

2014

There's a Hole in My Bucket Dear Liza, Dear Liza: The 30-Year Anniversary of the Hatch-Watchman Act: Resolved and Unresolved Gaps and Court- Driven Policy Gap Filling

Shashank Upadhye

Follow this and additional works at: <http://open.mitchellhamline.edu/wmlr>

Recommended Citation

Upadhye, Shashank (2014) "There's a Hole in My Bucket Dear Liza, Dear Liza: The 30-Year Anniversary of the Hatch-Watchman Act: Resolved and Unresolved Gaps and Court-Driven Policy Gap Filling," *William Mitchell Law Review*: Vol. 40: Iss. 4, Article 4.
Available at: <http://open.mitchellhamline.edu/wmlr/vol40/iss4/4>

This Article is brought to you for free and open access by the Law Reviews and Journals at Mitchell Hamline Open Access. It has been accepted for inclusion in William Mitchell Law Review by an authorized administrator of Mitchell Hamline Open Access. For more information, please contact sean.felhofer@mitchellhamline.edu.

© Mitchell Hamline School of Law

THERE'S A HOLE IN MY BUCKET DEAR LIZA, DEAR LIZA: THE 30-YEAR ANNIVERSARY OF THE HATCH-WAXMAN ACT: RESOLVED AND UNRESOLVED GAPS AND COURT-DRIVEN POLICY GAP FILLING[†]

Shashank Upadhye[†]

I. INTRODUCTION..... 1308
II. A BRIEF BACKGROUND TO THE HATCH-WAXMAN ACT 1311
III. BACKGROUND ON THE BRAND AND GENERIC DRUG APPROVAL PROCESS 1313

1. The holes in the Act and continuous attempts to fill them based on the Act itself, case precedent, and new legislation reminds me of the old song, “There’s a Hole In My Bucket,” which

is a children’s song based on a dialogue about a leaky bucket between two characters, called Henry and Liza. The song describes a deadlock situation: Henry has got a leaky bucket, and Liza tells him to repair it. But to fix the leaky bucket, he needs straw. To cut the straw, he needs a knife. To sharpen the knife, he needs to wet the sharpening stone. To wet the stone, he needs water. However, when Henry asks how to get the water, Liza’s answer is ‘in a bucket.’ It is implied that only one bucket is available—the leaky one, which, if it could carry water, would not need repairing in the first place.”

There’s a Hole in my Bucket, WIKIPEDIA http://en.wikipedia.org/wiki/There’s_a_Hole_in_My_Bucket (last visited Aug. 23, 2013). As with the song, some will say that the beginning and ending point with the entire regime is the Act itself and it has no problem.

† Shashank Upadhye is a partner in the Chicago office of Seyfarth Shaw, LLP. He is a globally recognized expert in the field of pharmaceutical IP and FDA regulatory law. He is formerly the VP-Global Head of IP for Apotex, Inc. (Toronto, Ontario); VP-Head of U.S. IP for Sandoz, Inc. and Eon Labs, Inc. He is also the author of an industry-leading treatise entitled, “Generic Pharmaceutical Patent and FDA Law” published by Thomson West publishing. He is also the author of eleven law review articles related to IP, pharmaceutical, antitrust, and international law. He received his LLM in IP (John Marshall Law School, Chicago, Ill.); JD (New England School of Law, Boston, Mass.); and BA and B.Sc. (Brock University, St. Catharines, Ont.). The views expressed herein are simply of the author alone, and do not represent the views of any client in the past, present, or future. Criticisms or comments about this paper can be directed to the author at: supadhye@hotmail.com.

IV. REPETITIVE THIRTY-MONTH STAYS AND EVERGREENING PATENTS..... 1319

V. THE 180-DAY EXCLUSIVITY PERIOD AND ITS FORFEITURE ... 1322

VI. CONGRESS EXPLICITLY CREATES VEHICLES TO STRIP EXCLUSIVITY 1324

VII. THE FAILURE TO MARKET—A PERVERSION OF A PROVISION 1327

VIII. DELISTING PATENTS AND FORFEITURE—PERVERSIONS OF PROVISIONS CONTINUE..... 1329

IX. THE SCOPE OF LITIGABLE PATENTS IN HATCH-WAXMAN SUITS..... 1335

X. THE “ALL” PATENTS-IN-SUIT THEORY HAS FAR-REACHING CONSEQUENCES FOR REMEDIES 1341

XI. A SOLUTION TO THE PROBLEM OF LITIGABLE PATENTS—A NEW MODEL FOR RESOLUTION..... 1347

XII. THE AUTHORIZED GENERIC: A GOOD OR BAD THING? 1350

XIII. FDA WRONGFULLY SAYS THAT MARKETING THE AUTHORIZED GENERIC TRIGGERS EXCLUSIVITY 1353

XIV. SCOPE OF INDUCED INFRINGEMENT AND NULLIFICATION OF THE MENS REA REQUIREMENT..... 1357

XV. CONCLUSION 1369

I. INTRODUCTION

The Hatch-Waxman Act governs the approval of medical devices and pharmaceuticals. Its official name is the Drug Price Competition and Patent Term Restoration Act of 1984.² Its

2. Drug Price Competition and Patent Term Restoration (Hatch-Waxman) Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended in scattered sections of 15, 21, 28, and 35 U.S.C.). Known more commonly by its popular title, the “Hatch-Waxman Act,” derived from the surnames of the Act’s principal sponsors, was passed with the express purpose of expediting the entry of noninfringing generic competitors into pharmaceutical drug markets in order to decrease healthcare costs for consumers. *See Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2471 (2013) (“In order to provide a swifter route for approval of generic drugs, Congress passed the Drug Price Competition and Patent Term Restoration Act of 1984, 98 Stat. 1585, popularly known as the ‘Hatch-Waxman Act.’ Under Hatch–Waxman, a generic drug may be approved without the same level of clinical testing required for approval of a new brand-name drug, provided the generic drug is identical to the already-approved brand-name drug in several key respects.”); *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2574 (2011) *reh’g denied*, 132 S. Ct. 55 (2011) (“In 1984, however, Congress passed the Drug Price Competition and Patent Term Restoration Act, 98 Stat. 1585, commonly called the Hatch-

unofficial name is the Litigator's Full Employment Act, because the Act, as promulgated, was cumbersome, indecipherable in certain areas, and hardly a model of elegant statutory draftsmanship.³ To this end, parties and their lawyers found gaps and have gamed the Act. Many complained the interpretation (and misinterpretation) of the Act created wrong law, wrong policy—or quite the opposite, the correct law and correct policy. Some have complained that the 1984 Act now does not do enough, and that the rationales justifying the Act no longer apply to modern realities.⁴ Others have complained that there is not enough protection for the brand pharmaceutical companies or patents,⁵ that generic companies are being pummeled with repetitive litigation thereby delaying generic drug entry,⁶ or that generic drug companies are not enjoying (or unduly enjoying) 180-day market exclusivities. Though the Hatch-

Waxman Amendments.”); see also Frank R. Lichtenberg & Joel Waldfogel, *Does Misery Love Company? Evidence from Pharmaceutical Markets Before and After the Orphan Drug Act*, 15 MICH. TELECOMM. & TECH. L. REV. 335, 348 (2009) (suggesting that the Orphan Drug program “works” well).

3. *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990) (“No interpretation we have been able to imagine can transform § 271(e)(1) into an elegant piece of statutory draftsmanship.”).

4. For example, in the product liability tort realm, branded drug companies are treated differently under state tort law than generic drug companies. This, it is argued, is unfair and plaintiffs have attempted to recover from brand companies for the injuries caused by generic companies. See, e.g., Victor E. Schwartz et al., *Warning: Shifting Liability to Manufacturers of Brand-Name Medicines When the Harm Was Allegedly Caused by Generic Drugs Has Severe Side Effects*, 81 FORDHAM L. REV. 1835 (2013); see also Gregory Dolin, *Exclusivity Without Patents: The New Frontier of FDA Regulation for Genetic Materials*, 98 IOWA L. REV. 1399 (2013) (discussing how to allow market exclusivities over genetic material instead of patent rights).

5. See Emily Michiko Morris, *The Myth of Generic Pharmaceutical Competition Under the Hatch-Waxman Act*, 22 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 245, 248 (2012) (“The Act fails to strike the right balance between these two sectors of the industry. It overshoots the mark in terms of fostering generic market entry while simultaneously undershooting the mark in terms of protecting brand-name pharma’s incentives to develop new drugs. Even after Hatch-Waxman’s attempt to restore patent duration to its full-expected term, the average effective life of a pharmaceutical patent is still shorter than that for any other type of patent.”).

6. See, e.g., FED. TRADE COMM’N, *GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION* 39 (2002), available at http://www.ftc.gov/sites/default/files/documents/reports/generic-drug-entry-prior-patent-expiration-ftc-study/genericdrugstudy_0.pdf (discussing consequences of repetitive litigations in generic drug patent infringement cases).

Waxman Act governs medical devices and pharmaceuticals, this paper only deals with the Act in relation to drugs.

Because of various courts' policy-driven considerations, combined with studies by independent (or biased) scholars, plus interpretations by the Food and Drug Administration (FDA) as it related to drug approvals, Congress has stepped in a few times to legislate again. For example, in 1997 Congress passed the FDA Modernization Act (FDAMA), which permitted collection of certain user fees to expedite the drug approval process.⁷ It also allowed for disseminating studies in an off-label manner.⁸ But, in the world of brand-drug–generic-drug approval and patent litigation, FDAMA did not do much. In 2002, a small change occurred that reauthorized the six-month pediatric exclusivity for brand pharmaceuticals, irrespective of whether the brand drug had demonstrated clinical pediatric efficacy. The most sweeping change, if it can be called that, was the 2003 Medicare Modernization Act (MMA).⁹

Unlike the Leahy-Smith America Invents Act of 2011,¹⁰ which was intended to—and did in fact—effect a wholesale change to American patent laws, the MMA sought to change certain aspects of the regulation of brand and generic drugs. It succeeded in part and failed in part. The MMA did little to deprive lawyers of their full employment as the fights over drug approvals simply shifted from one underlying basis to another.

7. Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, 111 Stat. 2296.

8. *See id.* § 401. This provision ultimately expired on September 30, 2006. 21 U.S.C. § 360aaa. It allowed certain off-label distribution. The act allowed manufacturers to distribute copies of peer-reviewed articles and book chapters and to sponsor independent continuing medical education programs describing uses of products beyond the approved indications. The FDA recently updated its guidance on how off-label distribution of truthful materials can be accomplished. FOOD & DRUG ADMIN., DOCKET NO. FDA-2008-D-0053, FDA DRAFT GUIDANCE FOR INDUSTRY: GOOD REPRINT PRACTICES FOR THE DISTRIBUTION OF MEDICAL JOURNAL ARTICLES AND MEDICAL OR SCIENTIFIC REFERENCE PUBLICATIONS ON UNAPPROVED NEW USES OF APPROVED DRUGS AND APPROVED OR CLEARED MEDICAL DEVICES (2008), available at <http://www.regulations.gov/contentStreamer?objectId=0900006480e6d838&disposition=attachment&contentType=pdf>.

9. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066.

10. Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011). The America Invents Act (AIA) is the most comprehensive update to the patent laws since the 1952 Act.

It is beyond the scope of this article to discuss each provision of the original Hatch-Waxman Act, its problems, and any solutions. Rather, this article will discuss certain provisions that were problematic, were (or were not) addressed, and whether the proposed remedy fixed the problems.

II. A BRIEF BACKGROUND TO THE HATCH-WAXMAN ACT

In the pre-1984 era of drug approvals, generic-drug manufacturers needed to await patent expiry before even beginning generic-drug development. This was because any early development (defined basically as pre-patent expiry) using the active ingredient would qualify as patent infringement. Generic-drug developers could start development only after a relevant patent expired. Because it took a few years to develop a generic version of the drug, and then a few years to obtain FDA approval, this delay led to a *de facto* patent extension.¹¹ Public policy dictated that when a patent expired, the generic drug would be available soon thereafter.¹² Similarly, for brand companies, because the FDA

11. *Proveris Scientific Corp. v. Innovasystems, Inc.*, 536 F.3d 1256, 1261 (Fed. Cir. 2008) (citations omitted) (“The second distortion was the *de facto* extension of effective patent life at the end of the patent term, which also resulted from FDA premarket approval requirements. Prior to the Hatch–Waxman Act, competitors’ activities involving a patented invention during the patent term constituted an act of infringement, even if undertaken for the sole purpose of obtaining FDA regulatory approval. Because such activities could not begin until patent expiration, patent owners enjoyed a *de facto* patent term extension while competitors spent time following patent expiration obtaining FDA premarket approval necessary for market entry.”); *Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 864 (Fed. Cir. 1984) (“Bolar argues that the patent laws are intended to grant to inventors only a limited 17-year property right to their inventions so that the public can enjoy the benefits of competition as soon as possible, consistent with the need to encourage invention. The [Food, Drug, and Cosmetic Act (FDCA)], Bolar contends, was only intended to assure safe and effective drugs for the public, and not to extend a pharmaceutical company’s monopoly for an indefinite and substantial period of time while the FDA considers whether to grant a pre-marketing clearance. Because the FDCA affected prevailing law, namely the Patent Act, Bolar argues that we should apply the patent laws to drugs differently.”), *cert. denied*, 469 U.S. 856 (1984).

12. *Sears, Roebuck & Co. v. Stiffel Co.*, 376 U.S. 225, 230 (1964) (“Finally, and especially relevant here, when the patent expires the monopoly created by it expires, too, and the right to make the article-including the right to make it in precisely the shape it carried when patented-passes to the public.”); *Scott Paper Co. v. Marcalus Mfg. Co.*, 326 U.S. 249, 255 (1945) (“As has been many times

maintained jurisdiction to approve drugs prior to commercial marketing, a brand company could not market the drug until it obtained that approval. Because the approval process could take a few years, any underlying patent term would continue to run even though the brand company could not commercially capitalize on the patent. Public policy dictated that brand companies recover some of the time spent pushing an FDA drug application through approval. In the pharmaceutical world, usually the latter term of the patent is more valuable because of market dynamics. In the electronics world, usually only the initial term of the patent is important because of the rapid advancements made.¹³

The 1984 Hatch-Waxman Act sought to reconcile these public policy considerations. First, Title II of the Act regulated the brand-drug approval process and provided for patent term extension. This title recaptured some time lost due to FDA entanglements, which was added to the end of the patent, thereby extending its term.¹⁴ Second, Title I of the Act regulated generic-drug development. This title created the generic-drug approval process,

pointed out, the means adopted by Congress of promoting the progress of science and the arts is the limited grant of the patent monopoly in return for the full disclosure of the patented invention and its dedication to the public on the expiration of the patent.”).

13. For example, in 2013 would anyone really care if the original 386 computer chip is still patented when no computer nowadays uses a 386 chip? So any remaining patent term on the 386 chip was likely rendered inconsequential when the 486 and Pentium chips were developed. On the other hand, on the day before the Lipitor patent expired, the value of the Lipitor drug was several billion dollars. See PFIZER, 2013 FINANCIAL REPORT, app. A, at 4, *available at* <http://www.pfizer.com/files/investors/presentations/FinancialReport2013.pdf> (“Lipitor has lost exclusivity in all major markets. Lipitor revenues were \$2.3 billion in 2013, \$3.9 billion in 2012 and \$9.6 billion in 2011. We lost exclusivity for Lipitor in the U.S. in November 2011. The entry of multi-source generic competition in the U.S. began in May 2012, with attendant increased competitive pressures. Lipitor lost exclusivity in Japan in June 2011, Australia in April 2012 and most of developed Europe in March and May 2012 and now faces multi-source generic competition in those markets.”).

14. Merck & Co. v. Kessler, 80 F.3d 1543, 1546–47 (Fed. Cir. 1996) (“In exchange, the Hatch–Waxman Act provides the holders of patents on approved patented products with an extended term of protection under the patent to compensate for the delay in obtaining FDA approval. This restoration period does not recover the full time lost from the patent term due to FDA’s premarket approval process but merely ‘ameliorates the loss incurred when patent terms tick away while the patented product is awaiting [FDA’s] regulatory approval for marketing.”).

the Orange Book patent listing rules and Paragraph I–IV certification system, the litigation system, and also the 180-day exclusivity incentive for generic companies to step up and challenge patents.¹⁵ By creating the generic-drug pathway, generic companies could “early work” any relevant patent under a safe harbor exemption so development could occur pre-patent expiry and hence facilitate early entry.¹⁶ Because of the serious nature of brand-versus-generic patent litigation and the rewards for both parties to game the system, the Act became litigation fodder.

The original Hatch-Waxman Act was enacted in 1984. 2014 will be its thirtieth anniversary. Part III of this paper discusses the background to the brand and generic drug approval process. Part IV discusses the problem related to delaying generic-drug entry via repetitive litigation on repetitive patents. This is normally known as the thirty-month stay evergreening. Parts V through VIII discuss the problem related to the so-called 180-day exclusivity and its forfeiture. Parts IX through XI discuss the problems related to the patents at issue in lawsuits, and more specifically, which patents should be part of the Hatch Waxman lawsuit. Parts XII and XIII discuss the issues relating to the so-called “authorized generic” (AGx) and whether the AGx is a good or bad thing. And finally, Part XIV discusses the issues related to inducement to infringe as it relates to Hatch Waxman suits and the judicial nullification of the mens rea requirements.

III. BACKGROUND ON THE BRAND AND GENERIC DRUG APPROVAL PROCESS

The mechanics related to the brand drug approval process is beyond the scope of this article. The author presumes some familiarity with it.¹⁷ When the brand company’s new drug application (NDA) is approved, the brand company is obligated to

15. *Bristol-Myers Squibb Co. v. Royce Labs., Inc.*, 69 F.3d 1130, 1131 (Fed. Cir. 1995).

16. *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1568 (Fed. Cir. 1997) (discussing how the Hatch-Waxman Act legislatively overruled *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858 (Fed. Cir. 1984)); *see also* 35 U.S.C. § 271(e)(1) (2006); SHASHANK UPADHYE, *GENERIC PHARMACEUTICAL PATENT AND FDA LAW* §§ 9:1–12 (2013).

17. For a more complete discussion about the brand drug approval process, *see* UPADHYE, *supra* note 16, §§ 6:1–22.

list certain patents in the Orange Book.¹⁸ Not all kinds of patents are listed; rather, only patents claiming certain physical aspects (such as compound, formulation, or polymorphs) or FDA approved methods of using the drug may be listed.¹⁹ Patents claiming metabolites, processes of making the drug substance²⁰ or drug product,²¹ and unapproved uses of the drug²² are not listed. The Orange Book listing of patents, therefore, puts the generic company on notice as to what patents might be implicated by the generic version.²³ A generic company also has to worry about non-

18. 21 U.S.C. § 355(b)(1)(G) (2012); *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1676 (2012) (“To facilitate the approval of generic drugs as soon as patents allow, the Hatch-Waxman Amendments and FDA regulations direct brand manufacturers to file information about their patents. The statute mandates that a brand submit in its NDA ‘the patent number and the expiration date of any patent which claims the drug for which the [brand] submitted the [NDA] or which claims a method of using such drug.’”).

19. 21 U.S.C. § 355(b)(1); 21 C.F.R. § 314.53(b)(1) (2013); *see also* UPADHYE, *supra* note 16, § 6:10 (providing a chart of listable and non-listable patents).

20. The drug substance is the actual medicinal compound, also known as the active pharmaceutical ingredient (API). 21 C.F.R. § 314.3.

21. The drug product is the dosage form containing the drug substance, for example, the pill, tablet, capsule, injection solution, etc. 21 C.F.R. § 314.3.

22. The FDA regulates how the drug product can be marketed to patients. An approved method of use means the FDA determined that the drug is safe and efficacious to treat a specific disease condition. *Bayer Schering Pharma AG v. Lupin, Ltd.*, 676 F.3d 1316, 1322 (Fed. Cir. 2012) (“The FDA-approved label for an approved drug indicates whether the FDA has approved a particular method of use for that drug.”). An unapproved use means the FDA has not yet approved the drug product to treat the disease condition. *Cook v. Food & Drug Admin.*, 733 F.3d 1, 3 (D.C. Cir. 2013) (“A drug is misbranded if, among other things, it was ‘manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered’ with the FDA. An unapproved new drug is one that is neither ‘generally recognized, among experts . . . as safe and effective’ for its labeled use, nor approved by the FDA as safe and effective for its proposed use.”). While a drug company may promote the use of the drug for approved uses only, physicians may prescribe the drug for approved and unapproved (also known as off-label) uses. Accordingly, it may be that the drug is used predominantly for off-label uses, but no drug company can actively promote the off-label use.

23. *See Yamanouchi Pharm. Co. v. Danbury Pharmacal, Inc.*, 231 F.3d 1339, 1342 (Fed. Cir. 2000) (“As the statute requires, Danbury, on March 26, 1997, sent Yamanouchi a Patent Certification Notice Letter. This certification letter informed Yamanouchi of Danbury’s paragraph IV ANDA filing. Accompanying the certification letter were affidavits from Drs. Bernard Loev and John K. Siepler supporting Danbury’s invalidity certification. The Notice Letter contained, as the statute requires, an analysis of the prior art and the reasons for the asserted

Orange Book patents, as those patents could also be implicated by the commercial launch of the generic version.²⁴ Finally, a generic company may worry about patents held by third parties to the extent that they too are implicated by the commercial launch.²⁵ The scope of patents is pictorially shown.

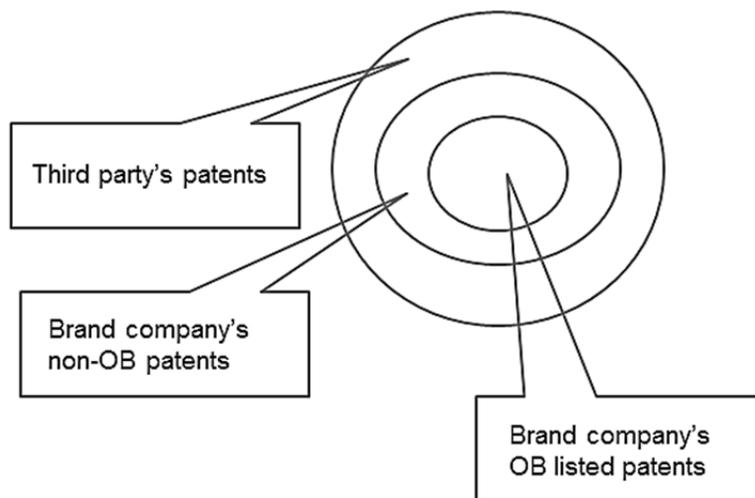


Figure 1: Scope of Patents

To obtain final approval of the generic drug application, the generic drug company must, in its abbreviated new drug application (ANDA), certify to the listed Orange Book patents. There are four types of patent certifications that the company may file:²⁶

invalidity.”).

24. See *Abbott Labs. v. Sandoz, Inc.*, 500 F. Supp. 2d 807, 846 (N.D. Ill. 2007), *aff'd*, 544 F.3d 1341 (Fed. Cir. 2008) (granting an injunction on non-Orange Book patents as, at the time, antibiotic related patents could not be listed in the Orange Book).

25. See *id.* Post-generic-launch patent litigation can occur where the brand company sues the launching generic company. This occurred in the clarithromycin XL (Biaxin XL) case. *Id.* Additionally, one generic company may sue another generic company for infringement. See, e.g., *Apotex, Inc. v. Eon Labs Inc.*, Nos. 01-CV-0482, 02-CV-1604, 2007 WL 656256 (E.D.N.Y. Feb. 26, 2007), *vacated*, Nos. 01-CV-0482(NG), 02-CV-1604, 2007 WL 8097571 (E.D.N.Y. Aug. 15, 2007) (cyclosporine); Complaint for Declaratory Judgment, *Teva Pharm. Indus. v. Andrx Corp.*, No. 2:07-cv-00244 (D.N.J. Jan. 12, 2007) (polymorphs of sertraline).

26. The patent certification language is differently stated, but this list is more

- Paragraph I—there are no patents in the Orange Book
- Paragraph II—the patent has expired
- Paragraph III—the patent has not yet expired and final approval should be delayed until the patent has expired; or
- Paragraph IV—the patent has not yet expired but is not an obstacle to final approval, and as such, final approval should be given when the ANDA is normally approvable.²⁷

If the generic company believes the patent to be an obstacle or otherwise does not wish to challenge a patent yet, it may file the Paragraph III certification.²⁸ This means that the ANDA can be filed and put into the FDA review queue, but the final approval will not come until that patent expires. The Paragraph IV certification instead generates subsequent patent litigation.²⁹ If the generic company believes a patent is not an obstacle to the final ANDA approval, the Paragraph IV certification to that patent is the appropriate certification.³⁰

Once the ANDA containing a Paragraph IV certification is filed, the generic drug company then will send a so-called Paragraph IV notice letter to the brand company informing it that the generic company has filed an ANDA against the brand drug version and explaining in great detail the basis why the patent certified against is not an obstacle to final approval.³¹ That is, the

in plain English.

27. See 21 U.S.C. § 355(j)(2)(A)(vii)(I)–(IV) (2012); see also *Fed. Trade Comm’n v. Actavis, Inc.*, 133 S. Ct. 2223, 2228 (2013); *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1676 (2012); *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 677 (1990).

28. *Caraco*, 132 S. Ct. at 1676 (“When no patents are listed in the Orange Book or all listed patents have expired (or will expire prior to the ANDA’s approval), the generic manufacturer simply certifies to that effect.”); *Dey Pharma, L.P. v. Sunovion Pharm. Inc.*, 677 F.3d 1158, 1159 (Fed. Cir. 2012) (“A generic company may then seek FDA approval using an abbreviated new drug application (‘ANDA’) with a certification for each patent in the Orange Book, such as a ‘paragraph III certification’ (that approval is not sought until the patent expires) . . .”).

29. *Caraco*, 132 S. Ct. at 1677 (“Filing a paragraph IV certification means provoking litigation.”).

30. *Id.* (“The generic manufacturer’s second option is to file a so-called paragraph IV certification, which states that a listed patent ‘is invalid or will not be infringed by the manufacture, use, or sale of the [generic] drug.’”) (alteration in original) (quoting 21 U.S.C. § 355(j)(2)(A)(vii)(IV)).

31. 21 U.S.C. § 355(j)(2)(B); see also *Bayer Schering Pharma AG v. Lupin, Ltd.*, 676 F.3d 1316, 1319 (Fed. Cir. 2012); *Caraco Pharm. Labs., Ltd. v. Forest*

notice letter will explain the bases for noninfringement and/or invalidity of the patent.³² Upon receipt of the notice letter, the brand company can evaluate the allegations contained therein and may choose to sue the generic company. If the brand company sues within forty-five days of receipt of the notice letter, the brand company obtains a thirty-month stay (injunction) of any ANDA final approval.³³ During this period, the FDA is enjoined from approving the ANDA. The purpose of this thirty-month litigation stay is to vet out the patent issues in the underlying litigation.³⁴ The thirty-month litigation stay can be terminated early if the generic company wins its lawsuit.³⁵ When the stay expires, the FDA may grant final ANDA approval (subject to meeting the normal regulatory requirements) permitting the generic company to launch its generic version, subject to any other legal impediments.³⁶ The generic company need not await a trial court verdict in the patent infringement case.

The generic company has twin motivations in filing an ANDA with a Paragraph IV certification. First, if the company believes that the patent is not an obstacle, then it behooves the company to challenge the patent and “clear the way” for its product. By challenging and possibly litigating the patent, it allows the company to enter the marketplace free from liability for patent infringement. A second motivation is to garner the so-called 180-day exclusivity. The 180-day exclusivity is said to be an incentive to challenge patents and bring generic versions to the market as early

Labs., Inc., 527 F.3d 1278, 1283 (Fed. Cir. 2008) (“All Paragraph IV ANDA filers must provide notice of their Paragraph IV certification to both the patent owner and the NDA holder. This notice must set forth a ‘detailed statement of the factual and legal basis for the opinion of the applicant that the patent is invalid or will not be infringed.’” (citations omitted)).

32. *Abbott Labs., Inc. v. Apotex Inc.*, 725 F. Supp. 2d 724, 728 (N.D. Ill. 2010) (describing the Paragraph IV notice letter and the arguments contained therein).

33. 21 U.S.C. § 355(j)(5)(B)(iii); *Fed. Trade Comm’n v. Actavis, Inc.*, 133 S. Ct. 2223, 2228 (2013).

34. *Caraco*, 132 S. Ct. at 1677 (“Assuming the brand does so, the FDA generally may not approve the ANDA until 30 months pass or the court finds the patent invalid or not infringed.”). There are instances where a thirty-month stay is not applicable. *See* UPADHYE, *supra* note 16, §§ 11:3, :21; *infra* Part IV.

35. 21 U.S.C. § 355(j)(5)(B)(iii)(I)–(IV).

36. *See, e.g., Research Found. of State Univ. of N.Y. v. Mylan Pharm. Inc.*, Civ. Nos. 09-184-LPS, 10-892-LPS, 2012 WL 1901267 (D. Del. May 25, 2012) (enjoining generic company prior to launch).

as possible.³⁷ If the ANDA applicant is the first generic company to file a Paragraph IV certification to a drug product, that applicant *may* obtain 180 days of market exclusivity that delays subsequent ANDA's from obtaining final approval.³⁸

The economics of the 180-day exclusivity makes a good deal of sense, and it is extremely profitable. For example, assume that the brand drug product is worth \$1 billion dollars per year. Because of automatic substitution laws that require a pharmacy to substitute a generic version when available, upon launch the generic company will capture a huge percent of the prescription market. Because of limited competition, the generic drug company can price its version relatively high, but considerably lower than the brand drug. If we assume that 80% of the market converts and the generic version is priced at 80% of the brand drug, then the 180-day exclusivity is worth about \$320 million.³⁹ Once the market becomes wide open genericized (say after day 181), then the price and market share plummet. For the remainder of the year, the first ANDA company may only make \$50 million dollars.⁴⁰ Thereafter, more companies will enter the market and the price and market

37. *Actavis*, 133 S. Ct. at 2228–29 (“Hatch-Waxman provides a special incentive for a generic to be the first to file an Abbreviated New Drug Application taking the paragraph IV route. That applicant will enjoy a period of 180 days of exclusivity (from the first commercial marketing of its drug).”); *Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, 540 F.3d 1353, 1356 (Fed. Cir. 2008) (“As an incentive for generic pharmaceutical companies to challenge suspect Orange Book listed patents, the Hatch-Waxman Act grants the first company to submit a Paragraph IV ANDA a 180-day period of generic marketing exclusivity during which time FDA will not approve a later-filed Paragraph IV ANDA based on the same NDA . . .”).

38. *Actavis*, 133 S. Ct. at 2229; *see also* 21 USC § 355(j)(5)(B)(iv)(I) (“Subject to subparagraph (D), if the application contains a certification described in paragraph (2)(A)(vii)(IV) and is for a drug for which a first applicant has submitted an application containing such a certification, the application shall be made effective on the date that is 180 days after the date of the first commercial marketing of the drug (including the commercial marketing of the listed drug) by any first applicant.”).

39. The calculation is roughly \$2.8 million per day (\$1 billion per year), multiplied by 80% (market conversion), multiplied by 80% (price), multiplied by 180 days, equals \$320 million.

40. Assume in open competition that the price now plummets to 10% and each company takes only a 10% share. Accordingly, the calculation becomes \$2.8 million per day, multiplied by 10%, multiplied by 10%, multiplied by a half year, equals \$50 million. It is not uncommon, though, for price to plummet to only 2–5% with even less market share, resulting in even less money.

share will plummet even further. Because most brand drug products are not billion-dollar plus, rather worth only a few hundred million, generic companies may make only a few million in sales per drug product. The drastic price and market erosion, though, benefits the consumers as their drug prices are reduced.

Accordingly, it makes sense for generic drug companies to challenge patents, win the lawsuits, enter the market, and try to capitalize on the 180-day exclusivity. For brand companies, it makes sense to litigate as much as possible, make the litigation as expensive and complex as possible, delay the litigation as much as possible, and delay ANDA approval as long as possible.

IV. REPETITIVE THIRTY-MONTH STAYS AND EVERGREENING PATENTS

The original 1984 Act created the regime for patent litigation to be vetted out during the thirty-month litigation stay. However, between 1984 and 2003 the thirty-month litigation stay was patent-by-patent specific.⁴¹ For a pending ANDA to obtain final approval, the ANDA must have addressed each patent listed in the Orange Book with a relevant patent certification.⁴² Accordingly, each time a new patent was listed in the Orange Book, any pending ANDA would require a patent certification to that new pop-up patent to obtain final approval.⁴³ If the ANDA applicant certified under Paragraph IV and timely notified the brand company of the certification via the required notice letter, then a timely filed new patent suit on that pop-up patent could earn a new thirty-month litigation stay.⁴⁴

41. *Apotex, Inc. v. Thompson*, 347 F.3d 1335, 1340 (Fed. Cir. 2003) (“SmithKline filed each of those actions within 45 days of receiving notice of the relevant paragraph IV certification by Apotex. The FDA treated each lawsuit as giving rise to an additional 30-month stay of the approval of Apotex’s ANDA.”); *see also* Food & Drug Admin., Response to American Pharmaceutical Partners, Inc. and Pharmachemie B.V. Citizen Petitions, No. 99P-1271/PSA1 & PSA2 (Aug. 2, 1999), <http://www.fda.gov/ohrms/dockets/dailys/080699/pdn0001.pdf>.

42. 21 C.F.R. § 314.94(a)(12)(i) (2013); *see also* Letter from Food & Drug Admin. to Applicant Regarding Topiramate Sprinkle Capsules (Apr. 15, 2009), available at [http://op.bna.com/hl.nsf/id/deln-7rcpgj/\\$File/Topiramateletter415.doc.pdf](http://op.bna.com/hl.nsf/id/deln-7rcpgj/$File/Topiramateletter415.doc.pdf). (“[U]nder the pre-MMA approach, an applicant could be eligible for 180-day exclusivity with respect to different patents (‘patent-by-patent’ exclusivity), including with respect to patent certifications to different patents submitted on different days.”).

43. *Apotex*, 347 F.3d at 1340.

44. *See, e.g.*, Frederick Tong, *Widening the Bottleneck of Pharmaceutical Patent*

Accordingly, one could clearly game the system by having new patents issue that may (or may not) claim the underlying drug product, list them, and subsequently earn new thirty-month litigation stays. This could delay the ANDA final approval for years beyond the original thirty-month litigation stay expiration date. In the 1984–2003 era, there were few penalties for frivolous pop-up patent listings.⁴⁵ As such, one could evergreen new patents and evergreen the thirty-month litigation stays.⁴⁶ The Federal Trade Commission took note of the problem and recommended changes.⁴⁷

When Congress passed the MMA in 2003, the concept of stacking thirty-month litigation stays was stopped.⁴⁸ Now, the only universe of patents that qualify for thirty-month stays is the patents listed in the Orange Book on the day the ANDA is filed.⁴⁹ One can think of this as “freezing” the Orange Book of the patent listing. Of course, different ANDA applicants could be subject to different thirty-month litigation stays by virtue of the ANDA filing dates. For

Exclusivity, 24 WHITTIER L. REV. 775, 788 (2003); see also *Apotex*, 347 F.3d at 1340 (“The FDA required Apotex to file certifications for the newly listed patents, and Apotex filed paragraph IV certifications for each of them. SmithKline subsequently sued Apotex in the United States District Court for the Eastern District of Pennsylvania on September 27, 2000, charging infringement of the '759 patent; on January 11, 2001, charging infringement of the '944 patent; and on May 2, 2001, charging infringement of the '233 patent. SmithKline filed each of those actions within 45 days of receiving notice of the relevant paragraph IV certification by Apotex. The FDA treated each lawsuit as giving rise to an additional 30-month stay of the approval of Apotex’s ANDA.”).

45. Courts have suggested that the filing of an ANDA is a statutory act of infringement and that the statute specifically allows a brand company to sue and earn a thirty-month stay. Accordingly, there is no Federal Rule of Civil Procedure 11 violation for a brand company in filing suit in the first place, and no investigation into the facts are really needed. *Celgene Corp. v. KV Pharm. Co.*, No. 07-4819 (SDW), 2008 WL 2856469 (D.N.J. July 22, 2008). Though once the lawsuit progresses, the regular rules of Rule 11 ought to apply and those penalties or sanctions should apply. Accordingly, if the plaintiff recognizes that the infringement suit cannot be maintained, it should be required to cancel its suit.

46. Wansheng Jerry Liu, *Balancing Accessibility and Sustainability: How to Achieve the Dual Objectives of the Hatch-Waxman Act While Resolving Antitrust Issues in Pharmaceutical Patent Settlement Cases*, 18 ALB. L.J. SCI. & TECH. 441, 452 (2008).

47. See FED. TRADE COMM’N, *supra* note 6, at 49.

48. 21 U.S.C. § 355(c)(3)(C) (2012).

49. See UPADHYE, *supra* note 16, § 11:3; see also 21 U.S.C. § 355(j)(5)(B)(iii) (identifying the patents that qualify for thirty-month litigation stays based on when an ANDA is filed).

example, if ANDA applicant #1 filed its ANDA on a certain date, then only those patents in the Orange Book at that time could qualify for thirty-month stays. But then if new patents issued that then were listed into the Orange Book, then applicant #2, who filed after its ANDA after the new set of patents listed into the Orange Book, could be subject to different thirty-month litigation stays based on those newly listed patents because it would have to certify to the newly listed patents.⁵⁰

Even if a patentee cannot get new thirty-month litigation stays on the pop-up patents, it can still sue on those patents.⁵¹ Indeed, the pop-up patents could be very powerful patents that could block a generic company's launch.⁵² In fact, depending on the litigation

50. See UPADHYE, *supra* note 16, § 11:3 (discussing the concept of the frozen Orange Book).

51. See *Mylan Labs., v. Thompson*, 389 F.3d 1272, 1277 (D.C. Cir. 2004) ("Meanwhile, in October 2001 Mylan filed with the FDA an ANDA to market its generic fentanyl transdermal system pursuant to 21 U.S.C. § 355(j) with a paragraph IV certification that ALZA's '580 patent was invalid or would not be infringed by Mylan's marketing of its generic product. As required under 21 U.S.C. § 355(j)(2)(B), on December 6, 2001, Mylan sent ALZA notice of its ANDA application and certification which ALZA received on December 10, 2001. On January 25, 2002, the forty-sixth day after notice was received, ALZA filed a patent infringement action against Mylan in the United States District Court for the District of Vermont. Because the action was not brought within the statutory 45-day window following notice receipt, there was no automatic 30-month stay and, under 21 U.S.C. § 355(j)(5)(B)(iii), Mylan's ANDA was to 'be made effective immediately.' Accordingly, on November 21, 2003, the FDA granted final approval of Mylan's ANDA."); see, e.g., *Mylan Labs., Inc. v. Leavitt*, 484 F. Supp. 2d 109, 115-16 (D.D.C. 2007) ("On May 22, 2002, Mylan filed an ANDA to the FDA for a generic version of amlodipine besylate. Mylan's ANDA contained a Paragraph IV Certification complete with Mylan's assertion that Pfizer's 303 Patent was invalid. Responding to this action, Pfizer initiated a patent infringement lawsuit in the United States District Court for the Western District of Pennsylvania. Though the filing of this lawsuit by Pfizer would ordinarily have triggered an automatic 30-month stay on approval of Mylan's ANDA with the FDA, 21 U.S.C. § 355(j)(5)(B)(iii), because Pfizer failed to file its lawsuit within 45 days after receiving notice of Mylan's Paragraph IV Certification, the statutory 30-month stay was not triggered . . ."); *Biovail Labs. Int'l SRL v. Impax Labs. Inc.*, 433 F. Supp. 2d 501 (E.D. Pa. 2006); see also *Alza Corp. v. Mylan Labs.*, 391 F.3d 1365 (Fed. Cir. 2004); UPADHYE, *supra* note 16, § 11:17.

52. *Pfizer, Inc. v. Mylan Labs., Inc.*, No. 02:02CV1628, 2007 WL 654274, at *35 (W.D. Pa. Feb. 27, 2007) ("AND NOW, this 27th day of February, 2007, in accordance with the foregoing Findings of Fact and Conclusions of Law, is it ORDERED, ADJUDGED, AND DECREED that judgment in this action is hereby entered in favor of Pfizer Inc. and against Mylan Laboratories, Inc. and Mylan

posture in the case, a patentee could seek a traditional preliminary injunction to block a generic launch upon thirty-month litigation stay expiry using the pop-up patent and/or use the pop-up patent as the actual basis for liability.⁵³

Congress recognized that repetitive thirty-month stays delayed generic drug entry and cured the problem in the 2003 MMA. Now the fight over the thirty-month stay involves ancillary litigation on whether to elongate or shorten the thirty-month stay.⁵⁴ The statute provided and still provides for elongation or premature termination of the stay based on the cooperation of the parties in the litigation.⁵⁵ Thus, the MMA fixed a huge problem in the 1984 Act.

V. THE 180-DAY EXCLUSIVITY PERIOD AND ITS FORFEITURE

If the 1984 Act can be comically known as the Litigator's Full Employment Act, then the 2003 MMA is the Continuing Litigator's Full Employment Act. The 180-day exclusivity and related machinations have caused extensive mischief, morphing well beyond original congressional intent.⁵⁶ The 180-day exclusivity was

Pharmaceuticals, Inc. Mylan Laboratories, Inc. and Mylan Pharmaceuticals, Inc., are hereby permanently enjoined from making, using, selling, offering to sell, or importing into the United States the Mylan Amlodipine Tablets described in ANDA No. 76-418 until after the expiration of Pfizer's '303 patent term, as extended by the pediatric exclusivity period."), *rev'd*, 236 Fed. App'x 608 (Fed. Cir. 2007).

53. See *Research Found. of State Univ. of N.Y. v. Mylan Pharm. Inc.*, Civ. Nos. 09-84-LPS, 10-892-LPS, 2012 WL 1901267 (D. Del. May 25, 2012) (finding no liability on the original Paragraph IV patents, the court enjoined the generic company based on the Chang 532 pop-up patent).

54. See UPADHYE, *supra* note 16, § 11:13 (discussing cases that extend the thirty-month stay), 11:15 (discussing cases that shorten the thirty-month stay).

55. 21 U.S.C. § 355(j)(5)(B)(iii) (2012) ("If such an action is brought before the expiration of such days, the approval shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under paragraph (2)(B)(i) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action.").

56. *Hi-Tech Pharmacal Co. v. U.S. Food & Drug Admin.*, 587 F. Supp. 2d 1, 4 (D.D.C. 2008) ("Entitlement to the 180-day exclusivity period can be forfeited, however, if a first ANDA-applicant fails to market the drug within a specified time period. Congress enacted the forfeiture provisions to 'ensure that the 180-day exclusivity period enjoyed by the first generic to challenge a patent cannot be used as a bottleneck to prevent additional generic competition.'" (citations omitted));

originally designed to provide an incentive (not a vested property right) to generic companies to step up to challenge Orange Book patents and bring products to the market early.⁵⁷ To understand why the situation is still problematic, we need to understand what the 180-day exclusivity is and why it matters.

First, economically, the amount of money in play is enormous. Obviously, for larger branded drugs the value of the 180-day exclusivity to the generic company is large and for smaller drugs the value proposition is less. The 1984 Act did not expressly provide for an outright 180-day exclusivity; rather, it was created as a function of subsequent ANDA filers. The 180-day exclusivity is created only when a second ANDA applicant files an ANDA with the relevant Paragraph IV certifications.⁵⁸ In other words, the first ANDA filer (with the Paragraph IV certification) receives only a 180-day exclusivity when a second ANDA filer (with the same Paragraph IV certification) files. Without a second ANDA filer

149 CONG. REC. S16104, 16105-06 (daily ed. Dec. 9, 2003) (statement of Sen. Orrin Hatch) (“This is good for the consumer and sound policy since the rationale behind the 180-day provision is to create an incentive for challenges to the pioneer’s patents, not to create an entitlement to the first applicant to file a patent challenge with the FDA in the Parklawn Building.”).

57. *Compare* Teva Pharm. USA, Inc. v. Leavitt, 548 F.3d 103, 107 (D.C. Cir. 2008) (“Unfortunately for Teva, an ANDA applicant’s right to a period of marketing exclusivity does not vest merely because a paragraph IV certification is filed.”), *with* Teva Pharm. USA, Inc. v. Sebelius, 595 F.3d 1303, 1318 (D.C. Cir. 2010) (“Finally, the FDA’s sole effort to root its interpretation in the policy underlying Hatch-Waxman—the thought that the interpretation benefits consumers by allowing full generic competition without a 180-day delay—betrays a misunderstanding of the exclusivity incentive. The statute’s grant of a 180-day delay in multiple generic competition for the first successful paragraph IV filer is a pro-consumer device. And it happens to be precisely the device Congress has chosen to induce challenges to patents claimed to support brand drugs. The statute thus deliberately sacrifices the benefits of full generic competition at the first chance allowed by the brand manufacturer’s patents, in favor of the benefits of earlier generic competition, brought about by the promise of a reward for generics that stick out their necks (at the potential cost of a patent infringement suit) by claiming that patent law does not extend the brand maker’s monopoly as long as the brand maker has asserted. As Congress deliberately created the 180-day exclusivity bonus, the FDA cannot justify its interpretation by proudly proclaiming that it has eviscerated that bonus.”).

58. 21 U.S.C. § 355(j)(5)(B)(iv)(I) (discussing how a second application with a Paragraph IV certification will be held behind a first applicant that has submitted an application containing a Paragraph IV certification).

(with the Paragraph IV certifications), the first filer will not receive the statutory 180-day exclusivity period:

Subject to subparagraph (D), if the application contains a certification described in paragraph (2) (A) (vii) (IV) and is for a drug for which a first applicant has submitted an application containing such a certification, the application shall be made effective on the date that is 180 days after the date of the first commercial marketing of the drug (including the commercial marketing of the listed drug) by any first applicant.⁵⁹

The statute designs the 180-day exclusivity to be the inverse of an outright grant of exclusivity. Yet too often parties argue that it is a vested property right, even though the D.C. Circuit has held that it is not a vested property right.⁶⁰ If it were an outright grant of immutable property, the 1984 statute and subsequent amendments would have so stated.⁶¹ Congress is presumed to legislate knowing the underlying state of the law. Congress was fully aware that fights over the 180-day exclusivity existed but chose not to grant it outright.⁶² Instead, the reverse happened.

VI. CONGRESS EXPLICITLY CREATES VEHICLES TO STRIP EXCLUSIVITY

In the MMA of 2003, Congress legislated to extinguish the 180-day exclusivity. Congress recognized that parties were “bottle-necking” or “parking” the exclusivity so that subsequent ANDA filers were blocked.⁶³ In response, Congress created not just

59. *Id.*

60. *Leavitt*, 548 F.3d at 107; *see also* UPADHYE, *supra* note 16, § 13:2.

61. C. Scott Hemphill & Mark A. Lemley, *Earning Exclusivity: Generic Drug Incentives and the Hatch-Waxman Act*, 77 ANTITRUST L.J. 947, 969–70 (2011) (suggesting that exclusivity should be earned).

62. *See* *Gross v. FBL Fin. Servs., Inc.*, 557 U.S. 167, 174 (2009) (“We cannot ignore Congress’ decision to amend Title VII’s relevant provisions but not make similar changes to the ADEA. When Congress amends one statutory provision but not another, it is presumed to have acted intentionally.”). In creating the forfeiture provisions, Congress touched that section of the Hatch-Waxman Act, touched the 180-day exclusivity provision, and yet still left the provision as a function of an inverse grant.

63. Erika King Lietzan, *A Brief History of 180-Day Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act*, 59 FOOD & DRUG L.J. 287, 314 (2004) (citing 149 CONG. REC. S15,746 (daily ed. Nov. 24, 2003) (statement of Sen. Charles Schumer)); *see also* 149 CONG. REC. S15,761 (daily ed. Nov. 24, 2003) (statement of Sen. William Frist).

one, but *six* different forfeiture buckets in the MMA to strip the 180-day exclusivity from the first ANDA filer.⁶⁴ Congress enacted these six forfeiture buckets in one section.⁶⁵ Legislative history also confirms that congressional intent was to deprive the first filer of its 180-day exclusivity as soon as possible.⁶⁶ It is important to differentiate between a forfeiture of the exclusivity versus a trigger of the exclusivity. A forfeiture is a binary event that can only occur if the exclusivity exists.⁶⁷ A trigger, though, starts the 180-day clock.

Congress did not do the best job in drafting the relevant MMA provisions. Yet clever parties have been successful in perverting the statute even more and twisting it beyond its intended purpose by arguing that forfeiture ought not to apply in certain situations.⁶⁸ Courts, regrettably, have agreed.⁶⁹ We can examine a few of these perversions and acceptable outcomes.⁷⁰

64. See 21 U.S.C. § 355(j)(5)(D)(i) (2012); *Hi-Tech Pharm. Co. v. U.S. Food & Drug Admin.*, 587 F. Supp. 2d 1, 4 (D.D.C. 2008) (“Entitlement to the 180-day exclusivity period can be forfeited, however, if a first ANDA-applicant fails to market the drug within a specified time period. Congress enacted the forfeiture provisions to ‘ensure that the 180-day exclusivity period enjoyed by the first generic to challenge a patent cannot be used as a bottleneck to prevent additional generic competition.’”).

65. 21 U.S.C. § 355(j)(5)(D)(i).

66. 149 CONG. REC. S16,104, 16,105-06 (daily ed. Dec. 9, 2003) (statement of Sen. Orrin Hatch).

67. 21 U.S.C. §355(j)(5)(D)(i).

68. *Teva Pharm. USA, Inc. v. Sebelius*, 638 F. Supp. 2d 42 (D.D.C. 2009), *rev'd*, 595 F.3d 1303 (D.C. Cir. 2010); *Hi-Tech Pharmacal Co. v. U.S. Food & Drug Admin. (Hi-Tech II)*, 587 F. Supp. 2d 13 (D.D.C. 2008) (discussing effect of delisting patents); *Granisetron Hydrochloride Injection and 180-day Generic Drug Exclusivity*, FDA Docket No.: 2007N-0389 (Jan. 17, 2008), *available at* <http://www.fda.gov/ohrms/dockets/dockets/07n0389/07n-0389-let0003.pdf>; *Ramipril Capsules and 180-Day Generic Drug Exclusivity*, FDA Docket No.: 2007N-0382 (Jan. 29, 2008), *available at* <http://www.fda.gov/ohrms/dockets/dockets/07n0382/07n-0382-let6.pdf>.

69. *Teva*, 638 F. Supp. 2d 42; *Mylan Labs. Ltd. v. U.S. Food & Drug Admin.*, 910 F. Supp. 2d 299, 314 (D.D.C. 2012) (“The administrative record on Ranbaxy’s failure to obtain tentative approval within 30 months is complete. Both FDA and Ranbaxy have filed summary judgment motions that are fully briefed. For the reasons stated in Part I.A., the Court concludes that, as a matter of law, FDA’s September 28, 2012 no-forfeiture decision is supported by the administrative record and is not ‘arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.’ Hence, summary judgment in favor of FDA and Ranbaxy is appropriate and will be entered.” (citations omitted)).

70. As a side note, despite a generic company’s reverence to the 180-day exclusivity as a reward for which no generic drug development would have

An area that does work is the so-called “failure to obtain tentative approval” bucket.⁷¹ Recall that in the pre-MMA regime, a party could file a shoddy ANDA just to secure the 180-day exclusivity status.⁷² Given the ANDA application’s poor quality, it could take years to obtain final ANDA approval. If the 180-day exclusivity was triggered only by a commercial launch or a court decision, then assuming that no court decision came, the launch was the only trigger. A poor-quality ANDA would not timely obtain final launch approval, preventing any other generic version of the same drug from entering the market. In the 2003 MMA, Congress recognized this and enacted this “failure to obtain tentative approval” bucket.⁷³ Based on the ANDA filing date, the first ANDA applicant would have only thirty months to obtain tentative (or final, if relevant) approval.⁷⁴

The effect of this provision is that first ANDA filers must now submit a quality ANDA that has the best chance of moving through the review system within thirty months of its filing date. Otherwise, the first ANDA filer will forfeit its exclusivity. Due to FDA review backlogs, though, the average pendency of ANDA reviews was about thirty-three to thirty-four months,⁷⁵ so a lot of first ANDA filers forfeited the 180-day exclusivity through no fault of their own. In challenging the forfeitures, many applicants complained that it was not the poor quality of the ANDA that caused long review periods; rather, it was the FDA review queue workload. That is, the delays in obtaining tentative approval in time were due to volume of work at the FDA, not due to ANDA quality issues. The FDA defended that the statute provided a thirty-month window, and if applicants were so concerned, then the remedy lay with Congress.

occurred but for its existence, it is interesting to note that no other country in the world has a generic drug exclusivity, even those countries that have a vibrant generic drug development program and marketing. This is further evidence that the 180-day exclusivity is a windfall when it happens, but is not a necessary predicate to generic drug development.

71. 21 U.S.C. § 355(j)(5)(D)(i)(IV) (2012).

72. *See, e.g.,* *Nostrum Pharm., L.L.C. v. U.S. Food & Drug Admin.*, No. 11-3111 (JAP), 2011 WL 2652147, at *2–3 (D.N.J. July 6, 2011) (stating that the ANDA was filed in March 2003 but not approved until May 2011, some 8 years and 2 months later).

73. 21 U.S.C. § 355(j)(5)(D)(i)(IV).

74. *See id.*

75. Derrick Gingery, *ANDA Application Backlogs, Submission Bubbles Plague User Fee Rollout*, PINK SHEET, Feb. 17, 2014, at 1.

Congress heard and acted. In the recent Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA), Congress enacted temporary stopgap measures to help ANDA applicants retain the 180-day exclusivity due to FDA review backlogs.⁷⁶ In addition, Congress authorized the Generic Drug User Fee Act (GDUFA) to allow the FDA to collect filing fees from ANDA applicants, the money from which is used to help reduce the backlog.⁷⁷ Under the FDASIA amendment, the previous thirty-month clock to obtain approval is now temporarily extended to forty months until September 30, 2015, and then is reduced to thirty-six months until September 30, 2016, then back to thirty months.⁷⁸ The combination of the extension of time and the GDUFA fees should allow ANDA applicants to meet the thirty, thirty-six, and forty month deadlines.

Accordingly, Congress stepped in twice to fix the problems. First, the MMA created the tentative approval in a thirty-month window to force the filing of higher quality ANDAs. Second, when the backlog became great, Congress extended the tentative approval window to forty months. So, when Congress knew that ANDA sponsors were fighting over the 180-day exclusivity, Congress still chose not to grant the exclusivity outright. While it can be suggested that Congress now agrees with the underlying case law precedent on the matter (and hence felt no need to codify it), equally, the status of the 180-day exclusivity remains in dispute. But we can safely state that recognizing that the thirty-month window to obtain tentative approval was not working under the modern realities and Congress, rather than courts or the FDA, stepped in to legislate a correction to the 1984 Act. Therefore, this part of the overall system works.

VII. THE FAILURE TO MARKET—A PERVERSION OF A PROVISION

Most of the perversions in the MMA, however, exist in the first forfeiture bucket; namely, the failure-to-market bucket.⁷⁹ This forfeiture bucket, in principle, is supposed to ensure that if the first

76. Food and Drug Administration Safety and Innovation Act, Pub. L. No. 112-144, § 1133, 126 Stat. 993, 1122 (2012).

77. *Id.* § 744B, 126 Stat. at 1011.

78. *Id.* § 1133, 126 Stat. at 1122 (codified as amended at 21 U.S.C. § 355(j)(5)(D)(i)(IV)); *see also* UPADHYE, *supra* note 16, § 14:15.70.

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

ANDA filer can launch the product without incurring patent liability, then it should do so. The provision is designed to prevent the 180-day exclusivity from being parked. To understand why this forfeiture bucket is problematic, it is important to examine the statutory structure, which is as follows:

(i) Definition of forfeiture event.—In this subparagraph, the term “forfeiture event”, with respect to an application under this subsection, means the occurrence of any of the following:

(I) Failure to market.—The first applicant fails to market the drug by the later of—

(aa) the earlier of the date that is—

(AA) 75 days after the date on which the approval of the application of the first applicant is made effective under subparagraph (B)(iii); or

(BB) 30 months after the date of submission of the application of the first applicant; or

(bb) with respect to the first applicant or any other applicant (which other applicant has received tentative approval), the date that is 75 days after the date as of which, as to each of the patents with respect to which the first applicant submitted and lawfully maintained a certification qualifying the first applicant for the 180-day exclusivity period under subparagraph (B)(iv), at least 1 of the following has occurred:

(AA) In an infringement action brought against that applicant with respect to the patent or in a declaratory judgment action brought by that applicant with respect to the patent, a court enters a final decision from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the patent is invalid or not infringed.

(BB) In an infringement action or a declaratory judgment action described in subitem (AA), a court signs a settlement order or consent decree that enters a final judgment that includes a finding that the patent is invalid or not infringed.

(CC) The patent information submitted under subsection (b) or (c) of this section is withdrawn

by the holder of the application approved under subsection (b) of this section.⁸⁰

The statute requires a comparison of two distinct events to determine which comes later in time: a “little (aa)” versus a “little (bb)” event. To determine the dates that apply to the little (aa) or little (bb) events, one must then drill down to examine the big (AA), big (BB), and big (CC) dates that may apply. Here is where the problem lies. Recall that the overall purpose and structure of the forfeiture statutes are to cause the forfeiture that will lead to open market competition. The forfeiture buckets are designed to strip any 180-day exclusivity entitlements.⁸¹ Under little (aa), the underlying dates are easily calculable as these dates rely mostly on regulatory affairs processes. Little (bb)/big (AA) and little (bb)/big (BB) are generally related to litigation whereas little (bb)/big (CC) is not litigation related, but is related to conduct of the patentee in delisting the patent from the Orange Book.

In examining the statutory setup regarding the failure to market provision, the purpose of the little (bb)/big (AA) or big (BB) provisions is to cause the forfeiture when any litigation exposure has been eliminated.⁸² Without those protections, the 180-day exclusivity holder might feel it necessary to launch the product, with potential risk of exposure, in order to capitalize on the 180-day exclusivity. The big (AA) and big (BB) provisions help protect against the potential at-risk launch exposure.

VIII. DELISTING PATENTS AND FORFEITURE—PERVERSIONS OF PROVISIONS CONTINUE

The little (bb)/big (CC) provision has been wrongly interpreted by the courts. The plain text of the statute puts no conditions on how or why the patent information is withdrawn (that is, the patent is delisted from the Orange Book). All that the statute requires is simply that the patent information is withdrawn.

80. 21 U.S.C. § 355(j)(5)(D)(i).

81. *Id.*; *Hi-Tech Pharmacal Co. v. U.S. Food & Drug Admin.*, 587 F. Supp. 2d 1, 4 (D.D.C. 2008) (“Entitlement to the 180-day exclusivity period can be forfeited, however, if a first ANDA-applicant fails to market the drug within a specified time period. Congress enacted the forfeiture provisions to ‘ensure that the 180-day exclusivity period enjoyed by the first generic to challenge a patent cannot be used as a bottleneck to prevent additional generic competition.’”).

82. 21 U.S.C. § 355(j)(5)(D)(i).

Motives or mechanics on the patent delisting are not relevant. Unfortunately, one court disagreed.⁸³

The D.C. Circuit added quite a load of nonstatutory baggage to the provision. To the court, the proper interpretation of the provision required that the patent was delisted pursuant to a court order that mandated its delisting.⁸⁴ It was not enough that the patentee simply recognize that the patent was improperly listed and that its delisting was necessary.⁸⁵ To the court, litigation was necessary to obtain a court order requiring the delisting and, without it, the patent could not be delisted voluntarily.⁸⁶ The court relied on the *broader* policy that the *original* 1984 Hatch-Waxman Act created—the 180-day exclusivity for the first filed generic company—and noted that it would be unfair for a patentee to manipulate that policy by delisting the patent(s) unilaterally.⁸⁷

83. See *Teva Pharm. USA, Inc. v. Sebelius*, 595 F.3d 1303, 1315 (D.C. Cir. 2010).

84. *Apotex, Inc. v. Sebelius*, 384 Fed. App'x 4, 4 (D.C. Cir. 2010) (citations omitted) (“When the Hatch-Waxman Act’s forfeiture provisions are viewed in the context of the statute’s incentive structure, it becomes clear that Congress could not have intended a brand manufacturer’s unilateral decision to cause the premature expiration of a patent (in the face of a generic applicant’s challenge to the patent in a paragraph IV certification) to strip the first generic applicant of the 180-day period of marketing exclusivity granted by the statute. We will thus affirm the district court’s decision to deny appellants’ motions for a preliminary injunction.”). In the interest of disclosure, I was the Global Head of IP for Apotex, Inc., who instigated the attempt to forfeit.

85. *Teva*, 595 F.3d at 1307 (“In response to Teva’s filing, Merck chose not to sue for infringement, as it might have. Instead, on March 18, 2005, Merck asked the FDA to delist the 075 patent, which the agency did, though without making the action public until April 18, 2008.”).

86. *Id.* at 1317 (“Setting aside the subsection at issue in this case—listed as (5) above, and codified as (bb)(CC)—the ‘failure to market’ forfeiture provision does not permit a brand manufacturer to vitiate a generic’s exclusivity without the generic manufacturer’s having had some say in the matter. No forfeiture can take place unless the brand manufacturer brings an infringement suit against the generic and either loses on the merits or enters an unfavorable settlement agreement. The latter necessarily entails some participation by the generic; the former invariably involves significant expense for the brand manufacturer, and affords the victorious generic the opportunity to ask the court to delay entering final judgment until a date that would not trigger forfeiture prematurely—before the agency grants final approval to the relevant ANDA.”).

87. *Id.* at 1318 (“We see nothing in the 2003 amendments to the Food, Drug, and Cosmetic Act that changes the structure of the statute such that brand companies should be newly able to delist challenged patents, thereby triggering a forfeiture event that deprives generic companies of the period of marketing

Of course, that is wrong.⁸⁸ First, it is arguable whether the original 1984 Hatch-Waxman Act created an overall policy to create a vested property right as a reward.⁸⁹ Second, even if there was an original broader policy, the 2003 MMA forfeiture provisions distinctly narrowed that policy in favor of causing a forfeiture of the 180-day exclusivity. Recall that the MMA created not just one, but six different provisions, each mutually exclusive, that were expressly defined to forfeit the 180-day exclusivity. The court stated that nothing in the MMA changed the overall policy allowing the first filer to maintain its exclusivity even though the patentee delisted the patent. Furthermore, by holding that the patent delisting provision of little (bb)/big (CC) could be invoked only through a litigation consequence, unilateral delisting would not qualify as a forfeiture.⁹⁰ Finally, certain studies indicate that awards of 180-day exclusivity occurred even when there was no litigation or no real challenges to patents.⁹¹

exclusivity they otherwise deserve. For that reason, the interpretation of the statute that the FDA has adopted in two recent adjudications, and that it regards itself as bound by law to apply to Teva's ANDAs for losartan products, fails at *Chevron* step one.”). For a complete description of the events in the losartan patent delisting case, its twists and turns, and its wrong conclusion, see UPADHYE, *supra* note 16, § 14:9.

88. Of course I am wrong, because the court decided what it decided and is deemed correct. I suggest the court is “of course” wrong because I continue to disagree with its position.

89. *Teva Pharm. USA, Inc. v. Leavitt*, 548 F.3d 103, 107 (D.C. Cir. 2008) (“Unfortunately for Teva, an ANDA applicant’s right to a period of marketing exclusivity does not vest merely because a paragraph IV certification is filed.”).

90. *Teva*, 595 F.3d at 1318 (“We see nothing in the 2003 amendments to the Food, Drug, and Cosmetic Act that changes the structure of the statute such that brand companies should be newly able to delist challenged patents, thereby triggering a forfeiture event that deprives generic companies of the period of marketing exclusivity they otherwise deserve. For that reason, the interpretation of the statute that the FDA has adopted in two recent adjudications, and that it regards itself as bound by law to apply to Teva’s ANDAs for losartan products, fails at *Chevron* step one.”). This (wrong) holding was reaffirmed in *Apotex*, 384 Fed. App’x 4.

91. *Hemphill & Lemley*, *supra* note 61, at 956–57 (“We found that for most drugs, the generic drug maker did little or nothing to earn the exclusivity award. Almost half of the awards (23) are no-suit awards, meaning that the generic firm didn’t have to spend money on litigation or face uncertainty about the outcome of the suit. Indeed, in some cases the basis for the award was a patent that was arguably irrelevant to the product described in the ANDA, in which case little or no effort was needed to develop a legal or design-around strategy. Another nine

The court's litigation-instigated delisting holding is quite a startling view of the statute. First, if Congress intended that a litigation consequence was necessary under little (bb)/big (CC), then Congress could have specifically said so.⁹² After all, the immediately adjacent statutory provisions, namely little (bb)/big (AA) and big (BB), each contain specific litigation consequences.⁹³ Second, if Congress intended that a litigation consequence was necessary, it could have created an umbrella provision in the text of little (bb)'s preamble itself before the recitation of the precise subsections in big (AA), (BB), and (CC). It did not do so.⁹⁴ Third, it is quite a feat of statutory gymnastics to ignore the expressed statutory policy scheme of the forfeiture provisions in which little (bb)/big (CC) is embedded and then jump over that narrower scheme to rest its decision in the overall broader policy of the 1984 Act.⁹⁵ Finally, if Congress intended to make the delisting provision contingent on the specific litigation counterclaims to delist or correct patent information under the nonspecific provision of 21 U.S.C. § 355(j)(5)(C)(ii)(I), then it could have so amended that provision too. It did not do so even though that subsection was enacted in the MMA at the same time as the little (bb)/big (CC) provision.⁹⁶

are settlements, which we reviewed in greater detail. None of these settlements did anything to open up the market to other generic entrants. Eight more were launches at risk. Only nine included a win by the generic firm, all but one of which included an invalidation or unenforceability determination as to at least one brand-name patent.”).

92. See *Stone v. Immigration & Naturalization Serv.*, 514 U.S. 386, 397 (1995) (“When Congress acts to amend a statute, we presume it intends its amendment to have real and substantial effect.”).

93. *Food & Drug Admin. v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000) (citations omitted) (“It is a ‘fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme.’ A court must therefore interpret the statute ‘as a symmetrical and coherent regulatory scheme,’ and ‘fit, if possible, all parts into an harmonious whole.’ Similarly, the meaning of one statute may be affected by other Acts, particularly where Congress has spoken subsequently and more specifically to the topic at hand.”).

94. 21 U.S.C. 355(j)(5)(D)(i) (2012).

95. See *Dolan v. U.S. Postal Serv.*, 546 U.S. 481, 486 (2006) (“A word in a statute may or may not extend to the outer limits of its definitional possibilities. Interpretation of a word or phrase depends upon reading the whole statutory text, considering the purpose and context of the statute, and consulting any precedents or authorities that inform the analysis.”).

96. *Gross v. FBL Fin. Servs., Inc.*, 557 U.S. 167, 174–75 (2009) (“We cannot

Another area that does not work, and remains to be seen whether it will ever work, is the fifth forfeiture bucket—the coercive agreement/antitrust violation forfeiture bucket.⁹⁷ This provision basically provides that if the patentee and the first ANDA filer (who has the 180-day exclusivity) settle a lawsuit on anticompetitive terms, the first filer will forfeit the exclusivity. In section 14:11 of my treatise, I discuss that this provision has no teeth given the existing case law, which refuses to find any settlement anticompetitive. Further, because the government is the sole plaintiff allowed to prosecute an anticompetition case, it will take years before any decision is capable of triggering the forfeiture.

However, the recent U.S. Supreme Court case of *Federal Trade Commission v. Actavis* may help.⁹⁸ The Supreme Court held that certain settlements that park the 180-day exclusivity can be deemed anticompetitive under the traditional antitrust rule-of-reason precedent.⁹⁹ Prior cases had deemed parking settlements as presumptively reasonable.¹⁰⁰ Now, the government and private

ignore Congress' decision to amend Title VII's relevant provisions but not make similar changes to the ADEA. When Congress amends one statutory provision but not another, it is presumed to have acted intentionally.”).

97. 21 U.S.C. § 355(j)(5)(D)(i)(V) (2012) (“Agreement with another applicant, the listed drug application holder, or a patent owner.[—]The first applicant enters into an agreement with another applicant under this subsection for the drug, the holder of the application for the listed drug, or an owner of the patent that is the subject of the certification under paragraph (2)(A)(vii)(IV), the Federal Trade Commission or the Attorney General files a complaint, and there is a final decision of the Federal Trade Commission or the court with regard to the complaint from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the agreement has violated the antitrust laws (as defined in section 12 of title 15, except that the term includes section 5 of title 15 to the extent that that section applies to unfair methods of competition.”); see also UPADHYE, *supra* note 16, § 14:11.

98. Fed. Trade Comm'n v. Actavis, 133 S. Ct. 2223, 2237 (2013) (“These complexities lead us to conclude that the FTC must prove its case as in other rule-of-reason cases.”).

99. *Id.*

100. *Id.* at 2230 (“Because different courts have reached different conclusions about the application of the antitrust laws to Hatch-Waxman-related patent settlements, we granted the FTC’s petition.”). Compare, e.g., Fed. Trade Comm’n v. Watson Pharm., Inc., 677 F.3d 1298 (11th Cir. 2012), *rev’d and remanded sub nom.* Fed. Trade Comm’n v. Actavis, Inc., 133 S. Ct. 2223 (2013) (settlements generally “immune from antitrust attack”), and *In re* Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323, 1332–37 (Fed. Cir. 2008) (similar), and *In re* Tamoxifen

plaintiffs will have an “easier” time proving that the agreement is anticompetitive. Frankly, due to the inherent nature and complexities of an antitrust trial, it may still take a long time to resolve.¹⁰¹

Because of the threat of anticompetition liability that exists against the patentee and the first filer, the mere investigation or initial prosecution of the first filer may be sufficient to cause the first filer to voluntarily (or perhaps not so voluntarily) relinquish or waive any 180-day exclusivity rights.¹⁰² A relinquishment is just that—an abandonment of any rights held by the first filer—thereby promoting competition by allowing any approvable ANDA applicant to obtain final approval and enter the market. A selective waiver allows the first filer to individually “anoint” another ANDA filer with rights to obtain final approval without necessarily opening the door to all ANDA filers.¹⁰³

In summary, the forfeiture provisions are an excellent start to open up the marketplace to generic competitors alike and eliminate some of the bottlenecks. *Actavis* will also likely stop some anti-competitive settlements that bottleneck the exclusivity.¹⁰⁴ The failure-to-market bucket remains the biggest culprit that maintains bottlenecks of the 180-day exclusivity and is not working as planned. Until the improper notion that the 180-day exclusivity is a vested property right that cannot be interfered with is eliminated, and that the forfeiture provision is restored to its proper policy background, games with the exclusivity will continue.

Citrate Antitrust Litig., 466 F.3d 187, 212–213 (2d Cir. 2006) (similar), *with In re K-Dur Antitrust Litig.*, 686 F.3d 197, 214–218 (3d Cir. 2012) (settlements presumptively unlawful), *and Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294, 1296 (11th Cir. 2003) (presumptively reasonable).

101. See *W. Penn Allegheny Health Sys., Inc. v. UPMC*, 627 F.3d 85, 97 (3d Cir. 2010) (“[D]iscovery in complex cases is expensive and time-consuming . . .”).

102. *Actavis*, 133 U.S. at 2234 (“The Circuit’s related underlying practical concern consists of its fear that antitrust scrutiny of a reverse payment agreement would require the parties to litigate the validity of the patent in order to demonstrate what would have happened to competition in the absence of the settlement. Any such litigation will prove time consuming, complex, and expensive.”).

103. For further details of the total relinquishment and selective waiver process, see UPADHYE, *supra* note 16, §§ 13:14–:16.

104. *Actavis*, 133 U.S. 2223; see also Aaron Edlin et al., *Activating Actavis*, 28 ANTITRUST, Fall 2013, at 16, 21.

IX. THE SCOPE OF LITIGABLE PATENTS IN HATCH-WAXMAN SUITS

Paragraph IV patent litigation is no doubt complicated, time consuming, and expensive. Plus there is a lot at stake given that brand manufacturers stand to lose millions (if not billions) of dollars in sales. Generic companies, though, play the important role of providing low-cost alternatives to help control healthcare costs.¹⁰⁵ To this end, brand companies have every desire to enforce as many patents as possible, and generic companies have an equally strong desire to reduce the number of patents in suit. This dichotomy has led to another broken part of the original Hatch-Waxman regime.

Which patents should form the basis of a Hatch-Waxman suit? Each side of the industry can validly state policy considerations as to why more or fewer patents ought to be in play. Generic companies may argue that a lawsuit is confined only to Paragraph IV patents. Brand companies will argue that any and all patents are ripe for adjudication. Several examples may help illustrate the issues and the impact in relation to the underlying statutes. The first place to start is the statutes to see if they answer the question.

The first statute to examine is 35 U.S.C. § 271(e)(2), which creates an artificial act of infringement for the ANDA applicant. It states:

It shall be an act of infringement to submit—

(A) an application under section 505(j) [21 U.S.C. § 355(j)] of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) [21 U.S.C. § 355(b)(2)] of such Act for a drug claimed in a patent or the use of which is claimed in a patent,

....

105. *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2574 (2011), *reh'g denied*, 132 S. Ct. 55 (2011) (“Under this law, ‘generic drugs’ can gain FDA approval simply by showing equivalence to a reference listed drug that has already been approved by the FDA This allows manufacturers to develop generic drugs inexpensively, without duplicating the clinical trials already performed on the equivalent brand-name drug.”); *ViroPharma, Inc. v. Hamburg*, 898 F. Supp. 2d 1, 29 (D.D.C. 2012) (quoting *Biovail Corp. v. Food & Drug Admin.*, 519 F. Supp. 2d 39, 50 (D.D.C. 2007)) (“The public ‘has a well-recognized interest in receiving generic competition to brand-name drugs as soon as possible . . . and a delay in the marketing of [the generic] drug could easily be against the public interest in reduced prices.’”).

if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug, veterinary biological product, or biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.¹⁰⁶

The purpose of this section is to confer subject matter jurisdiction to federal courts so that subsequent Paragraph IV litigation can be adjudicated.¹⁰⁷ From its plain language, § 271(e)(2)(A) defines the filing of an ANDA or § 505(b)(2) application as an act of infringement without more.¹⁰⁸ Whereas the traditional patent infringement statute, § 271(a), requires some make, use, sell, import, or offer for sale conduct, § 271(e)(2) merely requires the filing of an ANDA, and that the filing constitutes an artificial act of infringement for jurisdictional purposes.¹⁰⁹

Courts have routinely held that § 271(e)(2) is only a jurisdictional statute and provides no substantive rights.¹¹⁰ If substantive rights were accorded based on its literal language, then every patent that relates to the drug would be conclusively deemed infringed simply by filing the ANDA or § 505(b)(2) application. Moreover, if substantive rights are conclusive, then it is fair to ask which patent is infringed by the filing of the ANDA. Would it be

106. 35 U.S.C. § 271(e)(2) (2006).

107. *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676 (1990) (“The function of the paragraphs in question is to define a new (and somewhat artificial) act of infringement for a very limited and technical purpose that relates only to certain drug applications.”); *AstraZeneca Pharm. L.P. v. Apotex Corp.*, 669 F.3d 1370, 1377 (Fed. Cir. 2012) (“The Supreme Court has described § 271(e)(2) as creating ‘a highly artificial act of infringement’ triggered upon submission of an ANDA containing an erroneous Paragraph IV certification.”).

108. 35 U.S.C. § 271(e)(2)(A).

109. *Fed. Trade Comm’n v. Actavis, Inc.*, 133 S. Ct. 2223, 2228 (2013) (“Taking this last-mentioned route (called the ‘paragraph IV’ route), automatically counts as patent infringement, and often ‘means provoking litigation.’” (citation omitted)); *In re Rosuvastatin Calcium Patent Litig.*, 703 F.3d 511, 515 (Fed. Cir. 2012) (“Submission of an ANDA constitutes a statutory act of infringement pursuant to § 271(e)(2) of the Patent Act.”); *see* 35 U.S.C. § 271(e)(2)(A).

110. Though § 271(e)(2) is not a pure jurisdictional statute per se, it does confer jurisdiction. *Allergan, Inc. v. Alcon Labs., Inc.*, 324 F.3d 1322, 1330 (Fed. Cir. 2003) (“Section 271(e)(2) is not a jurisdictional statute in the strict sense of the word.”).

any patent held by the brand company and any other third party? Would it be simply any Orange Book-listed patent? If a patent is deemed to infringe conclusively by the most literal reading of the statute, then when could an ANDA be approvable based on some mysterious patent expiry? Finally, without knowing which patent is infringed, how could any ANDA or § 505(b)(2) applicant design around a patent? Or could it ever design around a patent given that the infringement is defined by the act of submitting an FDA application versus any substantive adjudication of whether any patent is indeed implicated?

The most logical, correct, and absurdity-avoiding reading of the statute is that it is simply a jurisdictional statute and confers no substantive benefits. I am quite sure that if the most literal reading of the statute deemed an ANDA automatically infringing without any inquiry, some brand company would have argued this already. But the question still remains: which patents are implicated by § 271(e)(2)?

Recalling the overall framework of the Orange Book, only certain patents may be listed in the Orange Book. Section 271(e)(2) has parallel language in 21 U.S.C. § 355(b)(1)(G), which governs the kind of patents that can be listed in the Orange Book.

21 U.S.C. § 355(b)(1)(G) Operative Language	35 U.S.C. § 271(e)(2)(A) Operative Language
The applicant shall file with the application the patent number and the <i>expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug</i> and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the <i>manufacture, use, or sale of the drug</i> .	It shall be an act of infringement to submit— (A) an application under section 505(j) [21 U.S.C. § 355(j)] of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) [21 U.S.C. § 355(b)(2)] of such Act <i>for a drug claimed in a patent or the use of which is claimed in a patent, . . . if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug, veterinary biological product, or biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.</i>

Admittedly, exact statutory symmetry does not exist. The language is slightly different, but parallels do exist.

Section 355(b)(1)(G) creates the affirmative obligation to list into the Orange Book the patents that can be implicated by the approval of an ANDA or § 505(b)(2) application. Once patents are listed in the Orange Book, the FDA cannot approve any ANDA or § 505(b)(2) application until all listed patents have been certified against using one or more of the relevant patent certifications.¹¹¹ Because the ANDA sponsor must certify to one or more patents, it is only when the sponsor notifies the brand company through the Paragraph IV notice letter that the brand company even becomes aware of the generic drug application.¹¹² If an ANDA sponsor certifies under either Paragraphs I, II, or III, it is not required to notify the brand company at all.¹¹³

When the brand company receives the Paragraph IV notice letter, it triggers the forty-five day window to bring suit. If it does so, then the suit generates the thirty-month litigation stay.¹¹⁴ A thirty-month litigation stay is not available in the absence of a Paragraph IV certification, which itself is tied to a specific patent.¹¹⁵ For example, suppose that a patent is set to expire within thirty months of an ANDA filing for which the ANDA sponsor filed a Paragraph III certification. If the patentee learns about the filing

111. A § 505(b)(2) application submits patent certifications under 21 U.S.C. § 355(b)(2)(A)(i)–(iv). An ANDA submits patent certifications under § 355(j)(2)(A)(vii)(I)–(IV).

112. *See id.* § 355(j)(2)(A)(vii)(IV), (j)(2)(B).

113. *See id.* § 355(j)(2)(B)(i) (“AGREEMENT TO GIVE NOTICE—An applicant that makes a certification described in subparagraph (A)(vii)(IV) shall include in the application a statement that the applicant will give notice as required by this subparagraph.”).

114. *Id.* § 355(j)(5)(B)(iii).

115. *See id.* § 355(j)(5)(B)(iii) (“If the applicant made a certification described in subclause (IV) of paragraph (2)(A)(vii) [355(j)(2)(A)(vii)(IV)], the approval shall be made effective immediately unless, before the expiration of 45 days after the date on which the notice described in paragraph (2)(B) [355(j)(2)(B)] is received, an action is brought for infringement of the patent that is the subject of the certification and for which information was submitted to the Secretary under subsection (b)(1) or (c)(2) of this section [355(b)(1) or 355(c)(2)] before the date on which the application (excluding an amendment or supplement to the application), which the Secretary later determines to be substantially complete, was submitted. If such an action is brought before the expiration of such days, the approval shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under paragraph (2)(B)(i) [355(j)(2)(B)(i)] or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action . . .”).

and chooses to bring suit, that action does not generate a thirty-month litigation stay. Said another way, the very nature of the litigation that precipitates a thirty-month stay is a function of a Paragraph IV certification. This is the first clear indication that Congress intended that any patent litigation confine itself to the Paragraph IV process.¹¹⁶ Otherwise, Congress could have simply permitted a thirty-month stay based on any patent-in-suit.

The 180-day exclusivity also plays a role in defining the underlying patents in litigation. The existence of the exclusivity is tied to the Paragraph IV patents. If Congress intended to give a reward of 180-day exclusivity to ANDA sponsors for moving ahead with an ANDA filing only, then it should have given exclusivity to any first ANDA sponsor, irrespective of the underlying patent certification status. Rather, Congress tied the 180-day exclusivity to Paragraph IV patents and offered that exclusivity reward to challenge patents.¹¹⁷ Said differently, if Congress intended that generic companies enjoy market exclusivity for stepping up and subjecting itself to patent litigation for simply filing an ANDA (versus challenging patents), then Congress could have simply tied the 180-day exclusivity to the act of filing an ANDA itself, whether or not any patents are challenged. But because Congress chose to limit the 180-day exclusivity to specific patents that are challenged via the Paragraph IV certification, then symmetry exists only if the underlying litigation is limited to just the Paragraph IV patents. It is asymmetric that only Paragraph IV patents can earn the reward but that more patents are in play in the lawsuit.

Similarly, Congress enacted the forfeiture provisions to undermine the expectation of exclusivity. In the failure to market forfeiture bucket, little (bb)/big (AA) and little (bb)/big (BB) implicate forfeiture based on the underlying Paragraph IV patent

116. *Id.* § 355(j)(5)(B)(iii)(I) (describing that the thirty-month stay can be terminated prematurely if the district court decides “that the patent” is invalid or not infringed). The antecedent basis for “the patent” is the patent that was the subject of the Paragraph IV certification.

117. *Fed. Trade Comm’n v. Actavis, Inc.*, 133 S. Ct. 2223, 2228–29 (2013) (“Hatch-Waxman provides a special incentive for a generic to be the first to file an Abbreviated New Drug Application taking the paragraph IV route. That applicant will enjoy a period of 180 days of exclusivity (from the first commercial marketing of its drug.)”; *Mylan Pharm., Inc. v. U.S. Food & Drug Admin.*, 454 F.3d 270, 273 (4th Cir. 2006) (“The 180-day exclusivity period created in § 355(j)(5)(B)(iv) is a significant boon to the recipient.”); *see* 21 U.S.C. § 355(j)(5)(B)(iv) (establishing exclusivity period).

litigation.¹¹⁸ There is nothing in the statute that suggests that non-Paragraph IV patents can precipitate any forfeiture. This is further evidence that patent litigation ought to be confined to the Paragraph IV patents.

With respect to little (bb)/big (CC), we saw in Part VIII above that the delisting of a patent from the Orange Book must be in reaction to a formal counterclaim to delist the patent. A counterclaim to delist a patent itself must have satisfied the prior procedures related to tendering an offer for confidential access alongside the Paragraph IV notice letter.¹¹⁹ This, of course, implies that it is only the Paragraph IV patents that can ultimately be delisted from the Orange Book.

Accordingly, it is exceedingly strange and contorted to suggest that (1) only Paragraph IV patents generate a notice letter informing the brand that the underlying ANDA even exists, (2) thirty-month litigation stays exist only when tied to a Paragraph IV patent, and (3) forfeitures can be triggered only by actual litigation (or counterclaims), but then suggest that non-Paragraph IV patents can also be part of any patent litigation. The only basis for that is the flimsy belief that the statutory act of artificial infringement confers a right to piggyback any patent into a suit.¹²⁰

Cases do indeed hold that non-Orange Book patents can be sued upon.¹²¹ Policy considerations also exist as to why all patents

118. 21 U.S.C. § 355(j)(5)(D)(i)(I).

119. *See id.* § 355(j)(5)(C)(i)(III).

120. Another flimsy justification for permitting “all” patents to be litigated is tied to the safe harbor exemption in 35 U.S.C. § 271(e)(1). If the principle purpose of § 271(e)(1)’s safe harbor is that any patent can be “early worked” in order to support drug development, then any patent should be able to be the subject in later litigation. If symmetry were a true concern, where only Paragraph IV patents were part of later litigation, then perhaps only Paragraph IV patents are immunized by the safe harbor, and non-Paragraph IV patents are not immunized by the safe harbor.

121. *See e.g.*, *Caraco Pharm. Labs., Ltd. v. Novo Nordisk*, 132 S. Ct. 1670, 1680 n.5 (2012); *AstraZeneca Pharm. v. Apotex Corp.*, 669 F.3d 1370, 1376–77 (Fed. Cir. 2012); *Impax Labs., Inc. v. Aventis Pharm., Inc.*, 468 F.3d 1366, 1372–73 (Fed. Cir. 2006); *Glaxo Grp. Ltd. v. Apotex, Inc.*, 376 F.3d 1339, 1343–44 (Fed. Cir. 2004); *Takeda Pharm. v. TWi Pharm.*, No. C-11-01601 JCS, slip op. at 39 (N.D. Cal. Apr. 8, 2013); *Cephalon Inc. v. Sandoz, Inc.*, No. 11-821-SLR, 2012 WL 682045, at *5 (D. Del. Mar. 1, 2012); *Bayer Healthcare L.L.C. v. Norbrook Labs., Ltd.*, Nos. 08-C-0953, 09-C-0108, 2009 WL 6337911, at *9 (E.D. Wis. Sept. 24, 2009); *Purdue Pharma Prod. L.P. v. Par Pharm. Inc.*, 642 F. Supp. 2d 329, 363 n.49 (D. Del. 2009); *Teva Pharm. USA, Inc. v. Abbott Labs.*, 301 F. Supp. 2d 819, 829

should be part of a suit. The first is a judicial management policy. Under a Paragraph IV patent-only system, a trial judge is not inclined to have non-Paragraph IV patents asserted later (for the first time) in a launch-based scenario. This scenario would require a judge to have a round one of Paragraph IV patent litigation, perhaps allow the generic company to launch, but then face a round two of non-Paragraph IV patent litigation. This would avoid eve-of-launch temporary restraining order or preliminary injunction filings and help judges control their dockets.¹²²

The second policy concerns patent infringement damage liability. While it may be more expensive and complicated in the first instance to have multiple patents in suits, if there objectively is potential liability on non-Paragraph IV patents later on, why would the generic company not want to know that and adjudicate that prior to being liable for future actual damages? Because of the uniqueness of the brand-generic drug pricing models, a patentee's damages may cripple the entire generic drug company's business.¹²³ It therefore seems appropriate to adjudicate all patents in one proceeding. The policy considerations, though, do not address the problem with the remedies in the patent suit.

X. THE "ALL" PATENTS-IN-SUIT THEORY HAS FAR-REACHING CONSEQUENCES FOR REMEDIES

Lost among all litigants and judges so far have been the remedies. The patent laws include remedies provisions for patent litigation in 35 U.S.C. § 271(e).¹²⁴ They are reprinted here with references to the relevant statutes in brackets as appropriate:

(3) In any action for patent infringement brought under this [§ 271], no injunctive or other relief may be

(N.D. Ill. 2004) (finding that non-Orange Book patents can be part of the lawsuit). *But see* Eisai Co. v. Mut. Pharm. Co., No. 06-3613 (HAA), 2007 WL 4556958, at *6 (D.N.J. Dec. 20, 2007); Abbott Labs. v. Zenith Labs., Inc., 934 F. Supp. 925, 936 (N.D. Ill. 1995) (finding that only Orange Book listed patents are part of lawsuit).

122. Judges have the right to control their docket. *See In re Fannie Mae Sec. Litig.*, 552 F.3d 814, 822 (D.C. Cir. 2009); *Landis v. North Am. Co.*, 299 U.S. 248, 254 (1936).

123. Each case stands on its own facts and circumstances and not every patent litigation results in crippling damages. Moreover, what is crippling to one company may not be crippling to another.

124. *See* 35 U.S.C. § 271(e)(2)–(5).

granted which would prohibit the making, using, offering to sell, or selling within the United States or importing into the United States of a patented invention under [§ 271(e)(1)].

(4) For an act of infringement described in [§ 271(e)(2)]—

(A) the court shall order the effective date of any approval of the drug or veterinary biological product involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed,

(B) injunctive relief may be granted against an infringer to prevent the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug or veterinary biological product, and

(C) damages or other monetary relief may be awarded against an infringer only if there has been commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug veterinary biological product, or biological product

. . . .

The remedies prescribed by subparagraphs (A), (B), and (C) are the only remedies which may be granted by a court for an act of infringement described in [§ 271(e)(2)], except that a court may award attorney fees under [§ 285].

(5) Where a person has filed an application described in [§ 271(e)(2)] that includes a certification under subsection [21 U.S.C. § 355(b)(2)(A)(iv)] or [21 U.S.C. § 355(j)(2)(A)(vii)(IV)], and neither the owner of the patent that is the subject of the certification nor the holder of the approved application under [21 U.S.C. § 355(b)] for the drug that is claimed by the patent or a use of which is claimed by the patent brought an action for infringement of such patent before the expiration of 45 days after the date on which the notice given under [21 U.S.C. § 355(b)(3)] or [21 U.S.C. § 355(j)(2)(B)] was received, the courts of the United States shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any action brought by such person under [28 U.S.C. § 2201] for a declaratory judgment that such patent is invalid or not infringed.

Starting with § 271(e)(3), this section refers to infringement actions brought under § 271(e)(1). The lack of any equitable enforcement for § 271(e)(1) conduct further solidifies that a safe harbor exists under § 271(e)(1).¹²⁵

The potential mischief really resides in § 271(e)(4). If one accepts that patent infringement under § 271(e)(2) is only limited to Paragraph IV certified patents, the remedy under § 271(e)(4) only applies to those patents.¹²⁶ This means that the ANDA approval date will be delayed to the expiry of the last Paragraph IV patent infringed.¹²⁷ This also means that there are dual barriers to launching the generic drug. The first barrier is that the final court judgment will include a court injunction to block the launch, irrespective of any FDA approval status.¹²⁸ The second barrier is that the ANDA will only be tentatively approvable and unable to be finally approved until the relevant infringed Paragraph IV patent expires.¹²⁹ Therefore, this means that if the ANDA applicant later tried to design around the patent (or tried to invalidate it again), not only would it have to get a court order declaring the patent not an obstacle to dissolve the injunction, but the FDA would require that court order to convert the status to final approval. The

125. The safe harbor exemption is given a liberal interpretation and a wide berth to thereby encompass a lot of activity that would implicate a lot of different patents. *Merck KGAA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 202 (2005); *Momenta Pharm., Inc. v. Amphastar Pharm., Inc.*, 686 F.3d 1348, 1356 (Fed. Cir. 2012).

126. *See, e.g., Pozen Inc. v. Par Pharm., Inc.*, 696 F.3d 1151, 1157 (Fed. Cir. 2012). (“Appellants are generic pharmaceutical manufacturers who filed ANDAs with the FDA seeking approval to market generic forms of Treximet before the expiration of Pozen’s patents. Appellants filed their application certifying that the patents listed in the Orange Book are ‘invalid or will not be infringed’ by the generic products. Such a certification constitutes an artificial act of infringement.”). Following the principle of antecedent basis, the second sentence clearly states that Appellants filed their application certifying against certain patents. The last sentence states that “[s]uch a certification” must relate to the certifications of the patents mentioned in the second sentence. Accordingly, this case implies that jurisdiction only exists for patents that are subject to Paragraph IV certifications.

127. *See* 35 U.S.C. § 271(e)(4)(A).

128. *See Pozen Inc. v. Par Pharm., Inc.*, 800 F. Supp. 2d 789, 825 (E.D. Tex. 2011), *aff’d*, 696 F.3d 1151 (Fed. Cir. 2012) (“Based on the parties’ written submissions and the evidence of record, and for the reasons stated above, the Court grants Pozen’s request for a permanent injunction under 35 U.S.C. § 271(e)(4)(B).”).

129. *See* 35 U.S.C. § 271(e)(4)(A).

mechanics of this remain to be seen. The FDA may not need a court order to re-approve the ANDA. For an ANDA applicant, therefore, obtaining final launch approval would be a two-step process.

For non-Paragraph IV patents, though, the remedies should be different. Even if a non-Paragraph IV patent is in suit and is infringed, it should qualify for the traditional court injunction against a generic launch; but the non-Paragraph IV patent ought not deprive the ANDA applicant of future final approval by allowing the re-dating penalty.¹³⁰ That is, the ANDA approval status (from a regulatory affairs perspective) would not be predicated on the status of non-Paragraph IV patent infringement. In practice, this would allow the ANDA applicant to design around the patent (or otherwise invalidate it) and only seek dissolution of an injunction. The applicant would not have to further pursue the FDA to convert the ANDA status to final approval. Only a single barrier exists to marketing. A design around the infringed patent would only require one step to launch; namely, dissolution of the injunction.

If, on the other hand, all patents qualified for ANDA approval re-dating (irrespective of whether Paragraph IV certified), then the ANDA applicant would have to pursue the two-step process for each patent. It is unlikely that Congress intended to create a Paragraph IV certification system if the remedies for the processes were the same. Furthermore, it is unlikely that Congress intended that Paragraph IV-certified patents could qualify for 180-day exclusivity but that any patent could be the basis of liability.

If one were to allow any patent to be part of the litigation and enjoy the full scope of remedies, then one can easily see how the system could be gamed by brand-drug companies. First, a brand company could choose to list only certain patents into the Orange Book and hold back others to assert during the subsequent litigation. While an ANDA applicant accepts that for any Orange Book-listed patent, it will be on actual notice of it and have to address it through the R&D and court process. It cannot be sure what patents, if any, that are also out there would need to be addressed. Therefore, the mere existence of the non-Orange Book patents has some *in terrorem* effect.¹³¹

130. See *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 394 (2006).

131. See, e.g., *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1364

In sum, recognizing that infringed patents (whether Paragraph IV certified) will generate an injunction, the injunction itself serves as a barrier. Then a second barrier may exist if the ANDA approval is re-dated to patent expiry. But in fairness to the proper administration of the system, only Paragraph IV-certified patents ought to generate the re-dating remedy. In another twist, usually the nature of Paragraph IV litigation is predicated on a patent suit commenced when the ANDA is filed. The remedies described in 35 U.S.C. § 271(e)(4)(B) and (C) are usually related to monetary and injunctive relief when a generic company launches while of the underlying Paragraph IV lawsuit is ongoing. But could the remedies discussed in § 271(e)(4) apply to patent suits commenced after the ANDA is approved and after the ANDA product has launched?

If we examine this fully, we can again see what the mischief is. For example, suppose Paragraph IV litigation is over (or never commenced). The ANDA is now finally approved and the generic company launched its generic product. The brand company obtains a new patent. Whether it lists this patent in the Orange Book is not relevant to the generic company who has a final ANDA approval. If an ANDA is finally approved, neither the law nor the FDA requires the ANDA holder to certify to the patent.¹³² From a regulatory affairs perspective the patent is irrelevant. Now assume litigation commences and the brand company wins that new patent suit. Usually for “regular” patent litigation, the remedy is simply the court injunction.¹³³ But in this case, the brand company seeks not only the court injunction, but also seeks a withdrawal of the ANDA approval followed by an order that precludes the FDA from finally re-approving the ANDA until the patent expires. In essence, the patentee obtains the dual remedy. Is this correct? It is a strained reading of § 271(e)(4)(A) to allow this situation to occur. Nothing in the statute contemplates this remedy.¹³⁴

Moreover, it causes an asymmetry between the rights and expectations of the parties. The generic company is now subjected

(Fed. Cir. 2005) (discussing the *in terrorem* effect of invalidly granted patents and how innovations can be stifled because of fear of patents).

132. See 21 U.S.C. § 355(j)(2)(A)(vii) (2012) (stating that only patent certifications are needed for applications pending, not for approved applications).

133. See *eBay*, 547 U.S. at 394.

134. See, e.g., *Research Found. of State Univ. of N.Y. v. Mylan Pharm. Inc.*, Civ. Nos. 09-184-LPS, 10-892-LPS, 2012 WL 1901267, at *4 (D. Del. May 25, 2012).

to this new lawsuit and the new remedy does not receive any benefit of any 180-day exclusivity or any other benefit. The ANDA sponsor also faces increased costs from repetitive litigation. The patentee gets all the benefits of new litigation and new remedies, including possible monetary damages. Plus, from a policy perspective, the generic company did not “early work” under a safe harbor against this new patent because the patent did not yet exist. The Paragraph IV process was designed to allow for “early working” of a patent with an ability to vet out the patent issues in litigation.

Finally, allowing a patentee to obtain an FDA re-dating remedy allows the patentee to game the system more. For example, it may be that the ANDA sponsor lost the first patent suit but now concentrated efforts to design around the patent successfully. Knowing that the ANDA sponsor could apply to the court to dissolve the injunction, the patentee is then motivated to muck around in the FDA process to prevent the FDA from granting final approval. This strategy is well documented through the patentee’s prolific use of citizen petitions. In fact, Congress reacted to the citizen petition abuses that attempted to block ANDA approval. Congress positively responded in enacting 21 U.S.C. § 355(q), which required better petition verification and compliance.¹³⁵ If the FDA had the ability to grant final approval but the ANDA sponsor was blocked from launching due to a court injunction, it would allow the company to launch as soon as it could overcome the patent injunction.

As one can see, if the statutes are construed so that only Paragraph IV patents are in suit and are the only ones to qualify for § 271(e)(4) remedies, then the generic company is happy. If the statutes are construed so that any patent can be asserted in the

135. See *Spear Pharm., Inc. v. William Blair & Co.*, 610 F. Supp. 2d 278, 286 (D. Del. 2009). (“Following *Dr. Reddy’s*, the Court cannot at this stage conclude that Valeant has not adequately stated a claim for relief. This is especially so in light of the fact that Congress has recognized that the Citizen Petition process is often abused to delay the introduction of generic drugs, and that one court has already concluded that ‘Valeant’s citizen petition delayed the approval of Spear’s ANDA.’”); see also 21 U.S.C. § 355(q)(1)(A) (regarding citizen petitions); U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: CITIZEN PETITIONS AND PETITIONS FOR STAY OF ACTION SUBJECT TO SECTION 505(Q) OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT (2011), available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM079353.pdf> (regarding the certification process and requirement that FDA document delays caused by citizen petitions).

litigation and can qualify for the full remedies of § 271(e)(4), then the patentee is happy. Is there a reasonable interpretation that makes everyone happy?

XI. A SOLUTION TO THE PROBLEM OF LITIGABLE PATENTS—
A NEW MODEL FOR RESOLUTION

An elegant solution of statutory construction exists. Whether a court will be bold enough to adopt this solution as a matter of statutory construction remains to be seen. Or perhaps Congress is needed to yet again step in and plug the hole in the bucket. The reasonable solution is to allow all patents to be part of a lawsuit but only Paragraph IV-certified patents can earn a remedy under § 271(e)(4)(A)–(C).

First, any patent can be asserted in the patent litigation so long as there is at least one Paragraph IV certified patent in suit. This avoids the situation where the patentee tries to bring in only patents that received 21 U.S.C. § 355(j)(2)(A)(viii) (“section viii”) statements. Because the belief is that Paragraph IV patents can only cause the subsequent lawsuit, then a lawsuit cannot solely be predicated on section viii patents.¹³⁶ Because there is at least one Paragraph IV patent in suit, other patents can also be brought into the suit and co-litigated. Naturally, only Paragraph IV patents can serve as the basis for any thirty-month litigation stay. The Paragraph IV patent in suit provides the vehicle to add the other patents.

As the case progresses, it may be that a trial judgment is not expected by the end of the thirty-month litigation stay. The patentee may move to elongate the thirty-month stay only by virtue of the underlying patent that confers that stay.¹³⁷ No other patent, even though in suit, may serve to elongate the statutory thirty-month stay. A patentee may also use that underlying Paragraph IV patent to seek a preliminary injunction post-thirty-month stay to block the launch. Similarly, the patentee may move on independent grounds for an injunction based on each patent in suit. If the judge issues the injunction to block the launch, the

136. Sometimes despite receiving no Paragraph IV certifications to patents, a brand company will sue a generic company assuming (or knowing) that the company filed section viii statements to relevant patents. As such, this lawsuit will have no Paragraph IV-certified patents.

137. 21 U.S.C. § 355(j)(5)(B)(iii) (discussing that the court may elongate or shorten a stay based on the cooperation of the parties); *see also* UPADHYE, *supra* note 16, §§ 11:12–13 (listing cases discussing elongating the stay).

judge must opine on each patent, in detail, as to why the injunction was granted.¹³⁸ This would allow the defendant to understand the rationale and appeal that injunction, if desired.

As to remedies, ultimately if the defendant loses, under § 271(e)(4)(A), the ANDA approval date would normally be re-dated to the expiry of the patent. Here, however, to avoid the misconstruction of the statute, only a Paragraph IV patent would qualify for the ANDA re-dating remedy under § 271(e)(4)(A). Of course, if the defendant also loses on a non-Paragraph IV patent, then a traditional permanent injunction would apply,¹³⁹ but that patent would not qualify for ANDA re-dating remedy. For example, suppose a lawsuit entails a Paragraph IV patent that expires on July 1, 2018 and a non-Paragraph IV patent that expires on September 1, 2020. In this case, it is envisioned that with respect to the 2018 patent, the ANDA is blocked by the court injunction that normally exists and the § 271(e)(4)(A) re-dating remedy. So, an ANDA applicant that wishes to design around the patent would not only have to go to court to get the injunction dissolved, it would need an order of some sort allowing the FDA to grant final approval. The 2020 patent, though, would only earn a traditional court injunction. As such, a successful design-around of the patent would only require court intervention. In this regard, if the ANDA applicant chose to accept the 2018 patent as a blocking patent, but chose to design around the 2020 patent, then the ANDA applicant could await 2018 and obtain final FDA approval. The remedy under § 271(e)(4)(A) would have fully expired. But the applicant cannot yet launch because of the court injunction on the 2020 patent. All this applicant need do is apply to the court to dissolve the 2020 patent injunction by arguing that the patent is no longer an obstacle.¹⁴⁰ In sum, the injunction under § 271(e)(4) is a statutory remedy, whereas the non-Paragraph IV patent injunction would be

138. See *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006) (“According to well-established principles of equity, a plaintiff seeking a permanent injunction must satisfy a four-factor test before a court may grant such relief. A plaintiff must demonstrate: (1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction.”).

139. See *id.* at 393–94.

140. Though any challenges are case-specific.

governed under the Supreme Court's traditional factors from *eBay v. MercExchange, L.L.C.*¹⁴¹

The elegance of this solution satisfies several concerns. First, it allows patentees to assert more than just Paragraph IV-certified patents. Second, it allows the court to adjudicate all relevant patents en toto versus in piecemeal. Third, it allows the ANDA applicant to vet any potential liability prior to any launch. Fourth, it properly allocates the statutory remedies to just those Paragraph IV patents. Fifth, it informs the ANDA applicant of which patents require the two-step process of dissolving the injunction and going to the FDA to seek final approval, versus those that require only the one-step process of dissolving the injunction. Sixth, it allows an ANDA sponsor to obtain final approval as soon as possible for asset recognition. A finally-approved ANDA has varying monetary value, but the approved ANDA is definitely worth more than an only tentatively approved ANDA. Under this system, if the finally-approved ANDA has asset value, it can be recognized even though the underlying product launch is encumbered by the court injunction.

One last word is needed on post-approval patent litigation. As mentioned above, once an ANDA is finally approved, the ANDA sponsor is not required to certify to any new patent that pops up into the Orange Book. As such, there can be no Paragraph IV patent litigation. Though a patentee may assert patent infringement based on the new patent, the only remedy that this patentee can obtain is court injunction or damages. However, in no circumstance could this patent cause a re-dating of the ANDA approval.¹⁴² It would be manifestly unfair if new patents could continue to deprive an ANDA holder of final ANDA approval.

141. *eBay*, 547 U.S. at 391.

142. *But see* Research Found. of State Univ. of N.Y. v. Mylan Pharm. Inc., Civ. Nos. 09-184-LPS, 10-892-LPS 2012 WL 1901267 (D. Del. May 25, 2012) (finding a permanent injunction based on non-Paragraph IV pop-up patent). This was a single district court case and the judgment on the re-dating of the ANDA legal issue was not appealed. An appellate court may disagree with this one court. Moreover, the ruling of one district court does not bind any other district court, even within the same district. *Camreta v. Greene*, 131 S. Ct. 2020, 2033 n.7 (2011) (quoting 18 J. MOORE ET AL., *MOORE'S FEDERAL PRACTICE* § 134.02(2)(d) (3d ed. 2011) ("A decision of a federal district court judge is not binding precedent in either a different judicial district, the same judicial district, or even upon the same judge in a different case.")).

XII. THE AUTHORIZED GENERIC: A GOOD OR BAD THING?

We saw from the discussion above that courts wrongfully view the 180-day exclusivity as a vested, immutable property right. The purpose of this exclusivity, therefore, is to grant some incentive and reward to the first ANDA applicant for its Paragraph IV challenge. But the actual marketplace is different. Generally first ANDA applicants do not enjoy any real sole exclusivity. Under the MMA's new definition of a "first applicant" there might indeed be many first applicants. In the "old" days, many ANDA applicants could file on the same day, but the FDA would often resort to time stamps or videotape to determine which ANDA applicant truly was first and only first. ANDA applicants facing a hard first-filing date would often camp out in front of the FDA to rush into the doors to be "first" in the door.¹⁴³ The MMA changed that by declaring that all ANDA applicants who file on the same *day* are considered first. Perhaps it is better to consider them as co-first applicants. If there are co-first applicants, then theoretically they all enjoy the 180-day exclusivity.¹⁴⁴ So in the marketplace, there is a fiction that exclusivity still means one and only one marketer.

Second, the marketplace is changed by the authorized generic (AGx). An AGx is not really an ANDA sponsor that markets an internally developed generic version. It can be, but most often it is not. Rather, the AGx is really a "license" to market the brand drug under the brand-drug company's NDA, but market the brand drug as a generic drug.¹⁴⁵ Usually, the AGx is simply the actual brand

143. The camping out posed even more of a problem post-September 11, 2001 as the police did not look too kindly on camp-outs in front of Washington, D.C. federal government buildings. See CTR. FOR DRUG EVALUATION & RESEARCH, FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: 180-DAY EXCLUSIVITY WHEN MULTIPLE ANDAs ARE SUBMITTED ON THE SAME DAY 4 (2003), available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm072851.pdf> ("Recently, there have been a number of cases in which multiple ANDA applicants or their representatives have sought to be the first to submit a patent challenge by lining up outside, and literally camping out adjacent to, an FDA building for periods ranging from one day to more than three weeks. Concerns about liability, security, and safety led the property owners to prohibit lines of applicants before the date submissions may be made.").

144. See 21 U.S.C. § 355(j)(5)(B)(iv)(II)(bb) (2012) (defining "first applicant").

145. In fact, some companies exist where the business model is to be the AGx of brand pharmaceuticals. For example, Greenstone Pharmaceuticals LLC is the AGx for its parent brand company, Pfizer, Inc. See, e.g., *About Us*, GREENSTONE,

drug bottled in brand drug bottles, but labeled with the AGx label.¹⁴⁶ It can also be that the brand-drug company contracts (like a contract manufacturing organization) with the marketing company to allow the drug to be made, bottled, and sold under that company's label. The AGx is rarely an ANDA-approvable product because, even if the brand gives that ANDA filer a license to market, that ANDA filer might be blocked by the 180-day exclusivity.¹⁴⁷

Assume for the moment that a sole ANDA applicant exists and is ready to market the drug. The brand-drug company will release the AGx to market and co-compete against the original ANDA applicant.¹⁴⁸ Once the ANDA applicant launches, the 180-day

<http://www.greenstonellc.com/about-us.aspx> (last visited Jan. 30, 2014); *see also About Patriot*, PATRIOT PHARMACEUTICALS LLC, <http://www.patriotpharmaceuticals.com/patriotpharmaceuticals/about.html> (last updated June 24, 2011); *Our Company*, SANDOZ, http://www.sandoz.com/about_us/our_company.shtml (last visited Jan. 30, 2014). Stand-alone companies also exist, such as Dava, Inc. *See About Dava*, DAVA, <http://www.davapharma.com/about.htm> (last visited Jan. 30, 2014); *What We Do, Authorized Generics*, PRASCO, <http://www.prasco.com/what-we-do/authorized-generics/> (last visited Jan. 30, 2014).

146. *See Mylan Pharm., Inc. v. U.S. Food & Drug Admin.*, 454 F.3d 270, 273 (4th Cir. 2006) (“The pioneer drug maker who holds the approved NDA wants to stave off possible competition from the ANDA applicants (the generic makers). One strategy for the NDA holder is to grant a third party a license to sell a generic version of the drug described in the approved NDA.”).

147. *See id.* at 274 (“That court held that 21 U.S.C. § 355(j)(5)(B)(iv) did not by its terms prohibit the holder of an approved NDA from marketing an authorized generic during the exclusivity period. Rather, the court held that the statute’s limits expressly apply only to later-filed ANDAs.”); *see also Teva Pharm. Indus. Ltd. v. Crawford*, 410 F.3d 51, 53 (D.C. Cir. 2005) (“Section 355(j)(5)(B)(iv) says nothing about how the holder of an approved NDA may market its drug; rather, that provision grants ‘exclusivity’ to the first to file an ANDA containing a paragraph IV certification by delaying the effective date upon which the FDA may approve any subsequent ANDA containing a paragraph IV certification with respect to the same drug.”).

148. One generic company challenged the ability of an AGx to launch during the 180-day exclusivity. *Mylan Pharm.*, 454 F.3d at 271. In that case, the first ANDA filer launched and the AGx also launched. *Id.* Because the AGx cut into the ANDA product market share, the first ANDA filer lost money. *Id.* That company then sued the FDA to force the FDA to block the launch, thereby restoring the sole market to the ANDA sponsor. *Id.* The company lost as the court held that the FDA does not have the power to block the launch of an AGx. *Id.* (“After the FDA denied the petition, Mylan commenced this action against the agency under the Administrative Procedure Act. 5 U.S.C. § 706(2)(A). The district court dismissed the case. We affirm the dismissal, concluding that the statute does not grant the

exclusivity is triggered and that clock begins to run. In the marketplace, though, the two companies compete, usually on price, which then drives market share. Customers are usually indifferent as to whether they buy the AGx or the ANDA sponsor's drug product.¹⁴⁹ In fact, signing up with the AGx usually ensures continuity of supply (avoidance of supply chain disruptions) and obvious similarity of patients to the drug they were taking in the past. But for the ANDA sponsor, the existence of the AGx costs lots of money.¹⁵⁰

Here is an example of how the marketplace dynamics work. First, we assume that a \$1 billion per year brand drug exists. If the ANDA applicant were alone, then it would make about \$320 million over the six months of exclusivity. This is because there is typically a conversion of 80% market share from brand drug to generic drug and the ANDA sponsor prices at 80% of the brand drug.¹⁵¹ This dynamic exists for half a year.¹⁵² If we assume just one competitor exists, then the market is dramatically different. Now,

FDA the power to prohibit the marketing of authorized generics during the 180-day exclusivity period afforded to a drug company in Mylan's position.”).

149. See FED. TRADE COMM'N, AUTHORIZED GENERIC DRUGS: SHORT-TERM EFFECTS AND LONG-TERM IMPACT 44 (2011), available at <http://www.rxobserver.com/wp-content/uploads/2012/07/2011-FTC-generic-drug-report.pdf>.

150. *Mylan Pharm.*, 454 F.3d at 273 (“The pioneer drug maker who holds the approved NDA wants to stave off possible competition from the ANDA applicants (the generic makers). One strategy for the NDA holder is to grant a third party a license to sell a generic version of the drug described in the approved NDA. The economic benefits of this practice are clear. Such an authorized generic appeals to patients because it is sold at a lower price than the branded pioneer drug. It also appeals to the pioneer drug maker, who benefits from sales of the authorized generic even after the patent protecting the pioneer drug has expired. By selling an authorized generic during the exclusivity period enjoyed by the first paragraph IV ANDA applicant, the pioneer drug maker prevents that applicant from winning all of the customers who want to switch from the branded drug to a cheaper generic form. “[T]he additional competition [for the applicant] from an authorized generic may result in significantly less profit during the period of 180-day exclusivity than if the applicant ‘had no authorized-generic competition during that time.’”).

151. Margaret A. Hamburg, FDA Comm’r, Remarks at the Generic Pharmaceutical Association Annual Meeting: Challenges and Opportunities for the Generic Drug Industry (Feb. 23, 2012), <http://www.fda.gov/NewsEvents/Speeches/ucm294978.htm>.

152. Hence \$2.8 million (\$1 billion per year) multiplied by 80% price, multiplied by 80% share conversion, multiplied by 50% for the half year, equals \$320 million.

even if we assume that the original ANDA sponsor takes 50% market share but, due to price competition, the price drops to 40% price, then that sponsor may make only \$80 million.¹⁵³

Typically though, most drugs are not \$1 billion or more. Most are not even \$600 million or more. Rather, most are in the range of \$100–400 million. Even using \$400 million as the new base, the revenues are less (e.g., \$128 million if solely on the market, \$40 million with the AGx). For a \$100 million drug, the revenues could be \$32 million and \$10 million. After 180 days, the market could open up again with even more generic launches, thereby further reducing market share and price. For the \$1 billion drug, after the 180-day exclusivity is over (hence about 6 months remain in the year), the original solely exclusive generic company will face dramatic market share reduction, perhaps to about 15%, but price may drop to about 10%. This results in the remainder of the year sales of \$7.5 million and then about \$15 million per year thereafter. For a \$100 million drug, the remainder of the year will be about \$750,000 and about \$1.5 million per year thereafter. It may also happen that price decreases to about 5%.

The point of this is that the AGx indisputably affects the marketplace during and after the 180-day exclusivity. By far the clearest winners in having AGxs in the marketplace are the consumers and payors. The overall loser is the original ANDA applicant who had to share the market in a duopoly with the AGx. The brand company is a winner too because it earns money from its AGx arrangement. Presumably while it held a monopoly, it recovered its investment. Therefore, the AGx income continues to contribute profit.

XIII. FDA WRONGFULLY SAYS THAT MARKETING THE AUTHORIZED GENERIC TRIGGERS EXCLUSIVITY

But what happens if the brand company and the first-filed ANDA applicant settle their lawsuit in which the ANDA applicant becomes the AGx marketer? When commercial marketing commences, the ANDA applicant does not market its own ANDA-approved product, but instead markets the AGx itself. What happens to the 180-day exclusivity? Does it remain “parked” with

153. \$2.8 million multiplied by 40% (half of the original 80% market conversion), multiplied by 40% price, multiplied by 50% for the half year, equals \$80 million.

the ANDA itself, only to be triggered by forfeiture and/or a commercial marketing of the actual ANDA product? Why would this be desirable? First, by signing the AGx deal, the ANDA sponsor is guaranteed to have a product to sell. A deal minimizes any supply chain or FDA approval problem for the ANDA sponsor. Second, by potentially parking the 180-day exclusivity, it bars the subsequent ANDA filers from obtaining approval. Therefore, the first ANDA sponsor maintains a veritable monopoly over other generic versions (or a duopoly with the brand company version).

This is where unlawful judicial gap filling again occurred. In a very strange and very nonstatutory interpretation, a federal district court in West Virginia ruled that when the first generic company marketed the AGx instead of marketing its own ANDA product, that event somehow triggered the 180-day exclusivity.¹⁵⁴ In the nifedipine XL case, Mylan (as the first ANDA applicant) and Pfizer were locked in typical Paragraph IV litigation regarding Pfizer's thirty milligram form of Procardia XL.¹⁵⁵ They settled on terms that granted Mylan the AGx rights to the thirty, sixty, and ninety milligram forms of Procardia XL and also rights to market Mylan's thirty milligram generic form that was the subject of its ANDA.¹⁵⁶ In other words, Mylan's ANDA was for just the thirty milligram form, but through the settlement Mylan also received the rights for the three other strengths as the AGx. Mylan began marketing all three strengths per its AGx deal. Teva (through its licensor Biovail, a subsequent ANDA filer) initially asked Mylan to waive its exclusivity as part of a business agreement. Mylan and Teva did not consummate a deal. Instead, Teva filed a citizen petition asking the

154. Mylan Pharm., Inc. v. Thompson, 207 F. Supp. 2d 476, 488 (N.D. W. Va. 2001).

155. *Id.* at 481 ("Procardia XL is sold exclusively by Pfizer for three available strengths (30, 60 and 90 mg). In April 1997, Mylan became the first generic manufacturer to file an ANDA directed towards a nifedipine tablet which is a generic bioequivalent of the 30 mg extended release Procardia XL tablet. Mylan's ANDA contained a 'IV certification' with respect to the Pfizer patent. Thereafter, Pfizer filed a civil action against Mylan in the United States District Court for the Western District of Pennsylvania for infringement of its patent.").

156. *Id.* ("On February 28, 2000, Pfizer and Mylan entered into a settlement agreement which, according to Mylan's complaint, (a) stipulated to the dismissal of the Pfizer-Mylan civil action, (b) granted Mylan a license to sell a private label version of 30, 60 and 90 milligram Procardia XL nifedipine extended release tablet supplied by Pfizer, and (c) permitted Mylan to market its own 30 milligram ANDA product.").

FDA to grant it final approval by stripping Mylan of its exclusivity. The FDA agreed and granted Teva final ANDA approval.¹⁵⁷ Mylan sued the FDA to declare its actions unlawful.

The FDA won at trial and the case was not appealed to judgment. The court relied on the FDA's interpretation that, though it was undisputed that Mylan did not market its own ANDA product, the FDA deemed the marketing of the AGx to be a commercial marketing trigger within the meaning of the then-existing 180-day exclusivity law. The court stated:

The FDA determined that Mylan's marketing of the Pfizer product following the settlement was "commercial marketing" that began the 180-day exclusivity period. The FDA explained its ruling:

whether Mylan markets the produce [sic] approved in its ANDA or the product approved is Pfizer's NDA is of little import to the statutory scheme; Mylan has begun commercial marketing of generic nifedipine, permitting Mylan to market nifedipine without triggering the beginning of exclusivity would be inconsistent with the intent of the statutory scheme.

Therefore, because more than 180 days had passed since March 28, 2000, the date the FDA determined Mylan began the commercial marketing, the exclusivity period had expired. At this point, this Court believes that the FDA's interpretation of the phrase "commercial marketing of the drug under the previous application" is a reasonable one. On the basis of this part of the FDA ruling, which this Court believes is a reasonable interpretation of the statute, Mylan must be deemed unlikely to succeed on the merits and, therefore, the defendants would prevail.¹⁵⁸

157. *Id.* at 482 ("Teva, a licensee of Biovail, filed a Citizen Petition with the FDA in which Teva requested that the FDA determine that the ANDA submitted by Mylan for a 30 milligram nifedipine extended release tablet for the treatment of hypertension and angina was not eligible for or, alternatively, is no longer eligible for the 180-day exclusivity period provided by the Hatch-Waxman Amendments and that the FDA approve the ANDA of Biovail for a 30 milligram extended release nifedipine tablet. The FDA granted Teva's Citizen Petition on February 6, 2001.").

158. *Id.* at 488 (citations omitted).

The FDA relied on the 2000 version of the statute. In 2000, the statute that governed the running of the 180-day exclusivity was as follows:

(iv) If the [ANDA] contains a certification described in subclause (IV) of paragraph 2(A)(vii) [Paragraph IV certification] and is for a drug for which a previous application has been submitted under this subsection continuing such a certification, the application shall be made effective not earlier than one hundred and eighty days after—

(I) the date the Secretary receives notice from the applicant under the previous application of the first commercial marketing of the drug under the previous application, or

(II) the date of a decision of a court in an action described in clause (iii) holding the patent which is the subject of the certification to be invalid or not infringed, whichever is earlier.¹⁵⁹

Here, under subparagraph (I), the operative statutory phrases are as follows: the “applicant under the previous application” is the first ANDA filer, and the phrase “commercial marketing of the drug under the previous application” must refer to the commercial marketing of the drug of the first ANDA.¹⁶⁰ If it were intended and/or reasonable to trigger the exclusivity by any sale by the first ANDA applicant, then it would have said so. But the statute is explicitly clear that the drug that is first marketed must be the drug that was the subject of the first ANDA itself. The district court either misinterpreted the statute or wrongfully deferred to the FDA’s interpretation of the statute under *Chevron* step 1.¹⁶¹ In fairness though, the district court entertained this case on a preliminary injunction, and with further analysis or explanation, the court might have come to a proper construction.

Here is an example of policy-based gap filling at its best (or worst). The policy justification is understandable. The plain language of the statute does not contemplate that the marketing of a completely different product, here the AGx, can trigger the 180-day exclusivity. To the FDA and this one district court, the 180-day

159. 21 U.S.C. § 355(j)(5)(B)(iv) (2000).

160. *Id.* § 355(j)(5)(B)(iv)(I).

161. *Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 842–43 (1984).

exclusivity is applicant specific, not ANDA specific. But the 180-day exclusivity is only created by a very specific kind of ANDA filing—the ANDA filing that is the first ANDA applicant to certify under Paragraph IV to at least one Orange Book patent. It is not created by any other ANDA filing. Accordingly, the FDA's and district court's interpretations are not statutory because the marketing of an AGx under a NDA has nothing to do with an ANDA. Had Mylan chosen to appeal, or in the event another scenario like this occurs again, the D.C. Circuit would likely have held that the statute does not contemplate triggering the 180-day exclusivity simply by the marketing of an AGx.

XIV. SCOPE OF INDUCED INFRINGEMENT AND NULLIFICATION OF THE MENS REA REQUIREMENT

There are two types of infringement: (1) direct infringement and (2) indirect infringement. Direct infringement is a strict liability tort and is governed under 35 U.S.C. § 271(a).¹⁶² A direct infringer is the real trespasser on the patent rights. Indirect infringement does not require an inducer to directly infringe but results in liability when the inducer knowingly puts things into motion that cause a direct infringement. For indirect infringement, there is a state-of-mind or mens rea component. Indirect infringement usually comes in two forms: (i) inducement to infringe under § 271(b), or (ii) contributory infringement under § 271(c).¹⁶³ The policy-based gap filling ideology has not left inducement to infringe untouched. Rather against the actual law, courts have essentially morphed the mens rea state-of-mind requirement into a strict liability standard.¹⁶⁴ This mischief usually

162. 35 U.S.C. § 271(a) (2006).

163. *Id.*

164. The law requires courts to evaluate the state of mind. *Metro-Goldwyn-Mayer Studios Inc. v. Grokster, Ltd.*, 545 U.S. 913, 937 (2005) (“The inducement rule, instead, premises liability on purposeful, culpable expression and conduct, and thus does nothing to compromise legitimate commerce or discourage innovation having a lawful promise.”); *DSU Med. Corp. v. JMS Co., Ltd.*, 471 F.3d 1293, 1305–06 (Fed. Cir. 2006) (“As a result, if an entity offers a product with the object of promoting its use to infringe, as shown by clear expression or other affirmative steps taken to foster infringement, it is then liable for the resulting acts of infringement by third parties. ‘The inducement rule . . . premises liability on purposeful, culpable expression and conduct.’ *Grokster*, thus, validates this court’s articulation of the state of mind requirement for inducement.”); *Civix-DDI, L.L.C. v. Hotels.com, L.P.*, 904 F. Supp. 2d 864, 869 (N.D. Ill. 2012) (“As such, because

plays out when arguing over the generic drug label and its contents.¹⁶⁵

Under the ANDA law, the generic company must copy the brand product label, except for some minor changes.¹⁶⁶ This ensures the sameness of the generic and brand drug label. Though, the generic company can omit certain information from the label. The omitted information is often, but not always, related to patents. A working example may indicate how the inducing infringement plays out.

Suppose brand drug XYZ is indicated for multiple disease conditions #1, #2, #3, and #4. Indications #2, #3, and #4 are protected by patents #2, #3, and #4 respectively, but indication #1 is no longer (or never was) patented itself. The method of use/treatment patents usually take the traditional form of a method of treating disease condition X by administering to a patient a therapeutic amount of drug XYZ. To this end, without

induced infringement is not a strict liability tort, there is a genuine dispute of material fact whether Hotels.com knowingly induced DoubleClick's alleged infringement and possessed specific intent to encourage another's infringement." (citation omitted)).

165. *AstraZeneca L.P. v. Apotex, Inc.*, 633 F.3d 1042, 1060 (Fed. Cir. 2010) ("The pertinent question is whether the proposed label instructs users to perform the patented method. If so, the proposed label may provide evidence of Apotex's affirmative intent to induce infringement." (citation omitted)); *Braintree Labs., Inc. v. Novel Labs., Inc.*, CV No. 11-1341 (PGS), 2013 WL 211252, at *11 (D.N.J. Jan. 18, 2013) ("Therefore, through its proposed label, Novel intentionally induces patients to ingest a composition infringing claims 15 and 18."); *Bone Care Int'l, L.L.C. v. Roxane Labs., Inc.*, Civ. A. No. 09-CV-285 (GMS), 2012 WL 2126896, at *9 (D. Del. June 11, 2012) ("In the Hatch-Waxman context, '[s]tatements in a package insert that encourage infringing use of a drug product are alone sufficient to establish intent to encourage direct infringement' for purposes of inducement to infringe under 35 U.S.C. § 271(b).").

166. 21 U.S.C. § 355(j)(2)(A)(v) (2012). ("[I]nformation to show that the labeling proposed for the new drug is the same as the labeling approved for the listed drug referred to in clause (i) except for changes required because of differences approved under a petition filed under subparagraph (C) or because the new drug and the listed drug are produced or distributed by different manufacturers."); *see also* *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2574 (2011), *reh'g denied*, 132 S. Ct. 55 (2011). As a result, brand-name and generic drug manufacturers have different federal drug labeling duties. A brand-name manufacturer seeking new drug approval is responsible for the accuracy and adequacy of its label. A manufacturer seeking generic drug approval, on the other hand, is responsible for ensuring that its warning label is the same as the brand name's label.

more, if the generic company includes the four indications, then it could be sued for infringing patents #2, #3, and #4 under an inducement to infringe theory. Prototypically, in inducement to infringe cases, the generic company is not sued for direct infringement because it is likely not directly administering drug XYZ to the patient. Rather, the claim for inducement is that the generic drug label includes patented method of treatment indications and therefore induces the local doctor, pharmacist, or patient to infringe. In other words, the generic drug company's label is an explicit instruction to aid and abet the infringement.

To get around this, generic companies will often avail themselves of the so-called section viii statement or "carve-out" strategy.¹⁶⁷ A generic company under section viii may redact or delete patented indications, leaving at least one unpatented indication. Returning to the example, the generic company may therefore redact indications #2, #3, and #4 from its label, leaving only unpatented indication #1 left. Theoretically, the generic company can only market its generic drug for that one indication. But generic companies do not "market" their drugs in well-known ways.

Generic companies introduce their drug products at the top of the distribution chain. The wholesalers then distribute down the chain ultimately to the retail pharmacy. Generic companies sell most, if not all, of their products to upstream wholesalers, rarely selling (if at all) to the local pharmacy. Generic companies do not advertise products on television, radio, or print media. Generic companies do not have sales representatives (known as "detailing") that visit doctors, do not sponsor medical symposia or conferences, and do not have large marketing budgets to promote generic drugs. Rather, a generic company may have just a few national

167. See 21 U.S.C. § 355(j)(2)(A)(viii); *Bayer Schering Pharma AG v. Lupin, Ltd.*, 676 F.3d 1316, 1318 (Fed. Cir. 2012) ("First, the ANDA applicant can include a statement, known as a 'section viii statement,' that the applicant is not seeking approval for the method of use that is claimed in the patent."); *AstraZeneca*, 633 F.3d at 1047 ("Apotex also submitted a section viii statement asserting that it was not seeking approval for the once-daily method of use claimed in the '603 and '099 patents and that its proposed generic label would contain no explicit mention of once-daily administration."); *Novartis Pharm. Corp. v. Actavis, Inc.*, No. 12-366-RGA-CJB, 2012 WL 6212619, at *3 (D. Del. Dec. 5, 2012) ("A section viii statement indicates that the applicant wants to market the generic drug for a different method of use than those claimed by relevant patents listed in the Orange Book.").

account managers that deal with customers at the wholesale or national chain drug store level. It would be incredulous to say that generic drug companies “market” or “promote” individual generic drugs in the same way that brand companies do.¹⁶⁸ Generic companies, instead, rely on the state-level substitution laws to get their products into the hands of the patient users.¹⁶⁹

When faced with possible section viii carve-outs, the brand company recognizes that the unpatented indication may provide the vehicle to carving out the patented indications. The company also recognizes that the patient will take the generic drug for whatever uses the doctor and patient agreed to. While the patient and doctor may know that the intent of the drug prescription is to treat a patented indication, the generic drug company does not and cannot know. In fact, it might be callous (but true) to say that the generic drug company does not care how the patient uses its drug. All the generic drug company does is put its product at the top of the distribution chain and whatever happens to the product downstream does not matter. Whether a patient takes the drug for indication #1 as labeled or for carved-out indications #2, #3, or #4, or for a complete off-label use, is of no consequence to the generic company.

Accordingly, a brand company, when faced with the carve-out situation, may try to sue the generic company for inducement to infringe the carved-out uses.¹⁷⁰ But to succeed, the brand company is supposed to prove a specific intent to induce infringement.¹⁷¹

168. See, e.g., *IMS Health Inc. v. Ayotte*, 550 F.3d 42, 46 (1st Cir. 2008), *abrogated by Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653 (2011) (“Detailing involves tailored one-on-one visits by pharmaceutical sales representatives with physicians and their staffs. This is time-consuming and expensive work, not suited to the marketing of lower-priced bioequivalent generic drugs (drugs that are pharmacologically indistinguishable from their brand-name counterparts save for potential differences in rates of absorption). The higher profit margins associated with brand-name drugs leaves the personal solicitation field open to brand-name drug manufacturers, who in the year 2000 spent roughly \$4,000,000,000 on detailing.”).

169. See *PLIVA*, 131 S. Ct. at 2581 (“But because pharmacists, acting in full accord with state law, substituted generic metoclopramide instead, federal law pre-empts these lawsuits.”). See, for example, MINN. STAT. § 151.21 (2012) or LA. REV. STAT. ANN. § 37:1241(A)(17) (West, Westlaw through 2013 Reg. Sess.), for a description of when pharmacists may substitute generic drugs.

170. See *Novartis Pharm. Corp. v. Wockhardt USA*, No. 12-cv-3967, 2013 WL 5770539 (D.N.J. Oct. 23, 2013).

171. *Commil USA, LLC v. Cisco Sys., Inc.*, 720 F.3d 1361, 1367 (Fed. Cir.

The brand company may allege that simply by putting it in the distribution channel, the generic company expects, wants, desires, or otherwise intends that all uses will be practiced and, hence, liability attaches.¹⁷² But the courts have been clear that specific intent is required, and such proof is rarely available.

But sometimes the proof may be there. For example, suppose that the brand drug XYZ is a \$500 million drug. The brand company would know roughly how the sales are split amongst the indications. Suppose that indication #1 (the unpatented one) is a very small sliver of the \$500 million and that most of the sales are keyed to the other patented indications. Often times a generic company in creating volume forecasts and inventory management models may create charts that show how the brand drug sales grew over time, what the expected new growth will be, and new volumes. Tie this information into when the generic drug company chose to begin development of the product and now there might be a story. The information may show that when the drug was indicated only for unpatented indication #1, it had small sales and hence the generic company did not want to make a generic of it. But as the sales increased when new indications came along, it suddenly formed a new attractive candidate to pursue for generic development. Over time, the information on new growth attributable to new indications may also be tied to the expected generic sales and volume forecasts. But here, again, the need for specific intent is required to show that the infringement was known and intended.¹⁷³

Courts, though, to shortcut a highly intense factual inquiry, may convert this specific intent state of mind requirement into a strict liability offense based simply on the label.¹⁷⁴ If the generic

2013), *reh'g denied* (Oct. 25, 2013).

172. See, e.g., *Novartis*, 2013 WL 5770539, at *8 (discussing that remaining FDA labeled indication was only 0.3% of the overall market and 99.7% of the market was for the carved-out use). *Novartis* argued that no generic in its right mind is actually limiting its sales to the 0.3% market and it is obvious that the entire game plan is to capitalize on the 99.7% carve-out use. *Id.*

173. Again, each case stands unique and nothing herein should be construed as some categorical statement of liability. Each case must be evaluated fully on its own facts and circumstances.

174. See generally *Akamai Techs., Inc. v. Limelight Networks, Inc.*, 692 F.3d 1301, 1308 (Fed. Cir. 2012), *cert. granted*, 2014 WL 112700 (U.S. Jan. 10, 2014) (No. 12-786) ("Induced infringement is in some ways narrower than direct infringement and in some ways broader. Unlike direct infringement, induced

company has any information that colorably implicates the patented method, then some will simply say that the label is an instruction and hence is an inducement.¹⁷⁵ This “gotcha” was predicated on the *Grokster* copyright case.¹⁷⁶

This is wrong because the mere words must amount to more. Courts short circuit the state of mind analysis by relying on the *Grokster* copyright case and other cases that use the word “instruction” as a basis for specific intent to induce infringement.¹⁷⁷ But it is important to understand what the “instruction” was in *Grokster* and related cases to put it into context. *Grokster* was a case involving file sharing over the Internet. The very existence and purpose of the Grokster system was to share files over the Internet.¹⁷⁸ Grokster instructed users how to engage in infringing uses.¹⁷⁹ The file sharing had no other legitimate purpose except as a file-sharing system. When users had problems or issues, Grokster

infringement is not a strict liability tort; it requires that the accused inducer act with knowledge that the induced acts constitute patent infringement.”).

175. See *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1054 (Fed. Cir. 2010); *Aventis Pharma Deutschland GmbH v. Cobalt Pharm., Inc.*, 355 F. Supp. 2d 586, 599 (D. Mass. 2005) (“Stripped of these arguments, Plaintiffs’ active inducement claim rests entirely on language in Cobalt’s proposed labeling instructions and package insert.”). One case goes even farther to suggest that even if the label is not “infringing,” the mere fact the drug is sold could be the basis for inducement. *Wyeth v. Sandoz, Inc.*, 703 F. Supp. 2d 508, 521 (E.D.N.C. 2010) (citations omitted) (“Furthermore, ‘[e]ven if [Sandoz] successfully persuaded the finder of fact that the labels [do] not instruct, direct, or encourage infringement . . . this would not be legally sufficient to establish that the labels do not induce infringement.’”).

176. *Metro-Goldwyn-Mayer Studios Inc. v. Grokster, Ltd.*, 545 U.S. 913 (2005).

177. *Id.* at 936 (citations omitted) (“Evidence of ‘active steps . . . taken to encourage direct infringement,’ such as advertising an infringing use or instructing how to engage in an infringing use, show an affirmative intent that the product be used to infringe, and a showing that infringement was encouraged overcomes the law’s reluctance to find liability when a defendant merely sells a commercial product suitable for some lawful use.”).

178. *Id.* at 919–20 (“Respondents, Grokster, Ltd., and StreamCast Networks, Inc., defendants in the trial court, distribute free software products that allow computer users to share electronic files through peer-to-peer networks, so called because users’ computers communicate directly with each other, not through central servers.”).

179. See *id.* at 923–24 (“The record is replete with evidence that from the moment Grokster and StreamCast began to distribute their free software, each one clearly voiced the objective that recipients use it to download copyrighted works, and each took active steps to encourage infringement.” (citations omitted)).

provided technical support regarding how to continue the copyright infringement.¹⁸⁰ So, Grokster not only provided the tool to infringe, but it also provided lessons regarding infringement. The system was specifically designed to share files and bypass security measures. Grokster also advertised its essentially infringing use.¹⁸¹ It provided a category of music knowing full well that the music was copyrighted.¹⁸² Further, Grokster, though intending to provide file sharing for copyrighted works, took no effort whatsoever to mitigate against copyright infringement.¹⁸³ Finally, the Grokster management showed a specific intent repeatedly in promotions and in internal documentation that it wanted copyright infringement to occur, provided tools to make it happen, and aided and abetted the infringement in almost every conceivable fashion.¹⁸⁴ In short, its very existence was to circumvent copyright law. Accordingly, the instructions in *Grokster* were specifically and solely designed to file share and violate the copyright law. One can think of the instructions as being part of the undisputed master plan to file share. The Court, though, also noted categorically that simply distributing a product that might infringe is not enough.¹⁸⁵

180. *Id.* at 923.

181. *Id.* at 925 (“Thus, StreamCast developed promotional materials to market its service as the best Napster alternative.”). Napster was a similar file sharing software used by many to exchange copyrighted materials illegally.

182. *Id.* at 926 (“The point, of course, would be to attract users of a mind to infringe, just as it would be with their promotional materials developed showing copyrighted songs as examples of the kinds of files available through Morpheus. Morpheus in fact allowed users to search specifically for ‘Top 40’ songs, which were inevitably copyrighted. Similarly, Grokster sent users a newsletter promoting its ability to provide particular, popular copyrighted materials.” (citations omitted)).

183. *Id.* at 926–27 (“Finally, there is no evidence that either company made an effort to filter copyrighted material from users’ downloads or otherwise impede the sharing of copyrighted files. Although Grokster appears to have sent e-mails warning users about infringing content when it received threatening notice from the copyright holders, it never blocked anyone from continuing to use its software to share copyrighted files. StreamCast not only rejected another company’s offer of help to monitor infringement, but blocked the Internet Protocol addresses of entities it believed were trying to engage in such monitoring on its networks.” (citations omitted)).

184. *Id.* at 925 (“StreamCast even planned to flaunt the illegal uses of its software; when it launched the OpenNap network, the chief technology officer of the company averred that ‘[t]he goal is to get in trouble with the law and get sued. It’s the best way to get in the new[s].’”).

185. *Id.* at 937 (“Accordingly, just as Sony did not find intentional inducement

The flavor and context of the *Grokster* case is clear. For inducement to infringe, the Court required bona fide culpable conduct where the inducer wanted the infringement to happen, planned to make it happen, goaded/aided/abetted the infringer to infringe, provided tools to make it happen, and expressly advertised in all words and actions to ensure that infringement would happen. Even when users had trouble infringing, *Grokster* expressly instructed users how to cure the problem to ensure infringement would happen.¹⁸⁶ Even the Federal Circuit, sitting en banc, restated these principles in the post-*Grokster* era.¹⁸⁷

The patent field adopted the copyright standard that requires specific intent to induce infringement. That is not controversial. What are controversial are the policy-driven decisions that have predetermined the outcome. If the concept of inducement requires a genuine aiding and abetting that rises to the level of a malicious coconspirator, then finding liability for simply having verbiage on a label, without more inquiry into the context and the state of mind of the generic company, is wrong.

Under the courts' strict liability standard, a generic company is liable simply because of the label contents. No amount of behind-the-scenes mitigation is worth anything. No opinion of counsel is

despite the knowledge of the VCR manufacturer that its device could be used to infringe, mere knowledge of infringing potential or of actual infringing uses would not be enough here to subject a distributor to liability. Nor would ordinary acts incident to product distribution, such as offering customers technical support or product updates, support liability in themselves. The inducement rule, instead, premises liability on purposeful, culpable expression and conduct, and thus does nothing to compromise legitimate commerce or discourage innovation having a lawful promise." (citations omitted)); *see also* *DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1305 (Fed. Cir. 2006) (en banc in relevant part) ("The 'mere knowledge of possible infringement by others does not amount to inducement; specific intent and action to induce infringement must be proven.'").

186. *Grokster*, 545 U.S. at 923 ("From time to time, moreover, the companies have learned about their users' infringement directly, as from users who have sent e-mail to each company with questions about playing copyrighted movies they had downloaded, to whom the companies have responded with guidance."). By way of analogy, the inducer solicited others to rob a bank; sat at the table with the bank robbers during the planning phase; provided the plans to the bank, technical details about the vault and tools to use to open the vault, timing of security guard paths and schedules, and details about when the most opportune time was to hit the bank; and provided the getaway car and keys. In short, here the only thing the inducer did not do was actually rob the bank.

187. *DSU Med. Corp.*, 471 F.3d at 1306 ("*Grokster*, thus, validates this court's articulation of the state of mind requirement.").

worth anything. For example, in practice, the counsel for a generic company may mitigate specific intent by (1) reviewing documents to ensure the market plans do not implicate patented indications; (2) reviewing regulatory documents to ensure that sufficient information is carved out of the label; (3) conducting training sessions with the generic company's sales and marketing personnel to advise on what can or cannot be done; (4) creating mitigation plans that, in the event a breach occurs, remedies a breach timely and correctly; or (5) obtaining independent legal advice that indicates the generic company has taken appropriate steps to remove any specific intent to induce infringement.¹⁸⁸ None of these exculpatory measures is meaningful to a judge who decides that strict liability attaches simply because of the label.

A further problem is the practical reality that a generic company's drug labels are rarely seen by anyone in the prescribing chain. In the distribution of a generic product, multiple bottles are packed into boxes with the labels (usually on a printed pad of paper) thrown in. Rarely are labels adhered to the bottles themselves. At the wholesaler or distributor, the box is opened, and the bottles are either repacked into boxes or put onto shelves. The labels are thrown out. Ultimately, it is very rare that the retail pharmacist will even see a generic company's drug label. Moreover, because generic companies do not promote their products to doctors directly, a doctor will rarely (if ever) see a generic

188. In a controversial case, the Federal Circuit recently held that an inducer's good-faith belief that the relevant patent is invalid may be sufficient to negate the specific intent for induced infringement. *See Commil USA, L.L.C. v. Cisco Sys., Inc.*, 720 F.3d 1361, 1367–68 (Fed. Cir. 2013) (“Under our case law, it is clear that a good-faith belief of non-infringement is relevant evidence that tends to show that an accused inducer lacked the intent required to be held liable for induced infringement.”); *see also* *Bettcher Indus., Inc. v. Bunzl USA, Inc.*, 661 F.3d 629, 649 (Fed. Cir. 2011) (finding opinion of counsel regarding noninfringement “admissible, at least with respect to [defendant]’s state of mind and its bearing on indirect infringement”); *Ecolab, Inc. v. FMC Corp.*, 569 F.3d 1335, 1351 (Fed. Cir.) (finding that a reasonable belief of noninfringement supported a jury verdict that the defendant lacked the intent required for induced infringement), *amended in part on reh’g*, 366 Fed. App’x 154 (Fed. Cir. 2009); *Kinetic Concepts, Inc. v. Blue Sky Med. Grp., Inc.*, 554 F.3d 1010, 1025 (Fed. Cir. 2009) (holding that defendant’s “belief that it can freely practice inventions found in the public domain” supports “a jury’s finding that the intent required for induced infringement was lacking”); *DSU Med. Corp.*, 471 F.3d at 1307 (finding a demonstrated belief of noninfringement sufficient to support a jury verdict that the defendant did not induce infringement).

company's drug label.¹⁸⁹ Even office copies of the Physician Desk Reference (PDR) do not have an actual copy of the generic drug company's label. Usually, the PDR contains only the original brand company's drug label. A generic company's drug label may be available through intense searching on the Internet. But that is hardly a ringing endorsement that the label is so prominent that it induces a doctor to prescribe the generic drug for patented uses. Usually, the absence of evidence is not evidence of its absence. Here, though, the absence of evidence of inducement is indeed an actual absence of evidence.¹⁹⁰

The author is cognizant that, if the inducement to infringe actually requires the state of mind inquiry, then it will complicate the case. The expenses will rise for both brand and generic companies alike. The complexity is bound to tie up more judicial resources with discovery disputes. Moreover, any future trial will be more complex. With the state of mind being so important and factually driven, it is unlikely (without "smoking gun" evidence) that summary judgment could be granted.¹⁹¹ Each party could likely

189. See Complaint for Declaratory, Injunctive, and Other Relief at 17–18, *Wyeth Pharm., Inc. v. Food & Drug Admin.*, Civ. A. No. 1:09-cv-01810-FJS (D.D.C. Sept. 22, 2009), 2009 WL 3226432 ("Because healthcare professionals assume that generic and branded drugs are completely interchangeable, they generally do not scrutinize the generic drug and the branded drug for labeling differences."); see also Plaintiff's Motion for Summary Judgment at 12–13, *Wyeth Pharm., Inc. v. Food & Drug Admin.*, No. 1:09-cv-01810-FJS (D.D.C. Oct. 23, 2009), 2009 WL 3460818 ("Healthcare professionals justifiably rely on the fact that the Hatch-Waxman Act requires generic drugs to be the same as their branded counterparts in all material respects and assume, as intended by Congress, that a generic product is freely interchangeable with the brand name drug and that it bears the same labeling as its branded counterpart. Accordingly, they have no reason to scrutinize the labeling for any differences and, as a matter of clinical practice, rarely do so.").

190. In his experience, the author has never heard of a generic company directly detailing a generic drug product to a doctor. The author has never received an inquiry from a doctor as to what information existed in the generic company's drug label and what differences existed, if any, between the generic company's drug label and the brand company's drug label. In fact, the author has never received an inquiry from any doctor to provide the generic company's drug label.

191. *United States ex rel. Taylor-Vick v. Smith*, 513 F.3d 228, 231 (5th Cir. 2008) ("It is indeed well-settled, as Vick points out, that we hesitate to grant summary judgment when a case turns on a state of mind determination."); *Miller v. Fed. Deposit Ins. Corp.*, 906 F.2d 972, 974 (4th Cir. 1990) (agreeing with the general rule that summary judgment is rarely granted when a state of mind is an

proffer sufficient genuine issues of material fact to thwart summary judgment. Imposing the strict liability infringement standard circumvents this and morphs the patent challenge to invalidity. But traffic management should not and cannot drive the result. Other solutions ought to be tried.

A solution would be to impose similar pleading requirements on the plaintiff to plead inducement with particularity. Under the rules of pleading inequitable conduct, a defendant (putative infringer) is required to plead the specific intent to defraud the patent office.¹⁹² The courts have imposed significant burdens on the defendant to allege the “who, what, where, when, why, and how” of the fraud.¹⁹³ In an effort to curb inequitable conduct defenses, the Federal Circuit has required *Twombly-Iqbal*-like particularity.¹⁹⁴ Generally, pleading this specificity is governed under the Federal Rules of Civil Procedure Rule 9(b).

If Rule 9(b) specificity is required for defensive purposes, then perhaps it is equally applicable for plaintiff’s purposes. If the plaintiff cannot plead inducement with particularity, then a Rule 12(b)(6) motion to dismiss should be appropriately granted. While Rule 8(a)(2) generally requires only a plain and concise statement in the complaint,¹⁹⁵ Rule 9(b) requires certain pleading

element of a claim; however, the rule did not apply in this case due to [Plaintiff’s] admission that he willfully violated the Act in question); *Nat’l Union Fire Ins. Co. of Pittsburgh, Pa. v. Turtur*, 892 F.2d 199, 205 (2d Cir. 1989) (“Questions of intent, we note, are usually inappropriate for disposition on summary judgment.”); *60 Ivy St. Corp. v. Alexander*, 822 F.2d 1432, 1437 (6th Cir. 1987) (“Summary judgment is seldom appropriate in cases where the parties’ intentions or states of mind are crucial elements of the claim because of the likelihood of self-serving testimony and the necessity for the factfinder’s credibility determinations.”).

192. *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1287 (Fed. Cir. 2011) (stating that to prove inequitable conduct, the alleging party must establish by clear and convincing evidence that the applicant “misrepresented or omitted material information with the specific intent to deceive the PTO”).

193. *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1327 (Fed. Cir. 2009) (“Based on the foregoing, and following the lead of the Seventh Circuit in fraud cases, we hold that in pleading inequitable conduct in patent cases, Rule 9(b) requires identification of the specific who, what, when, where, and how of the material misrepresentation or omission committed before the PTO.”).

194. *Id.* at 1326 (“Rule 9(b) requires that ‘[i]n all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity.’ ‘[I]nequitable conduct, while a broader concept than fraud, must be pled with particularity’ under Rule 9(b).”); *see also* *Ashcroft v. Iqbal*, 556 U.S. 662, 686–87 (2009); *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007).

195. FED. R. CIV. P. 8(a)(2) (requiring, in a claim for relief, “a short and plain

with particularity.¹⁹⁶ Note that Rule 9(b) only specifies that fraud and mistake need be pled with particularity and that “malice, intent, knowledge, and other conditions of a person’s mind” may be pled generally.¹⁹⁷ Accordingly, while pleading inequitable conduct with true Rule 9(b) particularity may be more palatable, there does not seem to be any prohibition against requiring inducement to infringe to be pled with some particularity that is beyond Rule 8(a)’s general rubric without actually invoking Rule 9(b) as a categorical requirement.¹⁹⁸ The danger with categorically invoking Rule 9(b) is that precedent does not allow for formally adding to the list of particulars.¹⁹⁹ If pleading direct (regular) infringement only requires plain Rule 8 specificity, there is support for pleading indirect infringement with heightened Rule 8 specificity that does not rise to the level of Rule 9(b) specificity.²⁰⁰

In conclusion, with regard to inducement to infringe, it is time to return the inducement to infringe inquiry back to its roots. A clearer understanding of inducement and the particulars of how it

statement of the claim showing that the pleader is entitled to relief”).

196. Warner Chilcott Co., v. Amneal Pharm., L.L.C., Civ. A. Nos. 11-5989 (FSH), 11-6936(FSH), 12-24774(FSH), 2013 WL 6627694, at *3 (D.N.J. Dec. 13, 2013) (“Inequitable conduct is subject to the higher pleading standards of Fed. R. Civ. P. 9(b).”).

197. FED. R. CIV. P. 9(b).

198. A defendant wanting a court to adopt the heightened standard of pleading should not formally invoke Rule 9(b). Pleading a quasi-heightened standard that is rooted in Rule 8(a) is better because it does not provide an upfront end run around Rule 9(b)’s limited list.

199. See, e.g., Swierkiewicz v. Sorema N.A., 534 U.S. 506, 512–15 (2002); Pratt v. Tarr, 464 F.3d 730, 731–32 (7th Cir. 2006).

200. Brandywine Commc’ns Techs., L.L.C. v. Casio Computer Co., 912 F. Supp. 2d 1338, 1343 (M.D. Fla. 2012) (citations omitted) (“The Federal Circuit’s recent opinion in *In re Bill of Lading* provides persuasive authority on the pleading requirements for induced infringement. The Federal Circuit concluded that whereas fulfilling the requirements in Form 18 is sufficient to plead a claim of direct infringement, ‘Form 18 should be strictly construed as measuring only the sufficiency of allegations of direct infringement, and not indirect infringement’ and a court must look to Supreme Court precedent for guidance regarding pleading requirements for claims of indirect infringement. Specifically, to state a claim for induced infringement, a plaintiff must affirmatively plead ‘facts plausibly showing that [Defendants] specifically intended their customers to infringe the [patent] and knew that the customer’s acts constituted infringement.’ Moreover, the Supreme Court has clarified that induced infringement requires ‘knowledge that the induced acts constitute patent infringement.’” (citations omitted)).

2014] HATCH-WAXMAN: RESOLVED & UNRESOLVED GAPS 1369

applies to generic companies is needed. Because inducement is factually intensive, it will require courts and litigants to really flush out the facts and evaluate them; it should not permit any further shortcutting by permitting complaints to allege bare-bones induced infringement.

XV. CONCLUSION

The purpose of this article is not to wail on the Hatch-Waxman Act, the courts, or the parties. But this article shows how implementations have caused significant problems in the marketplace and how court-driven policy has also been a culprit in the Act's interpretations and executions.