

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

RANBAXY LABORATORIES LIMITED, et al.,)	
)	
Plaintiffs,)	
)	
v.)	Civ. Case No. 05-1838 (RWR)
)	
MICHAEL O. LEAVITT, et al.,)	
)	
Defendants.)	
)	

**FEDERAL DEFENDANTS' MEMORANDUM IN
SUPPORT OF MOTION FOR SUMMARY JUDGMENT AND IN
OPPOSITION TO PLAINTIFFS' MOTIONS FOR SUMMARY JUDGMENT**

INTRODUCTION

Plaintiffs, IVAX Pharmaceuticals, Inc. (“Ivax”) and Ranbaxy Laboratories Ltd., Ranbaxy Inc., and Ranbaxy Pharmaceuticals, Inc. (collectively “Ranbaxy”), manufacturers of generic drugs, brought this action against the Food and Drug Administration (“FDA” or “agency”) seeking to preserve what they characterize as their “entitlement” to 180 days of generic marketing exclusivity. They contend that FDA has improperly delisted the patents upon which their alleged entitlement is based. Under the Federal Food, Drug, and Cosmetic Act (“FDCA” or the “Act”) and its implementing regulations, an innovator pharmaceutical company that seeks or has obtained FDA approval to market a new drug is required to submit information on any patent that it claims protects its drug from competition. Applicants, such as Ivax and Ranbaxy, seeking approval to market generic versions of such a drug submit abbreviated new drug applications (“ANDAs”) in which they must “certify” to each patent listed for that drug. One of the certification options (a “paragraph IV certification”) is to assert that a listed patent is invalid, unenforceable, or would not be infringed by the product proposed in the ANDA, and therefore

the patent does not bar immediate approval of the ANDA. If the ANDA applicant selects that option, the innovator company may sue the ANDA applicant for patent infringement.

As an incentive and reward to the generic applicant that is first to challenge an innovator company's patent by submitting such a certification, the Act authorizes FDA to delay approval of subsequent generic applications for 180 days. 21 U.S.C. § 355(j)(5)(B)(iv). That period has come to be known as the "180-day exclusivity period." If the innovator company requests that its patent submission be revoked or "delisted" before FDA has made any 180-day exclusivity determination, then the first generic company to have submitted a challenge to that patent will in many circumstances lose the potential 180-day exclusivity that it could have received had the patent remained listed. The statute is silent with respect to an innovator's request to remove patent information and with respect to whether ANDA applicants are entitled to receive 180 days of exclusivity for withdrawn patents. FDA has implemented the statute to permit an innovator to delist a patent, except in the rare circumstance – not present in the instant case – when the patent is the subject of patent litigation. 21 C.F.R. § 314.94(a)(12)(viii)(B).

Merck & Co. ("Merck") holds an approved new drug application ("NDA") for Zocor tablets (simvastatin), which is approved for the reduction of elevated cholesterol levels. Merck submitted three patents for submission in "Approved Drug Products with Therapeutic Equivalence Evaluations," also known as the "Orange Book," for simvastatin. Plaintiffs Ivax and Ranbaxy submitted ANDAs for simvastatin, each of which included challenges to two of the three patents. Merck did not sue Ivax or Ranbaxy for those patent challenges. Well over a year after being notified of those challenges, Merck requested that FDA delist the two patents that had been challenged, which FDA did pursuant to its regulation which allows such delisting when the patents are not the subject of litigation. *See* 21 C.F.R. § 314.94(a)(12)(viii)(B). Accordingly,

any ANDA for simvastatin that contains a challenge to one of the delisted patents will no longer be considered as continuing to maintain that challenge because there is no patent to challenge. Thus, when the simvastatin ANDAs are ready for final approval, FDA does not anticipate that it will award any 180-day exclusivity for that drug product, and it may approve all eligible ANDAs for the drug at that time.

Plaintiffs filed citizen petitions objecting in advance to that outcome, contending that FDA must keep the patents listed in contravention of the NDA holder's instructions because plaintiffs somehow became "entitled" to exclusivity by virtue of filing patent challenges, even when those patents were withdrawn and were thus no longer barriers to market entry. FDA denied those petitions.

As demonstrated below, nothing in the statute supports, much less compels, plaintiffs' argument that they are entitled to 180 days of exclusivity for a withdrawn patent. Plaintiffs' proposal that FDA keep such patents listed – contrary to the patent holder's request – is wrong as a matter of both law and public policy, as it is not compelled by the statute or regulations and would result in unjustified awards of exclusivity at the expense of public access to cheaper generic drugs. In making their strenuous arguments that FDA cannot require "litigation" prior to awarding 180-day exclusivity, plaintiffs cite statutory provisions and case law that do not encompass the circumstances of the instant case: that is, where a patent holder has voluntarily withdrawn its own patent prior to any litigation about that patent. In these circumstances, FDA's decision to delist patents is a permissible implementation of the statute.

In making their arguments, plaintiffs focus on the provision of the FDCA that provides the 180-day exclusivity benefit in isolation from the rest of the statute. Relying on this statutory section, plaintiffs argue that once a paragraph IV certification is made, the patent holder is

forbidden from withdrawing the patent. However, as explained in greater detail below, FDA does not make decisions about exclusivity until it actually approves an ANDA, and there are a number of situations in which a paragraph IV certification might not lead to exclusivity. In addition to ignoring the actual circumstances of this case, plaintiffs repeatedly mischaracterize FDA's regulation and Federal Register discussions relevant to these issues, as discussed in more detail below. Because the material facts are undisputed, and because FDA has reasonably applied the governing statute and regulation, plaintiffs' motions for summary judgment should be denied, and the federal defendants' motion for summary judgment should be granted.

STATUTORY AND REGULATORY FRAMEWORK

I. New Drug Applications (NDAs)

Under the FDCA, pharmaceutical companies seeking to market "pioneer" or "innovator" drugs must first obtain FDA approval by filing an NDA containing extensive scientific data demonstrating the safety and effectiveness of the drug. 21 U.S.C. § 355(a), (b). The statute also provides:

The applicant *shall* file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.

21 U.S.C. § 355(b)(1), (c)(2) (emphasis added). FDA must publish the patent information it receives, and does so, in the Orange Book. *Id.*; *see also* 21 C.F.R. § 314.53(e).

The statutory provisions governing patent listings assign control over patent submissions to the NDA holder. 21 U.S.C. §§ 355(b)(1) and (c)(2). Although the statute gives control over the listing to patent holders, it does not give discretion. As reflected in the statute, patents meeting the statutory requirements *shall* be listed, and obviously those not meeting the

requirements are not to be listed. There may be many reasons why an NDA holder would delist a patent, the most obvious one being that the NDA holder no longer believes that the patent meets the criteria set forth in 21 U.S.C. §§ 355(b)(1) and (c)(2) and at 21 C.F.R. § 314.53. In addition, the NDA holder could delist a patent as a result of an FTC settlement, or after reevaluating the patents in view of FDA's revised regulations on the criteria for patent listing. *See* 68 FR 36676, 36703-05 (June 18, 2003) (revising 21 C.F.R. § 314.53).

FDA interprets these provisions to afford FDA a ministerial role in the patent listing process. Rather than substantively review the accuracy of the patent listing itself – which the agency lacks the resources and expertise to do – FDA has established a “challenge” process whereby an outside party can express any doubts it has about the accuracy of a patent listing to the NDA holder through FDA. 21 C.F.R. § 314.53(f). Under this regulation, if a challenge is made, the NDA holder is given an opportunity to correct the listing. If the NDA holder does not alter or amend the listing, the patent remains listed. The regulation recognizes that a patent holder may generally withdraw or amend its patent as a result of the challenge, which could not occur if FDA were required to keep a patent listed when any paragraph IV certification had been filed to that patent. FDA's ministerial approach to patent listings has been upheld against numerous challenges. *Apotex, Inc. v. Thompson*, 347 F.3d 1335 (Fed. Cir. 2003); *aaiPharma Inc. v. Thompson*, 296 F.3d 227 (4th Cir. 2002); *Alphapharm PTY Ltd. v. Thompson*, 330 F. Supp. 2d 1 (D.D.C. 2004).

None of the statutory provisions specifically addresses what is to happen when an NDA holder requests FDA to delist a patent, either generally or in the context of 180-day exclusivity. The agency 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. The agency does not require an NDA holder to state the basis for delisting a patent, nor are such reasons relevant to the FDA's general ministerial role in delisting patents upon the NDA holder's request. As noted, the agency has established, by regulation, one narrow exception to the deference accorded an NDA holder's request (*i.e.*, if the patent is the subject of litigation), which is not applicable in this case. *See* 21 C.F.R. § 314.94(a)(12)(viii)(B).

II. Abbreviated New Drug Applications (ANDAs)

The Drug Price Competition and Patent Term Restoration Act of 1984 (known as the "Hatch-Waxman Amendments"), codified at 21 U.S.C. § 355 and 35 U.S.C. §§ 156, 271, 282, permits ANDAs to be submitted seeking approval for generic versions of approved drug products. 21 U.S.C. § 355(j).¹ The timing for approval of ANDAs depends, in part, on patent protections for the innovator drug.

A. Patent Certifications

Among other things, an ANDA must contain one of four specified certifications for each patent that "claims the listed drug" or "a use for such listed drug for which the applicant is seeking approval." 21 U.S.C. § 355(j)(2)(A)(vii).² This certification must state one of the following:

¹ Congress amended 21 U.S.C. § 355(j) in 2003. *See* The Access to Affordable Pharmaceuticals provisions of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (Dec. 8, 2003) (the "MMA"). The relevant provisions of these amendments do not apply to the patent certifications at issue in this case because the first relevant certification was submitted before the December 8, 2003 enactment date of the amendments. *See id.* § 1102(b)(1). Except where otherwise noted, this memorandum refers to the pre-December 2003 version of the statute.

² FDA has defined the "listed drug" to mean the approved new "drug product." 21 C.F.R. § 314.3(b).

- (I) that the required patent information relating to such patent has not been filed;
- (II) that such patent has expired;
- (III) that such patent will expire on a particular date; or
- (IV) that such patent is invalid or will not be infringed by the drug for which approval is being sought.

See id. § 355(j)(2)(A)(vii). If an applicant wishes to challenge the validity of a patent, or to claim that the patent would not be infringed by the product proposed in the ANDA, the applicant must submit a certification pursuant to paragraph IV of this provision. *Id.* § 355(j)(2)(A)(vii)(IV).³

The applicant must also provide notice of its so-called “paragraph IV certification” to the NDA holder and the patent owner explaining the factual and legal basis for the applicant’s opinion that the patent is invalid or not infringed. *Id.* § 355(j)(2)(B).

The filing of a paragraph IV certification “for a drug claimed in a patent or the use of which is claimed in a patent” is an act of infringement. 35 U.S.C. § 271(e)(2)(A). This enables the NDA holder and patent owner to sue the ANDA applicant. If such a suit is brought within 45 days of the date notice of the certification was received by the patent owner or NDA holder, FDA must stay approval of the ANDA for 30 months from that date (commonly referred to as the “30-month stay”), unless a final court decision is reached earlier in the patent case or the court orders a longer or shorter period. 21 U.S.C. § 355(j)(5)(B)(iii). If no action is brought within the requisite 45-day period, FDA may approve an ANDA with a paragraph IV certification effective

³ If a certification is made under paragraph I or II indicating that patent information pertaining to the drug or its use has not been filed with FDA or the patent has expired, the ANDA may be approved immediately. 21 U.S.C. § 355(j)(5)(B)(i). A paragraph III certification indicates that the ANDA applicant does not intend to market the drug until after the applicable patent has expired, and approval of the ANDA may be made effective on the expiration date. 21 U.S.C. § 355(j)(5)(B)(ii).

immediately, provided that other conditions for approval have been met. 21 U.S.C.

§ 355(j)(5)(B)(iii); 21 C.F.R. § 314.107(f)(2).

B. 180-Day Period of Market Exclusivity

In certain circumstances, the statute provides an incentive and reward to generic drug manufacturers that expose themselves to the risk of patent litigation. It does so by granting a 180-day period of marketing exclusivity *vis-à-vis* other ANDA applicants to the manufacturer who is first to file an ANDA containing a paragraph IV certification to a listed patent, provided certain conditions are met. 21 U.S.C. § 355(j)(5)(B)(iv); *see Teva Pharm. Indus. v. Crawford*, 410 F.3d 51, 52 (D.C. Cir. 2005); *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1064 (D.C. Cir. 1998); *Mylan Pharm., Inc. v. Henney*, 94 F. Supp. 2d 36, 40 (D.D.C. 2000), *vacated as moot sub nom. Pharmachemie B.V. v. Barr Labs., Inc.*, 276 F.3d 627 (D.C. Cir. 2002). The statutory provision governing 180-day exclusivity provides:

If the application contains a certification described in subclause (IV) of paragraph (2)(A)(vii) and is for a drug for which a previous application has been submitted under this subsection [containing] such a certification, the application shall be made effective not earlier than one hundred and eighty days after-

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

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

whichever is earlier.

21 U.S.C. § 355(j)(5)(B)(iv).⁴ Thus, under the statute, an ANDA applicant with a patent certification that is “previous” to all others for that patent may become eligible for a 180-day exclusivity period.⁵ During that period, it can market its product and approvals of other ANDAs for the same product are held in abeyance. This 180-day exclusivity is triggered by the earlier of (i) the ANDA applicant’s first commercial marketing of the drug (the “commercial marketing trigger”), or (ii) a decision of a court finding the patent at issue invalid or not infringed (the “court decision trigger”). *Id.*

C. Timing of Exclusivity Decisions

FDA makes exclusivity determinations only when an ANDA applicant is ready for final approval. FDA bases its decision upon the circumstances as they exist at that time, not at some time in the past. *See Dr. Reddy’s Labs., Inc. v. Thompson*, 302 F. Supp. 2d 340, 353 (D.N.J.

⁴ Courts have observed that the word “continuing” as it appears in the statute reflects a typographical error and should probably be read as “containing.” *See Purepac Pharm. Co. v. Friedman*, 162 F.3d 1201, 1203 n.3 (D.C. Cir. 1998); *Mova*, 140 F.3d at 1064 n.3. *See also* 21 C.F.R. §§ 314.107(c)(1) & (2).

⁵ FDA awards exclusivity for each patent that has been challenged, an approach that has been litigated extensively. In *TorPharm, Inc. v. FDA*, No. 03-2401 (D.D.C. Jan. 8, 2004) (final order) (Roberts, J.), this Court held that an award of shared exclusivity pursuant to FDA’s patent-based approach was not permissible under the statute. That decision was vacated when the D.C. Circuit found the issue moot on appeal. *Apotex Inc. (f/k/a TorPharm, Inc.) v. FDA*, Nos. 04-5046 & 04-5047 (D.C. Cir. Dec. 17, 2004). In a second case, Judge Huvelle came to the opposite conclusion and upheld FDA’s patent-based approach on the merits. *Apotex, Inc. v. FDA*, No. 04-CV-00605 (D.D.C. June 3, 2004). On appeal, the D.C. Circuit upheld Judge Huvelle’s *res judicata* determination and vacated her alternative holding on the merits. *Apotex Inc. v. FDA*, 393 F.3d 210 (D.C. Cir. 2004). In yet another case, the court approved FDA’s application of patent-based exclusivity pursuant to the agency’s regulations without discussing the statutory provisions. *Dr. Reddy’s Labs., Inc. v. Thompson*, 302 F. Supp. 2d 340, 358-60 (D.N.J. 2003). Thus, to date, no appellate court has addressed the merits of FDA’s patent-based approach, and two district court decisions from this district that reached opposite conclusions have been vacated. Apotex is currently challenging FDA’s patent-based policy again in *Apotex Inc. v. FDA*, No. 05-125 (D.D.C.) (Bates, J.).

2003); *see also* Memorandum from Office of Generic Drugs re 180-day Exclusivity for Omeprazole 40 mg at 2-4 (Sept. 2, 2005) (attached hereto as Ex. A).⁶ For example, if an ANDA applicant filed the first paragraph IV certification to a patent that expired before any ANDA was ready for approval, it would not be entitled to exclusivity based on that patent because the patent would not be a barrier to marketing when the approval decision was finalized. *Dr. Reddy's*, 302 F. Supp. 2d at 353-55. Although an ANDA applicant may believe that it was first to have filed a paragraph IV certification, FDA makes no determination whether a specific ANDA applicant may in fact be eligible for exclusivity until an ANDA is ready for approval because circumstances may change.

D. Patent Delisting and Certification

An FDA regulation provides that, if a patent is delisted, an ANDA applicant who has certified to that patent must amend its certification. 21 C.F.R. § 314.94(a)(12)(viii)(B). The regulation states:

If a patent is removed from the list, any applicant with a pending application (including a tentatively approved application with a delayed effective date) who has made a certification with respect to such patent shall amend its certification. The applicant shall certify under paragraph (a)(12)(ii) of this section that no patents described in paragraph (a)(12)(i) of this section claim the drug or, if other relevant patents claim the drug, shall amend the certification to refer only to those relevant patents. In the amendment, the applicant shall state the reason for the change in certification (that the patent is or has been removed from the list). A patent that is the subject of a lawsuit under Sec. 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. An applicant shall submit an amended certification. Once an amendment or letter

⁶ This memorandum, which explains FDA's timing procedures for making exclusivity determinations, was submitted to the court in *Apotex Inc. v. FDA*, No. 05-125 (D.D.C.) (JDB) (Docket No. 21) as part of the supplemental administrative record.

for the change has been submitted, the application will no longer be considered to be one containing a certification under paragraph (a)(12)(i)(A)(4) of this section.

Id. This regulation recognizes a limited exception to this delisting and amendment requirement when the patent is the subject of a lawsuit. This limited exception is not applicable here because there has been no litigation regarding the relevant patents. The reason for this limited exception is to avoid an unjust result that would occur if an ANDA applicant who is eligible for exclusivity prevails in the patent litigation but lost exclusivity if the NDA holder decided to delist.

Abbreviated New Drug Application Regulations; Patent and Exclusivity Provisions, 59 Fed. Reg. 50,338, 50,348 (Oct. 3, 1994) (attached hereto as Ex. B) (“If a patent were removed from the list immediately upon a court decision that the patent is invalid or unenforceable, an applicant with a subsequently filed application might seek to certify that there is no relevant patent and seek an immediately effective approval.”). One court has observed: “It would be cruelly ironic, and quite perverse, to use an ANDA applicant’s success in such an infringement action as the basis for denying exclusivity to the applicant.” *Torpharm, Inc. v. Thompson*, 260 F. Supp. 2d 69, 83 n.15 (D.D.C. 2003) (emphasis in original), *aff’d sub nom. Purepac Pharm. Co. v. Thompson*, 354 F.3d 877 (D.C. Cir. 2004).

Without proper paragraph IV certifications, the statute is clear that no ANDA applicant can obtain 180-day exclusivity. 21 U.S.C. § 355(j)(5)(B)(iv) (“If the application contains a [paragraph IV] certification . . . and is for a drug for which a previous application has been submitted [containing a paragraph IV certification], the application shall be made effective not earlier than one hundred and eighty days after . . .”). Absent either a previous application containing a paragraph IV certification or a subsequent application containing a paragraph IV

certification, there will be no delayed effective date of the subsequent ANDA, and thus no exclusivity. *Id.*

FACTUAL BACKGROUND AND ADMINISTRATIVE PROCEEDINGS

I. Zocor Approval

Merck holds approved NDA No. 19-766 for Zocor tablets, 5 milligrams (mg), 10 mg, 20 mg, 40 mg, and 80 mg. Zocor is also known by its generic name, simvastatin. FDA approved the NDA for Zocor 5 mg, 10 mg, 20 mg, and 40 mg in 1991, and the 80 mg strength in 1998.⁷ Merck submitted U.S. Patent No. 4,444,784 (“784 patent”), which was listed when the NDA was approved in 1991. The ‘784 patent and its associated pediatric exclusivity will expire on June 23, 2006. In 2000, Merck submitted U.S. Patent Nos. RE 36,481 (“481 patent”) and RE 36,520 (“520 patent”) for listing in the Orange Book.

II. Ivax’s ANDA

On December 15, 2000, Ivax submitted ANDA No. 76-052 for the 5 mg, 10 mg, 20 mg, and 40 mg strengths of simvastatin, which contained paragraph IV certifications to the ‘481 and ‘520 patents. Supplemental Administrative Record (“Supp. AR”) Tab 1. Ivax provided notice to Merck of its paragraph IV certifications. Supp. AR Tab 3. Merck did not sue Ivax for patent infringement based on those certifications. *Id.*

FDA has not tentatively approved Ivax’s ANDA, meaning that the ANDA has not met all scientific and procedural conditions for approval.⁸ In addition, Ivax’s ANDA contains a

⁷ See Electronic Orange Book, available at http://www.accessdata.fda.gov/scripts/cder/ob/docs/obdetail.cfm?Appl_No=019766&TABLE1=OB_Rx.

⁸ FDA grants “tentative approval” to an ANDA when 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 to

paragraph III certification to the '784 patent indicating that the applicant does not plan to market its product until that patent expires (*see* note 3, *supra*), and thus is barred from final approval at least until expiration of that patent on June 23, 2006. Supp. AR Tab 1.

III. Ranbaxy's ANDA

On November 28, 2001, Ranbaxy submitted ANDA No. 76-285 for all strengths of simvastatin, including the 80 mg strength. Administrative Record ("AR") Tab 1. Ranbaxy's ANDA also contained paragraph IV certifications to the '481 and '520 patents. *Id.* at 7. Ranbaxy notified Merck of those certifications. AR Tab 2. Merck did not sue Ranbaxy or any other ANDA applicant for patent infringement based on paragraph IV certifications to those patents. *Id.*; *see also* AR Tab 23 at 2. FDA tentatively approved Ranbaxy's ANDA on September 26, 2003. AR Tab 4. Ranbaxy's ANDA contains a paragraph III certification to the '784 patent, and thus is barred from final approval until expiration of that patent on June 23, 2006.

IV. Requests to Delist the '481 and '520 Patents

On October 10, 2003, Merck requested that the agency delist the '481 and '520 patents. AR Tab 6. Merck made this request long after Merck had received notice of paragraph IV certifications – some two and a half years after receiving notice from Ivax on April 11, 2001, and more than a year and a half after receiving notice from Ranbaxy on March 6, 2002. *See* AR Tab 2; Supp. AR Tab 3.

On November 3, 2003, FDA received a letter challenging the listing of those patents pursuant to the "challenge" regulation at 21 C.F.R. § 314.53(f). AR Tab 7. Accordingly, FDA forwarded the letter to Merck on November 21, 2003. Merck later confirmed that it had already

approval arising from patent infringement litigation. *See* 21 C.F.R. § 314.105(d).

requested that those patents be withdrawn from the Orange Book. AR Tab 8. On June 14, 2004, FDA received another request that the '481 and '520 patents be withdrawn. AR Tab 10. FDA withdrew the patents from the Orange Book in September 2004, pursuant to its regulation which allows such delisting upon the NDA holder's request unless the patents are the subject of litigation.⁹ On July 5, 2005, FDA received a letter from Ranbaxy's counsel requesting FDA to ask Merck to rescind its request to withdraw the listing. AR Tab 11. Merck has declined that request.

V. Citizen Petitions

On October 18, 2004, Ranbaxy submitted a letter to FDA requesting that the agency relist the '481 and '520 patents, out of concern that Ranbaxy would no longer be eligible for exclusivity for the 80 mg product as a result of FDA's delisting. AR Tab 5. Ranbaxy argued that the FDCA "contains no provision authorizing the removal of a patent from the list based on the withdrawal of a patent submission." *Id.* at 5.

On January 12, 2005, Ivax submitted a citizen petition, arguing that its eligibility for exclusivity for simvastatin was "established" when it submitted what it believed was the first substantially complete ANDA for simvastatin (5 mg, 10 mg, 20 mg, and 40 mg) containing paragraph IV certifications to the '481 and '520 patents, and that FDA erred in delisting those patents and thereby violated Ivax's "right" to exclusivity. AR Tab 12 at 1.

Ranbaxy submitted its own citizen petition on February 1, 2005, which made arguments similar to those in its October 18, 2004 letter, emphasizing the policy goals underlying

⁹ Although there was some delay between Merck's request to delist and FDA's actual delisting of the patents, that delay made no material difference to the ANDAs for simvastatin because all ANDAs are blocked from final approval by the unchallenged '784 patent until June 23, 2006, and any exclusivity issues based on the listed status of the patents will have no effect on the ANDAs until that date.

exclusivity. AR Tab 23. The Federal Trade Commission (“FTC”) submitted comments in full support of FDA’s patent delisting regulation, 21 C.F.R. § 314.94(a)(12)(viii)(B). AR Tab 14 at 6 (“Because Orange Book listing serves as the predicate for the 30-month stay and the 180-day exclusivity provisions of Hatch-Waxman, it is critical that only those patents meeting the statutory and regulatory criteria for inclusion in the Orange Book be listed.”). Teva Pharmaceuticals USA also submitted comments in support of FDA’s approach to delist patents, but subsequently withdrew those comments.¹⁰ AR Tabs 19 & 24. Ivax and Ranbaxy submitted supplementary comments in response to the FTC’s and Teva’s submissions. AR Tabs 15, 16, 17, 21, & 22.

FDA responded to the citizen petitions on October 24, 2005. AR Tab 23. In its response, FDA observed that, based on the statutory silence with respect to patent delisting, it could have addressed delisting requests in any number of ways, including by (1) refusing to delist a patent once a paragraph IV certification has been submitted (as Ranbaxy and Ivax requested); (2) delisting the patent immediately, regardless of the situation (even if there were patent litigation); or (3) withdrawing the patent in some circumstances, but not others. *Id.* at 8. The agency rejected the first option, disagreeing that petitioners had a “vested” exclusivity right upon the mere submission of a paragraph IV certification, regardless of the later status of the patent listing or paragraph IV certifications. *Id.* at 9. FDA also rejected the second option, noting the unfairness that would result if the first ANDA applicant were successful in challenging a patent, but that applicant’s exclusivity was denied by the delisting of the patent. *Id.* at 12. The agency

¹⁰ Teva and Ivax plan to merge by late 2005 or early 2006. *See* Teva and Ivax Shareholders Approve Pending Merger (Oct. 27, 2005), *available at* http://www.tevapharm.com/pr/2005/pr_554.asp.

adopted the third option, *i.e.*, that the patent should be withdrawn when it is delisted by the patent holder except in the limited circumstance when it is the subject of litigation.

VI. Litigation

Ranbaxy sued FDA on September 16, 2005, seeking a declaration that the patents should be relisted and that Ranbaxy is entitled to exclusivity for the 80 mg product based on its certifications to those patents. The parties agreed to a schedule that included issuance of FDA's decision on the citizen petitions and summary judgment briefing. Ivax sued FDA on November 7, 2005, seeking consolidation of its suit with the Ranbaxy case, and requested leave to file a summary judgment motion on that date and thereby comply with the FDA-Ranbaxy summary judgment briefing schedule. Neither Ranbaxy nor the government opposed Ivax's motions; this Court has not yet ruled on those motions. Because the issue presented in both cases is identical and the parties' arguments largely overlap, the government is responding to both parties' memoranda in support of their motions for summary judgment in this memorandum.

ARGUMENT

This Court may grant a motion for summary judgment under Federal Rule of Civil Procedure 56(c) if "there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c). When ruling on cross-motions for summary judgment, the court shall grant summary judgment "only if one of the moving parties is entitled to judgment as a matter of law upon material facts that are not genuinely disputed." *Barr Labs Inc. v. Thompson*, 238 F. Supp. 2d 236, 244 (D.D.C. 2002). Because the parties agree that there are no disputed material facts that would bar summary judgment at this time, and because the issues for resolution in this case are purely legal in nature, entry of

summary judgment for the party entitled to prevail as a matter of law is appropriate. *Bayer v. United States Dep't of Treasury*, 956 F.2d 330, 333-34 (D.C. Cir. 1992).

I. FDA'S DECISION IS ENTITLED TO DEFERENCE

FDA's administrative decisions are subject to review by the Court under the Administrative Procedure Act ("APA"), and may be disturbed only if "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). This standard is highly deferential to the agency. *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971). Indeed, "[t]here is a presumption in favor of the validity of the administrative action." *Bristol-Myers Squibb Co. v. Shalala*, 923 F. Supp. 212, 216 (D.D.C. 1996). The reviewing court must consider whether the agency's decision was based upon consideration of the relevant factors and whether there has been a clear error of judgment. *Overton Park*, 401 U.S. at 416. However, "under this narrow scope of review, 'the court is not empowered to substitute its judgment for that of the agency.'" *Bristol-Myers*, 923 F. Supp. at 216 (quoting *Overton Park*, 401 U.S. at 416).

When a court is reviewing an agency's construction of a statutory provision, the first step is to determine "whether Congress has spoken to 'the precise question at issue.'" *Consumer Electronics Ass'n v. FCC*, 347 F.3d 291, 297 (D.C. Cir. 2003) (quoting *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842 (1984)) ("Chevron step one") (internal citation omitted). To the extent there exists any ambiguity in the statutory provisions at issue and their relationship to other relevant portions of the Act, the Court should defer to FDA's well-considered interpretation of its own statute. See *Chevron*, 467 U.S. at 843-44 & n.11 (in case of ambiguity, court must uphold agency's interpretation if construction is permissible under the statute; court need not conclude that agency construction was only one it permissibly could

have adopted or even a reading that the court would have reached) (“*Chevron* step two”); *see also id.* at 843-44 (“The power of an administrative agency to administer a congressionally created . . . program necessarily requires the formulation of policy and the making of rules to fill any gap left, implicitly or explicitly, by Congress.”) (citing *Morton v. Ruiz*, 415 U.S. 199, 231 (1974)); *Barnhart v. Walton*, 535 U.S. 212, 222 (2002) (“In this case, the interstitial nature of the legal question, the related expertise of the Agency, the importance of the question to administration of the statute, the complexity of that administration, and the careful consideration the Agency has given the question over a long period of time all indicate that *Chevron* provides the appropriate legal lens through which to view the legality of the Agency interpretation here at issue.”); *United States v. Mead Corp.*, 533 U.S. 218, 229 (2001).

Chevron deference applies where, as here, “Congress delegated authority to the agency generally to make rules carrying the force of law.” *Mead*, 533 U.S. at 226-27. Congress has authorized and directed FDA to decide not only what drugs may lawfully enter the marketplace through the NDA and ANDA approval process, but also when they may enter the market. The statute is replete with references to findings and determinations that must be made by the agency in the drug approval process. *See, e.g.*, 21 U.S.C. §§ 355(d), 355(j)(4), 355(j)(5). Such determinations necessarily require interpretation of a statutory scheme that is undeniably “complex.” *See, e.g., American Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1079 (D.C. Cir. 2001); *Mova*, 140 F.3d at 1062.

The D.C. Circuit has repeatedly given *Chevron* deference to FDA’s interpretation of the FDCA, as well as the agency’s implementing regulations. *See, e.g., Mylan Labs., Inc. v. Thompson*, 389 F.3d 1272, 1281 (D.C. Cir. 2004); *Purepac Pharm. Co. v. Thompson*, 354 F.3d 877, 883 (D.C. Cir. 2004); *Serono Labs., Inc. v. Shalala*, 158 F.3d 1313, 1319, 1320 (D.C. Cir.

1998) (citing *Auer v. Robbins*, 519 U.S. 452, 461 (1997)). When, as here, a court is evaluating an agency's interpretation of its own regulations, the agency is entitled to "substantial deference." *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512 (1994); *United States Air Tour Ass'n v. FAA*, 298 F.3d 997, 1005 (D.C. Cir. 2002) (courts "defer to an agency's reading of its own regulation, unless that reading is plainly erroneous or inconsistent with the regulation") (internal citations omitted); *Wyoming Outdoor Council v. U.S. Forest Service*, 165 F.3d 43, 52 (D.C. Cir. 1999) (agency's construction of own regulation is controlling unless plainly erroneous or inconsistent with regulation); *Bristol-Myers*, 923 F. Supp. at 216.

Even if the governing regulation were invalidated and FDA left to regulate directly from the statute, *Chevron* deference extends to administrative determinations that are not embodied in rulemaking or formal adjudication. As the Supreme Court made clear in *Barnhart*:

[T]he fact that the Agency previously reached its interpretation through means less formal than "notice and comment" rulemaking . . . does not automatically deprive that interpretation of the judicial deference otherwise its due. If this Court's opinion in [*Christensen v. Harris County*, 529 U.S. 576 (2000)] suggested an absolute rule to the contrary, our later opinion in [*Mead*] denied the suggestion. Indeed, *Mead* pointed to instances in which the Court has applied *Chevron* deference to agency interpretations that did not emerge out of notice-and-comment rulemaking.

535 U.S. at 221-22 (citations omitted).

In *Mylan v. Thompson*, 389 F.3d at 1279-80, for example, the D.C. Circuit extended *Chevron* deference to FDA's exclusivity determination, embodied in a letter decision, which was less formal than FDA's citizen petition response in this case. The court explained that deference was appropriate because of "the complexity of the statutory regime under which FDA operates, the FDA's expertise or the careful craft of the scheme it devised to reconcile the various statutory provisions . . . [and that] FDA's decision made no great legal leap but relied in large part on its previous determination of the same or similar issues and on its own regulations." *Id.* at 1280.

Pursuant to *Chevron* step one, the Court first examines the language of the statute. In this case, the statute is silent with respect to an NDA holder's request to delist a patent. *See* 21 U.S.C. § 355(a), (b). Indeed, none of the statutory provisions address patent delisting, including those governing 180-day exclusivity. *See* 21 U.S.C. § 355(a) and (b) (referring only to conditions for patent listing); 21 U.S.C. § 355(j)(5)(B)(iv) (governing exclusivity based on certifications to patents, without addressing listing or delisting).

Plaintiffs argue that the statute “unambiguously forbids” FDA’s interpretation, citing the exclusivity provision at 21 U.S.C. § 355(j)(5)(B)(iv). *Ranbaxy Mem.* at 14-15; *see also* *Ivax Mem.* at 22. That argument is untenable, when, as here, the FDCA is completely silent on the issue of patent delisting, as even *Ranbaxy* concedes (“The statute does not address patent withdrawal.”). *Ranbaxy Mem.* at 23. This statutory silence cannot “unambiguously forbid” the agency’s interpretation. FDA’s interpretation of the statutory silence and the gap between the patent listing and exclusivity provisions in this complex regulatory regime is entitled to considerable deference. *See Mylan*, 389 F.3d at 1279-80 (granting *Chevron* deference to FDA’s interpretation of exclusivity provisions where several interrelated provisions resulted in ambiguities).

II. FDA’S INTERPRETATION IS REASONABLE

A. FDA Reasonably Determined to Delist Patents When They are Withdrawn by the Patent Holder

The statutory provisions governing patent listings assign control over patent submissions to the patent holder. *AR Tab 23* at 4. FDA performs only a ministerial role in the patent listing process, a role which has been approved by various courts. *See Apotex, Inc. v. Thompson*, 347 F.3d 1335; *aaiPharma Inc. v. Thompson*, 296 F.3d 227; *Alphapharm PTY, Ltd. v. Thompson*, 330

F. Supp. 2d 1. Instead of reviewing patents, FDA has established the challenge process by which a party can convey its doubts about the accuracy of a patent listing to the NDA holder through FDA, and the NDA holder may correct patent listings, either by withdrawing the patent or amending its information. 21 C.F.R. § 314.53(f).¹¹

Given the statutory silence, FDA could have adopted a number of approaches to patent delisting, including the one urged upon this Court by the plaintiffs, *i.e.*, maintaining the patent in the Orange Book if any ANDA has filed a paragraph IV certification. AR Tab 23 at 8.¹² In its regulation, however, FDA chose instead to honor the NDA holder's request to withdraw a patent. 21 C.F.R. § 314.94(a)(12)(viii)(B). This regulation also provides that the certifications of ANDA applicants must be amended when patents are delisted. Because a withdrawn patent no longer serves as a barrier to ANDA approval, FDA does not believe that – absent special circumstances not present here – the public should be denied the benefits of broad generic competition for a drug for six months based solely on an ANDA applicant's paragraph IV certification to that patent. AR Tab 23 at 10. The statute is silent on these issues – delisting and amendment of certifications – and thus FDA's interpretation is entitled to substantial deference.

¹¹ Ranbaxy recognizes that this ministerial role has been approved by courts, but argues that “no court has required it.” Ranbaxy Mem. at 23. Whether it has been “required” is not relevant to whether it is reasonable and permissible.

¹² Ranbaxy proposes a secondary option: FDA could purportedly allow an NDA holder to withdraw a patent but leave the patent in the Orange Book “so as to preserve the statutory grant of 180-day exclusivity.” Ranbaxy Mem. at 23. Ranbaxy's proposal makes no practical sense: a patent that is “withdrawn” is *withdrawn from the Orange Book*; it does not remain fictitiously listed there for some purposes but not for others. And, as the agency explained in its citizen petition response, FDA “does not believe that leaving all ‘delisted’ patents as to which an applicant has submitted a paragraph IV certification in the Orange Book only until the exclusivity expires is an acceptable way to reconcile delisting and exclusivity.” AR Tab 23 at 18. “[T]he patent may have to remain in the Orange Book for many years until the exclusivity expires, all the while acting as a barrier to ANDA approvals.” *Id.*

Plaintiffs assert that the exclusivity provision somehow vests an ANDA applicant with exclusivity at the very moment that it files a first paragraph IV certification – without any regard to later developments in the status of the patent listing or paragraph IV certifications. Ranbaxy Mem. at 15; Ivax Mem. at 34. Plaintiffs’ argument runs counter to the language of the statute, the purposes of the statute, FDA regulations, FDA administrative precedent, and case law.

1. A Paragraph IV Certification Does Not Automatically Entitle the Applicant to Exclusivity Without Regard to Changed Circumstances

Although plaintiffs argue that the filing of a paragraph IV certification automatically entitles them to 180-day exclusivity despite a later change in circumstances, that is not the case. In fact, there are various situations in which a paragraph IV certification does not lead to exclusivity, as explained in FDA’s citizen petition response:

there are a number of circumstances in which an ANDA applicant that was first to file a paragraph IV certification to a listed patent may, as a result of the passage of time or a change in circumstances, be required to amend its certification to something other than the paragraph IV certification upon which exclusivity depends.

AR Tab 23 at 9. One of these circumstances is when the listed patent expires before the ANDA is approved. *Id.* The correct certification in such a situation is a paragraph II, which is a certification that the patent has expired. *Id.* Another circumstance is when the ANDA applicant loses its patent litigation, in which case it will be required to amend its paragraph IV certification to a paragraph III, reflecting the fact that it will not be eligible for final approval until expiration of the patent. *Id.* It defies logic that the ANDA applicant would be entitled to exclusivity in that circumstance, as Ivax itself recognizes, Ivax Mem. at 17 n.7, notwithstanding that the ANDA applicant had incurred the risk and actual defense of patent litigation. In addition, a patent

certification must also be amended if for any reason the original certification is no longer accurate. 21 C.F.R. § 314.94(a)(12)(viii)(C). AR Tab 23 at 9.

Once an applicant amends its ANDA so that it no longer contains a paragraph IV certification, the applicant will lose its eligibility for exclusivity. *See, e.g.*, 21 U.S.C. § 355(j)(5)(B)(iv); *Dr. Reddy's Labs.*, 302 F. Supp. 2d at 354-55; *Mylan Pharm., Inc. v. Henney*, 94 F. Supp. 2d at 54. In its citizen petition response, the FDA noted that “the fact that an ANDA applicant may have undertaken some risk and incurred certain costs in challenging a patent is not an adequate basis for maintaining eligibility for exclusivity for which the applicant may once have qualified. . . .” AR Tab 23 at 10.

To account for possible changes in the status of patents and paragraph IV certifications, FDA does not make any specific exclusivity determinations until exclusivity could bar final approval of an ANDA, which is generally when any ANDA for the drug product is ready for final approval. *See Ex. A.* at 2-4. FDA’s practice of considering the status of the patents and paragraph IV certifications at the time of making its exclusivity determinations is fully consistent with the statute and has been upheld. *Ex. A.* at 2-4; *Dr. Reddy's*, 302 F. Supp. 2d at 353.

In sum, contrary to plaintiffs’ arguments, nothing in the statute requires exclusivity when, as here, circumstances change after a paragraph IV certification was filed.

2. FDA’s Reasoning has been Upheld

FDA’s approach toward patent listing and its effect on 180-day exclusivity have been upheld in litigation. In *Dr. Reddy's*, plaintiff (Reddy) made a very similar argument to that made by plaintiffs here. Reddy argued that it should be entitled to exclusivity based on a first-filed paragraph IV certification. *Dr. Reddy's*, 302 F. Supp. 2d at 353-55. FDA determined that Reddy was required to amend its certification to a paragraph II certification upon expiration of the

patent (which occurred before FDA approved Reddy's ANDA), and thus was not entitled to exclusivity. *Id.* at 354-55. Reddy argued that because the 180-day exclusivity provision referred to an application "containing" a paragraph IV certification, an application that contained such a certification "at some time during the approval process" should be entitled to exclusivity even if the paragraph IV certification was amended before final approval. *Id.* at 355. The court, however, upheld FDA's decision to deny exclusivity to an applicant who no longer had a valid paragraph IV certification on file at the time of final approval. *Id.* The court rejected the argument that the statute "requires the award of exclusivity if the ANDA applicant is the first applicant to file a paragraph IV certification on a patent, without more, because at that time the ANDA applicant exposes itself to patent litigation by providing the requisite notice of the certification." *Id.* at 351.

In its citizen petition response in the instant case, FDA noted that the *Dr. Reddy* "court found it reasonable for FDA to conclude that eligibility for exclusivity expired with the patent, even though the ANDA sponsor was the first to challenge the patent and had been sued by the NDA holder, thus incurring the cost of litigation." AR Tab 23 at 10. The court in *Dr. Reddy's* also held:

the purpose of the exclusivity period is to provide an incentive to challenge patents that block ANDA approval. . . . Once a listed patent expires, there is no longer a need to provide an incentive to challenge it in court. Consistent with this statutory purpose, the FDA construes the statute to award 180-day exclusivity based only upon paragraph IV certifications to unexpired patents. *See* 59 Fed. Reg. 50338, 50348. This construction makes sense in terms of the basic statutory objective of encouraging applicants to challenge listed patents that prevent final ANDA approval.

302 F. Supp. 2d at 354. The reasoning applies to a withdrawn patent, because a withdrawn patent no longer "prevents final ANDA approval." AR Tab 23 at 10.

Similarly, in *Purepac*, Torpharm had submitted a paragraph IV certification to the patent at issue (the '479 patent), and had been sued by the NDA holder based on that certification. 354 F.3d at 886. After it was determined that the patent was improperly filed, FDA delisted the patent because, in the unusual circumstances of that case, the patent should never have been listed. *Id.* The court held that 21 C.F.R. § 314.94(a)(12)(viii)(B) posed no bar to the delisting, even though Torpharm had filed a paragraph IV certification and was sued. *Id.* at 886-88. The D.C. Circuit accepted FDA's delisting of the patent and the loss of any related exclusivity (even though there had been litigation), *id.*, thus further supporting FDA's decision in this case that "exclusivity does not vest with the initial submission of the first paragraph IV certification to the patent, but can be lost as a result of subsequent changes in the status of the patent." AR Tab 23 at 20.

3. Plaintiffs' Proposal Would Undermine the Patent Challenge Process

Under FDA's patent challenge regulation, any party with doubts about the correctness of a patent listing can submit a statement to FDA challenging the patent listing, which FDA then forwards to the NDA holder. 21 C.F.R. § 314.53(f). The NDA holder then has an opportunity to correct the patent listing, either by withdrawing or amending the patent. Plaintiffs' argument would prevent such a withdrawal in response to a challenge under this regulation if there had been any paragraph IV certification filed to the patent.

As FDA observed in its citizen petition response, usually little time passes between listing a patent and submission of ANDAs containing paragraph IV certifications. AR Tab 23 at 15. Thus, if – as plaintiffs propose – all patents remained in the Orange Book after such a certification had been filed, ANDA applicants would have little incentive to use the challenge

process because the NDA holder would not have a meaningful opportunity to withdraw its patent, even if it believed that the patent no longer met the listing criteria. *Id.*

Ranbaxy argues that this rationale “makes no sense” because ANDA applicants can always object to a patent listing, and because keeping a patent listed to reward “successful notice” is no more a barrier to the use of the challenge process than keeping a patent listed when the patent is the subject of litigation. Ranbaxy Mem. at 29.¹³ This is not correct. First, although ANDA applicants can always object to a patent listing, they would have much less incentive to do so when it could not possibly result in delisting of the patent and would thus do nothing to relieve them of the burden of filing a paragraph IV certification or otherwise result in earlier generic approval. Second, the exception that FDA has established for patents that are the subject of litigation is much narrower than plaintiffs’ proposal that all patents for which paragraph IV certifications have been filed remain listed. FDA will delist all patents upon an NDA holder’s request that are not the subject of litigation – and, for all of those unlitigated patents – the challenge process may actually result in a substantive change. Under plaintiffs’ proposal, the challenge process would result in a substantive change less often because, as noted, many paragraph IV certifications are filed shortly after patent submissions, and the NDA holder would not be able to correct its listings once a paragraph IV certification had been filed, even if it so desired.

4. FDA’s Regulatory Approach Has Been Consistent

21 C.F.R. § 314.94(a)(12)(viii)(B) was promulgated in 1994 and has been followed – and heretofore unchallenged – since that date. FDA has not wavered from its policy of delisting a

¹³ By “successful notice” plaintiffs mean a situation when the paragraph IV notice to the patent holder (not litigation) allegedly causes delisting of the patent. AR Tab 23 at 17; Ranbaxy Mem. at 9.

patent upon an NDA holder's request if it is not the subject of litigation. *See* AR Tab 23 at 18-20 (noting cases of FDA's consistent decisions regarding delisting). Plaintiffs nevertheless argue that FDA's decision in this case came as a surprise, citing alleged inconsistencies in FDA's past statements concerning exclusivity in circumstances when an ANDA is not sued. Those arguments are baseless.

Plaintiffs argue that FDA "exercised its authority in a manner consistent with the structure Congress enacted when it promulgated its 1994 regulations" – in contrast to how plaintiffs characterize FDA's exercise of its authority in its decision in this case. Ranbaxy Mem. at 24. Those regulations, however, include the very same regulation that Ranbaxy challenges here. Plaintiffs also wholly mischaracterize the regulation and the preamble from the Federal Register setting forth the final rule. Ranbaxy's careful selection of language would suggest that FDA decided that anytime a patent is withdrawn by an NDA holder, the patent should nevertheless be "deemed to be relevant" until the applicable exclusivity period had expired. Ranbaxy states, for example, that "FDA then recognized that an [sic] pioneer's withdrawal of a patent should not result in the loss of exclusivity." *Id.* (citing Ex. B, 59 Fed. Reg. at 50,348); *see also id.* at 28 ("[FDA] accomplished [the purpose of Hatch Waxman] by prohibiting delisting of the pioneer's patents until any 180-day exclusivity expired."); *id.* at 35 ("the regulation did not intend to provide that the withdrawal of a patent not in litigation would affect exclusivity."); Ivax Mem. at 33-34.

These are mischaracterizations of both the regulation and the Federal Register preamble. In the preamble, FDA's comments were directed to preserving exclusivity in the situation where the NDA holder withdraws the patent "immediately upon a court decision that the patent is invalid or unenforceable," Ex. B, 59 Fed. Reg. at 50,348, and thus only addressed preserving

exclusivity when there was litigation. AR Tab 23 at 12. Elsewhere in the preamble (as well as in the text of the final rule), FDA made it clear that patents that were not the subject of lawsuits were subject to delisting. *See* Ex. B, 59 Fed. Reg. at 50,348, col. 3 (“A patent that is the subject of a lawsuit under § 314.107(c) will not be removed from the list until FDA determines either that no delay in effective dates of approval is required as a result of the lawsuit or that any such period of delay in effective dates of approval is ended.”). FDA said the same thing in the preamble to the proposed rule in 1989:

If, after one or more applicants have made paragraph IV certifications on a patent, that patent has been removed from the list for any reason other than because that patent has been declared invalid in a lawsuit brought by that patent owner within 45 days of receiving notice under § 314.95 any applicant with a pending application . . . should submit an amended patent certification. . . .

54 Fed. Reg. 28872, 28895-96 (July 10, 1989). *See also* AR Tab 23 at 11-12.

Ivax asserts that FDA’s post-*Mova* Guidance for Industry and November 1998 interim rule represent the agency’s position that exclusivity should be granted to the first ANDA applicant who files a paragraph IV certification without regard to whether there is a lawsuit. Ivax Mem. at 30-31 (citing Guidance for Industry: 180-Day Generic Drug Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act (June 1998) (“Guidance”), available at www.fda.gov/cder/guidance/2576fnl.pdf; and 180-day Generic Drug Exclusivity for Abbreviated New Drug Applicants Interim Rule, 63 Fed. Reg. 59,710, 59,711 (Nov. 5, 1998). Notably, in the portions of those documents that Ivax cites there was no discussion of exclusivity when there has been a request to delist a patent. Rather, FDA was characterizing the holdings in the *Inwood* and *Mova* district court decisions, and addressed the “threshold question of whether a ANDA applicant that was not sued for patent infringement as a result of its paragraph IV certification would nonetheless be eligible for exclusivity.” Guidance

at 5 (noting that “[t]here are many additional issues related to the application of the statutory provisions that have yet to be resolved.”). Moreover, the D.C. Circuit’s decision in *Mova* expressly reserved judgment on the question whether FDA could impose a litigation requirement, and limited its decision to striking down FDA’s “win first” version of the successful defense requirement. *Mova*, 140 F.3d at 1069.

In 1999, FDA proposed a rule which stated in part that “[p]ermitting an applicant who avoids a lawsuit to be eligible for exclusivity is consistent with the statutory language and goal of facilitating prompt entry of generic drug products into the market.” 180 Day Generic Drug Exclusivity for Abbreviated New Drug Applications, 64 Fed. Reg. 42873, 42,876 (Aug. 6, 1999) (proposed rule). Ranbaxy cites that language in support of its assertion that, “until now, FDA has been quite clear that it will not impose a litigation requirement in determining whether an applicant is eligible for 180-day exclusivity.” Ranbaxy Mem. at 17-18; *see also* Ivax Mem. at 32. Plaintiffs overstate the applicability of those general statements to this case. FDA’s proposed rule did not refer whatsoever to exclusivity in the circumstances of patent delisting, and was in any event withdrawn by FDA in 2002. *See* 67 Fed. Reg. 66,593 (Nov. 1, 2002).

Nor has there been any shift in agency policy necessitating another round of notice and comment rulemaking in order for the agency to continue to follow its long-standing regulation, 21 C.F.R. § 314.94(a)(12)(viii)(B), as Ranbaxy argues. Ranbaxy Mem. at 36. There is a distinction between “rulemaking” and the clarification of an existing rule; only “new rules that work substantive changes in prior regulations are subject to the APA’s procedures.” *Sprint Corp. v. FCC*, 315 F.3d 369, 374 (D.C. Cir. 2003). Here, FDA’s decision is entirely consistent with and in fact follows its existing regulation, and notice and comment rulemaking was not required.

B. FDA's Decision Furthers the Purposes of the Statute

As FDA fully set forth in its response to the citizen petitions, FDA's interpretation and its rejection of the arguments advanced in the citizen petitions furthers the goals of the Hatch-Waxman Amendments as follows: (1) FDA's decision maintains appropriate exclusivity incentives; (2) FDA's decision properly removes listed patents that would otherwise serve as unjustified barriers to entry; and (3) FDA's decision does not unduly place control of exclusivity in the NDA holder's hands. AR Tab 23 at 14-17.

Ranbaxy argues, citing no authority, that FDA is not authorized to consider policy issues when implementing the statute. Ranbaxy Mem. at 26. FDA is authorized, however, to implement its organic statute and may reasonably fill in statutory gaps and account for policy objectives in doing so. "The power of an administrative agency to administer a congressionally created . . . program necessarily requires the formulation of policy and the making of rules to fill any gap left, implicitly or explicitly, by Congress." *Chevron*, 467 U.S. at 843-44 (citing *Morton v. Ruiz*, 415 U.S. 199, 231 (1974)). "If Congress has explicitly left a gap for the agency to fill, there is an express delegation of authority to the agency to elucidate a specific provision of the statute by regulation." *Id.*

1. FDA's Decision Properly Maintains Incentives for Exclusivity

FDA appropriately considered the effects of maintaining or delisting a patent in its decision, including the effects on the exclusivity incentive. AR Tab 23 at 16-17. The agency "determined that as a 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 has requested that the patent be withdrawn." *Id.* at 16. "The narrow exception

applicable when the patent has been the subject of a lawsuit serves to continue to provide an incentive to the first applicant to pursue its patent litigation by assuring the applicant that the exclusivity reward will not be extinguished if the patent is removed from the Orange Book as a result of success in that litigation.” *Id.* at 17.

In addition, as FDA noted in its decision, patent delisting is relatively uncommon, and thus the lack of exclusivity in this circumstance is not likely to be a significant deterrent to an ANDA applicant’s patent challenge.¹⁴ Furthermore, as discussed above, exclusivity can be lost in a number of ways that are outside the control of the ANDA applicant who might be otherwise eligible: the patent could expire, *see Dr. Reddy’s*, 302 F. Supp. 2d at 353-54; or the exclusivity could be triggered by a court decision in litigation brought by a subsequent ANDA applicant before the first ANDA applicant can market its drug. *See Teva Pharm., USA, Inc. v. FDA*, 182 F.3d 1003, 1005 n.3 (D.C. Cir. 1999) (“The court-decision trigger can be activated by any subsequent ANDA applicant’s litigation whether or not the first applicant has enjoyed a period of exclusivity.”). In the latter case, the exclusivity may run before the first ANDA applicant is in a position to use it. All ANDA applicants who challenge patents are aware of the risk that, even if they are first to file a paragraph IV certification and thus may be eligible for exclusivity in the future, they may not have an opportunity to take advantage of that exclusivity period. And, given the relatively small risk that an ANDA applicant will certify to a patent that will subsequently be delisted, plaintiffs’ parade of horrors describing the potential behavior modifications that

¹⁴ Ranbaxy asserts that FDA’s decision affects its potential exclusivity for four different drugs, implying that FDA’s decision has fallen upon it with especially burdensome weight. Ranbaxy Mem. at 32. That argument is not relevant here, where FDA reasonably approached the delisting question from a broad, agency standpoint without regard to how it might affect one particular company.

ANDA applicants might undertake to avoid such a scenario is grossly overstated. *See* Ranbaxy Mem. at 32 (arguing that FDA's decision will invite unnecessary litigation).

Plaintiffs argue that the exclusivity incentive will be diminished for those ANDA applicants who lose their exclusivity as a result of a delisting when there has been no litigation, arguing that many such ANDA applicants provided "successful notice" that prompted the delisting and are as deserving of exclusivity as an applicant who provokes litigation by filing a paragraph IV certification. Ranbaxy Mem. at 19, 32; Ivax Mem. at 19, 29. FDA does not believe that "successful notice" is a relevant criterion for delisting decisions.

Importantly, plaintiffs do not simply propose that FDA refuse to delist only those patents for which an ANDA applicant has provided "successful notice" and thereby prompted the NDA holder to withdraw its patent. FDA does not inquire into the reasons why a patent is delisted, "and it would be entirely impractical to have a delisting decision depend upon an ANDA applicant's characterization of why the delisting was sought." AR Tab 23 at 17. Nor would it be reasonable for FDA to be expected to divine the reasons underlying the NDA holder's request, which could be varied and complex. *See* Statutory Framework Section at I, *supra*. Rather, plaintiffs propose that FDA refuse to delist *all* patents for which *any* ANDA applicant has filed a paragraph IV certification, thus expanding eligibility for exclusivity even to those applicants who may not have provided "successful notice" and who simply benefitted from the NDA holder's independently revised views on the scope of its patent. Thus, although plaintiffs suggest that "successful notice" should justify an award of exclusivity, their proposed solution is hardly tailored to reward that behavior.

Nor is it at all clear that "successful notice" is what happened in this case. Merck requested that its patents be delisted a year and a half after receiving Ranbaxy's notice, and over

two and a half years after receiving Ivax's notice. *See* Background Section at IV, *supra*. Merck made its request in October 2003, shortly after FDA issued revised regulations at 21 C.F.R. § 314.53 describing what types of patents must and must not be submitted to FDA. 68 Fed. Reg. 36,703 (Jun. 18, 2003); AR Tab 23 at 4 n.4. Thus, it seems unlikely on its face that the notices provided to Merck by Ivax and Ranbaxy prompted Merck's request to delist the patents. AR Tab 23 at 17 n.20.

Finally, even if "successful notice" did occur in this case, FDA has rationally distinguished between "successful notice" and litigating a patent for purposes of patent delisting decisions. AR Tab 23 at 17. By keeping a patent listed when it is the subject of litigation, FDA assures the ANDA holder that is litigating the case that it will not be deprived of its exclusivity if the case seems to be progressing in its favor and the NDA holder delists the patent. *Id.* Such assurance provides a continuing incentive to pursue the litigation to an ultimate conclusion of a court decision of invalidity, noninfringement, and unenforceability – a result that will potentially benefit the public by creating greater certainty about the status of the patent for other ANDA applicants. *Id.*¹⁵ In contrast, an ANDA applicant who has provided "successful notice" has defused litigation and requires no further incentive to pursue its patent infringement defenses. AR Tab 23 at 17.

¹⁵ Ranbaxy argues that such an applicant needs no further incentive to defend itself in a patent infringement case. Ranbaxy Mem. at 31. The vigor of that defense, however, can reasonably be expected to be commensurate with the expected reward, especially when the ANDA applicant has not marketed the drug and is not liable for infringement damages. If the applicant loses the litigation, absent extenuating circumstances, the result will be simply a delay in approval until expiration of the patent.

2. Listed Patents are Barriers to Generic Drug Entry and Should be Removed Upon an NDA Holder's Request Unless there is Sufficient Justification for Not Delisting

FDA properly considered the effects of maintaining or delisting a patent in its decision, including the significant delay that a listed patent may impose on generic drug entry. AR Tab 23 at 15. As with expired patents, a delisted patent no longer bars generic drug approval. *Id.* at 10. Listed patents can result in exclusivity and thus delay market entry for subsequent ANDA applicants, due to potential 30-month stays, the statutory 180-day delay, and the possible delay by the ANDA eligible for exclusivity in marketing the drug.¹⁶ Even if FDA's regulation provided that a patent were to be delisted upon expiration of the 180-day exclusivity period, ANDA applicants might still be required to wait for long periods of time before exclusivity is triggered at all (if, for example, the applicant eligible for 180-day exclusivity is unable to obtain approval of its ANDA, or fails to begin marketing). *Id.* at 15. Thus, FDA's regulation brings generic competition to the market sooner.

Ranbaxy discounts the relevance of delay that might result from the first applicant's inability to market or decision not to market because such delay "is inherent in 180-day exclusivity and is wholly unrelated to whether the exclusivity was earned by successful notice or design or by successful defense." Ranbaxy Mem. at 30. However, the likelihood of such delay

¹⁶ Ranbaxy argues that 30-month stays do not apply to patents for which the NDA holder has requested delisting, and thus such stays cannot delay generic entry in a delisting situation, citing a letter in which FDA assured an NDA holder that the request for delisting terminated any 30-month stays. Ranbaxy Mem. at 30; AR Tab 32. FDA does not disagree with that conclusion, but Ranbaxy's argument misses the points being made in that section of FDA's decision. First, a listed patent generally delays generic entry due to the possibility of a 30-month stay, and second, the possibility of losing such a stay is likely to deter an NDA holder from abusing the delisting process by withdrawing a listable patent because such a stay can be very valuable to the NDA holder. AR Tab 23 at 15-16.

would increase if eligibility for exclusivity were expanded in the manner sought by plaintiffs.

AR Tab 23 at 15. Plaintiffs' proposed expansion of exclusivity would likely delay generic drug entry for those drugs that plaintiffs' proposal would affect. *Id.*

Nor does this decision generally reflect "the agency's disagreement with Congress over the value of 180-day exclusivity." Ranbaxy Mem. at 30. In fact, FDA has interpreted the statute as granting multiple periods of exclusivity when multiple patents are listed – which greatly expands eligibility for exclusivity – in the face of repeated challenges. *See* note 5, *supra*. FDA's decision in this case, as in all of its exclusivity decisions, simply interprets the statute in light of the Congressional purpose.

FDA properly accounted for the burden upon subsequent ANDA applicants who would be required to certify to patents if they remained listed, even after an NDA holder's request to withdraw the patent. AR Tab 23 at 14-15 ("If a patent remains listed, any applicant submitting an ANDA for the drug product after the NDA holder requests delisting must nonetheless comply with the patent certification requirements of section 505(j)(2) [21 U.S.C. § 355(j)(2)]." Ranbaxy attempts to trivialize that burden, stating that a listed patent "is no obstacle to entry by subsequent ANDA applicants" because any ANDA applicant must undertake a patent analysis if it intends to market a drug before patent expiration, and "[w]riting down its analysis and sending it to the patent holder is hardly a burden and certainly not one that has any perceptible effect on approval by FDA." Ranbaxy Mem. at 29. FDA disagrees that an ANDA's filing of a paragraph IV certification, an act that is automatically considered an act of patent infringement – as well as being required to disclose its defenses to the very party who may sue it for infringement – is trivial. Nor are the administrative burdens accompanying those tasks a small matter. Indeed,

Ranbaxy argues that it deserves exclusivity *because* it went to the trouble of complying with all of the requirements for a paragraph IV certification.

Ranbaxy further argues that a delisted patent and an expired patent are entitled to different treatment, and that an applicant who has certified to a later-delisted patent should still be entitled to exclusivity. Ranbaxy Mem. at 33. Ranbaxy cannot deny, however that a withdrawn patent no longer bars *approval* of an ANDA, and would not dispute that FDA should delist such patents if there had been no paragraph IV certification filed to that patent. Thus, Ranbaxy is left to argue that a withdrawn patent “can still serve as a barrier to *competition*” because an ANDA applicant can still face a legal risk if it markets its drug under threat of infringement of the delisted patent. *Id.* at 34 (emphasis added). Although that may be theoretically true, it is notable that such a barrier to competition is of little concern to the FTC, which, informed by its expertise in matters concerning competition, fully supports FDA’s approach to delist patents upon an NDA holder’s request. AR Tab 14. Ranbaxy also argues that there may be “as there is in this case” a substantial question about whether the patent claims the drug and should be listed at all. Ranbaxy Mem. at 34. The fact that there may be such lingering questions of proper listing and liability suggests that plaintiffs did not in fact provide the “successful notice” that they assert, and does not justify granting plaintiffs exclusivity on the ground of the purported value of that contribution.

3. FDA’s Decision Properly Defers to the NDA Holder’s Request to Withdraw a Patent

FDA appropriately determined to defer to the NDA holder’s request to delist a patent except in limited circumstances. AR Tab 23. Plaintiffs argue that FDA’s decision is at odds with the statute because it allegedly places the exclusivity decision in the hands of the patent

holder. Ranbaxy Mem. at 31; Ivax. Mem. at 25. This is not so. As FDA stated in its petition response, the statute already gives unfettered control to the NDA holder over patent listing (but not discretion as to which patents must be listed), and a listed patent is an absolute prerequisite to exclusivity. AR Tab 23 at 15. Thus, there can be nothing “at odds” with interpreting the statute to give control to the NDA holder to delist a patent that it need not have listed in the first place.

FDA cited several reasons why an NDA holder would be unlikely to abuse the patent withdrawal process. NDA holders have no discretion to list or delist a patent, but must make such decisions based on statutory and regulatory criteria. In addition, an NDA holder who delists a patent will no longer be able to obtain a 30-month stay of generic approval, 21 U.S.C. § 355(j)(5)(B)(iii), or enjoy the delay in approval of multiple generics as a result of 180-day exclusivity. AR Tab 23 at 15-16. Thus, even if an NDA holder had discretion to abuse the patent listing process, it would have little economic incentive to do so.

Neither *Mova* nor *Inwood Laboratories, Inc. v. Young*, 723 F. Supp. 1523, 1526 (D.D.C. 1989), cited by Ranbaxy (Ranbaxy Mem. at 31-32), addressed an NDA holder’s power over listing or delisting, and do not support plaintiffs’ position that the power to delist patents grants too much power over exclusivity decisions to the NDA holder. FDA’s decision does not impermissibly “shift[s] its responsibility to make eligibility decisions to a private party.” Ranbaxy Mem. at 32 n.6. The statute already gives complete control to the NDA holder for listing a patent, which inherently gives NDA holders control over the possibility of exclusivity. AR Tab 23 at 15 n.19. FDA’s delisting decision and regulation do no more than reflect the NDA holder’s inherent control over exclusivity by patent listing.¹⁷

¹⁷ Plaintiffs also argue without any merit that the NDA holder’s listing decisions places too much power in the hands of the NDA holder because FDA declines to substantively review the propriety of patent listings. Ranbaxy Mem. at 32 n.6; Ivax Mem. at 27-28 n.9 (further arguing

Nor does *Torpharm Inc. v. FDA*, No. 03-2401, 2004 U.S. Dist. LEXIS 524 (D.D.C. Jan. 8, 2004) (RWR), vacated as moot by *Apotex Inc. (f/k/a TorPharm, Inc.) v. FDA*, Nos. 04-5046 & 04-5047 (D.C. Cir. Dec. 17, 2004), support Ivax's position in this case. Ivax Mem. at 26. That case concerned an entirely different issue: FDA's "shared exclusivity" policy, under which FDA grants shared exclusivity to two ANDA applicants who file first paragraph IV certifications to two different patents for the same drug, and each is blocked from being approved by the other's exclusivity. Ex. B to Ivax Mem. at 53-55. In such a situation, FDA will approve each application and grant the applicants shared exclusivity to avoid lengthy delays in generic market entry. *See Shared Exclusivity for Paroxetine Hydrochloride Tablets* (FDA Decision Jul. 30, 2003), available at http://www.fda.gov/cder/ogd/shared_exclus_paroxetine.htm.

C. FDA's Regulation Survives *Mova* and is Consistent with the *Mova* Holding

Plaintiffs also argue that the agency has improperly conditioned exclusivity on whether the patent is the subject of litigation, in violation of the text of the exclusivity provision and of the D.C. Circuit's decision in *Mova*, 140 F.3d 1060. Ranbaxy Mem. at 16; Ivax Mem. at 21. In so arguing, plaintiffs improperly conflate the agency's grant of exclusivity, at issue in *Mova*, with the agency's determination to delist patents in certain circumstances, at issue here.

As FDA explained in its decision, *Mova* held that FDA's "win first" successful defense requirement for exclusivity was inconsistent with the text of the exclusivity provision because it essentially wrote the commercial marketing trigger out of the statute. *Mova*, 140 F.3d at 1069-70; AR Tab 23 at 14. The court did not decide that the agency could never condition eligibility

that an NDA holder has *de facto* discretion to list or delist patents because there is no adequate enforcement mechanism to assure compliance with the requirements). As noted above, FDA's ministerial approach to patent listing has been repeatedly upheld. *See, e.g., Apotex*, 347 F.3d 1335; *aaiPharma*, 296 F.3d 227.

for exclusivity on a litigation requirement and in fact recognized that FDA could have adopted a “wait and see” approach to exclusivity, *i.e.*, it could have waited until the conclusion of litigation to determine whether the applicant won the litigation and thus obtained exclusivity, or lost the litigation and thereby lost exclusivity. *Mova*, 140 F.3d at 1069.

Following *Mova*, FDA determined that it would regulate directly from the statute and deleted the “successful defense” requirement that had been present in 21 C.F.R. § 314.107(c). AR Tab 23 at 14. In so doing, the agency determined that eligibility for exclusivity would not be conditioned on being sued by the patent holder. AR Tab 23 at 13-14. This approach was upheld in *Purepac Pharm. Co. v. Friedman*, 162 F.3d 1201 (D.C. Cir. 1998), although the court did not hold that the statute required that particular outcome, *i.e.*, having no litigation requirement at all. *Mova* stands for nothing more than the proposition that the agency could not adopt a “win first” litigation requirement for granting exclusivity; following *Mova*, the agency has declined to impose any litigation requirement for exclusivity.¹⁸

Notably, nothing in *Mova* addresses the “delisting” issue in the instant case or otherwise supports plaintiffs’ arguments that the agency cannot consider whether a paragraph IV certification resulted in litigation in determining whether to delist a patent upon an NDA holder’s

¹⁸ Ivax argues that FDA “seriously misreads *Mova*” in its decision, stating that the basis of the court’s decision was that the successful defense requirement was inconsistent with the explicit language of the statute itself, and that FDA cited only the court’s secondary conclusion that the successful defense requirement wrote the commercial marketing trigger out of the statute. Ivax Mem. at 30 n.10. Ivax’s argument is baseless: FDA clearly acknowledged that “[t]he *Mova* court held that FDA’s then-prevailing ‘win first’ successful defense approach to awarding exclusivity was inconsistent with the plain statutory language” and stated one reason for the court’s decision: the court decision trigger. AR Tab 23 at 14; *see also Mova*, 140 F.3d at 1069. The court also decided that the “win first” requirement was inconsistent with the statute because it permitted later applications to be approved even before a first applicant could become eligible for exclusivity upon conclusion of its litigation; FDA clearly stated that the “win first” requirement did not survive *Mova*. *See Mova*, 140 F.3d at 1069; AR Tab 23 at 14.

request. AR Tab 23 at 14. Absent patent litigation, FDA will delist a patent upon an NDA holder's request. FDA's decision allows for more extensive generic competition, sooner, and significantly decreased prices for consumers.

Plaintiffs also argue in vain that the "subject of a lawsuit under § 314.107(c)" language in 21 C.F.R. § 314.94(a)(12)(viii)(B) improperly cross-references the pre-*Mova* version of 21 C.F.R. § 314.107(c). Ranbaxy Mem. at 19-20; Ivax Mem. at 24. Plaintiffs' arguments are irrelevant for the obvious reason that there has been no patent litigation of any type in this case, so it does not matter what type of lawsuit is referenced in the regulation. Even if this issue were relevant, plaintiffs' arguments are not persuasive. Ivax argues that the agency has no rationale for using the pre-*Mova* definition of a lawsuit, *i.e.*, a defensive lawsuit in which the first ANDA applicant is sued within 45 days of the patent owner's receipt of notice, rather than a broader definition that would include declaratory judgment actions brought by ANDA applicants. Ivax Mem. at 24-25 (citing AR Tab 23 at 12 n.17). Although the agency has never had occasion to consider whether a broader definition should apply to include suits both against and by the first ANDA applicant, it in fact characterized the "lawsuit" referenced in the regulation as "a lawsuit as a result of the first applicant's paragraph IV certification." AR Tab 23 at 12 n.17. This is broader than the pre-*Mova* requirement that there be a successful defense in this litigation.

Ivax also argues that FDA has no rationale to distinguish between suits by the NDA holder against first and later ANDA applicants. Ivax Mem. at 24-25. This limitation of the exception in 21 C.F.R. § 314.94(a)(12)(viii)(B) to lawsuits resulting from the first applicant's paragraph IV certification, however, narrowly tailors the exception so that it will apply only in circumstances when the litigation concerns the first ANDA applicant and that applicant could lose its exclusivity as a result of delisting. That exception provides a continuing incentive to the

first ANDA applicant to challenge the patent in the litigation. AR Tab 23 at 17. In contrast, if FDA were to keep a patent listed contrary to the NDA holder's request when only a subsequent ANDA applicant were sued, the subsequent ANDA would have *less* incentive to challenge the patent in its litigation because the first ANDA would retain its eligibility for exclusivity and would thus block the second ANDA from marketing the drug for 180 days, even if the second applicant were to prevail in the litigation.

Perhaps even more important, even if this Court were to invalidate the regulation on the ground that it cross-references the pre-*Mova* regulation, FDA would be left to do as it did following *Mova*: regulate directly from the statute. The statute is silent on the issues raised in this case, and it is clear from the agency's decision letter that, even in the absence of the regulation, the agency would make the same decision and that decision would be permissible under the statute. AR Tab 23 at 17.

D. FDA's Approach is Not Arbitrary

Ivax proposes a hypothetical in which Merck sues Ivax but not Ranbaxy and then dismisses its suit against Ivax. Ivax asserts that, under FDA's approach, FDA would delist the patents for the 80 mg strength because Ranbaxy (the purported first-filer for that strength) was not sued, but would not delist for the 5, 10, 20, and 40 mg strengths because Ivax (the purported first-filer for that strength) was sued. Ivax Mem. at 18. Ivax argues that "the absurdity of this result [and the converse of that result] is obvious." *Id.*

FDA disagrees that such a result would be patently absurd, as each strength of a drug is a separate listed drug product and thus ANDA applicants submitting paragraph IV certifications for each strength may be eligible for separate periods of exclusivity. See *Apotex Inc. v. Shalala*, 53 F. Supp. 2d 454, 460-63 (D.D.C. 1999), *aff'd*, 1999 WL 956686 (D.C. Cir. Oct. 8, 1999)

(summary affirmance). Therefore, although the agency has not had to address this issue, delisting a patent for one strength and not for another would not be absurd, and would be no different from the case in which the same patent is listed for multiple similar drug products (*e.g.*, for both tablet and capsule forms), and in response to the NDA holder's request to delist, FDA delists as to one of the products for which there are no pending ANDAs and retains the listing for the drug for which the ANDA applicant filed the first paragraph IV certification and is in litigation.

Nor is it clear that FDA would retain a patent in the Orange Book if the lawsuit were dismissed, as Ivax's hypothetical asserts. Although the agency has not decided that issue and does not do so here, FDA observes that the regulation's litigation requirement is notably in the present tense, *i.e.*, "a patent that *is* the subject of a lawsuit," and it is possible that termination of a lawsuit would remove the barrier to delisting. And, even if Ivax were correct that FDA would maintain the patent in the Orange Book as a result of a lawsuit that was dismissed, the result (preserving the eligibility of the ANDA who was sued) would not necessarily be "absurd," as that ANDA both exposed itself to the risk of litigation and was forced to defend itself in litigation. In any event, the fact that FDA's decision could result in unforeseen consequences in a hypothetical situation not at issue here does not undermine the deference due to that decision, especially in view of the very complex statutory and regulatory Hatch-Waxman regime.

E. The MMA Does Not Inform FDA's Construction of the Applicable Statute

Finally, Ranbaxy argues that the MMA "confirms that a delisted patent does not nullify 180-day exclusivity," citing 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(CC) (2005). That provision provides that an ANDA applicant will forfeit its exclusivity if a patent is withdrawn if it fails to commercially market the drug within 75 days of patent withdrawal. *Id.* Congress added the

forfeiture provisions as an entirely new subsection, and as part of its complete restructuring of the exclusivity provisions in the MMA. 149 Cong. Rec. S15884 (Nov. 25, 2003). Nothing in the cited forfeiture provision confirms that, in the applicable statute, Congress intended that a first applicant with a paragraph IV certification should be entitled to exclusivity when a patent is withdrawn, even in the absence of patent litigation. AR Tab 23 at 5 n.7. The subsequent legislation cannot be used to “confirm” Ranbaxy’s preferred interpretation of the statute at issue when it is clear that Congress meant to entirely restructure that statute. *See United States v. Wilson*, 503 U.S. 329, 336 (1992) (“We have no difficulty with the general presumption that Congress contemplates a change whenever it amends a statute.”); *Fowler v. Unified School Dist.*, 128 F.3d 1431, 1436 (10th Cir. 1997) (“[A]bsent a clear indication that Congress intended the Amendments merely to clarify the proper interpretation of its prior Act, we consider the Amendments to implement a change in the Act.”).

CONCLUSION

For the foregoing reasons, federal defendants' motion for summary judgment should be granted, and plaintiffs' motions for summary judgment should be denied.

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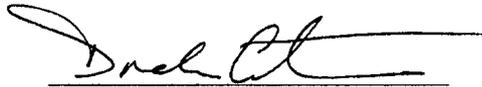
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