UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

RANBAXY LABORATORIES LTD., et al.,	)	
Plaintiffs,	)	
v.	)	**Civil Action No. 05-1838 (RWR)**
MICHAEL O. LEAVITT, et al.,	)	
Defendants.	)	

MEMORANDUM OPINION

Ranbaxy Laboratories Limited[1] ("Ranbaxy") and IVAX Pharmaceuticals, Inc. ("IVAX") each sued the Food and Drug Administration ("FDA") under 5 U.S.C. § 706 claiming that the FDA improperly nullified Ranbaxy and IVAX's rights to a 180-day period of exclusive marketing of a generic drug. Ranbaxy and IVAX moved for summary judgment against the FDA seeking to vacate the FDA's decision. The FDA filed a cross-motion for summary judgment. Because the FDA failed to give full effect to the unambiguous intent of Congress, Ranbaxy and IVAX's motions for summary judgment will be granted, and the FDA's cross-motion for summary judgment will be denied.

[1] Ranbaxy Laboratories Limited, an Indian Corporation, Ranbaxy Inc., a Delaware corporation, and Ranbaxy Pharmaceuticals, Inc., also a Delaware Corporation, are named as plaintiffs. All three organizations are commonly owned and operated. For convenience, these organizations will be collectively referred to as "Ranbaxy."

BACKGROUND

I. FDA STATUTORY AND REGULATORY SCHEME

A. FDA drug approval process and the Hatch-Waxman Amendments

The FDA regulates all drugs under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 et seq. (2000). In 1984, Congress amended the FDCA in passing the Drug Price Competition and Patent Term Restoration Act, known as the Hatch-Waxman Amendments, in order to "make available more low cost generic drugs[.]"[2] H.R.Rep. No. 98-857, pt. 1, at 14 (1984), reprinted in 1984 U.S.C.C.A.N. 2647, 2647. The Hatch-Waxman Amendments attempt to balance the conflicting policy objectives of "induc[ing] name-brand pharmaceutical firms to make the investments necessary to research and develop new drug products, while simultaneously enabling competitors to bring cheaper, generic copies of those drugs to the market." Abbott Labs. v. Young, 920 F.2d 984, 991 (D.C. Cir. 1990) (Edwards, J., dissenting).

To accomplish these ends, the amendments established new guidelines for the approval of both name-brand and generic drugs.

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[2] The Medicare Modernization Act ("MMA") of 2003 amended the Hatch-Waxman Amendment provisions dealing with rights to 180-day periods of exclusive marketing of generic drugs. Because Ranbaxy and IVAX filed their generic drug applications at issue here prior to the MMA's effective date, the pre-2003 version of the FDCA applies here. Unless otherwise noted, all references to the FDCA or the Hatch-Waxman Amendments refer to the pre-2003 version.

First, for pioneer drugs, a drug manufacturer must submit a new drug application ("NDA") to the FDA for approval. 21 U.S.C. §355(a), (b). The NDA must contain studies demonstrating that the drug is safe and effective and must also include the patent number and expiration date of any patents claiming the drug. 21 U.S.C. § 355(b)(1). When the NDA is approved, the FDA lists the patent information in the "Approved Drug Products with Therapeutic Equivalence Evaluations," known as the "Orange Book." 21 U.S.C. § 355(c)(2). Once the NDA is approved, the NDA holder may market the new name-brand, pioneer drug.

With the Hatch-Waxman Amendments, Congress also created a streamlined procedure for the FDA to approve quickly generic versions of the name-brand drug. Drug manufacturers are required to file an abbreviated new drug application ("ANDA"), which incorporates the data that the name-brand producer had already submitted to the FDA. In order to obtain the FDA's approval, the ANDA must demonstrate that a generic drug is "bioequivalent" to a name-brand drug. 21 U.S.C. § 355(j)(2)(A)(iv). The applicant must also certify that the generic drug will not infringe any patents listed in the Orange Book which claim the name-brand drug. 21 U.S.C. § 355(j)(2)(A)(vii). An ANDA applicant must certify for each patent listed in the Orange Book:

> (I) that such patent information has not been filed, (II) that such patent has expired, (III) . . . the date on which such patent will expire, or (IV) that such patent is invalid or will not be infringed by the

> manufacture, use, or sale of the new drug for which the application is submitted.

Id.

In a "paragraph IV" certification, the applicant must allege that the patent for the name-brand drug is either (1) invalid, or (2) will not be infringed by the marketing of the generic drug. 21 U.S.C. § 355(j)(2)(A)(vii). The ANDA applicant who files a paragraph IV certification must give notice of such certification to both the patent owner and the holder of the NDA for the drug that is claimed by the patent. 21 U.S.C. § 355(j)(2)(B)(i). The ANDA applicant is required to include in this notice "a detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed." 21 U.S.C. § 355(j)(2)(B)(ii). The name-brand producer then has 45 days to sue the ANDA applicant. 21 U.S.C. § 355(j)(5)(B)(iii). If the name-brand producer sues, the FDA must wait 30 months before approving the generic manufacturer's ANDA or until a court finds that the patent is invalid or not infringed, whichever is earlier. Id. If no suit is brought within 45 days, than the FDA may immediately approve the ANDA. Id.

Because filing a paragraph IV certification is an act of infringement under 35 U.S.C. § 271(e)(2)(A), the Hatch-Waxman Amendments give the first ANDA holder to file a paragraph IV certification 180 days of exclusive marketing of the generic product. 21 U.S.C. § 355(j)(5)(B)(iv). This provision states:

> If the application contains a [paragraph IV certification] and is for a drug for which a previous application has been submitted under this subsection [containing][3] 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.

Id. The exclusivity period is triggered by a court decision in a patent infringement suit, or the commercial marketing of the generic drug. Id. This period of exclusivity is an important component of the Hatch-Waxman Amendments because it "encourage[s] generic drug makers to incur the potentially substantial litigation costs association with challenging pioneer drug makers' patents" and brings generic drugs to the market faster. Mylan Pharms., Inc. v. Shalala, 81 F. Supp. 2d 30, 33 (D.D.C. 2000).

Initially, the FDA proposed a requirement that the ANDA holder be sued in order for that holder to be eligible for the 180-day exclusivity. Guidance for Industry: 180-Day Generic Drug Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act 3 (June 1998) available at

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[3] The statute literally reads "continuing," but the D.C. Circuit has interpreted this word to be a typographical error meant to be "containing." Mova Pharm. Corp. v. Shalala, 140 F.3d 1060, 1064 n.3 (D.C. Cir. 1998).

www.fda.gov/cder/guidance/2576fnl.pdf. The final rule, however, required that an ANDA holder successfully defend against a patent infringement suit to be eligible for the 180-day exclusivity. See 21 C.F.R. § 314.107(c) (1994).[4] The FDA thought this rule would eliminate an incentive for frivolous claims. The D.C. Circuit, however, rejected this interpretation as contrary to the statute, holding that the successful defense requirement's "practical effect is to write the commercial-marketing trigger out of the statute." Mova Pharm. Corp. v. Shalala, 140 F.3d 1060, 1069 (D.C. Cir. 1998); see also Inwood Labs., Inc. v. Young, 723 F. Supp. 1523, 1525 (D.D.C.), vacated as moot, 43 F.3d 712 (D.C. Cir. 1989) (holding that the FDA's interpretation that "the 180-day exclusivity commences only when the primary ANDA has been sued for patent infringement" is contrary to the clear statutory language) (internal quotation marks omitted). The FDA subsequently amended § 314.107(c) by removing the language that required an ANDA applicant to have won a patent infringement suit to be eligible for the 180-days of exclusivity. See 21 C.F.R. § 314.107(c) (2000).

[4] The FDA required a showing that "the applicant submitting the first application has successfully defended against a suit for patent infringement brought within 45 days of the patent owner's receipt of notice" under paragraph IV before being eligible for the exclusivity. Abbreviated New Drug Applications Regulations; Patent and Exclusivity Provisions, 59 Fed. Reg. 50338, 50367 (Oct. 3, 1994).

B. The Orange Book and the patent listing regulatory scheme

NDA patent information appears in the Orange Book because Congress included in the Hatch-Waxman Amendments a provision requiring the publication of such information to facilitate the new ANDA process. 21 U.S.C. § 355(c)(2). "Upon the submission of patent information [in the NDA], the Secretary shall publish it." Id. The statute does not address, however, how the FDA is to remove patents from this list. See id. The FDA has interpreted the Hatch-Waxman Amendments to afford the agency a ministerial role in listing and delisting patents in the Orange Book. (Defs.' Summ. J. Mot. at 5.) This scheme consists of a challenge process, whereby a third party can "dispute[] the accuracy or relevance of patent information . . . published by FDA in the list." 21 C.F.R. § 314.53(f). The FDA then confirms with the NDA holder whether the patent information listed in the Orange Book is correct. Id. If the NDA holder requests that the patent be removed from the Orange Book, or "delisted," the FDA will do so. (Defs.' Summ. J. Mot. at 5.) If the NDA holder does not elect to alter the listing, the FDA will not remove the patent from the Orange Book. 21 C.F.R. § 314.53(f). (See Defs.' Summ. J. Mot. at 5.) The FDA "believes that the general rule of deference to the NDA holder's views on the scope of a patent and its appropriateness for listing should apply equally to the

decision to list a patent and to delist a patent from the Orange Book." (Defs.' Summ. J. Mot at 5-6.)

The FDA has established one exception to this general rule. When the disputed patent is subject to litigation brought by the patent owner against the first ANDA applicant[5], such a patent "shall not be removed from the list." 21 C.F.R. § 314.94(a)(12)(viii)(B).[6] The FDA explains that allowing a NDA holder to withdraw the patent during or after litigation and nullify the 180-day exclusivity would provide an "unjust result" if the ANDA applicant had invested heavy resources into defending the litigation and then was denied the benefit of the 180-day exclusive marketing period. (Defs.' Summ. J. Mot. at 11 (quoting Abbreviated New Drug Applications Regulations; Patent and Exclusivity Provisions, 59 Fed. Reg. 50338, 50348 (Oct. 3, 1994)).) Any other ANDA applicant, including the first ANDA

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[5] The FDA has interpreted the reference in 21 C.F.R. § 314.94(a)(12)(viii)(B) to a "lawsuit under § 314.107(c)" to refer to a lawsuit brought against an ANDA applicant within the first 45 days after the patent owner and the NDA holder received notice. (Admin. R., Tab 23 at 12 n.17.) This definition of litigation appeared in the version of § 314.107(c) before it was amended to remove the "successful defense" requirement. (Id.) Section 314.94(a)(12)(viii)(B) was promulgated simultaneously with the "successful defense" regulation, 21 C.F.R. § 314.107(c) (1994).

[6] The section states that "[a] patent that is the subject of a lawsuit under § 314.107(c) shall not be removed from the list until FDA determines either that no delay in effective dates of approval is required under that section as a result of the lawsuit, that the patent has expired, or that any such period of delay in effective dates of approval is ended." 21 C.F.R. § 314.94(a)(12)(viii)(B).

applicant to file a paragraph IV certification who has not been sued within 45 days of notice, however, must amend the paragraph IV certification. 21 C.F.R. § 314.94(a)(12)(viii)(B). "Once an amendment or letter for the change has been submitted, the application will no longer be considered to be one containing a certification under paragraph [IV,]" id., and thus no longer eligible for the 180-day exclusivity.

II. ANDA APPLICATIONS OF RANBAXY AND IVAX

Both IVAX and Ranbaxy sought to take advantage of the 180-day exclusivity under the Hatch-Waxman Amendments to market generic versions of Zocor. Merck holds the NDA for Zocor, a pioneer drug that reduces cholesterol and is among the most widely prescribed drugs in the United States. (Ranbaxy's Statement of Material Facts as to Which There is No Genuine Issue ("Ranbaxy's Statement of Facts") ¶ 1.) Currently, Merck is the sole marketer of Zocor in the 5 mg, 10 mg, 20 mg, 40 mg, and 80 mg strengths. (Ranbaxy's Statement of Facts ¶ 1; see also Admin. R., Tab 6 (confirming that Merck's NDA includes the 20 mg strength).) Merck holds three patents for simvastatin, the active ingredient in Zocor - - U.S. Patent No. 4,444,784 ("the '784 patent"), which expires on June 23, 2006; U.S. Patent No. Reissued 36481 ("the '481 patent"); and U.S. Patent No. Reissued 36520 ("the '520 patent"). (Ranbaxy's Statement of Facts ¶ 2.) At the time the plaintiffs filed their ANDAs, these patents were listed in the Orange Book.

On December 14, 2000, IVAX submitted an ANDA for a generic version of Zocor in the 5-mg, 10-mg, 20-mg, and 40-mg strengths. (IVAX's Statement of Material Facts as to Which There is No Genuine Dispute ("IVAX's Statement of Facts") ¶ 3.) Ranbaxy submitted an ANDA in November 2001 seeking to approve a generic version the 10 mg, 20 mg, 40 mg and 80-mg strengths of simivastatin. (Ranbaxy's Statement of Facts ¶ 3.) Ranbaxy and IVAX certified under paragraph IV that the '481 and '520 patents were invalid or unenforceable, or that their drugs would not infringe those patents (Admin. R., Tab 1 at 12; Supp. Admin. R., Tab 1 at 15), and they certified under paragraph III that the '784 patent expires in June 2006. (Id.) The FDA gave tentative approval to Ranbaxy because "all scientific and procedural conditions for approval have been met, but the application cannot be fully approved because approval is blocked by a 30-month stay, some form of marketing exclusivity, or some other barrier. . . ." (Admin. R., Tab 4.) The FDA did not grant tentative approval to IVAX.[7] (Defs.' Summ. J. Mot. at 12.) Plaintiffs gave the required notice to Merck of certification under paragraph IV, detailing the factual and legal basis for their belief that their generic drug would not infringe the patents, or that the patents

[7] Plaintiffs believe that IVAX is entitled to exclusivity for 5 mg, 10 mg, 20 mg, and 40 mg strengths and Ranbaxy is entitled to exclusivity for the 80 mg strength. (Admin. R., Tab 12 at 12; Admin. R. Tab 13 at 1-2; see also Admin. R., Tab 23 at 2.)

are invalid or unenforceable. (Admin. R., Tab 1 at 1; Supp. Admin. R., Tab 1 at 15.) Merck did not sue either applicant within the 45-day period. (Admin. R., Tab 2; Supp. Admin. R., Tab 3.)

On October 10, 2003, Merck submitted a letter to the FDA requesting that the '481 and '520 patents be delisted from the Orange Book. (Admin. R., Tab 6.) The following month, the FDA received a letter from an intellectual property law firm challenging the listing of those patents pursuant to the agency's challenge process, and noting that the '481 and '520 patents are not properly listed in the Orange Book under a new FDA regulation issued on June 18, 2003.[8] (Admin. R., Tab 7.) The FDA forwarded the letter to Merck, which renewed its request that the patents be withdrawn. (Admin. R., Tab 8.) In June 2004, Merck sent a third request to the FDA to delist the patents. (Admin. R., Tab 10.) In September 2004, IVAX and Ranbaxy learned that the FDA had delisted the '481 and '520 patents from the Orange Book. (IVAX's Statement of Facts ¶ 10; Ranbaxy's Statement of Facts ¶ 11).[9]

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[8] The challenge letter is from the law firm Kenyon and Kenyon, which did not claim to be writing the letter on behalf of a client. (Admin. R., Tab 7.)

[9] Ranbaxy believes that Merck requested these patents to be delisted after it was prompted to do so by another generic applicant, Teva Pharmaceuticals ("Teva"), which had not filed an ANDA before IVAX and Ranbaxy and would thus have to wait 180 days to introduce its generic version of Zocor. (Ranbaxy Compl. ¶ 41.) The FDA does not dispute, or address, the allegation that

In early 2005, Ranbaxy and IVAX each submitted citizen petitions, requesting that the FDA confirm that it would not approve subsequent ANDAs until after the 180-day period and that the FDA relist the patents in the Orange Book. (Admin. R., Tab 12 & 13.) The FDA denied both petitions on October 24, 2005, deciding that it would not relist the disputed patents, that no applicant will be eligible for 180-day exclusivity for those patents, and that it will approve all subsequent ANDAs for simvastatin when they are otherwise eligible for approval. (Ranbaxy's Statement of Fact ¶¶ 16, 17; IVAX's Statement of Fact ¶¶ 12, 14; Admin. R., Tab 23.)

In its denial of the plaintiffs' citizen petitions, the FDA first noted that because the effect of a delisted patent on the 180-day exclusivity is not addressed in § 355(j)(5)(B)(iv), the silence is ambiguous and subject to the FDA's reasonable interpretation. (Admin. R., Tab 23 at 8.) The FDA, therefore, asserted that it is free to choose how to handle delisting requests. The FDA explained that they could address this problem in one of three ways: (1) refuse to delist a patent once a paragraph IV certification has been submitted; (2) always delist a patent immediately upon request; or (3) delist in some

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Teva and Merck were in cahoots. The FDA does, however, state that Teva submitted and then withdrew comments in support of the FDA's delisting approach. (Defs.' Summ. J. Mot. at 15.) The FDA also points out that Teva and IVAX are in the process of merging. See Teva and IVAX Shareholders Approve Pending Merger (Oct. 27 2005), at http://www.tevapharm.com/pr/2005/pr_554.asp.

situations, but not others. (Id.) The FDA asserted that the first option would be wrong under the statute because an ANDA application does not have a "vested" right to exclusivity just by filing a paragraph IV submission. (Id. at 9.) In support of this assertion, the FDA cites several changes of circumstance which would require an ANDA filer to amend its paragraph IV certification. An ANDA filer must change a paragraph IV certification to a paragraph III certification if the ANDA filer loses an infringement suit brought by the NDA holder. (Id.) An ANDA filer must change a paragraph IV certification to a paragraph II certification if the certified patent expires. (Id.) The FDA recognizes that the second option would be unfair in cases where the ANDA applicant won a lawsuit but the FDA later delisted the disputed patent, nullifying the 180-day exclusivity period. (Id. at 11.) The FDA adopted the third position that the patent should be delisted at the request of the NDA holder except in the limited circumstance when it is the subject of litigation. (Id. at 13.) The FDA asserts that subsequent events can affect an ANDA filer's entitlement to exclusivity. (Id. at 14.)

The FDA acknowledges that the first ANDA holder to file a paragraph IV certification "could become eligible for exclusivity" and "eligibility did not require that the applicant be sued as a result." (Id. at 14.) The FDA notes that "[e]ven though successful defense of a patent infringement lawsuit is not

a factor in eligibility for exclusivity, . . . it is reasonable to interpret the patent listing and 180-day exclusivity provisions of the Act to permit the [FDA] to leave a patent listed only when a lawsuit has been filed as a result of a paragraph IV certification." (Id. at 13.)

The FDA stated that listed patents are barriers to generic drugs and that delisting furthers the goals of competition and the entry of generic drugs into the market. (Id. at 15.) Under Ranbaxy and IVAX's approach, the FDA notes that the patent challenge process would become "largely ineffective." (Id. at 15.) The FDA also does not believe that the current delisting process provides an incentive to NDA holders to delist patents in order to undermine the 180-day exclusivity, as Ranbaxy and IVAX claimed. (Id. at 15-16.) Finally, the "FDA has determined that as general rule, the benefit derived from maintaining exclusivity does not justify the delay in generic drug approvals that would arise from leaving a patent listed when the NDA holder requested that the patent be withdrawn." (Id. at 16.)

Ranbaxy and IVAX separately sued the FDA, challenging the FDA's refusal to relist the '481 and '520 patents for Zocor and refusal to grant any ANDA applicant eligibility for 180-day exclusivity for the generic version of Zocor. These civil actions were consolidated and all three parties moved for summary judgment, contending that there are no genuine issues of material fact and that each is entitled to judgment as a matter of law.

DISCUSSION

Summary judgment is appropriate when there are no genuine issues of material fact, and the movant is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c); see also Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 250 (1986).

To determine if agency action is arbitrary and capricious, district courts employ the two-part test of Chevron U.S.A., Inc. v. National Resources Defense Council, Inc., 467 U.S. 837 (1984). First, a court must determine "[i]f 'Congress has directly spoken to the precise question at issue.'" New York v. Envtl. Prot. Agency, No. 03-1380, 2006 WL 662746, at *2 (D.C. Cir. Mar. 17, 2006) (quoting Chevron, 467 U.S. at 842). If Congress clearly expressed its intent, then "'that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress.'" Id. (quoting Chevron, 467 U.S. at 842-43). "When the statute is clear on its face, resort to the legislative history, much less to the agency's interpretation, is not necessary." Inwood Labs., Inc., 723 F.3d at 1525 (citing Eagle-Picher Indus. Inc. v. Envtl. Prot. Agency, 759 F.2d 922 (D.C. Cir. 1985)). However, if the court finds that "the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute." Mova Pharms. Corp., 140 F.3d at 1067 (quoting Chevron, 467 U.S. at 843) (internal quotations omitted).

Courts rely on "traditional tools of statutory construction" to determine Congressional intent and the meaning of the statute. Automated Power Exch., Inc. v. FERC, 204 F.3d 1144, 1151 (D.C. Cir. 2000). Chevron analysis often begins and ends with the statutory text because "the language of the statute itself is always the best indication of congressional intent." Abbott Labs., 920 F.2d at 987. The first canon of statutory construction is that courts must presume that the legislature meant what it said in a statute. Conn. Nat'l Bank v. Germain, 503 U.S. 249, 253-54 (1992). "When the words of a statute are unambiguous, then, this first canon is also the last: 'judicial inquiry is complete.'" Id. at 254.

If Congress has not clearly expressed its intent on the precise issue, considerable weight is due an agency's reasonable construction of a statutory scheme it is entrusted to administer. Chevron, 467 U.S. at 844. "[J]udicial deference to reasonable interpretations by an agency of a statute that it administers is a dominant, well-settled principle of federal law." U.S. Postal Serv. v. NLRB, 969 F.2d 1064, 1069 (D.C. Cir. 1992) (quoting Nat'l R.R. Passenger Corp. v. Boston & Maine Corp., 503 U.S. 407, 417 (1992)). "Nevertheless, the agency must examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made." Southern Co. Services, Inc. v. FCC, 313 F.3d 574, 579-80 (D.C. Cir. 2002) (internal quotation marks omitted). A

reviewing court must "consider whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment." Id. (internal quotations marks omitted).

The exclusivity provision of the Hatch-Waxman Amendments "is far from a model of legislative draftsmanship" and "[t]he legislative history of section 355(j)(5)(B)(iv) is limited." Mova Pharms. Corp., 140 F.3d at 1069, 1072.[10] Section 355(j)(5)(B)(iv) is, however, clear and unambiguous in "explicitly provid[ing] that a primary generic manufacturer may qualify for the 180 day exclusivity in one of two ways." Inwood Labs., Inc., 723 F. Supp. at 1526; see also Granutec, Inc. v. Shalala, 139 F.3d 889, 1998 WL 153410, at *3 (4th Cir. 1998) (unpublished disposition) ("The language of the statute may be complex, and even cumbersome, but it is plain and unambiguous. It does not include a 'successful defense' requirement, and indeed it does not even require the institution of patent litigation."). Of the two methods Congress has provided by which the first ANDA applicant's 180-day period of exclusivity is triggered, one requires litigation and one does not. 21 U.S.C.

[10] Judges of this court have found some portions to be ambiguous and others unambiguous. Compare Mylan Pharm., Inc. v. Shalala, 81 F. Supp. 2d 30 (D.D.C. 2000) (Roberts, J.) (finding the "court-trigger" sub-clause to unambiguously include a decision from any type of court), with Apotex Inc. v. FDA, 414 F. Supp. 2d 61 (D.D.C. 2006) (Bates, J.) (finding that the provision as to how many exclusivity periods can be awarded for one drug is ambiguous).

§ 355(j)(5)(B)(iv). Congress referenced litigation under subpart iii explicitly, indicating "Congress' presumably deliberate decision not to incorporate the lawsuit requirement in [the first] subpart." Inwood Labs., Inc., 723 F. Supp. at 1526.

Despite the cumbersome structure of the statute, there is no dispute among the parties about Congress's intent on a number of fronts. It is undisputed that Congress intended to make bioequivalent generic drugs available on the market for consumers more quickly. In re Barr Labs., Inc., 930 F.2d 72, 76 (D.C. Cir. 1991). It is undisputed that to protect patent holders, Congress allowed abbreviated approval for those generic drugs that implicated no patents listed in the Orange Book, and delayed abbreviated approval until after any implicated listed patents expired. See 21 U.S.C. § 335(j)(2)(A)(vii). There is also no dispute that Congress treated specially the first ANDA applicant willing to certify legitimately that any implicated unexpired patents listed in the Orange Book were invalid or would not be infringed by the generic drug.

The parties also agree that Congress made a paragraph IV certification an act for which patent holders could sue for infringement, and intended to reward the generic manufacturer for incurring the substantial risks and expense of defending an infringement suit and/or designing around the patent. See Teva Pharm. Indus. Ltd. v. Crawford, 410 F.3d 51, 54 (D.C. Cir. 2005). The parties agree that Congress's chosen reward was to bar

approval of successive applications for that generic drug until after the paragraph IV ANDA holder enjoyed a period of exclusive marketing. 21 U.S.C. § 355(j)(5)(B)(iv). Finally it is undisputed that Congress did not restrict this reward to only those ANDA holders who have been sued for infringement, or successfully defended such a suit, Mova Pharms. Corp., 140 F.3d at 1069; Inwood Labs., Inc., 723 F. Supp. at 1526, just as Congress did not restrict the reward to those ANDA holders who avoided suit by persuasion or effectively designing around the patent or otherwise.

The issue here, then, is whether the FDA can effectively restrict the reward to only a sued ANDA holder by delisting a patent after the ANDA holder successfully avoided suit. Here, both plaintiffs gave Merck detailed factual and legal submissions about how their generic drugs would not infringe the listed patents, or how the patents were invalid or unenforceable. (Admin. R., Tab 1 at 1; Supp. Admin. R., Tab 1 at 15.) Merck chose not to sue either ANDA filer. Had the FDA not delisted here, the plaintiffs would have been entitled to a period of marketing exclusivity triggered by their notice to the FDA of their first commercial marketing of the generic drug once the FDA approved their ANDAs.

Here, however, the FDA agreed to requests by Merck and a third party to delist the patents after the ANDA filers successfully avoided suit. (Admin. R., Tabs 6-10.) The FDA

delisting of these patents about which Ranbaxy and IVAX had previously filed paragraph IV certifications arguably vitiated those certifications and no subsequent ANDA for simvastatin need include a certification for those patents. (See Admin. R., Tab 23 at 15.) Upon the expiration of the '784 patent in June 2006, the FDA plans to approve any complete ANDA for simvastatin otherwise eligible for approval, denying Ranbaxy and IVAX the 180 days of exclusive marketing, which they would have enjoyed upon their ANDAs' final approval. (See id.)

But, the FDA refuses to delist a patent when litigation has ensued. See 21 C.F.R. § 314.94(a)(12)(viii)(B). The FDA recognizes "that if an ANDA applicant were successful in challenging a patent [in litigation], withdrawing the patent from the [Orange Book] immediately would destroy any exclusive benefit by permitting all other ANDAs for the drug product to be approved immediately." (Admin. R., Tab 23 at 12.) It would be "quite perverse[] to use an ANDA applicant's *success* in such an infringement action as the basis for *denying* exclusivity to that applicant." Torpharm, Inc. v. Thompson, 260 F. Supp. 2d 69, 83 n.15 (D.D.C. 2003). If Merck had sued plaintiffs because of their paragraph IV certifications, plaintiffs would have been in danger of losing their right to 180-day exclusivity period upon final FDA approval only if the patents were found to be enforceable or infringed. In this case, however, the FDA delisted the patents from the Orange Book, disregarding the

plaintiffs' success in avoiding suit. That disparate treatment here contravened the plain and undisputed intent of Congress. The delisting practice as applied here effectively eliminated Congress's "first commercial marketing" trigger, in violation of the clear command of Congress.

The FDA here was not preventing an unfair windfall to an ANDA applicant who lost in patent litigation, cf. 21 U.S.C. § 355(j)(5)(B)(iv)(II) (stating that a court decision "holding the patent which is the subject of the certification to be invalid or not infringed" triggers the exclusivity period), or barring exclusivity because the challenged patent had already expired, see, e.g., Dr. Reddy's Labs. Inc. v. Thompson, 302 F. Supp. 2d 340, 355 (D.N.J. 2003) (upholding the FDA's decision to delist a patent that had expired and not to award exclusivity to an ANDA applicant who had filed a paragraph IV certification for that patent prior to the patent's expiration), or dealing with a challenged patent that should never have been listed, see e.g., Purepac Pharm. Co. v. Thompson, 354 F.3d 877, 886-88 (D.C. Cir. 2003) (upholding the FDA's decision to delist a patent that was erroneously listed for the wrong drug and therefore would not provide the ANDA applicant with exclusivity even if the applicant won an infringement suit), or otherwise preventing some injustice that would have thwarted Congress's plain will. Although the FDA is due much deference in interpreting gaps or ambiguity in its statute, it cannot accord disparate treatment to the statute's

equal triggers which reflect the clear command of Congress. See 21 U.S.C. § 355(j)(5)(B)(iv)(stating that the two triggers of the exclusivity period are a court decision or commercial marketing). The delisting scheme the FDA chooses to implement cannot favor one of two equal statutory provisions over the other. See, e.g., Sierra Club v. Envtl. Prot. Agency, 356 F.3d 296, 301-03 (D.C. Cir. 2004) (holding that an agency cannot nullify clear statutory language in one part by relying on statutory silence in another).

CONCLUSION

The FDA has acted contrary to the clear intent of Congress in its decision to deny the plaintiffs' citizen petitions. The plaintiffs' motions for summary judgment will be granted and the FDA's motion for summary judgment will be denied. The decision will be remanded to the FDA. An appropriate order accompanies this Memorandum Opinion.

SIGNED this 30th day of April, 2006.

/s/
RICHARD W. ROBERTS
United States District Judge