

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

APOTEX, INC.,)	
)	
Plaintiff,)	
)	
v.)	Civil Action No. 99-729
)	(EGS)
DONNA SHALALA, <u>et al.</u> ,)	
)	
Defendants.)	

MEMORANDUM OPINION AND ORDER

EMMET G. SULLIVAN, UNITED STATES DISTRICT JUDGE.

INTRODUCTION

Plaintiff Apotex, Inc., through its TorPharm division (hereinafter "TorPharm"), commenced this lawsuit to enjoin the Food and Drug Administration ("FDA") from granting a 180-day period of exclusivity to Novopharm Limited ("Novopharm") to market generic over-the-counter ("OTC") strength ranitidine hydrochloride. Plaintiff claims that the FDA has ignored a key provision of the Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 355, and frustrated Congressional intent by creating an unwarranted delay for open competition in the billion dollar ranitidine hydrochloride market.

The Court consolidated plaintiff's application for a preliminary injunction with a hearing on the merits pursuant to Fed. R. Civ. P. 65(a)(2). Pending before the Court are cross-

motions for summary judgment pursuant to Federal Rule of Civil Procedure 56. The Court has considered the parties' motions, oppositions, replies, and counsels' oral arguments, as well as the applicable statutory and case law. For the following reasons, the Court concludes that defendants' and intervenor's motions for summary judgment are **GRANTED**, and plaintiffs' motion for summary judgment is **DENIED**.

BACKGROUND

I. Parties

Plaintiff TorPharm is a generic drug manufacturer that challenges the FDA's grant of a period of market exclusivity for 75 mg OTC ranitidine hydrochloride to intervenor defendant Novopharm. Defendants are Donna Shalala, Secretary of Health and Human Services; Jane Henney, Commissioner of the FDA; and the FDA. Intervenor defendant Novopharm is a generic drug manufacturer that received a 180-day exclusive period to market 75 mg OTC strength ranitidine hydrochloride.

II. The FDA's Statutory Scheme

A. New Drug Approval

The FDA has administrative jurisdiction of applications to market new drugs under the FDCA. Pharmaceutical companies that wish to market innovator or "listed" drugs must first obtain

FDA approval through the filing of a new drug application ("NDA"). See 21 U.S.C. § 355(a),(b). The FDCA requires an NDA applicant to submit data to the FDA that demonstrates the safety and effectiveness of the drug. In addition, the NDA applicant must submit information on any patent that claims the drug or a method of using such drug for which a claim of patent infringement could reasonably be asserted against an unauthorized party. See 21 U.S.C. § 355(b)(1), (c)(2). The patent information must include the patent number and the date of expiration. See 21 U.S.C. § 344(b)(1). The FDCA requires the FDA to publish this information, and the FDA does so in a publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly referred to as the "Orange Book"). See 21 C.F.R. § 314.53(e).

B. Abbreviated New Drug Approval

In 1984 Congress passed the Drug Price Competition and Patent Term Restoration Act, generally known as the Hatch-Waxman Amendments.¹ The Act provided generic drug manufacturers with greater access to the market for drugs and granted greater market protection to innovator drug manufacturers through special patent extensions and periods of exclusive marketing. The Act also

¹Congress added these provisions to the FDCA via Pub. L. No. 98-417, 98 Stat. 1585 (1985) and codified at 21 U.S.C. § 355(j).

established an abbreviated process by which the FDA could approve generic versions of listed drugs without requiring the submission of full safety and efficacy data. The Act also allows a generic drug manufacturer to seek approval of its drug product by submitting an abbreviated new drug application ("ANDA") that demonstrates, among other things, that the generic version of the drug is "bioequivalent"² to the innovator drug.

The FDCA requires an ANDA applicant who seeks approval of a generic drug to reference the particular listed drug that it intends to duplicate. See 21 U.S.C. § 355(j)(2)(A). "Listed drugs" are new drug products that have been approved under the FDCA for safety and effectiveness and that have not been withdrawn from sale for reasons of safety or effectiveness. See 21 C.F.R. § 314.3(b). A "drug product" is a finished dosage form (e.g., tablet, capsule, or solution) that contains a drug substance generally in association with one or more ingredients. See *id.* A "drug substance" is an "active ingredient that is intended to furnish pharmacological activity or other direct effect . . . but does not include intermediates used in the synthesis of such ingredient." *Id.*

The ANDA applicant must also submit information to show that the "route of administration, the dosage form, and the

²Bioequivalence means that the generic drug delivers the same amount of the active ingredient at the same rate and extent to the body as the innovator drug.

strength of the new drug are the same as those of the listed drug." See 21 U.S.C. § 355(j)(2)(iii) (emphasis added). Based on this and other statutory language, the FDA has concluded that each strength of drug product is a separately listed drug. See FDA Response to TorPharm Citizen Petition, at 3 (attached to plaintiff's complaint as Exh. H).³

The statute also requires that an ANDA contain a certification with respect to each patent that claims the pioneer drug or the method of the drug's use. See 21 U.S.C. § 355(j)(2)(A)(vii). The certification must state one of the following:

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

³The FDA stated that "[t]he Agency has previously considered whether different strengths of a drug could be eligible for market exclusivity under 505(j)(B)(5)(iv) of the Act and concluded that each strength of the drug could be independently eligible. In 1990, FDA determined that Purepac Pharmaceutical was not barred from final approval of its 20 mg nifedipine product by the 180-day market exclusivity the Agency had already awarded to Chase Laboratories for its 10 mg nifedipine product. Because each strength of the drug was a different drug product, exclusivity for the 10 mg product did not block approval of the 20 mg product. As a result, each strength was separately eligible for exclusivity." FDA Response to TorPharm Citizen Petition, at 3.

See *id.* Plaintiff and intervenor made certifications under paragraph IV, which requires the ANDA applicant to give notice of the filing of the ANDA to the patent owner and the NDA holder for the pioneer drug. See 21 U.S.C. § 355(j)(2)(B)(i). The required notice must include a detailed statement of the factual and legal basis for the ANDA applicant's opinion that the listed patent is either not valid or will not be infringed upon by the marketing of the generic drug. See 21 U.S.C. § 355(j)(2)(B)(ii).

Certifications pursuant to paragraph IV are specific to the listed drug and to the ANDA for which approval is being sought.

The FDA may give final approval to an ANDA with a paragraph IV certification that may become effective immediately despite the unexpired patent, unless the patent owner or NDA holder brings an action for infringement against the ANDA applicant within forty-five days of the date the patent owner and NDA holder receive notice of the paragraph IV certification. See 21 U.S.C. § 355(j)(5)(B)(iii); 21 C.F.R. § 314.107(f)(2). When a patent owner brings a patent action, the statute prohibits the ANDA from being approved until thirty months from the date that the patent owner and NDA holder received notice of the filing of the ANDA, unless a final decision is reached earlier in the patent case or the court orders a different time period. See 21 U.S.C. § 355(j)(5)(B)(iii).

When two or more ANDA applicants file paragraph IV

certifications, as in the instant case, the statute provides an important benefit to the earliest applicant to have submitted a paragraph IV certified ANDA. Specifically, the statute requires that approval of each of the subsequent ANDA's be delayed as follows:

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

The pharmaceutical industry refers to the first subparagraph as the "commercial marketing" trigger and to the second subparagraph as the "court decision" trigger. The 180-day exclusivity period provides an incentive for generic manufacturers to file paragraph IV certifications challenging patents that may be invalid, not infringed upon by the product that is the subject of the ANDA, or unenforceable.

III. Mova Decision

Until recently, the FDA required that in order to receive this 180-day exclusivity period for marketing drugs, the first ANDA applicant who submitted a paragraph IV certification must also have "successfully defended" a patent infringement suit. See 21 C.F.R. § 314.107(c)(1). This "successful defense" requirement was invalidated by the D.C. Circuit in *Mova Pharmaceutical Corp. v. Shalala*, 140 F.3d 1060 (D.C. Cir. 1998). Subsequent to the *Mova* decision, the FDA determined that until it promulgated new regulations under the statute, it would address new issues by direct reference to the FDCA. The FDA's "Guidance for Industry, 180-Day Generic Drug Exclusivity" provided that the first applicant to submit a substantially complete ANDA with a paragraph IV certification will be eligible for 180 days of exclusivity even if the patent owner or NDA holder does not sue the applicant. The D.C. Circuit recently upheld this post-*Mova* approach in *Purepac Pharmaceutical Co. v. Friedman*, 162 F.3d 1201 (D.C. Cir. 1998).

IV. Events

Glaxo Wellcome, Inc. ("Glaxo") is the patent owner and NDA holder for ranitidine hydrochloride, which it markets under the trade name "Zantac." Two of Glaxo's patents on ranitidine hydrochloride have not yet expired. The FDA has a number of Glaxo's products that contain ranitidine hydrochloride, including

150 mg and 300 mg ranitidine hydrochloride tablets, which are prescription drug products indicated for the treatment of ulcers and each of which has a separate listing and a separate number of the "Orange Book" of approved drug products. Glaxo enjoyed a period of exclusive marketing for 150 mg and 300 mg prescription strength Zantac.

Several drug manufacturers submitted paragraph IV ANDAs for the 150 mg and 300 mg strengths of Zantac. Genpharm was the first applicant to submit a "substantially complete" ANDA for the two listed drugs and was eligible for 180 days of generic exclusivity pursuant to 21 U.S.C. § 355(j)(5)(B)(iv). After Genpharm submitted its paragraph IV ANDA for the two drug products and provided the requisite notice, Glaxo sued Genpharm for patent infringement and tolled Genpharm's final approval. Genpharm prevailed in the litigation on August 15, 1997, but the Court issued this decision after another generic drug manufacturer, Boehringer-Ingelheim Corporation, obtained partial summary judgment that became final on January 31, 1997. The *Boehringer-Ingelheim* decision was the first "decision of a court" with respect to 150 mg and 300 mg ranitidine hydrochloride and, as such, controlled the court decision trigger. Genpharm, however, was the manufacturer that was eligible for the exclusive marketing period for these two products. This exclusive period began on March 3, 1997 (the date the *Boehringer* judgment became

non-appealable) and expired on August 29, 1997. Subsequently, the FDA approved applications by plaintiffs and other drug manufacturers to market these products.

In addition to the prescription strength Zantac products, Glaxo also applied for and received permission to market OTC strength Zantac, which is 75 mg ranitidine hydrochloride and is indicated for the treatment of heartburn. Glaxo's exclusivity for this product expires on June 19, 1999.⁴ In its NDA for 75 mg Zantac, Glaxo listed several patents, which are listed in the Orange Book with respect to the OTC 75 mg product. Several drug manufacturers, including plaintiff and intervenor, submitted ANDA's for this product and filed paragraph IV certifications, asserting that their generic products did not infringe upon Glaxo's patents. Plaintiff received tentative approval from the FDA on September 29, 1998, but has not received final approval for its ANDA. Intervenor Novopharm was the first applicant to submit a substantially complete paragraph IV ANDA for 75 mg OTC ranitidine hydrochloride and was eligible for 180

⁴The FDA grants three years of exclusivity to the holder of the NDA for a brand name drug when new clinical trials are essential to gaining approval of a second NDA. The FDA cannot approve any ANDAs for generic versions of the drug during that three-year period. Mem. of Intervenor-Def. Novopharm Ltd. in Supp. of its Mot. for Summ. J. & in Opp'n to Pl.'s Mot. for Summ. J., at 5.

"The [FDCA] also grants an additional six months of market exclusivity to the holder of the NDA for a brand name drug product as an incentive to conduct clinical studies to increase label information about the use of the drug in pediatric populations." *Id.*, at 6.

days of generic exclusivity.

Plaintiff initially sought a preliminary injunction, which would have compelled the FDA to approve plaintiff's generic version of Zantac 75 tablets for distribution immediately after June 19, 1999. During the April 1, 1999, status conference and without objection, the Court consolidated the trial on the merits with the hearing on the application for preliminary injunction pursuant to Fed. R. Civ. P. 65(a)(2).⁵ At plaintiff's request, the Court then directed that plaintiff's motion for preliminary injunction be converted into a motion for summary judgment and that the FDA and Novopharm file cross-motions for summary judgment pursuant to Fed. R. Civ. P. 56.

DISCUSSION

Summary judgment should be granted pursuant to Federal Rule of Civil Procedure 56 only if no genuine issues of material fact exist and the moving party is entitled to judgment as a matter of law. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322

⁵Fed. R. Civ. P. 65(a)(2) provides a means of securing an expedited decision on the merits and permits a court to "order the trial of the action on the merits to be advanced and consolidated with the hearing of the application." Before the Court can issue such an order, "the parties should normally receive clear and unambiguous notice [of the court's intent to consolidate the trial and the hearing] either before the hearing commences or at a time which will still afford the parties a full opportunity to present their respective cases." *University of Texas v. Camenisch*, 451 U.S. 390, 395 (1981)(citations omitted).

(1986). In ruling upon a motion for summary judgment, the Court must view the evidence in the light most favorable to the nonmoving party. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986); *Bayer v. United States Dep't of Treasury*, 956 F.2d 330, 333 (D.C. Cir. 1992). Likewise, in 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. *Rhoads v. McFerran*, 517 F.2d 66, 67 (2d Cir. 1975). The cross-motions for summary judgment pending before the Court present no genuinely disputed material facts that would preclude summary judgment.

Plaintiff challenges the FDA's grant to Novopharm of 180 days of marketing exclusivity for 75 mg OTC strength ranitidine hydrochloride, on the ground that the FDCA precludes the FDA from granting exclusivity periods for ANDA applications that concern the same patents involved in previously approved drugs of different strengths.

I. Chevron Analysis

Under the Administrative Procedure Act, a court must "hold unlawful or set aside agency action" that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2). Agency action is

defined as "the whole or part of an agency rule, order, license, sanction, relief or the equivalent, or denial thereof, or failure to act." 5 U.S.C. § 551(13).

In reviewing an agency's interpretation of a statute it is charged with administering, the Court must be guided by the framework of *Chevron, U.S.A Inc v. Natural Resources Defense Council, Inc.* 467 U.S. 837 (1984). See *Natural Resources Defense Council, Inc. v. Browner*, 57 F.3d 1122, 1125 (D.C. Cir. 1995). Under the Chevron two-step test, "[i]f the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." *Chevron*, 467 U.S. at 842-43. "[I]f the statute is silent or ambiguous with respect to the specific issue, [however,] the question for the court is whether the agency's answer is based on a permissible construction of the statute." *Id.* at 843. A court does not reach this second step "if a court, employing traditional tools of statutory construction, ascertains that Congress had an intention on the precise question at issue, that intention is the law and must be given effect." *Id.* at 843 n.9.

II. Step One of the Chevron Analysis

Plaintiff challenges the exclusivity period granted to Novopharm and contends that the three ranitidine hydrochloride

products rely upon the same underlying patent. The Court in *Glaxo, Inc. v. Boehringer-Ingelheim*, 954 F. Supp. 469 (D. Conn. 1996) (final judgment entered in 962 F. Supp. 295) (D. Conn. 1997)), determined that the 300 mg and 150 mg versions of the generic drug product did not infringe upon Glaxo's patent. Plaintiff argues that the FDA grants exclusivity periods for specific patents, which in this case have already been litigated, while the FDA argues that it grants exclusivity periods for specific drug products as they relate to the patents. The *Boehringer-Ingelheim* Court however, made no determination as to whether 75 mg ranitidine hydrochloride infringed upon Glaxo's patent.

Under step one of *Chevron*, the question before the Court is whether the "paragraph IV" language is clear. If Congress' intent is clear, then this Court's review must end there. See *Chevron*, 467 U.S. at 842-43; see also *Halverson v. Slater*, 129 F.3d 180, 184 (D.C. Cir. 1997). Not coincidentally, all the parties assert that the meaning of the statute is clear on its face and that the Court can resolve the merits of this case under the first prong of *Chevron*. "Under this analysis, the court must first exhaust the traditional tools of statutory construction to determine whether Congress has spoken to the precise question at issue." *Halverson*, 129 F.3d at 184 (citation omitted). The statute states that:

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

Plaintiff states that the "FDA can approve ANDAs, if 180 days has passed since any court decided a patent infringement action which arose after an ANDA provided certifications regarding patents." TorPharm's Amended Reply Mem. in Support of Injunctive Relief and in Opp. to Cross Motions, at 2. Further, plaintiff claims that the court decision trigger applies to any exclusivity period that is related to the patents in question and that the FDA "must apply the same trigger for all further ANDAs which involve the same patents." *Id.* Plaintiff also states that:

The Act does not enable [the] FDA to ignore the court decision ANDA trigger and award an additional ANDA exclusivity period after establishing a court decision trigger for the patents in issue. Neither [the] FDA nor Novopharm

cite any post-1994 Hatch-Waxman amendment legal authority which permits an additional ANDA exclusivity period in connection with the same patents for which [the] FDA granted an initial ANDA exclusivity period beginning with a court decision trigger.

Id., at 3.

In arguing that the statute clearly states that ANDA exclusivity periods may be granted only once with respect to each patent, plaintiff fails to direct the Court to the relevant provision that contains such language. Instead plaintiff argues that Congress' intent must have been such because legal jurisprudence is clear on the issue of re-litigating patents. Plaintiff states that "[i]t's clear from the language of the statute we have to look at the court decision trigger, and it talks about patents. It doesn't talk about strengths. It talks about patents." Tr. of Mot. Hr'g of 4/29/99, at 17. "[Congress] has said, 'We have determined there's one trigger and here it is. It's a court decision. We're capable of making that judgment. . . .'" When you [determine that a court decision trigger applies] and the next strength comes along on the same patents, Congress has said. . . let's not put another exclusivity period there. . . ." Tr. of Mot. Hr'g of 4/29/99, at 15. Plaintiff, however, cites no statutory or other legal authority that discusses the application of a case law trigger to different strengths solely because they rely upon the same patents. See *Glaxo, Inc., v. Novopharm, Ltd.*, 110 F.3d 1562, 1567 (Fed. Cir. 1997) (noting

that plaintiff failed to cite "any legislative history to indicate that Congress intended to limit the infringement analysis to any particular aspect of the ANDA or to alter a patentee's burden of proving infringement").

In fact, the Court finds significant the fact that plaintiff did not challenge earlier the FDA's requirement that Glaxo file an NDA with respect to the 75 mg OTC strength ranitidine hydrochloride. See Tr. of Mot. Hr'g of 4/29/99, at 19. Moreover, plaintiff admits that had it substantially completed its application before Novopharm, it would not have challenged the current procedure. See Tr. of Mot. Hr'g of 4/29/99, at 20. While these revelations in and of themselves are not dispositive of the issue, they cast significant doubts upon plaintiff's version of the alleged clarity of the statute. Plaintiff states that "it's possible [that the] FDA may explain to us that there are other intervening facts which suggest that an NDA is the appropriate route." Tr. of Mot. Hr'g of 4/29/99, at 20. This statement contradicts plaintiff's earlier statement, in which it stated that because the underlying patent is the same, the FDA cannot justify granting this period of exclusivity. As plaintiff has stated "the patents are the patents." Tr. of Mot. Hr'g of 4/29/99, at 16.

In contrast, the FDA and Novopharm argue that the court decision trigger provides that "an ANDA that makes a paragraph IV

certification for a drug for which 'a previous application' has also made a paragraph IV certification cannot be made effective until 180 days after a holding of a court invalidating 'the patent which is *the subject of the certification. . . .*'" Federal Defs.' Reply Mem. in Supp. of Mot. to Dismiss, at 1. Further, defendants maintain that the certification is specific both to the "product for which the ANDA is submitted" and to the "application of the identified patent *to the product proposed in that ANDA.*" *Id.*

Essentially, plaintiff posits that the strength, dosage, or form of the drug does not matter as long as the underlying patent remains the same. During the hearing on the pending motion, plaintiff argued that new patent litigation on different formulations cannot commence because the patents are not strength specific: "The patents are the patents. They're not strength-specific." Tr. of Mot. Hr'g of 4/29/99, at 16.

Herein lies the dispute between the parties. The Court notes that the purpose of the exclusivity incentive and the entire ANDA regime is to "make available more low cost generic drugs." *Granutec, Inc. v. Shalala*, 139 F.3d 889, 1998 WL 153410 at *9 (4th Cir. April 3, 1998) (unpublished). The idea behind the Hatch-Waxman Act is to increase the availability of generic drugs and encourage new drug research by granting substantial periods of non-patent market exclusivity. The FDCA grants a

period of exclusivity to the generic drug manufacturer who risked the possible patent infringement suit by the patent owner. Thus, a "paragraph IV" application is essentially the same as "an infringement of the patent according to the language of the statute and gives the patent holder a right of action against the applicant," *Zeneca, Ltd. v. Mylan Pharmaceuticals, Inc.*, 173 F.3d 820, 830 (Fed. Cir. 1999). A "paragraph IV" application is also a "technical" or "artificial" act of infringement under 35 U.S.C. § 271(e)(2) and gives rise to subject matter jurisdiction under the patent laws. See *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 675-77 (1990); see also *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d at 1568-70 (discussing ANDA approval in the context of patent infringement).

Plaintiff argues that intervenor defendant Novopharm has not risked anything in filing an ANDA for the 75 mg OTC strength ranitidine hydrochloride because Novopharm had already been through extensive litigation with Glaxo that determined that the 300 mg and 150 mg versions of Novopharm's products did not infringe upon Glaxo's patent. Tr. of Mot. Hr'g of 4/29/99, at 16-17. The FDA, however, claims that "[d]ifferent strengths of the same drug may be formulated differently for a variety of reasons, and varying formulations of the different strengths may provide separate and distinct bases for patent protection or for patent challenges." Mem. in Supp. of Defs.' Mot. to Dismiss and

in Opp. to P.'s Mot. for Injunction, at 19.

The Court rejects TorPharm's argument that the statute *clearly* states that new strengths of the same type of drug product fall under previous exclusivity periods. The statute, however, does make clear that the FDA considered the 75 mg strength of ranitidine hydrochloride different enough to warrant a 42-month period of exclusivity for Glaxo. Based on plaintiff's arguments, this period of exclusivity would appear to be unjustified as well. This Court disagrees. The Court finds that the statute clearly does not state that once a patent has been litigated with respect to one drug product and a period of exclusivity has been granted, the patent cannot be challenged with respect to the product as the strength or dosage changes. The FDCA also does not convey the notion that patents cannot be infringed upon in different ways by different strengths of what is the same drug.

III. Step Two of the Chevron Analysis

Should doubts persist as to whether Congress has "spoken to the precise question at issue," the Court also concludes that plaintiff's motion for summary judgment should be denied under step two of *Chevron*, which permits the Court to defer to a permissible agency construction of the statute. See *Chevron*, 467 U.S. at 843; see also *Natural Resources Defense*

Council, Inc. v. Browner, 57 F.3d at 1125. In attempting to discern Congressional intent, the Court finds that Congress has articulated competing intents--to increase the availability of low-cost generic drugs and to provide a period of exclusivity for the company that is the first to "risk" the possibility of a patent infringement lawsuit. Under *Chevron*, "[t]he Court need not conclude that the agency construction was the only one it permissibly could have adopted to uphold the construction, or even the reading the [C]ourt would have reached." 467 U.S. at 843 n.11.

The government contends that under its interpretation of the statute, Novopharm is eligible for 180 days of exclusivity for its version of 75 mg OTC strength ranitidine hydrochloride because it is a different product from the 150 mg and 300 mg prescription products. Precisely in order to address the very issue that is before the Court, the FDA previously required ANDA applicants to have defended a patent challenge successfully. Under that approach, the Court's questions about possible patent infringement would have been answered through the resulting litigation. After the Circuit Court invalidated this successful defense requirement in *Mova*, the FDA stated that until its new rulemaking is complete, it would grant 180 days of market exclusivity to the first applicant to submit a substantially complete ANDA with a paragraph IV certification, whether or not

the patent owner or NDA holder sues the applicant. Thus, under the post-*Mova* approach, Novopharm is entitled to 180 days of exclusive marketing despite the fact that Glaxo has not sued Novopharm under the patent. Plaintiff claims that Glaxo has not sued Novopharm because it cannot; the FDA claims that its interpretation of the statute, which has been upheld on several occasions, is correct.

No court has yet addressed the issue of whether the 180 day exclusive marketing period applies to the patents at issue or to the drug products as they relate to the patents. The Court is, however, persuaded by the arguments of the intervenors, who point out that the prescription-strength products are indicated for the treatment of ulcers while the OTC products are indicated for heartburn. Mem. of Intervenor-Def. Novopharm Ltd. in Supp. of its Mot. for Summ. J. & in Opp'n to Pl.'s Mot. for Summ. J., at 9. Following plaintiff's logic to its natural conclusion, no drug manufacturer could have an exclusive period for a new drug if the underlying patent had been litigated, no matter what the dosage, form, or strength, or for what illness or ailment the drug is used. Although the Court is of the opinion that Congress intended to increase the availability of generic drugs, the Court is not convinced that Congress' intent was to open up the market in this way, especially given the fact that the drugs are different drug products and have different indications. As such,

plaintiff argues that it could have filed an ANDA for 75 mg ranitidine hydrochloride to Glaxo's NDA for 300 mg and 150 mg hydrochloride. For reasons unexplained to the Court, plaintiff did not. Plaintiff also did not challenge Glaxo's submission of and the FDA's requirement of a NDA for 75 mg ranitidine hydrochloride.

If Congress' intent had been to allow a patent decision to apply to all lower strength versions of a particular drug product, the statute would have contained a particular provision that stated that once the patent was litigated, any drug product that was based on the underlying patent need not be re-approved. Since Congress did not make such a statement, its silence is clear that no such result was intended. Support for the FDA's interpretation is also found in the *Boehringer-Ingelheim* case. If the statute were as clear as plaintiff claims, the *Boehringer* Court most certainly would have noted that its decision applied to all drug products that claimed the underlying patent with respect to ranitidine hydrochloride.

The Hatch-Waxman Amendments provide that ANDAs must reference a particular listed drug product, and the Act requires the generic version of each drug to have the same strength as the listed drug. The Court is persuaded by the FDA's reasoning that "allowing separate exclusivity for various strengths encourages prompt entry onto the market of the greatest number of drug

strengths. . . in an attempt to obtain maximum protection from other generic drug competitors." Mem. in Supp. of Defs.' Mot. to Dismiss and in Opp. to P.'s Mot. for Injunction, at 17. As the FDA stated in its brief, "TorPharm's argument would require that [the Court] examine the *Boehringer* patent case and analyze whether the *Boehringer* court's decision regarding 150 and 300 mg ranitidine [hydrochloride] really ought to apply to the 75 mg product, and also would require [the Court] to analyze whether Glaxo had any basis for asserting that patents were applicable to the 75 mg product." *Id.*, at 19. This, the Court is not prepared to do.

CONCLUSION

Under either step one or step two of the Chevron analysis, the Court is persuaded that the FDA's interpretation of the statute, in view of the case law and its own administrative precedent, is permissible. Plaintiff has not referred the Court to any authority, statutory or otherwise, that could persuade the Court that Congress did not intend to grant a period of exclusivity to Novopharm for 75 mg ranitidine hydrochloride. Indeed, the statutory scheme and the resulting litigation appear to indicate that this period is exactly what Congress intended.

Further, as the FDA noted in its brief, "[a] decision of a court that one strength of a product does not infringe a

patent cannot automatically mean that a different strength also does not infringe. Different strengths of the same drug may be formulated differently for a variety of reasons, and varying formulations of the different strengths may provide separate and distinct bases for patent protection or for patent challenges." Mem. in Supp. of Defs.' Mot. to Dismiss and in Opp. to P.'s Mot. for Injunction, at 19. As a result, the Court is not persuaded that the 180-day period of marketing exclusivity that the Court has granted Novopharm is inconsistent with the FDCA. Therefore, plaintiff's motion for summary judgment is **DENIED**, defendant's and intervenor's motions for summary judgment are **GRANTED**, and this case is **DISMISSED WITH PREJUDICE**.

In anticipation that plaintiff will file a motion to stay pursuant to Fed. R. Civ. P. 62, the Court also concludes that the motion should be **DENIED**.

DATE

EMMET G. SULLIVAN
United States District Judge

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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

_____)
APOTEX, INC.,)
)
Plaintiff,)
)
v.) Civil Action No. 99-729
) (EGS)
DONNA SHALALA, et al.,)
)
Defendants.)
_____)

ORDER

Upon consideration of plaintiff's motion for summary judgment, and defendant's and intervenor's motions for summary judgment, it is hereby

ORDERED that plaintiffs' motion for summary judgment is **DENIED**; and it is

FURTHER ORDERED that defendant's and intervenor's motions for summary judgment are **GRANTED**; and it is

FURTHER ORDERED that the above-captioned case is **DISMISSED WITH PREJUDICE**.

In anticipation that plaintiff will file a motion to stay pursuant to Fed. R. Civ. P. 62, it is

FURTHER ORDERED that plaintiff's motion to stay should be **DENIED**.

DATE

EMMET G. SULLIVAN
United States District Judge

Notice:

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