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August 23, 2013

Hand Delivered

Division of Dockets Management
U.S. Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

RE: Docket No. FDA-2013-P-0247
Request to Supplement the Record and Petition for Reconsideration of Section III of FDA's Petition Response

Dear Dr. Woodcock:

On behalf of Novartis Pharmaceuticals Corporation ("Novartis"), the undersigned respectfully requests the Food and Drug Administration ("FDA") to supplement the record under 21 C.F.R. § 10.30(g) with respect to the above-identified Citizen Petition, to add information not in Novartis's original March 1, 2013 Petition. This additional information concerns the timing of Novartis's Petition, which FDA discussed in Section III of its August 1, 2013 Response to the Petition. Based upon the supplemented record, Novartis further requests reconsideration under 21 C.F.R. § 10.33, asking that FDA strike or modify Section III of the Response.[1]

I. Introduction

Novartis's Petition asked FDA to deny certain Abbreviated New Drug Applications ("ANDAs") by generic drug makers to sell a generic version of Novartis's Reclast (zoledronic acid) brand drug. Reclast is approved for both Paget's disease and osteoporosis. Novartis's Petition raised concerns that safety information protected by patents relating to the osteoporosis indication, which FDA would be required to omit from a Paget's-only label, was important for all patients.

In response to the Petition, FDA consulted with internal experts and made some modifications to the generic labels. FDA then approved the ANDAs with the modified labels

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[1] FDA docketed Novartis's Petition on March 4, 2013. *See* Docket No. FDA-2013-P-0247, FDA Acknowledgement Letter To Novartis (March 4, 2013), *available at* http://www.regulations.gov/#!documentDetail;D=FDA-2013-P-0247-0002.

and criticized the timing of Novartis's Petition in Section III of the Response. Novartis's request for reconsideration solely concerns Section III, and Novartis asks that FDA strike or modify that section in light of the additional information set forth below.

Novartis agrees with the policy goals underlying Section III of the Response. We understand that FDA is concerned with branded drug makers deciding to file citizen petitions, but then delaying the filing until the eve of approval in order to delay FDA's decisionmaking. Since the Novartis group of companies includes a significant generic business, Novartis is particularly well situated to understand and share this concern. Novartis has been careful in considering the filing of citizen petitions on label carve-out issues like those present here. This Petition was the first by Novartis since 2005.

Novartis appreciates FDA's goals in encouraging branded drug makers not to delay filing citizen petitions. However, in this instance Novartis made its filing promptly after confirming that generic companies had in fact sought Paget's-only label approval, a fact that Novartis was able to confirm only on February 26, 2013—just two days before Novartis first filed its Petition.

Novartis understands that its 505(q) certification discloses that Novartis first learned the information on which the Petition was based on November 8, 2011. That, however, was the date on which the osteoporosis method treatment patent issued, and thus the first date that a carved-out label was theoretically possible. In retrospect, Novartis could have also included the dates February 26, 2013, when Novartis first received confirmation that some generic sponsors were in fact seeking a Paget's-only approval, and February 20, 2013, when Novartis filed a patent lawsuit based on "information and belief" that some sponsors could have sought a Paget's-only approval.

II. Request to Supplement the Record

Novartis respectfully requests FDA to allow Novartis to supplement the record for its Citizen Petition under 21 C.F.R. § 10.30(g) with additional information that is directly relevant to the timing of that Petition and thus to Section III of FDA's Response.

In particular, Novartis is submitting (1) a complaint alleging patent infringement filed by Novartis on February 20, 2013, which was accompanied by a request for expedited discovery (Exhibit 1); (2) a hearing transcript on the motion for expedited discovery in which certain companies revealed to Novartis, for the first time, that they were seeking approval of generic versions of Reclast with carved-out labeling (Exhibit 2); (3) a copy of a protective order prohibiting Novartis from using information about the plans of certain ANDA applicants (Exhibit 3); and (4) a verification statement pursuant to 21 U.S.C. § 355(q)(1)(I) (Exhibit 4).

As explained further below in Novartis' petition for reconsideration, these documents support Novartis's contention, set forth below in the Petition for Reconsideration, that Novartis

did not intentionally delay filing its Petition to deprive FDA of adequate time to consider it before approval of the ANDAs. Instead, Novartis submitted the Petition promptly after confirming that certain ANDA applicants had in fact sought approval of labeling Paget's-only label.

III. Petition for Reconsideration

The undersigned submits this petition for reconsideration of the decision of the Commissioner of Food and Drugs to Docket No. FDA-2013-P-0247.

A. Decision Involved

Novartis respectfully requests FDA to reconsider Section III of its Response, wherein FDA asserted that Novartis's Petition represented an "egregious misuse" of the citizen petition process.

B. Action Requested

Based upon the supplemented record, which is discussed in more detail below, Novartis respectfully requests FDA to strike Section III in its entirety or, in the alternative, to modify any conclusions in Section III based on mistaken inferences resting on prior incomplete information regarding the Petition's timing. Even if FDA believes that Novartis should have submitted its petition earlier, and wishes to encourage other sponsors to do so, Novartis asks that FDA delete the statements that Novartis "misuse[d]" the petition process, as that and related statements are contrary to the evidence.

C. Statement of Grounds

Novartis believes that each of the requirements for granting reconsideration under 21 C.F.R. 10.33(d) is met:

- That relevant information or views contained in the administrative record (presuming that the Commissioner consents to Novartis's supplementation of the record) were not previously or not adequately considered. The supplemented record includes information demonstrating that Novartis was unsure that generic sponsors had requested a Paget's-only label until February 26, 2013. We acknowledge that this information was not presented earlier, but believe that in light of the Response it should be included in the record.

- Novartis's position is presented in good faith. Novartis has a good-faith basis for its contention that it did not intentionally delay filing the Petition, as set forth below.

- There are sound public policy grounds supporting reconsideration. Although FDA denied the principal relief sought in Novartis's Petition, the Petition did help FDA discharge its obligation to modify labeling based on Novartis' patents.

- Reconsideration is not outweighed by public health or other public interests. Novartis did not file a petition relating to a Paget's-only label until after it confirmed that the generic companies had in fact sought such an approval. Reconsideration would not permit sponsors to intentionally delay filing, but would recognize that Novartis here did not file what could have been a needless petition based on the view that a sponsor might have sought a Paget's-only approval.

Novartis knew since 2011 that certain generics had been pursuing ANDAs for Reclast because Novartis had received Paragraph IV letters that year challenging the validity of another Reclast-related patent, U.S. Patent No. 7,932,241 ("the '241 patent"). But those letters did not disclose that the generics were also seeking to carve out osteoporosis indications from their generic Reclast labels. Generics are under no obligation to inform a branded drug maker that they are seeking a Section viii carve-out. Here, the generics presumably sought such a carve-out to try to avoid Novartis's patent on methods of using Reclast to treat osteoporosis, U.S. Patent No. 8,052,987 ("the '987 patent"). By "carving out" osteoporosis indications from their label, the generics apparently were trying to insulate themselves from the accusation that their label invites infringement of Novartis's patented methods of osteoporosis treatment. The generics pursuing this strategy, however, chose not to alert Novartis to the contents of their labels.[2]

Moreover, Novartis could not have concluded that the generics were pursuing a Section viii strategy from the absence of Paragraph IV letters attacking the '987 patent. The U.S. Patent and Trademark Office awarded that patent on November 8, 2011, years after ANDAs first could have been filed for Reclast.[3] Accordingly, Novartis had no reason to expect Paragraph IV certifications of the '987 patent on any particular timetable. FDA imposes no deadline on generics for serving a Paragraph IV submission for "later listed" patents. Moreover, if a generic decided to file a Paragraph III submission, Novartis would not have received notice of that filing.

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[2] One in-house lawyer at Novartis had learned in October 2012 in a related patent litigation that Wockhardt was pursuing a Section viii carve-out. But that information was covered by a Protective Order that prevented the in-house lawyer from disseminating this information within Novartis, and also barred use of that information anywhere other than in that litigation. (A copy of that order is at Exhibit 3.) Decisionmakers on the Petition therefore did not know this information.

[3] Generics were first free to file ANDAs on Reclast as early as April 16, 2007, the date FDA approved Reclast for sale.

In other words, the generics could have waited until the last minute to reveal their position—as effectively occurred here.

Novartis indeed had reason to believe that the generics ultimately might choose to send Paragraph IV letters attacking, rather than seeking to avoid, the '987 patent, and/or that FDA would insist on a full label that included osteoporosis indications. Two generics—Hospira and Wockhardt—had sent Novartis Paragraph IV letters on November 15, 2011 and January 13, 2012, respectively, indicating their intent to sell generic Reclast under a full label. In light of these filings, it would not have been surprising for other generics to follow suit, and/or for FDA to decide that the generics would be required to mirror the full branded label.

On February 20, 2013, Novartis filed a lawsuit based on information and belief that some generic sponsors could have sought an approval of a Paget's-only label. Novartis further filed a motion for expedited discovery to determine the generic companies' actual intentions in that regard. The court held an emergency hearing to resolve Novartis's application on February 26, 2013.

At the hearing, the Magistrate Judge polled counsel for the generics on whether their clients were in fact pursuing a Paget's-only label. In response, counsel for four generics—Wockhardt, Dr. Reddy's, Pharmaceutics International and Emcure—publicly disclosed for the first time that their clients were indeed seeking to sell generic Reclast under a carved-out, Paget's-only label.[4]

Novartis did not file the Petition, which would be relevant solely to a carved-out Paget's-only label, until it learned that some generic sponsors were in fact seeking such an approval. Had Novartis known this information earlier, it would have known of the necessity of filing the petition earlier. We appreciate that FDA could not previously have considered this fuller context, as it was not included in the Petition; Novartis did not include it because it did not believe it central to the Petition's merits.

FDA's Response suggests that Novartis should have filed its Petition a month earlier than it did. But the relevant decisionmakers at Novartis were not considering the possibility of filing a citizen's petition then, and did not actively consider filing a petition until mid-February. Novartis did not file the petition until it had confirmation that the generics were actually pursuing Paget's-only labels.

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[4] The transcripts of this hearing, attached as Exhibit 2, are the subject of the accompanying motion to supplement the record. Counsel's statements can be found at 44:5-22 (Wockhardt), 57:13-25 (Dr. Reddy's), 81:1-3 (Pharmaceutics International), and 97:11-25 (Emcure).

It also appears that FDA read Novartis's 505(q) certification to mean that Novartis had sufficient information to file a Petition on November 8, 2011. The certification identifies that date as when "the information upon which [Novartis has] based the action requested herein first became known" to Novartis. Novartis believed that it first knew information on which the Petition was "based" when the '987 patent issued, because that patent's existence was the predicate for the generics' Paget's-only labels. The '987 patent thus formed the "basis" of the Petition.

Novartis did not read 505(q) as requiring the date when Novartis first confirmed that generic sponsors had sought a Paget's-only approval, a necessary condition for Novartis's petition to be relevant.[5] Although this information was not important for the underlying merits of the Petition (whether a Paget's only approval could be granted), it is relevant to Section III of FDA's Petition Response.

Notwithstanding its criticism of the Petition's timing, FDA agreed with several parts of Novartis's Petition, and changed the generics' labels as a result (albeit in a manner FDA characterizes as "minor"). For instance, FDA apparently changed the portion of the label concerning glucocorticoid-induced fractures, which the Petition addressed at Page 5. In subsection 5.5 of the branded label, entitled "**WARNINGS AND PRECAUTIONS**," there is a discussion of the risk of "Atypical Subtrochanteric and Diaphyseal Femoral Fractures." In describing this risk, the label warns that "[a] number of reports note that patients were also receiving treatment with glucocorticoids (*e.g.*, prednisone) at the time of fracture." The initial version of Dr. Reddy's label apparently included this statement.[6] In contrast, and consistent with the position in Novartis's Petition, the newer Emcure label does not.[7] The FDA further agreed with other observations in Novartis's Petition, as reflected in pages 8 and 10 of the Response.

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[5] Novartis understands that citizen's petition certifications may contain multiple dates. *See* FDA Guidance Document: http://www.fda.gov/downloads/Drugs/GuidanceCompliance Regulatory Information/Guidances/UCM079353.pdf. However, in this instance Novartis believed that that the "first" date when it learned the information on which the Petition was "based" was the date the '987 patent was issued. That patent led the generics to seek Paget's-only labels, and thus was the information on which the Petition was "based."

[6] *See* http://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=f94a5c9e-74bc-d09e- cd65-394b2a5de2ad.

[7] *See* http://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=0cb73e04-2574-4afd-ac33-981602005763.

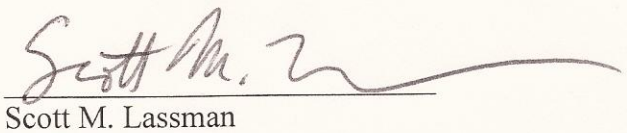
IV. Conclusion

Novartis hopes that FDA will consider the information provided herein to supplement the record, and modify or delete any conclusions based on inferences resting on prior incomplete information regarding the Petition's timing. As we noted at the outset, Novartis respects FDA's concern about the late filing of petitions that, unlike Novartis's Petition here, are intentionally delayed to prevent FDA from having adequate time to consider safety issues before approving ANDAs.

But given that Novartis did not file a Petition until confirming that the generics were seeking Paget's-only labels, we urge FDA to reconsider Section III of its response. Novartis's Petition raised issues worthy of consideration, as evidenced by FDA's handling of the Petition and agreement to address Novartis's concerns in the generics' labels. If Section III were not to be modified in light of the additional information above, it could chill others from submitting such concerns in similar circumstances.

We appreciate FDA's consideration of these issues. If FDA has any questions about any aspect of this submission, please do not hesitate to contact us.

Respectfully submitted,



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cc: Denise Esposito, Esq.