



September 26, 2002

Dockets Management Branch
U.S. Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, Maryland, 20852

CITIZEN PETITION

A. ACTION REQUESTED

On behalf of Andrx Pharmaceuticals, Inc. (Andrx), the undersigned submits this Petition under section 505(j) of the Federal Food, Drug and Cosmetic Act (FDCA), and 21 C.F.R. § 10.30, to request that the United States Food and Drug Administration (FDA) determine that Andrx, in its currently pending ANDA 76-159, will not be required to file a new certification or amend its current Paragraph I Certification with respect to U.S. Patent No. 6,361,795 (the '795 Patent) or a reissued version of the '795 patent in the event a reissue of the '795 patent is subsequently listed in the Orange Book.

Action on this Petition is urgently needed to

- (a) preempt future abuse by brand name drug marketers exploiting the complex but narrowly balanced provisions of the Hatch-Waxman Amendments; and
- (b) make a timely determination as to Andrx's right to proceed and obtain marketing approval for its generic extended release glipizide product, without any additional 30-month stay of approval because of a reissued patent listed in the Orange Book after filing of its ANDA 76-159;

Notably, this requested action does not in any way limit or preclude the patent owner in the enforcement of its lawful rights against infringers.

B. STATEMENT OF GROUNDS

1. Factual Background

Andrx filed its Abbreviated New Drug Application (ANDA), No. 76-159 in April 2001 for a generic version of Glucotrol XL[®] (glipizide extended release tablets, 10 mg). Following transmittal of notice to the NDA holder (Pfizer, Inc.) and holder of the Orange Book-listed patents (Alza Corporation) regarding the Paragraph IV Certification in this ANDA, both companies sued Andrx for patent infringement on July 9, 2001, pursuant to 35 U.S.C. § 271(e)(2). Consequently, FDA imposed a 30-month stay of approval on

03D-0426

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Andrx's ANDA pursuant to 21 U.S.C. § 355(j)(5)(B)(iii); that stay expires on November 29, 2003. Andrx is diligently defending that lawsuit in the U.S. District Court for the Southern District of Florida. A March 2003 trial date has been scheduled.

Subsequently, on March 26, 2002, over eight months after Pfizer and Alza sued Andrx, the Patent and Trademark Office (PTO) issued U.S. Patent No. 6,361,795 with specifications and claims relating to a composition for the delivery of glipizide (the same active drug that is the subject of the lawsuit). Apparently realizing the '795 patent claims, as issued, raised invalidity concerns, Alza almost immediately requested that the PTO reissue the patent to make the claims narrower. On April 25, 2002, the patent holder, Alza Corporation, sent a letter to FDA's Orange Book staff stating in its entirety:

ALZA Corporation wishes to identify U.S. Patent No. 6,361,795 B1 (issued to ALZA Corporation March 26, 2002; expires March 26, 2019). This patent relates to Pfizer Corporation's NDA 20-329, for Glucotrol XL[®].

Publication by the Agency of U.S. Patent No. 6,361,795 is not requested at this time, e.g., in the *Approved Drug Products with Therapeutic Equivalence Evaluations*, the 'Orange Book', because ALZA Corporation has submitted the patent for reissue by the Patent and Trademark Office. ALZA Corporation wishes to make this patent of record with the FDA, however, (i) so that anyone desiring notice of patents may become aware of it, and (ii) to preserve ALZA Corporation's right to file any reissued patent in the Orange Book.

Copy attached at Tab A. Notably, Alza's letter identifies the patent number and the NDA and admits that they are "related."

On May 14, 2002, Andrx amended its ANDA to include a Paragraph IV Certification with respect to the '795 patent in which Andrx certified "that the '795 patent will not be infringed by the making, using, or selling of Andrx's proposed product because the '795 patent is invalid or unenforceable." Andrx further provided notice of the May 14, 2002 Paragraph IV Certification to Pfizer and Alza that included a detailed statement of factual and legal bases in support of Andrx's position that the '795 patent is invalid and/or would not be infringed by Andrx's glipizide product.

On June 12, 2002, Alza's attorney sent a letter to Andrx challenging the validity of Andrx's Paragraph IV submission, stating in part that the submission "cannot be a Paragraph IV Certification since the '795 patent is not 'listed' in the Orange Book; accordingly, the May 14 document is a legal nullity." Tab B. In its June 12 letter, Alza did not take the position that the '795 patent claims did not cover the drug product, nor could they since they admitted that the '795 patent and the NDA were related. Instead,

Alza advised FDA that upon reissuance, Alza would then consider whether to list the '795 patent in the Orange Book:

Alza has specifically asked that the '795 patent not be listed in the Orange Book at this time....Alza has requested the Patent and Trademark Office begin a Reissue proceeding for the '795 patent and has proposed amendments to the patent's claims. Obviously, Alza is not aware of precisely what claims will be contained in the final reissue certificate. Once the Reissue Certificate issues, Alza will review the final claims to determine whether they should be listed in the Orange Book, e.g., for Glucotrol XL[®].

On June 13, 2002, Pfizer's attorney wrote a letter to Andrx stating that the '795 patent "has not been listed" in the Orange Book and "consequently, Andrx's Paragraph IV Certification as to the '795 patent is improper and a legal nullity." Pfizer's letter also noted that Alza has sought reissuance of the '795 patent with amended claims, and that:

Pfizer does not intend to assert infringement of the '795 patent against Andrx and its affiliated corporate entities until the PTO completes its consideration of Alza's reissue petition. When new claims are issued, Pfizer will review the claims to determine: (a) if the reissued patent should be listed in the Orange Book to Glucotrol XL[®], and (b) if any reissued claim covers [Andrx's] extended release glipizide product.

Tab C.

FDA has taken the position that the '795 patent will not be listed in the Orange Book, since Pfizer, the NDA holder, has not directly requested it, even though Pfizer's licensee and co-plaintiff has supplied the necessary information needed to list the patent in the Orange Book.¹

¹ While Andrx generally supports FDA's position that only the NDA holder can appropriately request a patent to be listed in the Orange Book, in this case, Alza is both Pfizer's licensee and co-plaintiff in the litigation. Furthermore, since Alza is not the NDA holder, it is curious that Alza felt the need to identify the patent to FDA at all. Presumably, even if the '795 patent is reissued, FDA will take the same position it already has- that is, not list a reissued '795 patent in the Orange Book based upon a request by Alza. The only possible explanation for Alza to even supply the information to FDA in the first place is to avoid FDA's prohibition of listing patents in the Orange Book 30 days post-issuance of the patent. As discussed more fully below, Pfizer and Alza cannot have it both ways; i.e. Pfizer, as the NDA holder, had a choice: (1) timely list the '795 patent in the Orange Book and start the process for any new potential 30 month regulatory stay, or (2) not list it timely, while being aware of its existence and relationship to the NDA product and thus be subject to a paragraph I certification. It is also noteworthy that Alza did not have to let the '795 patent issue in the first place. Instead of paying the issue fee, Alza could have withdrawn the application from allowance, or it could have filed a continuation

2. Legal Background

a. Patent Listing and Certification Criteria.

Under the patent listing provisions of the FDCA and FDA's implementing regulations, the sponsor of a New Drug Application (NDA) is required to submit to FDA "the patent number and the expiration date of any patent which claims the drug for which the [NDA] 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." 21 U.S.C. § 355(b)(1).

ANDA applicants must submit 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 . . . and for which information is required to be filed under subsection (b) or (c)." 21 U.S.C. § 355(j)(2)(A)(vii). A Paragraph IV Certification alleges that the patent is invalid, unenforceable, or will not be infringed by the ANDA product.

b. The 30-Day Patent Listing Deadline and The Consequences of Late-Listing of Patents

FDA regulations impose a strict 30-day deadline for the submission to FDA of newly issued patents for listing in the Orange Book. 21 C.F.R. § 314.53(d)(3). *See* 59 Fed. Reg. 50338, 50344 (Final Rule, Oct. 3, 1994). If an NDA sponsor fails to meet the 30-day listing deadline (late-listing), an applicant having a pending ANDA at the time of late listing is not required to amend its ANDA patent certification or to file a new certification to address that patent. 21 C.F.R. § 314.94(a)(12)(vi).

The rationale behind the 30-day listing deadline is to provide fairness to the ANDA filer. As FDA noted in the preamble to the final regulations, failure to timely list a patent may "result in injury to other applicants who devote resources towards submitting applications for duplicate products without realizing that those products may be covered by the patent." *Id.* FDA actually refused to allow a longer 60-day deadline, noting further that "potential [ANDA] applicants might be misled by outdated patent information." *See also* 54 Fed. Reg. 28872, 28910 (Proposed Rule, July 10, 1989) (noting that "Congress clearly intended to enforce timely [patent] submission."). The consequence of these strict rules on Orange Book patent listings is that an ANDA applicant can obtain approval of its application without being subjected to the 30-month stay based on a late-listed patent. 35 U.S.C. § 271(e)(2), 21 U.S.C. § 355(j)(5)(B)(iii).

application, to seek the same claims it is now seeking on reissue, only weeks after the '795 patent issued. Alza, however, did allow the '795 patent to issue and should now be constrained by its decision.

c. Reissuance and Intervening Rights

Under the patent law, an issued patent may be “reissued” if “through error without any deceptive intention, [the patent is] deemed wholly or partly inoperative or invalid, by reason of a defective specification or drawing, or by reason of the patentee claiming more or less than he had a right to claim.” 35 U.S.C. § 251. In a reissued patent, the claims may stand as originally issued, may be broadened (if a reissue is requested within two years of the original issuance) or narrowed, or may be rejected entirely as unpatentable, leaving no patent at all. Reissuance of a patent does not, however, create a new and independent patent, separate and apart from the original patent to which it relates. In fact, if a patent is reissued, the PTO assigns a reissue number designated by the prefix “RE-” and specifically references the original patent number on the face of the reissued version. And, even though the original patent is procedurally “surrendered” upon reissuance of the patent, any original claims that are “substantially identical” to claims that remain in the reissued patent may continue to be enforced as of the date of original issuance. 35 U.S.C. § 252.

Importantly, Congress recognized that a reissued patent could unfairly affect persons who engaged in certain activities in reliance on the original claims, only to find that those activities potentially infringe the claims of the reissued patent. To avoid retroactive enforcement of modified claims in the reissued patent, Congress provided that a reissued patent “shall not affect the right of any person” to continue using or selling a specific thing validly covered by the claims of the reissued patent, but not validly covered by the claims of the patent as originally issued. In addition, manufacture, use, and sale of a thing covered by the reissued patent may be permitted even if the person did not make, use, or sell the patented item, but made “substantial preparation” for such manufacture, use, or sale prior to the reissuance of the patent. 35 U.S.C. § 252. These concepts are known as “intervening rights.”

C. ARGUMENT

Andrx Should Not Be Required To Submit a New Patent Certification To A Reissued Version of the '795 Patent

The current situation with respect to the possible Orange Book listing of a reissued '795 patent raises a serious matter that FDA must address so as to preserve the pro-competitive intent of Hatch-Waxman and avoid a policy that would provide for further abuse of Hatch-Waxman and/or an anticompetitive result. Specifically, the proper balancing of interests between Pfizer and Andrx requires that Andrx not be required to amend its ANDA with regard to any patent certification for the '795 patent if it is later reissued and listed. Statutory requirements and strong public policy reasons compel FDA to adopt this approach.

Under the plain language of the governing statutory and regulatory provisions, an NDA applicant must submit patent information for listing in the Orange Book within 30 days “of issuance” of the patent. 21 U.S.C. § 355(b)(1), 21 C.F.R. § 314.53(d)(3). The statute and regulations do not provide for an extension of time, or a second chance, to list a “reissued” patent. Those regulations unequivocally allow pending ANDA sponsors to forego amending their ANDA patent certifications for any late-listed patents:

If a patent on the listed drug is issued and the holder of the approved application for the listed drug does not submit the required information on the patent within 30 days of issuance of the patent, an applicant who submitted an abbreviated new drug application for that drug that contained an appropriate patent certification before the submission of the patent information is not required to submit an amended certification.

21 C.F.R. § 314.94(a)(12)(vi) (emphasis added). More than 30 days have passed since the issuance of the '795 patent and the '795 patent has not been listed in the Orange Book. If Pfizer decides to list it for the first time after it is reissued (assuming it does get reissued), it must be deemed to be a late-listed patent under FDA's regulations. The statutory and regulatory language is unambiguous in this respect – the date “of issuance” cannot be construed to also mean the date “of reissuance.” Thus, FDA and the courts would not be authorized to require Andrx to amend its certification to respond to the late listing of the reissued patent.² Accordingly, listing of a reissued '795 patent should be deemed to be a late listing with respect to Andrx's previously pending ANDA.³

Moreover, as a matter of public policy, the rationale behind the late listing rule – i.e., protection of ANDA applicants' reliance on the patent landscape as it stands at the time of its ANDA filing – closely mirrors the rationale behind the intervening rights doctrine. Both serve to protect investment-backed expectations based on the status of

² *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984).; *IMS, P.C. v. Alvarez*, 129 F.3d 618, 621 (D.C. Cir. 1997) (“an agency's failure to follow its own regulations is fatal to the deviant action.”); *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512 (1994) (deference is not appropriate if the agency interpretation “is plainly erroneous or inconsistent with the regulation.”).

³ Andrx acknowledges FDA's historical reluctance to consider or address patent law issues, but in this situation, where FDA's regulations specifically incorporate and turn upon patent law terminology – i.e., when a patent “is issued” – the Agency simply has no choice but to consider and decide the matter raised here. As admitted in Alza Corporation's letter to the FDA, there can be no question that '795 patent claims are related to, i.e., cover the drug product. Andrx suggests that FDA may consult with the PTO as necessary on these issues, but, at the same time, believes that FDA can appropriately and defensibly grant this Petition using its own highly skilled legal personnel and resources, especially in light of the admissions made by Alza and Pfizer in the correspondence attached hereto as Exhibits A, B and C.

patents as originally issued. *See supra* at Sections B.2.b. – B.2.c. Hence, Andrx, having reasonably relied on the original issuance, but non-listing of the '795 patent, should not be penalized by requiring amendment of its ANDA certification if the patent is later listed for the first time after reissuance. Deeming a reissued '795 patent to be late-listed avoids an unfair and unauthorized extension of the 30-month stay against Andrx, in the event the patent holder brings an infringement action within 45 days of an FDA-mandated recertification to the late listed reissue patent. In addition, requiring such a certification amendment would be unnecessary to protect the claims of the patent as reissued, because the patent holder will be entitled to attempt to enforce its reissued patent against any generic applicant's commercial sale of an allegedly infringing product.

Additionally, FDA has been made aware of the '795 patent by Pfizer, through its patent licensor Alza. Pfizer and Alza have also informed FDA and Andrx that they believe the '795 patent discloses a patentable invention that may be asserted against Andrx if the requested "correction(s)" to the originally issued claims are granted, and have clearly admitted that the original '795 patent claims relate to (i.e., cover) Pfizer's NDA Glucotrol XL® product.⁴ In response to Alza's submission of the '795 patent to FDA, Andrx submitted its Paragraph IV Certification and Paragraph IV Notifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii). Although Andrx believes that its Paragraph IV Certification was proper despite notification from FDA that the '795 patent was not officially listed in the Orange Book, Andrx has now submitted a Paragraph I Certification to avoid any further delay in the regulatory review of its ANDA. As a result of Andrx's Paragraph I Certification, the '795 patent can now impose no barrier to immediate final approval of Andrx's ANDA. 21 U.S.C. § 355(j)(5)(B)(3)(i).

Even assuming *arguendo* that the reissued '795 patent is later listed in the Orange Book, Andrx submits that it would be fundamentally unfair to later delay Andrx's approval of its already pending ANDA by imposing a second 30-month stay because of a reissued '795 patent where the original patent could have been listed by the NDA holder in the Orange Book, and where it was, in fact, made of record with the FDA Orange Book Staff. Permitting an additional 30-month stay for a reissued '795 patent would, in this instance, bestow a windfall extension of exclusivity unintended by and contrary to the Hatch-Waxman amendments, which were intended to help advance and expedite the availability of generic drug products. In addition, it would be especially egregious if FDA were to grant any other generic company a 180-day exclusivity period against Andrx based on a Paragraph IV Certification to a reissued version of the '795 patent, given Andrx's good faith efforts to challenge the patent as originally issued.

⁴ If this were not the case, why else, then, would Alza have submitted information to FDA's Orange Book staff? Alza's intentions are especially transparent when considering that Alza's stated purpose was to provide notice to others and to preserve the right to file the patent in the Orange Book after reissuance.

Accordingly, FDA should specifically determine that Andrx shall not be required to amend its certification or otherwise certify to any future listing of a reissued patent arising out of the '795 patent.

D. CONCLUSION

Andrx's ANDA contains a valid Paragraph I certification to the '795 patent that is and will remain operative regardless of whether that patent is the subject of a reissue procedure and later listed in the Orange Book. Therefore, any reissue of the '795 patent must be considered the same as the '795 patent for purposes of FDA's regulatory patent certification scheme as it pertains to Andrx's ANDA, such that any future listing of a reissued version of the patent will be deemed "late listed" and would not subject Andrx to any additional 30-month stay of approval.

E. ENVIRONMENTAL IMPACT

The actions requested by this Petition are subject to categorical exclusion pursuant to 21 C.F.R. § 25.30.

F. ECONOMIC IMPACT

An Economic Impact Statement will be provided at the request of the Commissioner.

G. CERTIFICATION

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

Respectfully submitted,



Andrx Pharmaceuticals, Inc.

TAB A



April 25, 2002

VIA FACSIMILE AND FEDERAL EXPRESS

Ms. Mary Ann Holovac
US Food and Drug Administration
Center for Drug Evaluation and Research
Division of Data Management and Services
Information Services Team
HFD-93 Room #3012
12420 Parklawn Drive
Rockville, MD 20857

Re: NDA NO. 20-329

Dear Ms. Holovac,

ALZA Corporation wishes to identify U.S. Patent No. 6,361,795 B1 (issued to ALZA Corporation March 26, 2002; expires March 26, 2019). This patent relates to Pfizer Corporation's NDA 20-329, for Glucotrol XL[®].

Publication by the Agency of US Pat. No. 6,361,795 is not requested at this time, e.g., in the *Approved Drug Products with Therapeutic Equivalence Evaluations*, the "Orange Book", because ALZA Corporation has submitted the patent for reissue by the Patent and Trademark Office. ALZA Corporation wishes to make this patent of record with the FDA, however, (i) so that anyone desiring notice of patents may become aware of it and; (ii) to preserve ALZA Corporation's right to file any reissued patent in the Orange Book.

Respectfully Submitted,
ALZA CORPORATION

A handwritten signature in cursive script that reads "Michelle M. Daigneault".

Michelle M. Daigneault
Assistant Corporate Secretary

TAB B

Patterson, Belknap, Webb & Tyler LLP

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June 12, 2002

By FedEx

Ted W. Whitlock, Esq.
Intellectual Property Counsel
Andrx Pharmaceuticals, LLC
707 East Main Street
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Richmond, VA 23219

Re: U.S. Patent No. 6,361,795 B1

Dear Mr. Whitlock:

As you know, we are counsel to Alza Corporation. Alza has received a document concerning U.S. Patent No. 6,361,795 ("the '795 patent") signed by you, dated May 14, 2002, and entitled "Supplemental Patent Certification Under 21 C.F.R. § 314.94 and Notice of Certification of Invalidity or Noninfringement of a Patent Under 21 C.F.R. § 314.95" ("the May 14 Document"). This document purports to be a Paragraph IV Certification concerning Andrx' generic version of Glucotrol XL[®] - Pfizer's Glipizide Extended Release Tablet - and further purports to be a Paragraph IV Certification sent in compliance with 21 U.S.C. § 355(j)(2)(A)(vii) and 21 C.F.R. § 314.94(a)(12). In fact, the May 14 Document cannot be a Paragraph IV Certification since the '795 patent is not "listed" in the Orange Book; accordingly, the May 14 Document is a legal nullity.

A Paragraph IV Certification is only appropriate when a patent has been listed in the "Orange Book" (the listing of *Approved Drug Products with Therapeutic Equivalence Evaluations*). There has been no request that the '795 patent be listed in the Orange Book concerning Glucotrol XL[®]. In fact, as Andrx' counsel is aware and should have shared with you,

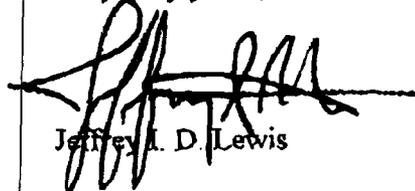
Ted W. Whitlock, Esq.
June 12, 2002
Page 2

Alza has specifically asked that the '795 patent not be listed in the Orange Book at this time. Therefore, there is no predicate for a Paragraph IV Certification.

Your counsel also should have told you that Alza has requested the Patent & Trademark Office begin a Reissue proceeding for the '795 patent and has proposed amendments to the patent's claims. Obviously, Alza is not aware of precisely what claims will be contained in the final Reissue Certificate. Once the Reissue Certificate issues, Alza will review the final claims to determine whether they should be listed in the Orange Book, e.g., for Glucotrol XI.[®] At that time Alza also will consider whether the final claims relate to any Andrx product or proposed product known to it. Until then, however, Alza cannot conduct such a review nor can it have a belief concerning whether Andrx' proposed extended release glipizide product infringes the '795 patent.

As a final matter, the May 14 Document suggests that Andrx has submitted a Notice to the U.S. Food & Drug Administration ("FDA") concerning the '795 patent and Andrx' purported Paragraph IV Certification. If such a Notice has been filed, we trust it will be withdrawn immediately and Alza's position made clear to the FDA.

Very truly yours,



Jeffrey A. D. Lewis

cc: Milton Sherman, Esq. (By Fax)
Alan Clement, Esq. (By Fax)

TAB C

KAYE SCHOLER LLP

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June 13, 2002

VIA FEDERAL EXPRESS

Ted W. Whitlock, Esq.
Intellectual Property Counsel
Andrx Pharmaceuticals, L.L.C.
707 East Main Street
11th Floor
Richmond, Virginia 23219

Re: Andrx Notice of Certification dated May 14, 2002
re U.S. Patent No. 6,361,795

Dear Mr. Whitlock:

Pfizer has requested that we evaluate and respond to the Supplemental Patent Certification Under 21 CFR § 314.94 and Notice of Certification of Invalidity or Noninfringement of a Patent Under 21 CFR § 314.95, dated May 14, 2002, in which Andrx Pharmaceuticals, L.L.C. ("Andrx") purports to make a "Paragraph IV certification" with respect to United States Patent No. 6,361,795 (the "'795 patent") owned by Alza Corporation. We were provided with the Notice by Alza and Pfizer has no record of having received it.

The '795 patent has not been listed in the FDA publication *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") with respect to Pfizer's extended release glipizide tablets, Glucotrol XL[®]. Consequently, Andrx's Paragraph IV certification as to the '795 patent is improper and a legal nullity. See 21 U.S.C. § 355(j)(2)(A)(vii) and 21 CFR § 314.94(a)(12).

As Andrx and its affiliated corporate entities are aware, Alza has submitted the '795 patent to the United States Patent and Trademark Office ("PTO") with a petition for reissue, and has filed a Preliminary Amendment seeking to amend the claims. Pfizer does not intend to assert infringement of the '795 patent against Andrx and its affiliated corporate entities until the PTO completes its consideration of Alza's reissue petition. When new claims are issued, Pfizer will review the claims to determine: (a) if the reissued patent should be listed in the Orange Book to Glucotrol XL[®], and (b) if any reissued claim covers the extended release glipizide product for which Andrx and its affiliated corporate entities have submitted ANDA No. 76-159 ("Andrx's

KAYE SCHOLER LLP

Ted W. Whitlock, Esq.

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June 13, 2002

Glipizide ANDA Product"). Pfizer has not made a determination of whether Andrx's Glipizide ANDA Product infringes the '795 patent at this time because Alza's petition for reissue and proposed amended claims have not yet been acted on by the PTO.

Very truly yours,



Milton Sherman

cc: Jeffrey I.D. Lewis, Esq. (via facsimile)
Alan B. Clement, Esq. (via facsimile)