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Novartis Tells FDA Skinny Labels Won't Work With $3.5B Drug

By **Dani Kass**

Law360 (September 15, 2022, 10:47 PM EDT) -- Novartis Pharmaceuticals has urged the U.S. Food and Drug Administration to reject generic versions of its blockbuster heart failure drug Entresto until its exclusivity expires in 2024, even if the generic-drug companies claim they can carve out protected uses.

The pharma giant on Monday filed a citizen petition saying that any of the at least 18 companies that have filed for approval of their generics could request to get on the market early by leaving uses where the exclusivity has expired off their labels. The FDA shouldn't allow them to do so because the label cannot be split in such a way, Novartis argued, saying it has both FDA and patent exclusivity.

In the hopes of protecting a drug that had $3.5 billion net sales worldwide in 2021 — with $1.7 billion being from the United States, according to the company's financial reports — Novartis has sued more than a dozen generic-drug makers for patent infringement. That litigation has since been consolidated in Delaware by the Judicial Panel on Multidistrict Litigation. The patents for the drug approved in 2015 expire between 2023 and 2036, according to the FDA's Orange Book.

Novartis told the FDA that any attempts by generic companies that have filed abbreviated new drug applications to get a Section VIII carveout won't work with its drug. The labels with those carveouts are commonly referred to as "skinny labels."

"To enable ANDA applicants to omit the protected use in this case, FDA would have to add wording or make other changes to the existing Entresto indication statement," the petition states. "However, such an approach is not consistent with FDA precedent and longstanding agency interpretations of the ANDA 'same labeling' regulations."

Novartis says the FDA gave it three years of exclusivity after conducting a new clinical investigation to show that the drug is safe and effective in a broader range of patients than first known. After that study, Novartis said it "significantly revised" its label to cover more patients, including superseding language about an indication for particular patients being diagnosed based on the level of left ventricular ejection fraction.

"Generic applicants cannot reference discontinued labeling, such as the now-superseded Entresto indication statement describing its use in patients with 'reduced ejection fraction,'" the petition states. "Moreover, an ANDA indication statement that categorizes the patient population by reference to ejection fraction would be inconsistent with the current Entresto labeling, which reflects the agency's

decision to no longer use LVEF as a strict diagnostic criterion to determine which patients may benefit from Entresto."

Skinny labels have been gaining particular attention in the past few years, largely because of a case between GlaxoSmithKline and Teva about how to carve out patent-protected indications of drugs and when these labels induce infringement. That case is currently pending as a petition at the U.S. Supreme Court.

A representative for Novartis said it filed a similar petition earlier this year, which the FDA rejected without comment in April. The agency is expected to respond to the new petition within 150 days, the company added.

Novartis' suits are against, at a minimum, various affiliates of Alembic Pharmaceuticals, Alkem Laboratories, Aurobindo Pharma, Biocon Pharma, Crystal Pharmaceutical, Dr. Reddy's Laboratories, Hetero Labs, Laurus Generics, Lupin Pharmaceuticals, Macleods Pharmaceuticals, MSN Pharmaceuticals Inc., Mylan Pharmaceuticals, Novugen Pharma, Teva Pharmaceuticals, Torrent Pharma and Zydus Pharmaceuticals.

That multidistrict litigation was initially assigned to then-U.S. District Judge Leonard P. Stark, with U.S. District Judge Richard G. Andrews taking over after his former colleague left for a spot on the Federal Circuit in March 2022.

On the same day Novartis' petition was filed, Judge Andrews began a bench trial testing Novartis' cases against Biocon, Dr. Reddy's, Hetero, Laurus, Macleods, Teva and Zydus, which is still ongoing.

Novartis on Thursday filed a pair of sealed proposed consent judgments and orders of injunctions for Laurus and Zydus, but none of the three companies responded to requests for confirmation of a settlement.

Representatives for the generic-drug companies didn't immediately respond to requests for comment Thursday.

The patents-in-suit are U.S. Patent Nos. 9,517,226; 9,937,143; 11,135,192; and 11,058,667.

Novartis is represented by Hogan Lovells, McCarter & English LLP and Venable LLP.

Alkem is represented by Morris James LLP and Taft Stettinius & Hollister LLP. Aurobindo is represented by Morris James LLP and Withers. Crystal is represented by Heyman Enerio Gattuso & Hirzel LLP and Parker Poe Adams & Bernstein LLP. Dr. Reddy's is represented by Stamoulis & Weinblatt LLC and Perkins Coie LLP. Hetero and Torrent are represented by Smith Katzenstein & Jenkins LLP and Pergament & Cepeda LLP. Laurus is represented by Young Conaway Stargatt & Taylor LLP and Sterne Kessler Goldstein & Fox PLLC. Mylan is represented by Potter Anderson & Corroon LLP and Parker Poe Adams & Bernstein LLP. Teva is represented by Shaw Keller LLP and Kirkland & Ellis LLP. Zydus is represented by Young Conaway Stargatt & Taylor LLP and Locke Lord LLP.

The MDL is In re: Entresto (Sacubitril/Valsartan) Patent Litigation, case number 1:20-md-02930, in the U.S. District Court for the District of Delaware. The individual cases include case numbers 1:22-cv-00032, 1:21-cv-01407, 1:21-cv-01797, 1:21-cv-01452, 1:21-cv-01347, 1:22-cv-00498, 1:21-cv-

01760, 1:22-cv-00186, 1:22-cv-00451, 1:22-cv-00083, 1:21-cv-01794 and 1:22-cv-00440, in the U.S. District Court for the District of Delaware.

--Editing by Rich Mills.
