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Brand Name or Generic? A Case Note on Caraco Pharmaceutical Laboratories v. Novo Nordisk

Michael Vincent Ruocco

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Brand Name or Generic? A Case Note on Caraco Pharmaceutical Laboratories v. Novo Nordisk

By Michael Vincent Ruocco*

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I. INTRODUCTION

If you have ever filled a drug prescription at any pharmacy in the United States, you have heard the words, “so, would you like brand name or generic?” Originator drugs (brand name drugs), those chemically-synthesized and biotechnology derived are the original drugs constructed in laboratories.¹ These drugs are put through various clinical tests,² and the originator company relies on various forms of intellectual property rights and patents in order to justify the initial investment required to bring the drug to market in the U.S.³ Typically, originator patents last for several years, thus guaranteeing that the originator company will be the only legal distributor of the drug. Almost all originator drugs are more expensive than their generic counterparts.⁴ Generic drugs are “duplicative copies of

* Michael Vincent Ruocco is a second year student at Pepperdine University School of Law. Michael graduated from the University of San Francisco with a Bachelor of Arts in Politics. He would like to thank Alex Baumann for her help and guidance during the writing process. He would also like to thank his girlfriend Emily Rose Casey for her loving support.

¹ *The Pharmaceutical Industry in the United States*, SELECT USA, <http://selectusa.commerce.gov/industry-snapshots/pharmaceutical-industry-united-states> (last visited May 21, 2013) [hereinafter “Select USA: Pharm Industry”].

² *Id.* Originator drugs are tested first on animals, and then humans, in what are referred to as clinical tests. *Id.*

³ *Id.* The major obstacle facing drug manufacturers, consumers, and insurance companies nationwide is the cost associated with bringing a pharmaceutical drug to market in the United States. Pharmaceutical Research and Manufacturers of America (PhRMA) “represents the country’s leading pharmaceutical research and biotechnology companies, which are devoted to inventing medicines that allow patients to live longer, healthier, and more productive lives.” *About PhRMA*, PhRMA, <http://www.phrma.org/about/about-phrma> (last visited Mar. 8, 2013). According to PhRMA, “the average cost to develop one new approved drug—including the cost of failures—is \$1,200,000,000.” *Chart Pack: Biopharmaceuticals in Perspective*, PhRMA (2012), available at http://www.phrma.org/sites/default/files/pdf/phrma_chart_pack.pdf.

⁴ Select USA: Pharm Industry, *supra* note 1. For example, filling my prescription for Adderall is a perfect example of how prices can drastically vary between brand name and generic brand versions of a drug. Adderall is the brand name version of a psychostimulant medication that is used to help treat attention deficit hyperactivity disorder (ADHD). The medication contains a combination of four different amphetamine salts: racemic amphetamine aspartate monohydrate,

chemically-synthesized drugs that contain the same active ingredient, are identical in strength, dosage, form and route of administration,” and can only be marketed once the originator’s patent expires.⁵ Generic drugs are attractive to most consumers because they are typically sold at substantially lower prices than the originator drugs.⁶ For a middle class family paying for things such as tuition, gas bills, grocery bills, and various other expenses, it is helpful in managing the family’s budget to have the choice of purchasing generic drugs that have the exact same ingredients and chemical effects as the brand name version.

Many families are unable to purchase generic versions of certain brand name drugs because the brand name manufacturers prevent generic versions of the drug from coming to market. They do this for one reason, and one reason only: PROFIT.⁷ The United States of

racemic amphetamine sulfate, dextroamphetamine saccharide, and dextroamphetamine sulfate. When I go to Rite Aid to fill my prescription for thirty capsules of Adderall, I have the choice between the brand name (Adderall) and its generic form. Adderall (brand name) comes in a time-release form (a technology used in drug capsules that helps dissolve the prescription drug into the blood stream over a certain period of time), while the generic form of Adderall comes in an “instant release” (instant release means the capsule or tablet is released into the blood stream immediately). On the one hand, if I elect to have my prescription for thirty capsules filled with brand name Adderall without first meeting my \$5,000 deductible with Anthem Blue Cross, the total cost to fill my prescription is \$125. Yet, if the pharmacist fills the prescription with the generic form of Adderall, and I have not yet met my deductible, the total cost is only \$15. Therefore, I always choose the generic brand.

⁵ Select USA: Pharm Industry, *supra* note 1. The “route of administration” typically refers to whether a drug is administered with time release or instant release technology. *See supra* note 4.

⁶ Many consumers have some type of health insurance that requires them to pay a certain amount of money for their doctor visits, prescriptions, etc. before the insurance company will help cover their medical costs. It is much more cost effective for the average consumer to purchase the generic form of a drug, as typically the generic version is much less expensive than the brand name version, especially if the insurance is not helping them pay for it. *See supra* note 4.

⁷ Take for example the drug Viagra, which is manufactured by Pfizer and is a brand name drug used to treat erectile dysfunction in men. Viagra was approved by the FDA in 1998 and sales of the drug surpassed 1,000,000,000 its first year. *See* David L. Shedlarz, Pfizer Inc. Financial Report (1998). According to Phrma, it should have cost Pfizer \$1,200,000,000 to bring the drug to market in the U.S. *See supra* note 3 explaining how much it costs to introduce a pharmaceutical drug in the U.S. Pfizer made almost all of the money that it cost them to research and

America is currently home to the world's largest market for pharmaceuticals and is the forerunner in biopharmaceutical research.⁸ It is estimated that U.S. pharmaceutical companies conduct eighty percent of the world's research on biopharmaceutical drugs and own most of the intellectual property rights to the new drugs that are developed.⁹ "Americans . . . spend a staggering \$200 billion a year on prescription drugs, and that figure is growing at a rate of about 12 percent [per] year (down from a high of 18 percent in 1999)."¹⁰ The U.S. pharmaceutical market has a favorable patent and regulatory environment, which allows pharmaceutical companies to freely price their drugs at whatever price level the market can sustain.¹¹ The success of a drug is largely based on its safety, quality, and efficacy.¹² Drug manufacturers are constantly competing with one another to produce the best product possible. Due to the free range of research, pricing, and marketing, the U.S. market is the preferred industry for major pharmaceutical companies.

This case note delves into the United States Supreme Court's recent decision in *Caraco Pharmaceutical Laboratories, Ltd. v. Novo*

develop the drug back within one year of the drug's approval. Viagra continued to do well, and in 2006 the drug made \$1,600,000,000 in sales, representing 3.4% of Pfizer's total revenue of \$48,000,000,000 for 2006. *See* Alan Levin, Pfizer Inc. Financial Report (2006). The drug continues to do well and in 2011, the drug made \$1,981,000,000 in revenue. *See* Frank D'Amelio, Pfizer Inc. Financial Report (2011).

⁸ Select USA: Pharm Industry, *supra* note 1. The U.S. is home to the largest and most innovative biopharmaceutical research in the entire world. *Biopharmaceutical Research Sector is Global Leader in Innovation*, PHRMA, <http://www.phrma.org/about/biopharmaceuticals> (last visited Jan. 25, 2013). The FDA has approved more than three hundred million drugs in the past decade. *Id.* Biopharmaceutical research has led to some of the most groundbreaking discoveries in medicine, such as HIV medication, which has transformed the virus from a death sentence into a manageable condition. *Id.*

⁹ Select USA: Pharm Industry, *supra* note 1.

¹⁰ MARCIA ANGELL, *THE TRUTH ABOUT THE DRUG COMPANIES: HOW THEY DECEIVE US AND WHAT TO DO ABOUT IT* (2005). *See also* JOHN ABRAMSON, *OVERDOSED AMERICA: THE BROKEN PROMISE OF AMERICAN MEDICINE* (2008) (highlighting the various expenses associated with prescription drugs); SHANNON BROWNLEE, *OVERTREATED: WHY TOO MUCH MEDICINE IS MAKING US SICKER AND POORER* (2007) (touching on the costs of pharmaceuticals and health care).

¹¹ *See* Select USA: Pharm Industry, *supra* note 1.

¹² *Id.*

Nordisk A/S, which closes a longstanding loophole whereby brand name manufacturers publish overbroad “use codes” that overstate the reach of their patents in Food and Drug Administration (FDA) regulatory filings, thus preventing generic drug manufacturers from supplying the drug at a much cheaper rate.¹³ Part II investigates the historical and regulatory background of pharmaceutical drugs and the stages they progress through (from clinical testing to the store shelf).¹⁴ Part III addresses the major problem that has developed in the pharmaceutical industry. Part IV states the facts of the lawsuit between the parties Caraco and Novo, while Part V conducts an in depth analysis on Justice Kagan’s majority opinion, followed by Justice Sotomayor’s concurring opinion. Part VI discusses the legal effects this case has had on the pharmaceutical industry and some possible solutions to the FDA’s current drug approval situation, which has proven to be largely inefficient and ineffective. Part VII provides FDA counterarguments to the suggested solutions; and part VIII addresses recent FDA and Congressional developments, while part IX summarizes and concludes.

II. HISTORICAL BACKGROUND

The Food and Drug Administration¹⁵ is responsible for regulating the manufacture, sale, and labeling of prescription drugs.¹⁶ If a

¹³ 132 S. Ct. 1670 (2012).

¹⁴ *Id.*

¹⁵ The Food and Drug Administration (FDA) is “an agency within the U.S. Department of Health and Human Services.” *FDA Fundamentals*, U.S. FOOD AND DRUG ADMINISTRATION, <http://www.fda.gov/AboutFDA/Transparency/Basics/ucm192695.htm> (last visited May 25, 2013). The agency has an “Office of the Commissioner and four directorates overseeing the core functions of the agency: Medical Products and Tobacco, Foods, Global Regulatory Operations and Policy, and Operations.” *Id.* FDA is primarily tasked with protecting the health of the general public by assuring the “safety, effectiveness, and security” of various drugs, foods, dietary supplements and other various products consumed by human beings. *Id.* FDA is also responsible for “protecting the public from electronic product radiation, assuring cosmetics and dietary supplements are safe and properly labeled, regulating tobacco products, and advancing the public health by helping to speed product innovations.” *Id.* “FDA’s responsibilities extend to the 50 United States, the District of Columbia, Puerto Rico, Guam, the Virgin Islands, American Samoa, and other U.S. territories and possessions.” *Id.*

company seeks approval from the FDA to sell a new drug, they must first test the drug in the laboratory and on animals to determine whether the drug is safe enough to be tested on humans.¹⁷ The company then submits an Investigational New Drug Application (IND) to the FDA. The FDA reviews the IND application and determines whether to approve the application for testing on human beings.¹⁸ Once the IND application is approved, the company will initiate a Phase I study to assess the safety of the drug.¹⁹ The initial testing phase typically lasts for several months and includes a test group comprised of 20-to-100 paid volunteers. Scientists and analysts study how the drug is “absorbed, metabolized, and excreted” in human beings.²⁰ Phase I also examines the side effects that occur from taking the drug and whether the drug increases as higher dosages are consumed.²¹

Once Phase I is complete and the drug is deemed safe, the company will initiate Phase II of the clinical trial, which focuses on the efficacy of the experimental drug.²² Phase II involves hundreds of human patients and can last anywhere from a couple of months to two years.²³ Typically Phase II clinical studies are “blind studies”

¹⁶ *How FDA Evaluates Regulated Products: Drugs*, U.S. FOOD AND DRUG ADMINISTRATION (Apr. 04, 2012), <http://www.fda.gov/AboutFDA/Transparency/Basics/ucm269834.htm>. The FDA uses a series of data and methods to determine whether products are safe for consumers. *Id.*

¹⁷ *Id.*

¹⁸ *Id.*

¹⁹ *Overview of Clinical Trials*, CENTER WATCH (2012), <http://www.centerwatch.com/clinical-trials/overview.aspx>.

²⁰ *Id.* According to Center Watch’s website: “About 70% of experimental drugs pass this phase of testing.” *Id.*

²¹ *Id.*

²² *Id.* Although information gathered from “human trials are analyzed by a team of experts before a drug is approved, it [is] impossible to anticipate all bad reactions—especially very rare safety risks—unless they had also happened with use of a similar drug.” *Id.* Further complicating matters is the fact that many of the patients selected for the clinical trials are already sick and may be taking other drugs simultaneously with the experimental drug.

²³ *Id.*

that incorporate control groups into the mix.²⁴ Blind studies “allow investigators to provide the pharmaceutical company and FDA with comparative information about the relative safety and effectiveness of the new drug.”²⁵ If the experimental drug completes Phase I and II testing, then Phase III begins. Phase III involves large scale testing on hundreds to thousands of human patients and can span several years in length.²⁶ “This large-scale testing . . . provides the pharmaceutical company and the FDA with a more thorough understanding of the effectiveness of the drug . . . the benefits, and the range of possible adverse reactions.”²⁷

Once Phase III is complete,²⁸ pharmaceutical companies are required to compile their clinical testing data and send it to the FDA’s Center for Drug Evaluation and Research (CDER) in a New Drug Application (NDA).²⁹ An NDA has several components as required by 21 U.S.C. § 355 (b)(1), the first being: “(A) full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective”³⁰ The report must also contain

(B) a full list of the articles used as components of such drug; (C) a full statement of the composition of such drug; (D)³¹ a full description of the methods used

²⁴ *Overview of Clinical Trials, supra* note 19. Blind studies “mean that neither the patients nor the researchers know who has received the experimental drug.” *Id.*

²⁵ *Id.* It is estimated that only one third of experimental drugs successfully complete Phase I and Phase II clinical trials.

²⁶ *Id.*

²⁷ *Id.* Ultimately the FDA is tasked with evaluating the pros and cons of a drug and whether it is safe enough for enough for mass human consumption. Some of the questions they consider are “if the [drug is] good for one person or a small group, will it be good for the whole population? Which safety risks are likely to be acceptable to patients who might take a drug and physicians who might prescribe it?” *How FDA Evaluates Regulated Products: Drugs, supra* note 16.

²⁸ Approximately “70% to 90% of drugs that enter Phase III studies successfully complete this phase of testing.” *Overview of Clinical Trials, supra* note 18.

²⁹ *How FDA Evaluates Regulated Products: Drugs, supra* note 16.

³⁰ 21 U.S.C. § 355 (b)(1) (2012).

³¹ This is a statement describing the drug’s components and label, which includes what the drug will be used to treat.

in, and the facilities and controls used for, the manufacture, processing, and packing of such drug.³²

It must also contain: “(E) such samples of such drug and of the articles used as components thereof as the Secretary may require; (F) specimens of the labeling proposed to be used for such drug, and (G) any assessments required”³³ In addition to the NDA, the manufacturer must also file “the patent number and the expiration date of any patent which claims the drug”³⁴ and any other method of use claims the manufacturer wishes to assert.³⁵

Pursuant to 21 C.F.R. § 314.53, brand-name manufacturers must provide descriptions of their method-of-use patents.³⁶ These descriptions are referred to as “use codes.” If the FDA approves a new brand manufacturer’s drug, the Secretary will then publish the information provided in the NDA, such as the patent number, expiration of patents, descriptions of method-of-use patents, etc.. This information is informally known as the Orange Book, but officially referred to as the “Approved Drug Products with Therapeutic Equivalence Evaluations.”³⁷ Unfortunately, the FDA

³² *Id.*

³³ 21 U.S.C. § 355 (b)(1) (2012).

³⁴ *Id.* This information is part of The Drug Price Competition and Patent Term Restoration Act of 1984; Establishment of a Public File and Request for Comments, 50 Fed. Reg. 26791–01. The “Hatch–Waxman amendments” require brand name manufacturers to publish this information so that generic drug companies would know when the manufacturing patents expire. 21 U.S.C. § 355 (2012).

³⁵ 21 U.S.C. § 355 (b)(1) (2012). “The FDA may approve a brand-name drug for multiple methods of use—either to treat different conditions or to treat the same condition in different ways.” *Caraco Pharm. Laboratories, Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1676 (2012). The applicant also has the opportunity to amend their NDA if they receive a patent after they file the NDA but before the FDA approves the application. *See* 21 U.S.C. § 355 (b)(1).

³⁶ *See* 21 C.F.R. §§ 314.53(c)(2)(ii)(P)(3), (e) (2011).

³⁷ *Caraco Pharm. Laboratories, Ltd.*, 132 S. Ct. at 1676. This list is referred to as the “Orange Book” because of “its orange colored cover.” 68 Fed. Reg. 36676–01 (June 18, 2003).

“does not attempt to determine if that information is accurate.”³⁸ Rather, the FDA assumes the information is completely accurate.³⁹

Once this process is completed, other companies seeking permission to sell a generic version of the drug may do so by filing an Abbreviated New Drug Application (ANDA).⁴⁰ The ANDA has several requirements and is specifically designed to expedite low-cost generic versions of brand-name drugs into the market, so that more people can afford to use the drug.⁴¹ Instead of conducting independent studies to obtain evidence on the generic drug’s safety and efficacy, ANDA applicants will typically show that the generic drug has the same active ingredients and is “biologically equivalent to the brand-name drug.”⁴² ANDA applicants will also demonstrate “that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the new drug have been previously approved for a [listed drug].”⁴³ FDA is prohibited from approving an ANDA application that would infringe on a patent, and thus the timing of when a generic drug will be approved is based on the “scope and duration” of patents in place for the brand-name drug.⁴⁴ As discussed prior, there are two types of patents: (1) that protects the actual drug compound; and (2) that protects the brand manufacturer’s rights to a specific method-of-use.⁴⁵

³⁸ *Caraco Pharm. Laboratories, Ltd.*, 132 S. Ct. at 1676. The FDA “determined that it is more efficient and accurate to ask the NDA holder to give us the exact use code description to be published in the Orange Book.” 68 Fed. Reg. 36676–01 (June 18, 2003).

³⁹ *Id.*

⁴⁰ See 21 U.S.C. § 355 (j)(2)(A) (2012).

⁴¹ Previously recognized in *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676 (1990).

⁴² *Caraco Pharm. Laboratories, Ltd.*, 132 S. Ct. at 1676.

⁴³ 21 U.S.C. § 355 (j)(2)(A)(i). This is basically a short cut to getting the FDA’s approval. A “listed drug” means that it has already been published in the FDA’s Orange Book and has already received FDA approval, meaning it has gone through all the required testing phases. *Id.*

⁴⁴ *Caraco Pharm. Laboratories, Ltd.*, 132 S. Ct. at 1676. The FDA cannot approve an ANDA application for a generic version of a drug if the brand name company still holds a valid patent on the drug compound. *Id.*

⁴⁵ *Id.* The method-of-use patent can continue long after the drug compound patent has expired (A drug compound patent usually lasts between five and fourteen years.).

After the generic company consults the Orange Book, they must file the ANDA and convince the FDA that its generic drug will not infringe on any of the brand-name drug manufacturer's patents.⁴⁶ In the case where all of the brand-name drug manufacturer's patents have expired (or will expire prior to the generic drug's approval) or are not listed in the Orange Book, the generic drug manufacturer simply states that information, and the ANDA is approved.⁴⁷

If the brand-name manufacturer's patents have not yet expired, there are two methods of certification the generic manufacturer can pursue. The first option is that the generic company can submit a section viii ("section viii") statement asserting that they will market the drug for one or more methods that are not covered by the brand name drug company's patents.⁴⁸ Typically a generic drug company will file a section viii statement when the brand-name drug company's drug compound patent has expired, and only a method-of-use patent still exists.⁴⁹ If the generic drug company elects to pursue a section viii route, they will propose, "labeling for the generic drug that 'carves out' from the brand's approved label the still-patented methods of use."⁵⁰ The FDA will under no circumstances approve an ANDA if the generic brand's modified label overlaps with any of the brand name's use code.⁵¹ As mentioned prior, the FDA assumes the brand's use code accurately describes the methods-of-use and does not conduct its own independent research to confirm any of this

⁴⁶ *Id.*

⁴⁷ See 21 U.S.C. §§ 355(j)(2)(A)(vii)(I)–(III) (2012).

⁴⁸ See 21 U.S.C. § 355(j)(2)(A)(viii) (2012).

⁴⁹ See *supra* note 33–35.

⁵⁰ *Caraco Pharm. Laboratories, Ltd.*, 132 S. Ct. at 1677. The expression "carved out" refers to removing patented methods of use from the new modified label that the generic drug company is proposing. The FDA is allowed to approve a generic drug's modified version of the brand name's label (as long as it does not include patented methods-of-use), which is an exception to the normal rule that states a generic drug label must have the same label as the brand name. See 21 U.S.C. §§ 355(j)(2)(A)(v), (j)(4)(G) (2012).

⁵¹ See Applications for FDA Approval to Market a New Drug: Patent Submission and Listing Requirements, 68 Fed. Reg. 36676, 36682–83 (June 18, 2003). There can be absolutely no overlap of the generic drug's label with the brand name company's label if the brand name company still has a valid patent on a method for using the drug.

information.⁵² Thus, whether section viii is available to a generic drug company hinges on how the brand name drug company describes its various patents.⁵³ Interestingly, if the FDA determines there is enough space for the generic manufacturer's proposed label, then it will approve the ANDA application.⁵⁴

The second option for a generic drug manufacturer is that it can choose to file a paragraph IV ("paragraph IV") certification, which in essence provides the patent is "invalid or will not be infringed by the manufacture, use, or sale of the [generic] drug."⁵⁵ A generic drug manufacturer will choose to file a paragraph IV certification in two scenarios. The first scenario is if the company wants to market and sell the generic drug for all purposes, instead of "carving out" the options that are still "supposedly" under patent.⁵⁶ The second scenario is if the generic drug manufacturer is unable to avoid an overlap with the brand name company's use code, despite having carved out various uses.⁵⁷ Filing a paragraph IV certification leaves the generic brand company vulnerable to litigation because the patent

⁵² *Caraco Pharm. Laboratories, Ltd.*, 132 S. Ct. at 1677. According to the FDA, it "lacks 'both [the] expertise and [the] authority to review patent claims; although it will forward questions about the accuracy of a use code to the brand, its own 'role with respect to patent listing is ministerial.'" Applications for FDA Approval, 68 Fed. Reg. at 36683 (June 18, 2003). This creates a vicious ineffective circle for drug approval. Basically, the brand manufacturer submits a description claiming a particular approved use for the drug, and the FDA in turn sends the description back to the brand company and asks that they make sure the description is accurate. The FDA is essentially asking the brand manufacturers to police the accuracy of their own use code descriptions. A brand manufacturer submitting an overbroad use code so that a generic form of the drug cannot be produced is never going to openly admit to FDA that their use code is overly broad and inaccurate. Furthermore, the FDA believes "its scarce resources would be better utilized in reviewing applications rather than reviewing patent claim." Abbreviated New Drug Application Regulations: Patent Exclusivity Provisions, 59 Fed. Reg. 50,338, 50,343 (Oct. 3, 1994).

⁵³ *Caraco Pharm. Laboratories, Ltd.*, 132 S. Ct. at 1677.

⁵⁴ *Id.*

⁵⁵ 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (2012). Filing a paragraph IV certification can almost guarantee that the brand name company will sue the generic company for patent infringement. See *infra* note 51.

⁵⁶ *Caraco Pharm. Laboratories, Ltd.*, 132 S. Ct. at 1677.

⁵⁷ *Id.* See *supra* note 50 for explanation of "carving out."

statute⁵⁸ considers the filing of a paragraph IV certification to be an act of infringement, giving the brand name company a valid cause of action.⁵⁹ If the brand manufacturer chooses to file a lawsuit against the generic manufacturer for filing a paragraph IV certification,⁶⁰ the FDA may not approve the generic company's ANDA for up to thirty months or until a final judgment on the lawsuit has been entered.⁶¹ Filing a paragraph IV certification has both pros and cons because although it exposes the generic company to potential litigation, the end result could allow the generic drug manufacturer to sell its drug for all uses approved by the FDA.⁶²

III. THE PROBLEM

At the end of the 20th century, evidence began to surface that numerous brand name drug companies were exploiting the statutory structure in order to prevent generic drug companies from certifying their drug, or at least significantly delaying the drug's appearance on the pharmaceutical market.⁶³ Sure enough, the Federal Trade Commission (FTC) published a study detailing these practices in July of 2002.⁶⁴ The FTC study focused its attention on brand name drug

⁵⁸ The "patent statute" is 35 U.S.C. § 271, and explains when a patent is considered to be infringed upon and the available and appropriate courses of action. *See generally* 35 U.S.C. § 271 (2010).

⁵⁹ *See* 35 U.S.C. § 271(e)(2)(A). "It shall be an act of infringement to submit an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act . . . for a drug claimed in a patent or the use of which is claimed in a patent." *Id.* The valid cause of action in this situation will be a lawsuit against the generic manufacturer for infringing a valid patent.

⁶⁰ If a generic company files a paragraph IV certification, the brand name company has forty-five days to bring an action for infringement against the party. *Id.*

⁶¹ *See* 21 U.S.C. § 355(j)(5)(B)(iii) (2012).

⁶² *Caraco Pharm. Laboratories, Ltd.*, 132 S. Ct. at 1677–78.

⁶³ *Id.*

⁶⁴ *General Drug Entry Prior to Patent Expiration: An FTC Study*, FEDERAL TRADE COMM'N (July 2002), *available at* <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf> [hereinafter FTC Study]. The Hatch–Waxman Amendments to the Federal Food Drug and Cosmetic Act substantially altered the way in which generic drugs receive market approval from the FDA. The Hatch–Waxman Amendments helped speed up the procedures for allowing generic drugs to be sold on the open market, and without a doubt greatly

manufacturing companies that were submitting inaccurate patent information to the FDA, in order to prevent generic drugs from coming to market.⁶⁵ In *Mylan*, a brand name drug manufacturer had listed a new patent just prior to the expiration of their original drug compound patent.⁶⁶ The new patent did not cover the drug's compound or its method of uses, however the brand name drug manufacturer was still able to extend its rights over the drug.⁶⁷ The generic manufacturer sued the brand name manufacturer and wanted them to remove their improper description listed in the Orange Book. However, the Federal Circuit Court of Appeals found that the Hatch-Waxman Amendments did not provide for this type of solution.⁶⁸ The FTC found, that as a result of the ruling in *Mylan*, generic manufacturers in *Mylan's* predicament only had one option, which was to file a paragraph IV certification and wait for the thirty-month waiting period to expire.⁶⁹ Once thirty months had expired, the FDA could approve the ANDA.⁷⁰

increased the amount of generic drugs in the market. *Id.* In fact, at the time the FTC finished conducting their study in 2002, they reported that generic drugs comprised more than forty seven percent of the prescriptions filled in the U.S., which was an enormous increase from nineteen percent in 1984 when Hatch-Waxman was first implemented. *Id.* Despite Hatch-Waxman's success, there were several provisions in the act that allowed for certain strategies to be used by brand name pharmaceutical manufacturers to hinder the availability of generic drugs. *Id.* The FTC study in 2002 took on the task of investigating whether the publication of overbroad use patents by brand name pharmaceutical manufacturers represented more isolated instances, or typical measures taken by manufacturers to ensure a generic form of the drug could not be brought to market. *Id.*

⁶⁵ *Caraco Pharm. Laboratories, Ltd.*, 132 S. Ct. at 1678. The FDA was treating the patent information submitted to them as true and correct; they never conducted any independent due diligence to ensure the descriptions were accurate. *Id.*

⁶⁶ See *Mylan Pharm., Inc. v. Thompson*, 268 F.3d 1323 (Fed. Cir. 2001).

⁶⁷ *Id.* The Federal Circuit in *Mylan* found that delisting the patent (removing the patent completely) was not a proper remedy under the Hatch-Waxman Amendments. *Id.* However, the decision in *Mylan* alerted Congress to a major problem. *Id.* Generic companies basically had no way of challenging inaccurate patent listings, thus the FDA was unable to approve applications for a generic form of the drug. *Caraco Pharm. Laboratories, Ltd.*, 132 S. Ct. at 1687.

⁶⁸ *Mylan Pharm., Inc.*, 268 F. 3d at 1323.

⁶⁹ See FTC Study, *supra* note 64, at 41-45.

⁷⁰ *Id.*

In response to this abuse, Congress created a legal counterclaim for generic drug manufacturers to contest incorrect and overbroad patent information that brand name manufacturers submit to the FDA.⁷¹ Congress passed the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, which allows generic drug manufacturers to:

assert a counterclaim seeking an order requiring the [brand manufacturer] to correct or delete the patent information submitted . . . on the ground that the patent does not claim either -- (aa) the drug for which the application was approved or (bb) an approved method of using the drug.⁷²

Essentially, the counterclaim allows a generic drug manufacturer to obtain a judgment in their favor, instructing the brand name drug manufacturer to “correct or delete” their overbroad or incorrect description regarding the patent, which is preventing FDA from certifying the generic manufacturer’s drug.⁷³

IV. FACTS

The petitioner seeks to sell and the respondent sells the popular diabetes drug repaglinide,⁷⁴ which is commonly used to treat type two diabetes.⁷⁵ Repaglinide is a pharmaceutical drug that helps

⁷¹ *Caraco Pharm. Laboratories, Ltd.*, 132 S. Ct. at 1678.

⁷² 21 U.S.C. § 355(j)(5)(C)(ii)(I) (2012). *See also* Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108–173 (2003). The Medicare Prescription Drug, Improvement, and Modernization Act is a federal law that was enacted in 2003; its primary purpose was to help make prescription drugs more affordable for Americans, especially for senior citizens.

⁷³ *Caraco Pharm. Laboratories, Ltd.*, 132 S. Ct. at 1678.

⁷⁴ *Consumer Medication Information: Repaglinide*, U.S. NATIONAL LIBRARY OF MEDICINE (Apr. 15, 2011), <http://www.ncbi.nlm.nih.gov/pubmedhealth/?term=repaglinide>.

⁷⁵ Type two diabetes is the most common form of diabetes, and millions of Americans suffer from this condition. *American Diabetes Association: Type 2*, AMERICAN DIABETES ASSOCIATION, <http://www.diabetes.org/diabetes-basics/type-2/> (last visited May 25, 2013). Type two diabetes is a condition where the body is unable to produce enough insulin. *Id.* Insulin is essential to the human body

balance the amount of glucose (sugar) in the human body.⁷⁶ It works to decrease the overall amount of glucose in the blood by stimulating the release of insulin from the pancreas.⁷⁷ Novo, respondent in this case, manufactures the brand name version of repaglinide called Prandin.⁷⁸ The FDA approved three uses for Prandin in order to treat type two diabetes: “repaglinide by itself; repaglinide in combination with metformin; and repaglinide in combination with thiazolidinediones (TZDs).”⁷⁹ Novo is a worldwide leader in diabetes care and obtained the original patent over the repaglinide drug compound, “known as the ‘035 patent.”⁸⁰ Their drug compound patent expired in 2009, but in 2004 Novo obtained a method-of-use patent for repaglinide to be used in combination with metformin (“‘358 patent”), which does not expire until 2018.⁸¹ Novo only held one patent for the three FDA approved methods of use for repaglinide at the time the Supreme Court granted certiorari.⁸²

Caraco, petitioner in this case, seeks to sell a generic version of the drug repaglinide for two of the three above-mentioned purposes.⁸³ In 2005 the company filed an ANDA with the FDA so that they could sell a generic brand version of repaglinide.⁸⁴ At this time,

because it helps the body use glucose for energy. *Id.* When you consume food, the body breaks down all of the sugars and starches into glucose for the body’s cells to use as energy. *Id.* Insulin helps get the sugar from the blood into the cells. *Id.* Serious problems arise when there is a build up of glucose in the blood. *Id.*

⁷⁶ *Consumer Medication Information: Repaglinide*, U.S. NATIONAL LIBRARY OF MEDICINE (Apr. 15, 2011), <http://www.ncbi.nlm.nih.gov/pubmedhealth/?term=repaglinide>.

⁷⁷ *Id.* The pharmaceutical drug comes in a tablet form and is usually ingested thirty minutes before or after a meal. *Id.*

⁷⁸ *Id.*

⁷⁹ *Caraco Pharm. Laboratories, Ltd.*, 132 S. Ct. at 1678.

⁸⁰ *Id.*

⁸¹ *Id.* Novo’s ‘358 patent is the patent at issue in this case and “claims a method for treating diabetes by administering . . . repaglinide in combination with metformin.” *Id.*

⁸² *Id.* at 1679. At the time certiorari was granted by the Supreme Court, Novo held no patent for the use of repaglinide with thiazolidinediones or its use alone. *Id.*

⁸³ *Id.*

⁸⁴ *Caraco Pharm. Laboratories, Ltd.*, 132 S. Ct. at 1679. In 2005, when Caraco filed its ANDA, “Novo’s use code for the ‘358 patent represented that the

Novo held a patent on the drug compound for Prandin, which was listed as patent '035 as well as a method-of-use patent for Prandin's use with metformin, which was listed as patent '358.⁸⁵ At the time Novo filed the ANDA, they informed the FDA that they would not market their new generic form of the drug until after the drug compound patent '035 had expired in 2009.⁸⁶ As for the remaining '358 patent, Caraco filed a paragraph IV certification stating that patent '358 was "invalid or would not be infringed [upon]."⁸⁷ As soon as Caraco filed their ANDA application and paragraph IV statement, Novo treated the filing as an infringement on the '358 patent and immediately initiated a lawsuit against Caraco.⁸⁸

The FDA advised Caraco that if they were not planning on marketing the drug repaglinide for the use with metformin, it should submit a section viii statement instead, which would allow Caraco to sell the drug for the other two uses of repaglinide that were not patented by Novo.⁸⁹ Caraco took the FDA's advice and filed a section viii statement in 2008, and carved out⁹⁰ the patented method-of-use from their generic drug's label.⁹¹ However, right before the FDA approved Caraco's section viii filing, Novo changed its use code description for the '358 patent, which described "a method for improving glycemic control in adults with type two diabetes."⁹² The newly altered code indicated that Novo's '358 patent protected all three methods-of-use for repaglinide that were approved by the FDA to treat diabetes, making Caraco's carved out label of uses insufficient.⁹³ Caraco's label now overlapped with Novo's use code on two of the uses approved by the FDA; Caraco was unable to carve

patent covered 'use of repaglinide in combination with metformin to lower blood glucose.'" *Id.*

⁸⁵ *Id.*

⁸⁶ *Id.*

⁸⁷ 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (2012).

⁸⁸ *Caraco Pharm. Laboratories, Ltd.*, 132 S. Ct. at 1679.

⁸⁹ *Id.*

⁹⁰ *Id.* In 2008, Novo still had a patented method of use for repaglinide and metformin to be used together. See also *supra* note 50 explaining "carving out."

⁹¹ *Id.*

⁹² *Novo Nordisk A/S v. Caraco Pharm. Laboratories, Ltd.*, 601 F.3d 1359, 1363 (Fed. Cir. 2010).

⁹³ *Caraco Pharm. Laboratories, Ltd.*, 132 S. Ct. at 1679.

out these two uses because, if they did, there would be no other uses left to market or sell.⁹⁴ As mentioned prior, the FDA had only approved repaglinide for three uses, all of which were encompassed by Novo's newly updated use code patent '358.⁹⁵ As a result of Novo's updated use code description, the FDA informed Caraco that it could no longer file a section viii statement seeking market approval for their generic drug.⁹⁶

Caraco immediately responded to Novo's infringement lawsuit by filing a statutory counterclaim against them.⁹⁷ "The counterclaim sought an order⁹⁸ requiring Novo to 'correct' its use code 'on the grounds that the '358 patent does not claim'⁹⁹ two approved methods of using repaglinide—alone and in combination with TZD's."¹⁰⁰ The U.S. District Court for the Eastern District of Michigan ruled in favor of Caraco, thus granting their motion for summary judgment.¹⁰¹ The District Court found that "Novo [had] improperly filed with the FDA for listing in the Orange Book the use code narrative for the method of use of the ['358] patent."¹⁰² Therefore, "Caraco was entitled to a mandatory injunction requiring Novo to request FDA to delist [its new listing,] and reinstate its former . . . listing."¹⁰³ Despite the District Court's ruling, the U.S. Federal Circuit Court of Appeals found that "Caraco Pharmaceutical Laboratories, Ltd. does not have a statutory basis to assert a counterclaim requesting such injunctive

⁹⁴ *Id.*

⁹⁵ *Id.*

⁹⁶ *Id.*

⁹⁷ *Id.*

⁹⁸ The order sought by Caraco "would permit the FDA to accept Caraco's proposed carve-out label and approve the company's ANDA." *Caraco Pharm. Laboratories, Ltd.*, 132 S. Ct. at 1679.

⁹⁹ See 21 U.S.C. § 355(j)(5)(C)(ii) (2012).

¹⁰⁰ *Caraco Pharm. Laboratories, Ltd.*, 132 S. Ct. at 1679. The counterclaim would permit the FDA to approve Caraco's ANDA and carved out label.

¹⁰¹ *Id.*

¹⁰² *Novo Nordisk A/S v. Caraco Pharm. Laboratories, Ltd.*, 656 F. Supp. 2d 729, 730 (E.D. Mich. 2009). The district court's ruling would have forced Novo to delist its new patent description and reinstate its former patent description, thus allowing Caraco to file its section viii.

¹⁰³ *Id.*

relief,” and therefore it reversed and vacated the injunction.¹⁰⁴ The Federal Circuit Court of Appeals analyzed 21 U.S.C. § 355, which allows for a generic company to file a counterclaim. The statute states that: “ANDA applicant may assert a counterclaim seeking an order requiring the holder to correct or delete the patent information . . . on the ground that the patent does not claim either (aa) the drug for which the applicant was approved or (bb) an approved method of using [it].”¹⁰⁵

The Federal Circuit Court of Appeals interpreted the information in (bb) to mean that Caraco was required to demonstrate that “the ‘358 patent [did] not claim any approved method of use.”¹⁰⁶ The Federal Circuit reiterates that a counterclaim can only be authorized if the “listed patent does not claim any approved methods of using the listed drug.”¹⁰⁷ They held that because Novo’s patent covered one method-of-use (repaglinide with metformin), the statutory counterclaim was unavailable to Caraco.¹⁰⁸ The court also ruled that the “counterclaim provision does not reach use codes because they are not ‘patent information submitted by the [brand] under subsection (b) or (c).”¹⁰⁹ Caraco filed a *writ of certiorari* with the United States Supreme Court, which was granted on June 27, 2011.¹¹⁰

¹⁰⁴ *Novo Nordisk A/S v. Caraco Pharm. Laboratories, Ltd.*, 601 F.3d 1359, 1360 (Fed. Cir. 2010).

¹⁰⁵ *See* 21 U.S.C. § 355 (j)(5)(C)(ii)(I) (2012).

¹⁰⁶ *Caraco Pharm. Laboratories, Ltd.*, 132 S. Ct. at 1679. The Federal Circuit Court found that “[a]n approved method means any approved method.” *Id.* at 1680. Since “the patent covers one approved method of use—repaglinide in combination with metformin—the counterclaim was unavailable [to Caraco].” *Id.*

¹⁰⁷ *Novo Nordisk A/S*, 601 F.3d at 1365.

¹⁰⁸ *Caraco Pharm. Laboratories, Ltd.*, 132 S. Ct. at 1680.

¹⁰⁹ *Id.* The Federal Circuit believed the patent information submitted consists only of the patent number and expiration date. *Id.* Judge Dyk disagreed and wrote a dissenting opinion. Dyk “would have read the phrase ‘the patent does not claim . . . an approved method of using the drug’ to include situations where, as here, the use code wrongly indicates that the patent covers one or more particular approved methods of use.” *Id.* (Dyk, J., dissenting). Furthermore, “he would have construed ‘patent information submitted . . . under subsection (b) or (c)’ to include use codes.” *Id.* (Dyk J., dissenting). Ultimately, the Supreme Court granted *certiorari* and sided with Judge Dyk.

¹¹⁰ *Caraco Pharm. Laboratories, Ltd.*, 132 S. Ct. at 1680. First, the Supreme Court was tasked with deciding when a “patent does not claim . . . an approved

V. ANALYSIS OF OPINION

A. Judge Kagan's Majority Opinion

Recognizing the importance of the statutory language in 21 U.S.C. § 355, Justice Kagan's opinion begins with an analysis of two statutory phrases against the backdrop of a third statutory phrase.¹¹¹ After a thorough review of the statutory language, Justice Kagan determined that the "statute permits a counterclaim whenever a patent does not claim a method of use for which the ANDA applicant seeks to market the drug."¹¹² She also determined that the counterclaim provides a way to correct the overbroad use codes by deleting or correcting the use code description.¹¹³ Next, Justice Kagan addressed and dismissed Novo's claim that the Court would be resurrecting a bill that Congress previously did not support, as Congress failed to pass S. 812,¹¹⁴ which would have allowed a

method of using' a drug. Second, [the Court had to] determine the content of patent information submitted . . . under subsection (b) or (c) of § 355." *Id.*

¹¹¹ *Id.* The third statutory phrase is the remedy for a prevailing counterclaimant, which is to either "correct or delete" the inaccurate patent. *Id.* When the Supreme Court conducts statutory interpretations, they take into consideration several factors, such as the language of the statute itself, the context the language is being used in, and the broader context of the statute as a whole. *See Robinson v. Shell Oil Co.*, 519 U.S. 337 (1997).

¹¹² *Caraco Pharm. Laboratories, Ltd.*, 132 S. Ct. at 1683. In her opinion, Justice Kagan conceded that the counterclaim clause of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 was confusing and not entirely clear. However, when the Court considered the statutory text and context together, they concluded, "a generic manufacturer in Caraco's position can use the counterclaim." *Id.* at 1681.

¹¹³ *Id.* at 1684.

¹¹⁴ Greater Access to Affordable Pharmaceuticals Act of 2002, S. 812, was a Congressional Senate Bill sponsored by Senator Charles Schumer and was introduced on May 1, 2001. Greater Access to Affordable Pharmaceuticals Act of 2002, S. 812, 107th Cong. (2002). S. 812 would have required pharmaceutical companies to register their patents with the FDA within thirty days of approval and would have allowed a generic company to challenge an overbroad patent description by filing a separate civil action. *Id.* at 8. The bill also would have allowed for the importation of prescription drugs into the United States from Canada. *Id.* The bill was never enacted into law. *Id.*

generic company to challenge an overbroad patent description.¹¹⁵ Finally, Justice Kagan and the Court rejected the argument that Congress enacted the counterclaim only to solve problems similar to those in *Mylan*.¹¹⁶ Justice Kagan and the Court ultimately decided that Caraco was allowed to bring a counterclaim, which requested Novo to correct its use code on the ground that the patent did not claim an approved method of use for the drug.¹¹⁷

1. A Company May Bring a Counterclaim to Show That a Method of Use is Unpatented.

A company that submits an ANDA application to the FDA and is subsequently sued for patent infringement may bring a counterclaim “on the ground that the patent does not claim an approved method of using the drug.”¹¹⁸ Both Caraco and Novo debate the true meaning of this language, with each interpretation resulting in a drastically different outcome.¹¹⁹ Novo argues that “not an” means “not any,” which means the counterclaim would only be available if the patent does not claim any approved method for using the drug.¹²⁰ If this were the true meaning, Caraco would be unable to bring a counterclaim against Novo because Novo’s ‘358 patent claims the use of repaglinide with metformin.¹²¹ Unsurprisingly, Caraco advocates for a different interpretation and takes “not an” to mean “not a particular one,” meaning the statute allows for a counterclaim whenever the ANDA applicant does not seek to market the drug under a method of use already claimed by another company’s patent.¹²² Caraco’s view would allow for use of the counterclaim because “Novo’s ‘358 patent does not claim the use of repaglinide with TZDs or its use alone.”¹²³ The Supreme Court engages in a

¹¹⁵ *Caraco Pharm. Laboratories, Ltd.*, 132 S. Ct. at 1684.

¹¹⁶ *See infra* notes 168–72.

¹¹⁷ *See infra* notes 181–83.

¹¹⁸ *Caraco Pharm. Laboratories, Ltd.*, 132 S. Ct. at 1681.

¹¹⁹ *Id.*

¹²⁰ *Id.*

¹²¹ *Id.*

¹²² *Id.*

¹²³ *Id.*

comical analysis of what “not an” means and ultimately sides with Caraco’s interpretation.¹²⁴

The Court explained that an approved drug might have multiple uses, not all of which are covered by a patent.¹²⁵ The Hatch-Waxman Amendments permits the FDA to approve applications for companies that wish to market generic forms of drugs for unpatented uses.¹²⁶ Essentially, the statutory scheme envisions that a patented use for a particular drug will not bar the marketing of a generic form for an unpatented use.¹²⁷ Generic manufacturers use the counterclaim to challenge an overbroad assertion of rights by brand name manufacturers.¹²⁸ Thus, the Court found that the “availability of the counterclaim 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.”¹²⁹

¹²⁴ *Caraco Pharm. Laboratories, Ltd.*, 132 S. Ct. at 1681. The Supreme Court took the position that the answer to the question “what does not an mean?” is “it depends.” The Court strongly believes that context determines the meaning of words, and gives various everyday life scenarios to demonstrate this. *Id.* Sometimes “not an” means “not any.” *Id.* “If your spouse tells you he is late because he ‘did not take a cab,’ you will infer that he took no cab at all (but took the bus instead).” *Id.* Furthermore, “if a sports-fan friend bemoans that ‘the New York Mets do not have a chance of winning the World Series,’ you will gather that the team has no chance whatsoever (because they have no hitting).” *Id.* However, the Court points out that other times “not an” means “not a particular one.” *Id.* “Suppose your spouse tells you that he got lost because he ‘did not make a turn.’ You would understand that he failed to make a particular turn, not that he drove from the outset in a straight line.” *Id.* Furthermore, “suppose your child explains her mediocre grade on a college exam by saying that she ‘did not read an assigned text.’ You would infer that she failed to read a specific book, not that she read nothing at all on the syllabus.” *Id.* The Court comically communicates that CONTEXT MATTERS!

¹²⁵ *Id.* An approved drug may have multiple uses. *See, e.g.*, 21 U.S.C. § 355(b)(1) (2012) (requiring that an NDA applicant file information about “any patent which claims the drug . . . or which claims a method of using such drug”). *Id.*

¹²⁶ *Caraco Pharm. Laboratories, Ltd.*, 132 S. Ct. at 1681. In other words, the statutory scheme “contemplates that one patented use will not foreclose marketing a generic drug for other unpatented ones.” *Id.* at 1682.

¹²⁷ *Id.*

¹²⁸ *Id.* at 1681.

¹²⁹ *Id.*

The Court highlights that under section 355, the FDA could approve Caraco's ANDA application so long as Novo does not possess a patent covering the uses listed in Caraco's ANDA application.¹³⁰ However, Novo argues that since they have a valid patent on one of the three approved uses, Caraco's counterclaim disappears; the Court completely disagrees with Novo's position.¹³¹ Novo further argues that Congress could have "imposed additional . . . qualifications on the term 'an approved method of use' and indeed did so in another place in the statute."¹³² The Court responds by saying the mere possibility that Congress could have provided clearer phrasing does not outweigh the natural reading of the statute.¹³³ If this were true, courts today would interpret most of the statutes passed by Congress in a much different way.¹³⁴ However, the Court does not wish to focus on the possibility that Congress could provide clearer language in the statute, rather it believes the words "not any" do not appear in the counterclaim provision because Congress did not

¹³⁰ *Id.* If Caraco does not try to patent a use already claimed by Novo, then the FDA could approve Caraco's ANDA application "regardless whether a patent protects yet a third method of using the drug." *Id.* Novo even "agrees that Caraco could bring a counterclaim if Novo's assertion of patent protection for repaglinide lacked any basis—for example, if Novo held no patent, yet claimed rights to the pair of uses for which Caraco seeks to market its drug." *Id.*

¹³¹ *Caraco Pharm. Laboratories, Ltd.*, 132 S. Ct. at 1681.

¹³² *Id.* at 1682. Novo points to "section viii itself, which applies when the brand's patent 'does not claim a use for which the ANDA applicant is seeking approval.'" *Id.* See 21 U.S.C. § 355(j)(2)(A)(viii) (2012).

¹³³ *Caraco Pharm. Laboratories, Ltd.*, 132 S. Ct. at 1682. The Supreme Court elaborates and said that if the possibility of clearer phrasing could outweigh the statute's most natural reading, then courts would interpret most statutes today much differently. They also turn Novo's argument around on itself and highlight that "Congress could have more clearly expressed Novo's proposed meaning in the easiest of ways—by adding a single letter to make clear that 'not an' really means 'not any.'" Furthermore, Congress used a "not any" in the very next subclause. See 21 U.S.C. § 355(j)(5)(C)(ii)(II) ("Subclause (I) does not authorize the assertion of a claim . . . in any [other] civil action."). The Court believes Congress knew how to say "not any" and would have used the word "not any" if that was the meaning they intended, and that this "sees, raises, and bests Novo's argument." *Caraco Pharm. Laboratories, Ltd.*, 132 S. Ct. at 1682.

¹³⁴ *Caraco Pharm. Laboratories, Ltd.*, 132 S. Ct. at 1682.

intend what Novo wishes they had.¹³⁵ Instead, the Court believes that Congress intended the counterclaim provision of the Hatch-Waxman Amendments to fit within the overall statutory scheme.¹³⁶ Fitting into the overall statutory scheme would mean that Congress created the counterclaim in order to assist in the approval of non-infringing generic drugs by the FDA.¹³⁷

2. Patent Information Submitted Under 21 U.S.C. §§ 355 (b), (c) Includes Use Codes.

Next, Novo argues that Caraco's counterclaim fails for another reason because the counterclaim is unable to provide a way "to correct use codes because they are not 'patent information' submitted by the brand under subsection (b) or (c) of [U.S.C.] § 355."¹³⁸ The Court addresses the first part of Novo's contention by highlighting that although the statute does not define "patent information," a use code must still qualify.¹³⁹ The statute does require a company (Novo in this situation) to describe the method-of-use claimed in their patent.¹⁴⁰ The Court finds this to be sufficient to fit under the

¹³⁵ *Id.* Novo wishes that Congress had intended to use the words "not any" because that would mean the FDA would be unable to approve Caraco's ANDA application because Novo holds a valid patent over one of the approved uses. *Id.* If Novo's reading of the statute were true, the FDA would only be able to approve Caraco's application if Novo did not have one single valid patent. *Id.*

¹³⁶ *Id.*

¹³⁷ *Id.* at 1683.

¹³⁸ *Caraco Pharm. Laboratories, Ltd.*, 132 S. Ct. at 1683. The Court once again disagrees with Novo's argument and sides with Caraco. *Id.*

¹³⁹ *Id.*

¹⁴⁰ *Id.* See 21 C.F.R. § 314.53(c)(2)(ii)(P)(1)(2)(3), which requires a company to include in its published information regarding its patent:

Information on each method-of-use patent including the following: (1) Whether 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) Identification 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) The description of the patented method of use as required for publication.

ordinary understanding of the language, and it is the “submitted under” phrase that presents the more difficult question.¹⁴¹ 21 U.S.C. § 355 (b), (c), “require an NDA applicant to submit specified information: ‘the patent number and the expiration companies to submit use codes.’¹⁴² The Court gives “under” a broad meaning in finding that “use codes fall within the counterclaim’s ambit if the phrase ‘submitted under’ reaches filings that not only subsections (b) and (c) themselves, but also their implementing regulations require.”¹⁴³ The date of any “patent claiming the drug or a method of its use.”¹⁴⁴ Novo contends only that information accompanies the counterclaim provision.¹⁴⁵ However, both (b) and (c) of section 355 oversee the regulatory process in which brand name companies provide additional patent information to the FDA, prior to and after the approval of an NDA.¹⁴⁶ Specifically, those subsections require brand Court believes the scope of the term “under” becomes principally clear when compared with other phrases such as “described in” and “prescribed by,” which appear in neighboring

Id.

¹⁴¹ *Caraco Pharm. Laboratories, Ltd.*, 132 S. Ct. at 1683.

¹⁴² *Id.* The FDA’s principal legal authority was section 505 of the Food Drug and Cosmetic Act and 68 Fed. Reg. 36697–36698, which defines the FDA’s general rulemaking authority.

¹⁴³ *Id.* Several Supreme Court cases support giving the word “under” a broad meaning. See *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661 (1990), in which the Court examined a similar statutory reference under 35 U.S.C. § 271(e)(1) that discussed “submission of information under a Federal law which regulates the manufacture, use, or sale of drugs.” *Caraco Pharm. Laboratories, Ltd.*, 132 S. Ct. at 1683. The Court found that submitting information under a ‘Federal Law’ “suggests doing so ‘in furtherance of or compliance with a comprehensive scheme of regulation.’” *Id.* at 1684 (citing *Eli Lilly*, 496 U.S. at 667). The Court in *Caraco* too believes that “[p]atent information submitted . . . under subsection (b) or (c)” most naturally refers to patent information provided as part of the “comprehensive scheme of regulation” premised on those subsections. *Id.* Also in *Ardestani v. I.N.S.*, 502 U.S. 129, 131 (1991), the Court held that a “regulatory proceeding ‘under section 554,’ . . . meant any proceeding ‘subject to,’ ‘governed by,’ or conducted ‘by reason of the authority of’ that statutory provision.” *Id.*

¹⁴⁴ *Id.*

¹⁴⁵ *Id.*

¹⁴⁶ *Caraco Pharm. Laboratories, Ltd.*, 132 S. Ct. at 1683.

provisions.¹⁴⁷ These phrases typically signify a patent number and expiration date. The Supreme Court contrasts this with the word “under,” which they believe naturally “reaches beyond [the] most barebones information of [a patent number and expiration date] to other patent materials the FDA demands in the regulatory process.”¹⁴⁸

The Court found that Congress’s decision once again fits the broader statutory context, as use codes are crucial to the implementation of the Hatch-Waxman Amendments.¹⁴⁹ Furthermore, use codes are no less important because an FDA regulation rather than a statute requires their submission.¹⁵⁰ The Hatch-Waxman Amendments helped speed the process by which a generic drug could be brought to market by requiring FDA to approve an ANDA application that is filed with a section viii statement, when a company seeks to market a generic form of a drug for unpatented methods of use.¹⁵¹ In order for the FDA to determine whether a patent covers a specific method of use, they refer to the “Orange Book,” which contains all the use codes submitted by drug companies during the regulatory process of bringing their drug to market.¹⁵² The Court points out that if the use codes submitted to FDA and published in the “Orange Book” are overly broad, it prevents FDA from approving ANDAs.¹⁵³

¹⁴⁷ *Id.* An example of these different phrases can be found in 21 U.S.C. §355(d)(6) (2012).

¹⁴⁸ *Id.*

¹⁴⁹ *Id.* The FDA explains how “[u]se codes are intended to alert ANDA and 505(b)(2) applicants to the existence of a patent that claims an approved use. They are not meant to substitute for the applicant's review of the patent and the approved labeling.” 68 Fed. Reg. 36676–01 (June 18, 2003).

¹⁵⁰ *See* 68 Fed. Reg. 36676–01 (June 18, 2003), which states that “[u]se codes are intended to alert ANDA and 505(b)(2) applicants to the existence of a patent that claims an approved use.” *Id.*

¹⁵¹ *Caraco Pharm. Laboratories, Ltd.*, 132 S. Ct. at 1684.

¹⁵² *Id.*

¹⁵³ *Id.* “An overbroad use code . . . throws a wrench into the FDA's ability to approve generic drugs as the statute contemplates. So it is not surprising that the language Congress used in the counterclaim provision sweeps widely enough to embrace that filing.” *Id.*

3. The Counterclaim Does Provide Remedies for Incorrectly Published Use Codes.

As mentioned prior, Novo contends that the counterclaim does not provide a way in which to correct overbroad use codes.¹⁵⁴ Section 355 clearly states that an “applicant [may] assert a counterclaim seeking an order requiring the [holder] to correct or delete the patent information.”¹⁵⁵ The Court interprets the statute to provide for two remedies: a brand company may either (1) correct or (2) delete its incorrect patent information from the Orange Book.¹⁵⁶ Novo argues that the counterclaim is purely a delisting provision and can only “correct erroneous patent numbers.”¹⁵⁷ Novo provides the Court with an example: if Novo mistakenly listed their patent number as ‘359 instead of ‘358 when submitting their drug patent information for publication in the Orange Book, then Caraco could bring a counterclaim and require Novo to “correct” its incorrect listing.¹⁵⁸ The Court seriously doubts that Congress enacted a counterclaim provision to correct a minor error¹⁵⁹ such as the mislabeling of a patent number.¹⁶⁰

¹⁵⁴ *Id.* at 1683. The Court argues that the description of possible remedies for an overbroad use code destroys “whatever remains of Novo’s argument.” *Id.* at 1684.

¹⁵⁵ *Id.* at 1678. “According to the statute, a successful claimant may obtain an order requiring the brand to ‘correct or delete’ its patent information.” *Id.* See also 21 U.S.C. § 355 (j)(5)(C)(ii)(I) (2012).

¹⁵⁶ *Caraco Pharm. Laboratories, Ltd.*, 132 S. Ct. at 1684. Usually a brand manufacturer will choose to delete a listing from the Orange Book entirely when it holds no relevant patent, and will correct the information located in the listing when the brand manufacturer has incorrectly described the patent’s scope. *Id.*

¹⁵⁷ *Id.* at 1685.

¹⁵⁸ *Id.* The Court does not take this argument very seriously and believes that Novo “considerably understates the matter.” *Id.*

¹⁵⁹ *Id.* Novo conceded to the Court that brand companies have strong incentives to ensure that correct and accurate information is published in the Orange Book (they also have major incentives to immediately correct any false or incorrect information as soon as possible) because this information alerts both the FDA and other companies that their drug patent is valid. *Id.* In other words, publishing correct information in the Orange Book protects brand name manufacturers from infringement by generic brand manufacturers. Furthermore, the Court believes that generic manufacturers would have absolutely no incentive

Furthermore, Novo has not even formulated a situation where the counterclaim provision would be used to correct inaccurate patent dates.¹⁶¹ Under Novo's interpretation of the counterclaim, its use is only appropriate if a listed patent "does not claim the drug or an approved method of using it."¹⁶² On the one hand, if a brand manufacturer mistakenly lists the expiration date of an otherwise valid patent (meaning it claims the drug or an approved use) as 2020 instead of 2015, the generic manufacturer would be barred from bringing the counterclaim altogether (under Novo's interpretation).¹⁶³ On the other hand, if the brand manufacturer mistakenly published a 2015 expiration date when in reality the patent has already expired, then the generic company could make use of the counterclaim provision.¹⁶⁴ However, in the latter situation, the correct remedy would be a delisting of the patent instead of a correction of the brand's listing.¹⁶⁵ Clearly, the counterclaim was created in order to correct and delist inaccurate use codes, and not only numbers and expiration dates under subsection (b) and (c) of 21 U.S.C. § 355.¹⁶⁶

to bring a counterclaim against a brand name manufacturer merely to correct a mislabeled patent. *Id.*

¹⁶⁰ *Id.* See, e.g., *TRW Inc. v. Andrews*, 534 U.S. 19, 31 (2001) (refusing to adopt an interpretation of a statute that would render a piece of it "insignificant, if not wholly superfluous"). If Novo's interpretation of how the counterclaim provision works were true, the counterclaim would be almost entirely pointless. The Court points out that it would have been, "in the most literal sense, to make a federal case out of nothing." *Caraco Pharm. Laboratories, Ltd.*, 132 S. Ct. at 1685.

¹⁶¹ *Caraco Pharm. Laboratories, Ltd.*, 132 S. Ct. at 1685.

¹⁶² *Id.*

¹⁶³ *Id.* In the above hypothetical, "the counterclaim would be useless: It authorizes a remedy only 'on the ground that' the listed patent does not claim the drug or an approved method of using it—and notwithstanding the wrong expiration date, this patent does so." *Id.*

¹⁶⁴ *Id.*

¹⁶⁵ Essentially, "Novo's reading of 'patent information,' like its reading of 'not an,' effectively deletes the term 'correct' from the statute." *Id.*

¹⁶⁶ *Id.*

4. No Evidence Points to Congress Rejecting S. 812 Because It Required Brands to Submit Patent Information Beyond a Number and Expiration Date.

Novo argues that the Court's interpretation of 21 U.S.C. § 355 basically revives parts of the Greater Access to Affordable Pharmaceuticals Act of 2002, which was expressly rejected by the United States Congress.¹⁶⁷ The bill would have required brand name companies to file specific information for method-of-use patents, such as a description of "the approved use covered by the patent claim."¹⁶⁸ Moreover, S. 812 would have provided generic brand companies with their own form of civil action to compel brand name companies to "delete" or "correct" inaccurate information filed with the FDA.¹⁶⁹ Novo argues that S. 812 would have allowed generic brand companies to challenge overbroad patent descriptions, and thus the Court "cannot read the statute Congress eventually enacted as doing so."¹⁷⁰ The Court wholeheartedly disagrees with Novo's argument and sees no reason to assume that the reason Congress did not pass S. 812 was because it required brand name companies to submit a description of the approved uses claimed by the patent.¹⁷¹

S. 812 had several titles and provisions, any of which could have been viewed unfavorably by Congress and been the reason for why the House of Representatives took no action on the bill.¹⁷² S. 812

¹⁶⁷ *Caraco Pharm. Laboratories, Ltd.*, 132 S. Ct. at 1685. S. 812 was able to successfully pass through the United States Senate, however the House of Representatives never voted on the bill, thus preventing it from being enacted into Law. *Id.* at 1686.

¹⁶⁸ *Id.* at 1686 (citing S. 812, 107th Cong., 2d Sess., § 103(a)(1), p. 7 (engrossed bill)).

¹⁶⁹ *Id.*

¹⁷⁰ *Id.*

¹⁷¹ *Id.* The Court believes, just like any layperson would, that "a bill can be proposed for any number of reasons, and it can be rejected for just as many others." *Id.* at 1686 (citing *Solid Waste Agency of N. Cook Cnty. v. Army Corps of Eng'rs*, 531 U.S. 159, 170 (2001)). Novo attempts to argue that S. 812 was rejected by Congress for one specific reason, however there were several aspects of S. 812 that were unappealing and thus altered.

¹⁷² *See generally* S. 812, 107th Cong. § 804(b) (2002). One of the biggest issues in S. 812 was Title II § 804 (b), which said, "[t]he Commissioner of Customs, shall promulgate regulations permitting pharmacists and wholesalers to

also received public criticism from several politicians because it called for an independent cause of action, which was a more lengthy legal action than the counterclaim provision that Congress ultimately adopted.¹⁷³ Moreover, Novo completely ignored a major reason as to why the bill was redrafted.¹⁷⁴ In between the demise of S. 812 and the counterclaim's enactment, "the FDA issued a rule requiring brands to supply material concerning method-of-use patents, including use codes."¹⁷⁵ According to the Court, the drafters of the counterclaim provision were completely aware of the FDA ruling and did not want to "duplicate its list of mandated filings."¹⁷⁶ Ergo, the drafting history of the counterclaim does not support Novo's ultimate conclusion of Congress rejecting S. 812 because it required brands to submit patent information beyond a patent number and expiration date.¹⁷⁷

5. Congress Did Not Establish the Counterclaim Merely to Solve the Problem Raised by the Federal Circuit's Decision in *Mylan*.

Novo made one last attempt at an argument and stated that "Congress established the counterclaim only to solve the problem raised by the Federal Circuit's decision in *Mylan*— the impossibility of deleting an improperly listed patent from the Orange Book."¹⁷⁸ As discussed earlier, *Mylan* involved a situation where a generic drug

import prescription drugs from Canada into the United States." S. 812, 107th Cong. § 804(b) (2002). Title II was highly controversial and likely would have resulted in numerous lawsuits between U.S. and Canadian pharmaceutical companies. *Id.*

¹⁷³ *E.g.* Senator Gregg in discussing the challenges of passing S. 812 stated, "the most significant issue is the fact that [S. 812] creates a new cause of action." 148 CONG. REC. 15424 (2002) (remarks of Sen. Gregg). Basically, "the creation of an independent cause of action [was] stronger medicine than the counterclaim Congress ultimately adopted." *Caraco Pharm. Laboratories, Ltd.*, 132 S. Ct. at 1686.

¹⁷⁴ *Caraco Pharm. Laboratories, Ltd.*, 132 S. Ct. at 1686.

¹⁷⁵ *Id.*

¹⁷⁶ *Id.*

¹⁷⁷ *Id.* The Court believes that "if anything, the statute's evolution indicates that Congress determined to enforce the FDA's new listing provisions, including its use-code requirement, through the new counterclaim." *Id.*

¹⁷⁸ *Id.*

manufacturer alleged that a brand name drug manufacturer submitted a patent that neither claimed the drug, or any of its approved uses; Mylan requested the patent be delisted.¹⁷⁹ However, the court in *Mylan* found that delisting the patent was not a remedy available to Mylan¹⁸⁰ under then current patent laws or the “Hatch–Waxman Amendments to the Federal Food, Drug, and Cosmetic Act (FFDCA) and to Title 35 of the United States Code.”¹⁸¹ Novo wanted the Court to strictly construe the counterclaim provision to only help generic drug manufacturers in *Mylan’s* exact situation.¹⁸² The Court once again disagrees with Novo.¹⁸³

Instead, the Court believes the decision in *Mylan* alerted Congress to a major problem, which was that “generic companies generally had no avenue to challenge the accuracy of brands’ patent listings, and that the FDA therefore could not approve proper applications to bring inexpensive drugs to market.”¹⁸⁴ The Court finds proof of this in the statute and its context, which demonstrate that the counterclaim provision is available to generic companies when brand companies publish patents with no basis, as well as overbroad patents.¹⁸⁵ Moreover, whether a brand name

¹⁷⁹ See generally *Mylan Pharm., Inc., v. Thompson*, 268 F.3d 1323 (Fed. Cir. 2001).

¹⁸⁰ “The Federal Circuit held that no such action was available, even assuming the allegation was true. Because several legislators saw *Mylan* as ‘exemplifying brands’ ‘perceived abuse’ of the FDA’s patent listing practices.” *Caraco Pharm. Laboratories, Ltd.*, 132 S. Ct. at 1686–87.

¹⁸¹ *Mylan Pharm., Inc.*, 268 F.3d at 1325. See also *supra* note 58.

¹⁸² *Caraco Pharm. Laboratories, Ltd.*, 132 S. Ct. at 1687.

¹⁸³ The Court does not draw any conclusions on whether the *Mylan* decision incentivized legislators to create a counterclaim or not. *Id.* Instead they emphasized the publishing of a study conducted by the FTC that deeply criticized brand name pharmaceutical companies, and illustrated how brand manufacturers would submit overbroad patents for publication to the FDA, thus preventing generic drug companies from bringing their version of the drug to market. *Id.*

¹⁸⁴ *Caraco Pharm. Laboratories, Ltd.*, 132 S. Ct. at 1687. The Court lamented how “the statute’s text and context demonstrate that the counterclaim is available not only (as in *Mylan*) when the patent listing is baseless, but also (as here) when it is overbroad.” *Id.* The opinion also goes on to say how “Congress’s decision to allow a counterclaimant to seek ‘correction’ of patent information explodes Novo’s theory, because the remedy for a *Mylan*–type impropriety is complete delisting.” *Id.*

¹⁸⁵ *Caraco Pharm. Laboratories, Ltd.*, 132 S. Ct. at 1687.

pharmaceutical company publishes an overbroad patent or whether it publishes a patent that covers absolutely no approved use, the bottom line is that the company is “submit[ing] misleading information to the FDA.”¹⁸⁶ Essentially, the brand name manufacturer takes advantage of the fact that the FDA does not have the manpower or necessary qualified individuals to police incorrect and misleading pharmaceutical drug patents.¹⁸⁷ This prevents or severely delays generic drugs that should otherwise go to market. Caraco’s situation was extremely serious, as Novo wanted to prevent Caraco from selling repaglinide for unpatented uses until 2018.¹⁸⁸

The Court considers Caraco to be in even more need of the counterclaim provision than Mylan, for several reasons. In *Mylan*, the brand company listed a patent that claimed no approved use of the drug.¹⁸⁹ When a brand company does this, the generic company has an alternative to the counterclaim provision, which is to make a paragraph IV certification maintaining that the published patent “is invalid or will not be infringed [on] by the generic drug.”¹⁹⁰ If the brand manufacturer decides to sue the generic company, the generic company can argue that their drug will not infringe the patent.¹⁹¹ The use of the counterclaim by the generic manufacturer against the brand manufacturer may result in a quicker delisting of the patent, however, “even without it the [generic manufacturer] can eventually get a judgment of non-infringement enabling the FDA to approve its ANDA.”¹⁹² In Caraco’s situation, where a brand company purposefully files an overbroad use code description with the FDA, the generic manufacturer is unable to use a paragraph IV certification because it would require the generic manufacturer to propose labeling identical to the brand name drug; furthermore, it cannot

¹⁸⁶ *Id.*

¹⁸⁷ *Id.* When brand name pharmaceutical companies submit incorrect patent information, their actions “delay or block approval of a generic drug that infringes no patent – and that under the statute should go to market.” *Id.* This is “the danger Caraco faces here, as much as it was the threat in *Mylan*: Novo seeks to preclude Caraco from selling repaglinide for unpatented uses until 2018, when Novo’s patent on a *different* use expires.” *Id.*

¹⁸⁸ *Id.*

¹⁸⁹ *Mylan Pharm., Inc. v. Thompson*, 268 F.3d 1323 (Fed. Cir. 2001).

¹⁹⁰ See 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (2012).

¹⁹¹ *Caraco Pharm. Laboratories, Ltd.*, 132 S. Ct. at 1687.

¹⁹² *Id.*

carve out any uses.¹⁹³ The proposed label will “infringe because it will include the use(s) on which the brand does have a patent.”¹⁹⁴ Thus, in Caraco’s situation, “a paragraph IV suit cannot lead to a judgment enabling FDA approval.”¹⁹⁵ The counterclaim provides the only way for Caraco (or a generic drug manufacturer in a similar situation) to bring its drug to market for “non-infringing uses.”¹⁹⁶ Novo’s view would eliminate the counterclaim, thus preventing it from being used where it is most helpful to generic drug manufacturers.¹⁹⁷ Thus, the Supreme Court in a 9-0 opinion ruled in favor of Caraco.

B. Justice Sotomayor’s Concurring Opinion

Justice Sotomayor concurs with the Court’s interpretation of the counterclaim in section 355¹⁹⁸ and agrees that its reading of the statute is the most sensible “in light of the existing regulatory scheme.”¹⁹⁹ However, she writes separately to make several additional observations.²⁰⁰

Sotomayor strongly believes that the counterclaim in section 355 can only “lessen the difficulties created by an overly broad use code; it cannot fix them.”²⁰¹ Section 355 was specifically designed to increase the production and approval time of generic drugs by the FDA, so that American citizens have the option of purchasing a more

¹⁹³ *Id.* “A paragraph IV certification (unlike a section viii statement) requires the generic company to propose labeling identical to the brand’s; it cannot carve out any uses.” *Id.* See *supra* note 50.

¹⁹⁴ *Caraco Pharm. Laboratories, Ltd.*, 132 S. Ct. at 1687.

¹⁹⁵ *Id.*

¹⁹⁶ *Id.* at 1687–88.

¹⁹⁷ *Id.* at 1688.

¹⁹⁸ *Id.* See also 21 U.S.C. § 355(j)(5)(C)(ii)(I) (2012). Justice Sotomayor agrees with the Court’s interpretation of the counterclaim in section 355 “to permit generic manufacturers to force brand manufacturers to ‘correct inaccurate use code.’” *Caraco Pharm. Laboratories, Ltd.*, 132 S. Ct. at 1688 (Sotomayor, J., concurring). She too finds “the counterclaim not ‘free of ambiguity.’” *Id.*

¹⁹⁹ *Caraco Pharm. Laboratories, Ltd.*, 132 S. Ct. at 1688 (Sotomayor, J., concurring).

²⁰⁰ *Id.* (Sotomayor, J., concurring).

²⁰¹ *Id.* (Sotomayor, J., concurring).

affordable version of their pharmaceutical drug.²⁰² The generic drug manufacturer must submit an ANDA with a section viii statement to the FDA.²⁰³ Once the FDA receives the ANDA and section viii statement, it can approve the application without further delay, as long as the use code is not overly broad.²⁰⁴ When an overly broad use code is submitted to the FDA, the process becomes much more complicated.²⁰⁵ Sotomayor correctly points out that the Court's decision now permits generic drug manufacturers to bring a counterclaim against the brand name manufacturer, once the brand name manufacturer sues the generic company for patent infringement.²⁰⁶ If the generic company successfully litigates the

²⁰² “The statutory scheme is designed to speed the introduction of low-cost generic drugs to market.” *Caraco Pharm. Laboratories, Ltd.*, 132 S. Ct. at 1688 (Sotomayor, J., concurring) (citing *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676 (1990)).

²⁰³ *Caraco Pharm. Laboratories, Ltd.*, 132 S. Ct. at 1688 (Sotomayor, J., concurring). Along with the ANDA and section viii statement, the generic drug company must submit a “proposed label that ‘carves out’ from the brand manufacturer’s label any patented method of use.” *Id.* See *supra* note 50 (providing an explanation of “carving out”).

²⁰⁴ *Caraco Pharm. Laboratories, Ltd.*, 132 S. Ct. at 1688 (Sotomayor, J., concurring).

²⁰⁵ *Id.* (Sotomayor, J., concurring). The reason an overbroad use code complicates things is very straightforward. The Federal Drug Administration “relies on use codes in determining whether to approve an ANDA, but it refuses to evaluate the [use code’s accuracy].” *Id.* (Sotomayor, J., concurring). “If the use code overlaps with the generic manufacturer’s proposed carve-out label (i.e., the use code is overly broad), FDA will not approve an ANDA with a section viii statement.” *Id.* (Sotomayor, J., concurring).

²⁰⁶ *Id.* at 1688 (Sotomayor, J., concurring).

After today’s opinion, the generic manufacturer can respond to this situation by taking the following steps: submit an ANDA with a paragraph IV certification (which requires a proposed label materially identical to the brand manufacturer’s label), wait for the brand manufacturer to institute suit, file a counterclaim, and then litigate the counterclaim. [If the generic company is] successful in securing the correction of the use code, [it can] return to the start of the process and do what it always wanted to do—file an ANDA with a section viii statement and a carve-out label.

Id. (Sotomayor, J., concurring).

counterclaim and compels the brand name company to either correct or delete the overbroad use code, they can return to the beginning of the process and submit their ANDA, section viii statement, and carve-out label.²⁰⁷

Justice Sotomayor finds two major problems with the counterclaim provision. First, it results in major delays and expenses, which the statutory scheme did not foresee; second, there is absolutely no guarantee that the process will work.²⁰⁸ The Court knows what will happen if a brand company initiates paragraph IV litigation over an overbroad use code,²⁰⁹ but it is unclear “if the brand name company does not file.”²¹⁰ Justice Sotomayor strongly believes the counterclaim “cannot restore the smooth working of a statutory scheme thrown off kilter by an overly broad use code.”²¹¹ At the very best, the statutory scheme allows the generic drug manufacturer to file an ANDA with a section viii statement, “but only after expensive and time-consuming litigation.”²¹² Justice Sotomayor laments that either the FDA or Congress needs to take action and address the problem.²¹³

²⁰⁷ *Id.* (Sotomayor, J., concurring).

²⁰⁸ *Id.* at 1688–89 (Sotomayor, J., concurring).

²⁰⁹ *Caraco Pharm. Laboratories, Ltd.*, 132 S. Ct. at 1689 (Sotomayor, J., concurring). The outcome of paragraph IV litigation over an overbroad use code “will be the correction of the use code through the assertion of a counterclaim—an outcome that is desirable, to be sure, for the generic manufacturer, but perhaps less so for the brand manufacturer.” *Id.* at 1689 (Sotomayor, J., concurring).

²¹⁰ *Id.* The FDA “may approve the generic manufacturer’s application, ‘without prejudice to infringement claims the patent owner might assert when the ANDA applicant produces or markets the generic drug.’” *Id.* (Sotomayor, J., concurring). However, the generic brand manufacturer having been forced to continue with a paragraph IV certification, “will have secured approval to market a drug with a label materially identical to the brand manufacturer’s.” *Id.* (Sotomayor, J., concurring). The Solicitor General’s Office informed the Court at oral arguments that “it would be inducement of infringement to sell a product with labeling that suggests that the product be used for a patented method of use.” *Id.* (Sotomayor, J., concurring). Basically, if a generic drug manufacturer filed a paragraph IV certification, the proposed labeling would be infringing, so long as the brand name manufacturer’s patent covered an approved method of using the approved drug. *Id.* (Sotomayor, J., concurring).

²¹¹ *Id.* (Sotomayor, J., concurring).

²¹² *Id.* (Sotomayor, J., concurring).

²¹³ *Id.* (Sotomayor, J., concurring).

Sotomayor goes on to say that the regulatory scheme is dependent on the accuracy of the use codes, and that the FDA’s “guidance as to what is required of brand manufacturers in use codes [is] remarkably opaque.”²¹⁴ Some of the confusion is due to the FDA’s failure to describe what is required of brand name manufacturers; Novo experienced difficulties and confusion in filing their use code description with FDA.²¹⁵ However, the Court explained in its

²¹⁴ *Caraco Pharm. Laboratories, Ltd.*, 132 S. Ct. at 1689 (Sotomayor, J., concurring). “The relevant regulation states simply that a brand manufacturer must provide ‘[t]he description of the patented method of use as required for publication.’” *Id.* (Sotomayor, J., concurring) (citing 21 C.F.R. § 314.53(c)(2)(ii)(P)(3)). The new drug application forms contain information with additional details explaining how:

Each approved use claimed by the patent should be separately identified . . . and contain adequate information to assist . . . applicants in determining whether a listed method of use patent claims a use for which the . . . applicant is not seeking approval.

Id. at 1689 (Sotomayor, J., concurring).

However, the form also mentions that brand name drug companies may “use no more than 240 total characters including spaces.” *Id.* (Sotomayor, J., concurring). Elsewhere, the “FDA acknowledges ‘that in some cases 240 characters may not fully describe the use as claimed in the patent.’” *Id.* (Sotomayor, J., concurring) (citing 68 Fed. Reg. 36683 (2003)). This indicates that use codes “are not meant to substitute for the applicant’s review of the patent.” *Caraco Pharm. Laboratories, Ltd.*, 132 S. Ct. at 1689 (Sotomayor, J., concurring).

²¹⁵ *Caraco Pharm. Laboratories, Ltd.*, 132 S. Ct. at 1689 (Sotomayor, J., concurring). Sotomayor points out that when Novo filed its initial NDA, it “submitted a use code for the § 358 patent that was not ‘overly broad’: It described narrowly the single patented method of use.” *Id.* (Sotomayor, J., concurring). Several years later the FDA required Novo to amend its label to “separate all indications with the following sentence: ‘Prandin is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type [two] diabetes mellitus.’” *Id.* at 1690 (Sotomayor, J., concurring). Novo proceeded to amend its use code to comply with the FDA requirements, and explained that the amendment corresponded with the requests of the FDA. Novo believed its newly amended use code “[complied] with FDA regulations, . . . on the ground it pressed before [the Court]: 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’).” *Id.* at 1690 (Sotomayor, J., concurring).

majority opinion why Novo was mistaken, yet Sotomayor believes “[Novo] can hardly be faulted for so thinking.”²¹⁶

Justice Sotomayor concludes by mentioning that prior to the enactment of the counterclaim provision, “Congress considered a bill that required brand manufacturers to submit a description of the approved use covered by the patent claim.”²¹⁷ The legislation allowed a generic manufacturer to bring an independent civil action and force a brand name manufacturer to correct or remove an overbroad use code.²¹⁸ S. 812 received all kinds of criticism and was eventually rejected by Congress. Politicians stated that the bill would encourage excessive litigation.²¹⁹ Sotomayor believes “[a]bsent greater clarity from FDA concerning what is required of brand manufacturers in use codes, Congress’s fears of undue litigation may be realized.”²²⁰

VI. POSSIBLE SOLUTIONS

Justice Sotomayor’s concurring opinion indicates that the Court’s decision in *Caraco* has not even come close to fixing all of the problems associated with the counterclaim provision and that both Congress and the FDA must take further steps to achieve a complete resolution.²²¹ As it stands today, the FDA will not review the patents submitted to it for compliance with the Hatch-Waxman Amendments

²¹⁶ *Caraco Pharm. Laboratories, Ltd.*, 132 S. Ct. at 1690 (Sotomayor, J., concurring). “The regulations also require submission of “a description of each approved method of use or indication.” *Id.* (citing 21 C.F.R. § 314.53(c)(2)(ii)(P)(1)). Also, the form on which the brand name drug company submits its use code “requires information on the indication or method of use for the Orange Book ‘Use Code’ description.” *Id.* (Sotomayor, J., concurring). Sotomayor states that “those sources at the least suggest (as Novo thought) that a method of use here is distinct from an indication and that either suffices as a use code.” *Id.* (Sotomayor, J., concurring).

²¹⁷ *Caraco Pharm. Laboratories, Ltd.*, 132 S. Ct. at 1690 (Sotomayor, J., concurring).

²¹⁸ *Id.* (Sotomayor, J., concurring).

²¹⁹ *Id.* (Sotomayor, J., concurring). *See supra* notes 171–173.

²²⁰ *Caraco Pharm. Laboratories, Ltd.*, 132 S. Ct. at 1690 (Sotomayor, J., concurring).

²²¹ *Id.*

that were passed in 1984.²²² The agency adopts a “hands-off” policy when it comes to patents and refuses to conduct any type of due diligence to safeguard from overly broad or inaccurate method-of use codes being submitted for publication in the Orange Book.²²³ The FDA’s current hands-off position is the reason why *certiorari* was granted for the *Caraco* case, because the FDA’s “policy incentivizes [brand manufacturers] to draft use code narratives that are inappropriately broad to force applicants to file Paragraph IV certifications.”²²⁴

A. Increase the Level of Review

Prior to the Court’s decision in *Caraco*, two senior attorneys (Mr. Malkin and Mr. Wasson) published an article making several recommendations for how the FDA should proceed. Their suggestions were criticized, yet they are now more relevant than ever.²²⁵ In essence, they suggest that the FDA “internally review patents beyond the ministerial requirements of its current regulations to more efficiently administer the balance between an NDA-holder and generic applicant.”²²⁶ First, and most importantly, the FDA should review patents submitted for publication in the Orange Book for accuracy and “should proactively refuse to list patents that do not meet FDA’s listing criteria.”²²⁷ Second, “in the event that an applicant submits carved-out labeling, confirm that the listed method-of-use patent does not claim a use for which the application is

²²² The FDA has stated: “because FDA has no expertise in the field of patents, the agency has no basis for determining whether a use patent covers the use sought by the generic applicant.” Abbreviated New Drug Application Regulations; Proposed Rule, 54 Fed. Reg. 28872, 28909 (July 10, 1989). See also *supra* note 52, where the FDA explains how its administration lacks both the expertise and authority to review patent claims.

²²³ *Id.*

²²⁴ Brian J. Malkin & Andrew S. Wasson, *Should FDA Undertake More Than A Ministerial Role With Respect to Patent Information?*, 1 THE FOOD AND DRUG LAW INST. FOOD AND DRUG POL’Y FORUM 1, 1 (2011) [hereinafter FDA: Ministerial Role].

²²⁵ See generally Malkin & Wasson, *supra* note 224.

²²⁶ *Id.* at 5. Malkin and Wasson advocate for various limits on the internal review. *Id.*

²²⁷ *Id.*

submitted.”²²⁸ The FDA should be allowed to retain use code narratives for informational use, so that they might refer back to them or compare them to future submissions.²²⁹

A major benefit of the above proposal is that the FDA will be able to act as a “neutral arbiter” and hold NDA applicants accountable for inaccurate information they submit for publication in the Orange Book.²³⁰ The FDA would be able to unilaterally delist patents that have over broad use codes.²³¹ Giving the FDA the ability to delist patents takes this power out of the hands of brand manufacturers (who often times have an interest in publishing overbroad use codes) and places it in the hands of a “neutral arbiter.”²³² Brand name manufacturers would have an incentive not to submit overbroad or inaccurate method-of-use patents for fear that they would be rejected by the FDA. Malkin and Wasson point out how this exact reasoning applies to the “FDA’s role in determining whether an applicant can carve-out . . . a product.”²³³ Basically, instead of the brand manufacturer having the sole power to decide the scope of the patent, which could potentially prevent a non-infringing generic drug manufacturer from achieving the approval of their “505(b)(2) ANDA, the FDA would ‘assume the decision making role.’”²³⁴ Most likely, “the number of questionable patent listings and use code narratives would decrease . . . because [brand manufacturers] would be less likely to submit inappropriate patent listings or use codes’ narratives knowing that this information would face a substantive FDA review.”²³⁵ Brand name manufacturers would be dissuaded from submitting inaccurate use codes to the FDA for publishing if there was a possibility that the patent could be rejected because its method-of-use statement is overbroad or wholly inaccurate.

²²⁸ *Id.*

²²⁹ *Id.*

²³⁰ FDA: Ministerial Role, *supra* note 224, at 6.

²³¹ *Id.*

²³² *Id.* Placing this type of power in the hands of the FDA would provide some “balance between competing interests.” *Id.*

²³³ *Id.*

²³⁴ *Id.*

²³⁵ FDA: Ministerial Role, *supra* note 224, at 6.

*B. Hire Patent Attorneys With Backgrounds in
Pharmaceuticals or Medicine*

The FDA has made it completely clear that it does not “have the expertise to review patent information,” which is why the FDA needs to hire patent attorneys with a background in pharmaceuticals or medicine.²³⁶ Having a small staff of patent attorneys with medical or scientific backgrounds “would confer other benefits on FDA.”²³⁷ The attorneys could assist with legal interpretations of “other complicated scientific issues that have regulatory and legal implications, such as the . . . biosimilars legislation or difficult scientific/regulatory issues like some bioequivalence determinations.”²³⁸ Furthermore, FDA patent attorneys could “work with the Patent Office on the patent term restoration program, which was also included in the Hatch-Waxman Act, allowing the FDA to engage in more robust and efficient discussions with the Patent Office on eligibility and regulatory review period determinations.”²³⁹ Having attorneys on staff who are experienced in patent law and have a thorough understanding of the scientific and medical realms would allow the FDA to react more quickly to unexpected and complicated patent issues that arise.²⁴⁰

The FDA’s legal department could begin small with four or five patent attorneys and make adjustments in the future as needed. The median salary for an attorney employed by the United States Government is \$87,008.²⁴¹ Assuming the FDA is able to employ six patent attorneys and pay each of them a median salary, they would

²³⁶ *Id.* Malkin and Wasson “concede that the 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 . . . this analysis would not be beyond the skills of the competent patent attorneys hired by the FDA.” *Id.*

²³⁷ *Id.* at 7.

²³⁸ *Id.*

²³⁹ *Id.*

²⁴⁰ FDA: Ministerial Role, *supra* note 224, at 7.

²⁴¹ See Pay Scale: Attorney, Government Salary (Feb. 6, 2013), available at http://www.payscale.com/research/US/Job=Attorney,_Government/Salary.

need to come up with an additional \$522,048 per year (\$43,504 per month) in order to fund the legal department.²⁴²

VII. FDA COUNTERARGUMENTS

The FDA might make several counterarguments against adopting the above suggestions; however, senior attorneys Malkin and Wasson, as well as Justice Sotomayor, provide several compelling counterarguments to the FDA taking a “hands-off” approach.

A. *The Scope and Validity of Patents Belong With the Courts*

The FDA has argued that expanding its role will be extensive and that it will not be able to accomplish the task due to its lack of experience.²⁴³ However, Malkin and Wasson highlight how the FDA has some experience in determining difficult and complex issues, “for example, responding to FTC’s call to clarify types of patents appropriately listed in the Orange Book.”²⁴⁴ The FDA is already familiar with the “hallmarks and characteristics” of various pharmaceutical patents, and it is not unreasonable to ask the FDA to perform a more thorough job in determining whether a patent that has been submitted for publication meets the FDA’s criteria.²⁴⁵ The FDA has mentioned that it would rather focus on ensuring that drugs are safe and effective for the American public and let drug manufacturers sort out their differences that arise from paragraph IV.²⁴⁶ However, if the FDA would take a more hands on approach and review NDA applications for accuracy, it may very well cut down on litigation and solve part of the problem.

Furthermore, the FDA’s previous contention that “disputes relating to the scope and validity of patents . . . belong with the

²⁴² *Id.*

²⁴³ FDA: Ministerial Role, *supra* note 224, at 7.

²⁴⁴ *Id.* In this particular situation the “FDA made a fine-grained determination that patents claiming active ingredients, formulations, methods of use, products-by-process and polymorphs could be listed in the Orange Book, while patents claiming metabolites, packaging, intermediates and processing could not be listed in the Orange Book.” *Id.*

²⁴⁵ *Id.*

²⁴⁶ *Id.*

courts, given the court's experience, expertise and authority in complex patent matters," may be dead in the water, given Justice Sotomayor's concurring opinion urging Congress and the FDA to take further action.²⁴⁷ Prior to the Supreme Court's decision in *Caraco*, the District Courts and the Federal Circuits, "ratified FDA's position," that they "lack expertise to weigh in on patent issues."²⁴⁸ However, in *Caraco*, Sotomayor specifically criticizes the FDA's guidance, referring to it as "remarkably opaque;" she also mentions how the FDA's approach towards reviewing use codes was part of the reason why *Caraco* went all the way up to the Supreme Court.²⁴⁹ Hopefully the FDA will recognize the Supreme Court's criticisms and take to heart what the Court and Malkin and Wasson have suggested.

B. The FDA's Patent Decisions Would Lead to Increased Litigation Against the Agency

Finally, the FDA may attempt to argue, "FDA's patent decisions would inevitably lead to increased litigation against the agency."²⁵⁰ Malkin and Wasson highlight that while this may be true in the short run, "avoiding litigation should not be a guiding principle for sound regulatory policy."²⁵¹ Simply put, the FDA cannot refrain from making substantive decisions just because one of the decisions could potentially end up in litigation.²⁵² Not to mention, if the FDA hires several patent attorneys, they would be able to effectively handle any lawsuit brought against the agency. The FDA might also argue that "there is no guarantee that a more robust patent review procedure

²⁴⁷ *Id.*

²⁴⁸ FDA: Ministerial Role, *supra* note 224, at 7. "[I]t is . . . true that these courts have found FDA's position to be reasonable, . . . these courts do not appear to mandate that the FDA maintain this policy, especially in light of the circumstances where it is not working or it causes a delay in the availability of generic products." *Id.*

²⁴⁹ See *supra* notes 209–10.

²⁵⁰ FDA: Ministerial Role, *supra* note 224, at 7.

²⁵¹ *Id.* The FDA is in the "business of making substantive decisions: each could potentially end up in litigation." *Id.* The FDA "would be paralyzed if it did not act due to fear of litigation." *Id.*

²⁵² *Id.*

would lead to facilitated generic entry.”²⁵³ However, it appears that a more substantive and robust review procedure would have “facilitated generic entry” in the case of *Caraco*.²⁵⁴ If a more proactive FDA would have made the decision that the “listed method-of-use patent did not claim a use for which the generic applicant submitted the application, the generic applicant would have been allowed to maintain its statement under subsection viii and would not have been subject to . . . unnecessary litigation.”²⁵⁵

VIII. RECENT FDA AND CONGRESSIONAL DEVELOPMENTS

In the past, the FDA has criticized the idea of taking a “more hands on approach” when it comes to increasing its substantive level of review of drug patents. Currently, “A Generic Drug User Fee Act is on the way, to enable the U.S. Food and Drug Administration to levy a user fee of around \$100,000 on each generic drug application filed for approval.”²⁵⁶ As of now, there is no fee for filing an ANDA with the FDA.²⁵⁷ According to estimates made by Infrastructure Development Finance Corporation (IDFC Securities),²⁵⁸ once Congress passes the act, it will generate an “additional \$229 million per annum from generic [drug manufacturers].”²⁵⁹ Of the \$229 million, “30% is likely to come from the processing of ANDA’s and drug master files [license to make bulk drugs], and the rest from its inspection of various facilities.”²⁶⁰ Other sources have mentioned

²⁵³ *Id.*

²⁵⁴ *Id.*

²⁵⁵ FDA: Ministerial Role, *supra* note 224, at 7.

²⁵⁶ *U.S. to Charge Fee on Generic Drug Sale Application*, BUSINESS STANDARD (June 21, 2012), available at http://www.business-standard.com/article/companies/us-to-charge-fee-on-generic-drug-sale-application-112062100065_1.html [hereinafter Fee’s on Generic Drug Sale Applications].

²⁵⁷ *Id.*

²⁵⁸ IDFC Securities limited is a subsidiary of Infrastructure Development Finance Corporation and “provides corporate finance and institutional securities services.” *Company Overview of IDFC Securities Limited*, BLOOMBERG BUSINESSWEEK (May 26, 2013), available at <http://investing.businessweek.com/research/stocks/private/snapshot.asp?privcapId=35248900>.

²⁵⁹ Fee’s on Generic Drug Sale Applications, *supra* note 256.

²⁶⁰ *Id.*

that these estimates could vary, depending on “the product’s market size.”²⁶¹ The proposed legislation is “expected to give the FDA the additional resources required to improve the review of drug [patents].”²⁶² The additional revenue raised from the passage of this act should give the FDA breathing room to hire additional patent attorneys who will thoroughly review and analyze complex patent issues and situations. Furthermore, the FDA’s legal department will be able to handle any lawsuit filed against the agency that relates to the FDA’s patent decisions. The additional revenue should also make the FDA’s patent review process more effective, as the agency will be able to hire additional members that will be tasked with reviewing drug applications to make sure they comply with the statutory requirements.

The recent development of a “Generic Drug User Fee Act” is extremely significant, and it is in everyone’s interest to get the legislation passed as soon as possible, as a “significant number of Indian companies are targeting various generic launches in the U.S., in the wake of expiring patents.”²⁶³ Indian drug companies play a major role in the U.S. market, and make up around ten percent of the U.S. pharmaceutical market.²⁶⁴ It is extremely important for Congress to quickly pass the Generic Drug User Fee Act, so that the FDA does not miss out on the potential for major increases in its revenue from the filing of ANDA applications on behalf of Indian pharmaceutical companies.²⁶⁵

IX. CONCLUSION

The United States Supreme Court decision in *Caraco* was a landmark decision in the pharmaceutical industry, especially for generic drug manufacturers like Caraco. The unanimous decision by the Court made it clear that generic manufacturers may bring a

²⁶¹ *Id.*

²⁶² *Id.* “Currently, it takes the regulator an average of 30 months to review an application; it aims to reduce the review time to 10 months by 2017.” *Id.*

²⁶³ *Id.* “Sales by Indian companies make up around 10 percent of the U.S. market.” *Id.* Indian drug companies file around 1,000 generic applications in the U.S. market every year. *Id.*

²⁶⁴ Fee’s on Generic Drug Sale Applications, *supra* note 256.

²⁶⁵ *Id.*

counterclaim to compel brand name manufacturers to either correct or delete overbroad method-of-use codes. The Court's ruling closed a longstanding loophole that has been exploited by brand name manufacturers since the late 1990's. However, Justice Sotomayor made it readily apparent that the Court's decision neither addressed all questions nor fixed all the problems with the counterclaim provision. The FDA to this day takes a "hands-off" approach when it comes to the substantive review of method-of-use codes submitted by brand name drug manufacturers for publication in the Orange Book.

In order to solve many of the lingering issues, the 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 that do not comply with FDA requirements. Furthermore, the FDA should create a separate legal department and hire several patent attorneys with backgrounds in science to grapple with the more complicated patent issues that arise. The FDA can no longer argue that U.S. courts support its "hands-off" level of review approach, as Sotomayor criticizes their current approach and urges the FDA to make major changes. After the *Caraco* decision, it appears that both the FDA and Congress are working together to provide for major changes regarding the FDA's review of drug patents. Congress will likely pass a "Generic Drug User Fee Act," which will allow the FDA to charge generic manufacturers up to \$100,000 per ANDA application. It is estimated that the new act will generate upwards of \$200 million dollars per year in revenue for the FDA, which should cover its costs for patent attorneys, and greatly increase the ANDA approval rate. It seems that both Congress and the FDA have heard the cries from the Supreme Court, especially those of Justice Sotomayor, and are working to develop a solution as quickly as possible.