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## Delayed Access to Generic Medicine: A Comment on the Hatch-Waxman Act and the "Approval Bottleneck"

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## Delayed Access to Generic Medicine: A Comment on the Hatch-Waxman Act and the "Approval Bottleneck"

### Cover Page Footnote

I would like to thank Professor George W. Conk for his invaluable guidance, feedback, and support throughout the process. I would also like to thank my fiancée, Sanam, for her support, and patience.

## COMMENT

# DELAYED ACCESS TO GENERIC MEDICINE: A COMMENT ON THE HATCH-WAXMAN ACT AND THE “APPROVAL BOTTLENECK”

Ankur N. Patel\*

*Prescription drug costs can be astronomical. The advent of generic drugs, which sell at substantially lower prices than their brand-name counterparts, can save consumers billions of dollars per year. The Hatch-Waxman Act, which governs the introduction of generic pharmaceuticals into the marketplace, produces an undesired side effect—the “approval bottleneck.” This Comment examines the “approval bottleneck”—a potential roadblock to the generic drug approval process, and comments on attempts to alleviate the problem.*

*This Comment suggests that developments in statutes and case law have made leaps in attempting to alleviate the “approval bottleneck” problem. The Comment evaluates these developments, which include (1) the ability of a subsequent Abbreviated New Drug Application (ANDA) filer to trigger the generic exclusivity period of the first ANDA filer; (2) the forfeiture provisions; (3) declaratory judgments and the relaxed declaratory judgment test; and (4) the rulings on covenants not to sue. Despite these attempts, however, the potential harm to consumers resulting from delayed access to generic medicines remains.*

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#### INTRODUCTION

Prescription drug costs can be daunting to consumers. The advent of generic drugs, which sell at “substantially lower prices than their brand-name counterparts,” can save consumers “tens of billions of dollars per year.”<sup>1</sup> The average price per dose of a generic drug can be drastically less than its brand-name counterpart, especially as more generic competitors enter the market.<sup>2</sup> A generic drug can cost as low as less than ten percent of the price of its brand-name counterpart.<sup>3</sup> Therefore, innovator companies, who develop brand-name drugs, will often try to delay the introduction of generic versions of their brand-name drugs. As a brief example, consider the following real-life situation. Sepracor, an innovator pharmaceutical

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1. Richard G. Frank, *The Ongoing Regulation of Generic Drugs*, 357 NEW ENG. J. MED. 1993, 1993 (2007); see FDA, *What Are Generic Drugs?*, <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/ucm144456.htm> (last visited Oct. 19, 2009) (“According to the Congressional Budget Office, generic drugs save consumers an estimated \$8 to \$10 billion a year at retail pharmacies. Even more billions are saved when hospitals use generics.”).

2. See Frank, *supra* note 1, at 1995.

3. See *id.*

company, holds the six patents for the brand-name drug Xopenex.<sup>4</sup> In accordance with the Hatch-Waxman Act,<sup>5</sup> which encourages generic pharmaceutical companies to bring cheaper generic versions of brand-name drugs to market, Breath, a generic pharmaceutical company, filed an Abbreviated New Drug Application (ANDA) in June 2005 to market a generic version of Xopenex.<sup>6</sup> As the first Paragraph IV ANDA filer, Breath is entitled to a 180-day exclusivity period during which no other generic version of Xopenex may enter the marketplace.<sup>7</sup> Sepracor brought a patent infringement suit against Breath for all six patents in October 2005.<sup>8</sup> However, Sepracor and Breath settled their lawsuit in early 2008, before a decision had been made as to the validity of Sepracor's patents or infringement by Breath.<sup>9</sup> The settlement allows Breath to enter the market with a generic version of Xopenex in August 2012.<sup>10</sup> In the meantime, in July 2005, Dey also filed an ANDA to market a generic version of Xopenex.<sup>11</sup> Sepracor, however, sued Dey on only five out of the six patents and provided a covenant not to sue in reference to the remaining patent.<sup>12</sup> Dey, as the second generic ANDA filer, cannot have its generic version of Xopenex approved until the exhaustion of the 180-day exclusivity provided to Breath.<sup>13</sup> However, due to the settlement, exhaustion of the exclusivity and, therefore, approval of Dey's generic version of Xopenex will not occur until after the launch of Breath's generic version of Xopenex in August 2012.<sup>14</sup> Is Dey stuck? What is the purpose of a covenant not to sue? Even if Dey can manage to overcome the "approval bottleneck," is there any remaining harm to consumers?

This Comment explores the evolution of the law impacting the "approval bottleneck"—including the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA),<sup>15</sup> *Minnesota Mining & Manufacturing*

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4. *See* Dey, L.P. v. Sepracor, Inc., 595 F. Supp. 2d 355, 358 (D. Del. 2009).

5. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended in scattered sections of 15, 21, 35, and 42 U.S.C.).

6. *See* Dey, 595 F. Supp. 2d at 358.

7. *See id.*

8. *See id.*

9. *See id.*

10. *See id.*

11. *See id.*

12. *See id.*

13. *See id.* at 358–59.

14. *See id.* at 359.

15. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (codified as amended in scattered sections of 5, 10, 20, 21, 25, 26, 29, 31, 42, 45, and 48 U.S.C.). The amended provisions from the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) apply to Abbreviated New Drug Applications (ANDAs) filed after December 8, 2003, but only if there was no Paragraph IV certification to the "listed drug" by any other ANDA filer prior to December 8, 2003 (post-MMA ANDAs). *See* Erika Lietzan & David E. Korn, *Issues in the Interpretation of 180-Day Exclusivity*, 62 FOOD & DRUG L.J. 49, 51 (2007); *see also* Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 1102(b)(1), 117 Stat. 2066, 2460 (codified at 21 U.S.C. § 355 note) (Effective Date of 2003 Amendments); *Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, 540 F.3d 1353, 1357 n.2 (Fed.

*Co. v. Barr Laboratories Inc.*'s<sup>16</sup> ruling on subsequent Paragraph IV ANDA filers, *MedImmune, Inc. v. Genentech, Inc.*'s<sup>17</sup> all-the-circumstances test, and *Caraco Pharmaceutical Laboratories, Ltd. v. Forest Laboratories Inc.*'s<sup>18</sup> ruling on covenants not to sue. Furthermore, the Comment examines whether enough has been done to eliminate the harm to consumers—delayed access to lower priced generic drugs—caused by the “approval bottleneck.”

Part I of this Comment provides a comprehensive background on the drug approval process. Part I also demonstrates how the Hatch-Waxman Act's attempt to strike a balance between innovation and low-cost generics can create an “approval bottleneck,” an undesirable side effect of the Act. Part II discusses the evolution of law and subsequent efforts to alleviate the “approval bottleneck.” Part III comments on the current state of affairs and on why the Hatch-Waxman Act still does not provide an ideal solution to overcoming the “approval bottleneck.” Part III then proposes one possible solution to the “approval bottleneck”—an elimination of the 180-day exclusivity. Without the 180-day exclusivity, the mechanism that creates an “approval bottleneck” no longer exists. However, the solution is not ideal because elimination of the 180-day exclusivity eliminates a valuable incentive currently available to generic companies to encourage challenging suspect patents.

### I. DEVELOPING THE “APPROVAL BOTTLENECK”

The Hatch-Waxman Act provides the regulatory framework governing the Food and Drug Administration's (FDA) approval of generic drugs.<sup>19</sup> The Act reflects a balance struck by Congress “between two competing policy interests: (1) inducing pioneering research and development of new drugs and (2) enabling competitors to bring low-cost, generic copies of those drugs to market.”<sup>20</sup> The balance, as discussed in Part I below, is a combination of market exclusivities for innovator companies and an abbreviated process for generic drug approvals. Part I.A provides a comprehensive background on the drug approval process. Part I.B discusses declaratory judgments, how declaratory judgments relate to the

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Cir. 2008) (“[T]he MMA contained a grandfather provision specifying that the amendments do not apply to Paragraph IV ANDAs filed before the date of the enactment of the MMA or to subsequent Paragraph IV ANDAs filed after the enactment of the MMA if the first Paragraph IV ANDA was filed prior to enactment of the MMA.”).

While it may seem trivial to discuss the pre-MMA regime in this Comment, a closer look demonstrates that disputes regarding pre-MMA ANDAs are still finding their way into courts due to the lengthy Hatch-Waxman litigation process. *See, e.g., Janssen*, 540 F.3d 1353; *Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278, 1282 (Fed. Cir. 2008).

16. 289 F.3d 775 (Fed. Cir. 2002).

17. 127 S. Ct. 764 (2007).

18. 527 F.3d 1278.

19. *See Drug Price Competition and Patent Term Restoration Act of 1984*, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended in scattered sections of 15, 21, 35, and 42 U.S.C.).

20. *Andrx Pharm., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1371 (Fed. Cir. 2002).

Hatch-Waxman Act, and the test to determine whether a declaratory judgment action shall proceed. Part I.C explains how the operation of the Hatch-Waxman Act may create an “approval bottleneck.”

### A. Drug Approval Process

Part I.A provides a comprehensive background on the drug approval process. Specifically, Part I.A.1 provides the process by which a novel compound may be approved and enter the marketplace as a brand-name drug. Part I.A.2 discusses the generic drug approval process. Finally, Part I.A.3 discusses the 180-day exclusivity, which is an incentive to generic companies to be the first to seek approval of a generic version of an innovative compound.

#### 1. New Drug Application

An innovator pharmaceutical company seeking to “introduce . . . into interstate commerce any new drug” must obtain FDA approval by submitting a New Drug Application (NDA).<sup>21</sup> The NDA requires an applicant to submit “information regarding the new drug’s safety and efficacy . . . .”<sup>22</sup> The applicant must also include in “the application the patent number . . . of any patent[s] which . . . could reasonably be asserted if a person not licensed by the [patent] owner engaged in the manufacture, use, or sale of the drug.”<sup>23</sup> The FDA lists the patents submitted by the innovator company in the “Orange Book.”<sup>24</sup> Once approved by the FDA,

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21. 21 U.S.C. § 355(a)–(b) (2006); *Caraco*, 527 F.3d at 1282.

22. *Janssen*, 540 F.3d at 1355; see 21 U.S.C. § 355(b)(1).

23. 21 U.S.C. § 355(b)(1); *Janssen*, 540 F.3d at 1355. Patents “are a form of legal protection for intellectual property. Ownership in IP represents a proprietary right in intangible products of the human mind . . . .” JANICE M. MUELLER, AN INTRODUCTION TO PATENT LAW 5 (2d ed. 2006). Patent protection “is necessary to encourage innovation.” JOHN R. THOMAS, PHARMACEUTICAL PATENT LAW 4 (2005). Patents are governed by Title 35 of the United States Code. *Id.* at 5. “Ordinarily, the patent term is set to 20 years from the date the patent application is filed.” *Id.* at 17; see also 35 U.S.C. § 154(a)(2) (2006). For pharmaceutical patents, the Hatch-Waxman Act provides that “the patent term may be extended for a portion of the time lost during clinical testing.” THOMAS, *supra*, at 17. The Act allows the patent holder to restore “to the patent term one-half of the time between” the submission of an Investigational New Drug Application, which allows testing in humans, “and the submission of an NDA, plus the entire period spent by the FDA approving the NDA.” *Id.* at 7–8, 17. However, there are caps to the length of the patent term. *Id.* The maximum term restored may not exceed five years and the remaining patent term after restoration may not exceed fourteen years following FDA approval of the New Drug Application (NDA). *Id.*

24. See *Janssen*, 540 F.3d at 1355. The “Orange Book” is the common name of the publication entitled *Approved Drug Products with Therapeutic Equivalence Evaluations*. FDA, Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations, <http://www.fda.gov/cder/ob/> (last visited Oct. 19, 2009). There are three kinds of patents that may be listed in the Orange Book: (1) compound claims, (2) formulation claims, and (3) method of use or treatment claims. See Richard G. Greco, *Litigating Pharmaceutical Patents Under the Hatch-Waxman Act*, in DEVELOPMENTS IN PHARMACEUTICAL AND BIOTECH PATENT LAW 2008, at 163, 168 (PLI Course Handbook, Sept. 11, 2008).

the drug is known as a “listed drug” (brand-name drug).<sup>25</sup> Tremendous time (generally from ten to fifteen years) and enormous costs (generally from \$500 million to \$2 billion) are required to develop a novel drug and bring it to market.<sup>26</sup> Therefore, innovator pharmaceutical companies are given incentives, in the form of market exclusivity, to take on the endeavor of bringing a novel drug compound to market.<sup>27</sup> Usually, five years of market exclusivity is awarded to the innovator pharmaceutical company for a novel drug.<sup>28</sup> During the market exclusivity period, the FDA will not approve any generic versions of the innovator’s brand-name drug.<sup>29</sup>

## 2. Abbreviated New Drug Application

In order to encourage lower-priced generic versions of listed drugs, the Hatch-Waxman Act provides for an accelerated approval process known as the Abbreviated New Drug Application.<sup>30</sup> Unlike the innovator company, a

25. See *Caraco*, 527 F.3d at 1282; see also 21 U.S.C. § 355(j)(2)(A)(i). “Listed drug” is the more accurate term. However, for the purpose of simplification, in this Comment “brand-name drug” is used synonymously with “listed drug.”

26. See PHARM. RESEARCH AND MFGS. OF AM., DRUG DISCOVERY AND DEVELOPMENT: UNDERSTANDING THE R&D PROCESS 1, 10 (2007), available at <http://www.phrma.org/files/RD%20Brochure%20022307.pdf> (“This whole process takes an average of 10–15 years.”); Christopher P. Adams & Van V. Brantner, *Estimating the Cost of New Drug Development: Is It Really \$802 Million?*, 25 HEALTH AFF. 420, 420 (2006) (“[T]he paper estimated the cost per new drug to be \$868 million. However, our estimates vary from around \$500 million to more than \$2,000 million, depending on the therapy or the developing firm.”); see also Joseph A. DiMasi, Ronald W. Hansen & Henry G. Grabowski, *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151, 180 (2003) (“[W]e estimated that total R&D cost per new drug is US\$ 802 million in 2000 dollars.”). See generally C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553, 1564 (2006) (noting the process “is a lengthy, expensive process, consuming years and many millions of dollars to conduct the necessary clinical trials”).

27. See David Bickart, *The Hatch-Waxman Act*, in DEVELOPMENTS IN PHARMACEUTICAL AND BIOTECH PATENT LAW 2008, at 8-1, 8-82 (PLI Course Handbook, Sept. 11, 2008). An innovator company submitting an application for a drug that is a new chemical entity, “a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been [previously] approved in any . . . [new drug] application,” receives five years of market exclusivity. 21 U.S.C. § 355(j)(5)(F)(ii); see Bickart, *supra*, at 8-81 to 8-85. A company that undertakes new clinical investigations on an existing chemical entity, such as investigations for new dosage forms, new indications, etc., may obtain three years of market exclusivity. See 21 U.S.C. § 355(j)(5)(F)(iii), (iv); Bickart, *supra*, at 8-82, 8-85 to 8-86. An innovator company that develops an orphan drug (used to treat rare diseases) receives seven years of market exclusivity. See 21 U.S.C. § 360cc; Bickart, *supra*, at 8-82, 8-87 to 8-90. “Rare disease” is defined as one that “affects less than 200,000 persons in the United States,” or that “affects more than 200,000 in the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for such disease or condition will be recovered from sales in the United States of such drug.” 21 U.S.C. § 360bb(a)(2). Lastly, if a company that conducts certain studies in children meets certain requirements, it will be rewarded an additional six-month market exclusivity period (Pediatric Exclusivity). See 21 U.S.C. § 355a(b); Bickart, *supra*, at 8-82, 8-90 to 8-94.

28. See *supra* note 27 (discussing market exclusivity for a new chemical entity).

29. See 21 U.S.C. § 355(j)(5)(F); *supra* note 27 and accompanying text.

30. See 21 U.S.C. § 355(j).



generic pharmaceutical company can obtain FDA approval to market a generic drug without having to conduct costly and lengthy clinical trials to prove safety and efficacy of the drug.<sup>31</sup> The generic company can instead rely on the innovator's clinical trial data, which was previously submitted to the FDA with the innovator's NDA.<sup>32</sup> Generic pharmaceutical companies, instead, are only required to show that the generic drug has the same active ingredient as the listed drug and is its bioequivalent.<sup>33</sup>

Even though the ANDA process provides for an accelerated approval of generic drugs, the FDA may not approve any ANDAs until the market exclusivity for the listed drug has expired.<sup>34</sup> Working in conjunction with the market exclusivity of a listed drug are the patents protecting the listed drug.<sup>35</sup> Therefore, even after the market exclusivity of a listed drug has expired, potentially clearing the way for FDA approval of a generic version, the patents covering the listed drug may still be valid and unexpired. Thus, in order for a generic pharmaceutical company to obtain FDA approval, the ANDA must contain a certification as to each patent submitted and listed in the Orange Book, which pertains to the listed drug.<sup>36</sup> The generic company must certify one of the following with respect to each Orange Book listed patent:

(I) no patent information has been filed with the FDA; (II) the patent has expired; (III) the patent will expire on a particular date and approval of the ANDA should be deferred until expiration; or (IV) in the opinion of the ANDA applicant, the patent is invalid or will not be infringed by the manufacture, use, or sale of the generic drug.<sup>37</sup>

These certifications, respectively referred to as Paragraph I, II, III, and IV certifications, will dictate the timing of the ANDA approval by the FDA.<sup>38</sup> Therefore, a generic pharmaceutical company that wishes to market a

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31. See *Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278, 1282 (Fed. Cir. 2008); see also 21 U.S.C. § 355(b), (j).

32. See *Caraco*, 527 F.3d at 1282; see also 21 U.S.C. § 355(j)(2)(A).

33. See *Caraco*, 527 F.3d at 1282; see also 21 U.S.C. § 355(j)(2)(A). “Bioequivalence means the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents . . . becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study.” 21 C.F.R. § 320.1 (2009).

Pharmaceutical equivalents means drug products in identical dosage forms that contain identical amounts of the identical active drug ingredient, i.e., the same salt or ester of the same therapeutic moiety . . . [but] do not necessarily contain the same inactive ingredients; and meet the identical compendial or other applicable standard of identity, strength, quality, and purity, including potency and, where applicable, content uniformity, disintegration times, and/or dissolution rates.

*Id.*

34. See 21 U.S.C. § 355(j)(5)(F).

35. See generally *supra* note 23 (discussing patents, what they are, and the length of patent protection).

36. See 21 U.S.C. § 355(j)(2)(A)(vii); *Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, 540 F.3d 1353, 1355–56 (Fed. Cir. 2008).

37. *Janssen* 540 F.3d at 1356 (citing 21 U.S.C. § 355(j)(2)(A)(vii)).

38. See *id.*

generic version of a listed drug, after expiration of the listed drug's market exclusivity, but before the expiration of Orange Book listed patents covering the listed drug, must include a Paragraph IV certification as to each patent listed but not expired.<sup>39</sup>

Filing an ANDA with a Paragraph IV certification is an act of patent infringement.<sup>40</sup> Therefore the generic drug company filing the ANDA must provide notice to the patentee (patent holder) and the NDA holder.<sup>41</sup> The notice shall "include a detailed statement of the factual and legal basis of the opinion of the applicant [generic drug company] that the [listed drug's] patent is invalid or will not be infringed" by the manufacture and sale of a generic version of the listed drug.<sup>42</sup> The notice must be provided to the patentee and NDA holder no later than twenty days from the postmark date of the FDA notice to the generic drug company stating that the ANDA has been filed.<sup>43</sup> Upon receiving the notice, the patentee and NDA holder have the option to sue for patent infringement "on all, some, or none of the patents included in the Paragraph IV Certification."<sup>44</sup>

If the patentee or NDA holder does not bring a patent infringement suit within forty-five days of receipt of the notice, the FDA may approve the ANDA upon completion of their review of the application.<sup>45</sup> If a suit is brought by the patentee or NDA holder then the FDA may not grant final approval of the ANDA until the earlier of (1) thirty months "beginning on the date of the receipt of the notice" by the patentee or NDA holder or (2) a district court decision that the patents subject to Paragraph IV certification are in fact invalid or not infringed.<sup>46</sup> For subsequent generic drug companies filing an ANDA, the approval date of their generic version of the listed drug is also subject to any 180-day exclusivity granted to the generic drug company, which was first in filing an ANDA to the listed drug, as will be discussed below.<sup>47</sup>

### 3. 180-Day Exclusivity

To further encourage the introduction of lower-priced generics, the Hatch-Waxman Act provides an incentive for generic pharmaceutical companies to "challenge suspect . . . patents" and take on the litigation costs and risks that come with the challenge.<sup>48</sup> The incentive is a grant—to the first generic drug company to submit an ANDA containing a Paragraph IV certification (First Paragraph IV ANDA Filer)—of "a 180-day period of

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39. See *Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278, 1283 (Fed. Cir. 2008).

40. See 35 U.S.C. § 271(e)(2)(A) (2006); *Janssen*, 540 F.3d at 1356.

41. See 21 U.S.C. § 355(j)(2)(B); *Janssen*, 540 F.3d at 1356.

42. See 21 U.S.C. § 355(j)(2)(B)(iv)(II).

43. See *id.* § 355(j)(2)(B)(ii).

44. See *Janssen*, 540 F.3d at 1356.

45. See 21 U.S.C. § 355(j)(5)(B)(iii); *Janssen*, 540 F.3d at 1356.

46. See 21 U.S.C. § 355(j)(5)(B)(iii); *Janssen*, 540 F.3d at 1356.

47. See 21 U.S.C. § 355(j)(5)(B)(iv).

48. *Janssen*, 540 F.3d at 1356.

generic marketing exclusivity during which time FDA will not approve a later-filed” ANDA containing a Paragraph IV certification (Subsequent Paragraph IV ANDA Filers) based on the same listed drug.<sup>49</sup> The 180-day exclusivity could be “worth hundreds of millions of dollars for a major drug.”<sup>50</sup> However, even though the FDA may not approve any other ANDAs prior to the expiration of the 180-day exclusivity, the First Paragraph IV ANDA Filer may not be the only generic version of the listed drug available during the 180-day exclusivity due to “authorized generics.”<sup>51</sup> An “authorized generic” is a generic version of the listed drug licensed under the innovator’s NDA by the innovator company.<sup>52</sup> Introduction of an authorized generic means greater generic competition during the 180-day exclusivity and, therefore, lower prices for consumers.<sup>53</sup> However, a criticism of authorized generics is that they diminish the value of the 180-day exclusivity because the innovator company licenses the authorized generic to enter the market at the same time that the First Paragraph IV ANDA Filer’s generic drug enters the market.<sup>54</sup> Therefore, the First Paragraph IV ANDA Filer can no longer enjoy one hundred percent of the generic sales.

With regards to being awarded the 180-day exclusivity, the First Paragraph IV ANDA Filer is entitled to the 180-day exclusivity period regardless of whether it was sued by the innovator company. If sued, it is entitled to the 180-day exclusivity period regardless of whether it actually wins the patent infringement suit.<sup>55</sup> However, there are a few limitations to the 180-day exclusivity including the limit that only one exclusivity is permitted per product.<sup>56</sup> To qualify for the 180-day exclusivity, the First

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49. *Janssen*, 540 F.3d at 1356; see 21 U.S.C. § 355(j)(5)(B)(iv) (2006); Purepac Pharm. Co. v. Thompson, 354 F.3d 877, 879 (D.C. Cir. 2004) (“In order to encourage paragraph IV challenges, thereby increasing the availability of low-cost generic drugs . . . the first company to win FDA approval of an ANDA containing a paragraph IV certification has the right to sell its drug without competition [from other generic competitors] for 180 days.”); *Minn. Mining & Mfg. Co. v. Barr Labs. Inc.*, 289 F.3d 775, 778 (Fed. Cir. 2002) (“This provision is designed to provide an incentive, in the form of a 180-day period of marketing exclusivity, to an ANDA filer that is the first to challenge a patent listed in the Orange Book.”).

50. Hemphill, *supra* note 26, at 1560.

51. See SHASHANK UPADHYE, *GENERIC PHARMACEUTICAL PATENT AND FDA LAW* § 13.12 (March 2009), available at WL, GENPHARMA Database.

52. See UPADHYE, *supra* note 51, § 13.12. An “authorized generic” is where the innovator company licenses another company to launch a generic version of the listed drug usually in competition with the First Paragraph IV ANDA Filer’s generic drug. See *id.* The authorized generic is licensed under the innovator’s NDA; Therefore, the FDA is approving no other ANDA during the 180-day exclusivity, but there are still two generics in the marketplace during the exclusivity period. See *id.*

53. See Frank, *supra* note 1, at 1995.

54. See UPADHYE, *supra* note 51, § 13.12.

55. See *Janssen*, 540 F.3d at 1356; Lietzan & Korn, *supra* note 15, at 59 (“Must a Generic Applicant Have Been Sued and Must It Have Prevailed in That Patent Infringement Suit To Obtain the Benefit of 180-Day Exclusivity? No to both.”).

56. Pre-MMA, the 180-day exclusivity was provided on a patent-by-patent approach, which created “mutual blocking exclusivities” and multiple exclusivity periods for a product.

## Paragraph IV ANDA Filer is only required to submit a substantially

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See UPADHYE, *supra* note 51, § 13.4; Lietzan & Korn, *supra* note 15, at 55. For example, mutual blocking exclusivities would occur if a First Paragraph IV ANDA Filer filed its application with certifications against all patents listed in the Orange Book covering the listed drug but did not notice a new patent appear in the Orange Book covering the listed drug, and a subsequent ANDA filer noticed the new patent and was first to file a Paragraph IV certification against the newly listed patent. See UPADHYE, *supra* note 51, § 13.4. This creates a mutual blocking position because the First Paragraph IV ANDA Filer has a 180-day exclusivity as to the patents originally listed in the Orange Book but cannot obtain final FDA approval because the first filer is blocked by the 180-day exclusivity granted to the subsequent filer, who was first to provide a Paragraph IV challenge against the additional patent later listed in the Orange Book on the same listed drug. See *id.*

In the pre-MMA regime, a similar situation can lead to multiple exclusivities being granted to a generic version of the same listed drug. The First Paragraph IV ANDA Filer is granted a 180-day exclusivity by certifying against the listed Orange Book patents. If a later patent appears, and the Paragraph IV ANDA Filer is first to file a Paragraph IV certification against that later patent, the filer is granted a 180-day exclusivity as to that patent as well, which effectively extends the exclusivity and further delays approval of any Subsequent Paragraph IV ANDA Filers' applications. See generally UPADHYE, *supra* note 51, § 13.4 n.1.

Post-MMA, "Congress endorsed a product-by-product approach . . . with [only] one 180-day exclusivity period per product." Lietzan & Korn, *supra* note 15, at 59; see also UPADHYE, *supra* note 51, § 13.5. Applying the new provision, "the first applicant to file the Paragraph IV certification [as] to any one patent in the Orange Book [covering the listed drug] earns the potential 180-day exclusivity regardless of whether later filers file Paragraph IV certifications to patents not [previously] certified" by the first applicant such as new patents that appear. See UPADHYE, *supra* note 51, § 13.5. Therefore, unlike the previous patent-by-patent approach, "going forward [post-MMA, there can be only] . . . one 180-day exclusivity period per product." Lietzan & Korn, *supra* note 15, at 59. However, different strengths (e.g., 10 mg, 20 mg, 30 mg) of a listed drug are deemed to be different products. See UPADHYE, *supra* note 51, § 13.5.

For pre-MMA ANDAs, if the First Paragraph IV ANDA Filer loses the patent infringement litigation and there is an "entry of a final, non-appealable judgment of [either patent] infringement" by the ANDA filer or of validity of the innovator's patent, then the Paragraph IV certification is no longer valid, which results in a loss of exclusivity with respect to each patent that is deemed infringed or valid. See Bickart, *supra* note 27, at 8-80. However, since there is a patent-by-patent approach in the pre-MMA setting, the First Paragraph IV ANDA Filer may retain the 180-day exclusivity if the applicant was also first to file on other patents for the same listed drug if there was no final, nonappealable judgment of infringement or invalidity as to the other patents. See *id.* at 8-75, 8-80; see also Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc., 527 F.3d 1278, 1286-87 (Fed. Cir. 2008) (stating how Ivax was the First Paragraph IV ANDA Filer as to two Lexapro patents, and even though it had lost its litigation on one of the patents (and was affirmed on appeal), Ivax retained its 180-day exclusivity because there was no final infringement or invalidity decision as to the second patent).

For post-MMA ANDAs, the results are similar. If there is a final, nonappealable judgment that the ANDA filer infringes a patent that was the subject of a Paragraph IV certification or that the patent is determined to be valid, the Paragraph IV certification as to that patent is invalid. See Bickart, *supra* note 27, at 8-71 to 8-72. This would require the ANDA filer to change its certification from Paragraph IV to Paragraph III. *Id.* However, the first ANDA filer does not forfeit its 180-day exclusivity unless it "amends or withdraws its [P]aragraph IV certification for *all* of the patents [of the listed drug] as to which it made such a certification . . ." *Id.*

For situations of patent expiration, a similar situation exists in both pre- and post-MMA settings: exclusivity based on an expired patent is no longer valid. See Bickart, *supra* note 27, at 8-73 (noting that the MMA takes "FDA's pre-2003 position that 180-day exclusivity cannot survive the expiration of the patent(s) upon which that exclusivity was based"); see also *infra* note 83 (discussing expiration of patents).

complete application and lawfully maintain a Paragraph IV certification.<sup>57</sup> One last comment on the 180-day exclusivity is that the exclusivity incentive only exists in the United States.<sup>58</sup> No other country rewards generic companies for filing drug approval applications prior to the expiration of the relevant patents.<sup>59</sup>

Having described how a company receives the 180-day exclusivity, Part I.A.3.a and I.A.3.b discuss what actually triggers the 180-day exclusivity. The triggering mechanism, however, is not uniform and instead depends on whether the MMA provisions apply. The amended provisions of the MMA apply to ANDAs filed after December 8, 2003, but only if there was no Paragraph IV certification to the listed drug by any other ANDA filer prior to December 8, 2003.<sup>60</sup>

a. *180-Day Exclusivity: Pre-MMA Triggering Provisions*

Since the 180-day exclusivity blocks subsequent ANDA filers from gaining FDA approval, it is crucial to determine when the 180-day exclusivity period begins. For pre-MMA ANDAs, the “180-day exclusivity period is triggered by the earlier of two events: (1) the [F]irst Paragraph IV ANDA [F]iler’s commercial marketing of a drug product [(commercial-marketing trigger)]; or (2) a court decision of noninfringement or invalidity [(court-decision trigger)].”<sup>61</sup> There was some confusion regarding the level

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57. See 21 U.S.C. § 355(j)(5)(B)(iv)(II)(bb) (2006). This definition was added as a result of MMA updates and was not included in the provisions relating to the 180-day exclusivity pre-MMA. See UPADHYE, *supra* note 51, § 13.2. Compare 21 U.S.C. § 355(j)(5)(B)(iv) (2000) (amended 2003), with 21 U.S.C. § 355(j)(5)(B)(iv) (2006). However, even though the substantially complete requirement was added as a result of the MMA, it applies to pre-MMA ANDAs, as it was prior FDA practice. See Erika King Lietzan, *A Brief History of 180-Day Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act*, 59 FOOD & DRUG L.J. 287, 290–91 (2004).

“If multiple [ANDA] applicants file substantially complete ANDAs with [P]aragraph IV certifications on the same day . . . [and are] first to do so, those applicants can share exclusivity.” Lietzan & Korn, *supra* note 15, at 55; see also UPADHYE, *supra* note 51, § 13.2. Sharing exclusivity was developed by FDA policy, as applicable to pre-MMA ANDAs and required by statute for post-MMA ANDAs. Lietzan & Korn, *supra* note 15, at 55.

58. See UPADHYE, *supra* note 51, § 13.1 (“No other country has an exclusivity period to reward generic companies to file generic applications for drugs to market before the relevant patent expires.”). Additionally, *Procedures for Marketing Authorization*, by the European Commission, makes no reference to any generic exclusivity and instead states that “[t]he generic . . . , once authorised, can . . . be placed on the market 10 or 11 years after the authorisation of the reference medicinal product, [listed drug], depending on the exclusivity period applicable for the reference medicinal product.” 2A EUROPEAN COMM’N, PROCEDURES FOR MARKETING AUTHORISATION 21 (2005), available at [http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol-2/a/vol2a\\_chap1\\_2005-11.pdf](http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol-2/a/vol2a_chap1_2005-11.pdf).

59. See *supra* note 58 (noting lack of exclusivity outside the U.S.).

60. See *supra* note 15 (discussing application of the MMA and its grandfather provision).

61. See *Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, 540 F.3d 1353, 1357 n.2 (Fed. Cir. 2008). Section 355(j)(5)(B)(iv) reads as follows:

(iv) If the application contains a certification described in subclause (IV) of paragraph (2)(A)(vii) and is for a drug for which a previous application has been

of court decision required for the court-decision trigger. However, the MMA provided clarity by stating that the court-decision trigger requires a final decision of a court where no appeal other than a petition to the U.S. Supreme Court for a writ of certiorari has been or can be taken.<sup>62</sup> Therefore a district or lower court decision will not suffice; a court of appeals decision is required, which, on average, takes a total of thirty-seven months from the start of the patent infringement lawsuit to obtain.<sup>63</sup> With regard to who can start the clock and trigger the 180-day exclusivity, “[o]nly the [F]irst Paragraph IV ANDA [F]iler can trigger its [own] 180-day exclusivity period via the commercial-marketing trigger.”<sup>64</sup> However, for the court-decision trigger, not only can the First Paragraph IV ANDA Filer trigger the 180-day exclusivity, “[S]ubsequent Paragraph IV ANDA [F]ilers can [also] trigger the [F]irst Paragraph IV ANDA [F]iler’s 180-day exclusivity period via a successful court judgment.”<sup>65</sup>

b. *180-Day Exclusivity: Post-MMA Triggering and Forfeiture Provisions*

For ANDAs that are subject to the MMA provisions,<sup>66</sup> there only exists a commercial-marketing trigger for the 180-day exclusivity.<sup>67</sup> The court-decision aspect, however, is still addressed as part of a series of forfeiture

submitted under this subsection continuing such a certification, the application shall be made effective not earlier than one hundred and eighty days after-

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

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

whichever is earlier.

21 U.S.C. § 355(j)(5)(B)(iv) (2000) (amended 2003).

62. See Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 1102(b)(3), 117 Stat. 2066, 2460 (codified at 21 U.S.C. § 355 note) (Effective Date of 2003 Amendments) (“[A] ‘decision of a court’ . . . means a final decision of a court from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken.”). This definition of the court-decision trigger applies to pre-MMA ANDAs. See *id.*; see also Lietzan & Korn, *supra* note 15, at 65–66 (stating “the 2003 legislation is retroactive” with respect to this topic).

63. See FTC, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY 47 (2002). A district court case averages twenty-five months and an appeal averages twelve months; therefore, estimated timing for reaching a final court decision is thirty-seven months. See *id.*

64. *Janssen*, 540 F.3d at 1357; see 21 U.S.C. § 355(j)(5)(B)(iv)(I) (2000).

65. See *Janssen*, 540 F.3d at 1357 (citing *Minn. Mining & Mfg. Co. v. Barr Labs., Inc.*, 289 F.3d 775, 780 (Fed. Cir. 2002)); see also UPADHYE, *supra* note 51, § 13.8.

66. See *supra* note 15 (discussing when the MMA applies and its grandfather provision).

67. See UPADHYE, *supra* note 51, § 13.9; see also Lietzan & Korn, *supra* note 15, at 65. Additionally, if there are multiple First Paragraph IV ANDA Filers, “the first applicant to commercially launch triggers the exclusivity as to all first applicants.” See UPADHYE, *supra* note 51, § 13.9.

events.<sup>68</sup> There are six events that could lead to a forfeiture of the 180-day exclusivity: (1) failure to market; (2) withdrawal of application; (3) amendment of certification; (4) failure to obtain tentative approval; (5) agreement with another applicant, the listed drug application holder, or a patent owner; and (6) expiration of all patents.<sup>69</sup> Of particular importance to the “approval bottleneck” problem are the failure-to-market forfeiture provision, the agreement forfeiture provision, and the amendment-of-certification forfeiture provision.

The failure-to-market forfeiture event is complex and includes aspects of the pre-MMA court-decision trigger. The statute reads as follows:

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

(aa) the earlier of the date that is—

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

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

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

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

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

(CC) The patent information submitted under subsection (b) or (c) of this section is withdrawn by the holder of the application approved under subsection (b) of this section.<sup>70</sup>

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68. See Lietzan & Korn, *supra* note 15, at 65 (“Although Congress eliminated the court decision trigger for beginning the period of exclusivity, it established a new court decision trigger for forfeiture of exclusivity.”); see also UPADHYE, *supra* note 51, § 13.9.

69. See 21 U.S.C. § 355(j)(5)(D) (2006); UPADHYE, *supra* note 51, § 14.2–.3, 14.11–.13, 14.16–.17. Forfeiture of the 180-day exclusivity requires just any one of the six events to occur. See 21 U.S.C. § 355(j)(5)(D).

70. *Id.* § 355(j)(5)(D)(i)(I).

The failure-to-market forfeiture provision attempts to prevent the First Paragraph IV ANDA Filer from indefinitely “parking” its exclusivity by having the applicant forfeit its 180-day exclusivity if “it fails to market its product by the later of *two* statutorily defined dates,” the (aa) date or the (bb) date.<sup>71</sup> While the application may seem straightforward, complications can arise, as illustrated by the Teva granisetron hydrochloride situation.<sup>72</sup> In the Teva application process, there was no (bb) date because no infringement litigation was brought.<sup>73</sup> The absence of a (bb) date left a gap in the forfeiture date calculations, which led to an FDA review and ultimately a decision that exclusivity was not forfeited.<sup>74</sup>

The second forfeiture provision of interest, the amendment-of-certification forfeiture provision, calls for forfeiture if the First Paragraph IV ANDA Filer amends the Paragraph IV “certification for all of the patents with respect to which that applicant submitted [such] a certification.”<sup>75</sup> The statute reads as follows:

(III) AMENDMENT OF CERTIFICATION.—The first applicant amends or withdraws the certification for all of the patents with respect to which that applicant submitted a certification qualifying the applicant for the 180-day exclusivity period.<sup>76</sup>

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71. See Bickart, *supra* note 27, at 8-71.

72. See Teva North America, FDA Decision Letter: ANDA 77-165: Granisetron Hydrochloride Injection, 1mg/mL, Docket No. 2007N-0389 (Jan. 17, 2008) [hereinafter Granisetron Letter], available at <http://www.fda.gov/ohrms/dockets/DOCKETS/07n0389/07n-0389-let0003.pdf>.

73. See *id.* at 5.

74. See *id.* Teva was first to file a Paragraph IV ANDA for granisetron hydrochloride injection on June 1, 2004. *Id.* at 1. The ANDA contained a Paragraph IV certification as to one patent and a Paragraph III certification as to the second patent, which meant FDA could not approve the ANDA until the expiration of the second patent on December 29, 2007. *Id.* at 4. The date for (aa) is the earlier of (1) seventy-five days after the first applicant’s ANDA is approved, which would not occur until approximately seventy-five days after December 29, 2007; or (2) thirty months after the submission of the ANDA, which is December 1, 2006. See *id.* Therefore the earlier date is December 1, 2006. See *id.* Forfeiture does not occur unless the applicant fails to market by the later date of (aa), which is December 1, 2006, or (bb). See *id.* at 3-4. However, there was no lawsuit brought against Teva regarding its Paragraph IV certification as to the one patent, nor was there a lawsuit brought against any subsequent ANDA filers. See *id.* at 5. Therefore there is no (bb) date. See *id.* An argument was made that since there is no later date, forfeiture should occur by the failing to market by the (aa) date. See *id.* This argument was rejected and therefore Teva was entitled to keep its 180-day exclusivity. See *id.* at 7. A consequence of this ruling by the FDA is that it gives rise to concerns about “parking” exclusivity because without a (bb) date, Teva can choose not to launch its product upon approval and still not forfeit its 180-day exclusivity, preventing subsequent ANDA filers from gaining FDA approval unless they themselves either are sued or bring a declaratory judgment action and create a (bb) date, which may then lead to possible forfeiture. See *id.* at 6. See generally *infra* Part II.

75. See 21 U.S.C. § 355(j)(5)(D)(i)(III). “[I]f the first applicant amends or withdraws its [P]aragraph IV certification for all of the patents as to which it made such a certification,” qualifying it for the 180-day exclusivity, the applicant forfeits its 180-day exclusivity. See Bickart, *supra* note 27, at 8-73.

76. 21 U.S.C. § 355(j)(5)(D)(i)(III).



To aid in the application of the amendment-of-certification forfeiture provision, the FDA has provided additional guidance regarding amendments to certification as it relates to settlements. The FDA takes the position that despite settling with the innovator company, the ANDA filer does not need to amend its Paragraph IV certification and, therefore, the First Paragraph IV ANDA Filer is still entitled to its 180-day exclusivity.<sup>77</sup> This decision contributes to the creation of “approval bottlenecks,” as discussed in Part II.

The third forfeiture provision of interest, the agreement forfeiture provision calls for a forfeiture of the 180-day exclusivity if the First Paragraph IV ANDA Filer enters an agreement that violates antitrust laws.<sup>78</sup> The statute reads as follows:

(V) AGREEMENT WITH ANOTHER APPLICANT, THE LISTED DRUG APPLICATION HOLDER, OR A PATENT OWNER.—The first applicant enters into an agreement with another applicant under this subsection for the drug, the holder of the application for the listed drug, or an owner of the patent that is the subject of the certification under paragraph (2)(A)(vii)(IV), the Federal Trade Commission or the Attorney General files a complaint, and there is a final decision of the Federal Trade Commission or the court with regard to the complaint from which no appeal (other than a petition to the Supreme Court for writ of certiorari) has been or can be taken that the agreement has violated the antitrust laws (as defined in section 12 of title 15, except that the term includes section 45 of title 15 to the extent that that section applies to unfair methods of competition).<sup>79</sup>

To clarify, if the ANDA filer enters an agreement that either the Federal Trade Commission (FTC) or a court finds to violate federal antitrust laws, and the decision is either not appealed or cannot be appealed, the ANDA filer’s 180-day exclusivity is forfeited.<sup>80</sup> Due the importance of preventing antitrust violations, and in order to better police any possible violations, Congress went one step further by requiring almost all agreements between Paragraph IV ANDA filers and the innovator drug companies (NDA holder or patent owner) or other competing applicants to be filed with the Assistant Attorney General and the FTC.<sup>81</sup> Given the length of time to reach a

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77. See FDA Decision Letter: Ramipril Capsules, Docket No. 2007N-0382 (Jan. 29, 2008) [hereinafter Ramipril Letter], available at <http://www.fda.gov/ohrms/dockets/DOCKETS/07n0382/07n-0382-let6.pdf>. In the citizen petition the FDA stated that, despite settling with the innovator company, the ANDA applicant does not need to amend its Paragraph IV certification and therefore the First Paragraph IV ANDA Filer is still entitled to its 180-day exclusivity. See *id.* “Consequently, despite the fact [of] the settlement agreement . . . there is no legal basis for the [FDA] to find that [the First Paragraph IV ANDA Filer] has forfeited its exclusivity.” See *id.*

78. See 21 U.S.C. § 355(j)(5)(D)(i)(V).

79. See *id.*

80. See Bickart, *supra* note 27, at 8-73 to 8-74.

81. See Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 1112, 117 Stat. 2066, 2461–63 (codified at 21 U.S.C. § 355 note) (Federal Trade Commission Review); Bickart, *supra* note 27, at 8-73.

nonappealable decision, however, it will probably be unlikely that forfeiture of the 180-day exclusivity will occur due to a collusive agreement, suggesting this provision has “no teeth.”<sup>82</sup>

The other three forfeiture provisions—Withdrawal of Application, Failure to Obtain Tentative Approval, and Expiration of All Patents—are an important part of the MMA’s attempt to alleviate abuses of the Hatch-Waxman Act but are not as important to the “approval bottleneck” situation.<sup>83</sup>

### B. Declaratory Judgments

Part I.B provides a background on declaratory judgments and explains how declaratory judgments relate to the Hatch-Waxman Act. Part I.B.1 provides an overview of declaratory judgments. Part I.B.2 addresses the role declaratory judgments play within the Hatch-Waxman Act (i.e., “civil action to obtain patent certainty”). Part I.B.3 discusses the reasonable-apprehension-of-suit test, the previous test used to determine whether a declaratory judgment action shall proceed or be dismissed for lack of

82. See UPADHYE, *supra* note 51, § 14.16.

This provision while verbose has no teeth because it will never happen . . . . It has no teeth because the forfeit will only occur after a ridiculously long period of time . . . . It requires that the FTC or Justice Department to have prosecuted the antitrust case through appeal. Given that the administrative proceeding at FTC could take years, plus appeals court review, this provision simply is so watered down that [while] facially it seems good, it has no teeth.

*Id.*

83. For completeness, a discussion of the three provisions follows. “(II) WITHDRAWAL OF APPLICATION.—The first applicant withdraws the application or the Secretary considers the application to have been withdrawn as a result of a determination by the Secretary that the application does not meet the requirements for approval under paragraph (4).” 21 U.S.C. § 355(j)(5)(D)(i)(II). Two factors can lead to forfeiture of the 180-day exclusivity in this provision. If the first applicant withdraws its ANDA, the exclusivity is forfeited. Bickart, *supra* note 27, at 8-72. Additionally, if the FDA determines that the applicant’s ANDA cannot satisfy FDA’s safety and efficacy requirements, the applicant’s 180-day exclusivity is also forfeited. See *id.*

The next forfeiture event is

(IV) FAILURE TO OBTAIN TENTATIVE APPROVAL.—The first applicant fails to obtain tentative approval of the application within 30 months after the date on which the application is filed, unless the failure is caused by a change in or a review of the requirements for approval of the application imposed after the date on which the application is filed.

21 U.S.C. § 355(j)(5)(D)(i)(IV). Tentative approval means the ANDA meets all FDA requirements for approval but cannot receive final approval due to another applicant’s exclusivity. See *id.* § 355(j)(5)(B)(iv)(II)(dd)(AA). The FDA had previously required a First Paragraph IV ANDA Filer to actively pursue its ANDA, otherwise it risked losing its 180-day exclusivity. See Bickart, *supra* note 27, at 8-72. However, there was no time limit for an ANDA applicant to resolve any issues raised by the FDA. See *id.* The new provisions provide for a thirty month time limit to obtain tentative FDA approval or the First Paragraph IV ANDA Filer forfeits its 180-day exclusivity provided there is no change in requirements. See *id.*

The last forfeiture event is “(VI) EXPIRATION OF ALL PATENTS.—All of the patents as to which the applicant submitted a certification qualifying it for the 180-day exclusivity period have expired.” 21 U.S.C. § 355(j)(5)(D)(i)(VI).

subject matter jurisdiction. Finally, Part I.B.4 discusses the all-the-circumstances test from the 2007 *MedImmune* decision, a newer test, utilized to evaluate whether declaratory judgment actions shall proceed.

### 1. Overview of Declaratory Judgments

In addition to the changes in the 180-day exclusivity, which include the new forfeiture provisions, the MMA created a newfound significance of declaratory judgments in the Hatch-Waxman/ANDA litigation setting.<sup>84</sup> Declaratory judgments “allow a party to sue another party to . . . clear up a lurking legal issue.”<sup>85</sup> Declaratory judgments are governed by federal statute. The relevant text of the federal statute states, “In a case of actual controversy within its jurisdiction . . . any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought.”<sup>86</sup> The statute requires “actual controversy” for a declaratory judgment action. The Supreme Court has affirmed that the “actual controversy” requirement of the Declaratory Judgment Act requires that the cases or controversies be sufficient to satisfy Article III of the U.S. Constitution,<sup>87</sup> which specifies judicial power.<sup>88</sup>

### 2. Civil Action To Obtain Patent Certainty

Part I.B.1 provided a brief overview of declaratory judgments. To bring it back to the Hatch-Waxman context, “a potential infringer [ANDA filer] may wish to ASK FOR A [declaratory judgment] against the patentee [innovator] to clear up the issue of whether the infringer is indeed infringing,”<sup>89</sup> which is where the “civil action to obtain patent certainty” provision is utilized.<sup>90</sup> MMA’s civil action to obtain patent certainty provision was “designed to prevent patentees [or NDA holders] from ‘gaming’ the Hatch-Waxman Act” through the use of tactics to delay generic competition.<sup>91</sup> Civil action to obtain patent certainty provides for an early resolution of patent disputes. The provision allows any ANDA filer to file a declaratory judgment action against the patentee or NDA holder for a “declaratory judgment that the [relevant Orange Book listed] patent is invalid or will not be infringed by the [generic] drug for which the

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84. *See id.* § 355(j)(5)(C).

85. *See* UPADHYE, *supra* note 51, § 15.1.

86. 28 U.S.C. § 2201(a) (2006).

87. *See* *MedImmune, Inc. v. Genentech, Inc.*, 127 S. Ct. 764, 771 (2007) (“[T]he phrase ‘case of actual controversy’ in the Act refers to the type of ‘Cases’ and ‘Controversies’ that are justiciable under Article III.” (citing *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 240 (1937))).

88. *See* U.S. CONST. art. III.

89. *See* UPADHYE, *supra* note 51, § 15.1.

90. *See* 21 U.S.C. § 355(j)(5)(C) (2006).

91. *See* *Teva Pharm. USA, Inc. v. Novartis Pharm. Corp.*, 482 F.3d 1330, 1342 & n.7 (Fed. Cir. 2007).

[ANDA] applicant seeks approval.”<sup>92</sup> While this is an MMA provision, the civil action to obtain patent certainty provision has been applied to pre-MMA ANDAs.<sup>93</sup> In order to bring a declaratory judgment action, the civil action to obtain patent certainty provision requires that (1) forty-five days have passed since the Paragraph IV notice was received by the patentee or NDA holder, (2) no patent infringement suit has been brought (or a patent infringement suit has been brought on some but not all the Orange Book listed patents, against which the ANDA filer filed a Paragraph IV certification), and (3) the ANDA filer provided the patentee and NDA holder an offer of confidential access.<sup>94</sup> Once these requirements are met, a judge must determine if there is a sufficient Article III case or controversy to allow the declaratory judgment action to proceed.<sup>95</sup> The ultimate question is one of subject matter jurisdiction, which is a court’s power “over the nature of the case and the type of relief sought; the extent to which a court can rule on . . . the status of things.”<sup>96</sup> Without a sufficient case or controversy, the court lacks subject matter jurisdiction over the case and must grant a moving party’s motion to dismiss for lack of subject matter jurisdiction.<sup>97</sup> The court often utilizes a test, as will be discussed in Parts I.B.3 and I.B.4, to determine whether there is sufficient controversy to allow the declaratory judgment action to proceed.

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92. See 21 U.S.C. § 355(j)(5)(C)(i)(II); *Novartis*, 482 F.3d at 1342; *Dey, L.P. v. Sepracor, Inc.*, 595 F. Supp. 2d 355, 358 (D. Del. 2009) (“To further facilitate the ability of subsequent ANDA filers to obtain a court judgment of non-infringement or invalidity of the NDA holder’s Orange Book patents, Congress extended the relevant federal court declaratory judgment jurisdiction . . .”).

93. See generally *Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, 540 F.3d 1353 (Fed. Cir. 2008); *Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278 (Fed. Cir. 2008).

94. See 21 U.S.C. § 355(j)(5)(C)(i); Brief for Plaintiffs-Appellees at 6–7, *Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, 540 F.3d 1353 (Fed. Cir. 2008) (No. 2008-1062).

If a patent infringement suit is brought within forty-five days with regards to some but not all of the patents of the listed drug, against which a Paragraph IV certification was made, a declaratory judgment action may still proceed regarding the other patents not subject to the infringement suit. See, e.g., *Novartis*, 482 F.3d 1330. *Novartis* had listed five patents in the Orange Book covering the listed drug Famvir. See *id.* at 1334. *Teva* had filed an ANDA with a Paragraph IV certification as to all five patents. See *id.* Within forty-five days, *Novartis* had brought a patent infringement suit against *Teva* with respect to only one of the five patents. See *id.* at 1334–35. As a result, *Teva* had filed a declaratory judgment to obtain patent certainty with respect to the remaining four patents. See *id.* at 1335. The U.S. Court of Appeals for the Federal Circuit reversed the dismissal of the declaratory judgment action and allowed the declaratory judgment to proceed. See *id.* at 1346.

The offer of confidential access allows the NDA holder or patentee to “review the [ANDA] application for the . . . purpose of evaluating possible infringement of the patent” subject to Paragraph IV certification. 21 U.S.C. § 355(j)(5)(C)(i)(III); see *supra* notes 41–44 and accompanying text (discussing the notice which must be provided by a Paragraph IV ANDA filer to the patentee and NDA holder).

95. See *supra* Part I.B.1.

96. BLACK’S LAW DICTIONARY 870 (8th ed. 2004).

97. See generally *MedImmune, Inc. v. Genentech, Inc.*, 127 S. Ct. 764, 768–69 (2007).

### 3. Reasonable-Apprehension-of-Suit Test

Prior to the 2007 *MedImmune* decision, the courts utilized a two-part reasonable-apprehension-of-suit test in the Hatch-Waxman setting in order to determine whether the declaratory judgment action presents a sufficient Article III controversy to permit the declaratory judgment action to proceed.<sup>98</sup> Under the reasonable-apprehension-of-suit test, sufficient controversy exists if there is both

- (1) an explicit threat or other action by the patentee which creates a reasonable apprehension on the part of the declaratory judgment plaintiff [ANDA filer] that it will face an infringement suit; and (2) present activity by the declaratory judgment plaintiff [ANDA filer] which could constitute infringement, or concrete steps taken with the intent to conduct such activity.<sup>99</sup>

ANDA filers seeking a declaratory judgment action against the patent/NDA holder would often run into difficulties passing the first prong of this stringent test and, therefore, would be denied declaratory judgment.<sup>100</sup> The stringent reasonable-apprehension-of-suit test soon gave way to the more lenient all-the-circumstances test.

### 4. All-the-Circumstances Test

In *MedImmune*, the Supreme Court disagreed with the validity of the U.S. Court of Appeals for the Federal Circuit's reasonable-apprehension-of-suit test.<sup>101</sup> The Court eliminated the test's validity in a footnote and went on to discuss the all-the-circumstances test.<sup>102</sup> The all-the-circumstances test is a more flexible test, which states that "the question in each case is whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory

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98. See *Teva Pharm. USA, Inc. v. Pfizer, Inc.*, 395 F.3d 1324, 1332 (Fed. Cir. 2005) ("This court has developed a two-part inquiry to determine whether there is an actual controversy in a suit requesting a declaration of patent non-infringement or invalidity."). The test was further evolved to the reasonable-apprehension-of-imminent-suit test. See *id.* at 1333.

99. See *id.* at 1332.

100. See UPADHYE, *supra* note 51, § 15.3. A Paragraph IV ANDA filer by undertaking the ANDA process, subjecting itself to Paragraph IV lawsuits and making a generic drug upon ANDA approval, has generally done enough activity to satisfy part (2) of the reasonable-apprehension-of-suit test. See *id.* An ANDA filer's declaratory judgment actions, when they do fail, do so because of part (1). See *id.* If some Orange Book patents are sued upon and others are not, then there is not much apprehension of suit as to the unlitigated patents. See *id.* Furthermore, if an innovator company provides an ANDA filer a covenant not to sue with respect to the unlitigated patents there is "even less apprehension of a suit." See *id.*

101. See *MedImmune*, 127 S. Ct. at 774 n.11 (noting that the reasonable-apprehension-of-suit test conflicts with several Supreme Court cases and that "eliminating any apprehension of suit, does not moot a declaratory judgment counterclaim of patent invalidity").

102. See *id.* at 771, 774 n.11.

judgment.”<sup>103</sup> There is no longer a need for reasonable apprehension, and as such the declaratory judgment plaintiff is not required to “bet the farm . . . by taking the violative action.”<sup>104</sup> The consequence of establishing a test with a lower threshold is an increase in the number of declaratory judgment challenges.<sup>105</sup> The Supreme Court did, however, emphasize “that the dispute [must still] be ‘definite and concrete, touching the legal relations of parties having adverse legal interests’; and that . . . [the dispute] be ‘real and substantial’ and ‘admi[t] of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts.’”<sup>106</sup> The implication of a more relaxed test is that it is another tool in overcoming the “approval bottleneck.”<sup>107</sup>

The Hatch-Waxman Act provides for an accelerated drug approval process for a generic version of the listed drug. To further encourage the introduction of generic versions, the Hatch-Waxman Act also provides for a 180-day exclusivity to the First Paragraph IV ANDA Filer.<sup>108</sup> However, if the First Paragraph IV ANDA Filer, which has been granted the 180-day exclusivity period, settles with the innovator company or takes other actions that result in delaying the launch of its generic version, the Hatch-Waxman side effect, an “approval bottleneck,” occurs. This “approval bottleneck” blocks Subsequent Paragraph IV ANDA Filers from gaining approval,<sup>109</sup> potentially causing an indefinite delay in access to generic drugs.

### C. “Approval Bottleneck”

While somewhat complex, the Hatch-Waxman Act attempts to balance the interests of both innovator and generic pharmaceutical companies.<sup>110</sup> However, an undesired side effect can arise through the operation of the Hatch-Waxman Act: the “approval bottleneck.” Innovator companies have

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103. *Id.* at 771 (quoting *Md. Cas. Co. v. Pac. Coal & Oil Co.*, 312 U.S. 270, 273 (1941)).

104. *Id.* at 772 (citing *Terrace v. Thompson*, 263 U.S. 197, 216 (1923)).

The flexibility of the new test can be illustrated through the case *Teva Pharmaceuticals USA, Inc. v. Novartis Pharmaceuticals Corp.* See *supra* note 94 (discussing the *Novartis* case). The district court in the case bound by the reasonable-apprehension-of-imminent-suit test dismissed the declaratory judgment suit for lack of jurisdiction. See *Teva Pharm. USA, Inc. v. Novartis Pharm. Corp.*, 482 F.3d 1330, 1342 & n.7 (Fed. Cir. 2007); see also *supra* note 100 (noting how suing on some patents but not on others is less likely to create a reasonable apprehension). However, the Federal Circuit applied the more flexible all-the-circumstances test and held there was sufficient controversy to confer jurisdiction when an innovator sues on one, but not the other, Orange Book listed patents for the listed drug. See *Novartis*, 482 F.3d at 1334–35, 1346.

105. Lisa A. Dolak, *Power or Prudence: Toward a Better Standard for Evaluating Patent Litigants' Access to the Declaratory Judgment Remedy*, 41 U.S.F. L. REV. 407, 442 (2007).

106. *MedImmune*, 127 S. Ct. at 771 (quoting *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 240–41 (1937)).

107. See *infra* Part II.

108. See *supra* Part I.A.

109. See *infra* Part I.C.

110. See *supra* note 20 and accompanying text.

strong incentives to prevent generic competition with its listed drug since generic versions sell at “substantially lower prices than their brand-name [innovator] counterparts,” resulting in substantial loss of revenue to the innovator company.<sup>111</sup> One way to prevent, or at least delay, generic competition is for the innovator company to enter into a settlement agreement with the generic company.<sup>112</sup> Furthermore, if the First Paragraph IV ANDA Filer (entitled to its 180-day exclusivity) settles with the innovator company, an “approval bottleneck” may result because no other generic company may obtain FDA approval until the First Paragraph IV ANDA Filer’s 180-day exclusivity is exhausted.<sup>113</sup> However, exhaustion of the exclusivity may be delayed, into the distant future, as a result of the settlement.<sup>114</sup> This “approval bottleneck” effectively prevents Subsequent Paragraph IV ANDA Filers from obtaining FDA approval, delaying generic entrants into the marketplace.

To further clarify, a settlement between the First Paragraph IV ANDA Filer and the innovator removes an opportunity for the commercial-marketing trigger, as the settlement agreement would call for a delay in generic entry.<sup>115</sup> The settlement also removes the opportunity for a court-decision trigger by the First Paragraph IV ANDA Filer’s own litigation because the settlement ended the litigation proceedings.<sup>116</sup> “Without the occurrence of either triggering event, the [Subsequent Paragraph IV ANDA] [F]iler is stuck” since the FDA cannot approve the Subsequent Paragraph IV ANDA Filer’s applications until the expiration of the 180-day exclusivity of the first applicant.<sup>117</sup> Therefore, an “approval bottleneck” is created. Subsequent Paragraph IV ANDA Filers cannot be approved by the FDA until the 180-day exclusivity for the first applicant is exhausted.<sup>118</sup> However, the first applicant will not exhaust the 180-day exclusivity until 180-days after the generic launch date specified by the settlement, which

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111. See Frank, *supra* note 1, at 1993.

112. See *infra* notes 115–16 and accompanying text.

113. See Hemphill, *supra* note 26, at 1586–89; Thomas B. Leary, *Antitrust Issues in the Settlement of Pharmaceutical Patent Disputes, Part III*, 30 SEATTLE U. L. REV. 377, 381–82 (2007) (“A settlement with the first challenger will avoid . . . [the risk of a patent being declared invalid], and under the applicable rules, it will block entry by later generics until 180 days after the first generic actually enters.”). Leary further states that “Hatch-Waxman settlements can block later generic challenges” and “[a]fter the pioneer settles with the first challenger for an extended entry delay, it can safely ignore the threat of additional generic entry.” See *id.* at 382, 389. These statements assumed that a declaratory judgment could not be brought by subsequent ANDA filers given that the previous test, the reasonable-apprehension-of-imminent-suit test, was the standard to be applied instead of the current all-the-circumstances test. See *id.* at 389 n.60.

114. See *infra* notes 115–16 and accompanying text.

115. See Hemphill, *supra* note 26, at 1568 (“The basic settlement structure is simple . . . . The generic firm abstains from entry . . . and the parties agree to dismiss the patent suit.”); see also *supra* Part I.A.3.

116. See *supra* note 115.

117. See Hemphill, *supra* note 26, at 1587–89; see *supra* Part I.A.3.

118. See *supra* note 47 and accompanying text.

the innovator company will try to push as far into the future as possible.<sup>119</sup> This “approval bottleneck” is solely a side effect of the statutory application of the Hatch-Waxman Act. The First Paragraph IV ANDA Filer actions have also been referred to as “parking”<sup>120</sup> the 180-day exclusivity.

The First Paragraph IV ANDA Filer would agree to such settlements delaying launch of its own generic version for reasons such as (1) a payment by the innovator company as part of the settlement; (2) saving litigation costs, especially if the litigation costs are greater than any added benefit of launching now versus waiting until the settlement date; or (3) uncertainty as to the probability of winning its patent litigation case and the settlement provides for a launch at a specified date that is prior to the expiration of the listed drug’s patents.<sup>121</sup> As a further incentive to settlement, the First Paragraph IV ANDA Filer still retains its 180-day exclusivity when it settles.<sup>122</sup> However, when an “approval bottleneck” situation arises, there are limited actions a Subsequent Paragraph IV ANDA Filer can take in order to defeat the parking of exclusivity by the First Paragraph IV ANDA Filer. As mentioned in Part I.A.3, “[S]ubsequent Paragraph IV ANDA [F]ilers can trigger the first Paragraph IV ANDA filer’s 180-day exclusivity period via a successful court judgment” (pre-MMA) or cause forfeiture of the 180-day exclusivity (post-MMA).<sup>123</sup> If the First Paragraph IV ANDA Filer has parked its exclusivity, “[S]ubsequent Paragraph IV ANDA [F]ilers have a strong incentive to generate a triggering” or forfeiture event (e.g., a court decision) clearing the path to the FDA’s approval of the subsequent ANDAs.<sup>124</sup>

Innovator companies, conversely, “have a strong incentive to prevent a [court decision] triggering event” or forfeiture event by any Subsequent Paragraph IV ANDA Filer.<sup>125</sup> Innovator companies instead prefer the 180-day exclusivity not to begin until commercial marketing of the First Paragraph IV ANDA Filer’s generic version of the listed drug on the date specified by the settlement.<sup>126</sup> This effectively blocks all generic competition until the settlement launch date. Therefore, innovator

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119. *See* Apotex, Inc. v. Pfizer Inc., 385 F. Supp. 2d 187, 190, 192 (S.D.N.Y. 2005) (“Some brand name drug manufacturers have succeeded in ‘parking’ 180-day marketing exclusivity period, indefinitely delaying ANDA approvals and bottlenecking the market. ‘Parking’ occurs when the brand name manufacturer convinces the first filer not to enter the market, often through a settlement agreement concluding a patent infringement suit. Absent an intervening court decision, the first filer’s failure to enter the market delays the triggering of the 180-day exclusivity period so that it neither begins nor ends, and subsequently filed ANDAs cannot be approved.” (citations omitted)).

120. *See id.*

121. *See* Hemphill, *supra* note 26, at 1568, 1574, 1588–89.

122. *See supra* note 77 and accompanying text.

123. *Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, 540 F.3d 1353, 1357 (Fed. Cir. 2008) (citing *Minn. Mining & Mfg. Co. v. Barr Labs., Inc.*, 289 F.3d 775, 780 (Fed. Cir. 2002)); *see supra* Part I.A.3.

124. *See Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278, 1284 (Fed. Cir. 2008).

125. *See id.*; *supra* Part I.A.3.

126. *See supra* Part I.A.3.



companies have “a strong incentive to avoid litigation” with Subsequent Paragraph IV ANDA Filers, which could potentially trigger the First Paragraph IV ANDA Filer’s 180-day exclusivity (pre MMA) or cause forfeiture of the 180-day exclusivity (post MMA) prior to the settlement launch date.<sup>127</sup> A final court decision in the suit with the Subsequent Paragraph IV ANDA Filer, before the settlement launch date, stating that the listed drug’s patents are invalid or will not be infringed, would trigger exclusivity or possible forfeiture of exclusivity prior to the settlement launch date.<sup>128</sup>

Therefore, if an innovator company can prevent a “[S]ubsequent Paragraph IV ANDA [F]iler’s court challenge, it can delay FDA approval of the subsequent Paragraph IV ANDA and thus delay the [S]ubsequent Paragraph IV ANDA [F]iler’s [generic] entry into the market” until after the settlement launch date.<sup>129</sup> Thus, innovator companies would either not sue Subsequent Paragraph IV ANDA Filers, or sue them for patent infringement only as to one or a few Orange Book patents for the listed drug, as opposed to all of the patents, in order to avoid overcoming the “approval bottleneck.”<sup>130</sup> Suing on one or a few patents does not overcome the “approval bottleneck” because, in order to trigger the exclusivity or forfeiture of the exclusivity, a Subsequent Paragraph IV ANDA Filer needs a court decision of invalidity or noninfringement with respect to all patents first subject to Paragraph IV certification by the First Paragraph IV ANDA Filer.<sup>131</sup> Some innovator companies have gone one step further to prevent any litigation with Subsequent Paragraph IV ANDA Filers; they have

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127. See *Caraco*, 527 F.3d at 1284; see *supra* Part I.A.3.

128. See *Caraco*, 527 F.3d at 1284; see *supra* Part I.A.3.

129. See *Caraco*, 527 F.3d at 1285.

130. See, e.g., *Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, 540 F.3d 1353, 1357–59 (Fed. Cir. 2008) (noting that Janssen, innovator, sued Apotex, Subsequent Paragraph IV ANDA Filer, on only one of the three patents with Paragraph IV certification); *Caraco*, 527 F.3d at 1288 (noting that Forrest, innovator, sued Caraco, Subsequent Paragraph IV ANDA Filer, for patent infringement on only one of the two patents with Paragraph IV certification by Caraco); *Dey, L.P. v. Sepracor, Inc.*, 595 F. Supp. 2d 355, 358 (D. Del. 2009) (noting that Sepracor, innovator, sued Dey, Subsequent Paragraph IV ANDA Filer, on only five out of the six patents with Paragraph IV certification by Dey); *Apotex, Inc. v. Pfizer Inc.*, 385 F. Supp. 2d 187, 190, 190–92 (S.D.N.Y. 2005) (noting that Pfizer, innovator, sued IVAX the First Paragraph IV ANDA Filer but did not sue Apotex, Subsequent Paragraph IV ANDA Filer).

131. See *supra* Part I.A.3; see also 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb) (2006) (noting that a court decision is needed “as to each of the patents with respect to which the first applicant submitted and lawfully maintained a certification qualifying the first applicant for the 180-day exclusivity”); 21 U.S.C. § 355(j)(5)(B)(iv)(II) (2000) (amended 2003) (noting that a court decision is needed for any “patent which is the subject of the certification to be invalid or not infringed”); *Caraco*, 527 F.3d at 1288 (noting that “only a judgment of invalidity or noninfringement with respect to both . . . patents can trigger [the First Paragraph IV ANDA Filer’s] exclusivity period,” since the applicant was first to file a Paragraph IV certification with respect to both patents covering the innovator’s product).

provided a covenant not to sue to the Subsequent Paragraph IV ANDA Filers on the patents subject to Paragraph IV certification.<sup>132</sup>

## II. EVOLUTION OF LAW THAT DIRECTLY OR INDIRECTLY ADDRESSES CONQUERING THE “APPROVAL BOTTLENECK”

Part I provided an overview of the drug approval process and its undesired side effect—the approval bottleneck. Part I also briefly discussed the struggle between innovator companies and Subsequent Paragraph IV ANDA Filers in dealing with the approval bottleneck. Part II expands the approval bottleneck discussion and discusses the evolution of law that directly or indirectly addresses the approval bottleneck, as well as efforts to conquer it. The laws range from case decisions, such as *MedImmune, Caraco*, and *Janssen Pharmaceutica, N.V. v. Apotex, Inc.*,<sup>133</sup> to statutes, such as the MMA.

### A. *Subsequent ANDA Filers Can Trigger the Exclusivity*

The first step taken towards conquering the approval bottleneck was a court’s decision to provide Subsequent Paragraph IV ANDA Filers with an ability to play a role in effecting the First Paragraph IV ANDA Filer’s 180-day exclusivity.<sup>134</sup> *Minnesota Mining & Manufacturing Co. v. Barr Laboratories* took a crucial step in overcoming the approval bottleneck by stating that Subsequent Paragraph IV ANDA Filers can trigger the First Paragraph IV ANDA Filer’s 180-day exclusivity via a successful court judgment.<sup>135</sup>

### B. *Medicare Prescription Drug, Improvement, and Modernization Act of 2003*

The MMA was originally considered by many to be a permanent solution to the approval bottleneck problem. However, as Part II.B will explain, the approval bottleneck, while mitigated, still remains. Part II.B.1 addresses the forfeiture provisions and their attempt to eliminate the approval bottleneck. Part II.B.2 discusses the civil action to obtain patent certainty provision and its mechanism to overcome the approval bottleneck. However, as also will be discussed in Part II.B.2, the civil action provision

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132. See, e.g., *Janssen*, 540 F.3d at 1358 (noting that Apotex, a Subsequent Paragraph IV ANDA Filer, filed Paragraph IV certifications with respect to three patents but was sued only with respect to the one patent and provided a covenant not to sue with respect to the remaining two patents); *Caraco*, 527 F.3d at 1289 (noting that Forest, the innovator, unilaterally granted Caraco, a subsequent Paragraph IV ANDA filer, an irrevocable covenant not to sue for infringement of the ‘941 patent); *Dey*, 595 F. Supp. 2d at 358 (noting that Sepracor, innovator, sued Dey, Subsequent Paragraph IV ANDA Filer, on only five out of the six patents with Paragraph IV certification by Dey and provided a covenant not to sue on the ‘289 patent); see also *infra* Part II.D.

133. 540 F.3d 1353.

134. See *supra* note 65 and accompanying text.

135. See *supra* note 65 and accompanying text.

has its shortcomings and was fairly inoperable until the 2007 *MedImmune* decision.

### 1. MMA Forfeiture Provisions

The prevailing wisdom after the passing of the MMA was that it had solved the approval bottleneck problem.<sup>136</sup> This notion likely was a result of the establishment of the forfeiture provisions.<sup>137</sup> However, after some time has passed to digest the MMA, further analysis suggests that the possibility of the approval bottleneck still remains.<sup>138</sup> “Like, the old rules, [the MMA] permit[s] a brand-name firm to neutralize the first filer’s challenge through settlement. . . . And the new rules still contain a bottleneck.”<sup>139</sup>

First, the agreement forfeiture provision may have suggested that an approval bottleneck was not possible because a settlement by the First Paragraph IV ANDA Filer, that either the FTC or a court finds to violate federal antitrust laws, leads to the forfeiture of the First Paragraph IV ANDA Filer’s 180-day exclusivity, which clears the path for Subsequent Paragraph IV ANDA Filers to gain FDA approval.<sup>140</sup> This provision, however, has “no teeth” because it requires the FTC or Justice Department to have prosecuted the antitrust case through appeal, as a nonappealable decision is required to cause a forfeiture of the 180-day exclusivity; the FTC administrative proceeding can take years, and one must add the time required for appeals court review.<sup>141</sup>

To recap, because the FDA is prevented from approving a Subsequent Paragraph IV ANDA Filer until the 180-day exclusivity is exhausted or forfeited, the settlement creates an approval bottleneck. The 180-day exclusivity will not be exhausted because the settlement delays launch of the First Paragraph IV ANDA Filer’s generic drug. The exclusivity will not

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136. See *Apotex*, 385 F. Supp. 2d at 190 (“The Medicare Amendments established forfeiture provisions to prevent bottlenecking . . .”); Hemphill, *supra* note 26, at 1587 & n.143 (“[T]he bottleneck does not apply to filings made after December 2003. Due to a statutory change, to simplify greatly a complicated scheme, FDA approval of those later-filed ANDA-IVs generally cannot be long delayed on account of a settlement between the innovator and a first-filing generic firm.”).

137. See 21 U.S.C. § 355(j)(5)(D) (2006); *Apotex*, 385 F. Supp. 2d at 190; see also *supra* Part I.A.3.b.

138. C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking To Preserve Drug Competition*, 109 COLUM. L. REV. 629, 659–60 (2009) (“The MMA’s passage led some to conclude that the settlement problem had been resolved. Five years after the MMA’s passage, however, there is little evidence that settlements . . . have become less popular.”).

139. *Id.* at 660.

140. See *supra* notes 78–82 and accompanying text.

141. See UPADHYE, *supra* note 51, § 14.16; *supra* notes 78–82 and accompanying text. “Congress did not provide for such a forfeiture as the result of any . . . type of settlement” with the innovator company other than a settlement agreement where “there is a final, unappealable order finding that the terms of the agreement violate the federal antitrust laws.” Ramipril Letter, *supra* note 77.

be forfeited in any reasonable time to diminish the harm from the approval bottleneck because forfeiture may only occur at some time in the distant future when and if a nonappealable decision of an antitrust violation has been reached. As a result, the approval bottleneck's existence has not been altered as a result of the agreement forfeiture provision.

Second, the amendment-of-certification forfeiture provision calls for forfeiture of the 180-day exclusivity if the First Paragraph IV ANDA Filer amends the Paragraph IV certification for all of the listed patents.<sup>142</sup> The rationale was that if the First Paragraph IV ANDA Filer enters into a settlement with the innovator company, it must amend its Paragraph IV certification because the certification is no longer valid. If the Paragraph IV certifications are amended, the First Paragraph IV ANDA Filer forfeits its 180-day exclusivity.<sup>143</sup> However, in a letter issued by the FDA, the FDA stated that despite settling with the innovator company, the ANDA Filer does not need to amend its Paragraph IV certification, and, therefore, the First Paragraph IV ANDA Filer is still entitled to its 180-day exclusivity.<sup>144</sup>

Third, the failure-to-market forfeiture provision attempts to prevent the First Paragraph IV ANDA Filer from indefinitely "parking" its exclusivity by having the applicant forfeit its 180-day exclusivity if "it fails to market its product by the later of *two* statutorily defined dates," the (aa) date or the (bb) date.<sup>145</sup> However, this provision also has shortcomings. The (aa) date is the earlier of seventy-five days after the First Paragraph IV ANDA Filer's ANDA is approved, or thirty months after the submission of the ANDA.<sup>146</sup> The (bb) date is seventy-five days after any one of the following three events: (1) a nonappealable court decision that all of the patents, which the First Paragraph IV ANDA Filer made a Paragraph IV certification against, are invalid or not infringed (the court decision can come from a patent infringement suit involving any ANDA Filer or a declaratory judgment action by any ANDA filer); (2) a settlement, which includes a judicial finding that all Paragraph IV certified patents, by the First Paragraph IV ANDA Filer, are invalid or not infringed; or (3) the innovator removes from the Orange Book all patents subject to the Paragraph IV certification by the First Paragraph IV ANDA Filer.<sup>147</sup> Determining the (aa) date and (bb) date is only half the formula because, once again, forfeiture occurs if the First Paragraph IV ANDA Filer fails to market its product by the later of the (aa) date or the (bb) date.<sup>148</sup>

If the First Paragraph IV ANDA Filer settles with the innovator company, the (aa) date will still occur, the earlier of seventy-five days after the First Paragraph IV ANDA Filer's ANDA is approved, or thirty months

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142. See *supra* notes 75–76 and accompanying text.

143. See *supra* Part I.A.3.b.

144. See Ramipril Letter, *supra* note 77; *supra* note 77 and accompanying text.

145. See Bickart, *supra* note 27, at 8-71; see also *supra* notes 70–71 and accompanying text.

146. See *supra* note 70 and accompanying text.

147. See Bickart, *supra* note 27, at 8-71; see also *supra* note 70 and accompanying text.

148. See *supra* notes 70–71 and accompanying text.

after the submission of the ANDA. However, there will likely be no (bb) date because there will be no court decision that the patents are invalid or not infringed and, as the FDA stated in a letter, without a (bb) date, there is no forfeiture of the 180-day exclusivity because there is no later of (aa) or (bb).<sup>149</sup> Therefore an approval bottleneck still exists.

To summarize, the First Paragraph IV ANDA Filer is allowed to delay launching its generic version per the settlement with the innovator without losing its 180-day exclusivity, which prevents subsequent ANDA approvals. In order to create a (bb) date, and lead to a possible forfeiture of the First Paragraph IV ANDA Filer's 180-day exclusivity, which clears the path for Subsequent Paragraph IV ANDA Filers, the responsibility falls on the Subsequent Paragraph IV ANDA Filers to obtain a nonappealable court decision that the Orange Book listed patents are invalid or not infringed, either in a patent infringement suit brought by the innovator company against the Subsequent Paragraph IV ANDA Filer or through a declaratory judgment action brought by the Subsequent Paragraph IV ANDA Filer against the innovator.<sup>150</sup> The Subsequent Paragraph IV ANDA Filer has no exclusivity incentive to overcome litigation costs, yet still needs to enter litigation with the innovator in order to create a (bb) date and lead to a possible forfeiture of the First Paragraph IV ANDA Filer's exclusivity, in order to enter the market.

## 2. MMA Civil Action To Obtain Patent Certainty

One way Subsequent Paragraph IV ANDA Filers can enter a patent litigation suit, in order to trigger the 180-day exclusivity or lead to a forfeiture of the exclusivity, is through the civil action to obtain patent certainty provision.<sup>151</sup> In order to prevent innovator companies from "gaming" the Hatch-Waxman Act by forestalling the resolution of patent disputes with ANDA filers," the MMA allows for a civil action to obtain patent certainty.<sup>152</sup>

This provision allows any ANDA applicant to file a declaratory judgment action against the innovator company, for a "declaratory judgment[,] that the [relevant Orange Book listed] patent is invalid or will not be infringed by the drug for which the applicant seeks approval," as long as the requirements are met and there is a sufficient Article III case or controversy.<sup>153</sup> Subsequent Paragraph IV ANDA Filers can bring a

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149. Granisetron Letter, *supra* note 72; *supra* note 74 and accompanying text.

150. See generally 21 U.S.C. § 355(j)(5)(D)(i)(I) (2006).

151. *Id.* § 355(j)(5)(C).

152. See *Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278, 1285 (Fed. Cir. 2008) (citing *Teva Pharm. USA, Inc. v. Novartis Pharm. Corp.*, 482 F.3d 1330, 1342, 1342 n.7 (Fed. Cir. 2007); see *supra* Part I.B. While this is an MMA provision, it has been applied to pre-MMA ANDAs. See generally *Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, 540 F.3d 1353 (Fed. Cir. 2008); *Caraco*, 527 F.3d 1278.

153. See 21 U.S.C. § 355(j)(5)(C)(i)(II); *Novartis*, 482 F.3d at 1342; see also *supra* Part I.B.

declaratory judgment action to determine that the relevant patents are invalid or not infringed.<sup>154</sup> If victorious, the First Paragraph IV ANDA Filer's 180-day exclusivity is triggered (pre MMA) or the failure to market forfeiture provision is triggered (post MMA).<sup>155</sup> The declaratory judgment, therefore, overcomes a potentially indefinite approval bottleneck, which hopefully will lead to FDA approval of the Subsequent Paragraph IV ANDA Filer's generic drug sooner than if the Subsequent Paragraph IV ANDA Filers had to wait until exhaustion of the 180-day exclusivity following the settlement launch date.<sup>156</sup>

### C. *MedImmune, Inc. v. Genentech, Inc.*

Declaratory judgment can be used to overcome an approval bottleneck; however, obtaining subject matter jurisdiction has proved to be a barrier to accessing this process.<sup>157</sup> It was not until the 2007 *MedImmune* decision, which relaxed the declaratory judgment test, that declaratory judgments became a more viable option for Subsequent Paragraph IV ANDA Filers.<sup>158</sup> Therefore, even though one option to conquer the approval bottleneck existed conceptually in 2002 with *Minnesota Mining & Manufacturing Co. v. Barr Laboratories, Inc.*, which allowed Subsequent Paragraph IV ANDA Filers to trigger the exclusivity of the First Paragraph IV ANDA Filer, the option previously lacked applicability due to the stringent reasonable-apprehension-of-suit test.<sup>159</sup> While the option was assisted with the MMA, which allowed a civil action to obtain patent certainty<sup>160</sup> (declaratory judgments), forcing the innovator companies into a patent lawsuit, parties could not take full advantage of the option until 2007 with the advent of the more lenient, all-the-circumstances declaratory judgment test.<sup>161</sup> As the law evolved to make it easier for Subsequent Paragraph IV ANDA Filers to overcome the approval bottleneck, innovator companies went one step

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154. See *supra* note 89 and accompanying text.

155. See generally *supra* Part I.A.3–B.2.

156. See generally *supra* Part I.B.1–C.

157. See *MedImmune, Inc. v. Genentech, Inc.*, 127 S. Ct. 764, 768–69 (2007); *supra* Part I.B.2.

158. See *supra* Part I.B.4. The MMA provisions allow for declaratory judgments but the actual controversy requirement must still be met. Prior to *MedImmune, Inc. v. Genentech, Inc.*, it was difficult for an ANDA filer to satisfy the declaratory judgment test and meet the requirement. See *supra* note 100 and accompanying text; see also Leary, *supra* note 113, at 389 n.60 (“Declaratory judgments are unavailable to these additional generic challengers if the pioneer simply does not threaten to sue.” (citing *Teva Pharm. USA, Inc. v. Pfizer, Inc.*, 395 F.3d 1324, 1338 (Fed. Cir. 2005))). After *MedImmune*, it is easier to meet the burden to allow a declaratory judgment action to proceed. See *supra* Part I.B.4; see also *Novartis*, 482 F.3d 1330, 1339–40, 1345–46 (stating that the district court, applying the pre-*MedImmune* standard, reasonable-apprehension-of-imminent-suit test, dismissed the declaratory judgment action for lack of jurisdiction, but the Federal Circuit, applying the new *MedImmune* all-the-circumstances test, reversed the dismissal).

159. See *supra* Part I.A.3, I.B.3.

160. See *supra* Part I.B.2.

161. See *supra* Part I.B.4.

further and provided a covenant not to sue as an attempt to remove subject matter jurisdiction in the declaratory judgment action.

#### D. Covenants Not To Sue

As previously mentioned, innovator companies have “a strong incentive to avoid litigation” with Subsequent Paragraph IV ANDA Filers to prevent conquering of the approval bottleneck.<sup>162</sup> With the MMA, Subsequent Paragraph IV ANDA Filers had the power of declaratory judgments and, when combined with the more lenient *MedImmune* all-the-circumstances test, declaratory judgments became a more viable option to deal with innovator companies trying to avoid litigation.<sup>163</sup> Realizing the power generic companies possessed to overcome the approval bottleneck, innovator companies, which previously did not sue, at least not on all of their patents subject to Paragraph IV certifications, went one step further by providing a covenant not to sue to Subsequent Paragraph IV ANDA Filers on all patents or any patents not sued upon.<sup>164</sup> A covenant is a “formal agreement or promise.”<sup>165</sup> Innovator companies hoped the covenant not to sue would prevent any declaratory judgment actions from proceeding, assuming there would no longer exist sufficient Article III case or controversy, and, therefore, any declaratory judgment actions brought by the Subsequent Paragraph IV ANDA Filer would be dismissed for lack of subject matter jurisdiction.<sup>166</sup> It has been previously held in some cases that covenants not to sue divest the court of jurisdiction over the declaratory judgment action, which further propagates the approval bottleneck.<sup>167</sup> However, there are distinguishable characteristics from those cases as they

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162. See *Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278, 1284 (Fed. Cir. 2008); see *supra* Part I.C.

163. See *supra* Part II.A–C.

164. See *supra* note 132.

165. BLACK'S LAW DICTIONARY, *supra* note 96, at 391.

166. See *Caraco*, 527 F.3d at 1288–89. *Caraco* had filed a Paragraph IV certification as to both the '712 and the '941 patent covering Forest's listed drug Lexapro but Forest chose to only sue on the '712 patent. *Id.* However, Forest soon realized the new all-the-circumstances test from *MedImmune* allowed the court in *Novartis* to find sufficient controversy between the parties when Novartis sued on one but not all of the patents Teva had filed a Paragraph IV certification on, and therefore “[a]fter the Novartis decision issued, Forest unilaterally granted Caraco an irrevocable covenant not to sue for infringement” on the '941 patent, which was previously not sued upon by Forest. *Id.* at 1288–89. Forest stated that its intention was to confirm “that there was no case or controversy between the parties regarding the '941 patent.” *Id.* at 1289; see also *supra* Part I.B.

167. See, e.g., *Amana Refrigeration, Inc. v. Quadlux, Inc.*, 172 F.3d 852, 855 (Fed. Cir. 1999) (“[A] covenant not to sue . . . is sufficient to divest a trial court of jurisdiction over a declaratory judgment action.”); *Super Sack Mfg. Corp. v. Chase Packaging Corp.*, 57 F.3d 1054, 1057–59 (Fed. Cir. 1995) (Super Sack's “promise not to sue Chase on the '796 and '652 patents” means “Chase can have no reasonable apprehension that it will face an infringement suit on the '796 and '652 patents . . . [so] it fails to satisfy the first part of our two-part test of justiciability.”); *Eli Lilly & Co. v. Zenith Goldline Pharm., Inc.*, 101 F. Supp. 2d 1139, 1142 (S.D. Ind. 2000) (“[I]t is well-established that a trial court may be divested or deprived of subject matter jurisdiction over a particular patent claim if the patentee covenants not to assert an infringement claim against a putative infringer . . .”).

“either have nothing to do with the Hatch-Waxman Act or were decided under the now-discarded ‘reasonable apprehension of suit’ test.”<sup>168</sup> This distinction is important because *MedImmune* lowers the standard for declaratory judgments.<sup>169</sup> Additionally, as for the non-Hatch-Waxman patent infringement cases, “a covenant not to sue [still] allows the recipient to enter the marketplace” at any time prior to judgment, unlike “in the Hatch-Waxman context, [where] regardless of a covenant not to sue, a generic drug manufacturer cannot enter the market without FDA approval,” which cannot occur for Subsequent Paragraph IV ANDA Filers when there is an unconquered approval bottleneck.<sup>170</sup>

After *MedImmune*, however, in the Hatch-Waxman setting, the treatment of covenants not to sue seems unsettled, as it is a very new area. Small nuances may make the difference as to whether or not a covenant not to sue divests a court of subject matter jurisdiction, propagating the approval bottleneck.<sup>171</sup> The court in *Caraco Pharmaceutical Laboratories, Ltd. v. Forest Laboratories Inc.* concluded that a covenant not to sue did not divest the court of jurisdiction over the declaratory judgment action because the “action present[ed] an ongoing Article III case and controversy.”<sup>172</sup> However, in *Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, decided in the same court about six months later, also a Hatch-Waxman case, the court affirmed the dismissal of Apotex’s declaratory judgment action.<sup>173</sup> Janssen, innovator company, sued Apotex, subsequent Paragraph IV ANDA filer, on one of the three patents covering the listed drug and provided a covenant not to sue with respect to the two remaining patents.<sup>174</sup> To better understand the nuances, an in-depth discussion of both *Caraco* and *Janssen* follow.

In *Caraco*, Ivax, a generic company, was the First Paragraph IV ANDA Filer against patents ‘712 and ‘941 covering Forest’s (an innovator company) listed drug Lexapro.<sup>175</sup> Ivax was, therefore, entitled to the 180-day exclusivity period.<sup>176</sup> Forest sued Ivax on the ‘712 patent but did not sue on the ‘941 patent.<sup>177</sup> Forest also sued Caraco, a Subsequent Paragraph IV ANDA Filer, on the ‘712 patent but not on the ‘941 patent.<sup>178</sup> Ultimately, Forest had won its case against Ivax on the ‘712 patent, which was decided to be valid and infringed, preventing Ivax from obtaining FDA approval.<sup>179</sup> However, Ivax was still entitled to its 180-day exclusivity

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168. Reply Brief for Plaintiff-Appellant at 9, *Caraco*, 527 F.3d 1278 (No. 07-1404).

169. See *supra* Part I.B.4.

170. See *Caraco*, 527 F.3d at 1296.

171. See generally *Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, 540 F.3d 1353 (Fed. Cir. 2008); *Caraco*, 527 F.3d 1278.

172. See *Caraco*, 527 F.3d at 1297.

173. *Janssen*, 540 F.3d at 1363–64.

174. See *id.* at 1357–59.

175. See *Caraco*, 527 F.3d at 1286.

176. See *id.*

177. See *id.*

178. See *id.* at 1288.

179. See *id.* at 1286.



because it was first to file a Paragraph IV certification as to the '941 patent,<sup>180</sup> and a generic company does not forfeit its 180-day exclusivity unless it loses or amends its Paragraph IV certification with respect to all subjected patents.<sup>181</sup> However, Ivax could not trigger its 180-day exclusivity. Ivax could not utilize the court judgment trigger because "Ivax ha[d] not obtained a judgment that both of Forest's . . . patents are invalid or not infringed."<sup>182</sup> Additionally, Ivax could not trigger its 180-day exclusivity via the commercial-marketing trigger until expiration of the '712 patent, which was five years out from when the court of appeals affirmed infringement in 2007.<sup>183</sup>

Caraco, as a Subsequent Paragraph IV ANDA Filer, could not obtain FDA approval until the expiration of the 180-day exclusivity, which Ivax has no way of triggering in the near future.<sup>184</sup> This situation is no different than one in which the First Paragraph IV ANDA Filer enters into a settlement with the innovator company, because in both situations there is an approval bottleneck preventing the Subsequent Paragraph IV ANDA Filer from obtaining approval. If there had been a settlement, Ivax would have chosen not to trigger its 180-day exclusivity via the commercial-marketing trigger by delaying launch of its generic version until the settlement date. There would be no court-decision trigger as the patent infringement suit would have been dropped as a result of the settlement. Therefore, with Ivax out of the picture, only Caraco has the ability to conquer the approval bottleneck and trigger Ivax's exclusivity period before the 2012 expiration date of the '712 patent, which is when Ivax can launch and trigger its own exclusivity via the commercial-marketing trigger.<sup>185</sup> However, in order for Caraco to trigger Ivax's exclusivity, it must obtain a court judgment that "both the '712 and '941 patents are invalid or not infringed."<sup>186</sup> Unfortunately, Forest did not sue Caraco regarding the '941 patent.<sup>187</sup> Following the *MedImmune* decision and the *Teva Pharmaceuticals USA, Inc. v. Novartis Pharmaceuticals Corp.*<sup>188</sup> decision, it should have been easy for Caraco to bring a declaratory judgment action with respect to the '941 patent.<sup>189</sup> However, in addition to not suing Caraco on the '941 patent, Forest, realizing the weakness in its argument after the *Novartis* decision, "granted Caraco an irrevocable covenant not to sue for infringement of the '941 patent."<sup>190</sup>

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180. *See id.* at 1286–87.

181. *See supra* note 56 (discussing loss of patent infringement case and its effect on exclusivity).

182. *See Caraco*, 527 F.3d at 1286.

183. *See id.* at 1286–87.

184. *See id.*

185. *See id.* at 1287.

186. *See id.*

187. *See id.* at 1288.

188. 482 F.3d 1330 (Fed. Cir. 2007).

189. *See supra* note 94; *see also supra* Part I.B.4.

190. *See Caraco*, 527 F.3d at 1289.

The district court, moved by the covenant not to sue, “ruled that there was no Article III controversy and granted Forest’s motion to dismiss.”<sup>191</sup> The court of appeals, however, reversed the district court’s decision and held that Caraco’s declaratory judgment action “presents an ongoing Article III case and controversy.”<sup>192</sup> The Supreme Court’s *MedImmune* decision was important to the court of appeals in reaching its decision.<sup>193</sup> The importance of *MedImmune* was supported by the fact that the court of appeals noted that there was no indication the district court had considered *MedImmune* in reaching its decision.<sup>194</sup> In applying *MedImmune*’s all-the-circumstances test, the court in *Caraco* stated the following: (1) there is injury-in-fact because, unlike a typical patent infringement case where an infringer can enter the market, a covenant not to sue does not allow Caraco to enter the marketplace because it prevents Caraco from overcoming the approval bottleneck;<sup>195</sup> (2) the injury is traceable to Forest because “Forest’s listing of the . . . patents . . . effectively denies Caraco an economic opportunity to enter the marketplace unless Caraco can obtain a judgment that both those patents are invalid or not infringed,”<sup>196</sup> and therefore the ‘941 patent, as one of the two listed patents, is a barrier that “deprives Caraco of an economic opportunity to compete”;<sup>197</sup> (3) Caraco’s injury is redressible by a favorable declaratory judgment that the ‘941 patent is invalid or not infringed, because then Caraco would only require a favorable decision regarding the ‘712 patent, which Forest has already sued on;<sup>198</sup> (4) the action is ripe for judicial review because “additional factual development would not advance the district court’s ability to decide Caraco’s action for a declaratory judgment” and if Caraco does not infringe the patent (or the patent is invalid) then “withholding court consideration of Caraco’s declaratory judgment action has the ‘immediate and substantial impact’ of forestalling Caraco’s ability to activate Ivax’s exclusivity period through the court-judgment trigger”;<sup>199</sup> and (5) the action is not moot because unlike a typical patent case where the threat of suit may be the only action preventing a competitor from entering into a marketplace, which a covenant not to sue would solve, in Hatch-Waxman cases, generic companies are prevented from entering the market until FDA approval, which cannot occur despite Caraco being granted a covenant not to sue because only a court judgment of noninfringement or invalidity on the ‘941 patent can trigger Ivax’s exclusivity and clear the way for FDA approval of Caraco’s ANDA (assuming Caraco prevails on the ‘712 patent case).<sup>200</sup>

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191. *See id.* at 1290.

192. *See id.* at 1297.

193. *See id.* at 1290.

194. *See id.*

195. *See id.* at 1291–92.

196. *See id.* at 1292.

197. *See id.* at 1293.

198. *See id.* at 1288, 1293.

199. *See id.* at 1295.

200. *See id.* at 1296–97.

Therefore, in applying these factors, Caraco's declaratory judgment action presented an Article III controversy according to the all-the-circumstances test and was allowed to proceed.<sup>201</sup> The court emphasized the fact that the covenant not to sue "does not eliminate the controversy with Caraco," because the controversy, "Forest's actions effectively prevent[ing] the FDA from approving Caraco's ANDA and thus exclud[ing] Caraco from the drug market[,] . . . can only be resolved by a judgment that determines whether Forest's '941 patent is infringed [or invalid]."<sup>202</sup>

In *Janssen*, Janssen's listed drug, Risperdal Oral Solution, is covered by three patents '663, '425, and '587.<sup>203</sup> Teva, a generic company, filed an ANDA with a Paragraph III certification on patent '663, therefore waiting for FDA approval until the '663 patent expires, and was the First Paragraph IV ANDA Filer against the remaining two patents, '425 and '587.<sup>204</sup> Teva was therefore entitled to the 180-day exclusivity generated from being the First Paragraph IV ANDA Filer as to those patents.<sup>205</sup> Janssen did not sue Teva on the '425 and '587 patents, allowing the FDA to approve Teva's generic drug as soon as the '663 patent expires.<sup>206</sup> Teva's 180-day exclusivity will begin as soon as Teva begins marketing its drug following FDA approval.

Apotex, a Subsequent Paragraph IV ANDA Filer, filed Paragraph IV certifications with respect to all three patents but was sued only with respect to the '663 patent and provided a covenant not to sue with respect to the '425 and '587 patents.<sup>207</sup> The facts thus far are very similar to the *Caraco* case, with a Subsequent Paragraph IV ANDA Filer being blocked from approval due to the approval bottleneck created by the First Paragraph IV ANDA Filer waiting until a future date to launch its generic version. However, in this case, the first Paragraph IV filer was waiting to launch as a result of submitting a Paragraph III certification with respect to the '663 patent. The situation still results in the Subsequent Paragraph IV ANDA Filer possibly being delayed in obtaining approval as a result of a delayed exhaustion of the 180-day exclusivity, assuming that the '663 patent is invalid or not infringed. The exclusivity will not run until the expiration date of the '663 patent unless a declaratory judgment action can proceed, where a decision favorable to Apotex can trigger Teva's 180-day exclusivity.

However, in contrast to *Caraco*, part way through the litigation Apotex also "stipulated to the validity, infringement, and enforceability of the '663

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201. *See id.* at 1297.

202. *See id.*

203. *Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, 540 F.3d 1353, 1357 (Fed. Cir. 2008).

204. *See id.* at 1358.

205. *See id.*

206. *See id.*

207. *See id.*

patent.”<sup>208</sup> The court once again stated that the *MedImmune* all-the-circumstances test dictates whether there is a “justiciable declaratory judgment action.”<sup>209</sup> In applying the test, the court noted that declaratory judgment jurisdiction must be present during all stages of the court’s review of the case, “not merely at the time the complaint is filed.”<sup>210</sup> In *Janssen*, “the harm that created a justiciable Article III controversy in *Caraco* was present when Apotex filed its [declaratory judgment action] . . . [but] that harm ceased to exist upon Apotex’s stipulation” of validity of the ‘663 patent.<sup>211</sup> Had there been no stipulation, “*Caraco* would have been controlling.”<sup>212</sup> By stipulating to the ‘663 patent, even if Apotex were to successfully invalidate the ‘425 and ‘527 patents in the declaratory judgment action, it still would not be able to obtain FDA approval until the expiration of the ‘663 patent.<sup>213</sup> Therefore, the court stated that the only harm that remains for Apotex is Teva’s 180-day exclusivity, which will be triggered with Teva’s commercial marketing upon the expiration of the ‘663 patent.<sup>214</sup> The exclusivity, by itself, is not a “cognizable Article III controversy” but an incentive provided to generic companies by the Hatch-Waxman Act.<sup>215</sup> Furthermore the court stated that Apotex’s ANDA can be approved on the 181st day after expiration of the ‘663, and, at that time, Apotex can launch its product without fear of suit by Janssen as to the remaining two patents because Apotex has been granted a covenant not to sue with respect to them.<sup>216</sup>

However, without a declaratory judgment, there is the possibility of some harm to Apotex and of delayed access to multiple generics of Risperdal Oral Solution. Apotex had argued that Teva may not launch upon expiration of the ‘663 patent, which would cause an indefinite delay in the approval of Apotex’s ANDA.<sup>217</sup> The indefinite delay in approval of Apotex’s ANDA would be the result of (1) a lack of commercial-marketing trigger of the 180-day exclusivity, if Teva happens to delay its launch; and (2) the lack of a court-decision trigger of the 180-day exclusivity, if a declaratory judgment action is not allowed to proceed with respect to the two patents that Teva was first to file a Paragraph IV certification against.<sup>218</sup> In response to Apotex’s argument of delay, the court stated that the possibility of delay fails the *MedImmune* standard because “at the time

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208. *See id.* at 1360. Additionally, Teva’s Paragraph III certification, which requires the FDA to wait until that patent expires, also implied its belief as to the validity of the ‘663 patent.

209. *See id.* at 1359; *see also supra* Part I.B.4.

210. *See Janssen*, 540 F.3d at 1360 (quoting *Steffel v. Thompson*, 415 U.S. 452, 459 n.10 (1974)).

211. *See id.*

212. *See id.*

213. *See id.* at 1361.

214. *See id.*

215. *See id.*

216. *See id.* at 1358, 1361.

217. *See id.* at 1362.

218. *See generally supra* Part I.A.3.

when the district court entered final judgment in this case, Apotex's alleged harm of indefinite delay of approval was too speculative to create an actual controversy to warrant the issuance of a declaratory judgment."<sup>219</sup> The harm was speculative because Teva could not yet have launched and at no time between filing the declaratory judgment "through the final judgment was there any basis to conclude that Teva will, or is likely to, delay in bringing its generic product to market."<sup>220</sup> The court of appeals's rationale is in line with *MedImmune*, where the Supreme Court stated that the dispute must be "definite and concrete" and "real and substantial" in order for the case to satisfy the Article III case or controversy requirement and to allow the declaratory judgment action to proceed.<sup>221</sup>

The court of appeals's decision in *Caraco*, reversing dismissal of the declaratory judgment action, and the *Janssen* decision, affirming the dismissal of the declaratory judgment action, taken together, suggest that the law may still be unsettled in this area and that small nuances can make a big difference in results.<sup>222</sup> Also, the declaratory judgment option to overcoming the approval bottleneck is far from ideal.

### III. THE STATUS OF THE "APPROVAL BOTTLENECK" AND A POSSIBLE SOLUTION

The threat of harm to a consumer, as a result of delayed access to generic drugs resulting from the approval bottleneck, may seem diminished given the many ways to overcome the approval bottleneck. However, there are many reasons, as Part III.A discusses, suggesting that these solutions are far from ideal. Part III.B goes on to discuss one possible solution to eliminate the approval bottleneck.

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219. See *Janssen*, 540 F.3d at 1362–63.

220. See *id.*

221. See *MedImmune, Inc. v. Genentech, Inc.*, 127 S. Ct. 764, 771 (2007) (quoting *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 240–41 (1937)).

222. *Dey, L.P. v. Sepracor, Inc.*, 595 F. Supp. 2d 355 (D. Del. 2009), is another example of a Hatch-Waxman case. It was a district court case, unlike *Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, 540 F.3d 1353 (Fed. Cir. 2008), and *Caraco Pharmaceutical Laboratories, Ltd. v. Forest Laboratories Inc.*, 527 F.3d 1278 (Fed. Cir. 2008). See *id.* In attempting to apply the rule of law regarding covenants not to sue, the struggle by the court and lack of clear direction from the previous two cases was noted through the following statements: "the instant case is intermediate to *Caraco* and *Janssen*" and "the instant case is more like *Caraco* than *Janssen*." See *id.* at 361–62. The court went on to state that Dey had not precluded itself from going to market like Apotex did in *Janssen*. *Id.* at 362. Additionally, the court acknowledged the possibility of going to market earlier than 2012 and therefore Dey was not just out to extinguish the 180-day exclusivity. *Id.* Therefore, with the given possibility to launch earlier, the court denied Sepracor's motion to dismiss the declaratory judgment action regarding the remaining patent. *Id.* This is yet another illustration of the lack of clarity in this area.

A. *No Present Ideal Solution To Overcome or Eliminate the “Approval Bottleneck”*

The MMA was expected to alleviate the approval bottleneck problem.<sup>223</sup> However, as mentioned in Part II.B.1, the forfeiture provisions do not live up to that expectation. The agreement forfeiture provision has “no teeth” because it requires the FTC or Justice Department to have prosecuted the antitrust case through appeal, as a nonappealable decision is required to cause a forfeiture of the 180-day exclusivity.<sup>224</sup> FTC proceedings alone could take years, and additional time is required for appellate review.<sup>225</sup> The amendment-of-certification forfeiture provision is likewise ineffective because the provision calls for forfeiture of the 180-day exclusivity, if the First Paragraph IV ANDA Filer amends the Paragraph IV certifications for all of the listed patents, which rarely occurs.<sup>226</sup> One reason it is rare to amend all Paragraph IV certifications is because when an ANDA filer enters into a settlement with the innovator company, the ANDA filer does not need to amend its Paragraph IV certification.<sup>227</sup> The Paragraph IV certification is still valid, even though there is a settlement, and, therefore, the First Paragraph IV ANDA Filer is still entitled to its 180-day exclusivity.<sup>228</sup> The failure-to-market forfeiture provision attempts to prevent the First Paragraph IV ANDA Filer from indefinitely parking their exclusivity and blocking Subsequent Paragraph IV ANDA Filers by having the applicant forfeit its 180-day exclusivity if it fails to market its generic version by the later of two statutorily defined dates, the (aa) date or the (bb) date, but this provision also has shortcomings.<sup>229</sup> If the First Paragraph IV ANDA Filer settles with the innovator company, the (aa) date will still occur, but there will likely be no (bb) date because there will be no court decision that the patents are invalid or not infringed.<sup>230</sup> Without a (bb) date, there is no forfeiture of the 180-day exclusivity because there is no way to compute the later of (aa) or (bb).<sup>231</sup>

Furthermore, the MMA’s civil action to obtain patent certainty did not provide a reasonable solution until the 2007 *MedImmune* decision.<sup>232</sup> Therefore, practically speaking, instead of preventing approval bottlenecks, the MMA just provided clarification of a process to overcome approval bottlenecks by explicitly stating that any ANDA filer can bring a declaratory judgment action to potentially declare the innovator’s patents invalid or not infringed.

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223. See *supra* note 136 and accompanying text.

224. See *supra* Part II.B.1.

225. See *id.*

226. See *id.*

227. See *id.*

228. See *id.*

229. See *id.*

230. See *id.*

231. See *id.*

232. See *supra* Part II.B.2–C.

Innovator companies, in trying to stay one step ahead, provided covenants not to sue to Subsequent Paragraph IV ANDA Filers in order to divest the court of subject matter jurisdiction over the declaratory judgment action.<sup>233</sup>

Second, dealing with covenants not to sue is another reason why there is no ideal solution to the approval bottleneck problem. With the lowered *MedImmune* standard, case law now provides for an avenue to overcome covenants not to sue, which could have propagated approval bottlenecks. Once again, however, there are some limitations that render this solution less than ideal.<sup>234</sup> The court in *Caraco* concluded that a covenant not to sue did not divest the court of jurisdiction over the declaratory judgment action.<sup>235</sup> However, in *Janssen*, decided in the same court about six months later, the court affirmed the district court's dismissal of a Subsequent Paragraph IV ANDA Filer's declaratory judgment action, where the innovator company sued the subsequent ANDA filer on one of the three patents and provided a covenant not to sue with respect to the two remaining patents.<sup>236</sup> This decision suggests small nuances will affect the determination of whether covenants not to sue divest the court of subject matter jurisdiction or whether there is an Article III case or controversy to allow the action to proceed.<sup>237</sup> In *Janssen*, unlike *Caraco*, the subsequent Paragraph IV ANDA Filer had removed a Paragraph IV certification with respect to one of the listed drug's patents by stipulating to its validity.<sup>238</sup> That action alone led the court to hold that there was no longer standing, and, therefore, the declaratory judgment action could not proceed.<sup>239</sup> Furthermore, as illustrated by the recent case of *Dey, L.P. v. Sepracor, Inc.*,<sup>240</sup> courts seem to struggle with application of the rule from *Janssen* and *Caraco*.<sup>241</sup> Therefore, while each case may still cause harm to the consumer by delaying access to generic medicine, small differences, which may not be ultimately clear, impact whether the declaratory action will proceed or not.

Third, the timing for a Subsequent Paragraph IV ANDA Filer to overcome the approval bottleneck is too long. In order to overcome the approval bottleneck by triggering the 180-day exclusivity or failure-to-market forfeiture provision of the First Paragraph IV ANDA Filer, a final court decision by the Subsequent Paragraph IV ANDA Filer is required.<sup>242</sup>

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233. See *supra* Part II.D.

234. See *supra* Part II.C–D.

235. See *supra* note 172 and accompanying text.

236. See *supra* notes 173–74 and accompanying text.

237. See *supra* Part II.D.

238. See *id.*

239. See *id.*

240. 595 F. Supp. 2d 355 (D. Del. 2009).

241. See *supra* note 222 (discussing the district courts' attempt to deal with covenants not to sue after *Janssen* and *Caraco*).

242. See *supra* Part I.A.3.

A final court decision requires a court of appeals decision.<sup>243</sup> A district court decision takes on average twenty-five months and a decision on appeal takes on average twelve months, for a total of thirty-seven months from the start of a patent infringement lawsuit.<sup>244</sup> Therefore, even if everything works as planned for the Subsequent Paragraph IV ANDA Filer (i.e., a declaratory judgment action is granted and the Subsequent Paragraph IV ANDA Filer wins the lawsuit declaring the innovator's patents invalid or not infringed), on average thirty-seven months have already passed just to trigger the 180-day exclusivity or failure-to-market forfeiture provisions, at which point the First Paragraph IV ANDA Filer will most likely introduce a generic into the market. Even if the first applicant does not enter the marketplace at this point, it will still be another 180 days (or seventy-five days for post-MMA ANDAs) before the FDA can approve the Subsequent Paragraph IV ANDA Filer's generic version of the listed drug, at which point a generic version is finally available to the consumer.<sup>245</sup> Had there been no approval bottleneck the FDA could have approved the Subsequent Paragraph IV ANDA Filer's generic version in a time frame similar to that of the first applicant. This time frame would entail approval at the earlier of thirty months after the innovator's receipt of ANDA notice or a district court determination that the listed drug's patents are invalid or will not be infringed (averaging twenty-five months).<sup>246</sup> Thus, the approval bottleneck causes delayed access to generic drugs and increases consumer harm by at least twelve months and possibly even longer if the Subsequent Paragraph IV ANDA Filer does not file an ANDA immediately following the First Paragraph IV ANDA Filer. Therefore, even in the most ideal case for the Subsequent Paragraph IV ANDA Filer, where the filer is able to overcome the approval bottleneck, there will still be delayed access to generic medicine for consumers as a result of the approval bottleneck.

Fourth, one of the main purposes of the Hatch-Waxman Act is to encourage generic companies to challenge suspect patents and, therefore, bring lower cost generics on the market earlier.<sup>247</sup> The Act even incentivizes the generic companies to challenge suspect patents and take on the litigation risk by granting a 180-day exclusivity to the First Paragraph IV ANDA Filer, which could be worth millions of dollars.<sup>248</sup> The 180-day exclusivity is not available to Subsequent Paragraph IV ANDA Filers.<sup>249</sup> This means there will be little incentive for the Subsequent Paragraph IV ANDA Filers to take on the costly and lengthy litigation process to overcome the approval bottleneck.<sup>250</sup> Even if the Subsequent Paragraph IV ANDA Filer is successful, when the Subsequent Paragraph IV ANDA Filer

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243. *See supra* Part I.A.3.

244. *See supra* note 63 and accompanying text.

245. *See supra* Part I.A.3.

246. *See supra* Part I.A.2; *supra* note 63 and accompanying text.

247. *See supra* note 48 and accompanying text.

248. *See supra* notes 49–50 and accompanying text.

249. *See supra* note 49 and accompanying text.

250. *See generally* Part I.A.3.



enters the market with its generic version of the listed drug, it will probably be competing with the First Paragraph IV ANDA Filer's generic version and possibly an authorized generic as well.<sup>251</sup> The increased number of generics may make it difficult for the Subsequent Paragraph IV ANDA Filer to recoup its litigation costs, especially given the lengthy process required to overcome an approval bottleneck, and, therefore, the Subsequent Paragraph IV ANDA Filer may decide not to pursue a valid suit against suspect patents.

The reasons laid out above highlight the shortcomings of the current state of affairs in addressing the approval bottleneck. The threat of harm to a consumer, as a result of delayed access to generic medicine, may seem diminished given the many ways to overcome the approval bottleneck, but is still not ideal. One potential solution to the problem is to completely eliminate the mechanism that creates the approval bottleneck, further discussed in Part III.B.

*B. A Permanent, Though Not Ideal, Solution to the  
"Approval Bottleneck" Problem*

The approval bottleneck is an undesired side effect of the operation of the Hatch-Waxman Act.<sup>252</sup> Specifically, the approval bottleneck comes to fruition as a result of the 180-day exclusivity.<sup>253</sup> Without the 180-day exclusivity there would be nothing stopping the FDA from approving a Subsequent Paragraph IV ANDA Filer's generic version of the listed drug via the normal FDA generic drug approval process timeline, which is what the First Paragraph IV ANDA Filer is normally subject to.<sup>254</sup> This would be the case because there would be nothing blocking FDA approval for a Subsequent Paragraph IV ANDA Filer based on the actions of the First Paragraph IV ANDA Filer since there would be no 180-day exclusivity to exhaust.<sup>255</sup> Further support for removal of the 180-day exclusivity, as a solution to the approval bottleneck, is the fact that the United States is the only country to offer such an incentive.<sup>256</sup>

However, the consequence of eliminating the 180-day exclusivity is the removal of a major incentive for ANDA filers to challenge suspect patents and take on the litigation risks.<sup>257</sup> Even without the 180-day exclusivity, generic companies may still challenge suspect patents solely for the purpose

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251. See generally Part I.A.3.

252. See *supra* Part I.C.

253. See *supra* Part I.C.

254. See *supra* Part I.A.2–3.

255. See *supra* Part I.A.2–3.

256. See *supra* note 59 and accompanying text. While a promising solution, even without the "approval bottleneck," there have been many tactics utilized in Europe "to block . . . generic drugs from the European market," which has been estimated to "cost European health-care systems as much as €3 billion (\$3.87 billion) between 2000 and 2007." Jeanne Whalen & Peppi Kiviniemi, *EU Blasts Drug Titans' Tactics*, WALL ST. J., Nov. 29, 2008, at B5.

257. See *supra* Part I.A.3.

of being able to produce a generic version of a listed drug. Some generic companies—especially the bigger generic companies, such as Teva, which challenges many innovator drug patents regardless of whether it has 180-day exclusivity—may not mind being the first to challenge suspect patents, even though patent invalidation would allow other generic companies to free ride on the successful litigation of the first challenger.<sup>258</sup> Furthermore, even without the 180-day exclusivity, a generic company may be incentivized to challenge suspect patents and be the first generic to market because early generic entrants usually maintain a higher market share among all other generic versions of the drug in the long run and, therefore, generate higher revenue.<sup>259</sup> Finally, even though currently the FDA may not approve any other ANDAs prior to the expiration of the 180-day exclusivity, the First Paragraph IV ANDA Filer may not be the only generic version of the listed drug available during the 180-day exclusivity due to an increase in the practice of authorized generics.<sup>260</sup> The authorized generic, licensed by the innovator company under its own NDA, is usually in competition with the First Paragraph IV ANDA Filer's generic drug, which means the 180-day exclusivity period is not worth as much because there are actually two generic versions of the listed drug on the market during the 180-day exclusivity. This practice, therefore, already reduces slightly the importance of the exclusivity period.

The exclusivity period was an incentive to challenge suspect patents and take on litigation risk.<sup>261</sup> As a final thought, one possible incentive option, if the exclusivity period is eliminated, is a litigation cost-sharing mechanism. If the court does in fact find the innovator's patents to be invalid or not infringed, the generic company, challenging the suspect patents, could be provided a portion of their litigation costs.

#### CONCLUSION

The evolution of law, from *Minnesota Mining & Manufacturing Co.* to the MMA, followed by the *MedImmune* decision and *Caraco*, takes significant steps toward solving the approval bottleneck problem, but shortcomings in these advances remain. The threat of harm to a consumer resulting from delayed generic entry caused by the approval bottleneck, while diminished, still exists. One potential solution is to abolish the 180-day exclusivity, which would put the United States on par with other countries. Even though abolishing the 180-day exclusivity would remove

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258. See Press Release, Teva Pharm. Indus. Ltd., Teva Reports Third Quarter 2008 Results (Nov. 6, 2008), [http://www.tevapharm.com/pr/2008/pr\\_800.asp](http://www.tevapharm.com/pr/2008/pr_800.asp) (stating that Teva has 86 Paragraph IV ANDA applications of which Teva believes it is the first to file on only 58 of the 86).

259. Gerson Lehrman Group, TEVA Wins First Generic Approval of Foxamax, Expect TEVA To Hold Market Share (Feb. 11, 2008), <http://www.glggroup.com/News/TEVA-wins-first-generic-approval-of-Foxamax-expect-TEVA-to-hold-market-share-21596.html> (“The first supplier to the market of a generic drug typically holds the market share.”).

260. See *supra* note 51 and accompanying text.

261. See *supra* note 48 and accompanying text.

an incentive for generic companies to challenge suspect patents, many generic companies will still seek approval of their generic versions, and the increased practice of “authorized generics” has already had an impact in reducing the value of the exclusivity period. Therefore, in the interests of consumers, the 180-day exclusivity should be eliminated.

*Notes & Observations*