UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ALPHAPHARM PTY LIMITED,	:	
	:	
Plaintiff,	:	
	:	
v.	:	Civil Action No. 03-2269 (JR)
	:	
TOMMY G. THOMPSON, Secretary of Health and Human Services, *et al.*,	:	
	:	
	:	
Defendants.	:	

MEMORANDUM

Plaintiff Alphapharm Pty Limited challenges the Food and Drug Administration's ("FDA") refusal to list the '884 patent for citalopram (brand name Celexa®) in its Orange Book and FDA's related refusal to receive Alphapharm's abbreviated new drug application ("ANDA") for review. Before the Court are the parties' cross-motions for summary judgment. For the reasons stated below, defendant's motion must be granted, plaintiff's cross-motion denied, and the case dismissed.

Background

The Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 et seq., prohibits the introduction into interstate commerce of any new drug unless FDA approves a New Drug Application ("NDA") for that drug. See 21 U.S.C. § 355(a). An NDA must include "the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the

application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." Id. § 355(b)(1); see also id. § 355(c)(2) (addressing patent information that could not be submitted before NDA approval). An applicant must amend an NDA application "[i]f . . . a patent which claims such drug or a method of using such drug is issued after the filing date but before approval of the application." Id. § 355(b)(1). If FDA approves the application, it must publish this information in the "'Orange Book,' an FDA publication that includes all patent information that companies have submitted to the agency." Purepac Pharm. Co. v. Thompson, 354 F.3d 877, 880 (D.C. Cir. 2004); see also 21 U.S.C. § 355(j)(7)(A)(ii) (requiring FDA to update patent information in the Orange Book every 30 days).

In 1984, Congress enacted the "Hatch-Waxman" amendments to the FDCA in order to expedite the process by which drug manufacturers can obtain FDA approval of generic versions of already-approved brand-name drugs, see Drug Price Competition and Patent Term Restoration Act of 1984, Pub.L. No. 98-417, 98 Stat. 1585 (1984); Purepac, 354 F.3d at 879. "[T]he amendments allow companies seeking such approval to submit Abbreviated New Drug Applications, known as ANDAs, that 'piggyback' on the safety-and-effectiveness information that the brand-name

manufacturers submitted in their NDAs." Purepac, 354 F.3d at 879 (citing 21 U.S.C. § 355(j)(2)(A); 21 C.F.R. § 314.94(a)(3)).

Lest drug innovation be discouraged, the Hatch-Waxman amendments provide that NDA applicants may obtain exclusivity periods for innovative drugs. During those exclusivity periods, FDA may not accept or approve ANDAs for generic versions that rely for approval on the innovative drug. See 21 U.S.C. §§ 355(c)(3)(E)(ii)-(iv); id. §§ 355(j)(5)(F)(ii)-(iv). A five-year exclusivity period is granted to an NDA holder "for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under [§ 355(b)]," although an ANDA applicant may submit an application referencing a listed drug after four years if the NDA holder of the drug has submitted patent listing information for the drug pursuant to 21 U.S.C. §§ 355(b)(1) or (c)(2). 21 U.S.C. § 355(j)(5)(F)(ii); see also 21 C.F.R. §§ 314.101(b), (e); 21 C.F.R. § 314.108(b)(2). A six-month extension of a marketing exclusivity period may be granted for the submission, at FDA's request, of studies about whether pediatric use of the new drug will produce health benefits in that population. See 21 U.S.C. § 355a.

The Hatch-Waxman amendments also "create[d] a strong incentive for a generic competitor to be the first to file an ANDA and receive FDA approval: a 180-day period of marketing

exclusivity vis-à-vis other generic competitors." Valley Drug Co. v. Geneva Pharms., Inc., 350 F.3d 1181, 1185 n.10 (11th Cir. 2003). "In other words, the first filer to receive FDA approval is entitled to market the generic versions of the drug for 180 days without competition from any other generic drug manufacturers." Id.; see also 21 U.S.C. § 355(j)(5)(B)(iv). However, "[l]ike NDAs, ANDAs must address patents that cover or might cover the relevant drugs." Purepac, 354 F.3d at 879. For each patent, ANDA applicants must file one of four "certifications" explaining why the ANDA should be approved despite a patent's claim on the drug: "[A] certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the listed drug . . . (I) that such patent information has not been filed, (II) that such patent has expired, (III) of the date on which such patent will expire, or (IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted." Id.; 21 U.S.C. § 355(j)(2)(A)(vii)(I)-(IV). (The last certification is known as a "paragraph IV" certification).

The facts presented by the instant case are these: FDA approved Forest Laboratories, Inc.'s NDA application for citalopram (under the brand name of Celexa®) on July 17, 1998. Forest was awarded a five-year period of marketing exclusivity

for an innovative drug under 21 U.S.C. § 355(j)(5)(F)(ii), and a six-month pediatric exclusivity under 21 U.S.C. § 355a. In its NDA application, Forest included patent information on three patents. See Defs.' Mem., at 11. Before its application was approved, however, Forest sent a letter to FDA discussing the three patents and amending its application to declare that "there are no patents which claim the drug or the drug product or which claim a method of using the drug product and with respect to which a claim of patent infringement could reasonably be asserted . . . ." Admin. R., tab 1, at 2.

After the NDA was approved, Forest sent another letter to FDA, again referencing the three patents mentioned in its application, but also adding a reference to a fourth -- the '884 patent. Id., tab 2, at 2. This letter concluded with a declaration that "none of these patents are relevant to [its] approved NDA," and, as stated in the previous letter, that "there are no patents which claim the drug or the drug product or which claim a method of using the drug product and with respect to which a claim of patent infringement could reasonably be asserted . . . ." Id.

The '884 patent had been issued and assigned to H. Lundbeck A/S on March 17, 1987. As with NDAs, patents may be extended up to five years if the patented item was subject to regulatory review by FDA before the item was marketed. See 67

Fed. Reg. 8,546, 8,546 (Feb. 25, 2002); see also Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. 98-417; Generic Animal Drug and Patent Term Restoration Act, Pub. L. 100-670. In September 1998, Lundbeck filed an application with the Patent and Trademark Office ("PTO") for a patent term extension. In response to a request for additional information from the PTO, Lundbeck stated:

> Applicant has demonstrated that the preparation of the citalopram intermediate . . . ; the citalopram intermediate itself . . .; and the process or converting the citalopram intermediate to citalopram, are used in the manufacture of the approved product.

Compl., Ex. C, at 2. The PTO then requested FDA's assistance in determining the '884 patent's eligibility for an extension. See 67 Fed. Reg. at 8,547. Thereafter, FDA advised the PTO that the human drug product patented at '884 "had undergone a regulatory review period and that the approval of Celexa represented the first permitted commercial marketing or use of the product." Id. The PTO then requested that FDA determine the product's regulatory review period, and FDA responded that the applicable regulatory review period for Celexa is 5,498 days. Id.; Compl., Ex. D, at 1. FDA published notice of its findings and, receiving no objection, informed the PTO that its determination was final. See Compl., Ex. E.

On December 6, 2002, Alphapharm sent a letter to FDA requesting that the '884 patent be listed in the Orange Book.

See Admin. R., tab 3, at 1. Alphapharm argued that the FDCA requires an NDA holder to submit to FDA for listing in the Orange Book "any patent which claims the drug for which the applicant submitted the application . . . and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use or sale of the drug," id. (quoting 21 U.S.C. § 355(b)(1)), and that patent '884 claims the drug citalopram. Alphapharm stated:

> The '884 patent was assigned by the inventor . . . [to] H. Lundbeck A/S, which in turn has licensed the rights to make, use and sell the drug citalopram under this patent in the United States to the U.S. pharmaceutical manufacturer Forest Laboratories, Inc.
> . . .
> [Lundbeck's] application for an extension of the term of the '884 patent: (a) constitutes a representation by the patent owner to the PTO that the '884 patent claims the drug citalopram; and (b) demonstrates the patent owner's reliance on this interpretation . . . .

Id., at 2 (emphasis omitted). Alphapharm also attached a letter from Forest, and said of it that it "constitutes evidence that Forest, the NDA holder and licensee under the '884 patent, believes that the '884 patent (a) claims the drug citalopram and (b) could reasonably be asserted against an unauthorized person or entity engaged in the manufacture, use or sale of citalopram." Id. (emphasis omitted). Alphapharm concluded its letter by stating that "Forest Laboratories should have submitted statutorily required patent information to FDA for the '884 patent, and has failed to do so." Id.

On December 16, 2002, FDA sent a letter to Forest, attaching Alphapharm's letter and requesting that Forest provide it with "written confirmation that the challenged data is correct or not correct pertaining to [its] Celexa NDA," and with "any corrections that need to be made to the patent and exclusivity information" relating to listing in the Orange Book. Id., tab 4. Forest responded on January 14, 2002, stating in a letter to FDA that

> the submission of patent information for Celexa™ is accurate, and complies with the requirements of U.S.C. §355(b)(1) and 21 C.F.R. §314.50(h) and §314.53(b). In addition, all of the information in the Request for Patent Term Extension for U.S. Patent No. ['884] is accurate.
>
> U.S. Patent No. ['884] is eligible for Patent Term Extension pursuant to 35 USC 156, but is not eligible for Orange Book listing (because it claims an intermediate of citalopram hydrobromide and a method of its manufacture).

Id., tab 5. FDA forwarded this response to Alphapharm. FDA did not (and continues not to) list the '884 patent in the Orange Book.

Four and a half years after approval of Forest's NDA, (on January 17, 2003), Alphapharm submitted an ANDA application for generic citalopram. The application included a paragraph IV certification of invalidity and noninfringement of the '884 patent. On March 20, 2003, FDA informed Alphapharm that the

> ANDA would not be received for substantive review pursuant to 21 C.F.R. § 314.101(b)(1), because (a) the application contained a paragraph IV certification

> against the '884 patent which the agency had declined to include in the Orange Book; and (b) only an ANDA with a paragraph IV certification against a listed patent could be received during the [five and a half] year combined [innovative drug and pediatric] exclusivity period awarded to this particular reference listed drug.

Compl., Ex. I, at 3. Thereafter, Alphapharm sent FDA four letters requesting reconsideration of its decision not to list the '884 patent and not to accept Alphapharm's ANDA. FDA responded on September 16, 2003, again declining to list the '884 patent or to receive Alphapharm's ANDA, and stating that, "[u]nless a patent is listed for Celexa, no applicant may submit an ANDA referencing that listed drug until the pediatric exclusivity on January 17, 2004," (five and a half years after approval of Forest's NDA). Admin. R., tab 10, at 3. Plaintiff instituted this action on November 5, 2003.

Analysis

Plaintiff complains that FDA's decisions not to list the '884 patent and not to receive Alphapharm's ANDA are arbitrary and capricious, not in accordance with the Administrative Procedure Act ("APA"), in excess of statutory authority, and in violation of the FDCA and related regulations. In reviewing these decisions of FDA, the first question I must answer is whether the language of the FDCA is clear and unambiguous. See Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc., 467 U.S. 837, 842-43 (1984). If I answer that

question in the affirmative, then the language of the FDCA controls. See id. But "if the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute." Id. at 843.

Alphapharm and FDA agree that this case turns on the propriety of FDA's decision not to list the '884 patent, since FDA may not receive any ANDA for review that references citalopram during its five and a half year exclusivity period unless the '884 patent is listed. Accordingly, I turn directly to the statutory provisions governing NDA applications and patent listing.

Because the '884 patent was issued long before Forest filed its NDA for citalopram (approximately ten years), 21 U.S.C. § 335(b)(1) determines Forest's obligations with respect to patents and FDA's related obligations with respect to listing. This provision states in relevant part that:

> [An NDA] applicant shall file with [its NDA] application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug. If an application is filed under this subsection for a drug and a patent which claims such drug or a method of using such drug is issued after the filing date but before approval of the application, the applicant shall amend the application to include the information required by the preceding sentence. Upon approval of

> the application, the Secretary shall publish information submitted under the two preceding sentences.

21 U.S.C. § 355(b)(1). The FDCA also provides in relevant part that

> [t]he Secretary shall, after due notice and opportunity for hearing to the applicant, withdraw approval of an application with respect to any drug under this section if the Secretary finds . . . the patent information prescribed by subsection (c) of this section was not filed within thirty days after the receipt of written notice from the Secretary specifying the failure to file such information.

Id. § 355(e)(4).

In published regulations, FDA has created a process to resolve disputes about the propriety of listing or, as is the case here, the propriety of not listing patents in the Orange Book:

> If any person disputes the accuracy or relevance of patent information submitted to the agency under this section and published by FDA in the list, or believes that an applicant has failed to submit required patent information, that person must first notify the agency in writing stating the grounds for disagreement. . . . The agency will then request of the applicable new drug application holder that the correctness of the patent information or omission of patent information be confirmed. Unless the application holder withdraws or amends its patent information in response to FDA's request, the agency will not change the patent information in the list. If the new drug application holder does not change the patent information submitted to FDA, a 505(b)(2) application or an abbreviated new drug application under section 505(j) of the act submitted for a drug that is claimed by a patent for which information has been submitted must, despite any

> disagreement as to the correctness of the patent information, contain an appropriate certification for each listed patent.

21 C.F.R. § 314.53(f). These regulations commit the resolution of disputes between ANDA applicants and patent holders regarding the validity or correctness of the listed patent information to actions between ANDA applicants and patent holders, rather than to FDA action.[1] See 59 Fed. Reg. 50,338, 50,348 (Oct. 3, 1994); see also 35 U.S.C. § 271.

FDA asserts that the Court's Chevron inquiry can end at step one, because this language of the FDCA is clear and unambiguous. FDA argues that the FDCA delegates to it only "a ministerial duty to list patents," that "FDA is not required to determine independently whether a patent meets the statutory criteria for listing," and that FDA may not list a patent unless the NDA applicant submits the patent information for listing. Defs.' Mem., at 16-17. Forest having certified that there are no patents relevant to its NDA, FDA says refusal to list the '884 patent in the Orange Book was consistent with its purely ministerial duty.

Alphapharm submits that "FDA's 'ministerial role'

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[1]FDA concedes that Alphapharm is not likely to have an opportunity to seek remedy under these provisions against Forest through private litigation. See Defs.' Mem., at 23 n.10; Defs.' Reply, at 12-13, 12 n.13. It argues, however, that the lack of remedy against Forest does not imply a remedy against FDA, see Defs.' Mem., at 23 n.10.

approach to its duty regarding patent listings is an impermissible interpretation [of the Hatch Waxman amendments] . . ., and renders 21 U.S.C. § 355(e)(4) meaningless and superfluous." Pl.'s Mem., at 23. It argues that §§ 355(b)(1) and (e)(4) must be read together, and that they require FDA it take appropriate (i.e. substantive) action to determine whether a patent belongs in the Orange Book.

On its face, § 355(b)(1) prescribes apparently ministerial duties, and nothing in § (b)(1) itself suggests that it is limited by § (e)(4) or any other subsection. Section (e)(4), however, is limited by another subsection -- subsection (c). 21 U.S.C. § 355(e)(4) ("The Secretary shall, after due notice and opportunity for hearing to the applicant, withdraw approval of an application with respect to any drug under this section if the Secretary finds . . . the patent information prescribed by subsection (c) of this section was not filed within thirty days after receipt of written notice from the Secretary specifying the failure to file such information." (emphasis added)). Subsection (c) prescribes the filing of patent information described in subsection (b) that "could not be filed with the submission of an application under subsection (b) of this section because the application was filed before the patent information was required under subsection (b) of this section or a patent was issued after the application was approved under such

subsection." Id. § 355(c)(2). In other words, subsection (c) addresses patent information that either post-dates the effective date of the Hatch-Waxman amendments, or patent information that comes into existence after approval of an NDA. This is not the same patent information mentioned in subsection (b)(1), which includes patent information that exists at the time of and is filed with the submission of an NDA, or patent information concerning a patent issued after the filing date but before approval of an NDA application.[2] These provisions are clear and unambiguous, and they support FDA's "ministerial role" theory.

Even if there were enough ambiguity in these provisions to move to Chevron step two, FDA's reading of its duties regarding patent listings is the most natural one. This Court will "set aside an FDA decision only if it is 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.'" Purepac, 354 F.3d at 883 (quoting 5 U.S.C. § 706(2)(A)). "FDA interpretations of the FDCA receive

[2]Even if subsection (e)(4) did apply to subsection (b)(1), it is not clear to the Court that it requires more than that FDA ensure the filing of certain documents, (as opposed to requiring a substantive review of those documents). See 21 U.S.C. § 355(e)(4) ("The Secretary shall, after due notice and opportunity for hearing to the applicant, withdraw approval of an application with respect to any drug under this section if the Secretary finds . . . the patent information prescribed by subsection (c) of this section was not filed within thirty days after the receipt of written notice from the Secretary specifying the failure to file such information.").

deference, as do its interpretations of its own regulations." Id. (internal citations omitted).

The Federal Circuit recently observed that FDA's "interpretation of the [Hatch-Waxman] Act set forth in 21 C.F.R. § 314.53(f) is a reasonable one: that the Act does not require it to police the listing process by analyzing whether the patents listed by NDA applicants actually claim the subject drugs or applicable methods of using those drugs." Apotex, Inc. v. Thompson, 347 F.3d 1335, 1349 (Fed. Cir. 2003).[3] This reading is consistent with FDA's claim, first announced shortly after the enactment of the Hatch-Waxman amendments, that it "has no expertise in the field of patents," and, therefore, "no basis for determining whether a use patent covers the use sought by the generic applicant." 54 Fed. Reg. 28,872, 28,909 (Jul. 10, 1989);

[3]Alphapharm's contention that FDA "openly admitted in [Apotex] that i[t] has a duty to ensure that a patent which should be listed is listed, and the Federal Circuit reiterated this position in its opinion," Pl.'s Mem., at 27, is belied by the language in the opinion itself: "Instead, the appellees [who are defendants here] contend that [§ 355(d)(6) and (e)(4)] require FDA to take action, if at all, only when the NDA's recitation of applicable patents is underinclusive (i.e., when pertinent patent information is omitted from the NDA), not when it is overinclusive (i.e., when the NDA contains patent information that should not be included)." Apotex, 347 F.3d at 1348 (emphasis added). Moreover, as the Fourth Circuit stated, "if Congress had meant for FDA to ensure that Orange Book listings are neither underinclusive nor overinclusive, it would have not have used the language it did . . . ." aaiPharma Inc. v. Thompson, 296 F.3d 227, 241 (4th Cir. 2002).

see also, e.g., aaiPharma, 296 F.3d at 241 ("[T]he FDA's reading of the statute is reasonable in light of the division of intellectual labor established by the Hatch-Waxman Act. FDA points out that the whole point of the Act's paragraph IV certification scheme is to let private parties sort out their respective intellectual property rights through patent infringement suits while FDA focuses on its primary task of ensuring that drugs are safe and effective. This division of labor is appropriate because FDA has no expertise in making patent law judgments.").

As the Fourth Circuit explained (in reviewing the "ministerial role" theory in the context of a § (c)(2), § (d)(6)[4], and § (e)(4) challenge), another reading would vastly expand the patent listing role of FDA:

> There can be no question that the FDA's reading . . . is reasonable. Indeed, [the] requirement that the FDA "shall file" the patent information submitted by NDA holders is most naturally read to suggest that Congress intended for the FDA to play a purely ministerial role. . . . According to [plaintiff, the FDA is obligated] to independently determine whether the NDA applicant has

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[4]Section (d)(6) provides:

> If the Secretary finds, after due notice to the applicant in accordance with subsection (c) of this section and giving him an opportunity for a hearing, in accordance with said subsection, that . . . (6) the application failed to contain the patent information prescribed by subsection (b) of this section.

21 U.S.C. § 355(d)(6).

listed all the patents that meet the statutory criteria for Orange Book listing. We conclude, however, that the statute can reasonably be read to impose only a much more limited duty on the FDA. . . . [T]he FDA's duty is not to ensure the correctness of the list of patents submitted for Orange Book listing, but simply to ensure that either a patent list has been filed or a declaration has been made that there are no patents to be listed. . . . If . . . subsection (d)(6) commands the FDA to second guess the NDA applicant's judgments about which patents claim its drug, that command is not limited to cases in which a third party has questioned the correctness of those judgments. . . . [I]t would require the FDA to "screen the universe of patents to determine which ones should be listed[.]" . . . We conclude that on the better reading of subsection (d)(6), the FDA is required only to ensure that each

> NDA applicant has submitted either a list of patents claiming its drug or a declaration that there are no patents to be listed.

aaiPharma, 296 F.3d at 238-40 (internal citations omitted).[5] Moreover, the D.C. Circuit has questioned whether FDA could look behind an NDA holder's request to list or delist a patent. See Am. Bioscience, Inc. v. Thompson, 269 F.3d 1077, 1085 (D.C. Cir. 2001) ("Indeed, it is not at all clear to us that FDA, under its

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[5]The "ministerial role" reading of FDA's duties regarding patent listing also has been found reasonable by other courts, (albeit addressing variations of the issue currently before the Court). As a Maryland court explained:

> [I]t is paramount to keep in mind that the FDA, in deciding to make an Orange Book listing, is not acting as a patent tribunal. It has no expertise -- much less any statutory franchise -- to determine matters of substantive patent law. In making its decision to list a patent, therefore, it is entirely appropriate and reasonable for the FDA to rely on the patentee's declaration as to coverage, and to let the patent infringement issues play out in other, proper arenas, as is the clear intent of the Hatch-Waxman Amendments. In fact, the legislation clearly reflects that Congress recognized that the FDA had a very limited, ministerial role in patent fights between patentees and generic marketers -- that of taking information from the patentee, publishing that information in the Orange Book, and awaiting the institution and/or outcome of patent litigation. Indeed, at least one court has explicitly recognized that the FDA's Orange Book listing, as it is not based (by statute, regulation, or practice) on any substantive evaluation of the patent, for which the FDA lacks the necessary expertise in the first place, is a matter to be settled in private litigation between the parties, not as part of an agency adjudication.

Watson Pharms., Inc. v. Henney, 194 F. Supp. 2d 442, 445-46 (D.Md. 2001) (citation and emphasis omitted).

regulations, would be authorized to reject the obvious intent of an NDA holder even if it acted directly contrary to a court order.").

I find FDA's acceptance of nothing more than a "ministerial role" in patent listing to be reasonable, a permissible construction of the FDCA, and neither arbitrary or capricious. Indeed, under Alphapharm's theory, subsections (b)(1) and (e)(4) would require FDA to vastly expand its activities with respect to patent listing. Alphapharm has not pointed to anything to indicate that Congress intended such a role for FDA and I find that the statute does not do so. The policy issues implicated by Forest's behavior and Alphapharm's frustration are interesting, but they are not for me to resolve and should be raised with Congress.

Because I have found FDA's decision not to list the '884 patent reasonable, it follows that FDA properly refused to receive Alphapharm's ANDA application. See Pl.'s Mem., at 21 ("The FDA's ruling of September 16, 2003 refused to accept Alphapharm's ANDA for citalopram as of its January, 2003 submission date solely because it contained a paragraph IV

certification for the '884 patent, which FDA has refused to list in the Orange Book. Consequently, both of FDA's refusals hinge on its refusal to list).

JAMES ROBERTSON
United States District Judge

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ALPHAPHARM PTY LIMITED, Plaintiff, v. TOMMY G. THOMPSON, Secretary of Health and Human Services, *et al.*, Defendants.	:	Civil Action No. 03-2269 (JR)

ORDER

For the reasons that will be stated in a memorandum to be issued tomorrow, the defendants' motion for summary judgment [#8] is **granted**, the plaintiff's cross-motion for summary judgment [#11] is **denied**, plaintiff's motion to supplement administrative record [#13] is **granted**, plaintiff's motion to stay [#27] is **denied**, and the case is **dismissed**.

JAMES ROBERTSON
United States District Judge