UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

Apotex, Inc., **Plaintiff.** **v.** **FOOD AND DRUG ADMINISTRATION, et al.,** **Defendants,** **and**	**Civil Action No. 06-0627 (JDB)**
TEVA PHARMACEUTICALS USA, INC., **Intervenor-Defendant,** **and** **RANBAXY PHARMACEUTICALS, INC.,** **Intervenor-Defendant.**	

MEMORANDUM OPINION

Plaintiff Apotex, Inc. ("Apotex") seeks a temporary restraining order and preliminary injunction to prevent defendants Food and Drug Administration ("FDA"), Michael O. Leavitt in his capacity as the Secretary of Health and Human Services, and Andrew Von Eschenbach in his capacity as the Acting Commissioner of Food and Drugs, from granting final approval under the Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman Act"), 21 U.S.C. § 355, to intervenor-defendants Teva Pharmaceuticals USA, Inc. ("Teva") and Ranbaxy Pharmaceuticals, Inc. ("Ranbaxy"), based upon their Abbreviated New Drug Applications ("ANDA") for pravastatin sodium ("pravastatin"), the generic version of the branded drug

Pravachol®. Although this action was actually filed prematurely in advance of the FDA's most recent decision, it is now effectively a challenge to the April 11, 2006 decision by the FDA issued to Apotex. For the reasons that follow, the Court will deny plaintiff's motion.

BACKGROUND

I. Prior Proceedings

This action stems from an earlier case ("Teva III") in which Teva sued defendants pursuant to the Administrative Procedure Act, 5 U.S.C. § 706(2)(A) ("APA"), and the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 et seq. ("FDCA"), challenging the determination that the dismissal of a previous action in the United States District Court for the Southern District of New York, Apotex Inc. v. Bristol-Myers Squibb Co., No. 1:04-CV-2922 (S.D.N.Y.) ("Apotex-BMS litigation"), had triggered the 180-day exclusive marketing period to which Teva might otherwise be entitled under the provisions of the Hatch-Waxman Act. See Teva Pharms. USA, Inc. v. FDA, 398 F. Supp. 2d 176, 179 (D.D.C. 2005) ("Teva III Dist. Ct. Mem. Op.").[1] Apotex, the plaintiff here, was an intervenor-defendant in Teva III, and vigorously opposed Teva's effort to prevent the FDA from granting final approval to any other ANDA for

[1]The Hatch-Waxman Act provides a 180-day period of generic exclusivity to the first company that files an ANDA containing a "paragraph IV certification" for a patent connected to the branded version of the drug. See 21 U.S.C. § 355(j)(5)(B)(iv). A paragraph IV certification alleges that the relevant patent is either invalid or will not be infringed by the proposed ANDA product. See 21 U.S.C. § 355(j)(2)(A)(vii)(IV). The exclusivity period begins on the earlier of two dates: (1) "the date on which the Secretary receives notice from the applicant under the previous application of the first commercial marketing of the drug under the previous application"; or (2) "the date of a decision of a court . . . holding the patent which is the subject of the certification to be invalid or not infringed." See § 355(j)(5)(B)(iv)(II). At issue here is the latter triggering-even, referred to as the "court-decision trigger." For a full discussion of the intricate statutory landscape established by the Hatch-Waxman Act, see this Court's earlier opinion and the FDA's April 11, 2006 administrative decision.

generic pravastatin in the relevant dosage form and strength. See generally 398 F. Supp. 2d 176. The complex factual background giving rise to Teva III -- including the underlying Apotex-BMS litigation -- is discussed in detail in this Court's October 21, 2005 decision and FDA's April 11, 2006 administrative decision on remand, and will not be repeated in full here.

At the request of the parties, the motion for preliminary injunction in Teva III was consolidated with a trial on the merits pursuant to Fed. R. Civ. P. 65(a)(2), and the Court treated the proceeding as "akin [to a motion for] summary judgment." Id. at 181 & n.1. On October 21, 2005, this Court ruled that because the Apotex-BMS litigation was dismissed for lack of subject matter jurisdiction at the request of the plaintiff in that case (Apotex), it constituted a private settlement agreement between the parties and, accordingly, was not "a decision of a court . . . holding the [relevant] patent . . . to be invalid or not infringed," as required by the plain language of the Hatch-Waxman Act and applicable FDA regulations, and, in this Court's view at the time, as contemplated by two prior decisions of the D.C. Circuit: (1) Teva Pharms. USA, Inc. v. FDA, 182 F.3d 1003 (D.C. Cir. 1999) ("Teva I"), and (2) Teva Pharms. USA, Inc. v. FDA, 2000 WL 1838303 (D.C. Cir. 2000) (unpublished disposition) ("Teva II"). See 398 F. Supp. 2d at 187-192.[2] Hence, the Court concluded that FDA's decision was "arbitrary, capricious, or otherwise not in accordance with law" under the APA and granted Teva's motion for a preliminary injunction. Id. at 179, 192. Apotex and the FDA then appealed this Court's ruling to the D.C. Circuit. Apotex moved this Court for a stay pending appellate review in the D.C. Circuit, but the motion was denied because, based upon the circumstances at the time, Apotex faced no

[2]The factual background for, and decisions in, Teva I and Teva II are detailed in this Court's October 21, 2006 decision and the FDA's April 11, 2006 administrative decision.

impending likelihood of irreparable injury and the balance of hardships did not tip decidedly in its favor. See Teva Pharms. USA, Inc. v. FDA, 404 F. Supp. 2d 243, 244-46 (D.D.C. 2005).

Before the D.C. Circuit, the FDA stated that its administrative decision was based on the view that Teva I and Teva II constituted substantive rules of law establishing that dismissals of declaratory judgment actions for lack of subject matter jurisdiction are court decisions within the language of the Hatch-Waxman Act. See Teva Pharms. USA, Inc. v. FDA, 441 F.3d 1, 5 & n.5 (D.C. Cir. 2006) ("Teva III"). The FDA represented that if it had understood that Teva I and Teva II stood only for the proposition that FDA had not sufficiently articulated the rationale in support of its administrative conclusions, then it would have reached the same conclusion as this Court reached in Teva III Dist. Ct. Mem. Op. See Pl.'s Exh. D. FDA's counsel all but promised that, on remand, FDA would adopt a "textual approach" to the statute, pursuant to which it would find that the Apotex-BMS dismissal did not qualify as a "decision of a court" and, accordingly, did not trigger the 180-day exclusivity period.

On March 16, 2006, the D.C. Circuit held that FDA had in fact operated under an erroneous interpretation of law -- namely, that Teva I and Teva II set forth substantive rules of law regarding what constitutes a "decision of a court" within the meaning of the Hatch-Waxman Act. See Teva III, 441 F.3d at 5. According to the panel, Teva I and Teva II did nothing more than reaffirm and apply the long-standing axiom of administrative law that agency action must be supported by thorough, reasoned decisionmaking. See id. Because "'[a]n order may not stand if the agency has misconceived the law,'" id. (citing SEC v. Chenery Corp., 318 U.S. 80, 94 (1943)), the panel vacated the Teva III Dist. Ct. Mem. Op. and remanded the case to this Court, with instructions to vacate FDA's agency decision and then remand to the FDA so that it could fulfill

its statutory mandate to "'bring its experience and expertise to bear in light of competing interests at stake' and make a reasonable policy choice." Id. at 5 (quoting PDK Labs., Inc. v. DEA, 362 F.3d 786, 797-98 (D.C. Cir. 2004)). The panel clearly expressed a desire for bona fide agency action that would explicitly articulate a specific rationale -- oral representations during arguments before courts could not suffice as a substitute. Id. (stating that "[t]he FDA's 'stated rationale for its decision is erroneous' and 'we cannot sustain its action on some other basis [it] did not mention,'" and describing the agency's statutory mandate and noting that it had not yet been fulfilled) (citing PDK Labs., 362 F.3d at 798). The D.C. Circuit also recalled that FDA had attempted to adopt a textual approach in Teva I, and hinted that, on remand, the agency would be expected to address the concerns expressed in Teva I regarding the reasonableness of such an approach. Id. at 5 n.5.

II. FDA's Decision on Remand

On remand, the FDA reconsidered its earlier decision in light of Teva III's pronouncement that Teva I and Teva II were purely procedural in nature. In a fifteen-page, single-spaced decision letter issued on April 11, 2006, the agency adopted a textual approach to the statute, under which, based upon the plain language of the Hatch-Waxman Act, only a decision of a court holding on the merits that a particular patent is invalid, not infringed, or unenforceable would suffice to trigger the 180-day exclusivity period. See Pl.'s Exh. A at 2, 6. The agency began by analyzing the meaning of the word "holding," referring to the definition adopted by the Seventh Edition of Black's Law Dictionary: "[a] court's determination of a matter of law pivotal to its decision; a principle drawn from such a decision." Id. at 6-7 (citing BLACK'S LAW DICTIONARY at 737 (7th ed. 1999)). Based on this definition, the FDA concluded that, to be sufficient, the "holding must be evidenced by a statement on the face of the court's decision demonstrating that the court has

made a determination on the merits [as to the] invalidity, noninfringement, or unenforceability [of the relevant patent]." Id. at 7. Under this approach, the determination must address one or more of the actual "elements or grounds of a claim or defense [of patent invalidity, noninfringement or unenforceability]; the substantive considerations to be taken into account in [making that] deci[sion], as opposed to extraneous or technical points, esp[ecially] of procedure." Id. (citing BLACK'S LAW DICTIONARY, supra, at 1003).

FDA then assessed the first of three concerns expressed by the D.C. Circuit in Teva I and referred to in footnote five of Teva III -- whether a textual interpretation of the statute (as contrasted with the estoppel-based interpretation that Apotex advocates)[3] would lead to absurd results that undermine the purpose of the statute. Id. Recognizing that, in light of Teva III, the preference for an estoppel-based approach allegedly embodied in Teva I no longer constrains its decisionmaking process, FDA concluded that a textual approach is preferable because it gives substantive effect to the words chosen by Congress. Id. at 8. The estoppel-based approach would, in FDA's view, "render[] the terms 'decision,' 'holding,' and 'invalid or not infringed' superfluous, in contravention of accepted canons of statutory construction." Id. (citing Bailey v. United States, 516 U.S. 137, 146 (1995)). The agency further expressed a concern that an estoppel-based approach would impose a large administrative burden by requiring it to resolve complex factual issues under the law in the absence of meaningful guidance from the courts. Id. at 8. FDA reasoned that the determination of whether one party is estopped from suing another is dependent upon a multifaceted composite of factual considerations and the legal consequences that flow

[3]The many contours, drawbacks, and advantages of the estoppel approach are detailed in this Court's earlier decision.

therefrom, which it is admittedly "ill-equipped" to evaluate. Id. at 8, 9. Based upon its previous experience, FDA characterized the estoppel-based approach as arduous and impractical, often leading to uncertain and inconsistent results, and, as illustrated by the instant case, "inexorably spawn[ing]" perpetual litigation that undermines the statute's purpose of providing lower-cost generic alternatives to the public in an expedient fashion. Id. at 9. FDA concluded that following a textual interpretation of the statute, on the other hand, greatly improves the likelihood of industry certainty by facilitating consistency, dispenses with the inherent subjectivity that plagues an estoppel-focused analysis, and reduces the administrative burden by enabling the agency to look at the four corners of a court order to determine whether the exclusivity clock has been triggered. Id. at 9.

Addressing the second concern raised in Teva I, FDA considered whether a textual approach would be consistent with its regulation, 21 C.F.R. § 314.107(c)(1), recognizing unenforceability as a "separate basis for a court decision trigger." See id. at 9. The plain language of the regulation, FDA concluded, parallels the terms of the statute: the exclusivity clock is triggered as of "[t]he date of a decision of a court holding the relevant patent invalid, unenforceable, or not infringed." § 314.107(c)(1); Pl.'s Exh. A at 10. Essentially, the only difference between the language of the regulation and that of the statute is that the former expressly provides for patent challenges based upon alleged unenforceability, whereas the latter does not. Pl.'s Exh. A at 10. Thus, "[e]ven if a patentee's representations have the apparent effect of rendering a patent unenforceable vis-a-vis a particular ANDA applicant, in the agency's view, a holding of unenforceability must result from a court's consideration of that issue on the merits, rather than FDA's evaluation of the effect of a patentee's statement." Id. at 10 (emphasis in

original). From FDA's perspective, then, an estoppel-based approach "turns the statutory language on its head, by compelling FDA -- rather than a court" to "make a 'decision' and a 'holding' of unenforceability." Id.

Turning to the final issue raised by Teva I, FDA discussed two perceived inconsistencies in its prior decisionmaking, specifically: (1) how the conclusion that it reached in Teva I could be justified under the "case-by-case" approach allegedly adopted by the agency in its earlier guidance document; and (2) how it could have reached a different conclusion with respect to the court action at issue in Teva I and the court action at issue in another case, Granutec, Inc. v. Shalala, 139 F.3d 889, 1998 WL 153410 (4th Cir. Apr. 3, 1998) (unpublished disposition). With respect to the guidance document, FDA pointed to "dramatic[] change[s]" in the regulatory landscape that have occurred since it considered the dismissal at issue in Teva I. Pl.'s Exh. A at 10. The Teva I opinion "suggested that [the agency] had failed to adopt any particular interpretation of the statute . . . [or] 'abide[] by the commitments it made in the [guidance document]." Id. at 10-11. Subsequently, FDA had proposed a new approach, under which exclusivity would be forfeited if the clock had not been triggered within a particular amount of time. Id. at 11. The proposed rule was withdrawn in 2002 "in part due to [FDA's] belief that the Teva I 'holding was directly at odds with the [triggering-period] approach.'" Id. Thereafter, Congress significantly changed the 180-day exclusivity provision through the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"), and FDA thought it unwise to waste precious resources drafting a regulation that would become less important in light of the MMA and perhaps be

"vulnerable to challenge if it diverged from Teva I." Id.[4] The agency concluded its analysis by stating that it "is [now] independently interpreting the statute in accordance with the direction of the Teva III court" and adopting an interpretation that it considers "fully consistent with the statutory language and the extensive regulatory and judicial history concerning the agency's treatment of the court decision trigger issue." Id.

On the second consistency point, the dismissals at issue in Teva I and Granutec were both predicated on statements made by the manufacturers of the branded drugs, which functioned to estop those companies from being able to file suit for patent infringement in the future. FDA reached different conclusions in those cases, determining that the dismissal underlying Teva I did not trigger the exclusivity period but the one in Granutec did. According to FDA, its conclusions are not irreconcilable, and they are consistent with the textually-based approach that the agency now espouses. Id. at 12. The Granutec dismissal was a court-issued memorandum decision that granted a motion for partial summary judgment on the basis that the relevant patent was not infringed. Id. at 12 (citing Glaxo, Inc. v. Boehringer Ingelheim Corp., No. 95-CV-01342 (D. Conn. Oct. 7, 1996)). A grant of partial summary judgment is, in FDA's view, a holding on the merits. Id. In contrast, the dismissal underlying Teva I was purely jurisdictional in nature, because it was based upon a determination that, in light of the statements made by the manufacturer of the branded drug, the non-movant (Teva) lacked a reasonable apprehension that it would be sued for infringement of the relevant patent. Id. (citing Teva I, 182 F.3d at 1004). In FDA's words, "once the court recognized that it lacked jurisdiction, it appropriately refused to

[4]The pre-MMA version of the statute applies to this case, and all statutory citations to the Hatch-Waxman Act and the FDCA are to the pre-amendment version of the statute.

decide the merits of the case and granted . . . the motion to dismiss." Id. Hence, FDA does not consider the Teva I dismissal to be a "decision of a court" under a textual interpretation of the statute, but does consider the Granutec dismissal based on a grant of partial summary judgment to be one. Id.

Next, FDA explained how the textual approach was more consistent with congressional intent. To begin with, although the textual approach could theoretically slow the entry of lower-cost generic drugs into the marketplace by more jealously safeguarding exclusivity entitlements, FDA noted that it also facilitates patent challenges "overall." Id. at 13. The estoppel approach, on the other hand, interprets the court-decision trigger more broadly, which may at first blush appear to further the underlying purpose of the statute by making generic products available to consumers at an expedited pace, id. at 13, but actually diminishes the value of the exclusivity entitlement and, accordingly, deters pharmaceutical companies from challenging patents, id. at 12, 13. By creating the exclusivity entitlement, the FDA observed, Congress manifested a belief that some incentive in addition to the prospect of earlier generic market entry was required in order to encourage pharmaceutical companies to undertake the risks and burdens of pursuing patent challenges. Id. at 12, 13. A narrower interpretation of the court-decision trigger (as provided by the textual approach) makes it harder to trigger the exclusivity periods, thereby preserving their value to pharmaceutical companies and, in FDA's view, leaving in place the incentive that Congress saw fit to create. Id. at 13.

Put another way, FDA recognized that each approach furthers certain policy objectives while undercutting others. Id. The agency pointed to the instant litigation involving Apotex and Teva as an example of the creative legal maneuvering in which pharmaceutical companies have

repeatedly engaged, flip-flopping between diametrically opposed positions in various litigation actions based upon their financial interests. Id. at 13-14. This behavior, FDA concluded, will occur "whenever the potential financial rewards are sufficiently high," and "a standard less objective and clear than the 'holding-on-the-merits' standard" would increase the opportunities for such disputes. Id. at 14. Because such contests are lengthy and costly, they often delay the entry of generic drugs into the market. Id. "It is in the public's interest, as well as FDA's own interest," FDA continued, "to have exclusivity triggering determinations governed by a legal regime that is clear and easily administered." Id. at 14. In its view, the estoppel approach "offers no guarantee of more rapid generic drug approvals, only a high likelihood of delay due to litigation, and the prospect that this area of law will remain unnecessarily unstable, thus undermining marketplace certainty and interfering with business planning and investment." Id.

Finally, FDA addressed the application of the textual approach to the facts of Teva III, and determined that the underlying Apotex-BMS dismissal is not a "decision of a court" because it contains no "'holding' that the subject patents are invalid, not infringed or unenforceable" and the face of the dismissal is devoid of any court determination touching on any of the patents at issue. Id. Like the dismissal at issue in Teva I, the Apotex-BMS dismissal is (by its own terms) wholly jurisdictional, FDA concluded, and does not constitute a "holding on the merits." See id. On this rationale, FDA determined that the "180-day exclusivity for pravastatin was not triggered by the [Apotex-BMS] dismissal" and proclaimed that "[a]bsent a material change in circumstances, FDA intends to approve only those ANDAs eligible for 180-day exclusivity for pravastatin when the [relevant] patent . . . expires on April 20, 2006. Approvals of all other pravastatin ANDAs will be delayed for 180 days after exclusivity has been triggered." Id.

III. The Current Proceeding

Taking note of the proverbial "writing on the wall," Apotex initially filed the complaint in this action and a motion for a temporary restraining order on April 5, 2006, in advance of FDA's remand decision. See generally Compl.; Pl.'s Mot. T.R.O. Teva was added as an intervenor-defendant on April 10, 2006. Apotex Inc. v. FDA, Civil Action No. 06-0627, dkt. no. 10 (D.D.C. Apr. 10, 2006) (Order). In its April 5th motion, Apotex argued that the representations of government counsel at the oral argument on appeal -- and in FDA's appellate briefs -- constituted "final agency action" on the basis of which it was entitled to pursue relief in this Court under 5 U.S.C. § 705. See Pl.'s Mot. T.R.O. at 12-13; see also Compl. at 13 ¶ 53. Unpersuaded -- and wary of potential jurisdictional complications -- this Court directed Apotex to re-file its motion following the release of the impending agency decision. On April 11, 2006, FDA issued its remand decision. See generally Pl.'s Exh. A. Three days later, on April 14, 2006, Apotex re-filed its motion, this time choosing also to pursue a preliminary injunction immediately. See Pl.'s Mot. T.R.O. & Prelim. Inj. Ranbaxy filed a motion to intervene on April 12, 2006, arguing that it was the first to file an ANDA containing a paragraph IV certification for one particular dosage of Pravachol® -- hence, Ranbaxy contended that it was entitled to the contested exclusivity period. See Ranbaxy Mot. Interv. as Defs. at 1. The Court granted Ranbaxy's motion the same day. Apotex Inc. v. FDA, Civil Action No. 06-0627, dkt. no. 16 (D.D.C. Apr. 12, 2006) (Order). The FDA and intervenor-defendants responded to Apotex's motion on April 18, 2006, and all parties have agreed that this matter should be addressed as a preliminary injunction request. Armed with the final agency decision, plaintiff's motion, and the memoranda of all parties, the Court will now address the merits of plaintiff's contentions.

LEGAL STANDARDS

When considering a motion for preliminary injunction or temporary restraining order, a court must weigh four factors: (1) the prospective irreparable injury to the movant in the event that the requested relief is denied; (2) the possibility of harm to other parties in the event that the relief is granted; (3) the likelihood that the movant will prevail on the merits; and (4) the public interest. See, e.g., Mova Pharms. Corp. v. Shalala, 140 F.3d 1060, 1066 (D.C. Cir. 1998).[5] "These factors interrelate on a sliding scale and must be balanced against each other," Davenport v. Int'l Bd. of Teamsters AFL-CIO, 166 F.3d 356, 360-61 (D.C. Cir. 1999), such that a particularly strong showing with respect to one may compensate for a weaker showing with respect to another, CityFed Fin. Corp. v. OTS, 58 F.3d 738, 747 (D.C. Cir. 1995). Specifically, the "likelihood of success on the merits" inquiry is inversely proportional to the "degree of irreparable harm" inquiry -- that is, a court may grant the sought-after relief when the movant is very likely to succeed on the merits, in the face of a lesser degree of potential irreparable injury. Cuomo v. U.S. Nuclear Reg. Comm'n, 772 F.2d 972, 974 (D.C. Cir. 1985).

Whether plaintiff is likely to prevail on the merits is, under the circumstances of this case, informed by the deferential standards of review under the APA. Pursuant to the relevant provisions of the APA, a court may vacate FDA's decision if it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law," 5 U.S.C. § 706(2)(A), or in excess of statutory authority, 5 U.S.C. § 706(2)(C). Agency actions are entitled to much deference, and the

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[5]Plaintiff has also moved for a stay pending appeal in the event that it does not prevail before this Court. That request is analyzed under the same four-pronged legal framework that applies to the motion for temporary restraining order and preliminary injunction. See Teva Pharms. USA, 404 F. Supp. 2d at 245 (citing Washington Area Metro. Auth. Comm'n v. Holiday Tours, 559 F.2d 841, 843-44 (D.C. Cir. 1977)).

standard of review is narrow. See Citizens to Preserve Overton Park, Inc. v. Volpe, 401 U.S. 402, 416 (1971). The reviewing court is not permitted to substitute its judgment for that of the agency. See id. That is, it is not enough for the agency decision to be incorrect -- as long as the agency decision has some rational basis, the court is bound to uphold it. See id. The court may only review the agency action to determine "whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment." Id.

The familiar framework of Chevron USA, Inc. v. Natural Resources Defense Council, 467 U.S. 837 (1984), applies here. At step one of Chevron, the Court first must inquire whether the statute "speaks clearly 'to the precise question at issue.'" Chevron, 467 U.S. at 842-43. If so, then the analysis proceeds no further -- the Court must "give effect to the unambiguously expressed intent of Congress." Id.; see also Robinson v. Shell Oil Co., 519 U.S. 337, 340 (1997) (if text is plain and unambiguous, then the analysis ends there). If, however, the statute is not clear in relation to the specific issue before the Court, then under Chevron step two, the Court must consider whether FDA's interpretation is supported by a "permissible construction" of the statute. Chevron, 467 U.S. at 843. But the Court will only reach the second inquiry under Chevron if it determines that the statute is "silent or ambiguous with respect to the specific issue" presented. Id. The "[e]xistence of ambiguity is not enough per se to warrant deference to the agency's interpretation. The ambiguity must be such as to make it appear that Congress either explicitly or implicitly delegated authority to cure that ambiguity." Am. Bar Ass'n v. FTC, 430 F.3d 457, 469 (D.C. Cir. 2005); see also Michigan v. EPA, 268 F.3d 1075, 1082 (D.C. Cir. 2001). Hence, under the Chevron step two deferential analysis, if the statute is "ambiguous in such a way as to make the [FDA's] decision worthy of deference," then this Court should "uphold the [FDA's]

interpretation of the ambiguous statute as long as that interpretation is 'permissible,' that is, if it is 'reasonable.'" Am. Bar Ass'n, 430 F.3d at 468 (quoting Chevron, 467 U.S. at 843, 845).

When the agency decision is based upon its interpretation of the statute that it is charged with administering, a court's deference to the agency is at its apex. See United States v. Mead, 533 U.S. 218, 226-27 (2001). Because FDA is interpreting its own statute here (the FDCA), the appropriate degree of deference will be determined based upon the circumstances surrounding that interpretation. See id. at 227-31. An agency will receive utmost deference if "it appears that Congress delegated authority to the agency generally to make rules carrying the force of law, and that the agency interpretation claiming deference was promulgated in the exercise of that authority." Mead, 533 U.S. at 226-27. The FDCA, pursuant to 21 U.S.C. § 371(a), grants explicit authority to FDA "to promulgate regulations for the efficient enforcement of" the statute. Similarly, the Hatch-Waxman Amendments permit FDA to promulgate regulations that are "necessary for the administration" of those amendments. See 21 U.S.C. § 355 note, Pub. L. No. 98-417, 105, 98 Stat. 1585, 1597 (1984).

As the D.C. Circuit noted in Teva III, it is the responsibility of FDA "to 'bring its experience and expertise to bear in light of competing interests at stake' and make a reasonable policy choice." 441 F.3d at 5 (quoting PDK Labs., Inc., 362 F.3d at 797-98). Frequently, the D.C. Circuit has given Chevron deference to FDA's interpretation of the FDCA and the agency's implementing regulations. See Novartis Pharms. Corp. v. Leavitt, 435 F.3d 344, 349 (D.C. Cir. 2006) (stating that "FDA interpretations of the FDCA receive deference, as do its interpretations of its own regulations unless plainly erroneous or inconsistent with the regulations"); 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).[6] It makes no difference, moreover, that an administrative determination is embodied in a decision letter, as here, rather than in a rulemaking or formal adjudication; Chevron deference still applies. See Mylan, 389 F.3d at 1279-80.

ANALYSIS

I. Whether Plaintiff is Likely to Prevail on the Merits of its Argument that the Apotex-BMS Dismissal Triggered the 180-Day Exclusivity Period for Pravastatin

To obtain emergency injunctive relief, plaintiff need not prevail on each factor of the four-pronged calculus. See Teva Pharms., 404 F. Supp. 2d at 245 (citing Holiday Tours, Inc., 559 F.2d at 843-44). Nevertheless, the case law in this Circuit indicates that the "likelihood of success on the merits" inquiry is the most salient consideration, because a plaintiff's failure to prevail on that prong necessitates an unusually strong showing as to the remaining three factors in order "to turn the tide in [its] favor." Davenport, 166 F.3d at 366. Hence, the Court will tackle this step in the analysis first. As noted above, whether plaintiff is likely to succeed on the merits is an assessment that is governed by the Chevron framework.

A. Chevron Step One

At step one of Chevron, the Court must first consider whether the relevant statutory provision, § 355(j)(5)(B)(iv)(II), is silent or ambiguous with respect to the issue presented. The provision appears, at first blush, to use language that is sufficiently uncomplicated to lend itself to but one interpretation of the qualifying event: a "decision of a court . . . holding the patent . . .

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[6]The FDA is entitled to the same "substantial deference" whether this Court is viewed as assessing the agency's interpretation of its statute or its implementing regulation. See Thomas Jefferson Univ. v. Shalala, 512 U.S. 504, 512 (1994); U.S. Air Tour Ass'n v. FAA, 298 F.3d 997, 1005 (D.C. Cir. 2002).

invalid or not infringed." § 355(j)(5)(B)(iv)(II). Any superficial simplicity, however, is deceptive. The Court is well aware of the confusion that this language has caused. One need not look very far to discover that there is considerable room for debate regarding what constitutes a "decision" or "holding." See, e.g., Teva III, 441 F.3d at 3, 4; Teva I, 182 F.2d at 1007-08. It seems, then, that careful, inventive lawyering has rendered uncertain what might otherwise have appeared straightforward and unambiguous. See Teva I, 182 F.3d at 1007-08 (noting that a "'decision' can take several forms" and the word "'holding' . . . is also susceptible to interpretation"). To be sure, the language of the statute does not foreclose the textual or holding-on-the-merits approach adopted by the FDA; nor does it require the estoppel-based interpretation that plaintiff so vehemently urges. See id. at 1012 (noting that the estoppel approach is not the only permissible construction of the court-decision trigger). But the latent ambiguity inherent in the terms "decision" and "holding" is sufficient to render the provision ambiguous. In fact, the FDA itself has previously acknowledged that the holding-on-the-merits approach is arguably more narrow than the language of § 355(j)(5)(B)(iv)(II) supports. See id. at 1011.

In this Court's view, the holding-on-the-merits approach arises more naturally from the statutory language than does the estoppel approach, and, accordingly, is the better interpretation. But that is not the proper inquiry. At Chevron step one, the mere possibility of more than one meaning, in a given context, for a statutory word or phrase is sufficient to warrant further inquiry into the agency's deliberative process. Under such circumstances, "'the text and reasonable inferences from it [do not] give a clear answer against'" either interpretation. See Cal. Indep. Sys. Operator Corp., 372 F.3d at 402 (quoting Brown v. Gardner, 513 U.S. 115, 120 (1994)). "In determining whether a statutory provision speaks directly to the question before [it, a court must]

consider it in context." See Holly Sugar Corp. v. Johanns, 437 F.3d 1210, 1213 (D.C. Cir. 2006) ((citing FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 132-33 (2000)). Here, it simply cannot be said that the FDA's approach is the only reasonable way to interpret the statute -- the statute never specifies that the "decision" and "holding" rendered by the court must be "on the merits" of the dispute. Hence, the provision is ambiguous, and the Court will proceed to step two of the Chevron analysis. Certainly, that assessment is consistent with the thrust of the D.C. Circuit's observations in Teva I and Teva III.

B. Chevron Step Two

1. Whether the FDA's Approach is a Permissible Construction of the Statute

At step two of Chevron, the threshold inquiry is whether the holding-on-the-merits approach may reasonably be divined from the text of the statute. See Chevron, 467 U.S. at 843. This Court readily concludes that it may: by its plain terms, the language of the provision requires a "decision of a court . . . holding the patent . . . invalid or not infringed," and makes no mention of notions of estoppel. A natural, and therefore permissible, construction of this language is that it requires a judicial decision addressing the merits of the patent infringement or invalidity action. Indeed, in so concluding, FDA has correctly commenced its analysis with the plain language of the statutory provision. See Barnhart v. Sigmon Coal Co., 534 U.S. 438, 450 (2002); Group Life & Health Ins. Co. v. Royal Drug Co., 440 U.S. 205, 210 (1979).

2. Whether the FDA's Approach is the Product of Reasoned Agency Decisionmaking

The Court must also consider whether the approach taken by the FDA is supported by reasoned agency decisionmaking. See Teva II, 2000 WL 1838303, at *2. Apotex argues that the

FDA's April 11, 2006 decision is identical to the views FDA espoused in Teva I and Teva II. Because the holding-on-the-merits approach was, in Apotex's view, rejected by the D.C. Circuit in Teva I and Teva II, and rejected by Judge Kollar-Kotelly of this Court on remand, it allegedly follows that it should likewise be deemed insufficient here. But Teva I and Teva II must be construed in light of Teva III, which states clearly that the D.C. Circuit neither invalidated the holding-on-the-merits interpretation that FDA now advocates nor established a substantive rule of law regarding the proper construction of the court-decision trigger. See Teva III, 441 F.3d at 3-4. Teva I and Teva II were purely procedural in nature, and they held only that "the FDA's conclusion [was] 'arbitrary and capricious inasmuch as [it] [took] an inconsistent position in another case and failed to explain adequately the inconsistency.'" Id. at 4 (citing Teva I, 182 F.3d at 1004) (emphasis added).[7] Hence, plaintiff's suggestion that the holding-on-the-merits approach itself is arbitrary and capricious is misleading -- it was the agency's failure to justify that approach under the law that was deemed arbitrary and capricious, not the approach itself. Because the FDA had suddenly reversed course and failed to follow the case-by-case method that it purportedly adopted in its earlier guidance document "without justification" and based on nothing more than a

[7]Apotex also relies on certain language in Teva I that it characterizes as a categorical recognition by the D.C. Circuit that dismissals like the Apotex-BMS dismissal are qualifying triggering events. See Pl.'s Mot. T.R.O. &. Prelim. Inj. at 17; see also Teva I, 182 F.3d at 1009 (stating that "the [Teva I] dismissal appears to meet the requirements of a triggering 'court decision' because th[e dismissing] court had to make a predicate finding with respect to whether [the manufacturer of the branded drug] would ever sue . . . for infringement in order to conclude that there was no case or controversy between the parties"). The problem with this argument is that, in the wake of Teva III, the language has little continuing force: its function was to identify weaknesses in the agency's logic that remained unaddressed as a result of the failure to engage in considered analysis. The language cannot be considered a determinative statement of law regarding the types of dismissals that would satisfy the statute; rather, it must be understood as an invitation for FDA to grapple with certain issues on remand.

desire for administrative ease, see Teva I, 182 F.3d at 1011, the FDA's ultimate conclusion could not be sustained as the product of a reasoned agency decisionmaking process, see Teva II, 2000 WL 1838303 at *2. Thus, in Teva I the FDA failed even to establish that it was entitled to deference under Chevron -- it "offered no particular interpretation of [the court-decision trigger] provision, relying instead on its authority to interpret the provision narrowly until it promulgate[d] a new rule." 182 F.2d at 1007.

The outcome in Teva I and Teva II rested on the FDA's abdication of its responsibility "to bring its experience and expertise to bear" upon the court-decision trigger interpretation. Teva III, 441 F.3d at 5 (quoting PDK Labs, Inc., 362 F.3d at 797-98). This Court is not convinced, however, that the FDA has similarly "failed to adequately explain" its conclusion here. The FDA's April 11, 2006 remand decision is not, as Apotex claims, "indistinguishable" from the agency's actions in Teva I and Teva II. This time, the FDA has not relied solely on administrative concerns. Rather, the record reveals that the FDA "brought its experience and expertise to bear," utilizing its resources and fulfilling its statutory mandate by carefully considering the statute's text, see Pl.'s Exh. A at 7, balancing the advantages and drawbacks of each approach, considering the competing policy interests that underlie the statute, examining the possible implications of congressional intent, and ultimately exercising its delegated discretion to choose from among the available options, see id. at 8-10, 12-14. As the FDA has acknowledged, neither the holding-on-the-merits approach nor the estoppel approach is without complication or idiosyncracy. Both approaches may, in theory, function to undercut legislative policy and congressional intent in some regard. However, the holding-on-the-merits approach offers benefits that the estoppel approach does not. Primarily, it preserves the incentive for companies to undertake the very

substantial risks and costs associated with patent challenges; it is congruent with the intent of Congress as expressed through the plain language of the statute; it facilitates certainty and consistency on an industry-wide basis; it offers heightened ease of administration;[8] and it reduces opportunities for lengthy, costly, and repetitive litigation. By facilitating patent challenges and reducing complex litigation, the holding-on-the-merits approach actually furthers the very policy that Apotex claims it undermines -- the goal of getting more low-cost generic products into the hands of consumers as quickly as possible. FDA's April 11, 2006 decision therefore constitutes a much more thorough, considered, and comprehensive analysis than the agency undertook in Teva I or Teva II. In any event, the choice between competing policy concerns is for the agency, not this Court, to make, and here FDA has properly adopted an interpretation that hews closely to the terms chosen by Congress to express its legislative judgment. See Teva Pharms. Indus., Ltd. v. Crawford, 410 F.3d 51, 54 (D.C. Cir. 2005).

3. Whether the FDA's Approach is Reasonable in Practice

The reasonableness of the agency's approach in practice plays an important part in the Chevron step two analysis. See Associated Gas Distribs. v. FERC, 899 F.2d 1250, 1261-63 (D.C. Cir. 1990); cf. Teva I, 182 F.3d at 1011 (stating that the FDA must interpret the court-decision

[8]It is perfectly appropriate for the agency to consider administrative convenience as one component of the overall mix of factors when developing an interpretive approach. See Teva II, 2000 WL 1838303, at *1 (quoting Teva Pharms., USA, 1999 WL 1042743, at *5); see also Clinton Mem'l Hosp. v. Shalala, 10 F.3d 854, 860 (D.C. Cir. 1993). The problem in Teva I and Teva II was that the agency attempted to insulate its otherwise unexplained action solely on that basis. See Teva II, 2000 WL 1838303, at *2 (quoting Teva Pharms., USA, 1999 WL 1042743, at *5). Here, in contrast, the agency has articulated many reasons for its decision to abandon the case-by-case method, reject the estoppel approach, and adopt the holding-on-the-merits approach. Under such circumstances, the Court "ha[s] no business second-guessing the agency." Teva II, 2000 WL 1838303, at *4 (Edwards, J., concurring in part and dissenting in part).

trigger clause of Hatch-Waxman in a manner that "avoid[s] absurd results and further[s] the statute's purpose"). An approach that is practically infeasible may thus prove not to be a permissible construction of the statute. For many of the same reasons that the holding-on-the-merits approach is supported by reasoned agency decisionmaking, it is also reasonable in practice.

Plaintiff's argument that the approach "nullif[ies] the crucial declaratory judgment mechanism for ANDA applicants," Pl.'s Mot. T.R.O. & Prelim. Inj. at 26, does not warrant a contrary conclusion. As long as the party filing the declaratory judgment action meets the "case or controversy" requirements of Article III (meaning that it has a reasonable apprehension of suit by the branded product manufacturer), that party may seek a court decision that qualifies as a triggering event under the statute. The holding-on-the-merits approach does not "nullify[] the crucial declaratory judgment mechanism," then, it only nullifies the manipulation of that mechanism, which has facilitated numerous sham lawsuits akin to the Apotex-BMS litigation.

As the FDA's remand decision acknowledged, the holding-on-the-merits approach is not perfect, but neither is the estoppel approach advocated by Apotex. For example, the estoppel approach completely ignores the language of the statutory provision, which requires a decision of a court with an actual holding. Pl.'s Exh. A at 8. The FDA has correctly noted that parties may be estopped for any number of reasons, based upon various considerations, which may be wholly unrelated to patent infringement, unenforceability, or invalidity. To make estoppel the pivotal focus is essentially to amend the statute's text, effectively deleting the words "holding the [relevant] patent . . . invalid or not infringed." Such an approach would "contraven[e] accepted cannons of statutory construction," id. (citing Bailey, 516 U.S. at 146), because, as the Court

discussed supra, it would run counter to the seemingly clear language of the statute.[9]

Plaintiff may well be correct that "some degree of legal analysis is unavoidable in the context of the court-decision trigger." See Teva II, 2000 WL 1838303, at *1 (quoting Teva Pharms., USA, 1999 WL 1042743, at *5). But the holding-on-the-merits approach does not entirely eradicate legal analysis; it merely focuses that analysis. Instead of engaging in the broader, more amorphous, subjective, and labor-intensive inquiries associated with estoppel (including what constitutes a reasonable apprehension of suit, what is sufficient to eradicate such an apprehension, and what is sufficient to prevent such an apprehension from ever arising in the first place), the FDA will instead concern itself with the more focused issues of what constitutes a holding "on the merits" of the patent suit, and whether that holding is the result of a court decision, rather than a decision or agreement of the parties.

Even if, as plaintiff contends, the estoppel approach is less imperfect than the holding-on-the-merits approach, that does not render the FDA's approach impermissible. See Am. Bar Ass'n, 430 F.3d at 468. The act of analyzing competing policy concerns against the backdrop of the statutory landscape that Congress has placed in its charge is the quintessential function of an administrative agency. See, e.g., Teva Pharms. Indus., 410 F.3d at 54. It is precisely the province of the agency to choose from among the permissible constructions and competing policy interests of a statute after assessing the benefits and disadvantages of each, and the Court may not

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[9]This observation does not conflict with the Court's earlier conclusion that the provision's text is not sufficiently unambiguous to end the inquiry at Chevron step one. The ambiguity in the language is latent in nature, arising from the fine legal distinctions that may be drawn when interpreting the meaning of individual words like "decision" and "holding." Hence, while the language is ambiguous when judged by Chevron step one standards, it does, nonetheless, lend itself strongly and naturally to the FDA's interpretation, and not the estoppel approach urged by Apotex.

substitute its judgment for that of the agency. See Am. Bar Ass'n, 430 F.3d at 468; see also Chevron, 467 U.S. at 866 (stating that "[t]he responsibilit[y] for assessing the wisdom of such policy choices . . [is] not [a] judicial one[]"); cf. Teva III, 441 F.3d at 4-5. Under Chevron's highly deferential standard, it matters not which is the better or even the correct interpretation, as long as the one advocated by the FDA is not entirely irrational. See Am. Bar Ass'n, 430 F.3d at 468. This is particularly so in an administrative context that, like the one currently before the Court, is admittedly fraught with complications and conflicts. See Barnhart, 535 U.S. at 222. Here, the FDA has been given substantial authority over an ambiguous statute in this complex arena, and has chosen a method that it believes properly strikes the delicate balance between competing legislative policies, thereby filling the gap left by Congress. See Teva III, 441 F.3d at 4 (citing Chevron, 467 U.S. at 843-44). Under such circumstances, the deference to which the agency is entitled is at its apex, see Mead, 533 U.S. at 226-27, and the Court cannot conclude that the FDA has acted irrationally or outside the scope of its authority, see Cal. Indep. Sys. Operator Corp., 372 F.3d at 399-400 (citing Chevron, 467 U.S. at 843-44; Motion Picture Ass'n of Am., Inc. v. FCC, 309 F.3d 796, 801 (D.C. Cir. 2002)). "[S]o long as [the FDA's] interpretation is 'permissible,' that is, if it is 'reasonable,'" it must be upheld under Chevron. Am. Bar Ass'n, 430 F.3d at 468 (quoting Chevron, 467 U.S. at 843, 845). Operating, as it must, within these well-settled principles, the Court concludes that the FDA's interpretation of its statute and implementing regulation is reasonable.

C. Whether the FDA's Remand Decision Adequately Addresses the Concerns Expressed in Teva I

In Teva III, the D.C. Circuit noted that

> the FDA states that in the absence of any perceived Teva I constraint, it would employ a 'textual' approach to interpreting the statute, and would take the position that dismissals of declaratory judgment actions are not court decisions holding a patent to be invalid or not infringed . . . . The agency took a similar position in Teva I, but failed to provide adequate explanation. In this litigation the FDA still has not answered the questions put to it by the Teva I court.

441 F.3d at 5 n5. Apotex argues that this language constitutes a requirement that the FDA, on remand in Teva III, reconcile the result that it reached in Teva I and Teva II under the cae-by-case method adopted in the earlier guidance document; reconcile the result that it reached in Teva I and Teva II, as well as the result that it has reached regarding the Apotex-BMS dismissal, with the result that it reached in Granutec; and explain how its departure from the estoppel approach is permissible in light of its regulation including a decision as to unenforceability as a possible triggering event. Apotex also submits that the FDA's remand decision has left these questions unanswered yet again.

As a threshold matter, Apotex is mistaken regarding the effect of the D.C. Circuit's statement in Teva III. It would be nonsensical if that language required the FDA to reconcile the results that it reached in Teva I, Teva II, and Granutec, or to justify the result that it reached here regarding the Apotex-BMS dismissal under the now-defunct case-by-case method. At the time of those earlier decisions, the FDA had committed itself to using the case-by-case method while it awaited promulgation of a new, final rule. In Teva I and Teva II, however, the FDA decided to apply the holding-on-the-merits approach, and did not explain its departure from the case-by-case method. The concerns expressed by the D.C. Circuit in Teva I were predicated upon the improper rejection of the case-by-case method and considerations of estoppel in favor of the holding-on-the-merits approach in the absence of any justification for the departure. Now, however, the

agency has explicitly rejected the case-by-case method, as well as the estoppel approach, in favor of the holding-on-the-merits approach, and that rejection has been fully explained in the April 11, 2006 decision letter. Teva III explicitly opened the door for the FDA to do this -- the FDA stated, at oral argument and in its briefs, that it would adopt the holding-on-the-merits approach if it were free to do so. Following these representations, the D.C. Circuit issued the Teva III opinion, which held that neither Teva I, Teva II, nor any other circuit precedent required the FDA to use the estoppel approach or the case-by-case method. As long as the FDA explained adequately its reasons for doing so, it could adopt whatever approach it preferred. The necessary corollary is that Teva III recognized the agency's authority to reject other approaches, including the one previously followed. Accordingly, decisions rendered under the case-by-case method when it was still viable have little, if any, bearing on assessments made under the new holding-on-the-merits approach, and it makes little sense to require the FDA to justify its decision here under the case-by-case method when that method is no longer being employed.

Instead, the Court interprets the language in Teva III as an admonishment to the agency that while it is free to reject certain approaches and adopt the one that it prefers, it must explain adequately its reasons for doing so, and it must reconcile any currently relevant aberrations that may be created as a result (including any inconsistency with the still-effective regulation on unenforceability). Teva III merely reminded the agency that it cannot commit the same sins as it did in Teva I. In any event, even if Apotex's interpretation of that language were correct, the Court is convinced that the FDA has satisfied its responsibilities in its remand decision. To begin with, the agency has explained why its decision is not arbitrary or capricious in light of its previous guidance document -- the guidance document is no longer viable. Because the FDA is

no longer required, by its own commitment, to make a case-by-case assessment based on considerations of estoppel, it is permissible for the FDA to reach a conclusion under its new approach that might not have been supported under a case-by-case assessment. Simply put, the guidance document can no longer be considered the frame of reference for proper agency action.

Moreover, the FDA has adequately articulated how the holding-on-the-merits approach is consistent with its implementing regulation. The language of the regulation parallels the language of the statute, except that the regulation adds the word "unenforceable" to the statutory terms "invalid or not infringed." By its plain terms, then, the regulation requires nothing less, and nothing more, than what the statute requires. The FDA has reasonably determined that both the statute and the regulation require a decision of a court that is a holding on the merits regarding the patent action. It cannot convincingly be argued that there is any incongruity between the regulation and the statute, such that it would be improper under the regulation to utilize a holding-on-the-merits approach that is reasonably supported by the terms of the statute itself. Both the statute and the regulation reflect the intent of Congress for the exclusivity clock to be triggered only by a judicial determination that the relevant patent is invalid, not infringed, or unenforceable.

Hence, neither a private agreement between litigants that procures a voluntary dismissal of a declaratory judgment action (like the Apotex-BMS dismissal), nor a determination by the FDA regarding whether or not the branded drug manufacturer is estopped from pursuing a patent action will satisfy the statute's requirements as also embodied in the regulation. Apotex's argument that the agency has "elevated the form of the dismissal over its substance," Pl.'s Mot. T.R.O. & Prelim. Inj. at 21, thus begs the question: Congress chose to focus on the nature of the dismissal, rather than its practical effect, by specifying a court decision with a holding. That is the legislative

scheme that Congress created, and the agency's holding-on-the-merits approach furthers that scheme. The relevant inquiry under the FDA's reasonable interpretation of the statute and regulation is not whether there is estoppel as a result of a given court proceeding, but rather whether the court has itself rendered a decision that holds -- on the merits -- that the relevant patent is invalid, not infringed, or unenforceable. Apotex's dissatisfaction with the way in which the agency's approach affects its interests in generic pravastatin does not offer the Court a sufficient basis to disturb the legislative scheme reasonably adopted by the FDA.

Finally, the agency has adequately explained why the court action at issue in Granutec was a triggering event, whereas the Apotex-BMS dismissal is not. The Granutec court granted partial summary judgment, through a memorandum opinion, in one party's favor on the basis of representations that had estoppel effect. By its very nature, summary judgment requires the weighing of substantive arguments and necessitates legal analysis -- the court is required to determine that there is no genuine dispute of material fact, and the moving party is entitled to prevail as a matter of law. See Fed. R. Civ. P. 56(c). Of course, under the FDA's April 11, 2006 decision, estoppel is no longer the relevant inquiry -- the focus is now on whether there is a court decision and what it holds. However, the result previously reached in Granutec would, as FDA concluded, be the same under the holding-on-the-merits approach that applies today.[10] In Granutec, the court was called upon to make a factual and legal finding with respect to the substantive arguments presented on the issue of patent invalidity, infringement, or

[10]In its opposition memorandum, defendant-intervenor Teva submits as well that Granutec has been superseded by statute, such that a partial grant of summary judgment would no longer qualify as a triggering event because it is not a "decision of a court" within the meaning of the statute pursuant to the MMA. See Teva Mem. Opp'n at 14.

unenforceability. This did not happen in the Apotex-BMS litigation. As this Court articulated in its prior decision, the Apotex-BMS dismissal was nothing more than a private settlement agreement between the parties, which required no court action whatsoever and lacked the requisite judicial imprimatur to constitute a "decision of a court." See 398 F. Supp. 2d at 190-91. It was a "decision," in essence, by the parties. The court was not called upon to make any substantive determinations, and its signature upon the face of the order added nothing of substance. See id. at 189-92. The same outcome would have been reached whether or not the court signed the document, because the action that made the document effective was taken by the parties, not by the court. See id. In contrast, the parties in Granutec could never have obtained the outcome in that case -- partial summary judgment -- without a court decision addressing the merits.

With respect to the results reached by the agency in Teva I and Teva II (prior to the D.C. Circuit's decisions in those cases), there is no inconsistency with the holding-on-the-merits approach. As the D.C. Circuit recognized, the dismissal at issue in those cases was not a holding on the merits. See Teva I, 182 F.3d at 1009 (recognizing that the "dismissal was not a judgment on the merits after consideration of evidence presented by the parties"). Hence, it would not qualify as a triggering event under the approach that applies as of April 11, 2006. The D.C. Circuit rejected the FDA's conclusion in this regard because the agency itself had made estoppel the focal point of the analysis, and the dismissal at issue in Teva I and Teva II did have preclusive effect. See id. Hence, the dismissal was, at the time, a qualifying triggering event, and the FDA's unexplained refusal to recognize it as such was improper. See id.

Not only did the agency's fifteen-page, single-spaced remand decision thoughtfully deconstruct the multifaceted implications of the estoppel and holding-on-the-merits approaches,

but it also sufficiently addressed each of the three concerns raised in Teva I and recalled in Teva III. There is no "want of reasoned decisionmaking" here. See Teva II, 2000 WL 1838303, at *2. Moreover, the agency's remand decision represents a permissible construction of the statute as a matter of textual interpretation as well as practice. Apotex is, accordingly, unlikely to prevail on the merits of its claim that the FDA acted arbitrarily, capriciously, in excess of statutory authority, or otherwise not in accordance with law when it determined that the Apotex-BMS dismissal is not a qualifying triggering event under § 355(j)(5)(B)(iv)(II).

II. Whether Plaintiff Will Suffer Irreparable Harm if Relief is Not Granted

The irreparable injury requirement erects a very high bar for a movant. See Varicon Int'l v. OPM, 934 F. Supp. 440, 447 (D.D.C. 1996). A plaintiff must show that it will suffer harm that is "more than simply irretrievable." Gulf Oil Corp. v. Dept. of Energy, 514 F. Supp. 1019, 1026 (D.D.C. 1981). In this jurisdiction, harm that is "merely economic" in character is not sufficiently grave under this standard. See Wisconsin Gas Co. v. FERC, 758 F.2d 669, 674 (D.C. Cir. 1985); Boivin v. US Airways, Inc., 297 F. Supp. 2d 110, 118 (D.D.C. 2003); Mylan Pharms., Inc. v. Shalala, 81 F. Supp. 2d 30, 42 (D.D.C. 2000). To successfully shoehorn potential economic loss into the irreparable harm requirement, a plaintiff must establish that the economic harm is so severe as to "cause extreme hardship to the business" or threaten its very existence. Gulf Oil, 514 F. Supp. at 1025; see also Wisconsin Gas, 758 F.2d at 674; Experience Works, Inc., 267 F. Supp. 2d at 96; Sociedad Anonima Vina Santa Rita v. Dep't of Treasury, 193 F. Supp. 2d 6, 14 (D.D.C. 2001). To warrant emergency injunctive relief, the harm alleged must be certain, great, actual, and imminent. See Wisconsin Gas, 758 F.2d at 674. Moreover, because Apotex has not established a likelihood of success on the merits, its showing of irreparable harm must be very

strong. See Cuomo, 772 F.2d at 974; Davenport, 166 F.3d at 366.

The Court is not convinced that Apotex can satisfy these standards. To be sure, if Apotex is correct that all generic exclusivity connected to pravastatin has already been triggered and extinguished, then it probably stands to lose a significant sum of money unless it is granted emergency injunctive relief. But if, as the FDA has concluded (reasonably, this Court believes), intervenor-defendants are statutorily entitled to benefit from a period of generic exclusivity that has not yet been triggered, then Apotex faces no harm whatsoever because the denial of emergency injunctive relief leaves its position untouched.

Apotex has never contended that it has a statutory entitlement to generic exclusivity; it has never claimed that it was the first to file an ANDA containing a paragraph IV certification with respect to one of the Pravachol® patents. Rather, Apotex merely submits that it stands to lose approximately $9.9 million dollars in sales over the course of one year if intervenor-defendants are permitted to exercise their statutory exclusivity entitlements. The Court will assume the accuracy of that dollar estimate for the moment, putting aside the FDA's contention that the relevant time period for the calculation of losses is only from the point when the intervenor-defendants launch their products on April 20, 2006 to the time that the case is resolved on the merits, probably just a few months. Even so, the harm that Apotex allegedly faces cannot be called anything other than "merely economic." Apotex "produces more than 260 generic pharmaceuticals in approximately 4000 dosages and formats which, in Canada, are used to fill over 60 million prescriptions a year -- the largest amount of any pharmaceutical company in [Canada]." See http://www.apotex.com/CorporateInformation/Default.asp?flash=Yes (last visited Apr. 18, 2006). Moreover, Apotex reaps annual revenues that total approximately $700

million USD. Id. (boasting annual revenue of more than $800 million in Canadian currency). Under the circumstances, it hardly seems possible that a $9.9 million loss in sales over a year would cause extreme hardship, much less threaten the company's very existence, and Apotex has not established (or even contended) that it would.

Apotex's speculative sales loss thus remains an economic loss that does not meet the irreparable harm standard. So, too, its concerns about a lost market share fall well short of the serious, irretrievable damage to its business required to warrant a preliminary injunction, particularly when one considers that the actual relevant period for assessing harms is probably only a few months. And even assuming that Apotex has adequately established a cognizable irreparable injury, the Court cannot conclude that the balance of hardships tips decidedly in its favor because, as discussed below, each of the intervenor-defendants stands to lose a much greater sum if the launch of their generic products is delayed. Particularly where Apotex has made a very weak showing of likely success on the merits, that balance of harms is fatal to its request for emergency injunctive relief.

III. Whether the Intervenor-Defendants Will Suffer Irreparable Harm if Emergency Injunctive Relief is Granted

In the event that Apotex receives the emergency injunctive relief that it seeks, the intervenor-defendants will be prevented from marketing their generic products on April 20, 2006. Both Teva and Ranbaxy are, the FDA has determined, entitled to enjoy a 180-day period of generic marketing exclusivity. Each company is prepared to launch on April 20, 2006, and estimates that it will suffer lost profits that far exceed the losses that Apotex allegedly faces over a

longer period of time. Specifically, Teva contends that a delay as short as seven days could cost it "tens of millions of dollars," and Ranbaxy anticipates losses totaling fifteen to twenty million dollars within the first six months of marketing. See Teva Mem. Opp'n at 20; Ranbaxy Mem. Opp'n at 16. But unlike the harm that Apotex allegedly faces, the potential injury that the intervenor-defendants face is not "merely economic." Rather, they stand to lose a statutory entitlement, which is a harm that has been recognized as sufficiently irreparable. See, e.g., Mova, 140 F.3d at 1067 n.6. Once the statutory entitlement has been lost, it cannot be recaptured.

Moreover, although intervenor-defendants are entitled to an exclusivity period of 180 days under the statute, in reality they will only enjoy an exclusivity period of approximately sixty days. On June 23, 2006, the patent for a branded drug by the name of Zocor® will expire. Generic versions of that drug (simvastatin) will then enter the market. Simvastatin and pravastatin are in the same drug class, have very similar treatment indications, and are, for all practical purposes, interchangeable for many patients. According to some reports, Pravachol® users are currently being advised to switch to Zocor® in anticipation of the arrival of generic simvastatin. See Interv.-Def.'s (Ranbaxy) Exhs. C, D. Intervenor-defendants estimate, not unreasonably, that the launch of generic simvastatin will diminish the value of the 180-day exclusivity period for generic pravastatin. Additionally, the manufacturer of Pravachol®, BMS, has already entered into agreements pursuant to which it will launch an "authorized generic" product on April 20, 2006.[11] This product will compete directly with the products marketed by intervenor-defendants. If intervenor-defendants are prevented from entering the market at the same time as the authorized

[11]An "authorized generic" or "brand generic" is a generic version of the branded drug that is produced by, or in partnership with, the same company that manufactures the branded drug. See generally Teva Pharms., 410 F.3d at 52-53.

generic, then they stand to lose a portion of the market that BMS will have already acquired. Hence, each day after April 20, 2006 that intervenor-defendants are foreclosed from marketing their generic pravastatin products will result in further erosion of the statutory entitlement and additional lost profits and market share. In light of the considerable economic injury facing intervenor-defendants, and the less substantial injury to Apotex, the balance of hardships clearly tips against granting Apotex the emergency injunctive relief that it seeks.

IV. Where the Public Interest Lies

Where, as here, the FDA is administering a statute that has been placed within its charge, and has no financial interest in the outcome, its interest is deemed to be aligned with that of the public. The public interest would not, as Apotex claims, be furthered by a court order preserving the alleged status quo. Such an order would effectively constitute a constructive extension of the brand manufacturer's patent (and period of pediatric exclusivity). That monopoly is set to end on April 20, 2006, and there are two pharmaceutical companies that are ready and willing to make generic alternatives to Pravachol® available to consumers on that date. The purpose of the relevant statutory provisions is to expedite and increase the availability of generic substitutes. If this Court were to grant Apotex's motion, then the public would be forced to wait until this litigation is completely resolved (at some unidentified point in the future) before it is able to benefit from low-cost versions and widespread availability of pravastatin. The fact that BMS, as the manufacturer of Pravachol®, plans to release an authorized generic on that date does not indicate otherwise. To be sure, an authorized generic may provide some benefit to the public in the form of reduced costs and greater product availability. But, as Teva notes, those benefits are

not likely to be as great as the ones that flow from real generic competition. The authorized generic faces no significant market pressure because the manufacturer is, essentially, competing with itself. Accordingly, it lacks a sufficiently strong incentive to undercut the pricing of the branded product. A third-party generic seeks to attract the consumers of the branded product, but the authorized generic naturally seeks (to a degree) to maintain a customer base for its more profitable branded product. Hence, the public interest is most directly furthered by the launch of generic pravastatin on April 20, 2006.[12]

CONCLUSION

For the foregoing reasons, plaintiff's motion for a temporary restraining order and preliminary injunction is denied. Apotex has also sought an injunction pending appeal. The legal analysis that applies to a request for a stay or injunction pending appeal is identical to that for a temporary restraining order or preliminary injunction and, accordingly, Apotex has failed to establish that the balance of harms or its likelihood of success on the merits favors the issuance of such relief. Nevertheless, in order to allow the Court of Appeals, if so requested, to determine whether it will exercise its discretion to grant an injunction pending appeal, this Court will grant that injunction for a brief period, through 5:00 p.m. on April 21, 2006. A separate order has been issued on this date.[13]

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[12]Apotex claims that the public interest is furthered by "faithful application of the laws." This is undoubtedly true, but it is of little aid here. In the Court's opinion, the holding-on-the-merits approach adopted by the FDA is more faithful to the statutory language, preferable from a policy standpoint, and facilitates consistency and industry certainty -- all things that amount to a "faithful application of the law."

[13]FDA requested that this proceeding be consolidated, under Fed. R. Civ. P. 65(a)(2), with a proceeding on the merits. The parties agreed to such a course of action with respect to the proceedings before this Court in Teva III. However, in light of the compressed time schedule

/s/ John D. Bates
JOHN D. BATES
United States District Judge

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with respect to the current proceedings, the Court is reluctant to do so in the absence of consent by all parties. Accordingly, the FDA's request is denied.

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