlikely to garner enough legislative consensus or political will to pass.

1. *USPTO-centric legislation: The Innovation Act and the CBO*

Given the unexpected impact of AIA proceedings on the delicate balance sought by the BPCIA and the Hatch-Waxman Act, several bills have unsurprisingly been proposed with language intended to mitigate the conflict. In February 2015, Representative Bob Goodlatte introduced the Innovation Act, which would have required petitioners to certify that they “do not own and will not acquire a financial instrument . . . designed to hedge or offset any decrease in the market value of an equity security of the patent owner or an affiliate of the patent owner” after filing the petition, provided that the petitioner or the real party in interest of the petitioner has not been sued or charged with infringement of the patent.³⁵⁰ While the initial draft of the Innovation Act sought to close the door on hedge funds using AIA proceedings against pharmaceutical and biotechnology companies for financial exploitation, some viewed the bill as not going far enough to address the pronounced effect the

350. See H.R. REP. NO. 114-235, at 15 (2015).

AIA was having on the biopharma industry.³⁵¹ According to PhRMA, “[a]llowing IPRs to interfere with the rules and processes established under [Hatch-Waxman and the BPCIA] create[s] significant unpredictability regarding patents, increases business uncertainty, and undermine[s] incentives to invest in developing new treatments cures.”³⁵²

In response, Representative Marian Elaine “Mimi” Walters of California proposed an amendment to the Innovation Act that would have exempted biopharmaceutical patents subject to Hatch-Waxman and BPCIA proceedings from IPR.³⁵³ This amendment proved too controversial, and was unfortunately withdrawn, in part due to the CBO estimating that exempting biopharma patents from IPR would cost taxpayers \$1.3 billion over ten years.³⁵⁴ The CBO’s estimates relied heavily on the CBO’s assumption that AIA proceedings do indeed expedite disputes governed by the Hatch-Waxman Act and the BPCIA; an assumption that has since been rebutted by recent history as well as industry experts.³⁵⁵ The CBO’s Cost Estimate for the America Invents Act itself was devoid of any federal budget savings related to the Act’s effect on generic or biosimilar approval.³⁵⁶ While informative, no study since has confirmed the CBO’s 2015 estimate nor considered the increase in legal costs borne by the biopharma industry because of having to defend its patents in duplicative proceedings. The notion that AIA proceedings expedite the elimination of “bad” patents that block generic or biosimilar entry appears even less likely to be true today, especially given that most of such proceedings occur concomitant with unstayed federal district court litigation.

351. See *Letters and Statements from Groups Opposed to H.R. 9*, INNOVATION ALLIANCE (June 25, 2015), http://innovationalliance.net/wp-content/uploads/2015/06/Letters-and-Statements-on-HR-9_062615-tc.pdf.

352. *Id.*

353. H.R. REP. NO. 114-235, at 184 (2015) (noting that Rep. Walters later withdrew the proposed amendment).

354. Joseph Walker, *Drug-Industry Rule Would Raise Medicare Costs*, WALL ST. J. (Aug. 31, 2015, 7:20 PM), <https://www.wsj.com/articles/drug-industry-bill-would-raise-medicare-costs-1441063248>.

355. Allison Gilchrist, *Patent Law Change Could Increase Health Costs by \$1.3 Billion over 10 Years*, PHARMACY TIMES (Oct. 16, 2015), <https://www.pharmacytimes.com/publications/issue/2015/october2015/patent-law-change-could-increase-health-costs-by-13-billion-over-10-years>. Note that the CBO scoring was provoked, in part, by the idea that the amendment was industry-specific; something that is debatable, as it is tied to a conflicting regulatory burden that—while relevant to only one industry—certainly does not favor one industry over another.

356. *Cost Estimate of H.R. 1249*, CONG. BUDGET OFF. (May 26, 2011), <http://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/122xx/doc12217/hr1249.pdf>.

Despite their forward thinking, however, neither the STRONG Patents Act nor the Innovation Act survived to reach the President's Office.³⁵⁷

The same year, Senator Chris Coons introduced the STRONG Patents Act, a bill that would impose a heightened standing requirement for AIA proceedings—essentially requiring a petitioner to have been sued or charged with patent infringement.³⁵⁸ (This proposal would have actually exacerbated the parallel proceedings problem, by forcing parties to file *after* suits were initiated and barring them from acting proactively, as the original Act intended).

The 115th Congress of 2016–2018 too saw attempts to curtail the effects of the AIA, albeit with more extreme proposals. The STRONG Patent Act was revived as the STRONGER Patents Act in the next Congress, though in revised form.³⁵⁹ Around the same time, the Restoring America's Leadership In Innovation Act, proposed by Representative Thomas Massie of Kentucky, sought to simply repeal most of the AIA, including abolishing post-grant review and inter partes review entirely.³⁶⁰ Given its extreme nature, many viewed that bill as dead on arrival.³⁶¹ These various attempts to amend or curtail the AIA have lacked sufficient support to advance Congress; thereby leaving the three administrative schemes—the Hatch-Waxman Act, the BPCIA, and the AIA—in tension.

2. *FDA-centric legislation: The Hatch Amendment*

In the summer of 2018, Senator Orrin Hatch filed a bill, the Hatch-Waxman Integrity Act of 2018, that would force generic or biosimilar manufacturers to choose between submitting an aNDA or an aBLA that relies on the innovator's clinical data package and engaging in the litigious framework of the statutes or challenging the patents in an AIA proceeding.³⁶² Exemplary language included: "(I) neither the

357. Klint Finley, *U.S. Senate Drives a Stake Through Heart of Patent Reform*, WIRED (May 21, 2014, 8:53 PM), <https://www.wired.com/2014/05/rip-innovation-act>.

358. See STRONG Patents Act of 2015, S. 632, 114th Cong. § 102(d) (2015).

359. See STRONGER Patents Act of 2017, S. 1390, 115th Cong. (2017).

360. See Restoring America's Leadership in Innovation Act of 2018, H.R. 6264, 115th Cong. § 4(a) (2018).

361. See, e.g., Dennis Crouch, *Legislation: Restoring America's Leadership in Innovation*, PATENTLY-O (July 2, 2018), <https://patentlyo.com/patent/2018/07/legislation-leadership-innovation.html> (noting that the proposed bill "has a 0% likelihood of passing" Congress).

362. BRIEF—Hatch Amendment to Incentivize Generic Drug Development, PHARMA LETTER (June 15, 2018) [hereinafter *Hatch Amendment*], <https://www.thepharmalletter.com/in-brief/brief-hatch-amendment-to-incentivize-generic-drug-development>.

applicant nor any party in privity with the applicant has filed, or will file, a petition to institute inter partes review or post-grant review of that patent.”³⁶³ A generic applicant of the Hatch-Waxman Act’s provisions could not challenge the validity of the patents both through AIA proceedings and through Hatch-Waxman district court litigation.³⁶⁴ According to Senator Hatch, the balance struck by the Hatch-Waxman Act of fostering generic drug competition while concurrently incentivizing pharmaceutical companies to create new medicines is upended or eviscerated by the AIA proceedings.³⁶⁵ As Senator Hatch states, his amendment would prohibit companies from using AIA proceedings to increase the pressures already brought by Hatch-Waxman litigation and would prevent the losers of Hatch-Waxman litigation from “getting a second bite at the apple” after the statutorily mandated District Court litigation.³⁶⁶

Unfortunately, former Congressman Henry Waxman³⁶⁷ has unequivocally stated that “he is strongly against” the Hatch-Waxman Integrity Act of 2018.³⁶⁸ Waxman has argued that the Hatch-Waxman Integrity Act of 2018 would “delay the ability to challenge and resolve invalid patents for brand-name drugs and thereby also delay development of lower-priced generics.”³⁶⁹ Waxman states that the IPR process provides several advantages:

- (1) inter partes reviews can be initiated shortly after granting a patent and are typically concluded in less than eighteen months in contrast to district court litigation which often takes two–three years to final verdict;
- (2) inter partes reviews can be initiated on patents not listed in the Orange Book that may be necessary for developing a generic medicine; and

363. Hatch-Waxman Integrity Act of 2018, S. 974, 115th Cong. § 5(c) (2018).

364. See Johnson, *supra* note 347 (explaining that the proposed amendment would allow parties to choose only one challenge procedure to employ instead of allowing them to enjoy the benefits of both systems).

365. See *Hatch Amendment*, *supra* note 362.

366. *Id.*

367. Former Rep. Waxman is, for obvious reasons, a compelling voice on this topic.

368. *Clause 8 Episode 6: Representative Henry Waxman*, HARRITY & HARRITY (Oct. 11, 2018), <https://harrityllp.com/henry-waxman-clause-8-episode-6>.

369. Henry Waxman et al., *Proposed CREATES Amendment Could Impede the Availability of Affordable Generic Drugs*, COMMONWEALTH FUND (July 17, 2018), <https://www.commonwealthfund.org/blog/2018/proposed-creates-amendment-could-impede-availability-affordable-generic-drugs>.

(3) exempting pharmaceutical patents from inter partes review entirely would mean that the pharmaceutical industry is treated differently from all other industries.³⁷⁰

Although Representative Waxman is correct regarding the general timelines regarding IPR, the vast majority of IPRs on small-molecule drugs occur after a Paragraph IV certification has been filed, making it likely that parallel litigation will occur.³⁷¹ In other situations, for example where a third party requests joinder to a petition for IPR, the PTAB is not restricted to the eighteen-month window for resolution of the IPR.³⁷² Waxman's third point is also self-defeating, as the Hatch-Waxman Act and the BPCIA (and thus the agencies and the courts) already treat pharmaceutical and biotechnology patents that cover FDA-approved medicines far differently from patents that cover other technologies—both beneficially and detrimentally.³⁷³ Patent term extensions, for example, are available only for pharmaceutical or biotechnology patents that cover an FDA-approved medicine.³⁷⁴ Similarly, the Hatch-Waxman Act has innovators publicly list the patents they believe read on their approved product in the public Orange Book—requiring innovators to expose which patents they deem most essential.³⁷⁵ And that's not even noting the mandatory interplay between the courts and the agency approval process.

Waxman's second argument, that IPRs can be initiated on patents not listed in the Orange Book, which might prevent or slow generic entry, is intriguing. However, this would not be litigated under the BPCIA's regimen, as the innovator may assert any patent potentially infringed by the aBLA applicant's product in such proceedings. Yet to Waxman's second argument, the proposal outlined would not preclude the patent office from reviewing the merits of such patents

370. *Id.*

371. See Prugo et al., *supra* note 268.

372. See Kiri Lee Sharon & Michele Simkin, *Timing Is Everything: Successful Joinder Motions at the PTAB*, PTAB TRIAL INSIGHTS (Oct. 19, 2016), <https://www.ptabtrialinsights.com/2016/10/timing-is-everything-successful-joinder-motions-at-the-ptab> (explaining that third-party joinder will lengthen the PTAB's review period for an IPR petition).

373. See Joanna Shepherd, *Disrupting the Balance: The Conflict Between Hatch-Waxman and Inter Partes Review*, 6 N.Y.U.J. INTELL. PROP. & ENT. L. 14, 45 (2016).

374. See *id.* at 23 (noting that the Hatch-Waxman Act permits an extension of the patent term specifically because of the delays resulting from the FDA approval process).

375. See Sokal & Gerstenblith, *supra* note 10 (describing the Orange Book listing requirement).

in AIA proceedings, as these patents would not be included in a Hatch-Waxman litigation.

In keeping with this proposal, a USPTO-centric legislative fix that recognizes the conflict between the two pathways and allows the FDA-centric and PTO-centric challenges to pass like ships in the night is a suitable remedy. But as readers will see, the U.S. government need not pass legislation to address the problem—administrative solutions exist that are far easier to implement and would not require engaging in the fraught and onerous legislative process (to the extent political consensus could even be reached).

B. *Judicial Solutions*

The outlook here is, as is generally the case for superstatutory policy-based concerns, dim.³⁷⁶ The judicial branch is tasked with addressing cases and controversies, not dictating policy outcomes.³⁷⁷ Anyone looking to the courts to save them or direct and guide policy proactively has a curious view of the judicial role in our system, and such a vain hope is likely prone to repeated disappointment. As the Supreme Court has routinely noted, the judicial role is one of calling balls and strikes, not addressing policy disputes.³⁷⁸ Judges cannot control which cases come to their dockets, nor which disputes before them are justiciable. Those on what they believe is the wrong side of a legislative problem are generally ill-served waiting for the appropriate judicial vehicle in which to challenge it. Doing so would be to invite judicial activism; it would also pave the way for unintended consequences. What's more, in terms of party disputes that might come before a court, it is difficult to envision one that would directly address the administrative conflict between FDA- and patent-centric disputes. Perhaps it is possible that, on appeal from a post-grant challenge, a district court BPCIA or Hatch-Waxman suit—

376. See, e.g., *SAS Inst. Inc. v. Iancu*, 138 S. Ct. 1348, 1357–58 (2018) (“Each side offers plausible reasons why its approach might make for the more efficient policy. But who should win that debate isn’t our call to make. Policy arguments are properly addressed to Congress, not this Court. It is Congress’s job to enact policy and it is this Court’s job to follow the policy Congress has prescribed.”).

377. See *Russo v. Ballard Med. Prods.*, 550 F.3d 1004, 1023 (10th Cir. 2008) (including the now-Justice Gorsuch, addressing the separation of powers).

378. See *John Roberts’ Baseball Analogy*, ABC NEWS (Sept. 12, 2005), <https://abcnews.go.com/Archives/video/sept-12-2005-john-roberts-baseball-analogy-10628259> (recounting the Chief’s now-famous confirmation hearing testimony); *Kagan on the Balls-and-Strikes Metaphor*, YOUTUBE (June 30, 2010), <https://www.youtube.com/watch?v=EAApRSLQcfM>.

or both—that the appellate court (or, in an even less likely outcome, the Supreme Court) might weigh in and resolve the dispute. But given the narrow mandate addressed to courts and the slim likelihood of a case appropriately raising the conflict, it seems unlikely that a court can solve the problem of administrative conflict between the schema. Add that to the delay that inheres in waiting for the appropriate judicial case to be raised between private parties and then appealed through the court and administrative systems, and you can see why a judicial resolution of the conflict is unlikely.

C. *Executive Solutions*

The last, and most promising, of the three options are executive, or regulatory, solutions. While this Article would endorse any positive attempts to mitigate the conflict, we do not deem longer-term legislative solutions like the Hatch Amendment or judicial action necessary (or politically and practically likely). It is within the power of the Trump administration and its delegated agencies, the FDA and the USPTO, to address and resolve much of the conflict.³⁷⁹ Indeed, it is our preferred and recommended means; it may be the means most preferred by the courts and Congress; it may also be the path of least resistance.³⁸⁰ It may not even require notice-and-comment rulemaking and could be implemented almost immediately.³⁸¹

This Article will not discuss “formal” APA rulemaking, a type of adjudicatory rulemaking that has fallen out of favor over the past forty years as an onerous and ossified means of promulgating regulations.³⁸² Most agencies today employ “informal” or “notice-and-comment” rulemaking, which has effectively replaced formal rulemaking as the first considered option for agency codification of rules.³⁸³

379. See Administrative Procedure Act, 5 U.S.C. §§ 552, 553 (2012) (laying out procedural requirements for formal, informal, and other forms of agency rulemaking).

380. See *SAS Inst. Inc.*, 138 S. Ct. at 1354–55 (finding that Congress imposes a “nondiscretionary duty” on the USPTO in determining whether to institute an inter partes review).

381. See Lubbers, *supra* note 200, at 471 (explaining that “U.S. agencies are seeking ways to circumvent the increasingly formal ‘informal’ rulemaking process,” which includes notice-and-comment rulemaking).

382. See *id.* at 473 (noting that even supposedly “informal” rulemaking has become ossified as the rulemaking process has become more complicated).

383. See Todd Garvey, Cong. Research Serv., R41546, A Brief Overview of Rulemaking and Judicial Review 1 (2017).

1. *Notice-and-comment rulemaking*

Both the FDA and the USPTO have substantive rulemaking authority delegated to them by Congress.³⁸⁴ Both can promulgate rules to mitigate the administrative conflict between them and the legislation discussed, a task easier than passing legislation through Congress and then implementing it. The USPTO could, for instance, issue a notice-and-comment rule that recognizes the Director's discretion at institution, and which enumerated the conflict between ongoing Hatch-Waxman or BPCIA litigation as one factor the PTAB could consider when deciding whether to institute a proceeding, in the interests of justice, systemic efficiency, and to address comity concerns.

Doing so, however, could spark concerns that such a rule might be outside of the Director's (or the Commissioner's) authority.³⁸⁵ For instance, in *SAS Institute Inc. v. Iancu*,³⁸⁶ the Supreme Court recently took a rather narrow view of the USPTO's ability to promulgate rules that stray too far from the statutory language.³⁸⁷ There, the Court held that the statutory grant did not allow the Director of the USPTO to promulgate rules allowing for partial institution.³⁸⁸ For the FDA's part, rulemaking is often an onerous and non-preferred means of policy implementation, as suggested by the FDA's general authority to—and preference for—guidance documents over rulemaking.³⁸⁹

Trying to implement a notice-and-comment rule would also involve notice requirements, delay, and would require a notice of proposed rulemaking and compliance with the Paperwork Reduction Act and other OMB-related regulatory review provisions.³⁹⁰ To wit, it could spark concerns that the rule would be “Economically Significant,” similar to the CBO scoring discussed earlier in this Article. It would

384. *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2142 (2016) (emphasizing the rulemaking authority granted to the USPTO by Congress with respect to inter partes review).

385. For an interesting take on the issue of the PTO's rulemaking authority and how the PTO promulgates rules both within and allegedly beyond their authority, see David A. Boundy, *Agency Bad Guidance Practices at the Patent and Trademark Office: a Billion Dollar Problem*, PATENTLY-O (Dec. 3, 2018), <https://patentlyo.com/lawjournal/2018/12/guidance-practices-trademark.html>. But see Vishnubhakat, *supra* note 77.

386. 138 S. Ct. 1348 (2018).

387. *Id.* at 1354–55 (“Where a statute’s language carries a plain meaning, the duty of an administrative agency is to follow its commands as written, not to supplant those commands with others it may prefer.”).

388. *Id.* at 1358.

389. See Stroud, *supra* note 146, at 629–30.

390. See Lubbers, *supra* note 200, at 473 (finding that informal rulemaking has procedurally ossified).

also beg whether such a rule was within the express grant provided by Congress, as at issue in *SAS Institute Inc. v. Iancu*, and would raise questions about whether it should be afforded *Chevron* deference.³⁹¹ While a potential avenue, the hurdles that rulemaking imposes make this a less-preferred option than those that follow.

2. *Administrative adjudication*

When Congress enacted the AIA and created IPR, it did not always give explicit guidance on how to administer certain provisions of the statute, but left gaps for the agency to fill. This was best demonstrated in two Supreme Court decisions from 2018, delivered on the same day, where the Court declared IPRs did not violate the separation of powers, and at the same time provided guidance declaring that the Director cannot grant partial institutions.³⁹² There, the Court noted that if “a lawful means exists for the Director to achieve his policy aims” he should use it, and not “be allowed to improvise on the powers granted by Congress’s by devising an extralegal path to the same goal.”³⁹³ Beyond ruling on partial institutions in *SAS Institute Inc. v. Iancu*, the Court did not comment directly on the Director’s broad discretionary authority regarding whether an IPR should be instituted.³⁹⁴ Or the Director’s broad authority over the proceedings in general.³⁹⁵

391. See *Chevron, U.S.A., Inc. v. Nat. Res. Def. Council*, 467 U.S. 837, 842–45 (1984) (elucidating the well-known deference standard courts administer when reviewing agency rulemakings).

392. See *Oil States Energy Servs., LLC v. Greene’s Energy Grp., LLC*, 138 S. Ct. 1365, 1377, 1379 (2018); see also *SAS Inst. Inc.*, 138 S. Ct. at 1358.

393. *SAS Inst. Inc.*, 138 S. Ct. at 1358 n.* (quoting *Civil Aeronautics Bd. v. Delta Air Lines, Inc.*, 367 U.S. 316, 330 (1961)).

394. See *id.* at 1356, 1358.

395. The Director has authority to conclude proceedings. See 35 U.S.C. § 318(b) (2012) (“[T]he Director shall issue and publish a certificate canceling any claim of the patent finally determined to be unpatentable, confirming any claim . . . determined to be patentable, and incorporating . . . any new or amended claim determined to be patentable.”). And the Director has authority to “establish[] and govern[]” everything between these two endpoints by promulgating regulations. See, e.g., § 316 (the Director may prescribe regulations that: “establish[] procedures for the submission of supplemental information after the petition is filed”; “set[] forth standards and procedures for discovery of relevant evidence”; “prescrib[e] sanctions for abuse of discovery, abuse of process, or any other improper use of the proceeding”; “provid[e] for protective orders governing the exchange and submission of confidential information”; “provid[e] for the filing by the patent owner of a response to the petition under section 313 after an inter partes review has been instituted”; “set[] forth standards and procedures for allowing the patent owner

To wit: § 314(a) of the AIA provides that the Director (or the PTAB under the delegation power of the Director)³⁹⁶ “may not authorize an inter partes review to be instituted unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least [one] of the claims challenged in the petition.”³⁹⁷ While the majority in *SAS Institute Inc. v. Iancu* concluded the plain meaning of §§ 314–318 indicated that the PTAB must address all challenged claims after institution in a final written decision, the dissent pointed out that the decision did not address the broad discretion given to the Director to institute a petition.³⁹⁸ Section 314 has been interpreted to give the Director broad discretion whether to even institute a petition; however, there are guidelines to guide his or her decision.³⁹⁹

Through precedential opinions, the Director, and thus the PTAB, can provide examples of how boards should interpret certain statutes or how they should decide.⁴⁰⁰ And the PTAB now has a new Precedential Opinions Panel, comprising at least the Director, the Chief APJ, and the Commissioner,⁴⁰¹ which is set to issue its first “binding” decision. These opinions are theoretically binding on all future PTAB decisions per the agency’s internal operating procedures, but are afforded almost no authority outside of these proceedings (or, perhaps, even in them) because *stare decisis* does not apply to agency decisions (and, we note, this alone could undermine administrative comity if these decisions do not factor in other agency/body goals and proceedings).⁴⁰²

to move to amend the patent”; and “provid[e] either party with the right to an oral hearing as part of the proceeding”); *see also* 37 C.F.R. §§ 41.1–.208 (2018). The Director’s regulations govern all aspects of the PTAB judges and their official duties.

396. *See* 37 C.F.R. § 42.2 (defining the terms most applicable to proceedings before the PTAB).

397. 35 U.S.C. § 314 (2012).

398. *SAS Inst. Inc.*, 138 S. Ct. at 1363–64 (Breyer, J., dissenting).

399. *See id.* at 1355–56; *see also* Gen. Plastic Indus. Co. v. Canon Kabushiki Kaisha, IPR2016-01357, Paper No. 19 at 15–16 (P.T.A.B. Sept. 6, 2017).

400. *See* Robert M. Yeh, *Precedential Decisions at the PTAB: An Endangered Species?*, 17 CHI.-KENT J. INTELL. PROP. 10, 14 (2018) (explaining precedential decisions).

401. *See* U.S. PAT. & TRADEMARK OFF., STANDARD OPERATING PROCEDURE 2 (REVISION 10): PRECEDENTIAL OPINION PANEL TO DECIDE ISSUES OF EXCEPTIONAL IMPORTANCE INVOLVING POLICY OR PROCEDURE, <https://www.uspto.gov/sites/default/files/documents/SOP2%20R10%20FINAL.pdf> (last visited May 20, 2019).

402. *See id.* at 17–18 (explaining how agency decisions are persuasive authority outside of the agency).

a. “General Plastic” discretion

*General Plastic Industrial Co. v. Canon Kabushiki Kaisha*⁴⁰³ is an example of a PTAB precedential decision that sets forth a standard of review for the Director’s delegated discretion over petition institution decisions.⁴⁰⁴ It counsels that legally, when deciding whether to institute a petition, the PTAB should consider, inter alia, seven factors:

1. whether the same petitioner previously filed a petition directed to the same claims of the same patent;
2. whether at the time of filing of the first petition the petitioner knew of the prior art asserted in the second petition or should have known of it;
3. whether at the time of filing of the second petition the petitioner already received the patent owner’s preliminary response to the first petition or received the Board’s decision on whether to institute review in the first petition;
4. the length of time that elapsed between the time the petitioner learned of the prior art asserted in the second petition and the filing of the second petition;
5. whether the petitioner provides adequate explanation for the time elapsed between the filings of multiple petitions directed to the same claims of the same patent;
6. the finite resources of the Board; and
7. the requirement under 35 U.S.C. § 316(a)(11) to issue a final determination not later than 1 year after the date on which the Director notices institution of review.⁴⁰⁵

According to the panel, the PTAB adopted these factors in the interest of policy goals; namely, the efficiency of the IPR process and the “fundamental fairness” to all parties involved.⁴⁰⁶ The PTAB noted that “[t]he absence of any restrictions” would allow petitioners to “strategically stage their prior art and arguments” essentially using the PTAB’s decisions as roadmaps to an institution.⁴⁰⁷ Because *General Plastic* has been given a precedential status, and has been made USPTO policy in the revisions to the trial practice guide, the PTAB should keep these factors in mind when determining whether to accept or deny a petition for an IPR; however, the PTAB noted

403. See *Gen. Plastic Indus. Co. v. Canon Kabushiki Kaisha*, IPR2016-01357, Paper No. 19 (Sept. 6, 2017).

404. *Id.* at 15–16 (Sept. 6, 2017) (outlining the factors that the PTAB should consider in determining whether to exercise its discretion).

405. *Id.*

406. *Id.* at 18.

407. *Id.* at 17.

that none of these factors were determinative and other policy considerations should be taken into account.⁴⁰⁸

While the seven factors of *General Plastic* focused initially on the situation of multiple petitions by the same petitioner, subsequent PTAB decisions further illustrate that the PTAB is willing to broadly apply the factors when exercising its discretion to institute. For example, when two petitions are filed by co-defendants, the later filed petition may be denied if the patent owner has already filed a response to the earlier filed petition or if the earlier filed petition has received an institutional decision.⁴⁰⁹ Similarly, in post-SAS cases where the PTAB found merit to certain grounds and claims, they exercised their discretion to deny institution where doing so would place a burden on the parties and the office and would not serve overarching policy goals well.⁴¹⁰

Most significantly, the PTAB has also found repeatedly that the state of the parallel district court proceeding and potential duplication of district court efforts an important factor that should be weighed when exercising its discretion under § 314(a)⁴¹¹ and did so in a case highlighted in the 2018 Trial Practice Guide update.⁴¹² Furthermore, the PTAB has recently exercised its discretion under § 314(a) and denied institution where the same prior art and evidence was already under consideration by a district court and a decision by the PTAB would occur after the resolution of the district court proceeding.⁴¹³

Thus, the open-ended nature of *General Plastic* and the decisions that have followed underscore that the PTAB will consider factors

408. *Id.* at 18.

409. *See* Shenzhen Silver Star Intelligent Tech. Co. v. iRobot Corp., IPR2018-00880, Paper No. 9 at 10–11 (P.T.A.B. Oct. 1, 2018).

410. *Deeper, UAB v. Vexilar, Inc.*, IPR2018-01310, Paper 7 at 2, 41–43 (P.T.A.B. Jan. 24, 2019) (denying institution where only two of twenty-three claims and one ground had merit, citing efficiency and resource concerns).

411. *NHK Spring Co. v. Intri-Plex Techs., Inc.*, IPR2018-00752, Paper No. 8 at 19–20 (P.T.A.B. Sept. 12, 2018); U.S. PAT. & TRADEMARK OFF., TRIAL PRACTICE GUIDE UPDATE (2018) [hereinafter TPG UPDATE], https://www.uspto.gov/sites/default/files/documents/2018_Revised_Trial_Practice_Guide.pdf.

412. *See* TPG UPDATE, *supra* note 410, at 10 (citing *NetApp, Inc. v. Realtime Data LLC*, IPR2017-01195, Paper 9 at 12–13 (P.T.A.B. Oct. 12, 2017) (“denying institution under § 314(a) of a follow-on petition filed by a different petitioner where, due to petitioner’s delay, the Board likely would not have been able to rule on patentability until after the district court trial date”)).

413. *ZTE (USA), Inc. v. Fractus, S.A.*, IPR2018-01457, Paper No. 10 (P.T.A.B. Feb. 28, 2019); *Thermo Fisher Scientific, Inc. v. Regents of the Univ. of Cal.*, IPR2018-01370, Paper No. 11 (P.T.A.B. Feb. 7, 2019).

that may not have been specifically enunciated by the PTAB in *General Plastic*. These cases demonstrate that the PTAB can institute or deny a petition for almost any policy reason, or perhaps, for no reason whatsoever. A petition may be denied because the PTAB believes the petition lacks merits or because the PTAB believes not all challenged claims should be reviewed.⁴¹⁴ It can do so for policy reasons related to parallel district court proceedings, or the PTAB even has the power to allow for a rehearing of the denial of a petition at its own discretion.⁴¹⁵ The Director essentially has broad and quasi-unreviewable discretion for instituting IPRs given the Supreme Court's interpretation of § 314.⁴¹⁶

3. *Guidance documents and revisions*

A less procedurally onerous but still proactive way to implement policy goals is the issuance of guidance documents, a type of memorandum or policy decision that may not require notice-and-comment rulemaking.⁴¹⁷ On the FDA side, Congress, “[b]y formulating the Hatch-Waxman Act broadly, . . . has given the FDA wide flexibility to regulate” by “mandat[ing] the use of guidance documents, a less costly and time-consuming form of regulating than formal or even informal rulemaking.”⁴¹⁸ But even passing nonbinding guidance documents at the FDA is onerous compared to the usual cursory review given the USPTO's guidance documents or policy statements; such guidance documents often include multiple studies on economic impact, industry buy-in, and multiple versions may circulate and be amended. Further, it is dubious whether influence or control over the USPTO's proceedings would even be within the FDA's congressionally delegated authority; rather, the FDA could comment or discuss the administrative conflict set up by the

414. See *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144–45 (2016).

415. See *NHK Spring Co.*, IPR2018-00752, Paper No. 8 at 18.

416. *Cuozzo Speed Techs.*, 136 S. Ct. at 2139, 2141.

417. See David L. Franklin, *Legislative Rules, Nonlegislative Rules, and the Perils of the Short Cut*, 120 YALE L.J. 276, 284 & n.33 (2010) (citing Todd D. Rakoff, *The Choice Between Formal and Informal Modes of Administrative Regulation*, 52 ADMIN. L. REV. 159, 166 (2000) (asserting that agencies are “avoiding ‘ossification’ . . . by increased use of ‘interpretative rules’ and ‘policy statements’”)); see also Lubbers, *supra* note 200, at 473 (“This precipitous drop in final rules published in the *Federal Register*—and the even more dramatic drop in proposed rules published for comment—are clear indications of the ossification of rulemaking or at least increased agency reluctance to use the APA’s rulemaking process.”).

418. Stroud, *supra* note 146, at 607.

respective schemes, offer proposed solutions, and emphasize that FDA (and by extension, USPTO) officials should seek to avoid such conflicts.

The USPTO, for its part (and the PTAB in particular), has relied on guidance and general policy documents to implement its procedures from day one.⁴¹⁹ The release of updates to the USPTO's Trial Practice Guide Update further demonstrates that the PTAB today is more than willing to consider the effect of AIA proceedings on the "economy" and "the integrity of the patent system," as well as "the efficient administration of the Office, and the ability of the Office to timely complete proceedings."⁴²⁰ Notably, the Trial Practice Guide Update makes it explicit that the Office will consider "events in other proceedings related to the same patent, either at the Office, in district courts, or the ITC."⁴²¹ The Trial Practice Guide Update invites parties to address in "their submissions whether any other such reasons exist in their case that may give rise to *additional factors* that may bear on the PTAB's discretionary decision to institute or not to institute, and whether and how such factors should be considered along with the *General Plastic* factors."⁴²² In response to the USPTO's invitation for "additional factors," we recommend that the following should also be considered as factors that weigh against institution in AIA proceedings:

whether a petitioner has made a Paragraph IV certification against an Orange Book-listed patent or is sponsoring a biosimilar product; whether the petitioner has provided notice to the holder of an aBLA and either failed to provide a copy of their aBLA to the reference product sponsor or is actively involved in the "patent dance;"

whether the patent on which the petitioner is seeking review is already a part of (or has already been a part of) a Hatch-Waxman dispute, and whether that dispute includes prior or ongoing validity challenges, or any of the same prior art, arguments, and parties; and whether a full Hatch-Waxman or biosimilar dispute has concluded or substantially concluded, particularly where the petitioner had the ability to test validity in that statutory schema.

Practitioners and judges should accept the invitation and consider addressing these comity concerns prior to institution in any

419. See Andrei Iancu, Director, U.S. Pat. & Trademark Off., Remarks at the American Intellectual Property Law Association Annual Meeting (Oct. 25, 2018), <https://www.uspto.gov/about-us/news-updates/remarks-director-iancu-american-intellectual-property-law-association-annual>.

420. TPG UPDATE, *supra* note 410, at 9.

421. *Id.* at 10.

422. *Id.* at 11 (emphasis added).

individual proceeding as a factor weighing heavily against institution, particularly where there is, already has been, or is highly likely to be a statutorily-mandated parallel district court validity proceeding. This Article also recommends the USPTO consider further revisions to the Trial Practice Guide explicitly recognizing the administrative conflict and highlighting it to the PTAB.

4. *Internal agency policies*

Agencies need the flexibility to run their day-to-day operations without ossified notice-and-comment rulemaking or the requirement to publish, vet, and delay the implementation of rules. This applies to the working procedures of administrative adjudicators, as well; no matter how brilliant or how prescient the authors of rules or guidance policies may be, it is impossible to fill all gaps and prepare for many conflicts. These day-to-day choices and gaps are often devolved to internal policy discussions, choices, and directives that do not rise to the level of even guidance documents. Should the USPTO address the comity problem between the AIA and the Hatch-Waxman and BPCIA Acts, it could do so through informal training, discussion, or policies encouraging administrative law judges to consider the conflict these proceedings present when exercising their discretion whether to institute. Such training and internal policymaking has the benefit of allowing each APJ and panel to consider the different facts of each case and could be implemented almost immediately; on the other hand, the lack of a formal internal policy may result in the continuation of the status quo or worse, like fitful ad hocery, as certain panels more familiar with or receptive to these considerations may act differently than others.

Altogether, we recommend that the USPTO hold internal discussions or training with PTAB judges to discuss the seriousness of the conflict presented by these proceedings running in parallel. Such informal policymaking could be coupled with a further revision of the trial practice guide, one which recognizes, even more than the last revision, the comity concerns that inhere in avoiding administrative conflict between the AIA and BPCIA and Hatch-Waxman litigation schemes. Sound policy directives and internal training can help encourage just, efficient, and speedy resolutions for disputes within our entire system of government and marketplace, not just from the lens of the individual proceedings. Doing so would assuage comity concerns and prevent administrative conflict. The USPTO would be wise to implement such an approach.

CONCLUSION

While AIA procedures have been effective for their intended purpose of reducing (or at least hampering) abusive patent assertions, the unanticipated conflict between the carefully balanced preexisting Hatch-Waxman and BPCIA approval pathways and the AIA's post-grant procedures has led to systemic inefficiencies that beg solutions. Principles of comity and administrative law—coupled with an understanding of the congressional and executive authority delegated to the Director of the USPTO—suggest that the USPTO is in the best position to address the conflict efficiently, justly, and based on individual disputes. Where there is parallel aNDA or aBLA litigation playing out, the required Article III suits that result will generally be the best avenue for validity challenges, particularly given the thirty-month stay of FDA approval and the tight timeline required of the Courts in the Hatch-Waxman context.⁴²³ The USPTO Director and the Administrative Patent Judges of the PTAB have the discretion and the authority to defer or deny institution where ongoing Hatch-Waxman Act or BPCIA litigation would cause duplicative or wasteful litigation, and they should do so. Meanwhile, the USPTO may pursue internal policy changes, updates to their Trial Practice Guide, notice-and-comment rulemaking to address the conflict; if these means do not address the problem, Congress can take up the issue with an amendment similar to the Hatch Amendment.

Addressing the conflict now can return us to the streamlined nature of Hatch-Waxman and BPCIA proceedings, will reduce unnecessary, duplicative litigation surrounding generic and biosimilar approval, and is a sound idea. As Director Iancu recently noted, “we’re going to get back to what the true congressional intent was for IPRs, which was to be an alternative to district court litigation.”⁴²⁴ Our hope is the USPTO takes the next logical step, addresses these comity concerns, and returns to the true intent of all *three* ships in the night.

423. See Ferrario et al., *supra* note 109 (summarizing the “automatic 30-month stay of FDA approval of the ANDA under the Hatch-Waxman Act”); Levine et al., *supra* note 109.

424. See Bonnie EslingerVt, *USPTO Head Lauds PTAB’s New Claim Construction Standard*, LAW360 (Nov. 13, 2018, 10:19 PM), <https://www.law360.com/ip/articles/1101445/uspto-head-lauds-ptab-s-new-claim-construction-standard>.