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IN THE HIGH COURT OF JUDICATURE AT BOMBAY

ORDINARY ORIGINAL CIVIL JURISDICTION

SUIT NO. 629 OF 2016

WITH

NOTICE OF MOTION (L) NO. 1887 OF 2016

Novartis AG & Another …Plaintiffs

Versus

Piramal Enterprises Limited & 2 Others …Defendants

Mr. Hemant Singh, *with Ms. Mamta Jha, Mr. Ashutosh Kane & Mr. Rishi Mody, i/b W.S. Kane & Co., for the Plaintiffs.*

Dr. Birendra Saraf, *with Ms. Melanie Desuza & Ms. Reshma Randive, i/b A.S. Dayal & Associates, for the Defendants.*

CORAM: G.S. PATEL, J

DATED: 26th July 2016

PC:-

1. On behalf of the Defendants, Dr. Milind Gharpure, Director - API Generics R&D, Piramal Enterprises Limited is personally present in Court. He is instructing Dr. Saraf. He states as a matter of an undertaking to the Court that the Defendant has deleted all references to Vildagliptin from its website and also removed the molecule from the Pharma Solution's website as also the API Product List. He further states that the project itself was abandoned in August 2015. The Defendant has no intention of commercializing the product currently. It has also surrendered the manufacturing license. As a matter of precaution and having regard to what is

stated in the plaint, the Defendants state that should it ever plan to commercially use this product in question during the tenure of the Plaintiffs patent, the Defendants will do so only with the Plaintiffs' prior written permission or with leave of the Court in a properly instituted proceedings to which the Plaintiff is a party, under an order of the Court.

2. Dr. Saraf makes these statements on the basis that the Defendants were using the product Vildagliptin and its intermediates in or about August 2015 for future use after the expiry of the Plaintiffs' patent. He claims that this is an industry standard and is permitted by Section 107A of the Indian Patent Act. He also states that the Defendants carried out feasibility studies at its R&D site in Mumbai in April-July 2015. This activity was dropped and the project itself was abandoned in August 2015, as the Defendant did not find it commercially viable. No further activity relating relating to Vildagliptin was made thereafter.

3. Moreover, the Defendants' R&D never reached the stage of lab-validation. No samples were ever provided to any customer for further validation or research. All activity was done in-house for development only. The Defendants applied for a manufacturing license in August 2015. It received this on 9th September 2015. That license was never used for commercial development but only for research and development work, i.e., for making minimal batches for plant validation. This was the limited research and development that was done under that license in Mmbai. The Defendants never manufactured commercial batches of the Vildagliptin. The commercial manufacturing license, the Defendants say, was sought

with an intention of its being used after the expiry of the patent in the event that the Defendants do succeed in developing the drug. Since the project was abandoned at the stage of R&D feasibility, no question of commercial manufacture ever arose.

4. I note these statements made by Dr. Saraf, on instructions from Dr. Gharpure. These are, of course, not accepted by Mr. Singh for the Plaintiffs. They are meant to provide a background and explanation of sorts.

5. It is, however, in my view sufficient to accept the specific undertakings given by and on behalf of the Defendants at the beginning of this order. Mr. Singh agrees that these undertakings are sufficient to protect the Plaintiffs' commercial and proprietary interests.

6. On these statements being accepted as undertakings to the Court, not only the Notice of Motion but the Suit itself can be disposed of. Mr. Singh does not press his prayer for damages.

7. The Suit is disposed of in these terms. Drawn up decree dispensed with. Refund of court fee, if any, in accordance with the Rules.

8. The Notice of Motion does not survive and is disposed of as infructuous. No order as to costs.

(G. S. PATEL, J.)