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Ge Lei J.D.

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# COUNTERCLAIM? NOT A REAL FIX TO PREVENT PATENT USE CODE ABUSE

*Ge Lei\**

## Introduction

“Despite the FDA request, the innovator companies have every incentive to submit the broadest possible narratives with their PUC [Patent Use Code] requests in order to reduce the possibility of carve-out ANDA [Abbreviated New Drug Application] approvals. . . . We anticipate that several [brand-name] companies will extract significant EPS [earning per share] and NPV [net present value] upside from utilization of [such] PUC (Patent Use Code) narrative strategies.”

—Morgan Stanley Research Europe.<sup>1</sup>

The Hatch-Waxman Act (“Hatch-Waxman”) aims to provide affordable healthcare by “mak[ing] available more low cost generic drugs.”<sup>2</sup> To expedite the entry of generic drugs onto the market, Hatch-Waxman provides two ways for a generic applicant to obtain FDA approval. A generic may submit a Section VIII statement, asserting that it seeks to market a drug for a use outside the scope of a brand’s method of use patents.<sup>3</sup> Alternatively, the generic may file a Paragraph IV certification (technically considered an act of infringe-

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1. Morgan Stanley Research Europe, *Pharmaceuticals: Potential Selective Upside for Industry post Prandin Ruling* 2, FDALAWBLAWG.NET (Sep. 1, 2010), <http://www.fdalawblog.net/files/morgan-stanley-rpt---puc-decision.pdf>.

2. H.R. REP. NO. 98-857, pt. 1, at 14 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2647; *See also* *In re Barr Labs., Inc.*, 930 F.2d 72, 76 (D.C. Cir. 1991) (Hatch-Waxman is “to get generic drugs into the hands of patients at reasonable prices – fast.” There is no doubt that Hatch-Waxman has been a great success. Before its passage, generic drugs accounted for only about 12% of all prescriptions in the United States. Today, by contrast, the number stands at 75% and domestic sales of generic drugs average more than \$50 billion per year. Since a generic version of a drug is 76% less than the brand price, generic version’s availability directly leads to more savings for the consumers. Moreover, the price of a particular drug would tremendously drop as more generics enter the market.).

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

ment) to challenge the validity or enforceability of the brand's patents.<sup>4</sup> A Section VIII statement appeals to generic applicants because, if approved, generic applicants will receive immediate FDA approval without being forced to resort to a court proceeding.<sup>5</sup>

A Section VIII statement is vulnerable to brand companies' abuse by listing broader use code. The FDA requires every New Drug Application ("NDA") holder to submit a patent use code corresponding with its method-of-use patents for a drug.<sup>6</sup> To prevent approval of Section VIII statements, brand companies have described their method-of-use patent as being broader than it actually is.<sup>7</sup> In this event, a generic applicant's proposed Section VIII statement is denied for overlapping the brand company's description of its method-of-use patent, or in other words, its "use code."<sup>8</sup> Under current law, the FDA accepts a brand company's submitted use code without question.<sup>9</sup>

A generic company may employ a counterclaim to force a brand company to correct an inaccurate use code.<sup>10</sup> However, this counterclaim option is not sufficient to fix broad listing abuse. A generic is left only with Paragraph IV certification if a use code is overbroad, which automatically leads to costly and prolonged litigation.<sup>11</sup> Even if a counterclaim succeeds, the generic's 180-day exclusivity is forfeited once it changes a Paragraph IV certification to a Section VIII statement.<sup>12</sup> Such action could, therefore, result in other generics freely utilizing the first generic's achievement. On the other hand, if

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4. See 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (2012). (The FDA has long required that every generic applicant use either a section viii statement or a paragraph IV certification, but not both.)

5. Purepac Pharm. Co. v. Thompson, 354 F.3d 877, 880 (D.C. Cir. 2004).

6. See 21 CFR § 314.53(c)(2)(ii)(P)(3) (2011).

7. See Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S, 132 S. Ct. 1670 (2012).

8. See 68 Fed.Reg. 36682, 36683 (2003).

9. *Applications for FDA Approval to Market a New Drug*, 68 Fed. Reg. 36676, 36682 (June 18, 2003) (The FDA had repetitively said that it lacked both the expertise and resources to review patents.).

10. See Caraco Pharm. Laboratories, Ltd., 132 S. Ct. at 1676 (The U.S. Supreme Court recently held in Caraco v. Novo Nordisk that a generic company could use the counterclaim provision to force a brand company correcting its broad use code.).

11. *Id.* at 1688-89.

12. 21 U.S.C. § 355(j)(5)(D)(i)(III) ("[T]he first applicant amends or withdraws the certification for all of the patents with respect to which that applicant submits a certification qualifying the applicant for the 180-day exclusivity period").

a brand company does not file suit, a counterclaim is unavailable.<sup>13</sup> This predicament reflects the fact that patent use code abuse cannot be solved through the availability of a counterclaim.

This note proffers a two-layer solution. The first layer is administrative, imposing on the FDA a duty to clarify use code regulation and to conduct use code review proceedings. The second layer is judicial, creating a cause of action to penalize brand manufacturers that intentionally submit overbroad use codes. Part I of this article will provide an overview of Hatch-Waxman, focusing on Section VII statements and the lack of an effective remedy to correct overbroad use codes. Part II of this article will discuss in detail the two-layer proposal that strives to resolve use code abuse. Part III will address the potential criticisms of the given proposal and endeavor to provide further support for the arguments made.

## I. Benefits and Loopholes in the Hatch-Waxman Act

Prior to the passage of Hatch-Waxman, generic drugs faced significant difficulty when entering the market. Hatch-Waxman has proved its success in inducing further development of pioneer drugs and bringing low cost generic drugs to consumers.<sup>14</sup> Under the current law, a generic company has two routes to market its generic drug when a brand's patents are unexpired—by utilizing Paragraph IV certification or a Section VIII statement. However, brand companies have developed a maneuver to impede Section VIII statements by listing overbroad use codes. Although the United States Supreme Court bolstered the counterclaim provision in attempts to correct overbroad use codes, further reform is needed.<sup>15</sup>

### A. Hatch-Waxman: Facilitating Entry of Generics

Congress passed the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman),<sup>16</sup> with the primary objective being to “strike a balance between two conflicting policy interests: (1) inducing pioneering research and development of new drugs, and (2) enabling competitors to bring low-cost, generic copies of

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13. See *Caraco Pharm. Laboratories, Ltd.*, 132 S. Ct. at 1688-89.

14. See FDA, *Greater Access to Generic Drugs* (Jan. 2006).

15. See *Caraco Pharm. Laboratories, Ltd.*, 132 S. Ct. at 1688-89.

16. Pub. L. No. 98-417, 98 Stat. 1585.

those drugs to market.”<sup>17</sup> Before Hatch-Waxman, pharmaceutical fields were unbalanced.

### 1. The Hatch-Waxman Act of 1984: Emergence of the Generic Pharmaceutical Industry

Pharmaceutical scales were unbalanced prior to Hatch-Waxman. The FDA required that generic manufacturers conduct full clinical trials to satisfy the safety and efficacy requirements already established by pioneer drug applicants.<sup>18</sup> This requirement posed a formidable barrier to generic manufacturers.<sup>19</sup> Moreover, such clinical studies were considered an act of infringement,<sup>20</sup> thereby forcing generic manufacturers to wait until the patents on a new drug expired before beginning the lengthy process of seeking FDA approval. In effect, brand companies enjoyed an extended term for their drug patents at the expense of the consuming public.<sup>21</sup>

Hatch-Waxman “effectively created the modern generic pharmaceutical industry.”<sup>22</sup> By filing an Abbreviated New Drug Application (ANDA), Hatch-Waxman allows a generic manufacturer to rely on clinical studies performed by the innovative drug manufacturer rather than conducting its own studies.<sup>23</sup> Further, generic companies are no

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17. *Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278, 1282 (Fed. Cir. 2008).

18. *Id.*

19. *Id.* at 53-54 (“The cost of research and development of a new drug, including the FDA approval process, can range from between \$250 to over \$600 million dollars; the time required to test a drug and obtain FDA approval is on average nine years.”).

20. *Roche Products, Inc. v. Bolar Pharm. Co.Inc.*, 733 F.2d 858, 863 (Fed. Cir. 1984) (Holding that using patented ingredient to perform tests necessary for it to obtain approval of the FDA was an act of infringement and not experimental because of its commercial purpose. Roche was superseded by Hatch-Waxman, which created an experimental use exception as stated in *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348 (Fed. Cir. 2003).).

21. Matthew Avery, *Continuing Abuse of the Hatch-Waxman Act by Pharmaceutical Patent Holders and the Failure of the 2003 Amendments*, 60 HASTING L. J. 171, 231 (2008).

22. See Avery, *supra* note 21, at 175.

23. H.R. Rep. No. 98-857, Pt. II, at 5. (The exception to infringement was created by the addition of section 271(e)(1) to the Patent Act. 35 U.S.C. § 271(e)(1). The statute states in relevant part: It shall not be an act of infringement to make, use, offer to sell, or sell within the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products. The courts generally have followed the

longer required to demonstrate a drug's safety and efficacy to the FDA in order to obtain approval.<sup>24</sup> Rather, generic companies must prove only that the generic version is bioequivalent<sup>25</sup> to the brand-name drug.<sup>26</sup> In making such changes to the pharmaceutical industry, “[t]he Hatch-Waxman scheme ensure[d] the quality of generic drugs, simplifie[d] the generic approval process, eliminate[d] duplicative research costs associated with clinical trials, and accelerate[d] consumer access to affordable drugs.”<sup>27</sup>

## 2. FDA Approval Process

To obtain FDA approval to market a new drug, a manufacturer must submit a New Drug Application (“NDA”).<sup>28</sup> The NDA is required to provide enough basic information to allow the FDA to determine the drug's possibility to enter the market.<sup>29</sup> According to Hatch-Waxman, NDA filings must list all patents that claim a new drug or a method using the drug.<sup>30</sup> Once an NDA is approved, a drug

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interpretation of this statute. *In Intermedics, Inc. v. Ventritex, Inc.*, 755 F. Supp. 1269 (N.D. Cal. 1991).).

24. 21 U.S.C. § 355(j)(2)(A)(iv) (2012).

25. Generic Pharmaceutical Association, *Bioequivalence: Key Points*, GPHA ONLINE.ORG, <http://www.gphaonline.org/issues/bioequivalence> (last visited Jan. 2, 2013) (“Bioequivalence means that the active ingredient in a generic medicine is absorbed into the body at the same rate and amount as in the brand-name product. This ensures that the generic delivers the same therapeutic effect as the brand counterpart and can be safely substituted with the brand product.”).

26. *See* *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676 (1990); *Merck KGAA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 196 n.1 (2005) (citing 21 U.S.C. § 355(j)(2)(A)(ii), (iv), and 21 U.S.C. §355(j)(8)(B)).

27. *See* *Avery*, *supra* note 21, at 176.

28. 21 U.S.C. §355(b) (2012).

29. FDA, *New Drug Application (NDA) Introduction*, FDA.GOV, <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/NewDrugApplicationNDA/default.htm> (last visited Jan. 2, 2013) (The FDA's decision regards “whether the drug is safe and effective in its proposed use(s), and whether the benefits of the drug outweigh the risks[;] whether the drug's proposed labeling (package insert) is appropriate, and what it should contain[; and] whether the methods used in manufacturing the drug and the controls used to maintain the drug's quality are adequate to preserve the drug's identity, strength, quality and purity.” “The documentation required in an NDA is supposed to tell the drug's whole story, including what happened during the clinical tests, what the ingredients of the drug are, the results of the animal studies, how the drug behaves in the body, and how it is manufactured, processed and packaged.”).

30. *See* 21 U.S.C. § 355 (b)(1) (“file with the [NDA] the patent number and the expiration date of any patent which claims the drug for which the applicant

is listed along with its associated “patent information” in the FDA publication “Approved Products With Therapeutic Equivalence Evaluations,” more commonly known as the “Orange Book.”<sup>31</sup>

With respect to each patent listed in the Orange Book for a pioneer drug, an ANDA applicant seeking to copy that drug must make one of the following four certifications in its ANDA in order to obtain FDA approval: (1) that no patent information for the pioneer drug has been submitted to the FDA (a “paragraph I certification”); (2) that the patent has expired (a “paragraph II certification”); (3) that the patent will expire on a specific date (a “paragraph III certification”); or (4) that the patent “is invalid or will not be infringed by the manufacture, use, or sale of the new drug” for which the ANDA applicant seeks approval (a “paragraph IV certification”).<sup>32</sup>

Paragraph IV certification is treated as an artificial act of patent infringement, allowing a brand company to sue a Paragraph IV filer.<sup>33</sup> Upon receiving notice of a Paragraph IV filing, the brand company has forty-five (45) days to sue the Paragraph IV filer for patent infringement.<sup>34</sup> If the brand company does not sue, the FDA may proceed to approve the ANDA.<sup>35</sup> However, if the brand company does file suit, the FDA may not approve the ANDA until the earlier of the expiration of the patent, the resolution of the suit, or thirty (30) months after the brand company’s receipt of notice (commonly referred as the “30 month stay”).<sup>36</sup>

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submitted the [NDA] or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.”) *See also* 21 C.F.R. § 314.53(c)(1)-(2) (2012) (The FDA regulations in turn stipulate a more exhaustive list of “patent information” that must also be submitted with the NDA.).

31. *Purepac Pharm. Co. v. Thompson*, 354 F.3d 877, 880 (D.C. Cir. 2004); *See also* 21 U.S.C. § 355(j)(7)(A)(i)(I) and (ii) (2012).

32. 21 U.S.C. § 355(j)(2)(A)(vii)(I)-(IV) (This framework seeks to facilitate the resolution of disputes over the validity and scope of patents that protect the brand company’s drug.).

33. 35 U.S.C. § 271(e)(2) and (4) (The statute requires that all paragraph IV filers provide notice to the challenged NDA and patent holder, including a detailed factual and legal analysis explanation.).

34. 21 U.S.C. § 355(j)(5)(B)(iii).

35. *Id.*

36. *Id.*

Paragraph IV certification imposes on the generic company huge litigation costs and a significant delay of time.<sup>37</sup> In recognition of this burden, the first generic company that files a Paragraph IV certification for a drug (“first filer”) receives 180 days of market exclusivity.<sup>38</sup> During this period of 180 days of market exclusivity, generic drug prices typically remain near the original price of the brand drug,<sup>39</sup> making this period highly profitable for the recipient generic manufacturer.<sup>40</sup>

## B. The Section VIII Statement Loophole

A Section VIII statement provides the mechanism for a generic to identify unpatented uses so that a generic drug may quickly enter the market. By listing broader use code, brand companies could preclude generic companies’ Section VIII statements. Although the counterclaim provision<sup>41</sup> may help deter the problem, it cannot remedy the injury. If a Section VIII statement is barred by a brand company’s overbroad use code, a generic company is forced to proceed with Paragraph IV certification, which is both costly and time-consuming.

### 1. Section viii Statements

In addition to Paragraph IV certification, Hatch-Waxman also offers an alternative means of obtaining approval of ANDA – a “Section VIII” statement.<sup>42</sup> A Section VIII statement applies when an

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37. C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1560 (2006).

38. 35 U.S.C. § 355(j)(5)(B)(iii)(IV)(iv) (2012).

39. For example, the first generic Prozac (Flouxetine) was sold at \$1.91 per capsule during the 180-day exclusivity period, but the generic price dropped to \$0.32 per capsule when that period ended and multiple generic versions became available. See Benjamin G. Druss et al., *Listening to Generic Prozac: Winners, Losers, and Sideliners*, 23 HEALTH AFF. 210, 214 (2004).

40. C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1560 (2006) (“An important feature of the regime is a large incentive to litigate the validity and scope of an innovator’s patents, a ‘bounty’ worth hundreds of millions of dollars for a major drug.”).

41. Congress authorized an ANDA applicant defending a patent infringement action to assert a counterclaim seeking an order requiring an NDA holder to correct or delete the patent information submitted by the holder. See 21 U.S.C. 355(j)(5)(C)(ii)(I) (2012).

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

ANDA applicant seeks to market a drug for FDA-approved uses other than the one covered by the NDA's patents.<sup>43</sup> Thus, a Section VIII statement allows a generic company to propose a label that "carves out" the still-patented method of uses while avoiding possible Paragraph IV litigation.<sup>44</sup> A Section VIII statement is attractive to generic applicants because the FDA may approve a Section VIII application immediately without the automatic 30-month stay required with Paragraph IV certification.<sup>45</sup>

A use code system has been created by the FDA to check Section VIII statements.<sup>46</sup> The FDA defines its role in listing patents in the Orange Book as purely "ministerial."<sup>47</sup> In fact, the FDA has explicitly stated that it does not want to review patents.<sup>48</sup> To skirt review of patent listings for the Orange Book, the FDA created an indirect system to evaluate Section VIII statements. First, an NDA holder submits a "use code narrative," or simply a "use code" describing the patent claims (e.g. "to relieve stuffy nose" or "to treat headache").<sup>49</sup> Rather than checking the submitted use code, the FDA accepts the use code as it is.<sup>50</sup> Second, the FDA compares an ANDA label to the submitted use code.<sup>51</sup> The FDA approves an ANDA only if: (1) the label carve-out is as safe and effective as the brand label (bioequivalent), and (2) if there is no overlap between the ANDA label and the use code.<sup>52</sup> Ensuring the accuracy of use codes is essential to this system's operation.

Ideally, a brand company submits patent use code that accurately reflects the scope of its associated method of use patent(s). A generic company then submits an ANDA with a Section VIII statement, claiming a use not covered by the brand's patents. If the FDA determines that the ANDA drug is bioequivalent to the brand drug,

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43. *See Id.*; *See also* Purepac Pharm. Co. v. Thompson, 354 F.3d 877, 880 (D.C. Cir. 2004).

44. *See* 21 CFR § 314.94(a)(8)(iv) (2011).

45. Purepac Pharm. Co. v. Thompson, 354 F.3d 877, 880 (D.C. Cir. 2004).

46. Applications for FDA Approval to Market a New Drug, 68 Fed. Reg. 36,676, 36,683 (June 18, 2003).

47. *Id.*

48. *Id.*

49. *See* 21 CFR § 314.53(c)(2)(ii)(P)(3) (2011).

50. *See* Applications for FDA Approval to Market a New Drug, 68 Fed. Reg. 36,676, 36,683 (June 18, 2003).

51. *Id.*

52. *See* 21 CFR § 314.127(a)(7) (2002).

and the ANDA label is just as safe and effective as the brand label, the ANDA will immediately be approved without any delay. However, this scenario is rarely the case.

## 2. Section viii Loophole Exemplified in *Caraco v. Novo Nordisk*

The FDA's refusal to supervise its use code system has opened the door to abuse by brand companies. Such abuse was exemplified in *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*.<sup>53</sup> Caraco dealt with an NDA held by Novo for repaglinide, a diabetes drug sold under the brand name PRANDIN.<sup>54</sup> Novo's original patent on the repaglinide compound expired in 2009.<sup>55</sup> The FDA has approved PRANDIN for three uses: (1) repaglinide by itself (i.e., monotherapy); (2) repaglinide in combination with metformin; and (3) repaglinide in combination with thiazolidinediones ("TZDs").<sup>56</sup> Novo's subsequent method-of-use patent (the '358 patent, expiring in 2018) claimed only the second use,<sup>57</sup> and its use code accurately described the '358 patent as covering only the "use of repaglinide in combination with metformin to lower blood glucose."<sup>58</sup>

In February 2005, Caraco filed an ANDA for a generic version of repaglinide,<sup>59</sup> and a Paragraph IV certification for non-infringement of the '358 patent,<sup>60</sup> prompting Novo to sue for patent infringement.<sup>61</sup> Based on the FDA's recommendation, Caraco then amended its ANDA to replace the Paragraph IV certification with a Section VIII statement, which clarified the fact that Caraco did not seek approval for the repaglinide-metformin combination therapy.<sup>62</sup> The FDA indicated that Caraco's Section VIII request was appropriate.<sup>63</sup> Approval of this request would have allowed Caraco to receive immediate approval for repaglinide's approved unpatented uses.<sup>64</sup>

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53. *Caraco Pharm. Laboratories, Ltd.*, 132 S. Ct. at 1670.

54. *Id.* at 1678.

55. *Id.*

56. *Id.*

57. *Id.*

58. *Id.*

59. *Id.*

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

61. *Id.*

62. *Id.*

63. *Id.*

64. *Id.*

However, following the submission of Caraco's Section VIII statement, Novo amended its use code description to "[a] method for improving glycemic control in adults with type 2 diabetes" – a description broad enough to encompass both the combination use claimed by the '358 patent and the unpatented uses.<sup>65</sup> Since the Novo's amended use code overlapped with Caraco's ANDA, the FDA reversed course and disallowed Caraco's labeling carve-out.<sup>66</sup> Caraco, thus, filed a counterclaim<sup>67</sup> to force Novo to amend its use code description.<sup>68</sup> This case made its way to the United States Supreme Court, with a unanimous decision that a generic company may employ the counterclaim provision to force a brand company to correct its inaccurate use code.<sup>69</sup>

### **3. Counterclaim Often Cannot Fix Overbroad Use Code Abuse**

The Supreme Court's decision is not the end of use code abuse. Importantly, Justice Sotomayor wrote a concurring opinion highlighting the incapability of the counterclaim provision to "restore the smooth working of a statutory scheme."<sup>70</sup> Justice Sotomayor stated, "I first underscore that the counterclaim can only lessen the difficulties created by an overly broad use code; it cannot fix them."<sup>71</sup> Regardless of whether a brand manufacturer brings suit, generics lose under the existing counterclaim approach.

#### ***a. Brand Company Sues Generic Company***

Let's take a look at the Section VIII process in the aftermath of the Supreme Court's opinion. If a brand company were to submit an overly-broad patent use code, covering all indications, even unpatented ones, a generic company's only option would be to file an ANDA with a Paragraph IV certification. The ANDA would overlap with the use code, rendering a Section VIII statement inapplicable.

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65. *Id.*

66. *Id.*

67. Like the original Hatch-Waxman Scheme for paragraph IV litigation, the counterclaim provision assigns the FDA no role in deciding the scope or validity of patents, and instead channels such disputes to courts.

68. Caraco Pharm. Laboratories, Ltd., 132 S. Ct. at 1679.

69. *Id.* at 1688.

70. *Id.*

71. Caraco Pharm. Laboratories, Ltd., 132 S. Ct. at 1688-89. (Sotomayor, J concurring).

Then, the generic company would have to submit a notice letter to the NDA holder and patent owner, which is required by statute. If the brand company were to file a lawsuit against the generic company within forty-five (45) days after receipt of notice, the generic company's ANDA would be automatically stayed for thirty (30) months. Following the Supreme Court's decision, the generic company could assert a counterclaim requiring the brand company to correct the overly broad use code. Litigation would then proceed with motions, discovery, dispositive motions, or even a trial, which is undoubtedly a very costly and time-consuming process. Assuming the generic company wins the counterclaim and the brand company is ordered to correct the overly-broad use code, the generic company could then switch its Paragraph IV certification to a Section VIII statement.

Forcing the brand company to correct its broad use code and allowing the generic company to assert a Section VIII statement seems like the most desirable result. However, it is difficult to imagine that any generic company would be willing to spend the time and effort pursuing this route since the generic company's 180-day exclusivity period will most likely be forfeited at the moment the company switches its Paragraph IV certification to a Section VIII statement. The 180-day exclusivity period is the award granted to the first filer that voluntarily subjects itself to possible patent infringement litigation. However, the 180-day exclusivity period will be forfeited if the first filer withdraws its Paragraph IV certification.<sup>72</sup> Once the first filer's 180-day exclusivity is forfeited, any other generic company may submit a Section VIII statement and launch immediately without litigation.

***b. Brand Company does not File Suit***

A worse scenario would arise if the brand company were to fail to file suit against the generic company after receiving notice of the generic company's ANDA filing with Paragraph IV certification. Hypothetically, the generic company could file a declaratory judgment action pursuant to a "civil action to obtain patent certainty" ("CAPC") provision of the Hatch-Waxman Act.<sup>73</sup> Under this provi-

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72. 21 U.S.C. § 355(j)(5)(D)(i)(III) (2012) ("[T]he first applicant amends or withdraws the certification for all of the patents with respect to which that applicant submits a certification qualifying the applicant for the 180-day exclusivity period.").

73. 21 U.S.C. § 355(j)(5)(C)(i) (2012).

sion, if a NDA holder fails to sue a Paragraph IV ANDA filer within forty-five (45) days, the ANDA filer may, in accordance with the Declaratory Judgment Act,<sup>74</sup> bring a declaratory judgment action regarding the invalidity or non-infringement of the relevant Orange Book listed patents.<sup>75</sup>

However, a declaratory judgment action could hardly achieve the generic company's goal here because there would be no way for the generic company to assert a counterclaim for correction of the patent use code. The text of the counterclaim notes that a counterclaim is available when a patent owner or a NDA holder sues an ANDA applicant in the first place.<sup>76</sup> Here, since the brand company failed to bring a patent infringement action against the generic company, the counterclaim would be rendered inapplicable.

Consequently, the FDA could approve the generic company's ANDA without prejudice to infringement claims.<sup>77</sup> However, it is unlikely that such action would be a true success for the generic company. First, the patent owner might assert an infringement claim when the ADNA applicant produces or markets the generic drug.<sup>78</sup> Second, the generic company, by proceeding with a Paragraph IV certification, would have to market its generic drug with "a label materially identical to the brand manufacturer's label."<sup>79</sup> Such requirements would place the generic company in an unfavorable position because the generic company could be placed in a position of violat-

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74. 28 U.S.C. § 2201(a) (2012).

75. 21 U.S.C. § 355(j)(5)(C)(i)(I) (2012).

76. 21 U.S.C. § 355(j)(5)(C)(ii)(I) (2012) ("[I]f an owner of the patent or the holder of the approved application . . . brings a patent infringement action against the applicant, the applicant may assert a counterclaim seeking an order requiring the holder to correct or delete the patent information.").

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

78. *Id.*

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

ing inducement infringement.<sup>80</sup> Therefore, a more favorable solution is necessary.<sup>81</sup>

## II. The Proposal

In order to eliminate NDA holders' deliberately overbroad listing, this proposal presents a two-level scheme. One is at the administrative level by adding clarity to the FDA's use code regulation and by creating an *ex parte* patent use code review proceeding. The goal of this review proceeding is to compel NDA holders to correct inaccurate use code quickly, enabling generic drugs to enter the market sooner. The second level is judicial. Following a judicial finding of overbreadth, the use code claimant would be able to file a cause of action to invalidate the errantly listed patent, along with all other patents listed for that drug, upon a showing of materiality and intent to deceive. The combined effect of these procedures would carry out

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80. Transcript of Oral Argument at 24, *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670 (2012), 2011 WL 6020517 at \*24 (U.S. 2012) ("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."); *See also* Brief for the United States as Amicus Curiae Supporting Petitioners at 32, *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670 (2012), 2011 WL 3919720 at \*32 (U.S. 2011) ("So long as the [new drug application (NDA)] holder's patent covers some approved method of using the approved drug, the proposed labeling will be infringing.").

81. Three possible existing solutions could not provide much help either. First, precedents demonstrate that holding the FDA accountable under the Administrative Procedure Act ("APA") for overlooking broader use code is not promising. In *aaiPharma Inc. v. Thompson*, 296 F.3d 227, 241 (4th Cir. 2002), the FDA's failure to list a third party's patent in Orange Book for an approved drug when such drug's NDA holder who had such listing power refused to do so did not violate the APA. The Fourth Circuit performed a two-step analysis by concluding that, the Congress did not clearly express its intent on the FDA's role in assessing Orange Book listings. Then, it was reasonable for the FDA to interpret the statute as requiring it to ensure that a list of patents must be filed, but not burdening it to insure that all patents that could pertain the an NDA are submitted. Second, in 2002, Congress failed to pass a bill that would create an independent cause of action for generic applicants to challenge overbroad descriptions of a patent. Third, in the shadow of the FDA regulation, antitrust courts are disinclined to hold brand companies' listing broader use code anticompetitive. *See more* Stacey L. Dogan & Mark A. Lemley, *Antitrust Law and Regulatory Gaming*, 87 *TEX. L. REV.* 685, 695 (2009) ("[A]ntitrust courts seem increasingly willing to permit private anticompetitive acts that occur in the shadow of regulation, relying on regulators to perform the traditional antitrust function of protecting competition and sometimes turning a blind eye even when regulators cannot or do not do so.").

the goals of Hatch-Waxman and reduce the incidence of use code abuse.

### A. *Ex Parte* FDA Review of Patent Use Codes

The proposal set forth herein heightens specificity of patent use codes. Justice Sotomayor concluded in *Caraco*, that the “FDA’s guidance as to what is required of brand manufacturers in use codes [is] remarkably opaque.”<sup>82</sup> Presently, an NDA must submit a description or indication of each approved method of use for each method-of-use patent.<sup>83</sup> However, the content of a proper description or indication is unspecified. Thus, more clarity must be added. Under the current law, it will take several litigation years to correct an incorrect use code through a counterclaim provision, if such action is even possible. By contrast, the proposed *ex parte* patent use code review provides an efficient method to challenge inaccurate use code listings. The mission of this review proceeding is to allow generic drugs to quickly enter the market where they are currently precluded by an overbroad use code. The hallmark of this proceeding therefore is expedience.

#### 1. Adding Clarity to the FDA’s Use Code Regulation

Use codes should be limited to descriptions of approved methods of use. An indication entails the disease or condition to be treated<sup>84</sup> and, therefore, may cover more than the drug’s listed patents allow.<sup>85</sup> In contrast, the description of method of use is a brief summary of what an approved method-of-use patent actually covers, including specific terms and identifications.

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82. *Caraco Pharm. Laboratories, Ltd.*, 132 S. Ct. at 1689 (Sotomayor, J., concurring).

83. See 21 C.F.R. § 314.53 (c)(2)(R)(ii)(P) (2012).

84. See 67 Fed. Reg. 65448 (codified at 21 C.F.R. 314) (Oct. 24, 2002).

85. For example, in *Caraco*, at first, Novo’s use code described its patent as covering only the “use of Repaglinide in combination with Metformin to lower blood glucose,” which was not overbroad. Later the FDA asked Novo change its label to “[r]eplace all the separate indications” with the following sentence ‘Prandin is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.’” Subsequently, Novo amended its use code description to “[a] method for improving glycemic control in adults with type 2 diabetes.” Novo contended that its amendment “complies with all applicable regulations and directly tracks the FDA-mandated indication.” See *more* Brief for Respondent at 14, *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670 (2012), 2011 WL 4957382 at \*14 (2011).

For instance, drug A is used for curing a headache and has three FDA-approved methods of use: (1) administering A only; (2) administering A with drug B; and (3) administering A with drug C. A brand drug's patents cover only the second use—administering A with drug B. If the use code only allows descriptions of approved methods of use for the brand drug, such use code is constrained to “administering A with drug B.” However, if indication is permissible, such use code might be “curing headaches,” which is overly broad compared to what its patents claim. Further explanations or indications can be submitted as supplemental information separate from use codes by the NDA holder. This supplemental information is provided to aid the FDA and the competitors to fully appreciate the drug's use.

A sufficient application of changed clarity is illustrated in *Caraco*.<sup>86</sup> Novo's use code states a method for “improving glycemic control in adults with type 2 diabetes.”<sup>87</sup> This use code would not satisfy the proposed regulation because it is an indication, the disease or condition to be treated, rather than what the method-of-use patent covers, use of “repaglinide in combination with metformin.”<sup>88</sup> Limiting use codes to descriptions of method of use would only make it more difficult to submit overbroad use codes. Therefore, further abuse would be restricted in the first step.

## 2. Creation of an FDA Review Unit

A review unit within the FDA is necessary to ensure that use codes are co-extensive with their associated patents. The FDA holds the position that it lacks the resources and expertise to review the substance of patents and that patent issues should be resolved by private litigants in court.<sup>89</sup> This stance disproportionately harms ANDA

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

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

88. *Id.*

89. See *Legislative and Regulatory Responses to the FTC study on Barriers to Entry in the Pharmaceutical Marketplace: Hearing Before S. Comm. On the Judiciary*, 108th Cong. 6-7 (2003) (statement of Daniel Troy, FDA Chief Counsel, “Aa]s we understand the statute, it requires us to publish patent information on approved of the NDA, thus making the agency's role ministerial, and courts have so held. I think that one of the signal features of Hatch-Waxman is that generic and innovator firms are supposed to resolve their disputes about patent listings and

applicants and overemphasizes obstacles in regulating fidelity between use codes and their associated patents.

An FDA review unit should be modeled after the United States Patent and Trademark Office (“USPTO”) Central Review Unit (“the CRU”). Like the CRU,<sup>90</sup> members of a FDA review unit would require significant experience in patent review, which would help compensate for the FDA’s lack of expertise. The FDA review unit’s duties would begin with reviewing assertion by third parties of use code overbreadth and determine whether full review is warranted. Where such review decisions are made, the review unit would then review a NDA holder’s brief and the third party’s response, if any, together with the issued patents’ information. Comparing the listed use code with all approved methods of use for a drug might provide additional assistance. After reviewing the documents, the review unit would issue a judgment concluding whether the listed use code is accurate. The initial stage of such review unit could very well be comprised of three to five individuals who have former patent review experience.

Review proceedings detailed *infra* would be structured to minimize burdens placed upon the FDA. The review proceeding would be an *ex parte* proceeding, so that the FDA review unit’s involvement would be limited to only two rounds—the initial review decision and a final judgment. Unlike litigation or patent reexamination, the evidence presented for FDA review would be highly constrained, including only the use code and associated patents. The review unit’s responsibility would only arise if a third party asserts that the listed use code is overly- broad or inaccurate.

Moreover, patent use code is simply a description of what the method of using a drug is; it resembles an abstract of a patent. For instance, U-1238 is “treatment of anemia due to chronic kidney disease,” which is quite simple and clear.<sup>91</sup> By comparing all the FDA

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about patents in general in private litigation in the courts, where the expertise really resides with respect to patent questions.”).

90. Remy Yucel, *Central Reexamination Unit (CRU) 2011 in Review*, available at [http://www.fr.com/files/Uploads/Documents/Seattle\\_Post-Grant\\_Seminar-Fish\\_Richardson-CRU\\_Presentation\\_by\\_Irem\\_Yucel.pdf](http://www.fr.com/files/Uploads/Documents/Seattle_Post-Grant_Seminar-Fish_Richardson-CRU_Presentation_by_Irem_Yucel.pdf), (last visited on July 25, 2012) (CRU constitutes “reexamination specialists with several years of primary examiner experience,” “currently at 87 (14 chemical, 19 mechanical and 54 electrical),” “16 technical support staff,” “7 supervisory reexamination specialists and 1 supervisor for the TSS.”).

91. See generally FDA, *Orange Book: Approved Drugs Products with Therapeutic Equivalence Evaluations, Patent Use Codes*, available at <http://www>.

approved uses of a particular drug with the NDA holder's method patent on the particular drug, it would appear more apparent whether the NDA holder's submitted use code accurately reflects what the method patent covers.

Therefore, the proposed FDA review unit, with further organizational refinement expected, should be created to conduct review on patent use code. Additionally, cooperation with the patent examiner<sup>92</sup> who handles the prosecution of the method patent at dispute would also be necessary to further advance the review proceedings and help alleviate the burden on the FDA.

### 3. Patent Use Code Review Proceedings

FDA use code review would share procedural similarities to *ex parte* reexamination at the USPTO.<sup>93</sup> To initiate use code review, a third party would submit a request to the FDA review unit, along with a notice of service upon the relevant NDA holder. In an expedited proceeding, the review unit would determine (1) whether to instigate use code proceedings, and (2) whether the challenged use code is inaccurate. Also, the appeals process would be limited in order to balance the interests of the parties with the need for expediency. See figure 1 for illustrations.

#### *a. Instigating Review*

Unlike patent reexamination, a party who requests a patent use code review proceeding would be a party whose Section VIII statement was barred by an overbroad use code.<sup>94</sup> Every interested party would not be allowed to challenge patent use codes due to the concern for limiting resources. This use code review would be designed to remedy a real and imminent injury, not a possible or unforeseeable harm. Resources would be better utilized if the battle were to be

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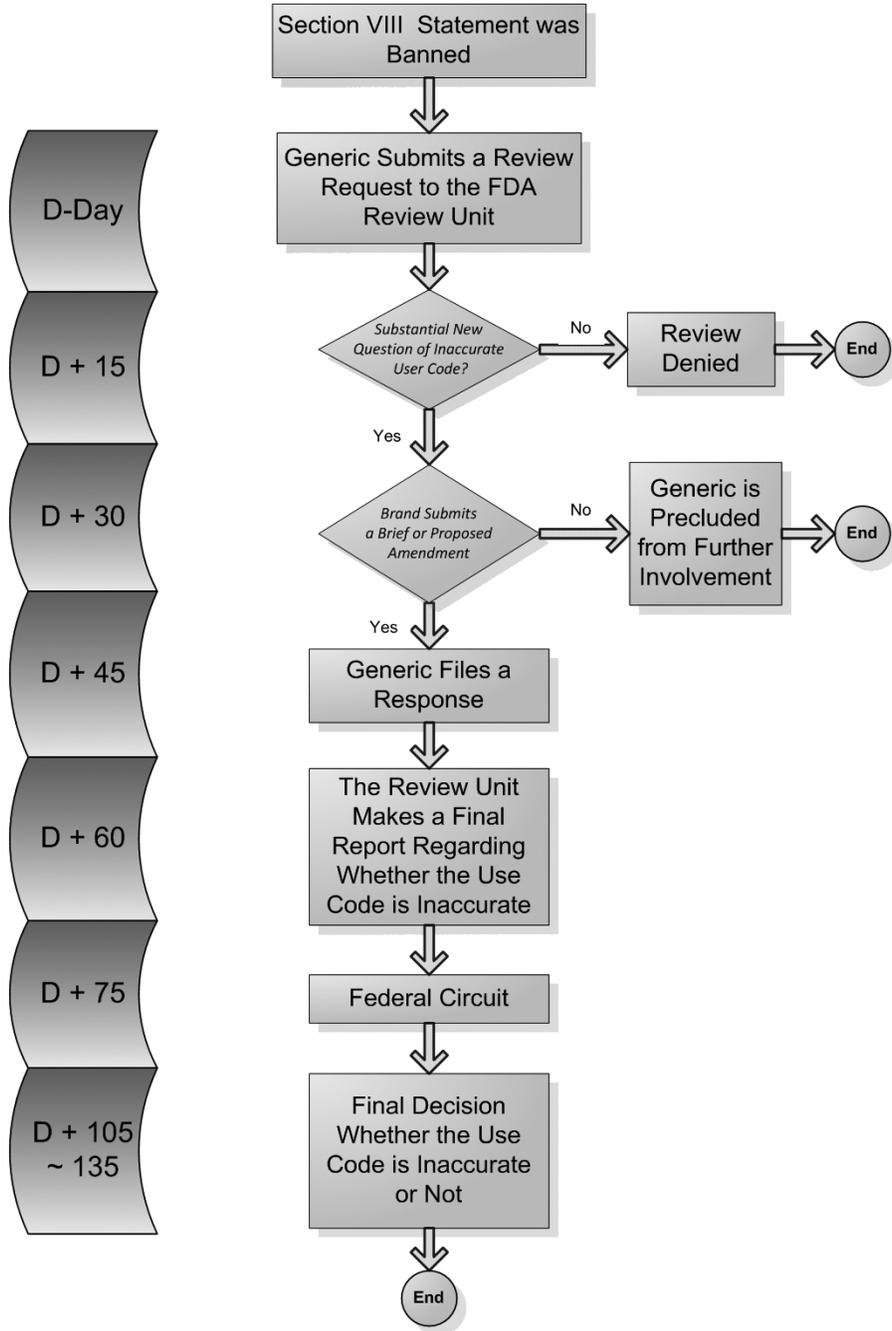
[accessdata.fda.gov/scripts/cder/ob/docs/patternsall.cfm?utm\\_campaign=Google2&utm\\_source=fdaSearch&utm\\_medium=website&utm\\_term=usecode&utm\\_content=1](http://accessdata.fda.gov/scripts/cder/ob/docs/patternsall.cfm?utm_campaign=Google2&utm_source=fdaSearch&utm_medium=website&utm_term=usecode&utm_content=1), (lastly visited on July 25, 2012).

92. The FDA already works with the patent office to determine patent term extensions, where FDA approval delays issuance of a patent. So there are instances of coordination between the agencies.

93. See generally USPTO, *2209 Ex Parte Reexamination [R-7]*, USPTO .GOV, <http://www.uspto.gov/web/offices/pac/mpep/s2209.html> (last visited Jan. 2, 2013).

94. See 35 U.S.C. § 311(a) ("A person who is not the owner of a patent may file with the Office a petition to institute an inter partes review of the patent.").

**Figure 1.**  
***Ex Parte* FDA Review of Patent Use Codes**



fought to resolve an existing problem. Additionally, if every interested party can instigate use code review, too high of a burden may be placed on the review unit, which would run contrary to the review proceeding's intention.

The threshold standard for initiating such use code review would be relatively low. Such patent use code review would adopt the patent *ex parte* reexamination standard, "substantial new question of patentability," with adjustment to substantial questions of inaccurate or broader use code.<sup>95</sup> For instance, an allegation would be sufficient if it stated that there are three FDA-approved methods of use for drug X, that the patents of drug X's NDA holder cover only the second FDA-approved method of use, and that the NDA holder's use code is so broad that it encompasses two or all three of the FDA-approved methods of use. The goal of this review proceeding would be to obtain the correct use code quickly by filing a review request. Making the threshold for review initiation too high would contradict this goal.

#### ***b. Use Code Review Procedure***

Adopting *ex parte* patent reexamination rather than *inter partes* patent reexamination would be optimal for a use code review procedure's character and expediency. The procedure need only require one round of communications among a third party, the FDA, and the NDA holder in order to reach a final conclusion. The necessary evidence for a code review proceeding would be limited, unlike *inter partes* patent reexamination, where substantive patent review and prior art search are involved. Existing briefs, the disputed patent, information associated with the patent, listed use codes, and all FDA-approved uses for the drug would constitute the required evidence.

Substantially similar to *ex parte* patent reexamination, with exception to the time limit, the general framework of such a use code review procedure would run as follows. A third party would submit a request to the FDA review unit, along with service upon the relevant NDA holder. The review unit would then make the decision whether or not to proceed with review within fifteen (15) days. If the review is approved and the NDA holder decides to take action, the NDA holder would be allowed to submit a brief in opposition or a proposed amendment within fifteen (15) days after receiving the review unit's notification. If no action is taken by the NDA holder, the third party

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95. See 35 U.S.C. § 303(a).

would be precluded from any further engagement in the review proceeding. However, if a brief is submitted by the NDA holder, the third party would be allotted fifteen (15) days to file a response, at which point the third party's substantive involvement would terminate. After reviewing all evidence, the review unit would then make a final report within fifteen (15) days and determine whether the use code is overbroad.

A primary difference between use code review and patent *ex parte* reexamination is that a third party or a NDA holder may appeal an adverse decision directly to the Federal Circuit.<sup>96</sup> Such an appeal decision would have to be made within fifteen (15) days after the review unit issues its final office action. The sole reason for such a review proceeding would be to force NDA holders to correct inaccurate or broad use code so that generic companies can proceed with a Section VIII statement sooner than later. Since time and uniformity is crucial to generic companies and consumers, an appeal would need to go directly to the Federal Circuit rather than United States District Court so that the time frame surrounding the completion of litigation may be shortened. The evidence that would be considered during an appeal would be restrained to what has already been considered by the review unit. No supplemental evidence would be necessary for the Federal Circuit to make a decision regarding whether or not the use code is overbroad.<sup>97</sup>

Moreover, the timeline for patent use code review proceedings should be pre-arranged and should consist of a relatively short timeframe. Considering each party's fifteen (15) day limit, it would be preferable for such a use code review proceeding to be performed within two months. Since appeals to the Federal Circuit would likely be imminent, an expedited appeals process of one to two months would be preferable.

### *c. Judicial Proceeding for Use Code Abuse*

Although FDA review would provide a mechanism to correct errant use codes, a judicial proceeding is still necessary to incentivize NDA holders to accurately list their use codes in the initial applica-

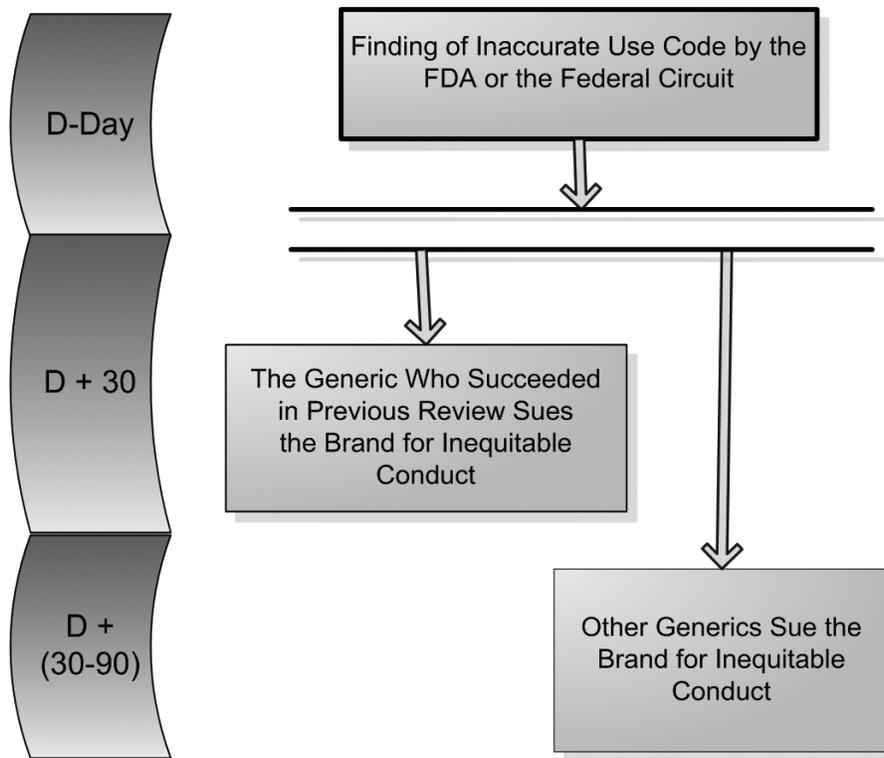
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96. See USPTO, *supra* note 93.

97. Although the idea of use code review is borrowed from patent reexamination, the estoppel effect that applied in patent reexamination shall not be applied here. Estoppel concern might thwart generic companies pursuing review proceeding, which also runs against the objective of this review proceeding.

tion. Such a proceeding would be available to a generic company that succeeds in an FDA review. The judicial proceeding would be modeled after patent law’s defense of inequitable conduct, where upon a showing of materiality and intent to deceive, a patent covered by an overbroad or inaccurate use code may be invalidated. See figure 2 for illustrations.

**Figure 2.**  
**Judicial Proceeding for Use Code Abuse**



**1. General Framework**

The proposed judicial proceeding would be created to eradicate patent use code abuse. A generic company that brought a previous use code review proceeding would have a thirty day window to file a cause of action against the NDA holder who listed overbroad or inaccurate use code in a United States District Court after the FDA (if there is no appeal, in which case the time is calculated from the time the NDA holder failed to appeal) or the Federal Circuit’s holding.

After the thirty day window, all other generic companies would have up to sixty days to file such judicial proceedings. Like other actions, the generic company should properly allege jurisdiction and venue. Jurisdiction would be available to all United States District Courts because such litigation would be tied to patent law and Hatch-Waxman. Comparable to similar litigation, motions, dispositive motions, discovery, and trial would be available, with details omitted here. The aggrieved party would also have the right to appeal any decision rendered at trial to the Federal Circuit.

The crux of this judicial proceeding is that the court may find inequitable conduct on a NDA holder's action, which would in turn invalidate all patents the NDA holder has for a drug. "Inequitable conduct is an equitable defense to patent infringement that, if proved, bars enforcement of a patent."<sup>98</sup> It evolved from the Doctrine of Unclean Hands to deter egregious misconduct.<sup>99</sup> Although normally used as a defense, inequitable conduct would be used more like a cause of action here. Adopting the inequitable conduct theory from the patent law,<sup>100</sup> intent and materiality must be shown by clear and convincing evidence.<sup>101</sup> Since inequitable conduct is a drastic action,<sup>102</sup> the standard for finding inequitable conduct should be strict.

The materiality element would only be satisfied by a "but for" materiality. This means that but for a NDA holder's affirmative misrepresentation of material information to the FDA or the NDA holder's submission of materially false information to the FDA, a generic company's Section VIII statement would not have been permitted. The NDA holder's attestation when submitting the use code could constitute affirmative misrepresentation of material information. Any brief or response the NDA holder provides during the patent use code review proceeding could also be held against the NDA holder. Listing an overbroad or inaccurate use code itself would be considered submission of materially false information to the FDA.

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98. *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1285 (Fed. Cir. 2011).

99. *Id.*

100. *See Id.* at 1287 ("In line with this wider scope and stronger remedy, inequitable conduct came to require a finding of both intent to deceive and materiality.").

101. *Id.*

102. *See id.* at 1288 ("the taint of a finding of inequitable conduct can spread from a single patent to render unenforceable other related patents and applications in the same technology family.").

Although the “sliding scale” is abrogated in patent law, strictly following patent law here would contradict the goal of this judicial proceeding because discovery of direct evidence of intent would be too difficult.<sup>103</sup> Thus, in order to eradicate use code abuse, a sliding scale should be permissible when intent may be inferred and/or the strength of material evidence is high. Discovery could facilitate the evidence of intent by finding internal correspondence or hidden documents. Further, a NDA holder’s attesting could demonstrate intent. In fact, similar to Novo in *Caraco*,<sup>104</sup> a NDA holder’s strategic broadening of its use code could be the most reasonable inference of intent.

Although this proposed inequitable conduct action is borrowed from the patent system, pleading shall not be as strict as pleadings required in the patent system.<sup>105</sup> A finding by the FDA or the Federal Circuit that a NDA holder’s listed use code is broad or inaccurate would be generally sufficient for the pleading requirement. In addition, intent and materiality should be pleaded by generic companies. Setting the pleading standard low would allow generic companies to bring a judicial proceeding rather than preventing them from justified litigation. Such a system would promote the goal of eliminating the patent use code abuse problem so that more affordable drugs can better benefit US consumers.

## 2. 180 Exclusivity

As with Paragraph IV certifications, the first generic company to file the proposed judicial proceeding would be entitled to 180 days of market exclusivity.<sup>106</sup> This would be an award granted to a generic company who is willing to spend the time and money to pursue the patent use code review and judicial litigation. In order to eradicate

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103. *See id.* at 1290.

104. *Caraco Pharm. Labs, Ltd.*, 132 S. Ct. at 1689.

105. *See Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1326 (Fed. Cir. 2009) (“[I]nequitable conduct . . . must be pled with particularity.”).

106. *See generally* Colleen Kelly, *The Balance Between Innovation and Competition: The Hatch-Waxman Act, the 2003 Amendments, and Beyond*, 66 Food & Drug L. J. 417, 424 (2011). (A first Paragraph IV certification filer will receive 180 days of market exclusivity- as an award because the first filer is willing to challenge the validity and scope of a NDA holder’s patents. This 180-day exclusivity is very valuable for generic companies. Multiple generic companies that file their Paragraph IV certifications on the same day can share the 180 days exclusivity.).

use code abuse, this award would be a large incentive to generic companies.

One of two results would occur as a result of litigation between the brand company and the generic company when dealing with a Paragraph IV certification—either the brand company's patents would be invalidated, or the generic company's manufacturing and/or use of the generic drug would not infringe the brand company's patents. If the latter outcome were to result, a judgment between only the two parties would exist. However, a judgment from the proposed judicial proceeding would have a broader effect in that all generic companies would be able to enter the market if inequitable conduct were to be found. Thus, a 180-day exclusivity period could be reasonably applied.

The 180 days of market exclusivity would only apply if a generic company were to succeed in a previous FDA review, were to be the first to file for the judicial proceeding, and were to obtain a favorable judgment that invalidates a NDA holder's patents by finding inequitable conduct. A Paragraph IV certification, as well as the proposed judicial proceeding, would invalidate a NDA holder's patents or render the patents unenforceable. This would mean that a generic company that brought either proceeding could utilize the same labeling of its generic drug as that of the brand drug.<sup>107</sup> By not conflicting with the Paragraph IV certification's 180-day exclusivity period, any generic company that either files for a Paragraph IV certification first or brings this proposed judicial action first can receive 180 days exclusivity.

For instance, generic company A is the first generic company to file for Paragraph IV certification, on April 15, 2013. Generic company B is the first generic company to bring judicial action, on April 20, 2013. Only company A would be entitled to 180-day exclusivity. However, if company A's judgment is unfavorable, A's exclusivity would be forfeited, with company B being able to obtain the 180-day exclusivity period if B succeeds in its judicial proceeding. If company B was the first generic company to file for Paragraph IV certification and company A was the second, the same mechanism applies. Another scenario would be if both company A and company B were

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107. As for section viii statement, a generic version drug's label is different from brand drug because the generic version is claiming a not-patents-covered way of using the drug.

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to file their respective proceedings on the same day. If this were to happen, A and B could share the 180-day exclusivity.

### *c. Advantages of the Proposed Regulatory Scheme*

The advantages of the proposed regulatory scheme can be illustrated by three separate perspectives: an equity perspective, a fidelity perspective, and an efficiency perspective. By implementing this proposed scheme, brand companies would think twice before utilizing overbroad patent use code to delay generic companies' section viii statement. Facilitating a quicker entrance of generic drugs into the market also fulfills the goal of Hatch-Waxman. Moreover, a more equal division of each party's responsibility and more efficient use of the federal government's resources would propel the pharmaceutical arena toward a more productive field.

#### **1. An Equity Perspective**

Under the current regulatory scheme, brand companies' intentional listing of overbroad or inaccurate patent use code would automatically render generic companies' Section VIII statement meaningless. Although a counterclaim might lessen the problem to some extent, it would not solve the problem entirely. Forcing generic companies to file Paragraph IV certification and to proceed with litigation due to overbroad use code listings is a flagrant maneuver to manipulate the system. Since evenhandedness is destroyed by brand companies in this scenario, change is needed from an equity perspective.

The approach proposed in this article favors generic companies. However, it aims to achieve an equal playing field for both parties. First, an administrative review would only be necessary in the case that a brand company lists overbroad or inaccurate use code. Additionally a judicial proceeding would be needless unless the brand company acted in bad faith, and thus, subjected itself to inequitable conduct. The typical result from an FDA review would be to ensure that use codes are commensurate with their associated method of use patents. This regulatory scheme is designed to curb brand companies' bad behaviors so that more equity shall be given to generic companies.

## 2. Efficiency Perspective

Time is extremely crucial for generic companies. Generic drugs may occupy 80-90% of the market, often within months of entering the marketplace.<sup>108</sup> The sooner generic drugs are available to consumers, the sooner more savings may accrue for the public.<sup>109</sup> Therefore, an enticing selling point of this regulatory scheme is that it tends to quickly resolve disputes. An initial administrative review could be completed within two months, and an appeal, if any, could potentially conclude within one to two months. Thus, if the proposed procedure were to be enacted, a generic company could potentially market its generic drugs within two to four months of bringing such action. In contrast to the counterclaim provision, which typically takes two to three years to complete, the proposed approach would largely expedite the litigation process as well as the time frame for bringing more affordable drugs to consumers.

The proposed judicial proceeding would not interfere with a Section VIII statement because its availability is tied to a generic company's favorable administrative review decision. Once the generic company obtains a favorable decision, it could launch its generic versions through a Section VIII statement. Therefore, the proposed judicial proceeding would serve to impose more serious punishments upon a brand company that acted in bad faith without delaying the entrance of generic drugs into the marketplace.

## 3. FDA Review Coupled with Judicial Enforcement Fulfills the Mandate of Hatch Waxman

The goal of Hatch-Waxman is to provide US consumers affordable healthcare by "mak[ing] available more low cost generic

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108. For example, the generic form of Prozac (fluoxetine) claimed approximately 65% of the market within a month of generic entry, 80% by the end of the first generic competitor's 180-day exclusivity period, and leveled out at almost 90% after a year of generic competition. See Benjamin G. Bruss et al., *Listening to Generic Prozac: Winners, Losers, and Sideliners*, 23 HEALTH AFF. 210, 214 (2004).

109. For example, the introduction of generic ramipril in mid-2008 immediately diminished the brand-name manufacturer's market share, resulting in large cost savings for consumers. See Press Release, King Pharmaceuticals, King Pharmaceuticals Reports Year-End and Fourth-Quarter 2008 Financial (Feb. 26, 2009) (Company's nearly \$200 million revenue loss in Q4 2008 as compared to Q4 2007 was "primarily due to the market entry of generic substitute for" brand-name ramipril.).

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drugs.”<sup>110</sup> Compared to a Paragraph IV certification, a Section VIII statement is created as an expedited way for generic companies to obtain ANDA approvals. By listing broader use code, brand companies could entirely prevent Section VIII statements, delaying generic drugs’ availability. Evisceration of the Section VIII process is particularly inappropriate, given the mechanism’s crucial function in the larger regulatory scheme. Limiting the availability of the process is inconsistent with Hatch-Waxman.

This proposed *ex parte* FDA use code review intends to ensure that listed use codes are commensurate with their associated patents, so that a Section VIII statement will not be barred. Allowing a Section VIII statement proceeds smoothly rather than being rendered useless and fulfills the mandate of Hatch-Waxman by facilitating the process by which generic drugs enter the market.

### III. Criticisms of Proposed Regulation

Critics may object to this proposed regulation for the potential burden it could impose upon the FDA. However, by minimizing the FDA’s involvement during the proposed use code review proceeding, such burdens could be eliminated. Unlike the failed “Greater Access to Affordable Pharmaceuticals Act of 2002,” which created an independent cause of action,<sup>111</sup> the judicial proceeding proposed in this article would be based solely upon a prior use codes review and would be limited to adjudication based on inequitable conduct. Moreover, although the proposed regulation benefits generic companies over brand companies, the regulation is specifically tailored toward enforcing the objectives of Hatch-Waxman as well as preventing actual injury to consumers by allowing quicker access to more affordable generic drugs.

#### A. *Ex Parte* Use Code Review Will Not Overburden the FDA

The FDA has repeatedly stated that it lacks both resources and expertise to review patents and that patent disputes shall be decided by the courts.<sup>112</sup> One of the FDA’s principal concerns could, there-

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110. See H.R. Rep. No. 98-857, *supra* note 2.

111. S. 812, 107th Cong., Greater Access to Affordable Pharmaceutical Act of 2002, 2d Sess., § 103(a)(1), p. 7 (2002).

112. *Applications for FDA Approval to Market a New Drug*, 68 Fed. Reg. 36676, 36683 (June 18, 2003).

fore, be that use code review proceeding will create too large of a burden. However, if the proposed regulation were to be enacted, such a concern from the FDA could be minimized on several fronts.

First, once clarity is added to the FDA's use code regulation, further review would be largely unnecessary. Moving away from indication (which is a broad concept encompassing the disease or condition to be treated) and toward descriptions of method-of-use patents (which would only encompass the summary or abstract of the patent) would lower incidents of use code controversies. Theoretically, indication can be broader than what a patent covers. By eliminating indication, brand companies would hesitate before submitting broader use code because the use code would not comply with the FDA regulation.

Second, by creating a review unit with patent experts and fees associated with use code review, the necessary costs for a review's operation would be offset. Therefore, the concern for a lack of resources could be alleviated.

Third, barriers to instigate use code review would further reduce involvement of the FDA. It is likely that one of the FDA's primary concerns is that the FDA has to review every listed use code. The proposal at hand would eliminate this concern, as it would not require the FDA to check every use code. With the proposed regulation, the FDA review unit's involvement would arise only when a third party requests a review proceeding. A further limit on the review proceeding that exists with the present proposal is that the third party's section viii statement must have been barred in order for a third party to be eligible to initiate a use code review. This means that the petitioner must have first filed a section viii statement. These requirements would significantly reduce the overall number of review proceedings, and thus lessen the FDA's concern over tedious and inefficient review.

Moreover, procedural aspects inherent in the review proceeding would minimize burdens on the FDA. The review proceeding at hand would be limited to an *ex parte* review. The proposed review unit's involvement would therefore contain, at most, two parts: issuing a review determination and/or reporting a final judgment. Unlike patent reexamination, the evidence that would be subject to review would be constrained to the use code and associated patents.

## **B. Proposed Judicial Proceeding is Different from an Independent Action**

In 2002, Congress failed to pass the “Greater Access to Affordable Pharmaceuticals Act of 2002” which would have allowed generic companies to bring civil actions to “delete” or “correct” the information filed by brand companies, thereby allowing generic applicants to challenge overbroad descriptions of a patent.<sup>113</sup> Some commentators envision the bill’s failure as attributable to Congress’s hostility toward the creation of an independent action.<sup>114</sup> Because the proposed judicial proceeding contains an independent cause of action, critics may object to the proposal herein as duplicative of the failed bill. However, the proposed scheme significantly differs from the failed proposal of an independent cause of action.

Unlike the independent cause of action proposed in the “Greater Access to Affordable Pharmaceuticals Act of 2002,” the proposed judicial proceeding at hand is based on the result of a previous use code review. A party who is eligible to bring such judicial proceeding is substantially restrained, and not every interested party is allowed to bring suit. Only a party who has previously filed a patent use code review proceeding and has succeeded in that review proceeding would be allowed to initiate the proposed judicial proceeding during a 30-day window. Also, other generic companies would only be able to file the proposed judicial proceeding after the party that succeeded in the review chose inaction.

In addition, the proposed judicial proceeding would focus only upon a finding of inequitable conduct, whereas the failed bill’s action aimed to “delete” or “correct” the information filed by brand companies. Unlike an independent cause of action, the proposed judicial action would not have the concern of creating enormous litigation burden on courts.<sup>115</sup> Instead, the extent of the proposed judicial action would be controlled by the frequency of use code review and the success rate of a party who brought the review—the though being that the burden of selective litigation would be outweighed by the benefit of reducing code abuse. Thus, the failed bill would not pro-

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113. S. 812, 107th Cong., 2d Sess., § 103(e)(i).

114. Caraco Pharm. Labs., Ltd., 132 S. Ct. at 1686 (remarks of Sen. Gregg “Probably the most significant issue is the fact that it creates a new cause of action.”) (citing 148 Cong. Rec. 15424 (2002)).

115. *Id.* at 1690 (“Congress rejected the bill, in part over criticism that it would encourage excess litigation.”).

hibit the enactment of the proposed regulation at hand. With its specific advantages of fidelity to the Hatch-Waxman goal, equity to brand innovators and generic manufacturers, and efficiency for injured parties to seek an effective remedy, the proposed regulation would likely receive favorable recognition among members of Congress.

### **C. Use Code Dispute-Resolution Scheme Provides a Meaningful Remedy to Generic Companies**

The proposed patent use code dispute-resolution scheme is deliberately structured to govern inaccurate use code listing and, therefore, may be criticized for being biased toward generic companies. However, employing a two-layer regulation to eradicate use code abuse does not go so far as to become unjustly discriminatory. On the contrary, the proposed scheme serves an important public purpose of preventing the real injury of patent use code abuse.

Patent use code abuse presents a significant burden upon society. If regulation continues as it stands, brand companies are likely to continue to employ the patent use code strategy to stall generics from entering the market.<sup>116</sup> As long as a brand company has a patent covering one approved method of using a drug, the brand company may compose broader use codes that would preclude all generic companies from making unpatented uses for that drug.<sup>117</sup> Unless Congress intervenes to curb this tactic, brand companies will continue to exploit the loophole.

The proposal at hand aims to achieve an equal playing field for both parties. By eliminating patent use code abuse, generic companies can successfully carve out unpatented uses for a drug, just like the objective Hatch-Waxman endeavors to achieve. Under the proposed regulation, additional judicial proceeding would be applicable only when a brand company has acted in bad faith to deceive. Rather than unjustly discriminating against brand companies, this article's proposal serves to remedy injustice caused by the wrongful manipulation of specific brand companies.

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116. See Morgan Stanley Research Europe, *supra* note 1.

117. Brief for Generic Pharmaceutical Association as Amici Curiae Supporting Petitioners, Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S, 2011 WL 3947567 \* 31 (U.S. 2011).

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*COUNTERCLAIM? NOT A REAL FIX*

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## Conclusion

The Supreme Court's recent opinion in *Caraco v. Novo Nordisk* suggests a win for generic companies; however, reality reflects that Paragraph IV counterclaims cannot fix the growing problem of patent use code abuse. To address this concern, a two-layer solution has been proposed. At the administrative level, the FDA should limit use codes to descriptions and establish a review unit to ensure a proper scope surrounding use codes. At the judicial level, an independent cause of action has been set forth that would penalize new drug applicants that intentionally misrepresent the scope of their patent. This proposal remedies the real injury of patent use code abuse and would fulfill Congress's goal of making available more low-cost, generic drugs.