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VIA HAND DELIVERY

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, Room 1061 (HFA-305)
Rockville, MD, 20852

CITIZEN PETITION

The undersigned, on behalf of Pfizer Inc ("Pfizer"), submit this petition under sections 505(b) and (j) of the Federal Food, Drug and Cosmetic Act ("FDCA" or "the Act") and sections 21 C.F.R. § 10.25 and § 10.30 to request that the Commissioner of Food and Drugs ("FDA" or "the Agency") adhere to the statutory limitations of section 505(j)(5)(B)(iv) of the Act in issuing final approvals to ANDA applicants. The recent public announcements of Alpharma Inc. and Teva Pharmaceutical Industries, Ltd. of a business arrangement with respect to the marketing of gabapentin capsules suggest that Alpharma's subsidiary Purepac Pharmaceutical Co. intends to "permit" Teva to share some of its 180-day "exclusivity" period under Section 505(j)(5)(B)(iv) of the Federal Food Drug and Cosmetics Act ("FDCA"). In return, Teva apparently intends to pay sales-based compensation to Purepac and in some unspecified manner "share" Purepac's potential risk for patent infringement damages Purepac might incur as a result of its own gabapentin sales. Thus, while marketing generic gabapentin under its own abbreviated new drug application ("ANDA"), Purepac also seeks to generate additional economic benefit by purporting to authorize FDA to approve Teva's ANDA before the statutory bar on approval has expired.

2004P-0227

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A. Action Requested

Pfizer requests that:

1) FDA acknowledge that the "market exclusivity" awarded by section 505(j)(5)(B)(iv) to the first-filed ANDA containing a paragraph (iv) certification is not a right or asset subject to transfer or waiver in favor of one or more specified subsequent ANDA applicants. The plain language of section 505(j)(5)(B)(iv) bars approval of subsequent ANDAs until 180 days after the earlier of the events specified by statute.

2) FDA deny any request that the Agency issue final approval to Teva's ANDAs 75-435 and 75-827, or any other ANDA for gabapentin capsules or tablets, until the prerequisites of section 505(j)(5)(B)(iv) of the Act, as in effect on December 7, 2003, are met; i.e., 180 days after the earlier of (a) Purepac beginning commercial marketing of the drug product approved under its ANDA or (b) a decision of a court from which no appeal can be taken as to the validity of U.S. patent number 6,054,482 or the noninfringing nature of any of the pending applications. A prompt and favorable response to Pfizer's request is essential to foreclose damage to any of the parties resulting from unwarranted expectations that FDA may act in violation of FDCA in giving effect to the arrangement contemplated by Purepac and Teva.

3) FDA deny any similar request for transfer or waiver of the statutory bar set forth in section 505(j)(5)(B)(iv).

B. Statement of Grounds

Pfizer Inc holds a number of authorizations to market gabapentin, which Pfizer, through its subsidiary Warner-Lambert, obtained by filing New Drug Applications containing detailed and proprietary studies under Section 505(b)(1) of FDCA. Pfizer has not transferred, licensed or accorded any right of reference in the

data supporting its gabapentin NDAs to any ANDA applicant. Pfizer markets gabapentin under the trade name Neurontin®.

The recent decision by the U.S. Court of Appeals for the District of Columbia Circuit in *Purepac Pharm. Co. v. Thompson*, 354 F.3d 877 (D.C. Cir. 2004) held that Purepac's ANDA for gabapentin capsules was the first ANDA to be filed containing a so-called paragraph (iv) certification with respect to U.S. patent number 6,054,482 (exp. April 25, 2017) (the "'482 patent"). Pursuant to the court's ruling, no other ANDA for gabapentin capsules, including Teva's ANDAs, can be made effective before the date which is 180 days after either Purepac commences commercial marketing or the '482 patent is held invalid or not infringed by final judgment from which no appeal may be taken. Patent litigation with respect of the '482 patent is ongoing in the District of New Jersey against Purepac, Teva and a number of other ANDA applicants, but no judgment has been entered. Purepac, however, has had an approval for its gabapentin capsules since September 12, 2003 and thus is free to commence marketing under FDCA subject to the requirements of the patent laws. Purepac has not yet commenced marketing but apparently intends to do so in the near future pursuant to its arrangement with Teva.

Pfizer believes that Purepac's attempted authorization or approval of Teva's ANDA is unfounded under FDCA and that FDA cannot shorten the 180-day waiting period imposed on Teva's ANDAs by Section 505(j)(5)(B)(iv). As explained below, there is no statutory basis for FDA to convert the benefit Purepac receives from this statutory waiting period into an alienable property right from which Purepac can derive economic benefit independent of gabapentin sales. While FDA may once have proposed a rule authorizing "exclusivity waivers", that proposed rule properly was withdrawn for legal and public policy reasons. The plain language of the statute, and the statute's intent of "protecting both the interests of drug manufacturers who produce new drugs and the interests of generic drug manufacturers and their consumers, " *Abbott Laboratories v. Young,* 920 F.2d 984, 985 (D.C. Cir. 1985), compel FDA to grant the relief requested.

I. The Plain and Unambiguous Language of FDCA Bars Accelerated Approval of TEVA's Pending Gabapentin ANDAs

The plain and unambiguous language of Section 505(j)(5)(B)(iv)[1] governs the effective date for approval of Teva's pending ANDAs for gabapentin capsules and tablets.

> 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 continuing [sic] 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.

Teva's gabapentin capsule ANDA and tablet ANDA both contain paragraph (iv) statements and both were filed after Purepac's corresponding applications containing paragraph (iv) certifications. Thus, Teva's applications can be approved only upon the expiration of the 180-day waiting period imposed by FDCA. Nothing in Section (j)(5)(B)(iv) admits of any exception to this waiting period; nor is there any other statutory language authorizing Purepac, or indeed FDA, to lift this bar.

Indeed, when FDA previously attempted to accelerate approval of later-filed ANDAs under its "successful defense" rule, the United States Court of Appeals for the District of Columbia rejected FDA's interpretation of FDCA. *Mova*

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[1] The Medicare Prescription Drug, Improvement and Modernization Act of 2003 ("MMA") significantly revised the provisions of 21 U.S.C. §355(j)(5)(B)(iv). However, the revised provisions do not apply to these ANDAs as they were pending prior to the enactment of the MMA.

Pharmaceutical Corp. v. Shalala, 140 F.3d 1060 (D.C. Cir. 1998). Notwithstanding FDA's public policy rationale for the "successful defense" rule, the court could not accept an interpretation that "permits later applications to be approved even though neither trigger has been satisfied." *Id.* at 1069. Similarly, courts have overturned FDA's interpretation of "a court decision" as contrary to the plain language of the statute; *Teva Pharmaceuticals, USA, Inc. v. FDA*, 182 F.3d 1099 (D.C. Cir. 1999); *Torpharm, Inc. v. Shalala*, 1997 WL 33472411 (D.D.C. Sep 15, 1997).[2] These decisions make clear that the Agency's role in administering 21 U.S.C. §355(j)(5)(B)(iv) is to apply the language as written.

As the 4th Circuit noted in reaching a conclusion identical to that reached by the D.C. Circuit in *Mova,*

> Congress has plainly laid out the requirements for the 180-day exclusivity period in the statute (albeit in tortured language), and, thus, our inquiry into Congressional intent must end there. Having found the exclusivity requirements embodied in the statutory language of *21 U.S.C.A. § 355*(j)(4)(B)(iv) clear and conclusive, we are bound to hold invalid any attempt to alter the terms of that statute.

Granutec, Inc. v. Shalala, 1998 U.S. App. LEXIS 6685 at *20 (April 3, 1998) (unpublished disposition).

Thus, the plain language must govern and defeat Purepac's effort to turn the benefit it derives from the statutory bar against final approval of Teva's application into a marketable asset comparable to a *bona fide* property right.

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[2] In the MMA, Congress specifically addressed this issue by more clearly defining the type of court decision that would operate as a "forfeiture event" and the terms of that "forfeiture" of the 180-day advantage, after which *all* approved ANDA applicants would be able to enter the market.

II. Purepac and Teva Cannot Properly Rely on FDA's Now-Withdrawn 1999 Rulemaking Proposal

In August of 1999, FDA proposed a comprehensive set of rules governing so-called generic "exclusivity" under Section 505(j)(5)(B)(iv). *180 Day Generic Exclusivity for Abbreviated New Drug Applications and Proposed Rule,* 64 Fed. Reg. 42873 (Aug. 6, 1999). In these proposals, FDA set forth certain situations in which a first-filed ANDA holder would be required to "forfeit" the benefit of the effectiveness bar imposed on subsequent ANDA filers, *id.* at 42877-79, and also proposed to allow first-filed ANDA holders to waive the limitation applicable to subsequent ANDA filers in whole or in part. *Id.* at 42881. FDA never adopted the proposed rule and, in fact, withdrew it with a pledge to "regulate directly from the statute and [other] applicable regulations," 67 Fed. Reg. 66593 (Nov. 1, 2002). Nevertheless, and despite continuing judicial signals that FDA should not depart from the express provisions of FDCA, Purepac and Teva apparently believe that FDA will continue to adhere to the waiver authorization proposed in the rulemaking. FDA should immediately advise these parties and the generic drug community generally that this belief is unfounded.

A. The 1999 Waiver Proposal Was Based on a Faulty Analogy

In addition to conflicting with the language of Section 505 (j)(5)(B)(iv), FDA's 1999 "waiver" proposal mistakenly relied on a prior FDA interpretation of Section 505(j)(5)(D) of the Act. Section (j)(5)(D) precludes ANDA filing for a period of five years following approval of an NDA for a new molecular entity or ANDA approval for three years following approval of an NDA amendment relying on new clinical investigations. It is intended to protect the interests of pioneer companies holding NDAs whose extensive proprietary testing provides support for ANDA filers. The statutory delays imposed by section 505(j)(5)(D) are dependent upon the subsequent applicant's reliance on and reference to the data contained in the listed drug's NDA or NDA supplement. Thus, FDA was acting consistently with those proprietary interests when it concluded in 1994 that "the submission or

approval of an ANDA when the holder of the exclusivity permits FDA to receive or approve the ANDA" could be authorized under Section 505(j)(5)(D). 59 Fed. Reg. 50338, 50359 (Oct. 3, 1994).

In explaining this interpretation of Section 505(j)(D), FDA made clear that "exclusivity" -- that is, the statutory delay in approving later applications -- was not in and of itself a transferable commodity:

> *New drug exclusivity is not a property right, but is rather a statutory obligation on the agency.* This statutory obligation is based on data and information in an *approved application.* Although an applicant may purchase an application or rights to data and information in an application (i.e., exclusive rights to a new clinical investigation), from which exclusivity would flow, *there is no property right to exclusivity itself that can be transferred separately and apart from the application or data upon which exclusivity is based.*

Id. (emphasis added).

The now-withdrawn 1999 proposal to permit first-filed ANDA holders to "waive" 180-day exclusivity in favor of a selected subsequent applicant collided with, rather than complemented, the 1994 rulemaking. Unlike the NDA holder who owns the proprietary data on which all ANDA filers rely, and who can transfer or assign rights in those data at its discretion, the first-filed ANDA applicant holds no transferable asset, and "no property right to exclusivity itself." *See id.* The ANDA approval bar imposed by Section 505(j)(5)(B)(iv) creates a period of market "exclusivity" for the first-filer, but, as FDA made clear in the 1994 rulemaking, that statutory benefit is not a transferable asset or property right.

B. The Decision in *Boehringer Ingelheim Corp. v. Shalala* Cannot Justify "Waiver" In Derogation of the Data Rights of an NDA Holder

In *Boehringer Ingelheim Corp. v. Shalala*, 993 F. Supp. 1 (D.D.C. 1997), a district judge declined "at this early juncture" to issue a temporary restraining order

to prevent FDA from approving a subsequently filed ANDA during the 180-day "exclusivity" period when the first-filed ANDA holder had "waived" with respect to the approved applicant. In its brief analysis, the District Court held that FDA's decision to implement the waiver was reasonable because it accelerated generic competition when the first filer was unwilling, or unable, to commence commercial marketing. *Id.* at 2. The *Boehringer Ingelheim* opinion, however, cannot support or justify the proposed Purepac/Teva arrangement.

The later decision of the Court of Appeals in *Mova* considered and rejected the rationale of *Boehringer Ingelheim*. Speaking to the argument that FDA could go beyond the statutory language of FDCA to accelerate generic marketing by subsequent ANDA filers, the Court said:

> The second applicant, even though it has designed its product well and avoided suit, is barred from selling its product until the first applicant's lawsuit finishes (maybe years later). The ingenious second applicant is thus harmed, and the public is deprived of the fruits of its ingenuity--a result seemingly at odds with Congress's apparent purposes, in enacting section 355(j)(5)(B)(iv), of rewarding innovation and bringing generic drugs to market quickly. . . .
>
> Yet ***we are not persuaded that this . . . anomaly suffices to show that a literal reading of the statute leads to results manifestly inconsistent with the intent of Congress.*** The legislative history of section 355(j)(5)(B)(iv) is limited, and fails utterly to specify or even provide any signals as to whether Congress intended that a second ANDA applicant who was not sued for patent infringement would have to wait until one of the statutory triggers was satisfied, or instead be able to immediately market its product. Congress may very well never even have thought about this question. ***But it is not inconceivable that Congress meant what the statute says, i.e., that the second applicant would have to wait for the first lawsuit to finish.***

140 F.3d at 1072 (emphasis added). Thus the Court of Appeals has clearly confirmed that, contrary to the district court's approach in *Boehringer Ingelheim*, the plain words of the statute govern the approval of ANDAs under Section 505(j)(5)(B)(iv).

C. The 1999 Proposal Did Not Support the Policy of the Hatch-Waxman Amendments to FDCA

The Hatch-Waxman amendments to FDCA represent a compromise between advancing the public interest in expediting and simplifying FDA approval of generic drugs and acknowledging the proprietary rights, including patent rights, of NDA holders. While, on first impression, permitting the transfer or assignment by "waiver" of 180-day exclusivity might appear to support accelerated availability of generic drugs, it does not acknowledge the statutory protection accorded NDA holders' proprietary data. In addition, opening the door to using first-filed status as a property right raises other serious policy concerns.

The 180-day approval delay is intended to benefit prudent ANDA filers who are the first to file an ANDA application containing a paragraph (iv) certification who believe that they can commercially market a generic product and have a *bona fide* challenge to the validity or coverage of patents listed by the NDA holder. As FDA noted in promulgating its proposed rules implementing the Hatch-Waxman Amendments,

> Every other exclusivity provision in the 1984 Amendments begins with date of approval of the application. Congress' decision to begin the 180-day period under section 505(j)(4)(B)(iv)(I) of the act from "the first commercial marketing of the drug," rather than from the effective date of the ANDA, serves a rational policy only if Congress contemplated a situation in which an approval of an ANDA is in effect but the applicant's decision not to market the drug deserves to be protected because a delay in marketing serves the public interest.

54 Fed. Reg. 28872, 28894 (July 10, 1989)

Allowing the first-filer to await the outcome of its patent challenge serves the public interest by allowing that filer to gain the benefit of the reward Congress intended without imposing, in a factual vacuum, an obligation to market imprudently. If the language of Section 505(j)(5)(B)(iv) is interpreted as written, generic companies will strive to file applications expeditiously where there is a reasonable prospect of ANDA approval, commercial marketing and successful patent litigation. In other words, the decision to file as contemplated by Hatch-Waxman would necessarily entail a serious business commitment and patent position justifying the 180-day exclusivity benefit.

On the other hand, with free alienability, an ANDA applicant can seek gain by producing a fileable – even if not ultimately approvable – application, thus vesting a new and potentially lucrative "waiver" asset. FDA would then have to devote even more resources to ensuring at the threshold that ANDA applications represented *bona fide* commercial initiatives. Similarly, with free alienability, an ANDA applicant with a weak patent position could speculate on the possibility that a subsequent applicant will come forward with a non-infringing product and drag out patent litigation, thus making good on the speculative filing. The Hatch-Waxman amendments were not intended to burden the courts with patent litigation induced by ANDA filers whose intention is to secure a marketable "exclusivity" rather than a commercial drug marketing opportunity. FDA's acquiescence in deals such as the one contemplated by Purepac and Teva invites and encourages speculation in "exclusivities", not investment in development of ANDA products that don't infringe on data and know how protected by valid patents

.C. Environmental Impact

The subject matter of this petition is not within any of the categories of action for which an environmental assessment is required pursuant to 21 C.F.R. § 25.22 (1999), and is exempt pursuant to 21 C.F.R. § 25.30(h) (1999) in that it is concerned with FDA's procedures in administering the Act.

D. Economic Impact

Not requested.

E. Certification

The undersigned certify, that, to the best of their knowledge and belief, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioners that are unfavorable to the petition.

Respectfully submitted,

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News Room

Press Release Archive

April 28, 2004

Alpharma and Teva Enter Into Agreement Relating to Gabapentin

Fort Lee, NJ...April 28, 2004 . . . Alpharma Inc. (NYSE:ALO), a leading global specialty pharmaceutical company, today announced it has entered into an agreement with Teva Pharmaceutical Industries, Ltd ("Teva") regarding gabapentin capsules and tablets, the generic version of Neurontin®, a product with annual brand sales of over $2 billion. The agreement provides for Teva to share a portion of Alpharma's potential patent litigation risks regarding a gabapentin launch and permits Teva to launch gabapentin within Alpharma's exclusivity period. The agreement also provides for certain payments to Alpharma based on Teva's sales during the exclusivity period and includes certain obligations for the supply and purchase of gabapentin active pharmaceutical ingredient.

"We are excited to enter into this agreement with Teva," commented Ingrid Wiik, President and Chief Executive Officer of Alpharma. "This alliance greatly enhances our launch prospects for gabapentin and will expedite consumer access to this important growing product at favorable prices."

In 2003, the United States Food and Drug Administration (FDA) granted Alpharma final approval for gabapentin 100 mg, 300 mg and 400 mg capsules and confirmed that the company is eligible for 180 day market exclusivity on these capsules. The company is awaiting final FDA approval for the 600 mg and 800 mg gabapentin tablets and expects confirmation that it has secured exclusivity for tablets as well. Apotex (a generic competitor) has again challenged Alpharma's eligibility for exclusivity in the U.S. District Court and this litigation is on-going. The company is also involved in patent litigation with Pfizer regarding gabapentin.

Alpharma Inc. (NYSE: ALO) is a growing specialty pharmaceutical company with expanding global leadership positions in products for humans and animals. Uniquely positioned to expand internationally, Alpharma is presently active in more than 60 countries. Alpharma is the #5 manufacturer of generic pharmaceutical products in the U.S., offering solid, liquid and topical pharmaceuticals. It is also one of the largest manufacturers of generic solid dose pharmaceuticals in Europe, with a growing presence in Southeast Asia. Alpharma is among the world's leading producers of several important pharmaceutical-grade bulk antibiotics and is internationally recognized as a leading provider of pharmaceutical products for poultry, swine, cattle, and vaccines for farmed-fish worldwide.

Statements made in this release include forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements, including those relating to future financial expectations, involve certain risks and uncertainties that could cause actual results to differ materially from those in the forward looking statements. Information on other significant potential risks and uncertainties not discussed herein may be found in the Company's filings with the Securities and Exchange Commission including its Form 10-K for the year ended December 31, 2003

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TEVA PHARMACEUTICAL INDUSTRIES LTD.

Press Release

Teva And Alpharma Enter Into Agreement Relating To Gabapentin

Jerusalem, Israel, April 28, 2004 - Teva Pharmaceutical Industries Ltd. (Nasdaq: TEVA) announced today that it has entered into an agreement with Alpharma Inc. (NYSE:ALO) pertaining to pending Abbreviated New Drug Applications (ANDAs) for gabapentin 600 mg and 800 mg tablets, and gabapentin 100 mg, 300 mg and 400 mg capsules, the bioequivalent versions of Pfizer's Neurontin® Tablets and Neurontin® Capsules. Neurontin® Tablets and Neurontin® Capsules had U.S. sales of over $2 billion for the twelve-month period ended December 31, 2003 according to IMS.

Alpharma holds a final ANDA approval for its gabapentin capsules and is awaiting final ANDA approval for the tablets. Teva Pharmaceuticals USA, Inc. ("Teva USA") currently holds tentative approvals for both the tablets and the capsules. The parties believe that the Alpharma ANDAs for the products are entitled, under the Hatch-Waxman Act, to a 180-day period of marketing exclusivity, although another generic manufacturer has challenged these rights in litigation pending in a U.S. District Court. Patent litigation is pending with Pfizer on these products.

Under the terms of the agreement, Alpharma will permit Teva USA to launch its gabapentin within Alpharma's exclusivity period, and Teva will make certain payments, based on Teva USA's sales, to Alpharma relating to the period of exclusivity. In addition, the parties have agreed to certain risk sharing arrangements relating to patent litigation risks regarding a gabapentin launch.

Mr. Israel Makov, President and CEO of Teva, commented: "We are pleased to enter into this agreement with Alpharma. We believe that this agreement will facilitate the introduction of the generic version of this important product and thereby significantly reduce its cost to the U.S. consumer."

Teva Pharmaceutical Industries Ltd., headquartered in Israel, is among the top 30 pharmaceutical companies and among the largest generic pharmaceutical companies in the world. The company develops, manufactures and markets generic and innovative human pharmaceuticals and active pharmaceutical ingredients. Close to 90% of Teva's sales are in North America and Europe.

Safe Harbor Statement under the U. S. Private Securities Litigation Reform Act of 1995: This release contains forward-looking statements, which express the current beliefs and expectations of management. Such statements are based on current expectations and involve a number of known and unknown risks and uncertainties that could cause Teva's future results, performance or achievements to differ significantly from the results, performance or achievements expressed or implied by such forward-looking statements. Important factors that could cause or contribute to such differences include Teva's ability to successfully develop and commercialize additional pharmaceutical products, the introduction of competitive generic products, the impact of competition from brand-name companies that sell their own generic products or successfully extend the exclusivity period of their branded products, Teva's ability to rapidly integrate the operations of acquired businesses, including its recent acquisition of Sicor Inc., the availability of product liability coverage in the current insurance market, the impact of pharmaceutical industry regulation and pending legislation that could affect the pharmaceutical industry, the difficulty of predicting U.S. Food and Drug Administration and other regulatory authority approvals, the regulatory environment and changes in the health policies and structure of various countries, acceptance and demand for new pharmaceutical products and new therapies, uncertainties regarding market acceptance of innovative products newly launched, currently being sold or in development, the impact of restructuring of clients, reliance on strategic alliances, exposure to product liability claims, dependence on patent and other protections for innovative products, fluctuations in currency, exchange and interest rates, operating results and other factors that are discussed in Teva's Annual Report on Form 20-F and its other filings with the U. S. Securities and Exchange Commission. Forward-looking statements speak only as of the date on which they are made, and the Company undertakes no obligation to update publicly or revise any forward-looking statement, whether as a result of new information, future developments or otherwise.

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