

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF NEW JERSEY

_____)
)
MEDA PHARMACEUTICALS INC.,)
)
Plaintiff,)
)
vs.)
)
ZYDUS PHARMACEUTICALS USA, INC.,)
)
Defendant.)
_____)

Civil Action No. 10-1475-MLC-DEA

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 JUN 24 2010
 AT 8:30
 WILLIAM T. WALSH M
 CLERK

FINDINGS OF FACT AND CONSENT JUDGMENT AND ORDER

The Court, upon the consent and request of Plaintiff Meda Pharmaceuticals Inc. ("Meda") and Defendant Zydus Pharmaceuticals USA, Inc. ("Zydus"), hereby makes the following Findings Of Fact and issues the following Consent Judgment And Order.

FINDINGS OF FACT

1. This Court has subject matter jurisdiction over this patent infringement action ("the Action") and personal jurisdiction over all of the parties to the Action. Venue is proper in this Court as to all parties to the Action.
2. In this Action, Meda has charged Zydus with infringement of United States Patent No. 5,164,194 ("the '194 Patent") in connection with Zydus's submission of Abbreviated New Drug Application ("ANDA") 91-409 directed to a generic azelastine hydrochloride nasal spray to the U.S. Food and Drug Administration ("FDA").
3. To date in this Action, Zydus has not rebutted the statutory presumption that the '194 Patent is valid and enforceable.

4. Zydus admits that the submission of ANDA 91-409 to the FDA for the purpose of obtaining regulatory approval to engage in the commercial manufacture, use, and/or sale of a generic 0.1% azelastine hydrochloride nasal spray product, the use of which is claimed in the '194 Patent, within the United States before the expiration of the '194 Patent is a technical act of patent infringement. This admission, however, is without prejudice to any defense or counterclaim of Zydus that the asserted claims of the '194 Patent are invalid.

CONSENT JUDGMENT AND ORDER

Accordingly, pursuant to the above Findings of Fact, and upon the consent and request of Meda and Zydus, **IT IS HEREBY ORDERED, ADJUDGED, AND DECREED THAT:**

1. The filing of ANDA 91-409 was a technical act of infringement of the '194 Patent under 35 U.S.C. § 271(e)(2)(A).
2. Zydus, its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with them who receive actual notice of this Order by personal service or otherwise, are hereby enjoined from manufacturing, using, offering to sell or selling within the United States, or importing into the United States, the generic 0.1% azelastine hydrochloride nasal spray defined by ANDA 91-409 during the life of the '194 Patent, including any extensions and pediatric exclusivity, absent authorization by Meda, unless all of the claims of the '194 Patent are found invalid or unenforceable by a court decision from which no appeal has been or can be taken.
3. Meda and Zydus each expressly waives any right to appeal or otherwise move for relief from these Findings Of Fact And Consent Judgment And Order.
4. This Court retains jurisdiction over Meda and Zydus for purposes of enforcing these Findings Of Fact And Consent Judgment And Order.

5. These Findings Of Fact And Consent Judgment And Order shall finally resolve this Action between Meda and Zydus. Each party shall bear its own fees and costs in connection with this Action, including attorney fees.

6. The Clerk of the Court is directed to enter this final judgment forthwith.

SO ORDERED:

This 24th day of June, 2010

SO ORDERED: Mary L. Cooper
MARY L. COOPER, U.S.D.J.