Chicago-Kent Law Review

Volume 81
Issue 2 *Symposium: Secrecy in Litigation*

Article 13

April 2006

The Hatch-Waxman Act and Market Exclusivity for Generic Manufacturers: An Entitlement or an Incentive?

Ashlee B. Mehl

Follow this and additional works at: https://scholarship.kentlaw.iit.edu/cklawreview

 Part of the Law Commons

Recommended Citation

Ashlee B. Mehl, *The Hatch-Waxman Act and Market Exclusivity for Generic Manufacturers: An Entitlement or an Incentive?*, 81 Chi.-Kent L. Rev. 649 (2006).
Available at: https://scholarship.kentlaw.iit.edu/cklawreview/vol81/iss2/13

This Notes is brought to you for free and open access by Scholarly Commons @ IIT Chicago-Kent College of Law. It has been accepted for inclusion in Chicago-Kent Law Review by an authorized editor of Scholarly Commons @ IIT Chicago-Kent College of Law. For more information, please contact jwenger@kentlaw.iit.edu, ebarney@kentlaw.iit.edu.

THE HATCH-WAXMAN ACT AND MARKET EXCLUSIVITY FOR GENERIC DRUG MANUFACTURERS: AN ENTITLEMENT OR AN INCENTIVE?

ASHLEE B. MEHL*

INTRODUCTION

The United States patent system is the driving force behind pharmaceutical innovation in the United States today.[1] Patent protection allows a research-based pharmaceutical firm to use market exclusivity to recover the tremendous investment necessary to discover and develop new drugs; it also ensures the company's ability to further profit from its innovations before generic drug manufacturers can copy and market the drug at a greatly reduced cost.[2] Without strong intellectual property rights, innovation and pharmaceutical development in research-based firms would deteriorate and consumers might not have access to the medicines they need.[3] On the other hand, United States consumers often do not want to pay the prices that these firms charge for their patented products.[4] Therefore, the work of generic firms in providing lower-cost versions of off-patent drugs is crucial to ensuring that the American public is able to fully benefit from the medical innovation and technology produced by research-based firms.[5] Unfortunately, in the past, the expense and time required for a generic manufacturer to have its own version of a new drug approved by the Food

* J.D., Chicago-Kent College of Law, Illinois Institute of Technology, 2006; B.S., Chemistry, Miami University, 2003. I would like to thank Professor Timothy Holbrook for his invaluable guidance and assistance with this paper, and my parents, Devon and Natalie Mehl, and my sister, Kimberly Moder, for their constant love and support.

1. *See* Gregory J. Glover, M.D., J.D., Pharm. Research and Mfrs. of Am., Competition in the Pharmaceutical Marketplace, Part II, Address Before the Federal Trade Commission and the Department of Justice—Antitrust Division (March 19, 2002).

2. *Id.*

3. *See id.* (patent protection promotes innovation, which leads to the development of the new drugs that eventually become available in generic form at the expiry of patent rights).

4. Douglas A. Robinson, Note, *Recent Administrative Reforms of the Hatch-Waxman Act: Lower Prices Now in Exchange for Less Pharmaceutical Innovation Later?* 81 WASH. U. L.Q. 829, 830 (2003).

5. Senator Hatch recently confirmed the importance and success of the Hatch-Waxman Act, commenting that it "is of great importance to my fellow Utahns and the rest of the American public as it saves an estimated $8 to $10 billion for consumers each year." 149 CONG. REC. S16104, 16104 (daily ed. Dec. 9, 2003) (statement of Sen. Hatch).

and Drug Administration (the "FDA") was substantial and deterred many generic firms from doing so.[6]

Congress attempted to solve this problem by establishing a regulatory framework to strengthen incentives for continued innovation by research-based firms while simultaneously expediting and encouraging earlier market entry of generic drugs.[7] The result was the Drug Price Competition and Patent Restoration Act of 1984, more commonly known as the Hatch-Waxman Act (the "Act").[8] In order to reach its goal, Congress used the Act to create a delicate balance between the rights of research-based firms and generic firms, a balance crucial to the American pharmaceutical industry and the public alike.[9] This Note analyzes how a particular provision of the Act, the generic exclusivity provision, promotes the Act's policies, and this Note then proposes an amendment to ensure that it continues to do so.

In addition to expediting the market entry of generic drugs after patent expiration, Congress also intended the Act to encourage generic firms to challenge drug patents in the midst of their terms.[10] A generic firm successfully challenges a patent when it creates a generic version of the patented drug that does not infringe, or when it establishes the patent's invalidity.[11] This allows the generic firm to market its product immediately,[12] driving down drug prices for consumers earlier than otherwise would have been possible.[13]

6. Prior to the Act, generic manufacturers had to perform their own safety and efficacy studies on the drug product, even though those studies were duplicative of the pioneer manufacturer's efforts to receive FDA approval for the brand-name drugs. FED. TRADE COMM'N., GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY 3–4 (2002). The high cost and time commitment required for this process was likely a significant reason that approximately 150 off-patent brand-name drugs did not have generic equivalents before the Hatch-Waxman Act was passed in 1984. *Id.* at 4.

7. *See* Robinson, *supra* note 4, at 830.

8. *Id.*

9. Senator Hatch commented that congressional debate over amendment of the Act must "observe the principle of balance contained in the original 1984 law so that both research based firms and generic firms receive new incentives that will allow them to continue to produce and distribute the products that the American public deserves." 149 CONG. REC. at 16104.

10. *Id.*

11. *See* 149 CONG. REC. S16104, 16106 (daily ed. Dec. 9, 2003) (statement of Sen. Hatch).

12. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355 (2000). The Act provides that "[i]f the applicant made a [paragraph IV] certification . . . the approval shall be made effective immediately unless, before the expiration of 45 days after the date on which the notice . . . is received, an action is brought for infringement of the patent that is the subject of the certification . . . ." 21 U.S.C. § 355(j)(5)(B)(iii) (2005). On the other hand, if the pioneer does file suit within the forty-five-day window, the Act provides that the abbreviated new drug application "shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided . . . ." *Id.*

13. The Congressional Budget Office conducted a study of pharmacy data in 1993 and 1994 and found that the average price of a generic prescription was half that of the same brand-name prescription, saving consumers an estimated eight to ten billion dollars in 1994 alone. FED. TRADE COMM'N., *supra* note 6, at 9.

Congress included the generic exclusivity provision in the Act to provide an additional incentive to encourage these patent challenges. The provision rewards the first generic firm to challenge a drug patent (the "first-filer") with 180 days of generic market exclusivity, during which time no other generic version of the same drug may enter the market.[14] This quasi-monopoly is given in exchange for the important public benefit produced by the efforts of those generic firms: earlier consumer access to less expensive generic versions of the drugs that are often essential to consumers' well-being.[15]

However, the FDA and the courts have disagreed on how to best implement the provision.[16] When a generic firm challenges the pioneer's patent as invalid or not infringed, the pioneer has the ability to contest that challenge in court before the generic product can enter the market.[17] Not surprisingly, in most cases the pioneer firm sues to contest the generic firm's challenge and preserve its patent term.[18] The generic exclusivity provision, however, makes no mention of how that litigation might affect the award of generic exclusivity.[19] The provision simply prevents all generic versions of a drug for which a previous application has been submitted from entering the market until the first-filer's exclusivity has expired.[20] The FDA's initial regulations required that the first-filer be sued by the patentee and successfully defend itself in that lawsuit (the "successful defense requirement"),[21] before that first-filer could receive generic exclusiv-

14. Senator Hatch recently discussed Congress's intentions to use exclusivity to provide an incentive for early patent challenges. 149 CONG. REC. at 16104.

15. *See* FED. TRADE COMM'N., *supra* note 6, at 9 (discussing consumers' savings as a result of the availability of generic drug products).

16. The FDA promulgated its final successful defense requirement in the face of a district court decision that held the regulation invalid. Abbreviated New Drug Application Regulations, 54 Fed. Reg. 28872, 28895 n.1 (proposed July 10, 1989) (to be codified at 21 C.F.R. pts. 10, 310, 314, 320). The appellate court later officially invalidated the regulation. Mova Pharm. Corp. v. Shalala, 140 F.3d 1060, 1076 (D.C. Cir. 1998).

17. The pioneer has forty-five days in which to file suit against the generic that attempts early market entry with a paragraph IV certification. 21 U.S.C. § 355(j)(5)(B)(iii). If the pioneer sues, the FDA automatically stays approval of the ANDA for thirty months, preventing the generic from entering the market. *Id.*

18. An FTC study revealed that the pioneer sues the first-filer 72 percent of the time. FED. TRADE COMM'N., *supra* note 6, at 14.

19. The Act simply provides that if an ANDA application "is for a drug for which a first applicant has submitted an application containing such a certification, the application shall be made effective on the date that is 180 days after the date of the first commercial marketing of the drug . . . by any first applicant." 21 U.S.C. § 355(j)(5)(B)(iv)(I).

20. *Id.*

21. *See Mova Pharm.*, 140 F.3d at 1065 (citing 21 C.F.R. § 314.107(c)(1) (1994), the previous regulation).

ity under the Act.[22] The D.C. Circuit Court of Appeals, however, invalidated the successful defense requirement as contrary to the provision's plain language.[23]

Since that time, the FDA has awarded exclusivity to the generic firm that is first-in-time to challenge the drug patent, regardless of whether litigation ensues thereafter.[24] Although recent provisions provide for forfeiture of generic exclusivity, reducing some of the delays that were caused by the first-to-file regime, problems remain regarding the exclusivity provision, and further action is necessary to ensure that exclusivity awards are granted consistently with the Act's purposes.[25]

In order to reconcile exclusivity awards with the Act's underlying purpose of facilitating the earliest possible market entry of generic drugs, prevent gaming of the system that delays generic competition, and ensure that exclusivity awards provide a continuing incentive for legitimate patent challenges, Congress should amend the Act to provide for forfeiture of the first-filer's exclusivity when the first-filer is not the first generic firm to successfully challenge the pioneer patent.

Part I of this Note explores the history and policy of the Act and explains the delicate balance it created between rights of pioneer drug companies and the ability of generic firms to enter the market with their own products. Part II examines the dispute that arose out of the generic exclusivity provision of the Act, and details the conflicting reasoning of the FDA and the courts in interpreting that provision. Part III outlines the current state of generic exclusivity law in light of the recent amendments implemented to prevent abuse of the system. Lastly, Part IV proposes a solution to the remaining problems, which ensures that grants of generic exclusivity facilitate generic competition and provides an appropriate incentive and reward to generic firms that challenge pharmaceutical patents.

22. The FDA enacted the successful defense requirement according to its "longstanding interpretation of the act," Abbreviated New Drug Application Regulations; Patent and Exclusivity Provisions, 59 Fed. Reg. 50338, 50353 (Oct. 3, 1994) (to be codified at 21 C.F.R. pt. 314), even though it acknowledged that the Act could "be interpreted in several ways . . . ." Abbreviated New Drug Application Regulations, 54 Fed. Reg. 28872, 28894 (proposed July 10, 1989) (to be codified at 21 C.F.R. pts. 10, 310, 314, 320).

23. *Mova Pharm.*, 140 F.3d at 1076.

24. *See* Purepac Pharm. Co. v. Friedman, 162 F.3d 1201, 1204–05 (D.C. Cir. 1998) (explaining that a decision from the D.C. Circuit Court of Appeals, which invalidated the FDA's successful defense requirement, required the FDA to "go back to the drawing board" and grant exclusivity to first-filers regardless of whether they were sued by the pioneer).

25. The forfeiture provisions enacted in 2003 are detailed later in this Note. *See* 21 U.S.C. § 355 (j)(5)(D) (listing forfeiture events).

I. THE HATCH-WAXMAN ACT: LEGISLATIVE HISTORY AND POLICY

A. Policy Motivations and Enactment

Congress enacted the Drug Price Competition and Patent Restoration Act of 1984, more commonly known as the Hatch-Waxman Act, to facilitate earlier market entry of generic drugs while protecting the patent rights of pioneer drug manufacturers.[26] Put simply, the Act allows the generic manufacturer (the "generic") to use the patented drug information to prepare its own FDA application prior to expiration of the patent rights, provides an abbreviated process for FDA approval of generic drug applications, and protects the patent rights of the research-based drug company (the "pioneer") by adding up to five years of exclusivity onto its patent term.[27] Furthermore, the Act allows the generic to seek market entry prior to expiration of the pioneer's patent term by challenging the patent as invalid or not infringed by its generic product.[28] Once the generic makes that challenge, the pioneer has the ability to sue the generic to contest that claim and prevent the generic's early market entry.[29]

Prior to the Act, the patent rights of pioneer drug companies were diluted by the significant time gap between their receipt of patent protection on a new drug and the FDA approval necessary to begin to sell that new drug on the market.[30] Typically, when the pioneer makes a potentially important discovery, it protects that innovation by immediately applying for a patent.[31] However, regardless of any patent rights that attach to it, a new drug cannot be marketed without FDA regulatory approval.[32] To begin that process, the pioneer must file a new drug application (an "NDA") with the FDA that contains extensive safety and efficacy data for the drug, allowing the FDA to determine the drug's marketability.[33] Because the patent term runs throughout this approval process, by the time the FDA has approved the drug and the pioneer is able to begin marketing it, the pioneer's effective patent term has been significantly shortened.[34] To compensate, the Act

26. *See* 149 CONG. REC. S16104, 16104 (daily ed. Dec. 9, 2003) (statement of Sen. Hatch) (discussing Congress's intent in first drafting the Act).

27. Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 671, 676 (1990).

28. *Id.* at 677.

29. *Id.* at 677–78 (discussing the "highly artificial act of infringement" created by the Act).

30. *Id.* at 669–70.

31. *Id.* at 669.

32. *See id.* at 669–70 (noting that the "clock" on the patent term runs even when that patent relates to a product, such as a new drug, that cannot be marketed without subsequent regulatory approval).

33. *See id.* at 669, 676.

34. *Id.* at 669–70.

provides an increased term of market exclusivity on the back end of the patent term to offset the patent term lost on the front end while the pioneer awaits FDA approval.[35] Specifically, the Act increases the patent term for one-half of the time the drug spends in human clinical trials plus the time for the drug application period, allowing a total extension of up to five years.[36]

Although the pioneer's effective patent term for its drug is effectively shortened on the front end while awaiting FDA approval, prior to the Act the term was also effectively lengthened on the back end while generics underwent the same lengthy FDA approval process for their own versions of the drug.[37] A generic cannot market its product while it awaits FDA approval, and the pioneer therefore retains market exclusivity during this time despite expiration of its patent rights.[38] To speed generic drugs to the market, the Act relaxed the generic approval process that was responsible for the excess delay.[39] As long as it demonstrates bioequivalence, a generic may use the extensive safety and efficacy studies conducted by the pioneer in submitting its own FDA application for a generic version of that drug.[40] Because this approval process available to the generic is much less burdensome than that of the pioneer, the application filed by a generic is known as an abbreviated new drug application (an "ANDA").[41] Congress created the abbreviated approval process to encourage generic manufacturers to develop their drugs and market them as quickly as possible upon expiration of the pioneer's patent.[42]

B. Generic Drugs: An Excuse from Infringement and "Artificial" Infringement

Prior to the Act, the generic remained unable to begin the testing and production necessary for FDA approval of its product until the pioneer's patent term expired.[43] While the Act's abbreviated generic approval proc-

35. *Id.* at 671.

36. Gerald J. Mossinghoff, *Overview of the Hatch-Waxman Act and its Impact on the Drug Development Process*, 54 FOOD & DRUG L.J. 187, 190 (1999).

37. *Eli Lilly*, 496 U.S. at 670.

38. The patentee essentially had a "de facto" monopoly because generics are unable to enter the market to compete with the pioneer until they obtain their own regulatory approval. *Id.*

39. *Id.* at 676.

40. *Id.*

41. *Id.*

42. *Id.*

43. In 1984, the Federal Circuit held that the manufacture, use, or sale of a patented invention during the patent term was an act of infringement, even if that use was limited to conducting tests and

ess reduced some delay in generic market entry, this provision alone does not reduce the pioneer's de facto monopoly term, as generics would otherwise be unable to begin even that abbreviated process until the patent term expired.[44] Because the generic version of a drug would ideally be publicly available as soon as the patent term expired, the Act provides that any experimental tests performed by the generic, in order to collect the bioequivalence data required for its ANDA, will not constitute patent infringement.[45] To take advantage of this "safe harbor" provision, the generic must submit a certification as to whether its generic drug infringes any of the patents that cover the brand-name drug.[46] The generic makes one of four certifications for each patent: (I) that no patent information on that brand name drug has been submitted to the FDA; (II) that the listed patent has expired; (III) that the listed patent will expire on a certain date, before which time the generic will not enter the market; or (IV) that the patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the ANDA was submitted.[47] These options are referred to as paragraph I, II, III, and IV certifications, respectively.[48] When the generic makes a paragraph I or II certification, the FDA may approve its ANDA immediately.[49] The FDA may approve a paragraph III certification anytime after the patent's expiration date.[50] The implications of a paragraph IV certification are not nearly as simple.[51]

A generic makes a paragraph IV certification when it does not want to wait for the expiration of the pioneer's patent rights before it begins to market its own generic version of the drug.[52] Instead, it alleges that it is

developing information needed for the generic to achieve regulatory approval. Roche Prods., Inc. v. Bolar Pharm. Co., 733 F.2d 858, 861, 863 (Fed. Cir. 1984).

44. *Id.* at 864.

45. The Patent Act provides as follows:

> It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

35 U.S.C. § 271(e)(1) (2000).

46. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 355(b)(2)(A)(i)–(iv) (2000).

47. *Id.*

48. Mova Pharm. Corp. v. Shalala, 140 F.3d 1060, 1063 (D.C. Cir. 1998).

49. 21 U.S.C. § 355(c)(3)(A).

50. *Id.* § 355(c)(3)(B).

51. *See* 21 U.S.C. § 355(c)(3)(C) (2005). When the generic applicant makes a paragraph IV certification the date of potential FDA approval depends on the outcome of many further procedural events mandated by the Act. *See* Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 677–78 (1990).

52. *Eli Lilly*, 496 U.S. at 677. If the generic planned on waiting until expiration of the patent to market its product, it would make a paragraph III certification, which indicates the date of patent expiration. *Id.* When the generic makes that certification, it cannot begin marketing until the indicated date, the date the patent expires. *Id.*

justified in early market entry because its drug does not infringe the pioneer's patent or because the patent is invalid.[53] The generic must then notify the patent holder of its paragraph IV certification and provide a detailed factual and legal explanation of why its generic drug does not infringe or why the patent is invalid.[54] In order to prevent frivolous paragraph IV certifications, Congress made the mere filing of the certification itself an act of infringement that gives the pioneer the right to sue the generic.[55] The generic "infringes" when it submits an ANDA that is "in error as to whether commercial manufacture, use, or sale of the new [generic] drug . . . violates the relevant patent."[56] This infringement is referred to as "artificial" because the manufacture, sale, or use of the generic drug has not yet actually occurred.[57]

Once the pioneer receives the requisite notice, it has forty-five days in which to file an infringement suit based on the generic's paragraph IV certification.[58] During that forty-five day window, the FDA may not approve the ANDA and the generic may not file a declaratory judgment action seeking patent invalidity or non-infringement.[59] If the pioneer does not sue the generic during that forty-five day window, the FDA may approve the ANDA immediately.[60] On the other hand, if the pioneer does file suit within the window, the FDA may not approve the ANDA for thirty months, or until a court rules that the patent is invalid or not infringed, whichever is earlier.[61]

C. *Early Market Entry by Generics Prior to Patent Expiration*

If the pioneer does not sue the generic during the forty-five day window, or if the pioneer does sue the generic but the generic prevails in court based on its invalidity or non-infringement challenge, that generic has "successfully challenged" the patent because it has achieved the result it sought and is able to enter the market with its product before it otherwise

53. 21 U.S.C. § 355(b)(2)(A)(iv).
54. *Id.* § 355(b)(3)(D)(ii).
55. *Eli Lilly*, 496 U.S. at 678.
56. *Id.*
57. *Id.*
58. 21 U.S.C. § 355(c)(3)(C).
59. *Id.* (stating that the ANDA will be made effective immediately unless the pioneer files suit within forty-five days, necessarily requiring that the FDA wait forty-five days to see if the pioneer sues); *id.* § 355(c)(3)(D)(i)(I)(aa) (stating that no declaratory judgment action may be brought until the forty-five days have passed).
60. *Id.* § 355(c)(3)(C).
61. *Id.* §§ 355(c)(3)(C)(i)–(iv).

could have.[62] By successfully challenging the pioneer, the generic has fulfilled Congress's intent for the Act, as earlier generic market entry and its resultant public benefit were the specific results Congress sought.[63]

However, in order for a generic to produce these desired results, it must assume great risk and expense. As the generic makes its paragraph IV certification—well before it knows whether it will be successful in its challenge—it must invest the time and money needed for product development, pay the legal fees for evaluations of invalidity and infringement of the pioneer's patent, and assume the risk of the expensive and lengthy litigation that could result if the pioneer files suit.[64] To counteract this risk and expense, the Act rewards the first generic to file a paragraph IV certification on a pioneer drug (the "first-filer") with its own 180-day period of market exclusivity, during which time no other generic may receive ANDA approval.[65] The first-filer's exclusivity begins to toll upon its first commercial marketing of the drug (the "commercial marketing trigger"), and the relevant Act provision provides that the FDA may not approve another ANDA until 180 days after that initial marketing:

> [I]f the [ANDA] contains a [paragraph IV certification] and is a drug for which a first applicant has submitted an application containing such a certification, the application shall be made effective on the date that is 180 days after the date of the first commercial marketing of the drug . . . by any first applicant.[66]

II. PROBLEMS OF GENERIC EXCLUSIVITY: FIRST TO CHALLENGE VERSUS FIRST TO WIN

The FDA and the courts have disagreed over what qualifications are necessary for a first-filer to be entitled to exclusivity.[67] Initially, the FDA

62. The generic challenges the pioneer patent in an attempt to enter the market before expiration of the pioneer patent term; a "successful" challenge is therefore one that allows this desired result, whether it does so by avoiding suit or by a lawsuit that subsequently invalidates the patent or holds it not infringed. Senator Hatch, one of the Act's co-authors, noted his satisfaction with the Act because it "has done so much to help consumers have access to more affordable medications." 149 CONG. REC. S16104, 16106 (daily ed. Dec. 9, 2003) (statement of Sen. Hatch).

64. *See* 21 U.S.C. §§ 355 (j)(2)(A)(i)–(viii) (2000 & 2005) (enumerating all the required elements of an ANDA).

65. *Id.* § 355(j)(5)(B)(iv)(I) (2005).

66. *Id.*

67. The FDA promulgated its final successful defense requirement in the face of a district court decision that held the regulation invalid. Abbreviated New Drug Application Regulations, 54 Fed. Reg. 28872, 28895 n.1 (proposed July 10, 1989) (to be codified at 21 C.F.R. pts. 10, 310, 314, 320). The D.C. Circuit later officially invalidated the regulation. *Mova Pharm.*, 140 F.3d at 1076.

regulations required that the first-filer complete a successful defense of an infringement suit brought by the pioneer before it was awarded generic market exclusivity.[68] In other words, the FDA did not automatically grant exclusivity to a first-filer, but awarded it only if that first-filer was sued by the pioneer, and prevailed in the resulting litigation, before another generic received ANDA approval for that same drug.[69]

This interpretation was reversed by the D.C. Circuit Court of Appeals in *Mova Pharmaceuticals Corp. v. Shalala*.[70] In that case, the first-filer sought to secure its right to exclusivity throughout its litigation with the pioneer, despite the readiness of another generic to bring its own version of the pioneer drug to market.[71] The court sided with the first-filer, invalidating the FDA's regulation as inconsistent with the plain language of the exclusivity provision, and preventing the FDA from approving the subsequent generic's ANDA until the first-filer concluded its litigation.[72]

The following sections detail the FDA's reasoning in promulgating its successful defense requirement and the judicial reasoning that invalidated it. Although both the FDA and the courts made valid points, neither provided a complete solution to the problems created by a straightforward application of the provision's plain language.

A. The FDA: Exclusivity Contingent upon a Successful Defense

In 1989, the FDA drafted regulations that governed application of the 180-day exclusivity provision.[73] The regulations were issued in 1994.[74] At that time, the FDA had granted exclusivity to only three generics.[75] The FDA regulation provided, in relevant part, that

> [i]f an abbreviated new drug application contains a certification that a relevant patent is invalid, unenforceable, or will not be infringed and the application is for a generic copy of the same listed drug for which one or more substantially complete abbreviated new drug applications were previously submitted containing a certification that the same patent was invalid, unenforceable, or would not be infringed *and the applicant sub-*

68. Abbreviated New Drug Application Regulations, 54 Fed. Reg. at 28894.

69. *See* Abbreviated New Drug Application Regulations; Patent and Exclusivity Provisions, 59 Fed. Reg. 50338, 50353 (Oct. 3, 1994) (to be codified at 21 C.F.R. pt. 314).

70. *See* 140 F.3d at 1060.

71. *Id.* at 1062.

72. *Id.* at 1076.

73. *See* Abbreviated New Drug Application Regulations, 54 Fed. Reg. at 28894.

74. Abbreviated New Drug Application Regulations; Patent and Exclusivity Provisions, 59 Fed. Reg. at 50338.

75. The FDA enacted the successful defense requirement according to its "longstanding interpretation of the act," *id.* at 50353, even though it acknowledged that the Act could "be interpreted in several ways . . . ." Abbreviated New Drug Application Regulations, 54 Fed. Reg. at 28894.

> *mitting the first application has successfully defended against a suit for patent infringement brought within 45 days of the patent owner's receipt of notice submitted under § 314.95*, approval of the subsequent abbreviated new drug application will be made effective no sooner than 180 days from [the date the applicant submitting the first application first commences commercial marketing of its drug product].[76]

Unless and until the first-filer successfully defended against patent infringement, the FDA approved any subsequently-filed ANDAs as usual.[77] In other words, before the FDA would recognize the first-filer's right to exclusivity, the first-filer had to (1) be sued by the pioneer during the forty-five day window, and (2) prevail in the resulting litigation.[78]

The FDA reasoned that its successful defense requirement was necessary for two main reasons: first, to preserve the unique function of the provision's commercial marketing trigger while preventing the provision from providing an incentive for delay in generic competition; and second, to prevent exclusivity from providing a windfall to a first-filer that did not devote the time and money necessary for patent litigation.[79]

First, the FDA reasoned that to grant exclusivity to a generic without regard to whether that generic had been sued rendered the commercial marketing trigger superfluous.[80] With the exception of the generic exclusivity provision, all of the Act's other exclusivity provisions are triggered on the date the FDA approves the relevant application.[81] Uniquely, the generic exclusivity provision is not triggered until the first-filer's first commercial marketing of the drug, regardless of whether the FDA has already approved the ANDA.[82] The FDA reasoned that Congress included this unusual trigger because of its intent to protect a generic that was not yet ready to go to market although the FDA had approved its ANDA.[83]

The need for this special protection is clear when the terms of the provision are examined as they would operate if exclusivity were triggered on the FDA approval date. The Act provides that if the pioneer sues the first-filer during the forty-five day window, the FDA must stay approval of the first-filer's ANDA until thirty months have passed or until a court has decided the lawsuit, whichever is earlier.[84] However, those thirty months may

76. *See Mova Pharm.*, 140 F.3d at 1065 (citing 21 C.F.R. § 314.107(c)(1) (1994)).

77. *See* Abbreviated New Drug Application Regulations; Patent and Exclusivity Provisions, 59 Fed. Reg. at 50353.

78. *Id.*

79. *Id.*

80. Abbreviated New Drug Application Regulations, 54 Fed. Reg. at 28894–28895.

81. *Id.* at 28894.

82. *Id.*

83. *Id.*

84. 21 U.S.C. §§ 355(c)(3)(C)(i)–(iv) (2005).

expire before the litigation has resolved. In that situation, the Act does not prevent the FDA from approving the first-filer's ANDA, regardless of the state of the litigation concerning the patent dispute.[85] If the generic exclusivity provision were triggered in the usual way—upon FDA approval of the ANDA—the first-filer could find itself in the midst of litigation at the time its ANDA was approved, and its exclusivity reward would begin to toll. However, no generic is likely to market its drug in the midst of the litigation that will determine whether that marketing will infringe the patent.[86] To do so opens the door for an award of monetary damages based on the actual commercial manufacture and sale of an infringing product, above and beyond the artificial infringement created by the paragraph IV certification alone.[87] On the other hand, if the generic stays off the market, it remains unable to benefit from its exclusivity reward and essentially forfeits as much of that exclusivity as overlaps with the remainder of its litigation.[88]

It was because of this troubling scenario, the FDA reasoned, that Congress deviated from its standard triggering language to provide that generic exclusivity is not triggered upon ANDA approval, but is preserved until the litigation concludes and the first-filer begins to commercially market its product.[89] If the first-filer is not sued by the pioneer there is no need for this special protection (the generic can begin to market immediately upon ANDA approval), and the unique commercial marketing trigger is useless.[90] The FDA reasoned that absent litigation between the pioneer and the first-filer, not only is the commercial marketing trigger useless, but it could be used to thwart congressional intent by allowing for further delay in generic market entry.[91] Knowing its exclusivity will be preserved all the while, the generic can wait as long as it wants before beginning its commercial marketing, triggering its exclusivity, and can keep all other generics out of the market in the interim.

On the other hand, the FDA reasoned, if the Act includes an inherent litigation requirement within its generic exclusivity provision, the commercial marketing trigger furthers the Act's underlying policy. A first-filer's exclusivity should be preserved so long as it may still be the first firm to

85. *Id.* § 355(c)(3)(C) (explaining that the ANDA "may be made effective" after the thirty-month period or upon the occurrence of any one of a list of events before the expiration of that period).

86. *See* Abbreviated New Drug Application Regulations, 54 Fed. Reg. at 28894.

87. 35 U.S.C. § 271(e)(4)(C) (2000).

88. *See* Abbreviated New Drug Application Regulations, 54 Fed. Reg. at 28894.

89. *Id.*

90. *Id.* at 28894–28895.

91. *Id.* at 28894.

bring a generic drug product to market. This result is in the best interests of the first-filer and the public alike because it allows the first-filer to minimize its potential damages[92] and thereby keep its costs low for its consumers. Furthermore, this result ensures that exclusivity remains an effective incentive to file a paragraph IV certification because it preserves that exclusivity in the event that the first-filer is actually sued by the pioneer.

After the D.C. Circuit invalidated the FDA's successful defense requirement, it became clear that unfettered exclusivity awards to first-filers often produced undesirable results.[93] The first-filer maintained control over generic competition until it decided to bring its product to market. That control was abused, for example, when a first-filer colluded with the pioneer.[94] In these cases, the pioneer would agree to settle its suit with the first-filer, paying the first-filer to stay off the market during the life of the pioneer's patent.[95] This preserved the pioneer's highly profitable monopoly and created substantial profit for the first-filer, but froze all other generics out of the market and thereby deprived the public of all generic products. Fortunately, recent amendments to the Act, discussed in greater detail below, corrected this (and other) problems by providing that the first-filer must forfeit its exclusivity if it colludes with the pioneer or does not market its product within a reasonable time.[96] In light of the amendments, even the FDA might not consider its successful defense requirement beneficial today.

In addition to preserving the function of the commercial marketing trigger, the FDA had a second argument in support of its successful defense requirement. The FDA reasoned that the successful defense requirement was necessary to prevent the first-filer that was not sued from receiving a windfall in the form of a grant of generic exclusivity.[97] Because that first-filer had not "devoted the considerable time and money necessary for patent litigation," the FDA explained, any profits produced by its exercise of

92. *Id.*

93. The FTC studied the anti-competitive effects produced by agreements made between the pioneer and the first-filer. FED. TRADE COMM'N., *supra* note 6, at 25. Three types of agreements were made that delayed the start the first-filer's exclusivity period and the FDA's ability to approve subsequent ANDAs: (1) the pioneer paid the generic to stay off the market; (2) the pioneer licensed the generic to use the patents for the brand-name product prior to their expiration; and (3) the pioneer allowed the generic to market the brand-name product as a generic product, but under the pioneer's NDA instead of the generic's ANDA. *Id.* at 17, 25–26.

94. *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, 305–06 (2004).

95. *See id.*

96. 21 U.S.C. § 355(j)(5)(D)(i)(I) (2005).

97. Abbreviated New Drug Application Regulations; Patent and Exclusivity Provisions, 59 Fed. Reg. 50338, 50353 (Oct. 3, 1994) (to be codified at 21 C.F.R. pt. 314).

exclusivity were not needed to reimburse it for that expense, and would simply provide it a windfall.[98]

The FDA was incorrect in concluding that first-filers that are not sued are undeserving of or do not need exclusivity awards.[99] First, even if the first-filer is not sued, it is deserving of exclusivity so long as it produces the desired public benefit. A first-filer produces the desired public benefit when it brings its product to market. Further, assuming it goes to market with its product reasonably quickly, that first-filer has arguably produced a greater public benefit than the first-filer that is sued by the pioneer and must delay generic competition until its litigation resolves. It is not fair to deny a first-filer that has successfully designed around the patent—and is therefore not sued by the pioneer—the reward of exclusivity.[100]

Second, the first-filer needs the financial reward that exclusivity provides regardless of whether it is sued by the pioneer. Because the pioneer sues the first-filer more often than not,[101] the mere filing of a paragraph IV certification requires the first-filer to assume a substantial risk of expensive litigation. The FDA ignored that risk.[102] Additionally, in order to file its ANDA and make its paragraph IV certification, the first-filer necessarily makes a great investment in product development and in a legal assessment of the validity and infringement of the pioneer's patent.[103] Those front-end expenses exist regardless of litigation, and exclusivity should provide a

98. *Id.*

99. *See* Inwood Labs., Inc. v. Young, 723 F. Supp. 1523, 1526 (D.D.C. 1989).

100. As the court reasoned in the *Inwood* decision, the FDA's successful defense requirement

> ignores the contribution that manufacturers such as Inwood [a first-filer that was not sued] make by submitting documentation to a patent holder which is so detailed and persuasive that the patent holder decides not to file a lawsuit. Such a contribution is equally valuable in terms of opening up the market to generic competition.

Id.

101. The data in a FTC study revealed that the pioneer sued the generic in 72 percent of cases. FED. TRADE COMM'N., *supra* note 6, at 14.

102. In reasoning that a reward of exclusivity to a first-filer that was not sued would provide that first-filer with a windfall, the FDA focused only on the fact that the non-sued first-filer had "not devoted the time and money necessary for patent *litigation*," Abbreviated New Drug Application Regulations; Patent and Exclusivity Provisions, 59 Fed. Reg. at 50353 (emphases added), completely overlooking the expense and risk involved in filing the ANDA, before the first-filer even knows whether it will be sued.

103. In terms of its product, the first-filer must demonstrate that its generic product has

> the same active ingredient, route of administration, dosage form and strength, and proposed labeling as the brand-name drug. The ANDA must also contain sufficient information to demonstrate that the generic drug is "bioequivalent" to the relevant brand-name product. As a result of providing this information, the generic applicant is allowed to rely on the FDA's previous findings of safety and effectiveness for the referenced brand-name drug . . . .

FED. TRADE COMM'N., *supra* note 6, at 5. In terms of legal analysis, "[a]n ANDA filer that makes a paragraph IV certification must provide a notice to both the patent holder and the NDA filer with a *detailed statement of the factual and legal basis for the ANDA filer's assertion* that the patent is invalid or not infringed." *Id.* at 6–7 (emphasis added).

reward to a first-filer that effectively uses its front-end investment to avoid a suit by the pioneer.[104]

B. *The D.C. Circuit: Exclusivity Goes to the First to File*

1. *Inwood v. Young*: A Sign of Things to Come

The D.C. District Court decided *Inwood v. Young* on May 12, 1989, and the case was pending appeal when the FDA proposed its successful defense requirement.[105] The FDA noted that the court disagreed with its regulation, but the FDA did not alter the regulation because the *Inwood* decision was vacated as moot on appeal.[106] Nonetheless, the decision set the stage for future cases that ultimately invalidated the successful defense requirement.[107]

In *Inwood*, the pioneer did not sue the first-filer for infringement during the forty-five day window.[108] The first-filer therefore began marketing its drug two weeks after its ANDA was approved, notified the FDA of that commercial marketing, and sought 180 days of exclusivity under the Act.[109] Because the FDA imposed a lawsuit requirement as a precondition to the first-filer's receipt of exclusivity, it refused to grant exclusivity in this case because the pioneer did not sue the first-filer within the forty-five day window.[110]

In spite of the FDA's regulations, the court issued an injunction that prevented the FDA from approving subsequent ANDAs for that drug product until 180 days after the first-filer's initial commercial marketing.[111] The court focused on the statutory language of the Act itself and the exclusivity provision specifically, which made exclusivity dependent upon first commercial marketing of the product without any explicit lawsuit requirement.[112]

104. *See id.* at 7 (discussing the role of exclusivity as an economic incentive to first-filers).

105. Abbreviated New Drug Application Regulations, 54 Fed. Reg. 28872, 28895 n.1 (proposed July 10, 1989) (to be codified at 21 C.F.R. pts. 10, 310, 314, 320).

106. Abbreviated New Drug Application Regulations; Patent and Exclusivity Provisions, 59 Fed. Reg. at 50353.

107. *See* Mova Pharm. Corp. v. Shalala, 955 F. Supp. 128 (D.D.C. 1997), *aff'd*, Mova Pharm. Corp. v. Shalala, 140 F.3d 1060 (D.C. Cir. 1998).

108. Inwood Labs., Inc. v. Young, 723 F. Supp. 1523, 1525 (D.D.C. 1989).

109. *Id.*

110. *Id.*

111. *Id.* at 1527.

112. Because another provision of the Act makes an explicit reference to a lawsuit requirement, the court presumed that Congress's omission of a lawsuit requirement in the exclusivity provision was deliberate. *Id.* at 1526.

Furthermore, the court reasoned that the FDA's "reward" policy applied equally to those generics that successfully designed around the patent and were not sued.[113] As discussed above, a generic that is not sued but is first to bring its product to the market still provides the public with the benefit of earlier access to generic drugs and thereby furthers the underlying goal of the Act.[114] For that reason, the FDA's successful defense requirement unnecessarily prevented a deserving first-filer from receiving exclusivity.[115]

Additionally, the court reasoned that to require a lawsuit placed too much control of exclusivity in the hands of the pioneer—the pioneer could elect not to sue the first-filer and thereby extinguish generic exclusivity altogether, as any later generics would not be the first-to-file and therefore would not receive exclusivity even if they were to successfully defend a lawsuit.[116] However, this portion of the court's reasoning is unconvincing because it is based on an illogical scenario. If the pioneer does not file suit, the generic may enter the market immediately upon expiration of the forty-five day window.[117] Thus, the first-filer destroys the pioneer's highly profitable monopoly before its patent has expired. It is not likely that the pioneer would elect not to sue the first-filer, giving up its own legal monopoly, solely to defeat the quasi-monopoly rights that would accord to the first-filer as a result of the suit.[118] However, in light of what is actually at stake for the pioneer that does not sue the first-filer, the court's "reward" reasoning becomes even stronger—if the pioneer considers its case against the first-filer too weak to justify bringing suit, even with preservation of its monopoly at stake, it seems that the first-filer has truly earned the reward of exclusivity.[119]

2. The Next Step: *Mova v. Shalala*

In 1997, the D.C. District Court invalidated the FDA's successful defense requirement in its *Mova v. Shalala* decision, and the D.C. Circuit

113. *Id.*

114. *Id.*

115. *See id.*

116. *Id.* at 1526–27.

117. 21 U.S.C. § 355(c)(3)(C) (2005).

118. The FTC reported that the pioneer sues the first-filer approximately 75 percent of the time. FED. TRADE COMM'N., *supra* note 6, at 13. In the other 25 percent of cases, the FDA approved most of the applications, allowing market entry and destruction of the pioneer's monopoly. *Id.*

119. *See Inwood Labs.*, 723 F. Supp. at 1526 (reasoning that the non-sued first-filer's ANDA may be so "detailed and persuasive" that the pioneer decides not to file suit).

Court of Appeals affirmed in 1998.[120] The *Mova* decision provides an important comparison to the *Inwood* case because *Mova* illustrates the application of the successful defense requirement when the pioneer does sue the first-filer.[121]

Mova was the first generic to file a paragraph IV certification ANDA for a patent owned by Upjohn Company.[122] Upjohn sued Mova within the forty-five day window, but when Mylan, another generic manufacturer, later filed its own paragraph IV ANDA, Upjohn did not sue.[123] The FDA therefore approved Mylan's ANDA despite the fact that Mova was the first-filer.[124] Mova filed suit to compel the FDA to delay the approval of Mylan's ANDA and preserve Mova's right to exercise exclusivity.[125] The FDA argued that the statute was ambiguous as to exclusivity awards when the first-filer was sued for patent infringement and the second ANDA applicant was not sued.[126] Therefore, the FDA reasoned that its "successful defense" requirement was a necessary agency interpretation to resolve that ambiguity in a way that furthered the policy of bringing generic drugs, like Mylan's, to market earlier.[127] Because Mova had not yet successfully defended the lawsuit, the FDA reasoned, it was not entitled to exclusivity.[128]

Citing its earlier decision in *Inwood*, the court held that although the language was "complex, and even cumbersome," it was not ambiguous and certainly did not include a successful defense requirement.[129] Although the court granted Mova the relief it sought, it acknowledged that the statute might produce unintended results without the successful defense requirement.[130] First, elimination of the requirement could encourage frivolous ANDA filings by generics racing for the highly valuable market exclusivity.[131] Second, the provision could delay market entry of generic drugs because it required later filers that were ready to go to market to wait for the conclusion of what is often lengthy litigation (as was the situation in the

120. Mova Pharm. Corp. v. Shalala, 955 F. Supp. 128 (D.D.C. 1997), *aff'd*, Mova Pharm. Corp. v. Shalala, 140 F.3d 1060 (D.C. Cir. 1998).

121. *Id.* at 129.

122. *Id.*

123. *Id.* at 129–30.

124. *Id.* at 130.

125. *Id.* at 129. The issue before the court was whether Mova was likely to be able to show that the FDA regulation was inconsistent with the statutory language and therefore unenforceable as exceeding the FDA's authority under the statute. *See id.* at 130.

126. *Id.* at 130.

127. *Id.*

128. *Id.*

129. *Id.*

130. *Id.* at 131.

131. *See id.*

Mova case itself).[132] Still, the court rejected the FDA regulation and concluded that any remedy for potential abuses lied with Congress.[133]

3. The D.C. Circuit Affirms and Invalidates "Successful Defense"

On appeal, the D.C. Circuit Court of Appeals affirmed the invalidity of the FDA regulation.[134] Nonetheless, the court acknowledged that additional regulations were necessary to clarify the provision's terms and preserve the statutory scheme.[135] However, "[w]hen the agency concludes that a literal reading of a statute would thwart the purposes of Congress, it may deviate no further from the statute than is needed to protect congressional intent."[136]

The court reasoned that the FDA's regulation was clearly inconsistent with the language of the statute, which plainly awarded exclusivity to the generic that was first-in-time to file a patent challenge.[137] Therefore, the court invalidated the FDA's successful defense requirement in favor of the court's "wait and see" approach, which it reasoned was more consistent with the statutory language because it did not hinge exclusivity awards upon the first-filer's participation in litigation with the pioneer.[138] The court's "wait and see" solution grants exclusivity to the generic that is first-in-time to file an ANDA, consistently with the statutory text, and then requires the FDA to stay any subsequent ANDA until the first-filer resolves its suit.[139] If the first-filer loses, exclusivity does not apply; if it wins, exclusivity applies.[140]

The court's solution preserves exclusivity for a first-filer that is not sued by the pioneer, ensuring that the first-filer receives the statutory reward for bringing an early challenge to the pioneer's patent.[141] As long as

132. *See id.*

133. *Id.*

134. Mova Pharm. Corp. v. Shalala, 140 F.3d 1060, 1076 (D.C. Cir. 1998).

135. *Id.* at 1071. To solve the problem of the first-filer that is never sued, the court discussed the possibility of requiring only that the first-filer be sued within forty-five days of filing instead of requiring a complete successful defense. *Id.* Alternatively, the court suggested that the FDA could prescribe a time-limit during which the non-sued first-filer must bring its product to market to maintain its right to exclusivity. *Id.* at 1071 n.11. As to a first-filer that loses its suit, the court pointed to an FDA regulation that required the first-filer to withdraw its paragraph IV certification and make a new certification under paragraph III, and proposed that the FDA interpret the regulation to render the exclusivity period inapplicable after such an amendment. *Id.* at 1071.

136. *Id.* at 1068.

137. *Id.* at 1069.

138. *Id.*

139. *Id.*

140. *Id.*

141. *See id.*

that first-filer brings its product to market, it will produce the desired public benefit by providing early access to its generic drug. In this way, the court's solution corrected an undesirable result of the FDA's successful defense requirement.

However, the court's solution created two problems with the statutory scheme. First, the court's "wait and see" approach requires a second-filer that is not sued, and is therefore capable of entering the market, to wait indefinitely for the resolution of the first-filer's suit before it can do so.[142] This "meritorious second applicant" is prevented from bringing its drug to market, even though it is the first generic capable of doing so, because the FDA must preserve the exclusivity of the first-filer until the first-filer resolves its litigation.[143] The public is thereby denied the earliest possible access to a generic drug.[144]

Congress intended the Act to facilitate the earliest possible market entry of generic drugs and included the generic exclusivity provision as one way to facilitate that goal, not undermine it. The court admitted that its "wait and see" solution produced a situation in which "the public is deprived of the fruits of [the second applicant's] ingenuity—a result seemingly at odds with Congress's apparent [purpose] . . . of rewarding innovation and bringing generic drugs to market quickly."[145] In the case of a meritorious second applicant, preservation of the first-filer's generic exclusivity should yield to the public interest in access to that second applicant's product.[146] Although the court refused to accept the FDA's successful defense requirement, it did not "foreclose the FDA from attempting to address the problem of the meritorious second applicant in some narrower way, as long as that solution conforms to the statute."[147]

The second problem created by the court's "wait and see" approach gives the pioneer a large degree of control over the generic market, creating the exact problem the D.C. District Court was concerned about in *Inwood*.[148] The pioneer may sue the first-filer, preserving its own monopoly and staying FDA-approval of the first-filer's ADNA for thirty months, and then elect not to sue later generics, saving itself from additional litigation

142. *Id.* at 1069.

143. *Id.* at 1072, 1074.

144. *Id.* at 1072.

145. *Id.*

146. *See* 149 CONG. REC. S16104, 16105–16106 (daily ed. Dec. 9, 2003) (statement of Sen. Hatch).

147. *Mova Pharm.*, 140 F.3d at 1074.

148. The *Inwood* court expressed concern over the pioneer manipulating the generic exclusivity provision to prevent generic competition. Inwood Labs., Inc. v. Young, 723 F. Supp. 1523, 1526–27 (D.D.C. 1989).

while freezing the entire generic market for the duration of its litigation with the first-filer.

C. *The FDA's Elimination of the Successful Defense Requirement and the Judicial Response*

In June 1998, approximately two months after the appellate decision in *Mova*,[149] the FDA issued an industry-wide guidance concerning the application of generic exclusivity in light of the court's invalidation of its successful defense requirement.[150] Until it officially removed the old requirement from the regulatory scheme, the FDA indicated that it would "regulate directly from the statute" and "make decisions on 180-day generic drug exclusivity on a case-by-case basis."[151] The FDA specifically indicated that the first-filer would receive exclusivity upon filing its ANDA, regardless of whether it was sued.[152] Shortly thereafter, in its *Purepac* decision, the D.C. Circuit Court of Appeals held that the FDA's industry guidance had effectively eliminated the successful defense requirement and confirmed that the first-filer did not need to be sued in order to receive exclusivity rights.[153]

III. THE CURRENT STATE OF GENERIC EXCLUSIVITY LAW

A. *Forfeiture and Exclusivity Triggers*

In 2003, Congress passed several amendments to the Act that have substantially changed the exclusivity provisions. The amendments detail

149. In the meantime, the Fourth Circuit had also invalidated the FDA's successful defense requirement in a 1998 case, although its decision was never published. Granutec, Inc. v. Shalala , Nos. 97-1873, 97-1874, 1998 WL 153410, at *7 (4th Cir. Apr. 3, 1998).

150. CENTER FOR DRUG EVALUATION AND RESEARCH, U.S. DEP'T OF HEALTH AND HUMAN SERVS., GUIDANCE FOR INDUSTRY: 180-DAY GENERIC DRUG EXCLUSIVITY UNDER THE HATCH-WAXMAN AMENDMENTS TO THE FEDERAL FOOD, DRUG, AND COSMETIC ACT 1 (1998), *available at* http://www.fda.gov/cder/guidance/2576fnl.pdf.

151. *Id.* at 4.

152. *Id.* at 4–5.

153. Purepac Pharm. Co. v. Friedman, 162 F.3d 1201, 1204 (D.C. Cir. 1998). Purepac was the second generic manufacturer to file an ANDA on a pioneer patent, and although its application was tentatively approved by the FDA, final approval was stayed pending the completion of the first-filer's exclusivity period. *Id.* at 1202. The first-filer was not sued by the pioneer, but its ANDA had not yet been fully approved by the FDA, so it could not yet market its product. *Id.* Thus, its exclusivity period had not yet begun to run. *Id.* Purepac argued that although the court's *Mova* decision eliminated the successful defense requirement, it did not eliminate the lawsuit requirement all together, and that the FDA therefore had no grounds to award exclusivity to a first-filer who had not been sued at all. *Id.* at 1204. The court disagreed and held that the FDA regulations were properly in line with the plain language of the statute. *Id.* at 1205.

many circumstances under which the first-filer will forfeit its exclusivity.[154] First, the first-filer forfeits its exclusivity if it fails to market the drug by the later of (1) seventy-five days after the date on which (a) approval of its application is effective, or (b) thirty months after its application was submitted, whichever is earlier; or (2) seventy-five days after the date on which (a) a court has found the patent invalid or not infringed, (b) a court has signed a settlement order or consent decree finding the patent invalid or not infringed, or (c) the patentee has withdrawn the patent information pertaining to the approved NDA.[155]

In other words, the first section of the provision gives the first-filer that has not been sued seventy-five days from the date of its ANDA approval to begin its exclusive commercial marketing.[156] This provision prevents the first-filer from sitting on its exclusivity and delaying market entry by subsequent generics.[157] If the first-filer does not enter the market within seventy-five days, exclusivity is forfeited and other generics are immediately able to enter the market.[158] The first section may also apply when the first-filer has been sued, and its ANDA is therefore stayed for thirty months. If the litigation is resolved (and the ANDA is therefore approved) more than seventy-five days before expiration of the automatic thirty-month stay, the first-filer must enter the market within seventy-five days of that resolution.[159] If the litigation is not resolved before expiration of the thirty-month stay, although the ANDA may be automatically approved by the FDA, the court will look to the second section of the forfeiture provision, which provides a later marketing deadline.[160]

According to the second section of the forfeiture provisions, the first-filer may wait to go to market until seventy-five days after (1) the patentee withdraws its NDA patent information; (2) the court signs a settlement decree that its patent is invalid or not infringed; or (3) the litigation con-

154. *See* Lietzan, *supra* note 94, at 288–89.

155. 21 U.S.C. § 355(j)(5)(D)(i)(I) (2005).

156. *Id.*

157. This provision solves one of the problems that motivated the FDA's successful defense requirement because it prevents the non-sued first-filer from preserving its exclusivity indefinitely until it decides to begin commercially marketing its product. Abbreviated New Drug Application Regulations, 54 Fed. Reg. 28872, 28894 (proposed July 10, 1989) (to be codified at 21 C.F.R. pts. 10, 310, 314, 320).

158. 21 U.S.C. § 355(j)(5)(D)(i)(I)(aa)(AA) (stating that if the first-filer that is not sued by the pioneer has seventy-five days after the forty-five day window has lapsed to begin to market); *Id.* § 355(j)(5)(D)(iii) (stating that if the first-filer forfeits its exclusivity no other generic is eligible for exclusivity).

159. *Id.* §§ 355(j)(5)(D)(i)(I)(aa)(AA)–(BB).

160. Forfeiture occurs if the first-filer fails to market its product by the later of the first and second sections of the "failure to market" provision. *Id.* § 355(j)(5)(D)(i)(I).

cludes and the patent is held invalid or not infringed.[161] This provision further confirms that Congress sought to preserve exclusivity beyond the date of ANDA approval in order to encourage the first-filer to remain off of the market until its litigation concluded. Preservation of exclusivity is justified in this scenario because the first-filer may still be the first to successfully bring a generic product to market.

Additionally, exclusivity is forfeited if the first-filer (1) withdraws its application or the application is considered withdrawn for failing to meet the requirements for approval; (2) amends or withdraws its paragraph IV certifications that qualified it for exclusivity; (3) fails to obtain tentative approval of its application within thirty months after it was filed (unless that failure was caused by a change in requirements for approval after the application was filed); (4) enters into an agreement with another ANDA applicant, the NDA holder, or a patent holder, and the Federal Trade Commission or a court finds that the agreement violates antitrust laws; or (5) does not begin its exclusivity before all the patents as to which it filed a paragraph IV certification have expired.[162] In the case of any forfeiture by the first-filer, the exclusivity period itself is also forfeited and will not "roll over" to any subsequent generic who files an ANDA.[163]

B. Inadequacies of the Amendments

One of Congress's primary goals in passing the Act was to strike a balance between the needs of research-based pharmaceutical firms and generic firms so that both would have the incentive necessary to continue to produce and distribute the drugs that the American public needs.[164] As a corollary to that goal, Congress intended to create an atmosphere that would encourage generics to challenge patents during their terms and bring low-cost generic drugs to consumers earlier.[165] Congress's passage of the 2003 amendments reemphasized this purpose and brought the focus back to the needs of the consumers for whom the Act was created. Specifically, Congress's amendments indicate its intolerance for delay caused by the generic exclusivity provision. The forfeiture provisions clearly indicate that the first-filer's exclusivity is not intended as an absolute guarantee but is

161. *Id.* §§ 355(j)(5)(D)(i)(I)(bb)(AA)–(CC).
162. *Id.* §§ 355(j)(5)(D)(i)(II)–(VI).
163. *Id.* § 355(j)(5)(D)(iii).
164. 149 CONG. REC. S16104, 16104 (daily ed. Dec. 9, 2003) (statement of Sen. Hatch).
165. *Id.* at 16104–16105.

meant to yield if that exclusivity produces delay in consumer access to generic drug products.[166]

The 2003 amendments correct the main concern that motivated the FDA to promulgate the successful defense requirement because they prevent the abuses that might otherwise result from an award of exclusivity to a first-filer that is not sued by the pioneer.[167] However, the amendments provide a more narrow solution to those problems than did the FDA because the amendments adhere to the plain language of the exclusivity provision and appropriately further the Act's policy. Consistent with the plain language of the provision, and unlike the successful defense requirement, the amendments do not deny the grant of exclusivity to the generic that is first-in-time to file its ANDA.[168] The amendments do provide that a first-filer that either colludes with the pioneer to stay off the market, or otherwise unnecessarily delays its commercial marketing, will forfeit its exclusivity.[169] Therefore, the first-filer loses its statutory right to exclusivity only when it uses that exclusivity in a manner contrary to the purposes of the Act. The 2003 amendments ensure that the exclusivity functions in accordance with the plain language of the provision itself and with congressional policy: the first-filer that provides the public with generic competition receives exclusivity, regardless of whether it produces that public benefit through successful defense of a lawsuit or successful avoidance of a lawsuit.

On the other hand, the 2003 amendments do not correct the problems created by D.C. Circuit's "wait and see" application of the provision. The problem of the meritorious second applicant survived the congressional amendments, and further action is needed to correct it.[170] The amendments emphasize the policy of the exclusivity provision: the first-in-time to file will automatically receive exclusivity, but will forfeit its exclusivity once it becomes clear that preservation is not facilitating earlier generic competition. Because the existence of a meritorious second applicant is one such

166. *See id.* at 16105–16106.

167. 21 U.S.C § 355(j)(5)(D)(i)(I) (stating that the first-filer that is not sued forfeits its right to exclusivity if it does not bring its product to market within seventy-five days of its ANDA approval date); *id.* § 355(j)(5)(D)(i)(V) (the first-filer forfeits its exclusivity if it enters into an agreement with the pioneer that violates antitrust laws).

168. *Id.* § 355(j)(5)(B)(iv)(I).

169. *Id.* § 355(j)(5)(D)(i)(I) (stating that the first-filer that is not sued forfeits its right to exclusivity if it does not bring its product to market within seventy-five days of its ANDA approval date); *id.* § 355(j)(5)(D)(i)(V) (stating that the first-filer forfeits its exclusivity if it enters into an agreement with the pioneer that violates antitrust laws).

170. Senator Hatch has specifically discussed the problem of the meritorious second applicant that was created by the D.C. Circuit's decision in the *Mova* case. *See* 149 CONG. REC. at 16105.

circumstance, it must be added to the list of events that will forfeit the first-filer's exclusivity.[171]

The first-filer that is not sued receives exclusivity because it is able to bring its product to market and produce the public benefit of generic competition; the first-filer that is entrenched in litigation when its ANDA is approved maintains exclusivity because it is working to produce that same public benefit and may still be the first to do so.[172] The D.C. Circuit ensured these congruent results by invalidating the FDA's successful defense requirement.[173] The 2003 amendments provide that the first-filer that is not sued forfeits its exclusivity once it becomes apparent that its exclusivity will produce no public benefit.[174] Now, further amendment is necessary to ensure a congruent result in the case of the first-filer that is entrenched in litigation. The first-filer that is entrenched in litigation should similarly forfeit its exclusivity once it becomes apparent that its exclusivity will produce no public benefit—in other words, when a meritorious second applicant is ready to bring its product to market before the first-filer.[175] Otherwise, the exclusivity provision creates an entitlement for the first-filer at the expense of other generic firms and the public alike.[176]

IV. A PROPOSED SOLUTION: EXCLUSIVITY FORFEITED BY AN INTERVENING SUCCESSFUL CHALLENGER

In order to ensure that United States courts apply the exclusivity provisions of the Act in a way that best furthers the Act's underlying policies and protects the interests of both generic manufacturers and the public, Congress should amend the Act to provide forfeiture of the first-filer's exclusivity when the first-filer is not the first generic to successfully challenge the pioneer patent. This action would remedy past misinterpretations and applications of the Act and ensure that future exclusivity awards act as an incentive to further the policies of the Act.

One of Congress's central goals in promulgating the Act was to provide the public with earlier access to low-cost generic drugs.[177] However,

171. *Id.* at 16105–16106.

172. *See* Mova Pharm. Corp. v. Shalala, 140 F.3d 1060, 1069 (D.C. Cir. 1998) (explaining why the first-filer that is entrenched in litigation maintains exclusivity); *See* Inwood Labs., Inc. v. Young, 723 F. Supp. 1523, 1526 (D.D.C. 1989) (explaining why the first-filer that is not sued receives exclusivity).

173. *Mova Pharm.*, 140 F.3d at 1076.

174. 21 U.S.C. § 355(j)(5)(D)(i)(I) (2005).

175. 149 CONG. REC. at 16105–16106.

176. *See id.*

177. *See* Fed. Trade Comm'n., Generic Drug Entry Prior to Patent Expiration: An FTC Study i–ii (2002).

in order for a generic to challenge the pioneer patent, the generic must assume the risk of litigation with the pioneer and the expense necessary both to complete its ANDA and evaluate the validity and infringement of the pioneer patent. Congress enacted the generic exclusivity provision to counteract the deterrent effect created by that risk and expense.[178] By its plain language, this provision provides market exclusivity to any generic that is the first-to-file a challenge to a pioneer patent.[179] However, since the provision's enactment, the FDA and courts alike have realized that exclusivity awards based on that simple language alone produce unintended consequences. Different FDA regulations, judicial interpretations, and congressional amendments have attempted to reconcile that language with the Act's purposes.[180]

Three problematic scenarios result from completely unfettered awards of exclusivity to the generic that is first-in-time to file. First, if the first-filer is sued by the patentee and loses the lawsuit, the first-filer remains unable to market its infringing product prior to patent expiration, and is therefore unable to trigger its exclusivity, excluding all other generics from the market until the patent expires as well.[181] Second, if the first-filer is sued by the patentee and remains in litigation when a second-filer completes its ANDA, is not sued by the pioneer, and is ready to go to market, the public is denied access to that second-filer's generic product even though the first-filer is unable to market its own product.[182] Finally, if the first-filer is not sued by the pioneer, the first-filer may remain off the market indefinitely, excluding all other generics from the market until it decides to commercially market its own product.[183] The first and third problems have been solved by regulation[184] or amendment,[185] but the second problem remains and must be corrected.[186]

Because Congress intended the Act to produce earlier generic market entry, the generic exclusivity provision should not be applied to excuse

178. *See id.*

179. 21 U.S.C. § 355(j)(5)(B)(iv)(I) (2005).

180. *See id.* § 355(j)(5)(D) (recent forfeiture amendments); *Mova Pharm.*, 140 F.3d at 1069–72 (court's interpretation); Abbreviated New Drug Application Regulations; Patent and Exclusivity Provisions, 59 Fed. Reg. 50338, 50353 (Oct. 3, 1994) (to be codified at 21 C.F.R. pt. 314) (FDA interpretation).

181. Mova Pharm. Corp. v. Shalala, 140 F.3d 1060, 1067 (D.C. Cir. 1998).

182. *Id.* at 1072.

183. *Id.* at 1067.

184. FDA regulation requires that a first-filer that loses its suit must amend its certification to make a new paragraph III certification, forfeiting its right to exclusivity. *Id.* at 1071 & n.12 (citing 21 C.F.R. § 314.94(a)(12)(viii)(A)).

185. 21 U.S.C. § 355(j)(5)(D) (2005).

186. 149 CONG. REC. S16104, 16105–16106 (daily ed. Dec. 9, 2003) (statement of Sen. Hatch).

unnecessary delay in that market entry.[187] So long as the first-filer remains able to be the first generic to bring its product to market, it is entitled to have its exclusivity preserved. This is illustrated by Congress's inclusion of the commercial marketing trigger, which preserves exclusivity throughout the pendancy of the first-filer's litigation despite the FDA's approval of the first-filer's ANDA.[188] In that case, the reward of exclusivity is not denied to the first-filer because the first-filer is still capable of fulfilling the Act's purpose and is in the process of attempting to do so.[189] However, once a meritorious second applicant is able to antedate the first-filer's market entry, the public interest in the earliest possible access to a generic product outweighs its interest in preservation of the first-filer's exclusivity.[190] Therefore, the presence of a meritorious second applicant should forfeit the first-filer's exclusivity, allowing the second-applicant to immediately begin marketing its product.[191]

This change is in accordance with the 2003 amendments to the Act, which illustrate that Congress is intolerant of delay that is not necessary to fulfill the Act's purposes. When a first-filer colludes with the pioneer or otherwise unnecessarily delays its market entry, it is denied exclusivity.[192] In providing for this result, Congress affirmed that exclusivity is not an entitlement of the first-filer, but a reward provided for creating a public benefit.[193] Congress thus created a balance between the first-filer's right to exclusivity and the public's interest in access to generic drugs: exclusivity will be preserved only so long as the first-filer's delay in market entry is reasonable and does not unnecessarily prevent generic competition.

The current "wait and see" approach, although improved by the 2003 amendments, still allows for unreasonable delay in generic market entry. As Senator Hatch recently confirmed on the Senate floor, the meritorious second applicant problem remains despite the new forfeiture provisions.[194] The meritorious second applicant is denied the ability to bring its product to market despite the fact that it has invested its time and money and has

187. *See id.*

188. *See* Abbreviated New Drug Application Regulations, 54 Fed. Reg. 28872, 28894 (proposed July 10, 1989) (to be codified at 21 C.F.R. pts. 10, 310, 314, 320).

189. *Id.*

190. 149 CONG. REC. at 16105–16106.

191. *See id.*

192. 21 U.S.C § 355(j)(5)(D)(i)(I) (2005) (stating that the first-filer that is not sued forfeits its right to exclusivity if it does not bring its product to market within seventy-five days of its ANDA approval date); *id.* § 355 (j)(5)(D)(i)(V) (the first-filer forfeits its exclusivity if it enters into an agreement with the pioneer that violates antitrust laws).

193. 149 CONG. REC. at 16105–16106.

194. *Id.* Senator Hatch is a Republican from Utah.

assumed the risk of litigation in order to file its ANDA.[195] The public is denied the benefit of access to a generic drug that is otherwise ready to be marketed.[196] This result will be corrected by further amending the provision's language to provide that the first-filer forfeits its exclusivity if it is not the first generic to successfully challenge a pioneer's patent.[197]

A first-filer successfully challenges a patent when it invalidates or successfully designs around a pioneer's drug patent. When the pioneer does not sue the first-filer during the forty-five day window, the first-filer has successfully challenged the patent and is entitled to exclusivity. The FDA's successful defense requirement was improper because it did not allow this result and thereby undermined both the incentive and reward functions of the exclusivity provision.[198]

A first-filer also successfully challenges the pioneer's patent when the first-filer is sued by the pioneer during the forty-five day window but prevails in the litigation, either by invalidating the pioneer patent or by proving that its product does not infringe. The commercial marketing trigger currently preserves the first-filer's exclusivity throughout its litigation until it is reasonably able to market its product,[199] but should only do so as long as that preservation is in the public interest. As long as the first-filer may be the first to bring a generic product onto the market, the public has an interest in preserving its exclusivity.[200] On the other hand, when a second-filer is able to bring its generic product to market before the first-filer, the public does not have an interest in preserving the first-filer's exclusivity through

195. *See* Mova Pharm. Corp. v. Shalala, 140 F.3d 1060, 1072 (D.C. Cir. 1998) (discussing unfairness to the "ingenious second applicant").

196. Senator Hatch predicted that

> the first time that a blockbuster product is kept off the market, perhaps for over a year, due to the application of this new law [the "wait and see" approach] and there is a second generic ready, able and willing to go to market, there will be a great public clamor, as there should be.

149 CONG. REC. at 16106.

197. Senator Hatch believes that exclusivity should only be granted to the "first successful challenger of a pioneer firm's patents." *Id.* at 16104–16105. Because the forfeiture solution proposed herein does just that, resolving Senator's Hatch's main problem with "wait and see" application (the meritorious second applicant), and does so in a way that is more consistent with the statutory language and recent amendments than the FDA's successful defense requirement, he would likely be in support of this more narrow solution.

198. *See* Inwood Labs., Inc. v. Young, 723 F. Supp. 1523, 1526 (D.D.C. 1989) (explaining that the non-sued first-filer "successfully pursue[s] a patent infringement lawsuit and thereby open[s] up the market to generic competition").

199. *See* Abbreviated New Drug Application Regulations, 54 Fed. Reg. 28872, 28894 (proposed July 10, 1989) (to be codified at 21 C.F.R. pts. 10, 310, 314, 320) (explaining the function of the commercial marketing trigger).

200. *See id.*

the rest of the first-filer's litigation.[201] The public interest is in early accessibility to a safe, low-cost generic product.[202]

Therefore, the FDA should be allowed to evaluate other generic ANDAs while the first-filer is in litigation.[203] If a subsequent ANDA is approved by the FDA before the first-filer successfully challenges the pioneer patent, a new forfeiture provision in the Act should provide that the first-filer forfeits its exclusivity, allowing the approved product to come to market.[204] Congress could simply add this additional forfeiture provision to the list already included in the Act as of 2003.[205]

This proposed provision would be somewhat of a compromise between the FDA's initial successful defense requirement and the D.C. Circuit's wait and see approach. It is consistent with the plain language of the exclusivity provision because, unlike the FDA's regulation, it provides exclusivity to the generic that is first-in-time to file an ANDA. It is also most consistent with the policy of the Act as a whole: contrary to the FDA's initial regulation, it preserves exclusivity for the deserving first-filer that is not sued, and contrary to the D.C. Circuit Court's "wait and see" requirement, it allows the meritorious second applicant to enter the market and provide the public with the earliest possible access to safe, low-cost generic drugs.

Furthermore, the new provision would produce other desirable results. First, it would prevent gaming of the system by the pioneer firms. As discussed above, the "wait and see" approach allows the pioneer to exercise its discretion in bringing suit against later generic applicants (once the pioneer has sued the first-filer) because the pioneer knows that those generics will remain frozen out of the market until resolution of the pioneer's litigation with the first-filer.[206] This additional forfeiture provision, on the other hand, forces the pioneer to sue any ANDA applicant that it believes infringes. Otherwise, upon expiration of the forty-five day window, that subsequently-filed ANDA will be approved and the generic will enter the

201. 149 CONG. REC. at 16105–16106.

202. *See id.*

203. This was how the FDA operated under its successful defense requirement, examining and approving subsequent ANDAs in the midst of the first-filer's unresolved litigation with the pioneer. *See* Mova Pharm. Corp. v. Shalala, 140 F.3d 1060, 1062 (D.C. Cir. 1998).

204. As illustrated by the demise of the FDA's successful defense requirement, statutory amendment, as opposed to FDA regulation, will ensure judicial compliance with this policy and is therefore a desirable solution to the problem. *See id.* at 1076 (enjoining the FDA's application of its successful defense requirement).

205. *See* 21 U.S.C. §§ 355(j)(5)(D)(i)(I)–(VI) (2005) (listing various circumstances that result in forfeiture of the first-filer's exclusivity). Also, Congress may be willing to reevaluate the statute and make an amendment. *See* 149 CONG. REC. at 16105.

206. 21 U.S.C. § 355(j)(5)(B)(iv)(I).

market, destroying the pioneer's monopoly.[207] Subsequent generics will simultaneously be deterred from filing frivolous ANDAs because of the increased risk of litigation with the pioneer.

Second, the additional forfeiture provision will produce more patent challenges because it will provide an incentive for generics to challenge the pioneer's patent even when those generics will not be the first-filer.[208] Subsequent generics will have an increased incentive to file a legitimate ANDA if they know that they will not be forced to "wait and see" what happens with the first-filer's litigation before they are able to enter the market.

CONCLUSION

Congress should amend the Hatch-Waxman Act to provide forfeiture of the first-filer's exclusivity when it is not the first generic to successfully challenge the pioneer patent. This amendment reconciles exclusivity awards with the Act's underlying purpose because it ensures that exclusivity awards do not delay generic competition; it prevents gaming of the system because it decreases frivolous ANDAs and eliminates the pioneer's ability to conveniently exercise its discretion in bringing suit; and it best promotes the public interest because it provides a strong incentive for generics to continue to challenge pioneer patents. As explained by Senator Hatch himself, "the rationale behind the 180-day provision is to create an incentive for challenges to the pioneer's patents, not to create an entitlement to the first applicant to file a patent challenge with the FDA in the Parklawn Building."[209]

207. The FDA can immediately approve an ANDA once the forty-five days pass without the pioneer filing suit. *Id.* § 355 (j)(5)(B)(iii).

208. It is also possible that the exclusivity provision should be amended to provide exclusivity to the first generic to make a successful challenge of the pioneer patent, regardless of whether that generic was the first-in-time to attempt to do so. *Cf.* 149 CONG. REC. at 16106 (discussing the possibility of awarding exclusivity to a subsequent-filer that is the first to successfully invalidate the pioneer patent). This would further increase incentive for generic challenges.

209. *Id.* at 16105–16106.