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Insufficient Mechanisms for Orange Book Corrections and the FDA's Ministerial Role: A Need for Reform Note

Jane F. Djung

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Note

INSUFFICIENT MECHANISMS FOR ORANGE BOOK CORRECTIONS AND THE FDA'S MINISTERIAL ROLE: A NEED FOR REFORM

JANE F. DJUNG

The Hatch-Waxman Act revolutionized the prescription drug industry by streamlining the process for generics to gain FDA approval. The Act is credited as the primary source of infusing generics into the present day pharmaceutical landscape. However, overly broad use codes provided by the brand drug manufacturers for publication in the Orange Book may preclude generic manufacturers from a section viii statement, which may severely impede the healthcare consumer from access to affordable generic drugs.

*Although the FDA is responsible for publishing the Orange Book, it does not review its substantive information. As a result, generic companies were left without a mechanism to challenge an overly broad use code that may prevent or impede the launch of a generic drug. As a patch for this procedural hole, Congress introduced the counterclaim provision as part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. However, to invoke the counterclaim provision, the generic company must engage in a cumbersome process as highlighted by Justice Sotomayor in *Caraco Pharmaceuticals v. Novo Nordisk*.*

This Note explores the road to the counterclaim provision, examines the Supreme Court's construction of the counterclaim provision, and highlights Justice Sotomayor's illuminative remarks. Finally, this Note argues for elevated FDA oversight and proposes requiring use codes to be identical to the FDA-approved use, provided that the approved method of use is within the scope of the patent claims.

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INSUFFICIENT MECHANISMS FOR ORANGE BOOK CORRECTIONS AND THE FDA'S MINISTERIAL ROLE: A NEED FOR REFORM

JANE F. DJUNG*

I. INTRODUCTION

Generic prescription drugs are a vital component of the national healthcare landscape. Since the introduction of the revolutionary Drug Price Competition and Patent Term Restoration Act of 1984¹—colloquially known as the Hatch-Waxman Act—thirty years ago, generic drugs have impacted the prescription drug market by providing affordable necessary drugs to the public, saving American consumers, taxpayers, and federal and state governments trillions of dollars.² Prescription generic drugs have since grown to be a mainstay in the prescription drug landscape, as American healthcare consumers have increasingly relied on their safety and effectiveness.³

A published national compendium called the “Orange Book,” formally known as the Approved Drug Products with Therapeutic Equivalence Evaluations,⁴ plays a pivotal role, within the context of the Hatch-Waxman Act, in determining generic drug entry into the marketplace. The Orange Book is a publication by the U.S. Food and Drug Administration (FDA) of all FDA-approved drugs under the Federal Food, Drug, and Cosmetic Act (FD&C Act) and the drugs’ respective information, including a drug’s therapeutic equivalence evaluation, active ingredient, patent information, and application holder, among other things.⁵ This publication is heavily relied upon by: (1) healthcare providers and pharmacies as a reference for

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¹ Pub. L. No. 98-417, 98 Stat. 1585 (1984) [hereinafter Hatch-Waxman Act].

² Generic Pharm. Ass’n, *Generic Drug Savings in the U.S. Fourth Annual Edition: Savings \$1 Trillion Over 10 Years*, GPHA 1, 3 (2012), available at <http://www.gphaonline.org/media/cms/IMSSStudyAug2012WEB.pdf>.

³ *Id.*

⁴ FOOD & DRUG ADMIN., DEVELOPMENT APPROVAL PROCESS, <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079068.htm> (last updated Mar. 14, 2014).

⁵ *Id.*

essential safety and efficacy information;⁶ and (2) generic prescription drug companies for information about branded drugs (pioneer drugs or brand drugs) in determining whether to market a generic version of a branded drug.⁷ The submission of inaccurate information to the Orange Book by a brand-name drug company (innovator drug company or brand company) could severely impede or preclude the healthcare consumer from having access to necessary affordable generic drugs. Although the FDA is responsible for maintaining and publishing the Orange Book pursuant to the Hatch-Waxman Act,⁸ the FDA does not critically evaluate the accuracy of substantive information pertaining to patents and use codes⁹ provided by brand-name drug companies.¹⁰ The FDA contends that it only holds a “ministerial role” in this regard.¹¹ This lack of FDA oversight significantly impacts generic drug companies, the brand-name drug companies, and ultimately, the healthcare consumer.

Some assert that the Hatch-Waxman Act has not achieved its intended purpose of balancing the interests of market entry for generics and supporting continued innovation. From the perspective of brand-name drug companies, some contend that the Act has benefited generics at the cost of harming innovation for new or improved drugs. The task of discovering new medicines is a lengthy, costly, and risky research endeavor by name-brand drug companies. By the time an FDA-approved drug product reaches the market, ten to fifteen years will have elapsed since the first synthesis of the new active substance.¹² Furthermore, a significant amount of research is involved before the first synthesis of the new drug candidate is even achieved. On average, only one to two out of every ten thousand

⁶ Terry G. Mahn, *Is It Time for FDA to Revise Its Orange Book Rules to Deal with Skinny Labeled Generic Drugs?*, 1 FOOD & DRUG POL’Y F., OCT. 12, 2011, at 1, 2.

⁷ *Id.*

⁸ See FOOD & DRUG ADMIN., *supra* note 4 (stating that under the Hatch-Waxman Act, the FDA is required to make a list of approved drug products publically available along with monthly supplements).

⁹ The use code is “a description of any method-of-use patent [that a brand drug company] holds.” 21 C.F.R. §§ 314.53(c)(2)(ii)(P)(3), (e) (2011); *Caraco Pharm. Labs., Ltd. v. Novo Nordisk*, 132 S. Ct. 1670, 1676 (2012). The use code is supplied by the brand drug company and is submitted to the FDA to be published in the Orange Book. *Caraco*, 132 S. Ct. at 1676.

¹⁰ See, e.g., *Apotex, Inc. v. Thompson*, 347 F.3d 1335, 1348–49 (Fed. Cir. 2003) (concluding that the FDA does not have a “duty . . . to review submitted information to determine whether all of the listed patents claim the drug that is the subject of the NDA”); *aaiPharma Inc. v. Thompson*, 296 F.3d 227, 242–43 (4th Cir. 2002) (stating that the FDA serves a “ministerial” role with respect to the Orange Book); *Am. Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1080 (D.C. Cir. 2001) (“The FDA, pursuant to longstanding practice and its own regulations, and based on its acknowledged lack of expertise and resources, has refused to become involved in patent listing disputes, accepting at face value the accuracy of NDA holders’ patent declarations and following their listing instructions.”).

¹¹ *aaiPharma Inc.*, 296 F.3d at 243.

¹² Int’l Fed’n of Pharm. Mfr. & Ass’ns, *The Pharmaceutical Industry and Global Health: Facts and Figures 2012*, IFPMA, 1, 7 (Dec. 2012), available at http://www.ifpma.org/fileadmin/content/Publication/2013/IFPMA_-_Facts_And_Figures_2012_LowResSinglePage.pdf.

compounds synthesized will successfully pass all stages of development required to become an FDA-approved drug.¹³ The research required to bring innovative drugs to market is exceeding difficult and costly. The cost of developing one drug has been estimated at over \$1.3 billion.¹⁴

Without innovation from brand-name drug companies, necessary drugs now available for the betterment of people's health may not have come to fruition. Innovation from brand-name drug companies has substantially improved healthcare. For instance, in the past ten years, well over three hundred medicines have been approved for hard-to-treat diseases.¹⁵ Conditions, such as cardiovascular diseases, which necessitated extensive treatment in the 1970s, are now more easily managed with oral drugs.¹⁶ The annual death rate for cancer patients has been reduced by fifty percent due to drug advancements.¹⁷ In addition to improving the healthcare of individuals, healthcare costs—including hospitalization costs—have significantly decreased.¹⁸ Specifically, for every dollar spent on innovative cardiovascular drugs, over three dollars were saved in healthcare costs.¹⁹ Brand-name drug companies bear the risk of developing innovative drugs—especially for unmet medical needs—which ultimately provide a common good for all.

Brand-name drug companies clearly have a strong interest and need to recoup their financial research investments.²⁰ Without a financial reward, there can be no future innovation. With the level of risk and mounting research costs required to bring innovative drugs to the market coupled with the concerns of patent life, brand-name companies have strong incentives to find ways to prolong their ability to maintain market exclusivity without generic competition.

¹³ *Id.*

¹⁴ *Id.* at 8.

¹⁵ *Id.* at 16.

¹⁶ *Id.*

¹⁷ *Id.*

¹⁸ *Id.* (“[F]or every dollar spent on prescription drugs in the United States, more than two dollars are saved in hospitalization costs”).

¹⁹ *Id.* at 32.

²⁰ See Lawrence Perkins, *Pharmaceutical Companies Must Make Decisions Based on Profit*, 175 W.J. MED. 422, 422–23 (2001) (“[Pharmaceutical companies] must generate the highest level of profitability possible to fulfill [their] fiduciary duty of maximizing shareholder value. . . . The revenue generated from a successful product must recover the cost of not only that product’s research and development but also the cost of failed ventures.”); Pharm. Research & Mfg. of Am., *Intellectual Property Protections Are Vital to Continuing Innovation in the Biopharmaceutical Industry*, PHRMA, <http://www.phrma.org/innovation/intellectual-property> (last visited Sept. 1, 2014) (“For every 5,000 to 10,000 experimental compounds considered, typically only one will gain [FDA] approval, after 10 to 15 years of research and development costing an average of \$1.2 billion The few successes must make up for the many failures . . . [where] only two out of every 10 medicines will recoup the money spent on their development.”).

For healthcare consumers, the government's most recent National Health Expenditure Accounts report shows that \$2.6 trillion was spent in the United States on healthcare in 2010, "which translates to \$8,402 per person or about [eighteen] percent of the nation's Gross Domestic Product."²¹ The National Health Expenditure Accounts report further notes that healthcare spending is expected to grow by about six percent per year through 2018, which would overtake the annual growth of the overall economy by slightly over two percent per year to reach \$4.4 trillion by 2018.²² With rapidly escalating healthcare costs, the use of lower-cost generic prescription drugs plays an essential component in holding down the growth rate of healthcare spending. Over the past decade, the U.S. healthcare system amassed about \$1.07 trillion in savings due to the availability of generic drugs, with \$192.8 billion saved in 2011.²³ For thirty years, generic prescription drugs have allowed millions of Americans to obtain the medicine they need at an affordable cost. Efforts and policies that aid in this national goal should be considered, while unnecessary impediments, such as inaccurate Orange Book listings, should be discouraged or eliminated.

This Note examines the lack of FDA review of the Orange Book within the context of the Hatch-Waxman Act with particular attention paid to the rationale behind the FDA's longstanding view of its role. This Note also focuses on the lack of an efficient and effective procedural mechanism available for generic companies faced with overly broad use codes. In addition, cases (and events) that led up to the counterclaim provision as a remedy for the procedural hole are examined.

Part II describes the Hatch-Waxman Act and provides an overview of the pathways for generic market entry by means of paragraph I–IV certifications or a section viii statement. It further explains how the innovator's patents may determine whether a generic company must file a paragraph IV certification or a section viii statement. Part III provides an explanation of the FDA's ministerial role with regard to the Orange Book. Part III further highlights procedural issues that exist for a generic company that challenges an incorrect Orange Book listing, summarizes Federal Circuit Court cases that underscore this issue, and introduces the counterclaim provision as Congress's solution for this procedural hole. Part IV focuses on the Supreme Court case *Caraco Pharmaceutical Laboratories v. Novo Nordisk*,²⁴ in which the counterclaim provision was employed, and how the Court construed the provision. Part IV also focuses on issues with the counterclaim provision and highlights Supreme Court

²¹ Generic Pharm. Ass'n, *supra* note 2, at 1.

²² *Id.*

²³ *Id.*

²⁴ 132 S. Ct. 1670 (2012).

Justice Sonia Sotomayor's criticisms of the provision. Lastly, Part V suggests a need for additional administrative measures, offers some reasonable and practical suggestions provided by jurists and commentators, and proposes a possible solution.

II. THE HATCH-WAXMAN ACT

A. Purpose

The primary legal embodiment that delineates the relationship between generic drug companies and innovator brand drug companies is the Hatch-Waxman Act.²⁵ The Hatch-Waxman Act, which introduced amendments to the Federal Food, Drug, and Cosmetic Act, is "often credited with creating the modern generic drug industry."²⁶ The policies underpinning this revolutionary Act were implemented to facilitate the entry of prescription generic drugs into the market while encouraging brand drug innovation by introducing complex mechanisms that involve FDA labeling regulations, FDA drug safety and efficacy regulations, and patent law.²⁷

To balance the facilitation of market entry for generic drugs with the preservation of brand drug companies' incentives for continued innovation, the Act established Title I and II.²⁸ Title I sets forth the procedures under which the FDA may approve applications for generic versions of pioneer drugs under the FD&C Act, while Title II restores some of the patent life lost for new drugs as a result of FDA premarket testing and approval requirements.²⁹

Prior to its enactment, there were two primary reasons for the lack of generics available to the public: cost and the length of time required to gain entry into the market. In 1983, the Supreme Court held in *United States v. Generix Drugs*³⁰ that generic drugs were considered "new drugs."³¹ As a result, generics were held to the same rigorous efficacy and safety testing

²⁵ Natalie M. Derzko, *The Impact of Recent Reforms of the Hatch-Waxman Scheme on Orange Book Strategic Behavior and Pharmaceutical Innovation*, 45 IDEA 165, 166 (2005).

²⁶ Lisa Barons Pensabene & Dennis Gregory, *Hatch-Waxman Act: Overview* (2013), available at http://www.fitzpatrickcella.com/DB6EDC/assets/files/News/Hatch-Waxman%20Act%20Overview%20pensabene_dgregory.pdf.

²⁷ Derzko, *supra* note 25, at 166.

²⁸ Pub. L. No. 98-417, 98 Stat. 1585, 1598 (1984) (stating that under Title I (Abbreviated New Drug Applications), the "Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355) is amended" and that under Title II (Patent Extension), "Title 35 of the United States Code is amended by adding" § 156).

²⁹ *Id.*; Ellen J. Flannery & Peter Barton Hutt, *Balancing Competition and Patent Protection in the Drug Industry: The Drug Price Competition and Patent Term Restoration Act of 1984*, 40 FOOD DRUG COSM. L.J. 269, 270-71 (1985) (stating the reasoning underlying Title I and Title II and indicating that Title II (patent life restoration) may pertain to human biological products and medical devices).

³⁰ 460 U.S. 453 (1983).

³¹ *Id.* at 461; Flannery & Hutt, *supra* note 29, at 273.

standards as new drugs³² without consideration given to any of the previously compiled data of the innovator drug, even though many of the scientific studies for the generic version were merely duplicating results of the brand drug.³³ This standard for generics—essentially a New Drug Application (NDA) drug approval process³⁴—was “prohibitively costly” and time-consuming; hence, it did not necessarily motivate generic drug manufacturers to place generic drugs into the stream of commerce.³⁵ The generation of safety and efficacy data was required for the generic, in part, because the FDA took the stance that any prior NDA information generated by a brand company for a new drug was confidential information.³⁶ Furthermore, in order for a generic company to commence any clinical studies, it had to wait until the brand company’s patents for a particular drug of interest expired. Any unlicensed activity of a patent protected drug by another company could result in infringement litigation.³⁷

The Hatch-Waxman Act is credited as the primary source for the infusion of generics into the present day landscape of pharmaceuticals. The Hatch-Waxman Amendments effectively introduced mechanisms—albeit complex ones—that revolutionized the prior regime and widened the door for less-expensive generic prescription drugs to enter the market and be accessible to millions of healthcare consumers. Before its adoption, no streamlined FDA approval process existed for generic drugs.³⁸ At the time of enactment, less than twenty percent of prescribed drugs were generic.³⁹ Today, seventy-five percent of all prescriptions are filled with a generic drug.⁴⁰ Although the accessibility of less-costly generics has benefited healthcare consumers, the Hatch-Waxman statutory scheme has proven to

³² For a new drug to enter the market, the brand manufacturer must receive FDA approval of a new drug application (NDA). Prior to the Hatch-Waxman Act, before submitting a NDA, the generic manufacturer had to subject the generic version of the drug to the investigational new drug (IND) process, which included Phase I, II, and III clinical testing, to demonstrate that the drug was safe and efficacious for a particular indication. See PETER BARTON HUTT ET AL., FOOD AND DRUG LAW 624–32, 676–77 (3d ed. 2007) (providing a general description of the IND and NDA processes).

³³ Derzko, *supra* note 25, at 167.

³⁴ HUTT ET AL., *supra* note 32, at 676–77.

³⁵ Derzko, *supra* note 25, at 167.

³⁶ *Id.* The paper NDA process was available and provided a limited exception to the strict NDA requirements by permitting a generic drug company to rely on the published safety and efficacy data of an innovator drug. *Id.* But usually published data was deemed inferior and hence, was insufficient to warrant NDA approval. *Id.*

³⁷ Pensabene & Gregory, *supra* note 26, at 1, 3.

³⁸ Frederick R. Ball & Elese Hanson, *Patent Use Codes, the Orange Book and Section viii Statements: A Response to Terry Mahn’s Is It Time for FDA to Revise Its Orange Book Rules to Deal with “Skinny-Labeled” Generic Drugs?*, 1 FOOD & DRUG POL’Y F., Dec. 14, 2011, at 1, 2; Pensabene & Gregory, *supra* note 26, at 1.

³⁹ Ball & Hanson, *supra* note 38, at 2.

⁴⁰ *Id.*

be a thorn in the side of brand pharmaceutical companies.⁴¹ In the wake of the Hatch-Waxman Act, pioneer drug companies were—and still are—progressively concerned with the implications of the Act on their revenue, which affects their ability to sustain new innovation. The intricate and complex Hatch-Waxman Act, while attempting to balance the “two countervailing tasks” of meeting the interests of social welfare concerns in providing affordable drugs to the public and accommodating the brand drug companies, is susceptible and vulnerable to “both innovators and generics [that engage] in strategic behavior . . . to better their own economic positions.”⁴²

B. *Pathways for Generic Market Entry: Paragraph I–IV Certifications and the Section viii Statement of the Hatch-Waxman Scheme*

Pursuant to the Hatch-Waxman Act, a generic company may seek approval from the FDA to market a generic version of a branded drug. Under the Hatch-Waxman Act there are two types of applications for approval of a generic drug: (1) an Abbreviated New Drug Application⁴³ (ANDA); and (2) a paper NDA.⁴⁴ For an ANDA, a generic drug company must demonstrate that the generic version “is effectively a duplicate” of the Reference Listed Drug (RLD)⁴⁵—the brand drug. Rather than producing independent scientific safety and efficacy data, the ANDA applicant can “piggy-back[] [off of] the brand’s NDA.”⁴⁶ In order for the ANDA to be accepted, the generic must contain the same active ingredient, route of administration, dosage form, strength, intended use, and labeling as the RLD.⁴⁷ The ANDA applicant must establish that the generic drug in question is equivalent in bioavailability—bioequivalent—to the RLD.⁴⁸ A drug is deemed bioequivalent when it delivers the same concentration of the active ingredient to the patient’s blood stream, or site of action, over the same time period as the RLD.⁴⁹

⁴¹ *Id.*

⁴² Derzko, *supra* note 25, at 167, 168.

⁴³ 21 U.S.C. § 355(j) (2012).

⁴⁴ *Id.* § 355(b)(2) (2012); Derzko, *supra* note 25, at 171–72. Paper NDAs are outside the scope of this Note and will not be discussed.

⁴⁵ 21 U.S.C. §§ 355(j)(2)(A)(ii), (iv) (2012); Pensabene & Gregory, *supra* note 26, at 2.

⁴⁶ Caraco Pharm. Labs., Ltd. v. Novo Nordisk, 132 S. Ct. 1670, 1676 (2012).

⁴⁷ 21 U.S.C. §§ 355(j)(2)(A)(ii)–(iv) (2012).

⁴⁸ 21 C.F.R. § 320.1 (2014) (defining “bioavailability” as “the rate and extent to which the active ingredient or active moiety is absorbed from a drug product and becomes available at the site of action” and “drug product” as “finished dosage form, e.g., tablet, capsule, or solution, that contains the active drug ingredient, generally, but not necessarily, in association with inactive ingredients”); Caraco, 132 S. Ct. at 1676.

⁴⁹ Pensabene & Gregory, *supra* note 26, at 2; see HUTT ET AL., *supra* note 32, at 755 (inferring that bioequivalence is when two drugs have the same bioavailability or “biological availability”).

The Hatch-Waxman Act introduced several mechanisms by which an ANDA applicant (the generic drug company) may gain entry into the pharmaceutical market by challenging the innovator drug company's patent exclusivity. The ANDA applicant, after consulting the Orange Book, may make one of the following four certifications:⁵⁰ (1) paragraph I certification (there is no appropriate patent listed in the Orange Book); (2) paragraph II certification (the pertinent listed patent has expired); (3) paragraph III certification (the appropriate listed patent and other non-patent market exclusivities are scheduled to expire before the requested approval);⁵¹ or (4) paragraph IV certification (a statutory and artificial infringement of the brand drug).⁵² For a paragraph IV certification, the ANDA applicant must provide a notice letter to the NDA holder⁵³ (the brand company) within twenty days after the FDA accepts the ANDA.⁵⁴ The notice letter alerts the brand company that an ANDA has been submitted to the FDA and provides the basis for the certification—that the brand company's drug patent is not valid or will not be infringed upon.⁵⁵ The ANDA applicant that submits a paragraph IV certification for the “purpose of such submission is to obtain approval . . . to engage in the commercial manufacture, use, or sale of a drug . . . before the expiration of [the RLD's] patent” is committing an act of statutory patent infringement,⁵⁶ which in turn provides a right for the brand company to sue for infringement within forty-five days of receiving the certification.⁵⁷ If the brand company elects to file an infringement suit, the FDA may not approve the generic company's ANDA for thirty months (the “thirty-month stay”)⁵⁸ or until a court holds that the listed patent is invalid or not infringed, whichever is earlier. However, if the NDA holder does not respond within the forty-five day time frame, the ANDA applicant is permitted to file a declaratory judgment action for non-infringement and

⁵⁰ 21 U.S.C. §§ 355(b)(2)(A)(i)–(iv) (2012).

⁵¹ “Non-patent” and “patent-based factors” exclusivity include orphan drug exclusivity (seven years), new chemical entity exclusivity (five years from the first approval of the NDA, but an ANDA along with a paragraph IV certification can be filed after four years of the NDA approval, three years after the first NDA approval), and pediatric exclusivity (tacks on six months of market exclusivity to any patent exclusivity). Pensabene & Gregory, *supra* note 26, at 2–3.

⁵² 21 U.S.C. § 355(b)(2)(A)(iv) (2012).

⁵³ For large pharmaceutical companies, the patentee and NDA holder are usually the same entity. However, if the patentee is a different entity from the NDA holder, then the ANDA applicant must also provide a notice letter to the patentee. Pensabene & Gregory, *supra* note 26, at 3.

⁵⁴ 21 U.S.C. § 355(b)(3) (2012).

⁵⁵ *Id.* §§ 355(b)(3), (j)(2)(B) (2012); Pensabene & Gregory, *supra* note 26, at 3.

⁵⁶ 35 U.S.C. § 271(e)(2) (2012); Pensabene & Gregory, *supra* note 26, at 3.

⁵⁷ 21 U.S.C. § 355(j)(5)(B)(iii) (2012); *Caraco Pharm. Labs., Ltd. v. Novo Nordisk*, 132 S. Ct. 1670, 1677 (2012).

⁵⁸ 35 U.S.C. § 355(j)(5)(B)(iii) (2012); *Caraco*, 132 S. Ct. at 1677. If the RLD has NCE (new chemical entity) exclusivity, the thirty-month stay commences once the market exclusivity expires. Pensabene & Gregory, *supra* note 26, at 5.

patent invalidity, and the brand company loses its right to a thirty-month stay.⁵⁹ The policy underlying the thirty-month stay is intended to provide the brand drug company certainty that the generic drug company cannot launch the generic drug during litigation within the thirty-month period.⁶⁰

To incentivize generic companies to file ANDAs along with paragraph IV certifications, the Hatch-Waxman Act provides a 180-day marketing exclusivity period to the first ANDA applicant who prevails in a paragraph IV litigation.⁶¹ This first paragraph IV filer exclusivity⁶² precludes final approval for all other ANDAs asserting paragraph IV certification.⁶³ A generic company entitled to exclusive marketing rights against all other generics for 180 days garners a large revenue gain.⁶⁴ Obtaining this exclusivity is an underlying motivation for the generic industry.⁶⁵

The Hatch-Waxman scheme also provides ANDA applicants with another pathway toward marketing generic drugs through a section viii statement.⁶⁶ Unlike a paragraph IV certification, a section viii statement is not a statutory act of infringement; and hence, not an immediate trigger for patent infringement litigation.⁶⁷ Instead, a section viii statement—commonly known in the industry as “skinny labeling”⁶⁸—is a mechanism used by generic companies to “carve out”⁶⁹ methods of use for a particular brand drug. A section viii statement is usually employed when the brand company’s patent on the composition of matter (the chemical drug compound itself) has expired and the brand company still holds a valid, unexpired patent for some FDA-approved treatment with the drug.⁷⁰ For a section viii statement, the generic company asserts to the FDA that its generic label does not overlap with the innovator brand company’s

⁵⁹ 21 U.S.C. §§ 355(c)(3)(D)(i)(I)(aa), (j)(5)(C)(i)(I)(aa) (2012); 35 U.S.C. § 271(e)(5) (2012).

⁶⁰ Pensabene & Gregory, *supra* note 26, at 5.

⁶¹ 21 C.F.R. § 314.107(c) (2012); Derzko, *supra* note 25, at 174.

⁶² Pensabene & Gregory, *supra* note 26, at 4.

⁶³ However, this “first-filer exclusivity” does not block approval for section viii statements filers.

Id.

⁶⁴ See Jeremiah Helm, Comment, 14 MICH. TELECOMM. TECH. L. REV. 175, 180 (2007) (“The value of this bounty can be considerable”); Fei Mei Chan, *Generic-Drug Firms Compete for Profits*, FORBES (Dec. 12, 2001), <http://www.forbes.com/2001/12/12/1212sf.html> (stating that with the 180-day exclusivity, “the generic company has a virtual market monopoly”); *India’s Ranbaxy Gains; U.S. Drug Regulator Approves Generic Version of Novartis Drug*, REUTERS (June 26, 2014), <http://news.yahoo.com/indias-ranbaxy-gains-u-drug-regulator-approves-generic-035719879--sector.html> (indicating that the generic drug maker, Ranbaxy, may bring in over \$200 million in revenue from its generic version of Novartis AG’s blood pressure drug, Diovan, over the 180-day exclusivity).

⁶⁵ Ball & Hanson, *supra* note 38, at 2.

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

⁶⁷ Pensabene & Gregory, *supra* note 26, at 4.

⁶⁸ Terry G. Mahn, *Skinny Labeling and the Inducement of Patent Infringement*, UPDATE 39, 39–40 (2010).

⁶⁹ *Id.* at 41.

⁷⁰ Caraco Pharm. Labs., Ltd. v. Novo Nordisk, 132 S. Ct. 1670, 1677 (2012).

FDA-approved drug label.⁷¹ In other words, assuming the ANDA meets other criteria, the generic company wishes to obtain FDA-approval to manufacture and market the generic drug for an FDA-approved treatment that is not patent-protected—“a carve out” from the brand company’s approved label.⁷² Unlike a paragraph IV certification where the generic company must “bear the same label as the brand-name product,” a generic company seeking a section viii statement proposes a label that is not identical and does not overlap with any of the claimed uses.⁷³ Since a section viii statement does not, in theory, create a statutory infringement on a brand company’s patent or assert that the patent is invalid, the FDA may grant immediate approval.⁷⁴

The FDA will approve an ANDA with a section viii statement only if (1) there is no overlap between the proposed label submitted by the ANDA applicant and the use described in the Orange Book, and (2) removing the information about the claimed method of use from the label does not render the drug less safe or effective.⁷⁵

C. *The Innovator’s Patents Determine a Paragraph IV Certification or a Section viii Statement*

The type of patent held by the brand drug company determines whether the ANDA applicant (a generic company) should assert a certification (paragraph I–IV) or section viii statement.⁷⁶ Essentially, there are two types of patents pertaining to brand-name drugs: a composition of matter patent (claiming the drug compound itself) and a method of use patent (claiming a particular method of using the drug).⁷⁷ Oftentimes, a brand drug company may be the owner of both types of patents for a drug where the drug compound expires before the method of use patent.⁷⁸ Once the drug compound patent has expired, the FDA-approved methods of use that are not patent protected can be vulnerable to generics seeking a section viii statement.⁷⁹ The presence of a valid composition of matter patent

⁷¹ *Caraco*, 132 S. Ct. at 1677; 21 C.F.R. § 314.94(a)(8)(iv) (2012).

⁷² *Caraco*, 132 S. Ct. at 1677.

⁷³ *Id.*

⁷⁴ Ball & Hanson, *supra* note 38, at 2.

⁷⁵ *Bayer Schering Pharma AG v. Lupin, Ltd.*, 676 F.3d 1316, 1318 (Fed. Cir. 2012).

⁷⁶ See *Caraco*, 132 S. Ct. at 1676 (“[T]he FDA cannot authorize a generic drug that would infringe a patent . . . [which] depends on the scope and duration of the patents”).

⁷⁷ *Id.*; FOOD & DRUG ADMIN., IMPLEMENTATION OF PROVISIONS OF THE DRUG PRICE COMPETITION AND PATENT RESTORATION ACT OF 1984, <http://www.fda.gov/newsevents/testimony/ucm115218.htm> (last updated July 24, 2009).

⁷⁸ *Caraco*, 132 S. Ct. at 1676.

⁷⁹ See *id.* at 1677 (“A section viii statement is typically used when the brand’s patent on the drug compound has expired and the brand holds patents on only some approved methods of using the drug.”)

effectively precludes a section viii statement because any use of the drug itself, even for a method of use not patented by the drug company, is an infringement.⁸⁰ Alternatively, an ANDA applicant may assert a paragraph IV certification when a patent exists for the drug compound itself or for a method of use for that drug.⁸¹

III. THE ROAD TO THE COUNTERCLAIM PROVISION

A. *The Orange Book's Role within the Hatch-Waxman Act and Listing Practices*

In accordance with the Hatch-Waxman Act, the FDA must maintain and publish a list of patents associated with approved drugs.⁸² This national compendium is the “Approved Drug Products with Therapeutic Equivalence Evaluations”—commonly known as the Orange Book—which effectively serves two functions: (1) as a reference for healthcare providers and pharmacies containing essential safety and “effectiveness” information about brand drugs and their respective generics;⁸³ and (2) as a source of use codes and patent term information, among other things, for branded drugs.⁸⁴ In this respect, the Orange Book is exceedingly important within the context of paragraph IV certifications and section viii statements. Under the Hatch-Waxman Amendments and FDA regulations, brand drug companies are required to submit “the patent number and 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.”⁸⁵ Once the FDA approves the NDA, the brand company is to supply a description of all methods of use patents it holds—known as the “use code.”⁸⁶ Prior to 2003, the NDA applicant was required to include: (1) the patent number and date

If the ANDA applicant follows this route, it will propose labeling for the generic drug that ‘carves out’ from the brand’s approved label the still-patented methods of use. The FDA may approve such a modified label as an exception to the usual rule that a generic drug must bear the same label as the brand-name product.”) (citations omitted); Arti Rai, *Use Patents, Carve-Outs, and Incentives – A New Battle in the Drug-Patent Wars*, 367 NEW ENG. J. MED. 491, 491 (2012) (indicating that when “the main product patent on a brand-name drug expires before the use patents[,]” generic companies may file a section viii statement, which provides the generic drug “a potential path to market”).

⁸⁰ 35 U.S.C. § 271 (2012).

⁸¹ See *Caraco*, 132 S. Ct. at 1677 (“A generic manufacturer will typically take this [paragraph IV certification] path in either of two situations: if it wants to market the drug for all uses, rather than carving out those still allegedly under patent; or if it discovers . . . that any carve-out label it is willing to adopt cannot avoid the brand’s use code.”).

⁸² 21 U.S.C. §§ 355(b)(1), (c)(2) (2012).

⁸³ See Mahn, *supra* note 6, at 2 (stating that generics found to be therapeutically equivalent to the brand drug are given an “A” rating, which results in an accepted substitution for the brand drug).

⁸⁴ *Id.*

⁸⁵ 21 U.S.C. § 355(b)(1) (2012); *Caraco*, 132 S. Ct. at 1676.

⁸⁶ *Caraco*, 132 S. Ct. at 1676.

of patent expiration; (2) the type of patent (composition of matter or method of use patent); (3) the patent owner name; and (4) the information of the entity which is to receive patent certification if the patent owner is not in the U.S.⁸⁷ In the 2003 Amendments, the FDA issued supplementary regulations requiring the NDA holder to supply information for each method of use patent claiming the approved drug, which includes:

- (1) [w]hether the patent claims one or more approved methods of using the approved drug product and a description of each approved method of use or indication and related patent claim of the patent being submitted; (2) [i]dentification of the specific section of the approved labeling for the drug product that corresponds to the method of use claimed by the patent submitted; and (3) [t]he description of the patented method of use as required for publication.⁸⁸

Notwithstanding the detailed requirements necessary for Orange Book use code listing, the FDA does not substantiate the patent information supplied by the brand company.⁸⁹ Because of the lack of FDA oversight, it is possible that an innovator drug company may list inaccurate use codes⁹⁰ (including broad use codes),⁹¹ which frustrates the purpose of the Hatch-Waxman Act—the interest in facilitating generic drugs into the market. In order for a generic company to market a generic version of a brand drug, it must first consult the Orange Book to determine the type of certification needed, if any (paragraph I–IV certifications or a section viii statement).⁹² An inaccurate use code or overly broad use code could preclude, or at least make it exceedingly more difficult for, a generic version of the drug to reach the marketplace. In the presence of an overly broad use code, a generic company wishing to “carve-out” a method of use for a brand drug is precluded from using a section viii statement to garner a more immediate FDA approval.⁹³ Instead, the generic company must now file a paragraph IV certification (statutory infringement) and litigate the validity of the

⁸⁷ Derzko, *supra* note 25, at 170.

⁸⁸ Ball & Hanson, *supra* note 38, at 2 (paraphrasing 21 C.F.R. § 314.53(c)(2)(O) (2012)).

⁸⁹ *Id.*; Derzko, *supra* note 25, at 171.

⁹⁰ *See Mylan Pharms., Inc. v. Thompson*, 268 F.3d 1323, 1330–32 (Fed. Cir. 2001) (exemplifying an allegation of improper Orange Book listing).

⁹¹ *Caraco*, 132 S. Ct. at 1679, 1687.

⁹² *See id.* at 1676 (“After consulting the Orange Book, a company filing an ANDA must assure the FDA that its proposed generic drug will not infringe the brand’s patents.”).

⁹³ *Id.* at 1688 (Sotomayor, J., concurring) (“[I]f the use code overlaps with the generic manufacturer’s proposed carve-out label (*i.e.*, if the use code is overly broad), FDA will not approve an ANDA with a section viii statement.”).

brand company's patent.⁹⁴ Since the FDA is not responsible for the accuracy of the use codes and does not mandate that the brand company correct inaccurate use codes, improper listing practices effectively impede generic market entry. In 1994, the FDA was taken to task concerning its role with respect to the Orange Book.⁹⁵ The FDA responded:

[The] FDA does not have the resources or the expertise to review patent information for its accuracy and relevance to an NDA. Therefore, the agency declines the comment's requests to ensure that patent information is complete and relevant to an NDA and to confirm, upon request, the validity of patent information submitted to the agency. The agency believes that the declaration requirements[,] . . . as well as the applicant's potential liability if it submits an untrue statement of material fact, will help ensure that accurate patent information is submitted.⁹⁶

Even in recent years, including after the 2003 Amendments, the FDA maintains its assertion that "the agency [has] a purely 'ministerial' role as to patent listing issues."⁹⁷

B. *The FDA's "Ministerial" Orange Book Role: Court Validation*

The courts have validated the FDA's longstanding view of its "ministerial" role over the Orange Book. In *aaiPharma Inc. v. Thompson*,⁹⁸ the Fourth Circuit held that there are no statutory inconsistencies with the FDA's view.⁹⁹ The issue was whether there is an FDA obligation to police the accuracy of the NDA holder's Orange Book listing.¹⁰⁰ To assess the FDA's interpretation of its governing statute, the court employed the two-step framework established in *Chevron U.S.A., Inc., v. Natural Resources Defense Council, Inc.*¹⁰¹ The two-step *Chevron* framework requires that the court first determine "whether Congress has directly spoken to the precise question at issue."¹⁰² If congressional intent is clear then that is the "end of the matter."¹⁰³ Second, if the court determines that Congress has not

⁹⁴ See *id.* (Sotomayor, J., concurring) (stating that "the generic manufacturer can . . . submit an ANDA with a paragraph IV certification . . . [and] wait for the brand manufacturer to institute suit" when the generic manufacturer is precluded from a section viii statement).

⁹⁵ Derzko, *supra* note 25, at 171.

⁹⁶ *Id.* (quoting 59 Fed. Reg. 50,338, 50,345 (Oct. 3, 1994)).

⁹⁷ *Id.* at 214.

⁹⁸ 296 F.3d 227 (4th Cir. 2002).

⁹⁹ *Id.* at 241.

¹⁰⁰ *Id.* at 237.

¹⁰¹ *Id.* at 237–39 (indicating that the court is employing the two-step framework as stated in *Chevron U.S.A. Inc., v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842–44 (1984)).

¹⁰² *Chevron U.S.A. Inc.*, 467 U.S. at 842.

¹⁰³ *Id.*

directly addressed the “question at issue,” or if the statute is equivocal or silent, then the court must determine whether the “agency’s [own] answer is based on a permissible construction of the statute.”¹⁰⁴ The FDA relied on 21 U.S.C. § 355(c)(2), which states:

[I]f the holder of an approved [new drug] application could not file patent information [for a patent claiming a new drug] because no patent had been issued when an application was filed or approved, the holder shall file such information . . . not later than thirty days after the date the patent involved issued. Upon the submission of patent information under this subsection, the [FDA] shall publish it.¹⁰⁵

The FDA contended that this clearly points to the NDA holder’s responsibility for filing the necessary information, while the FDA’s role is “passive.”¹⁰⁶

However, *aaiPharma* (a generic company) asserted that subsections (d) and (e)¹⁰⁷ indicate that the FDA has a responsibility to ensure that eligible patents are listed in the Orange Book. Subsections (d) and (e) respectively provide the basis by which the FDA may reject an NDA: (1) if “the application failed to contain the patent information prescribed by subsection (b) of this section[,] . . . [the FDA] shall issue an order refusing to approve the application”;¹⁰⁸ and (2) if “the patent information prescribed by subsection (c) of this section was not filed within thirty days after the receipt of written notice from the [FDA] specifying the failure to file such information,” the FDA “shall . . . withdraw approval of an application.”¹⁰⁹

The court recognized that in isolation, each provision may be construed as an unequivocal expression of congressional intent with regard to the question at issue.¹¹⁰ However, under step one of the *Chevron* framework, the provisions taken collectively appeared as though there was ambiguity with the question at issue.¹¹¹ Hence, the court proceeded to step two, where the court ultimately determined that the FDA’s reading of its role as ministerial was based on a permissible interpretation of section 355.¹¹² *aaiPharma* effectively condoned the FDA’s longstanding Orange Book “ministerial” responsibility, which does not include determining the merits of patent listings.

¹⁰⁴ *Id.* at 843.

¹⁰⁵ 21 U.S.C. § 355(c)(2) (2012); *aaiPharma Inc. v. Thompson*, 296 F.3d 227, 238 (4th Cir. 2002).

¹⁰⁶ *aaiPharma Inc.*, 296 F.3d at 238.

¹⁰⁷ 21 U.S.C. §§ 355(d)–(e) (2012).

¹⁰⁸ *Id.* § 355(d) (2012); *aaiPharma Inc.*, 296 F.3d at 238.

¹⁰⁹ 21 U.S.C. § 355(e) (2012); *aaiPharma Inc.*, 296 F.3d at 238.

¹¹⁰ *aaiPharma Inc.*, 296 F.3d at 238.

¹¹¹ *Id.*

¹¹² *Id.* at 238–40.

C. *Procedural Issues in Challenging Orange Book Use Codes and the Lack of FDA Oversight*

In the 1990s, indications suggested that innovator drug companies were strategically taking advantage of the Hatch-Waxman Act and the Orange Book to prevent or delay the entry of generic drugs.¹¹³ In 2002, the Federal Trade Commission (FTC) produced a study that detailed the strategic—but anticompetitive—conduct, which included a specific focus on the practice of brand companies submitting inaccurate patent information to the FDA and the lack of Orange Book listing review.¹¹⁴ Furthermore, as early as 2002, the FTC had formally recognized issues regarding Orange Book listing practices and issued a citizen’s petition to the Commissioner of the FDA regarding the “listability” of patents in the Orange Book.¹¹⁵ In seeking guidance for Orange Book listing criteria, the FTC underscored the issue that “generic competition can be delayed on name-brand drug products if the name-brand companies newly list ‘irrelevant and undefendable’ patents in the Orange Book near the expiration of the name-brand drug product’s original patents.”¹¹⁶ As of 2002, there was no substantive recourse for a generic company to challenge the accuracy of an inaccurate Orange Book listing.¹¹⁷ By regulation, the limited measure available was to notify the FDA in writing, and in turn, the FDA would only request that the brand drug company confirm the accuracy of the listed information.¹¹⁸ Since the FDA views its responsibility in maintaining the Orange Book as “purely ministerial,” it “[does] not change the patent information in the list,” except when “the [NDA] holder withdraws or amends its patent information in response to the FDA’s request.”¹¹⁹ In other words, the FDA does not mandate any corrections or delisting of the brand name company’s use code and patent listings.¹²⁰ Because the “Orange Book listing elevates every patent as a potential source of delay to generic competition,” the “Orange Book can be a strategic weapon.”¹²¹

¹¹³ *Caraco Pharm. Labs., Ltd. v. Novo Nordisk*, 132 S. Ct. 1670, 1678 (2012).

¹¹⁴ FTC, *GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY* i–iv, 39–40, 42–45, 48 (July 2002), [hereinafter *FTC STUDY*] available at http://www.ftc.gov/sites/default/files/documents/reports/generic-drug-entry-prior-patent-expiration-ftc-study/genericdrugstudy_0.pdf (focusing on strategic conduct by the brand pharmaceutical companies submitting inaccurate patent listings and taking advantage of the multiple thirty-month stays).

¹¹⁵ *Id.* at 54–56.

¹¹⁶ *Id.* at A-25.

¹¹⁷ *Id.* at iv, 44–45.

¹¹⁸ 21 C.F.R. § 314.53(f) (2012); *FTC STUDY*, *supra* note 114, at 44.

¹¹⁹ 21 C.F.R. § 314.53(f) (2012).

¹²⁰ *FTC STUDY*, *supra* note 114, at 44.

¹²¹ See Ball & Hanson, *supra* note 38, at 3 (indicating that the Orange Book was a “strategic weapon” in pre-2003 Amendments).

D. Federal Circuit Cases: An Impetus

Several generic companies have brought the issue of inaccurate Orange Book listings to the courts. Several Federal Circuit cases collectively serve as part of a significant force for congressional action.¹²²

1. Mylan v. Thompson: *No Private Right of Action for Orange Book Correction*

In *Mylan Pharmaceuticals, Inc. v. Thompson*,¹²³ the Federal Circuit held that generic companies—ANDA applicants—do not have a private right of action to challenge the NDA holder's Orange Book listing as improper and to delist the patent.¹²⁴ The court asserted that Mylan's action—essentially a right of action for delisting—was not a proper or “recognized” patent infringement defense under patent law, but a private right of action.¹²⁵ In addition, the court stated that it is impermissible for a private party to enforce the FD&C Act.¹²⁶

There, Mylan sued Bristol-Myers Squibb seeking an order requiring Bristol-Myers Squibb to delist its patent from the Orange Book.¹²⁷ In anticipation of the Bristol-Myers Squibb patent expiration for its drug BuSpar® (buspirone hydrochloride), Mylan acquired tentative approval of its ANDA application under a paragraph III certification (certification whereby the generic waits for the appropriate patent to expire before it is fully authorized for generic entry into the market).¹²⁸ However, shortly before the buspirone patent expired,¹²⁹ Bristol-Myers Squibb produced patents claiming the metabolite of the drug to the FDA,¹³⁰ which

¹²² *Caraco Pharm. Labs., Ltd. v. Novo Nordisk*, 132 S. Ct. 1670, 1678 (2012) (stating that *Mylan Pharms., Inc. v. Thompson* was responsible, in part, for congressional action); Derzko, *supra* note 25, at 181 (indicating that both *Mylan Pharms., Inc. v. Thompson* and *Andrx Pharms., Inc. v. Biovail Corp.* were cases that resulted in congressional action).

¹²³ 268 F.3d 1323 (Fed. Cir. 2001).

¹²⁴ *Id.* at 1332–33.

¹²⁵ *Id.* at 1332 (“Mylan’s arguments further bolster our conclusion that its claim is not a recognized defense to patent infringement. . . . Therefore, we are forced to conclude that Mylan’s action here against [BMS] is in essence an attempt to assert a private right of action for ‘delisting’ under the [FD&C Act].”).

¹²⁶ *See* 21 U.S.C. § 337(a) (2012) (“[A]ll such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States.”); *Mylan Pharms., Inc.*, 268 F.3d at 1330 (“It is well settled . . . that the FDCA creates no private right of action.” (quoting *In re: Orthopedic Bone Screw Prods. Liab. Litig.*, 193 F.3d 781, 788 (3d Cir. 1999))). Recognized defenses against patent infringement include only statutory defenses (which include non-infringement, unenforceability, and invalidity in the context of patentability) and inequitable conduct defense (which include unclean hands, fraud, and misuse). *Mylan Pharms., Inc.*, 268 F.3d at 1331.

¹²⁷ *Mylan Pharms., Inc.*, 268 F.3d at 1325.

¹²⁸ *Id.* at 1327.

¹²⁹ *Id.* at 1327–28 (indicating that BMS produced patents just eleven hours before the expiration of the original drug patent).

¹³⁰ *Id.* at 1328.

“ostensibly extend[ed] its rights over the drug, but in fact cover[ed] neither the compound nor any method of using [the compound].”¹³¹

As a result of *Mylan*, the FTC correctly noted that the sole option for a generic company is to file a paragraph IV certification, which creates a statutory infringement and subjects the ANDA to a thirty-month stay before it can be approved.¹³² Hence, the lack of express statutory provisions enabling an action to challenge a brand company’s Orange Book listing impedes the underpinning of the Hatch-Waxman Act—to facilitate the entry of generics into the market.

2. *Andrx v. Biovail & aaiPharma v. Thompson: No Remedy for Generics Under the Administrative Procedure Act*

In *Andrx Pharmaceuticals, Inc. v. Biovail Corp.*,¹³³ the Federal Circuit concluded that although there is not a private right of action for delisting as established in *Mylan*, a generic company has the option to bring a claim against the FDA under the Administrative Procedure Act (APA).¹³⁴ Improper Orange Book listing conduct by the brand company (Biovail) was of controversy in *Andrx*.¹³⁵ In 2001, *Andrx* (a generic company) prevailed in a non-infringement paragraph IV certification suit against Biovail concerning U.S. Patent No. 5,529,791 (patent ’791) for the active ingredient, diltiazem hydrochloride.¹³⁶ As a result, the FDA was ready to approve *Andrx*’s ANDA; however, in the following month, Biovail listed an extended time-release formulation of diltiazem hydrochloride claimed in U.S. Patent No. 6,162,463 (patent ’463).¹³⁷ In view of Biovail’s new listing, the FDA could no longer approve *Andrx*’s ANDA application.¹³⁸ *Andrx* contended that listed patent ’463 did not properly claim diltiazem hydrochloride and requested that the FDA delist patent ’463 from the Orange Book.¹³⁹ Biovail affirmed that patent ’463 claims diltiazem hydrochloride, the drug itself, as supplied in the original NDA.¹⁴⁰ In

¹³¹ *Caraco Pharm. Labs., Ltd. v. Novo Nordisk*, 132 S. Ct. 1670, 1678 (2012) (referring to the brand company’s Orange Book listing practice in *Mylan Pharms., Inc. v. Thompson*).

¹³² *Id.* (referring to the FTC STUDY indicating that this was the only recourse for generics in this predicament).

¹³³ 276 F.3d 1368 (Fed. Cir. 2002).

¹³⁴ *Id.* at 1378–80.

¹³⁵ *Id.* at 1377 (indicating that an incorrect patent listing, which did not claim the drug approved in the brand company’s original NDA, does not “permit [the brand company] Biovail to benefit from additional thirty-month stay”). *Andrx Pharms., Inc. v. Biovail Corp.* also significantly dealt with the brand company’s effort to garner multiple thirty-month stays, which is currently not available under the 2003 Amendments. *Id.* at 1374, 1377. The issue of multiple thirty-month stays is outside the scope of this Note.

¹³⁶ *Id.* at 1372.

¹³⁷ *Id.*

¹³⁸ *Id.*

¹³⁹ *Id.* at 1373.

¹⁴⁰ *Id.*

addressing Andrx's request for relief in court,¹⁴¹ the Federal Circuit concluded that although there is not a private right of action for delisting an Orange Book listing as established in *Mylan*, a generic company may bring a claim against the FDA under the Administrative Procedure Act to compel the FDA to approve the ANDA.¹⁴²

Federal Circuit Judge Alan Lourie criticized the Federal Circuit's suggestion.¹⁴³ In a dissenting opinion in another case, Judge Lourie asserted that when the Hatch-Waxman Act was enacted, the FDA did not anticipate having substantive issues of patent listing and that "[r]equiring patent listings to be addressed only by APA actions involving the FDA amounts in practical terms to a distortion of the provisions of the Food and Drug Act relating to patent listings and challenges."¹⁴⁴ Essentially, the Federal Circuit in *Andrx* put the FDA in the untenable position of having to address inaccurate patent listings in the Orange Book when the FDA has continuously expressed a lack of expertise and resources to review patent listings.¹⁴⁵

Recently, Federal Circuit Court Judge Timothy Dyk asserted that despite *Andrx*, prevailing in an APA challenge might not be likely.¹⁴⁶ In order to prevail, the generic company must be able to demonstrate that the FDA's refusal to police the Orange Book use codes conflicts with a statute or was "arbitrary and capricious."¹⁴⁷

The Federal Court's proposition for relief under an APA challenge was tested in the Fourth Circuit. In *aaiPharma v. Thompson*, a generic company (aaiPharma) brought a lawsuit under APA for the FDA to require the NDA holder (Eli Lilly) to submit a patent for listing in the Orange

¹⁴¹ *Id.*

¹⁴² *Id.* at 1378–80; FTC STUDY, *supra* note 114, at 44.

¹⁴³ See *Minn. Mining & Mfg. Co. v. Barr Labs., Inc.*, 295 F.3d 1274, 1275 (Fed. Cir. 2002) (Lourie, J., dissenting) ("Requiring patent listings to be addressed . . . by APA actions involving the FDA amounts in practical terms to a distortion of the provisions of the Food and Drug Act relating to patent listing and challenges.").

¹⁴⁴ *Id.* at 1275 (Lourie, J., dissenting).

¹⁴⁵ Derzko, *supra* note 25, at 181.

¹⁴⁶ See *Novo Nordisk v. Caraco Pharm. Labs., Ltd.*, 601 F.3d 1359, 1381–82 (Fed. Cir. 2010) (Dyk, J., dissenting) ("Nor would there be a remedy in a suit under the [APA]. To be sure, we have held that an APA action could be brought to challenge FDA action in refusing to police use codes in the Orange Book, but at the same time we expressed no view as to whether such an action would succeed. To succeed in such an action, the ANDA applicant would have to establish that the FDA's refusal to police codes was arbitrary and capricious, or contrary to the statute. We have subsequently held that the FDA is under no statutory obligation to determine the correctness of particular patent listings in the Orange Book, and that nothing in the Hatch-Waxman Act requires the FDA to screen Orange Book submissions . . . and refuse those that do not satisfy the statutory requirements for listing.") (citations omitted).

¹⁴⁷ *Apotex, Inc. v. Thompson*, 347 F.3d 1335, 1348–49 (Fed. Cir. 2003); *Novo Nordisk*, 601 F.3d at 1381–82 (Dyk, J., dissenting).

Book.¹⁴⁸ aaiPharma asserted that the FDA's refusal to "police the correctness of Orange Book listings [was] arbitrary and capricious" because the FDA had delegated its administrative duties to private parties (NDA holders).¹⁴⁹ The Fourth Circuit confirmed that the "arbitrary and capricious" standard is narrow as established by the Supreme Court.¹⁵⁰ In determining whether an agency's act is "arbitrary and capricious," the court must determine whether "the agency . . . examine[d] the relevant data and articulate[d] a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made.'"¹⁵¹ An agency's rule may be deemed "arbitrary and capricious" if: (1) "the agency has relied on factors which Congress has not intended it to consider"; (2) the agency "entirely failed to consider an important aspect of the problem"; (3) the agency has "offered an explanation for its decision that runs counter to the evidence before the agency"; or (4) the rule "is so implausible that it could not be ascribed to a difference in view or product of agency expertise."¹⁵² Under this standard of review, the Fourth Circuit determined that, with respect to the Orange Book, the FDA was not arbitrary and capricious.¹⁵³ First, the court asserted that the FDA's "ministerial" role rested on a permissible construction of the Hatch-Waxman Act.¹⁵⁴ The primary reason for this "ministerial" role is that the paragraph IV certification scheme was to have private parties' intellectual property rights settled via patent infringement suits, while the FDA was to focus on the effectiveness and safety of the drugs.¹⁵⁵ Consequently, it seems unlikely that Congress's intent was to have the FDA take on this responsibility of reviewing the merits of Orange Book listings.¹⁵⁶ Second, the court stated that "[w]hen an agency has discretion about whether to take on enforcement responsibilities, an explanation that it lacks the resources and

¹⁴⁸ aaiPharma Inc. v. Thompson, 296 F.3d 227, 233–34 (4th Cir. 2002).

¹⁴⁹ *Id.* at 241.

¹⁵⁰ *See id.* at 242 (indicating that the Supreme Court had established that the standard of review was set forth in *Motor Vehicle Manufacturers Association of the United States v. State Farm Mutual Auto Insurance Company*, 463 U.S. 29, 43 (1983)).

¹⁵¹ *Motor Vehicle Mfrs. Ass'n v. State Farm Mutual Auto Ins. Co.*, 463 U.S. 29, 43 (1983) (quoting *Burlington Truck Lines, Inc. v. United States*, 371 U.S. 156, 168 (1962)).

¹⁵² *Id.* at 43.

¹⁵³ aaiPharma Inc., 296 F.3d at 242–43.

¹⁵⁴ *Id.* at 242. Several courts have affirmed the policy that the FDA serves a "ministerial" role with respect to the Orange Book. *See, e.g., Apotex, Inc. v. Thompson*, 347 F.3d 1335, 1347–49, 1352 (Fed. Cir. 2003) ("[T]he Hatch-Waxman Act does not require the FDA to review patents substantively before listing in the Orange Book."); aaiPharma Inc., 296 F.3d at 242–43 ("[T]he FDA may persist in its purely ministerial approach to the Orange Book listing process."); *Am. Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1084 (D.C. Cir. 2001) ("[T]he FDA has a longstanding policy not to get involved with patent disputes. It administers the Hatch-Waxman Amendments in a ministerial fashion simply following the intent of the parties that list patents.").

¹⁵⁵ aaiPharma Inc., 296 F.3d at 241.

¹⁵⁶ *Id.*

the expertise to do so is enough to satisfy the requirement of reasoned agency decision making.”¹⁵⁷ Lastly, the FDA has never wavered in its position that it lacks the necessary resources and expertise to make patent law judgments.¹⁵⁸

It was apparent from case law that the Hatch-Waxman Act was not equipped to handle Orange Book listing issues and “was ripe for reform in this respect.”¹⁵⁹ To further support this contention, Federal Circuit Judge Sheldon Plager asserted a need for reform:

The need for the FDA to properly police the administration of the Act in this regard was made even more acute by our decision in *Mylan* If neither the Administration nor the courts see fit to make clear FDA’s obligation to administer the act in a responsible way, Congress should consider doing so.¹⁶⁰

Clearly, there was a significant need for reform of Orange Book listing practices within the context of the Hatch-Waxman Act as evidenced by the *FTC Study*, the courts and case law, and the frustration suffered by generic companies. Brand drug companies are “playing a new game: by inaccurately describing the scope of their method of use patents to [the] FDA, they are limiting the immediate approval pathway provided by section viii.”¹⁶¹

E. *The Counterclaim Provision: Congress’s Answer to Inaccurate and Overly Broad Orange Book Listings*

To address the manipulative Orange Book listing practices,¹⁶² Congress created a legal counterclaim provision to a paragraph IV infringement lawsuit¹⁶³ under the auspices of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.¹⁶⁴ The new provision permits generic ANDA applicants sued for patent infringement to:

assert a counterclaim seeking an order requiring the [brand

¹⁵⁷ *Id.* at 242.

¹⁵⁸ *Id.* at 242–43.

¹⁵⁹ Derzko, *supra* note 25, at 184.

¹⁶⁰ *Apotex, Inc. v. Thompson*, 347 F.3d 1335, 1353–54 (Fed. Cir. 2003) (Plager, J., concurring).

¹⁶¹ Ball & Hanson, *supra* note 38, at 3.

¹⁶² Based on the legislative history leading up to the counterclaim provision, it was well-known in Congress that brand drug companies were manipulating the Orange Book in the context of the Hatch-Waxman Act to further stave off generic entry. See Derzko, *supra* note 25, at 224–26 (“What we saw, regrettably under Hatch-Waxman, was [that] there were games being played This bill is an attempt to address those issues.” (quoting 149 CONG. REC. S8193 (daily ed. June 19, 2003) (statement of Sen. Gregg))).

¹⁶³ 21 U.S.C. § 355(j)(5)(C)(ii)(I) (2012).

¹⁶⁴ Pub. L. No. 108-173, 117 Stat. 2456. .

drug manufacturer] to correct or delete the patent information submitted by the [brand drug manufacturer] . . . on the ground that the patent does not claim either—(aa) the drug for which the [brand drug manufacturer’s NDA] was approved; or (bb) an approved method of using the drug.¹⁶⁵

In other words, this counterclaim provision enables a generic ANDA applicant to pursue a judgment that would compel a brand drug company to amend or delist patent information that precludes the FDA’s approval of the generic ANDA.¹⁶⁶

The counterclaim provision was recognized as a “patch” on the “procedural hole” that manifested in *Mylan* and *Andrx*.¹⁶⁷ By establishing the counterclaim provision, legislators have recognized and addressed the issue and have tacitly rejected the idea of an administrative delisting mechanism. Although the counterclaim provision does provide a mechanism for delisting, generics view the procedural path as cumbersome and costly because the counterclaim is only used when engaged in a paragraph IV infringement action.¹⁶⁸ Generic companies would have preferred an administrative review mechanism.¹⁶⁹ Yet some scholars have recognized that such an administrative mechanism would be very unlikely.¹⁷⁰

IV. THE COUNTERCLAIM PROVISION AT WORK

A. *Caraco v. Novo Nordisk: Construing the Counterclaim Provision*

*Caraco v. Novo Nordisk*¹⁷¹ illuminates an underlying defect in the counterclaim provision.¹⁷² This Supreme Court case underscores the view

¹⁶⁵ 21 U.S.C. § 355(j)(5)(C)(ii)(I) (2012).

¹⁶⁶ *Caraco Pharm. Labs., Ltd. v. Novo Nordisk*, 132 S. Ct. 1670, 1678 (2012).

¹⁶⁷ *Derzko*, *supra* note 25, at 242.

¹⁶⁸ See Alan Bennett et al., *Supreme Court Rules on Patent Use Codes*, ROPES & GRAY (Apr. 19, 2012), <http://www.ropesgray.com/zh/news-and-insights/Insights/2012/04/supreme-court-rules-on-patent-use-codes.aspx> (“Justice Sotomayor highlighted the fact that the availability of a counterclaim does not solve the problem inherent in the statute: because there is no validation of use codes submitted to FDA by brand manufacturers, costly and time-consuming litigation is necessary to correct overly broad use codes.”); Dianna Goldenson El Hioum, *Caraco Pharmaceutical Laboratories, Ltd. v. Novo Nordisk A/S: Generics May Seek Correction of Overly Broad Use Codes*, MERCHANT & GOULD (May 1, 2012), http://www.merchantgould.com/Resource_WP_2012_05_CaracoPharm.aspx (“Justice Sotomayor . . . points out that excess litigation might be avoided if the FDA clarifies its ‘remarkably opaque’ use code requirements so generics would not have to resort to the counterclaim provision to clear a path to market entry for non-infringing drugs. Until that happens or Congress amends Hatch-Waxman, . . . a cumbersome path to section viii approval is likely to continue.”).

¹⁶⁹ *Derzko*, *supra* note 25, at 242.

¹⁷⁰ *Id.*

¹⁷¹ 132 S. Ct. 1670 (2012).

¹⁷² *Id.* at 1678.

that NDA holders have manipulated the scheme by supplying inaccurate or overly broad use codes to preclude or stave generics from the market, especially in the context of section viii statements.¹⁷³

Caraco, a generic company, sought to manufacture and market repaglinide, a diabetes drug. Novo Nordisk, a brand drug company, manufactures the brand-name version of repaglinide—marketed as Prandin®—which has been approved by the FDA for three uses in the treatment of diabetes: (1) repaglinide, the drug itself; (2) repaglinide in combination with metformin; and (3) repaglinide in combination with thiazolidinediones (TZDs).¹⁷⁴ Novo Nordisk, the original NDA holder, owned patent U.S. No. RE 37,035 (patent '035) for the compound itself, which was set to expire in 2009.¹⁷⁵ In 2004, Novo Nordisk was granted a method of use patent—U.S. Patent No. 6,677,358 (patent '358)—which “claims a ‘method for treating [diabetes by] administering . . . repaglinide in combination with metformin.’”¹⁷⁶ Patent '358 was not set to expire until 2018.¹⁷⁷ However, Novo Nordisk did not hold a method of use patent for repaglinide in combination with TZDs.¹⁷⁸ With this information in 2005, Caraco indicated to the FDA that it would wait until after patent '035 (the composition of matter patent for repaglinide)¹⁷⁹ expired in 2009 to market the generic version, but duly filed its ANDA along with a paragraph IV certification for patent '358 (repaglinide in combination with metformin).¹⁸⁰

Because Novo Nordisk's use code was only for patent '358 (the “[u]se of repaglinide in combination with metformin to lower blood glucose”), the FDA advised Caraco that it could file a section viii statement, a “carve-out,” for the other two uses not patent protected but FDA-approved—the use for the treatment of diabetes with repaglinide itself and the use for the treatment of diabetes with repaglinide in combination with TZDs.¹⁸¹ This would permit Caraco to enter its generic version into the market without an infringement suit by Novo Nordisk.¹⁸² Before the FDA could approve Caraco's ANDA, Novo Nordisk amended its use code to read a “method

¹⁷³ Ball & Hanson, *supra* note 38, at 3–4.

¹⁷⁴ *Caraco*, 132 S. Ct. at 1678.

¹⁷⁵ *Id.*; *Novo Nordisk v. Caraco Pharm. Labs., Ltd.*, 601 F.3d 1359, 1362 (Fed. Cir. 2010).

¹⁷⁶ *Caraco*, 132 S. Ct. at 1678. (quoting a claim in U.S. Patent No. 6,677,358 as stated in *Novo Nordisk v. Caraco Pharm. Labs., Ltd.*, 601 F.3d 1359, 1362 (Fed. Cir. 2010)).

¹⁷⁷ *Id.*

¹⁷⁸ *Id.* at 1678–79.

¹⁷⁹ *Novo Nordisk*, 601 F.3d at 1362.

¹⁸⁰ *Caraco*, 132 S. Ct. at 1679.

¹⁸¹ *Id.* (quoting the Orange Book use code as stated in *Novo Nordisk v. Caraco*, 601 F.3d at 1362–63).

¹⁸² Caraco would be able to market their generic immediately for the two uses, provided that the ANDA was “otherwise in order” with regard to bioequivalence, etc. *Id.*

for improving glycemic control in adults with type 2 diabetes[.]”¹⁸³ which encompassed all three FDA-approved methods. As a result of this overly broad use code, the FDA could no longer accept Caraco’s carve-out label; Caraco was effectively blocked from its ANDA and could not bring its generic version to market under a section viii statement.¹⁸⁴

Caraco reacted to Novo Nordisk’s newly broad use code by employing the statutory counterclaim provision in the on-going paragraph IV infringement suit, which it had initiated in 2005.¹⁸⁵ The counterclaim was used to mandate Novo Nordisk to correct the use code to accurately reflect only the method of use for which there was patent protection.¹⁸⁶ But the first issue at hand for the court was to determine the meaning and scope of the counterclaim provision.¹⁸⁷

Construction of the counterclaim provision hinged on the meaning of the words “*not . . . an*” in the provision stating that the generic company that “sued for patent infringement may bring a counterclaim” based “on the ground that the patent does *not* claim . . . *an* approved method for using the drug.”¹⁸⁸ The Federal Circuit construed “*not . . . an* approved method” to mean “*not . . . any* approved methods.”¹⁸⁹ Hence, based on the Federal Circuit’s construction, the “Hatch-Waxman Act authorizes a counterclaim only if the listed patent *does not claim any* approved methods of using the listed drug.”¹⁹⁰ The Federal Circuit effectively found that since Novo Nordisk had a valid patent for one FDA-approved method of use (repaglinide in combination with metformin), it would preclude Caraco from using the statutory counterclaim provision.¹⁹¹ However, the Supreme Court disagreed with the Federal Circuit and found that the “text and context demonstrate that the counterclaim is available not only (as in

¹⁸³ *Id.* (quoting the amended use code as stated in *Novo Nordisk*, 601 F.3d at 1363).

¹⁸⁴ *Id.*

¹⁸⁵ *Id.*

¹⁸⁶ *Id.*

¹⁸⁷ *Id.* at 1681–83.

¹⁸⁸ 21 U.S.C. § 355(j)(5)(C)(ii)(I) (2012) (emphasis added); *Caraco*, 132 S. Ct. at 1680–81.

¹⁸⁹ *Novo Nordisk v. Caraco Pharm. Labs., Ltd.*, 601 F.3d 1359, 1364–65 (Fed. Cir. 2010).

¹⁹⁰ *Id.* at 1365 (emphasis added).

¹⁹¹ *Id.* at 1380 (Dyk, J., dissenting). The Federal Circuit held that Congress intended the provision to allow courts to order a correction of patent numbers and expiration dates listed in the Orange Book but not to use code language. *Id.* at 1366. However, Federal Circuit Judge Dyk dissented from this construction and interpreted the provision in the context of the underlying basis for the counterclaim provision. *Id.* at 1368 (Dyk, J., dissenting) (“In 2003, Congress enacted the counterclaim provision of the Hatch-Waxman Act in order to prevent manipulative practices by patent holders with respect to the Orange Book listings. These practices were designed to delay the onset of competition from generic drug manufacturers.”). He construed the provision to be used by an ANDA applicant “to assert the counterclaim to correct or delete the Orange Book ‘patent information submitted . . . under subsection (b) or (c)’ on the ground that the patent does not claim ‘the drug for which the application was approved’ or ‘an approved method of using the drug.’” *Id.* at 1370 (quoting 21 U.S.C. § 355(j)(5)(C)(ii) (2012)).

Mylan) when the patent listing is baseless, but also (as here) when it is overbroad.”¹⁹² The Supreme Court’s statutory construction interpreted “not . . . an” within the context of the statute.¹⁹³ Also, by construing the statutory provision within the context of the overall purpose of the Hatch-Waxman framework and its underlying goal, the Supreme Court stated that

the counterclaim naturally functions to challenge the brand’s assertion of rights over whichever discrete use (or uses) the generic company wishes to pursue. That assertion, after all, is the thing blocking the generic’s entry on the market. The availability of the counterclaim thus matches the availability of FDA approval under the statute: A company may bring a counterclaim to show that a method of use is unpatented because establishing that fact allows the FDA to authorize a generic drug via section viii.¹⁹⁴

Novo Nordisk asserted that the underlying basis for the counterclaim provision was to aid generic companies that found themselves in the same predicament as in *Mylan*—when the brand company’s use codes were baseless.¹⁹⁵ However, the Supreme Court contended “*Mylan* alerted Congress to a broader problem—that generic companies generally had no avenue to challenge the accuracy of brands’ patent listings.”¹⁹⁶

B. Counterclaim Provision Defects

1. Justice Sotomayor’s Concurring Opinion: Not a “Fix” for Overly Broad Orange Book Listings

Notwithstanding the Supreme Court’s decision in *Caraco*, severe inefficiencies in employing the counterclaim provision exist.¹⁹⁷ Although Justice Sonia Sotomayor agreed with the Court’s holding and analysis, she thoughtfully stated that the counterclaim provision “can only lessen the difficulties created by an overly broad use code; it cannot fix them.”¹⁹⁸ Because a section viii statement is not an act of infringement, the

¹⁹² *Caraco*, 132 S. Ct. at 1687.

¹⁹³ *Id.* at 1681 (giving examples of when “not an” is interpreted as “not any” and when it does not mean “not any” within different contexts and concluding that “[t]he meaning of the phrase turns on its context”). In addition, the Supreme Court also acknowledges that Congress did not intend “not an” to mean “not any” because Congress employed “not any” in an immediate, subsequent subclause which indicates to the Court that Congress “knew how to say ‘not any’ when it meant ‘not any.’” *Id.* at 1682.

¹⁹⁴ *Id.*

¹⁹⁵ *Id.* at 1686, 1687.

¹⁹⁶ *Id.* at 1687.

¹⁹⁷ *See id.* at 1688–89 (Sotomayor, J., concurring) (discussing the problems associated with the process and asserting that “the counterclaim cannot restore the smooth working of a statutory scheme thrown off kilter by an overly broad use code”).

¹⁹⁸ *Id.* at 1688.

counterclaim provision is not available for generics proposing a “carve-out” label. As a result, a generic company in this predicament, wishing to employ the counterclaim provision to correct an overly broad Orange Book listing so that it can effectively file an ANDA application with a section viii statement must: (1) change its proposed non-infringing “carve-out” label to the identical brand company’s label and submit a paragraph IV certification to create a statutory infringement; (2) wait for the innovator brand company to sue for infringement; and (3) file the counterclaim provision.¹⁹⁹ Finally, if the generic company prevails, then it can file the section viii statement as originally intended.²⁰⁰

As asserted by Justice Sotomayor, this drawn-out procedure presents two salient issues: (1) “[the process] results in [a] delay and [an] expense the statutory scheme [did] not envision”²⁰¹—which effectively undermines the underpinning of the Hatch-Waxman Act; and (2) the process is not “guarantee[d]” to work because the counterclaim provision is available only if the brand manufacturer files a paragraph IV suit.²⁰² Justice Sotomayor raised concern over the lack of clarity when the brand company elects not to file suit,²⁰³ provided that the generic proceeds with its ANDA application.²⁰⁴ She asserted that the FDA may still approve the ANDA application “without prejudice to [the] infringement claims the patent owner might assert when the ANDA applicant produces or markets the generic drug.”²⁰⁵ Consequently, the generic company subjects itself to liability under the patent doctrine of induced infringement²⁰⁶ if the brand company still holds a patent for some approved method of using the drug—a precarious position for the generic drug company.²⁰⁷ To this end, Justice Sotomayor proclaimed that a “fix is in order, but it must come from Congress or FDA.”²⁰⁸

2. “Remarkably Opaque” FDA Regulations and Guidance for Orange Book Listing Practices

In 2003, the FDA issued a “final rule” concerning patent submissions and listing requirements in the hopes that it would provide clarity and

¹⁹⁹ *Id.*

²⁰⁰ *Id.*

²⁰¹ *Id.*

²⁰² *Id.* at 1689.

²⁰³ *Id.*

²⁰⁴ Alternatively, the generic company may decide not to pursue its ANDA application; hence, a generic version is precluded from entering the market.

²⁰⁵ *Caraco*, 132 S. Ct. at 1689 (Sotomayor, J., concurring).

²⁰⁶ 35 U.S.C. § 271(b) (2012).

²⁰⁷ *See Caraco*, 132 S. Ct. at 1689 (Sotomayor, J., concurring) (suggesting that a generic company being “forced to proceed[] with a paragraph IV certification” and subject to an induced infringement claim “is not a position . . . a generic manufacturer wants to be in”).

²⁰⁸ *Id.*

minimize opportunities and attempts for drug companies to “tak[e] advantage of [the] process,” among other things.²⁰⁹ As set forth by the “final rule” pertaining to method of use claims,

the [NDA] applicant shall submit information only on those patents that claim indications or other conditions of use *that are described in the pending or approved application . . .* For approved applications, the applicant submitting the method of use patent shall identify with specificity the section of the approved labeling that corresponds to the method of use claimed by the patent submitted.²¹⁰

The language in the new final rule (shown above in italics) replaced “of the pending or approved application” as stated in the pre-2003 listing rule. From the FDA’s perspective, this new limiting language clarifies that only method of use patents pointing to FDA-approved uses are to be listed in the Orange Book.²¹¹ In addition, a declaration form was instituted in an attempt to simplify patent listing and thwart deceptive listing practices. For the most part, the declaration form includes a series of “yes” or “no” questions pertaining to patent information.²¹² A handful of “yes” or “no” questions concerning drug substance, drug product, and method of use will ultimately determine whether the FDA will list the patent in the Orange Book.²¹³ In addition to the binary questions, the form requires that the NDA applicant provide a “description of the approved indication or method of use”—the Orange Book “Use Code”—in fewer than 240 characters.²¹⁴ Lastly, the declaration certification warns that “willful and knowingly false statements” are deemed criminal offenses.²¹⁵

Notwithstanding the 2003 FDA listing rules, issues remain, as

²⁰⁹ Derzko, *supra* note 25, at 214. In addition, the final rule applies to only patents listed after August 18, 2003. *Id.*

²¹⁰ 21 C.F.R. § 314.53(b)(1) (2012) (emphasis added).

²¹¹ See Derzko, *supra* note 25, at 216 (suggesting that there is no longer ambiguity about what type of method of use can be listed in the Orange Book).

²¹² Form FDA 3542, Patent Information Submitted Upon and After Approval of an NDA or Supplement, 2 (July 2007) asks “yes” and “no” questions pertaining to patents. For an image of the Form FDA 3542 (July 2007), see Deborah Herzfeld, Tom Irving & Donna Meuth, *Orange Book Use Codes: Impact of Caraco v. Novo Nordisk*, STRAFFORD (June 5, 2012), <http://media.straffordpub.com/products/orange-book-use-codes-impact-of-caraco-v-novo-nordisk-2012-06-05/presentation.pdf>. See also Derzko, *supra* note 25, at 218 (indicating that such forms with “yes” and “no” questions provide a “simple algorithm” for FDA personnel to “easily characterize a patent as being listable or not”). The form is in accordance with section 505(b) and (c) of the Federal, Food, Drug, and Cosmetic Act.

²¹³ For an image of the FDA Form 3542 (July 2007), see Herzfeld, Irving & Meuth, *supra* note 212.

²¹⁴ *Id.*

²¹⁵ *Id.* (“A willfully and knowingly false statement is a criminal offense under 18 U.S.C. 1001.”); Derzko, *supra* note 25, at 218.

evidenced in *Caraco*.²¹⁶ Although the central issue to the case was the counterclaim provision, broad Orange Book listing by the innovator drug company was the cause of this dispute.²¹⁷ Justice Sotomayor noted that “[p]recisely because the [Hatch-Waxman] regulatory scheme depends on the accuracy and precision of use codes,” the “FDA’s guidance as to what is required of brand manufacturers in use codes [is] remarkably opaque”²¹⁸ and further illuminates deficiencies in the FDA’s determinative listing criteria.²¹⁹ These deficiencies include that 240 characters “may not fully describe the use as claimed in the patent,” a problem also recognized by the FDA,²²⁰ and the confusion as to whether the method of use or the indication satisfies the use code.²²¹

V. REFORM SUGGESTIONS

A. *The Need for Elevated FDA Oversight*

Currently, a generic company’s only recourse, if it takes issue with an inaccurate or overly broad Orange Book use code listing,²²² is to employ the counterclaim provision in a paragraph IV litigation.²²³ Many federal judges and commentators have criticized the lack of FDA oversight and guidance regarding such a pivotal national compendium.²²⁴ Some

²¹⁶ See *Caraco Pharm. Labs., Ltd. v. Novo Nordisk*, 132 S. Ct. 1670, 1689 (2012) (Sotomayor, J., concurring) (describing some issues in the “FDA’s guidance as to what is required of brand manufacturers in use codes” and highlighting the inefficiency of counterclaim provision).

²¹⁷ *Id.* at 1689 (Sotomayor, J., concurring) (“[W]e are here today because of FDA’s opacity in describing what is required of brand manufacturers.”).

²¹⁸ *Id.*

²¹⁹ *Id.* at 1689–90 (Sotomayor, J., concurring) (explaining that “Novo [Nordisk] understood its . . . use code to comply with FDA regulations . . . that the regulations permit a brand manufacturer to submit for publication in the Orange Book a description of *either* the patented method of use *or* the indication (which refers to ‘what a drug does[.]’)” and further suggesting that limiting brand manufacturers to 240 characters in describing the use code may not be sufficient).

²²⁰ *Id.* at 1689.

²²¹ *Id.* at 1690.

²²² The generic party that takes issue with the accuracy of an Orange Book listing can “notify the FDA.” Then, the FDA will request the innovator drug company to confirm the listing information. *Apotex, Inc. v. Thompson*, 347 F.3d 1335, 1347 (Fed. Cir. 2003). However, the FDA cannot supplant the innovator drug company’s assertion of Orange Book information. *Id.*; Ball & Hanson, *supra* note 38, at 4.

²²³ See Ball & Hanson, *supra* note 38, at 4, 10 n.60 (stating that “[in] view of [FDA’s] limited role, the only remedy for ANDA applicants lies with the courts” and referencing 68 Fed. Reg. at 36,683, which states “[t]he courts have the experience, expertise, and authority to address complex and important issues of patent law”). This Note has established that the likelihood of prevailing in a challenge against the FDA under the APA is unlikely.

²²⁴ See generally *Caraco*, 132 S. Ct. at 1689 (Sotomayor, J., concurring) (“Precisely because the regulatory scheme depends on the accuracy and precision of use codes, I find FDA’s guidance as to what is required . . . [for] use codes [is] remarkably opaque.”); *Apotex*, 347 F.3d at 1353–54 (Plager, J., concurring) (“The need for the FDA to properly police the administration of the Act in this regard was made even more acute by our decision in *Mylan Pharmaceuticals, Inc. v. Thompson*”); Michael

commentators assert that the lack of FDA oversight “render[s] section viii null and void,” which effectively forestalls a pathway for generics to enter the market.²²⁵ Furthermore, the FDA’s policy and regulatory regime may encourage NDA holders to list improper use code descriptions to garner a thirty-month stay as a result of the generic being required to file paragraph IV certifications so that it can employ the counterclaim provision.²²⁶ Consequently, some have gone so far as to say that the FDA should police the Orange Book, while others have seemingly sided with the FDA and have expressed consternation about subjecting the FDA to burdens that it is not equipped to manage.²²⁷ During oral arguments in *Caraco*, Justice Kennedy questioned the FDA’s reliance on the Orange Book when the FDA “doesn’t do anything to ensure the accuracy of the code.”²²⁸ The answer to this profound—yet simple—question is mired in complex issues and implications, which this Note has touched upon. Some commentators have offered meaningful solutions that may yield effects that are in congruence with the underlying principle for the Hatch-Waxman Act—facilitating generic entry into the market.

B. *Additional Administrative Measures*

The FDA has invariably contended that it has only a “ministerial” role with respect to Orange Book listings based on practical interests²²⁹ and a lack of expressed statutory mandate.²³⁰ However, mounting judicial concerns, as evidenced in *Caraco*, may cause the FDA to consider taking some internal measures to alleviate the issue.

Vincent Ruocco, *Brand Name or Generic? A Case Note on Caraco Pharmaceutical Laboratories v. Novo Nordisk*, 33 J. NAT’L ASS’N ADMIN. L. JUDICIARY 341, 385 (2013) (“[T]he FDA must rise to the occasion and raise its substantive level of review, police patent codes for accuracy, and proactively refuse to list overbroad method-of-use patents . . .”).

²²⁵ Ball & Hanson, *supra* note 38, at 3.

²²⁶ Brian J. Malkin & Andrew S. Wasson, *Should FDA Undertake More Than a “Ministerial” Role with Respect to Patent Information?*, 1 FOOD & DRUG POL’Y F., Feb. 23, 2011, at 1.

²²⁷ See James N. Czaban & Brian H. Pandya, *Caraco v. Novo Nordisk – A Divided Supreme Court*, WILEY REIN (Dec. 7, 2011), <http://www.wileyrein.com/publications.cfm?sp=articles&id=7648> (stating that Chief Justice Roberts had “expressed concerns” about “greater burdens on the FDA” because the FDA does not have patent lawyers on staff).

²²⁸ Transcript of Oral Argument at 18, *Caraco Pharm. Labs., Ltd. v. Novo Nordisk*, 132 S. Ct. 1670 (2012) (No. 10-844) (quoting Justice Kennedy).

²²⁹ 68 Fed. Reg. 36,683 (June 18, 2003) (“In addition to the absence of any statutory basis for a substantive agency review of patents, we have long observed that we lack expertise in patent matters. . . . [O]ur patent listing role remains ministerial.”).

²³⁰ *Id.* at 36,682 (“In the absence of explicit statutory language, we believe an approach that requires the NDA applicant or holder or patent owner to identify the approved methods of use protected by the patent is most consistent with the general balance adopted in Hatch-Waxman.”).

1. Staff Patent Lawyers and Agents

One solution is for the FDA to develop an “internal competency” to determine the accuracy of patent listings in the Orange Book.²³¹ Many jurists suggest that the FDA should employ registered U.S. Patent and Trademark Office attorneys (or patent analysts), especially those who have pharmaceutical backgrounds,²³² to determine the accuracy of such listings. Judge S. Jay Plager, in his concurring opinion in *Apotex v. Thompson*, asserted that

[i]t does not seem to me to be an unreasonable expectation that the FDA have on its staff a handful of competent patent analysts, along with its multitude of scientific specialists, who, at a minimum, could make an initial judgment about the propriety of a listing, consistent with the statutory requirement that the NDA holder file required patent information. . . . This would provide a neutral arbiter between the NDA holder and the ANDA applicant regarding an important matter of process, and would provide some balance between these competing interests, a balance that the Hatch-Waxman Act was intended to establish in the first place.²³³

Commentators have indicated that the FDA already practices a similar exercise in comparing use code descriptions to a proposed generic label when determining whether a generic company may carve out a brand manufacturer’s label.²³⁴ In addition, the FDA is capable of recognizing patent claim types (active ingredient, formulations, method of use, products by process, polymorphs) and can distinguish between some listable claims and unlistable claims such as intermediate compound and processing claims.²³⁵ This suggests that the FDA already has some patent knowledge and expertise.²³⁶ Furthermore, employing patent attorneys within the FDA to analyze the finer points for determining listing validity may be within reason.²³⁷

In *Teva Pharmaceuticals v. Leavitt*,²³⁸ a case concerning the FDA’s Orange Book policy, Judge Stephen Williams contended that even though

²³¹ Malkin & Wasson, *supra* note 226, at 1.

²³² *Apotex, Inc. v. Thompson*, 347 F.3d 1335, 1353 (Fed. Cir. 2003) (Plager, J., concurring); Malkin & Wasson, *supra* note 226, at 1–2., 5.

²³³ *Apotex*, 347 F.3d at 1353 (Plager, J., concurring).

²³⁴ Malkin & Wasson, *supra* note 226, at 6.

²³⁵ *Id.*

²³⁶ *Id.*

²³⁷ *See id.* (“[T]he analysis of determining whether a method-of-use patent claims a use for which the generic application is submitted requires a more refined skill-set than a patent listing determination . . . [and] would not be beyond the skills of the competent patent attorneys hired by FDA.”).

²³⁸ 548 F.3d 103 (D.C. Cir. 2008).

the FDA's ministerial role is an administrative policy choice that is "consistent with the statute," the statute does not require a ministerial role.²³⁹ He further concluded that "to read the majority opinion as implying that the statute locks the FDA into a ministerial role would be inappropriate" and that "[s]uch a reading would prevent the FDA from taking a more active role in the listing process."²⁴⁰ Judge Williams' view is consistent with the notion of an internal patent listing review process for allowable Orange Book listings. The Hatch-Waxman Act does not expressly or even impliedly bar the FDA from patent review for listing purposes. As noted, courts have held that the FDA's longstanding policy of maintaining a "ministerial" role is reasonable under the FD&C Act; however, there is no statutory prohibition preventing the FDA from expanding its responsibilities.²⁴¹

2. Elevated Oversight for Orange Book Use Code Amendments

It is perhaps onerous for the FDA to completely assume responsibility for actively scrutinizing all use code submissions by innovator companies. However, amendments to use codes should rise to the level of elevated oversight.²⁴² Due to the volume of patents submitted and number of declarations for a patent, it may arguably be burdensome for the FDA to police all Orange Book use codes. On average per year, 379 patents are submitted for Orange Book listing with approximately fourteen percent of individual patents being named in more than one NDA submission.²⁴³ This results in approximately 432 patents declared on Form FDA 3542,²⁴⁴ which is used for filing an NDA or supplement. For the FDA to police all submitted use codes may be considered a daunting and burdensome task at this time. However, amendments make up a fraction of this volume, which may result in a reasonably manageable workload.²⁴⁵ It has been suggested

²³⁹ *Id.* at 108 (Williams, J., concurring) (quoting the majority opinion in *Teva*, 548 F.3d at 106).

²⁴⁰ *Id.* at 110.

²⁴¹ Malkin & Wasson, *supra* note 226, at 5 (basing this view on Judge Williams concurring remarks in *Teva Pharms., USA, Inc.*, 48 F.3d at 110).

²⁴² See Julie Dohm, Comment, *Expanding the Scope of the Hatch-Waxman Act's Patent Carve-Out Exception to the Identical Drug Labeling Requirement: Closing the Patent Litigation Loophole*, 156 U. PA. L. REV. 151, 191–92 (2007) (indicating that generic companies have proposed that brand manufacturers "disclose relevant patents when amending labels" and further suggesting that "[t]he FDA can then make a judgment call as to whether the label updates are genuinely for consumer health or competitive gain").

²⁴³ The annual average number of patents was based on "[t]he numbers of patents submitted to the FDA for listing in the Orange Book in 2010, 2011, and 2012 were 351, 329, and 458, respectively." 78 Fed. Reg. 36,194 (June 17, 2013).

²⁴⁴ *Id.*

²⁴⁵ *But see* Dohm, *supra* note 242, at 192 ("[T]he FDA would have to engage in the review of patents listed or unlisted in the *Orange Book*. . . . [Its] workload would increase in amount and difficulty if the FDA had to inquire into the purpose of the amendments and the intent of the NDA holders.").

that the brand company's intention should be considered when amending a use code—"for consumer health or competitive gain"²⁴⁶—which would add unnecessary burdens on the agency. This Note, however, does not advocate or consider any level of evaluation of the brand company's motivation for its use code amendment to the FDA.

In reviewing amendments, the FDA may be able to quickly assess whether a use code amendment is broadened from its previous version. This quick assessment may serve as a red flag and indicate whether an amendment deserves additional scrutiny. For instance in *Caraco*, if Novo Nordisk's use code amendment was subjected to elevated FDA scrutiny—especially since the use code was clearly broadened—Caraco might not have been blocked from its initial section viii statement.

The amendment of existing use codes by a brand manufacturer may be a result of the "remarkably opaque" Orange Book guidelines²⁴⁷ set forth by the FDA or may be due to a desire to prolong exclusivity in the market by foreclosing generic entry. For either reason, amendments to use codes should be subject to enhanced FDA scrutiny and evaluation.

3. Implementation of an Orange Book Listing Challenge Mechanism

Instead of proactive oversight by the FDA, the FDA could consider implementing a mechanism at the administrative level for generic companies to "challenge" a use code and correct overly broad use codes.²⁴⁸ Although it has been suggested that this mechanism should be used in circumstances where a brand manufacturer omits a patent for listing in the Orange Book,²⁴⁹ this suggestion may be extrapolated to instances where a generic company suspects an overly broad use code has been listed.

Standards by which an ANDA filer may bring a challenge should be implemented to weed out unwarranted challenges. For a challenge to be heard, the ANDA filer must be able to establish a reasonable likelihood of success or a more likely than not case for the challenge. The challenger must be able to specifically point to patent claims to demonstrate that a use code supplied by the brand manufacturer is overly broad.

²⁴⁶ *Id.* at 191–92 ("The FDA can then make a judgment call as to whether the label updates are genuinely for consumer health or for competitive gain. . . . [T]he agency's workload would increase in amount and difficulty if the FDA had to inquire into the purpose of the amendments and the intent of the NDA holders.").

²⁴⁷ *Caraco Pharm. Labs., Ltd. v. Novo Nordisk*, 132 S. Ct. 1670, 1689 (2012) (Sotomayor, J., concurring).

²⁴⁸ *See Dohm, supra* note 242, at 194 ("[T]he FDA should set up a mechanism whereby a generic can challenge the pioneer's failure to submit to the FDA a patent for inclusion in the *Orange Book*.").

²⁴⁹ *Id.* The practice for brand companies to exclude patents from Orange Book listing is also an issue for section viii statements. *See id.* at 193–94 (indicating that patent exclusion from the Orange Book is a tactic brand companies use to preclude "proposed carve-outs"). Patent exclusion is not within the scope of this Note.

Because of the FDA's unwavering view on its ministerial role, congressional action may be needed to effect administrative action.²⁵⁰ Even before *Caraco v. Novo Nordisk*, judges and commentators have suggested that Congress should implement statutory provisions that would expressly grant the FDA additional authority to actively review Orange Book listings or to provide a mechanism for ANDA filers to challenge Orange Book use codes.²⁵¹ In his concurring opinion in *Apotex v. Thompson*, Judge Plager opined that the current FDA practice of correcting an Orange Book listing at the administrative level—where the FDA “will not modify the listing unless the NDA holder agrees” to a modification—is lacking.²⁵² He contends that the FDA “could make an initial judgment about the propriety of a listing, consistent with the statutory requirement that the NDA holder file required patent information”²⁵³ and could serve as a “neutral arbiter between the NDA holder and the ANDA applicant . . . and would provide some balance between these competing interests, a balance that the Hatch-Waxman Act was intended to establish in the first place.”²⁵⁴ This notion is still viable since the counterclaim provision may only be employed upon an infringement suit.²⁵⁵

4. *Generic Drug User Fee Act: Funds to Support Substantive Orange Book Review*

Historically, the FDA has maintained that it does not have the resources to provide services beyond a ministerial role. Instituting generic filing fees may provide a means for the FDA to fund additional patent attorneys. Until October 2013, the FDA did not charge fees for processing ANDAs. Many commentators in the field have long asserted that instituting an ANDA filing fee would yield the necessary revenue for the FDA to support patent law expertise and other resources to properly review

²⁵⁰ See *Caraco*, 132 S. Ct. at 1689 (Sotomayor, J., concurring) (“A fix is in order, but it must come from Congress or FDA.”).

²⁵¹ See *Apotex, Inc. v. Thompson*, 347 F.3d 1335, 1354 (Fed. Cir. 2003) (Plager, J., concurring) (“If neither the Administration nor the courts see fit to make clear FDA’s obligation to administer the Act in a responsible way, Congress should consider doing so.”); Derzko, *supra* note 25, at 242 (asserting that Judge Plager “would agree that some kind of administrative mechanism beyond just allowing for a patent infringement counterclaim is in order”); see also Christopher R. Walker, *Deadly Delay / Postponed Pills*, 10 J. MARSHALL REV. INTELL. PROP. L. 255, 271–72 (2010) (“[R]eforms may take the shape of a new statutory provision to challenge Orange Book listings The remedy to prevent such occurrences in the future is clear statutory language that grants the FDA additional power.”).

²⁵² *Apotex*, 347 F.3d at 1353 (Plager, J., concurring).

²⁵³ *Id.*

²⁵⁴ *Id.*

²⁵⁵ Judge Plager also indicates that he was “not impressed with the argument that the problem is cured because ultimately the validity of any listed patent will be determined by a court” and that “[t]he ultimate judicial vindication, . . . comes much later, and at considerable additional cost.” *Id.*

Orange Booking listings.²⁵⁶ In July 2012, the FDA implemented the Generic Drug User Fee Amendments (GDUFA),²⁵⁷ building on the success of the Prescription Drug User Fee Act (PDUFA).²⁵⁸ PDUFA currently funds approximately half of new drug review efforts. This increased funding has effectively terminated the “slow and unpredictable review and approval” process for NDAs while maintaining the high standards required.²⁵⁹ PDUFA funds provide the FDA with the ability to hire additional staff to expedite the NDA review process. For instance, the FDA nearly doubled the number of full-time drug review staff members from 1,277 in 1992 to 2,503 in 2004.²⁶⁰ Substantively, the FDA was able to generally improve drug development by providing the brand drug companies guidance for reducing unnecessary drug trials and improving application submissions. Furthermore, with the added resources, the FDA strengthened its review process and standards, making it “more rigorous, consistent, and predictable.”²⁶¹ Collectively, these improvements resulted in decreased development costs and lessened review periods.²⁶² In effect, these desirable developments allowed the FDA to provide the public with more efficient access to new drugs.

Similar to PDUFA, GDUFA’s underlying policy rationale is “to speed access to safe and effective drugs to the public and reduce costs to industry.”²⁶³ GDUFA requires that ANDA applicants now pay a fee for the review of their application and for the inspection of generic drug facilities. Hence, GDUFA funds will enable the FDA to address the backlog of

²⁵⁶ Ruocco, *supra* note 224, at 383–84.

²⁵⁷ 21 U.S.C. § 379j-42(a)(4) (2012); FDA, GENERIC DRUG USER FEE AMENDMENTS OF 2012 (2012), available at <http://www.fda.gov/ForIndustry/UserFees/GenericDrugUserFees/default.htm> (indicating that GDUFA includes ANDA, Drug Master Fees File fees (DMF), Prior Approval Supplement (PAS), Backlog, and Facility fees) (last updated Aug. 6, 2014).

²⁵⁸ 21 U.S.C. §§ 379j(a)(2)(A), (a)(3)(A) (2012); FDA, PRESCRIPTION DRUG USER FEE ACT, <http://www.fda.gov/forindustry/userfees/prescriptiondruguserfee/default.htm>. The FDA, pursuant to its administrative policy to promote supplementary funds without raising new taxes, proposed to institute user fees for NDAs, for instance \$126,200 for a full NDA. HUTT ET AL., *supra* note 32, at 678–81. This was met with resistance from pharmaceutical companies and Congress. *Id.* at 678–79. The pharmaceutical industry feared that these fees were planned to replace—not add to—appropriated funds. *Id.* By 1992, the NDA approval time “reached a high of three years.” *Id.* at 679. As a result, the pharmaceutical industry’s opposition toward user fees waned, and the industry agreed to support fees. *Id.* The pharmaceutical industry and the FDA reached an agreement that user fees would supplement, not replace “existing FDA baseline appropriations.” *Id.* PDUFA was enacted in 1992 with the underlying reason to provide the FDA with additional funds to support the NDA process in order to improve FDA’s efficiency while maintaining high standards. *Id.* at 679–81.

²⁵⁹ HUTT ET AL., *supra* note 32, at 680.

²⁶⁰ *Id.*

²⁶¹ *Id.*

²⁶² *Id.* (indicating that the NDA applications median approval time reduced from 13.2 months before the PDUFA in 1993 to 6.4 months in 2003).

²⁶³ GDUFA Legislation and Background, FDA, <http://www.fda.gov/ForIndustry/UserFees/GenericDrugUserFees/ucm337385.htm> (last updated Feb. 26, 2014).

pending applications, reduce the median time for ANDA review, and promote inspections.²⁶⁴

With this newly enacted fee collection regime, the FDA may also be able to fund efforts toward actively reviewing the Orange Book beyond its current ministerial role by hiring patent attorneys to delineate patent claims and use codes. In 2013, GDUFA was anticipated to garner \$299 million²⁶⁵ in funding for the FDA, in part, by charging \$51,520 for each original ANDA application.²⁶⁶ Since the approval process for an ANDA application is significantly less complex and time consuming, the GDUFA ANDA fee pales in comparison to a PDUFA NDA fee of \$1,958,800 in 2013.²⁶⁷ The current \$51,520 rate for an ANDA review is rather nominal; hence, the FDA may be able to reasonably increase the rate to cover the costs necessary to substantively review Orange Book listings.²⁶⁸

5. *Change in Listing Requirements: Use Codes Should Be Identical to the Patent Claim*

As suggested by some practitioners, an alternative that the FDA may resort to without significantly increasing the burden upon itself is to require use codes to be identical in language to the patent's claims.²⁶⁹ Not allowing the brand company to "free-hand" its use code language would eliminate any listing manipulation.²⁷⁰ Furthermore, it would extinguish any guesswork and additional verification needed by the FDA in determining whether a use code is duly listed. Proponents of this practice assert that this alternative may significantly prevent "variability" or "abuse" without incurring costs or overburdening the FDA.²⁷¹ This proposed practice may not require the FDA to provide additional patent law staff to construe the use code against the patent claim.

²⁶⁴ Alexander Gaffney, *FDA Tries to Clear ANDA Backlog Before User Fee Assessment*, REGULATORY FOCUS (Aug. 23, 2012), <http://www.raps.org/focus-online/news/news-article-view/article/2142/fda-tries-to-clear-anda-backlog-before-user-fee-assessment.aspx> (assuming that there are approximately 2,500 ANDAs backlogged); Kurt R. Karst, *Our GDUFA Cup Runneth Over! FDA Sets Several 2013 User Fee Rates*, FDA L. BLOG (Oct. 25, 2012), http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2012/10/our-gdufa-cup-runneth-over-fda-sets-several-fy-2013-user-fee-rates.html (indicating that there are well over 2,000 ANDAs backlogged as of 2012).

²⁶⁵ Karst, *supra* note 264.

²⁶⁶ 2013 *Frequently Asked Questions: Abbreviated New Drug Applications (ANDA) and Prior Approval Supplement (PAS) Fees*, FDA, <http://www.fda.gov/forindustry/userfees/genericdruguserfees/ucm363561.htm> (last updated Aug. 2, 2013).

²⁶⁷ 77 Fed. Reg. 45,639, 45,642, 45,643 (Aug. 1, 2012), available at <http://www.gpo.gov/fdsys/pkg/FR-2012-08-01/pdf/2012-18711.pdf>.

²⁶⁸ The FDA has listed its anticipated ANDA fee of \$58,730 for 2015. *Abbreviated New Drug Application (ANDA) and Prior Approval Supplement (PAS) Fees*, FDA, <http://www.fda.gov/ForIndustry/UserFees/GenericDrugUserFees/ucm319568.htm> (last updated July 31, 2014).

²⁶⁹ SHASHANK UPADHYE, *GENERIC PHARMACEUTICAL PATENT AND FDA LAW* 549 (2011).

²⁷⁰ *Id.* at 549; Ball & Hanson, *supra* note 38, at 5.

²⁷¹ Ball & Hanson, *supra* note 38, at 5, 7.

Although, this suggestion attempts to limit the ability for brand manufacturers to “free-hand” use codes to limit manipulation, a requirement for use codes to be identical in language to patent claims may pose some issues. Sometimes method of use patent claims are broader in scope than that of the FDA-approved use of the drug.²⁷² Patent claims are oftentimes drafted years in advance of the FDA-approved indication and method of use. The patentee attempts to anticipate the FDA-approved method of use of the drug when filing the patent application. Thus, this practice may result in claims that are broader than the eventual FDA-approved method of use.²⁷³ Hence, requiring the brand manufacturer to use only the claim language as a use code may present the same issue at hand—an overly broad use code.

This suggested listing requirement would also impose an additional burden on the FDA to evaluate and discern whether the FDA-approved use falls within the patent claims. The suggested listing practice of requiring only the claim language to be used may not place responsibility on the NDA filer to ensure that the FDA-approved use is supported by the claims. Since the FDA-approved use may have language that is different than the patent claims, it would necessitate further FDA evaluation that involves expertise that the FDA asserts it does not have. As a result, this listing requirement suggestion may not succeed in simplifying the current listing regime.

6. *Change in Listing Requirements: Use Codes Should Be Identical to the FDA-Approved Use*

Arguably a more effective change in listing requirements is to require use codes to be identical to the FDA-approved method of use, provided that this approved method of use is within the scope of the patent claims. A use code that is identical to the FDA-approved method not only forecloses the ability for the NDA applicant to draft “creative” use codes, but it would only allow the more precise FDA-approved method of use language to be used rather than the claim language, which tends to be broad in scope. This proposed listing requirement places the duty on the NDA filer to ensure

²⁷² See Li Feng & Bryan C. Diner, *The U.S. Supreme Court “Cracks the Code,” Allowing Generic Drug Manufacturers Increased Access to the Market Through Skinny Labeling*, FINNEGAN (June 2012), <http://www.finnegan.com/resources/articles/articlesdetail.aspx?news=5144c2c5-a42f-4ecc-b326-7545d95d417f> (suggesting that brand manufacturers should “secure broad patents” and that “method of use patent claims should be drafted broadly”).

²⁷³ See *id.* (suggesting that “it is a good practice to . . . envision what kind of uses, down to the very details such as dosages, administration routes and regimens, indications, and combination therapies, will be sought for approval at the FDA, and draft the patent claims accordingly[.]” because “label language is not easily predicted”).

that the FDA-approved use is within the scope of the claims²⁷⁴ and simplifies the FDA's task of discerning whether a section viii carve-out is possible.

This proposed listing requirement may be straightforward in instances where the FDA-approved method of use is the same or narrower in scope than the patent claims. Although it may appear to be more complex in instances where the FDA-approved use is broader than the patent claim, the proposed listing requirement may still be viable. Consider an example where “[t]he FDA [has] approve[d] Drug X to treat Condition Y in surgical patients,” where surgical patients include both pre-surgical and post-surgical patients.²⁷⁵ The NDA filer has an Orange Book listed patent claim for the method of using Drug X to treat Condition Y in pre-surgical patients.²⁷⁶ Under the current listing practices, the NDA filer may draft a use code for Drug X to state “treatment of Condition Y in surgical patients”—an “exact[] match[]” to the FDA-approved indication.²⁷⁷ This use code would preclude an ANDA filer from a section viii statement. For generic market entry, the only path for the ANDA filer would be to assert the counterclaim provision to have the broad use code narrowed to the treatment of Condition Y in pre-surgical patients.²⁷⁸ But before the counterclaim can even be asserted, the ANDA filer must file a paragraph IV certification and wait for the NDA filer to file suit.²⁷⁹

However, this example would play out very differently in the proposed listing requirement regime. Under the proposed listing requirement, the NDA filer would be precluded from using the use code “treatment of Condition Y in surgical patients”²⁸⁰ even though it is an exact match to the FDA-approved use. Because the scope of the patent claim is for pre-

²⁷⁴ Form FDA 3542 and Form FDA 3542a expressly state that submissions are made “under penalty of perjury that the foregoing [information] is true and correct.” *Patent Information Submitted Upon and After Approval of an NDA or Supplement*, FDA, 3 (Nov. 2014), <http://www.fda.gov/downloads/aboutfda/reportsmanualsforms/forms/ucm048345.pdf> [hereinafter Form FDA 3542]; Patent Information Submitted with the Filing of an NDA, Amendment, or Supplement, FDA (Nov. 2014), at 3, available at <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM048352.pdf> [hereinafter Form FDA 3542a].

²⁷⁵ This is a hypothetical example taken from Terry G. Mahn, *Drug Labeling Games – Skinny Labels Getting an FDA Assist*, PHARMACEUTICAL COMPLIANCE MONITOR (Mar. 7, 2014), <http://www.fr.com/files/Uploads/Documents/Mahn.PharmaComplianceMonitor.DrugLabelingGames%E2%80%93SkinnyLabelsGettinganFDAAssist.March2014.pdf>.

²⁷⁶ *Id.*

²⁷⁷ *Id.*

²⁷⁸ *See id.* (indicating that the ANDA filer “could argue that the use code is too broad and should be narrowed to cover only pre-surgical patients” in a paragraph IV litigation).

²⁷⁹ *See* Caraco Pharm. Labs., Ltd. v. Novo Nordisk, 132 S. Ct. 1670, 1688 (2012) (Sotomayor, J., concurring) (illustrating that “the generic manufacturer . . . submit[s] an ANDA with a paragraph IV certification [and] . . . wait[s] for the brand manufacturer to institute suit” before a counterclaim is filed).

²⁸⁰ *Id.*

surgical patients, the NDA filer would only be allowed to draft a use code for Drug X for “treatment of Condition Y in pre-surgical patients.” As a result, a section viii statement for treatment of Condition Y in post-surgical patients is not foreclosed to ANDA filers.

The FDA may be far from adopting this listing requirement; however, some recent activity suggests a slight shift toward this standard. In November 2013, the FDA revised the Information and Instructions for Patent Information Submitted Upon and After Approval of an NDA or Supplement (Form FDA 3542) and Patent Information Submitted with the Filing of an NDA, Amendment, or Supplement (Form FDA 3542a).²⁸¹ Although the fields that require information on both forms were not changed, the instructions accompanying the method of use information were altered. The revised instructions for section 4.2a in both Form FDA 3542 and Form FDA 3542a state that the NDA filer should “[i]dentify the precise words of the approval labeling that describe with specificity the patented method of use.”²⁸² Prior to this revision, the section 4.2a for Form FDA 3542 and Form FDA 3542a stated that the NDA filer should “[s]pecify the part of the proposed drug labeling that is claimed by the patent.”²⁸³ Some commentators suggest that this revision may be an effort by the FDA “to bring more order to use code issues examined in [*Caraco v. Novo Nordisk*].”²⁸⁴ Although this instructional revision does not by any means suggest that the FDA requires the use code to be identical to the approved method of use or indication, it may compel the NDA filer to examine the approved method of use and patent claims with more particularity than before.²⁸⁵

This increase in the number of use codes is not necessarily problematic. In recent years, the average number of use codes in the Orange Book has grown by ninety-eight use codes per year.²⁸⁶ To date, there are approximately 1,411 use codes published in the Orange Book.²⁸⁷

²⁸¹ Form FDA 3542, *supra* note 274, at 4; Form FDA 3542a, *supra* note 274, at 4.

²⁸² Form FDA 3542, *supra* note 274, at 4; Form FDA 3542a, *supra* note 274, at 4.

²⁸³ *FDA Revises Forms for Submission of Patent Information to the Orange Book: Federal Circuit Decision in Novartis AG v. Lee Alters Patent Term Adjustment*, HOGAN LOVELLS PHARMACEUTICAL AND BIOTECHNOLOGY ALERT (Feb. 26, 2014), <http://ehoganlovells.com/rv/ff00159909f1481b42df376f3f4c9382a7182abe>.

²⁸⁴ *Id.*

²⁸⁵ Form FDA 3542 and Form FDA 3542a explicitly state that the NDA Applicant “verif[ies] under penalty of perjury that the [application information] is true and correct.” Form FDA 3542, *supra* note 274, at 3; Form FDA 3542a, *supra* note 274, at 3.

²⁸⁶ The average growth in number of use codes was based on the growth in number of use codes for years 2011, 2012, and 2013, determined to be 78, 104, and 117, respectively. See Kurt R. Karst, *Updated Analysis Shows Patent Use Codes Have Nearly Tripled Since 2003*, FDA L. BLOG (July 8, 2013), http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2013/07/updated-analysis-shows-patent-use-codes-have-nearly-tripled-since-august-2003.html.

²⁸⁷ *Id.*

This growing number of use codes may increase the likelihood of ANDA filers employing the counterclaim provision.²⁸⁸ This proposition, of course, is highly dependent on the manner in which the use codes were drafted—duly tailored to the approved method of use or broadly described.²⁸⁹ The increase in use codes as a result of adopting the listing regime—where the use code must be identical to the FDA-approved method of use, provided that it is within the scope of the claims—would effectively make the use codes specific and precise and would reduce the use of the counterclaim provision.

Given the longstanding view of the FDA’s ministerial role, perhaps the FDA may be more likely to institute a change in listing requirements rather than a proactive use code evaluation. Although changes in listing requirements may still require an increase in the number of hours per Form FDA 3542 and Form FDA 3542a,²⁹⁰ it may be the least burdensome measure for the agency to implement relative to actively policing the Orange Book use code submissions and amendments or implementing an administrative Orange Book correction “challenge,” which would require substantially more staff and hours dedicated to use code review.

VI. CONCLUSION

Since the FDA continues to maintain its longstanding view of having only a “ministerial” role in managing the accuracy of use codes in the Orange Book—a pivotal publication for the prescription drug industry—and no substantive delisting or correction mechanism is available, generic companies that wish to simply file a section viii statement are faced with only one path for use code corrections—the counterclaim provision. To employ the counterclaim provision, generics must face paragraph IV litigation, which is procedurally cumbersome and costly. The counterclaim provision is not an effective patch on a procedural hole; it is not a fix.

To clarify issues with regard to listing practices, the FDA has implemented its “final rule” and instituted declaration forms. Unfortunately, this “final rule” and current guidelines are “remarkably opaque.”²⁹¹ The lack of oversight of a crucial publication—the Orange Book—is a source of frustration in facilitating the entry of generic drugs

²⁸⁸ *Id.*

²⁸⁹ *Id.*

²⁹⁰ See 78 Fed. Reg. 57,165 (Sept. 17, 2013) (reporting on the number of total hours spent and the “[a]verage burden per response” for Form FDA 3542 and Form FDA 3542a).

²⁹¹ See *Caraco Pharm. Labs., Ltd. v. Novo Nordisk*, 132 S. Ct. 1670, 1689 (2012) (Sotomayor, J., concurring) (“Precisely because the regulatory scheme depends on the accuracy and precision of use codes, I find FDA’s guidance as to what is required of brand manufacturers in use codes remarkably opaque.”).

into the healthcare market. Many commentators agree that policing the Orange Book is needed while others feel that this creates a burden on the FDA. However, there is agreement that the current regime is insufficient. Although it may be burdensome at this time for the FDA to bear total responsibility for policing the Orange Book, an elevated oversight, a change in listing requirements, or at least a modification to the guidelines provided by the FDA is much needed.

