

* **IN THE HIGH COURT OF DELHI AT NEW DELHI**

% *Date of Decision : May 30, 2016*

+ **FAO(OS) (COMM) 34/2016**

TEVA API INDIA PVT.LTD. & ANR. ..Appellant
Represented by: Mr.A.S.Chandhiok, Sr.Advocate
instructed by Ms.Aparna Gaur,
Ms.Rajeshwari, Mr.Tahir AJ,
Ms.Sweta Kakkar, Ms.Shruti
Sharma, Advocates

versus

MERCK SHARP & DOHME CORP & ANR.Respondents
Represented by: Mr.Sudhir Chandra, Sr.Advocate
instructed by Ms.Tusha Malhotra,
Ms.Udita M.Patro, Advocates

CORAM:

HON'BLE MR. JUSTICE PRADEEP NANDRAJOG

HON'BLE MS. JUSTICE MUKTA GUPTA

PRADEEP NANDRAJOG, J.

1. The respondents sued appellants alleging infringement of their rights flowing from Indian Patent No.209816 concerning a molecule having an International Non-Proprietary name SITAGLIPTIN. It is the case of the respondents that IN 209816 has 20 claims of which the pharmaceutically acceptable salts are covered by claims 1, 2, 3, 5, 6, 7, 8, 9, 10, 14, 15, 16, 17 and 19. It is the case of the respondents that combining Sitagliptin and another drug known as Metformin HCL, the combination is sold under the trade mark JANUMET. Stand alone Sitagliptin is sold under the trade mark JANUVIA. The respondents alleged that the appellants are manufacturing and selling its patented product. Injunction prayed for is to restrain the

appellants from manufacturing, selling in any manner Sitagliptin or any of its pharmaceutically acceptable salts including Sitagliptin Malate, Sitagliptin Phosphate and Sitagliptin Sulphate.

2. Along with the suit respondents filed IA No.1998/2016 claiming an ex-parte ad-interim injunction in terms of the injunction sought for in the plaint.

3. Issuing summons in the suit and notice in IA No.1998/2016, vide order dated February 10, 2016, the learned Single Judge has restrained the appellants as prayed for by the respondents.

4. The summons have been issued returnable for August 02, 2016.

5. Aggrieved by the long date given by the learned Single Judge, and the mandate of law being to try and decide an application for injunction and especially when an ex-parte ad-interim injunction is issued within 30 days, the appellants filed IA No.3675/2016 invoking Order 39 Rule 4 of the Code of Civil Procedure, admitting that the appellants were manufacturing the offending product but claimed that the same was purely for R&D. Admitting exports it was pleaded that the export was to submit the product and the data to the regulatory authorities around the world, so that when the patent expired, the appellants could market the product.

6. The right has obviously been claimed under Section 107A of the Patent Act, 1970, which reads as under:-

“107A. Certain acts not to be considered as infringement-
For the purposes of this Act, -

(a) any act of making, constructing, (using, selling or importing) a patented invention solely or uses reasonably related to the development and submission of information required under any law for the time being in force, in India, or in a country other than India, that regulates the manufacture, construction, (use, sale or import) of any product;

(b) importation of patented products by any person from a person (who is duly authorized under the law to produce and sell or distribute the product),

Shall not be considered as an infringement of patent rights.”

7. Taking cognizance of IA No.3675/2016 on March 18, 2016, the learned Single Judge issued notice which was accepted by learned counsel for the respondents in Court. The order dated March 18, 2016 records:-

“Issue notice. Learned counsel for the plaintiffs accepts notice.

Learned counsel for the defendants states that she would like to file additional documents in support of the application.

Let the same be filed within three days. Reply, if any, be filed within one week thereafter.

List on 07.04.2016”.

8. The order dated April 07, 2016 simply records:-

“At joint request, adjourned to 08.07. 2016.”

9. The appellants thereafter filed an application seeking review of the order dated February 10, 2016 which has been registered as RA No.201/2016, of which notice has been issued for 08.07.2016. In the review application it is pleaded that a perusal of the plaint would evince that the case of the respondents is that the appellants are not producing the offending product in a commercial way. It is pleaded that the exports are to countries where regulatory approval are required.

10. The grievance in the appeal is to the learned Single Judge not hearing the applications filed by the appellants to vacate the ex-parte ad-interim injunction and mandate of law requiring an endeavour to be made

to decide applications seeking injunction and if ex-parte injunction is granted, to decide applications seeking vacation thereof within 30 days.

11. Now, the order dated April 07, 2016 records date July 08, 2016, being with the consent of learned counsel for the parties and there was a debate before us concerning said order. There were oral statements of facts asserted and assertions denied, with counter statements of facts orally made and denied, but we do not go into said controversy because we must go by the order as it is recorded. It records a consent.

12. Be that as it may, the learned Single Judge ought to have made an attempt to decide the interim applications expeditiously and especially keeping in mind that an ex-parte ad-interim order was issued. The applications filed by the appellants simply stated that the offending goods were exported, not by way of a commercial sale, but to obtain regulatory approval in the countries abroad, and this aspect of the matter requires a short and a crisp hearing not lasting beyond 15-20 minutes. The learned Single Judge has only to see the documents presented by the two groups showing the quantity of export.

13. As told to us, the patent expires in India in the year 2022, and we are still six years away.

14. The position therefore would be that the appellants are, what are popularly known as generic companies, manufacturing and selling pharmaceutical products invented by others; upon patents lapsing. Being pharmaceutical products, marketing authorizations have to be obtained and for which the regulatory authorities of different municipal jurisdiction satisfy themselves that the product intended to be sold is upto the specification set by the municipal laws of the country concerned.

15. Appellants claim that they do not intend to commence marketing of its product, and subject to the plea of revocation of the patent, would urge

limitedly that keeping in view Section 107A of the Patent Act, 1970 the injunction granted needs to be vacated.

16. The case of the respondents would be that a Court has the jurisdiction to grant an injunction before a wrong is committed in order to stop it from happening and a quia timet action would lie. To which the response of the appellants would be that it is not enough to say that I fear that something will happen. There must be some concrete basis for the allegation that an infringement of the claimant's right is likely to take place.

17. Now, this would need an evaluation of facts with respect to the documents filed by the parties, and in the context of the appellants claiming that the quantities exported are for R&D purposes and for obtaining permissions from various countries, the quantity exported needs to be considered.

18. Pleadings have yet to be completed in the suit. The suit file has been summoned by us that we find that the appellants have not even filed a written statement.

19. In our opinion, the continuation of the injunction granted is not causing any injuries to the appellants because the marketing authorization which they require would at best take 2-3 years and as noted by us hereinabove, the respondents patent would lapse in the year 2022. The key provided by the length of time between the expiry of the patent and the time taken for marketing authorization guides the Court that the interim applications should be decided latest by the end of the current year.

20. Declining to interfere with the impugned orders we dispose of the appeal directing that within a week from today the appellants shall file their written statement of defence along with the relied upon documents.

Within three weeks thereafter the respondents shall file the replication along with such further documents which the respondents' desire.

21. The next date fixed before the learned Single Judge is July 08, 2016, and we hope and expect that on said date the learned Single Judge would spare half an hour to decide the interim applications.

22. No costs.

CM No.19905/2016

Dismissed as infructuous.

(PRADEEP NANDRAJOG)
JUDGE

(MUKTA GUPTA)
JUDGE

MAY 30, 2016

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