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Novartis Prevails In Patent Suit Vs. Dr. Reddy's Over Lamisil

IP Law Bulletin (Friday, September 03, 2004)--Swiss drug giant Novartis has fended off a patent challenge from Indian generic maker Dr. Reddy's against its widely prescribed oral antifungant Lamisil.

Dr. Reddy's Laboratories withdrew its challenge to the Lamisil patent and conceded that it is valid, enforceable and had been infringed by the Indian generic maker, Novartis said Friday.

Dr. Reddy's said it pulled its legal challenge "because the time needed to obtain a favorable Federal Circuit decision prior to patent expiration would not be met."

Novartis filed the lawsuit the U.S. District Court for the Southern District of New York in July 2002. Although the court recently granted a bifurcation motion, it denied Reddy's request to set a trial date.

"In view of the length of time necessary to get through summary judgment motions, a trial and an appeal, the company has decided not to pursue further the litigation directed to the '534 patent which will expire in late 2006. The parties have dismissed all pending claims against each other," Dr. Reddy's said.

Instead of challenging the validity of the patent on the drug, Dr. Reddy's amended its Abbreviated New Drug Application (ANDA) for the tablets from a Paragraph IV Certification to a Paragraph III Certification on the remaining unexpired Orange Book Patent listed for the drug.

A Paragraph III Certification requires FDA to wait for the expiration of the patent before approving the ANDA. A Paragraph IV Certification alleges that the patent is invalid or not infringed, and allows the patent holder to sue the generic applicant for patent infringement, triggering an automatic 30-month approval delay while the case is litigated.

Under the terms of the consent judgment, Dr. Reddy's Laboratories will not

manufacture, use, sell or import into the United States a generic version at least until the patent expiration date of December 2006.

The judgment also covers any pediatric exclusivity extension issued by the U.S. Food and Drug Administration (FDA) for the patent, Novartis said.

A section of the Food and Drug Administration Modernization Act of 1997, signed into law by President Bill Clinton in 1997, permits certain applications to obtain an additional six months of marketing exclusivity if the sponsor submits requested information relating to the use of the drug in the pediatric population.

Novartis said it has a strong patent position for Lamisil that relies on "an abundance of evidence showing terbinafine hydrochloride to be a distinctive molecule with a unique mode of action."

"Chemically and therapeutically, terbinafine is unique in its class in the treatment of onychomycosis," the Swiss drug maker said.

Lamisil is the leading prescription treatment to effectively treat onychomycosis, a fungal infection that commonly affects the toes or fingernails. An estimated 35 million Americans suffer from onychomycosis, a fungal infection that aggressively discolors, thickens, and destroys the nail plate of the toenails or the fingernails.

Novartis was represented in this matter by attorneys for Fitzpatrick, Cella, Harper & Scinto.

Dr. Reddy's was represented by attorneys for Budd, Lerner, Gross, Rosenbaum, Greenberg & Sade, P.C.

The case is Novartis Corp., et al v. Dr. Reddy's Lab., et al, case no. 1:02-cv-05560-RCC-THK, U.S. District Court for the Southern District of New York.