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July 3, 2003

VIA U.S. MAIL

Dockets Management Branch
Food and Drug Administration
Room 1-23
12420 Parklawn Drive
Rockville, MD 20857

Re: Docket Number 02P-0447 (Citizen Petition) - Submission of Second Supplemental Comments by Dr. Reddy's Laboratories, Inc.

Dear Sir or Madam:

Please accept the attached second supplemental comments (in four copies) submitted on behalf of Dr. Reddy's Laboratories, Inc., in response to the Citizen Petition filed by Pfizer, Inc., on October 11, 2002.

Sincerely,

David G. Adams

2002P-0447 SUP2

July 3, 2003

VIA U.S. MAIL

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

Re: Docket Number 02P-0447 (Citizen Petition) – Second Submission of Supplemental Comments by Dr. Reddy's Laboratories, Inc.

Dear Sir or Madam:

These supplemental comments are submitted on behalf of Dr. Reddy's Laboratories, Inc., (Reddy) with regard to the Citizen Petition filed by Pfizer, Inc., (Pfizer) on October 11, 2002 (Pfizer Petition). This second submission of supplemental comments on behalf of Reddy[1] responds to supplemental comments filed by Pfizer on June 26, 2003 (Pfizer Sup.).

Pfizer makes two arguments in its June 26 comments: (1) that "Reddy's application does not fall within the 'Parkman policy,' because Reddy is seeking a change to an ANDA that may not be made under §505(j)" and (2) that "Reddy seeks approval at a time when Pfizer's patents prevent approval of an ANDA in the first instance."[2] Both arguments are without merit.

1. The "Parkman Policy" Does Not Limit 505(b)(2) NDAs to Modifications that Could Be Submitted Under Section 505(j).

Although Pfizer asserts that the Parkman Letter[3] did not contemplate modifications to an ANDA that are not "permitted for applications under section 505(j)," Pfizer acknowledges in the same discussion that the Parkman Letter expressly contemplated 505(b)(2) NDAs for modifications involving new indications.[4] Modifications involving new indications are not, of course, permitted under section 505(j). Pfizer appears to acknowledge this point by noting that the Parkman Letter

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1 Reddy's prior supplemental comments were submitted on June 4, 2003.

2 Pfizer Sup. at 3-4.

3 Letter to all NDA and ANDA holders and applicants from Paul D. Parkman, M.D., dated April 10, 1987.

4 Pfizer Sup. at 3.

referred to "changes that can be approved through a suitability petition *or an NDA supplement*."[5] While it is clear that a new indication can be approved under an NDA supplement, it is also clear that an NDA supplement is not permitted under section 505(j). As the Parkman Letter makes clear, an NDA supplement to an ANDA is, in fact, a 505(b)(2) NDA.[6] The Parkman Letter thus makes the point that 505(b)(2) NDAs *can* be submitted for product modifications, such as new indications, that are not permitted under section 505(j) – which is directly contrary to Pfizer's proposition.

Pfizer also continues to mischaracterize the manner in which Reddy's NDA relies on the Norvasc® NDA. Pfizer characterizes this reliance as "selectively plucking data out of Pfizer's Norvasc NDA," and as "cherry-picking."[7] Reddy does not seek approval for its NDA based on "cherry-picking" of data from the Norvasc NDA. Like any other 505(b)(2) NDA for a modified version of an RLD (e.g., an NDA for a modified strength, dosage form, or route of administration),[8] the Reddy NDA relies on the approval of the RLD to support the safety and effectiveness of the original RLD formulation for which an ANDA could have been submitted.

2. Section 505(b)(2) Does Not Require Prior Approval of a Placeholder ANDA.

Pfizer complains that FDA's interpretation of section 505(b)(2) permits the approval of Reddy's NDA "at a time when Pfizer's patents prevent approval of an ANDA in the first instance."[9] Pfizer argues that FDA must require Reddy to obtain approval of an ANDA for an unmodified version of Norvasc, subject to Pfizer's patent rights regarding the unmodified product, prior to allowing Reddy to submit a 505(b)(2) NDA for the modified product.[10]

Pfizer fails appreciate that the primary purpose of the Parkman Letter was to prevent such an unnecessary, two-stage process requiring a generic applicant to first obtain approval of an ANDA for a placeholder product that the applicant does not intend to market. The Parkman Letter states:

> A similar case may arise where an applicant wishes to seek approval of a modification of an approved product but has no interest in marketing the drug in

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5 *Id.* (emphasis added).

6 Parkman Letter at 1.

7 *Id.* at 2.

8 This reliance is also the same as the reliance allowed under section 505(j) for similar product modifications that can be approved based on suitability petitions. The ANDA applicant relies on the safety and effectiveness of the formulation of the RLD and provides additional data and information demonstrating that the modified ANDA product will be bioequivalent or have the same therapeutic effect.

9 *Id* . at 4 ("At that point, Reddy could perhaps obtain approval of certain product changes").

10 *Id.*

> its originally approved form. Assuming that clinical data were required for approval, the statute could be interpreted to require that such an applicant to first manufacture, and obtain approval of an ANDA for the listed drug's approved form and then file a 505(b) supplement to the approved ANDA containing the clinical data to obtain approval of the modification. . . . FDA has concluded that such an interpretation is inconsistent with the legislative purpose of the [statute] because it would serve as a disincentive to innovation and would require needless duplication of research. . . .[11]

Although Pfizer claims that it does not challenge the "Parkman procedure,"[12] Pfizer actually challenges the most fundamental element of that procedure. Pfizer would have Reddy obtain approval of an ANDA for an unmodified version of the Norvasc formulation, which Reddy does not intend to market at this time, so that Pfizer could assert patent rights against the product that Reddy *does not* intend to market in order to delay marketing of the product that Reddy *does* intend to market. Pfizer thus seeks to use the Food, Drug, and Cosmetic Act to broaden its patent protections to reach products other than those against which the patents are ostensibly asserted.

Pfizer's patent rights are, of course, addressed directly in the statute, as well as under FDA's interpretation of section 505(b)(2). The statute permits Pfizer to assert its patent rights against Reddy with regard to the product for which Reddy seeks approval. In fact, Pfizer did assert its patent rights against the product for which Reddy seeks approval, and lost in court.[13] Faced with a judicial decision that its patents do not block generic competition from the product for which Reddy seeks approval, Pfizer asks FDA to require that Reddy first develop and obtain approval for placeholder product, against which Pfizer's patents might be more effective.[14]

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[11] Parkman Letter at 1.

[12] Pfizer Sup. at 3-4.

[13] *Pfizer, Inc. v. Dr. Reddy's Laboratories*, LTD, No. 02-CV-2829, 2002 WL 31833744 (D.N.J.), *appeal docketed*, Nos. 03-1227 (Fed. Cir. Jan. 24, 2003), 03-1258 (Feb. 11, 2003).

[14] In fact, Pfizer would not be able to assert its patents against the approval of a placeholder ANDA for an amlodipine besylate. Should FDA require Reddy to file a placeholder ANDA for a product that Reddy does not intend to market, Pfizer will have not cause of action for infringement. Pfizer has already litigated this issue in its infringement suit against Reddy's NDA, where the court expressly rejected Pfizer's position. *Pfizer, Inc. v. Dr. Reddy's Laboratories*, LTD, Letter Order (Jan. 31, 2003) ("The recently decided Federal Circuit case, Warner-Lambert Company v. Apotex Corp. [316 F.3d 1348 (Fed. Cir. 2003)], holds that merely filing a new drug application prior to patent expiration is not in itself an act of infringement unless the applicant intended to manufacture or sell its new product before the patent expired") (Tab 1). Although Pfizer has appealed the district court's decision, Pfizer has not challenged this aspect of the court's ruling. *See* Brief for Plaintiff-Appellant Pfizer, Inc., *Pfizer, Inc. v. Dr. Reddy's Laboratories* (attached as Tab A to Reddy's Supplemental Comments dated June 4, 2003). Pfizer instead seeks to circumvent the court's ruling by having FDA provide a mechanism by which it could reassert its patents in yet another meritless lawsuit, against a placeholder ANDA, brought solely to delay approval of Reddy's pending NDA.

Pfizer fails to explain why the statute requires this bizarre and anti-competitive scenario. Indeed, Pfizer's proposed two-stage approval process runs directly contrary to the structure and purpose of the Act. Section 505(j) is designed to allow generic applicants to seek approval for modifications to RLDs without having first to develop and obtain approval for an unmodified version of the RLD. This is what the ANDA suitability process is all about. When an ANDA applicant seeks approval for a new dosage form in order to avoid a patent on the dosage form of the RLD, the ANDA applicant is not required first to obtain approval of an ANDA for the original, patented dosage form. Congress clearly drafted the 1984 Amendments to avoid such a scenario and to encourage product modifications that will result in greater generic competition.[15]

It is also important to note that Pfizer apparently does not challenge, at least at this time, FDA's approval of 505(b)(2) NDAs for these same types of modifications without requiring an approved ANDA for the unmodified product.[16] Had Reddy filed a 505(b)(2) NDA for a new dosage form in order to avoid a Pfizer patent, Pfizer would consider the NDA to fall within the Parkman Letter, which Pfizer is not at this point prepared to challenge. Pfizer fails, however, to provide any basis in the statute or in logic for the proposition that section 505(b)(2) requires an intermediate, placeholder ANDA for approval of a modified salt form of the active ingredient but not for a modified dosage form or a new indication.

Pfizer simply cannot argue credibly that Congress intended to allow Pfizer to delay the marketing of a generic drug that does not infringe Pfizer's patents by requiring that Reddy first develop and obtain approval of an additional placeholder product that Reddy does not intend to market at this time. The statute provides Pfizer with the right to assert its patents against the product Reddy seeks to market. Pfizer exercised its right and lost in court. Pfizer cannot now seek expanded patent protection to delay non-infringing products under a statute that was designed to reward innovation and encourage generic competition.

Respectfully submitted,

David G. Adams
Counsel to Dr. Reddy's Laboratories, Inc.

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[15] Pfizer's proposal would also have irrational and anti-competitive effects related to 180-day exclusivity. The proposal could delay generic competition from other applicants, or even preclude it altogether. If the applicant that does not intend to market its product is the first applicant to submit a paragraph IV certification, there may be difficulties in triggering 180-day exclusivity. On the other hand, if that applicant files a subsequent paragraph IV certification, its approval may be blocked even though it does not intend to market a competing product. In Reddy's case, there is already an ANDA with a paragraph IV certification submitted by Mylan that may be entitled to 180-day exclusivity. Pfizer's proposal would thus serve Congress wisely designed the statute to avoid placeholder ANDAs. Congress' wisdom and intent should be heeded here.

[16] Pfizer states in its most recent comments that it expresses "no opinion" on whether the original "Parkman" policy was permissible. Pfizer Sup. at 3 n.1.