

IN THE HIGH COURT OF DELHI AT NEW DELHI

Reserved on: January 31, 2014
Decision on: February 28, 2014

CS (OS) 3193 of 2012 & CC No. 49 of 2013, IA Nos. 10389-90 of 2013, 10638 of 2013, 20025 of 2013, 18788 of 2013

TEVA PHARMACEUTICAL INDUSTRIES LTD & ORS

..... Plaintiffs

Through: Mr. Dushyant Dave, Senior Advocate,
Mr. Sudhir Chandra, Senior Advocate
with Mr. Praveen Anand,
Ms. Archana Shankar,
Mr. Nischal Anand and
Mr. Aman Taneja, Advocates

Versus

NATCO PHARMA LIMITED

..... Defendant

Through: Mr. Chetan Sharma, Senior Advocate
with Ms. Rajeshwari, Mr. Tahir Abdul,
Ms. Sudipa, Mr. Amit Gupta & Ms.
Urvashi Singh, Advocates

CORAM: JUSTICE S. MURALIDHAR

JUDGMENT
28.02.2014

1. IA No. 10390 of 2013 is an application under Order VII Rule 10 CPC filed by Natco Pharma Limited ('Natco') for return of the plaint for want of jurisdiction. IA No. 10389 of 2013 is an application filed by Natco under Order VII Rule 11 CPC seeking rejection of the plaint. Natco has also filed IA No. 10638 of 2013 under Sections 10 and 11 of the CPC praying that

further proceedings in CS (OS) No. 3193 of 2012 should be stayed in view of the pendency of the earlier suit CS (OS) No. 1708 of 2007.

The 2007 Suit

2. The background to the present applications is that Teva Pharmaceuticals Industries Ltd. ('Teva'), Yeda Research and Development Co. Ltd. ('Yeda') and Regent Drugs Ltd. ('RDL') filed CS (OS) No. 1708 of 2007 in this Court against Natco for a permanent injunction restraining infringement of Indian Patent No.190759 and for a permanent injunction restraining Natco and its agents from directly or indirectly managing, selling or offering for sale, exporting, marketing, commercialising or registering glatiramer acetate under the mark 'Glatimer' or any other mark whatsoever which is an infringement of the rights of Teva and Yeda in the aforementioned Indian Patent No. 190759. The second prayer was for an order restraining Natco and its agents from exporting the infringing drugs, formulations/bulk drugs outside India. The other prayers were for rendition of accounts of profits of Natco and a decree for damages in the sum of Rs.25 lakhs.

3. At the hearing of the aforementioned suit on 17th September 2007, the Court directed summons in the suit and notice in IA No. 10579 of 2007 under Order XXXIX Rules 1 and 2 CPC. The counsel for Natco then present in Court on caveat sought time to file a reply. It was stated by learned counsel for Natco that "the process employed by them for producing glatiramer acetate which is marketed by them under the name of Glatimer is entirely different from the process which has been patented by the plaintiffs under Indian Patent No. 190759". The Court directed Natco to file its affidavit to the above effect disclosing the process employed by Natco within one week.

4. On 21st September 2007, Natco filed a counter claim for revocation of Indian Patent No.190759 on the ground that the said patent related to a process for manufacture of a Copolymer-1 fraction and that the suit is based on an invalid patent. The grounds for seeking invalidation were set out in the counter-claim. Inter alia, it was submitted that the claims under the said patent did not meet the criteria of patentability under the Patents Act, 1970; that the claim was not novel or new in view of Teitelbaum et al., 1971 and US 3,849,550 and that the said documents disclosed the process claimed in IP 190759; that given the fact that the process of preparation of Copolymer-1 was published, the process conditions for its extraction, isolation and purification were known to a person skilled in the art; the process as claimed in IP 190759 lacks inventive step; that the complete specification does not sufficiently and fairly describe the invention and the method by which it is to be performed; that nowhere in the specification or the claim has the explanation for the manner in which these steps are effected been set out; that the patent was obtained by false representation and misleading statements and that even otherwise the claim under IP 190759 was not patentable.

5. Natco also filed their written statement on 20th October 2007 raising the preliminary objection as to the validity of the patent. Along with the reply to IA No. 10579 of 2007 filed by Natco, an affidavit dated 21st September 2007 was filed by Dr. A.K.S Bhujanga Rao, Executive Vice President (R&D). In the said affidavit, Dr. Bhujanga Rao disclosed that Natco was working on glatiramer acetate for the last four years and that the project was initiated around 2003 with the objective of producing a cost effective product for

treatment of multiple sclerosis in Indian patients since effective medication is not available in the country. It was stated that the objective of Natco was to develop a novel as well as commercially viable route for the production of glatiramer acetate and accordingly after about 2-3 years of intensive research, Natco developed a novel route for producing the product and that Natco had applied for patents to protect its proprietary steps in the said route.

6. In para 5 of the said affidavit, Dr. A.K.S Bhujanga Rao detailed the steps comprising of the novel route adopted by Natco. Certain relevant documents were also enclosed with the said affidavit.

7. Issues were framed in the said suit on 14th May 2012 and the application for interim relief was disposed of as not pressed on that date.

The 2012 Suit

8. On 3rd November 2012, Teva, Yeda and Teva API India Limited ('Teva India') filed CS (OS) No. 3193 of 2012 against Natco praying for a permanent injunction to restrain Natco and its agents from, directly or indirectly, manufacturing, selling, offering for sale, export or registering the product that has been held by the United States District Court ('UDSC') from infringing the Plaintiff's patent 190759. The other reliefs were for rendition of accounts and a decree for damages in the sum of Rs. 25,00,000.

9. In the plaint in the said suit, it was stated that Plaintiff No.3, Teva India was the subsidiary of Teva Pharmaceuticals Finance Netherlands B.V. of Netherlands, which was ultimately owned by Teva. It was stated that Teva is

the exclusive licensee of Yeda, pursuant to a license agreement between the parties and that the Indian Patent No. 190759 dated 23rd May 1995 in respect of “a method for manufacturing Copolymer-I” was registered in favour of Yeda. The plaint stated that previously Teva, Yeda and RDL had filed CS (OS) No. 1708 of 2007. It referred to the affidavit dated 21st September 2007 filed by Dr. A.K.S Bhujanga Rao in which it was asserted that the process employed by Natco in producing glatiramer acetate was different from that of the Plaintiffs and that Natco has its own patent process which was on record.

10. Para 27 of the plaint referred to the fact that there was an article dated 17th January 2012 in the newspaper ‘Business Line’ which reported that Natco would work with Mylan Pharmaceuticals Inc. (‘Mylan’) of USA to launch glatiramer acetate in India for the treatment of multiple sclerosis. Para 28 of the plaint stated that in its Annual Report (2010-2011), Natco indicated that Mylan and Natco had tied-up for manufacturing and supply of glatiramer acetate. In para 29 of the plaint, it was stated that in and around 7th June 2008, Natco signed an agreement with Mylan relating to the development and marketing of glatiramer acetate in the US.

11. On 29th June 2009, Mylan submitted to the US Food and Drug Administration (‘USFDA’) an abbreviated new drug application (‘ANDA’) seeking approval to manufacture and sell Mylan’s proposed glatiramer acetate, i.e., Copolymer-1 product, before the expiration of the orange book patents.

12. In view of the ANDA application made by Mylan, Teva and Yeda sued Mylan and Natco in the US District Court, Southern District of New York ('SDNY') for infringement of US Patent Nos. 7,199,098; 6,939,539; 6,054,430; 6,620,847, 5,981,589; 6,342,476; 5,800,808; 6,048,898 and 6,362,161. It is stated that included among the patent claims asserted in the US action against Mylan and Natco were Claims 2 and 3 of US '430 and Claims 2 and 3 of US '898. It is stated that, in the said US suit, Natco counterclaimed and sought a declaratory judgment of non-infringement, unenforceability and invalidity of the US patents.

13. In para 39, it was stated that, after the trial, the US Court found that the glatiramer acetate product that Mylan and Natco sought to sell in the US infringed the Claims of US '430 and US '898. It was asserted in para 40 of the plaint that "The US Court decision leads to an incontrovertible conclusion of infringement of rights of Plaintiffs No. 1 and 2 in IN '759 based on the manufacture of glatiramer acetate by Defendant No.2 for export and sale in the United States." It was stated in para 41 that Natco's act of manufacturing the glatiramer acetate product for sale in the US and elsewhere amounted to a clear infringement of the Indian Patent No. 190759 and was, therefore, liable to be restrained by a permanent injunction.

14. In the cause of action para, i.e., para 42 of the plaint, it was stated that the cause of action arose "in and around 2010-2011" when it came to the knowledge of the Plaintiff that Natco had tied-up with Mylan for manufacture and supply of Glatiramer Acetate. Reference was made to the business line article of January 2012. It was stated that the Plaintiff had come

to the Court “as soon as the evidence of the Defendants’ infringement was collated.”

15. In order to justify the territorial jurisdiction of this Court to entertain the present suit, it was stated in para 43 of the plaint as under:

“43. This Hon’ble Court has territorial jurisdiction to entertain the present suit as the Defendant No.2 is involved in a large number of activities which establish beyond doubt that they have purposefully availed of Delhi and targeted Delhi and the customers, consumers, suppliers and host of other persons for various aspects of their business activities. The same is evident from the following:

(i) The Defendants are selling and/or offering for sale its products through M/s Belsons Pharmaceutical Distributors located at 16, Subhash Marg, Darya Ganj, New Delhi-110 002, which claims to be the sole authorized medicine distributor and agent of NATCO in New Delhi;

(ii) The Defendants have admitted in other infringement proceedings that it supplies products to various hospitals all over India and its drugs are found with amongst all chemists all over India and it has a distribution network in almost every city in India including all the districts in the country;

Hence, this Hon’ble Court has territorial jurisdiction under Section 20 of the Code of Civil Procedure. Further, the Defendants have been carrying on business in New Delhi through a variety of activities including activities through a liaison agent located in Pitampura, Delhi. As evident from the MTNL telephone directory of Delhi, the Defendants are also carrying on business from D-70, Okhla Phase-I, New Delhi-110 020. Further particulars of the Defendants activities

shall be proved after discovery and the Plaintiffs crave leave to rely on additional evidence at a later stage of the proceedings.”

Natco’s application under Order VII Rule 10 CPC

16. The Court is not referring, at this stage, to the written statement filed by Natco and the replication filed by the Plaintiffs, but would like to refer first to the application filed by the Plaintiffs under Order VII Rule 10 of the Code of Civil Procedure, 1908 (‘CPC’), i.e., IA No. 10390 of 2013, questioning the jurisdiction of this Court to entertain the suit.

17. In the said application, it has been stated in para 3 that Natco does not have any manufacturing facility at New Delhi. It neither practices the process in Delhi nor exports the product from Delhi. It is stated that Natco manufactures Copolymer-1 under the mark ‘GLATIMER’, but not at Delhi. Natco does not carry on any business within the jurisdiction of this Court. It is pointed out that the suit patent is a process patent for preparation of Copolymer-1. Natco submits that the patent for the product, though applied for by the Plaintiff, has been rejected. Thus, for the purposes of the suit, no part of the cause of action has arisen within the jurisdiction of this Court. It is further submitted that assuming without admitting that Natco is carrying on business within the jurisdiction of this Court, the Plaintiffs have not obtained leave to sue Natco has been obtained under Section 20(b) CPC.

Submissions of counsel

18. This Court has heard the submission of Mr. Sudhir Chandra, learned Senior counsel, Mr. Dushyant Dave, learned Senior counsel and Mr.

Praveen Anand, learned counsel for the Plaintiffs and of Mr. Chetan Sharma, learned Senior counsel and Ms. Rajeshwari, learned counsel for Natco.

19. It is submitted on behalf of the Plaintiffs that under Section 48(b) of the Patents Act, 1970, a patentee has not only the exclusive right to prevent third parties from infringing the patented process, but also stopping them from selling or offering for sale any product obtained directly by the patented process. It is stated that the Plaintiffs have a real and reasonable apprehension that Natco is going to launch the product by the Mylan process in the Indian market within the jurisdiction of this Court.

20. In the written submission, it is stated by the Plaintiffs that the threat of Natco launching the product through the impugned process within the jurisdiction of this Court becomes imminent because Natco is already selling glatiramer acetate by the Indian process in New Delhi under the brand name Glatimer; that it has an office at Okhla, New Delhi, which is listed in the MTNL Directory; that its authorised distributor is in New Delhi; that it supplies various products to various hospitals and chemists at New Delhi; that it carries out its activities through a liaison agent in New Delhi and that Natco has obtained an import license from the Central Drug and Standard Control Organization, New Delhi. It is stated that Natco has marketing approval to sell glatiramer acetate in India and, therefore, there is a reasonable apprehension that the said product manufactured by the Mylan process will be sold in India without Natco having to obtain a second market approval from the Indian regulatory agencies. Reliance is placed on the

decisions in *Kuldip Singh v. Subhash Chander Jain (2000) 4 SCC 50* and *Bristol Myers Squibb v. V C Bhutada 2013 (56) PTC 268 (Del)*.

21. It is Natco's case that there is no averment/pleading in the plaint that the process patent is being practised at Delhi. It is again pointed out that the product patent has been refused and, therefore the Plaintiff has no enforceable rights in respect of the resultant product, glatiramer acetate. It is further submitted that the specific case of the Plaintiffs is that the product is meant for export market, and even on that token, the possible sale in India, including the apprehension of sale, is *prima facie* not credible enough to substantiate *quia timet action*. In particular, it is pointed out that there is no pleading that there is an infringement of process patent IN 190759 within Delhi. There is no denial that Natco's manufacturing units are presently only in Hyderabad and not in Delhi. Natco relies on the decisions in *Astra Zeneca Canda Inc. v. Novopharm Limited 2009 FC 1209* and *Connaught Laboratories Limited v. Smithkline Beecham Pharma Inc. (1998) 86 CDR (3d) 36*.

Decision on the application under Order VII Rule 10 CPC

22. At the outset, it must be stated that it was repeatedly stressed by learned Senior counsel for the Plaintiffs that CS (OS) No. 3193 of 2012 is a *quia timet action*. Only an apprehension has been expressed that Natco, having tied up with Mylan, is likely to export the infringing Copolymer-I to US and other countries.

23. The second factor is that, admittedly, Indian patent No. 190759 is a process patent. The present suit is not about the infringement by Natco of a product patent held by the Plaintiffs. It appears that the Plaintiffs' application No. 93/Del/2003 for the product glatiramer acetate was rejected after a pre-grant opposition by Natco. Copy of an order dated 3rd March 2009 of the Controller of Patents has been placed on record by Natco. The Plaintiffs on their part do not dispute the above fact. They appear to have filed an appeal before the IPAB against the rejection of their application for grant of a product patent in respect of the product glatiramer acetate. This is an important distinction to be borne in mind since the pleadings will have to be appreciated from the point of view of what is specifically averred in respect of each of the above factors in the plaint and in reply to the application under Order VII Rule 10 CPC by the Plaintiffs.

24. A third factor to be kept in view is that in examining whether the application under Order VII Rule 10 CPC raises credible grounds of objection as to the jurisdiction of the Court, the Court is expected to proceed on the basis that the averments in the plaint are *prima facie* correct. The Court at this stage can examine the plaint, the documents filed along with it, and the pleadings in the application under Order VII Rule 10 CPC. The Court is not expected to look into the written statement and replication in the suit. Also, at this stage, the Court will not countenance an attempt by the Plaintiffs to travel outside of the above pleadings to find a factual basis for resisting the plea of lack of jurisdiction.

25. In the above background, it is seen that in para 40 of the plaint it has been averred that the Plaintiffs have an apprehension that the product manufactured by Natco, by allegedly infringing Indian Patent No. 190759, would be exported by Natco to the US.

26. In reply to IA No. 10390 of 2013, the Plaintiffs state as under:

“The Defendants have two different Glatiramer Acetate (GA) products – one for sale within India and the other for export to Mylan, and are using two different manufacturing processes to make these products. The Defendants admit this in paragraph 5 of their Written Statement as well as in the affidavit dated 6th July 2013 filed by Dr. AKS Bhujanga Rao. This suit does not concern the process used by Defendants for making the Glatiramer Acetate product sole by them for the Indian market (hereinafter referred to as the “GA-first product”). The present suit concerns the process for making the Glatiramer Acetate product that the Defendants are manufacturing in India on behalf of Mylan for sale outside India (hereinafter referred to as a “GA-second product”). This submission is without prejudice to the Plaintiffs’ reasonable apprehension that the Defendants might also be selling the “GA-second product” in India including New Delhi.”

27. Further the Plaintiffs state:

“Therefore, the cause of action in suit CS (OS) No. 1708 of 2007 is different from that of CS (OS) No. 3193 of 2012 and also the prayers contained therein are clearly distinct. As explained above, the earlier suit pertained to the GA – first product, sold in India, and the present suit pertains to the separate and distinct GA - second product made in India for export to the US and other countries. This necessitated the filing of the present suit.”

28. It is, therefore, clear that the case of the Plaintiffs concerns the infringement of the process involved in the GA-second product, which the Plaintiffs term as the 'Mylan process' and about the possible infringement for the purposes of 'export' of the said product to the US and elsewhere.

29. The averments in a plaint alleging infringement or apprehended infringement of a process patent would have to be precise. In *Astrazeneca Canada Inc. v. Novopharm Limited*, the Court referred to the adoption of the device of 'wordsmithing' in pleadings and the possibility of the Court not entertaining pleadings that lacked material facts. It was held that "an action cannot be brought on speculation in the hope that sufficient facts may be gleaned on discovery that will support the allegations made in the pleadings." In *Connaught Laboratories Limited v. Smithkline Beecham Pharma Inc.*, the Court in Ontario held that a statement of claim initiating a *quia timet* proceedings alleging patent infringement "must allege a deliberate expressed intention to engage in activity the result of which would raise a strong possibility of infringement; the activity to be engaged in must be alleged to be imminent and the resulting damage to the plaintiff must be alleged to be very substantial if not irreparable; and, finally, the facts pleaded must be cogent, precise and material. It is not sufficient that they be indefinite or speak only of intention or amount to mere speculation."

30. In light of the above legal position, the averments in the plaint in the instant case would have to be examined to ascertain if there is any specific plea that there is a violation of the process patent within the jurisdiction of

this Court. The Court finds that there is no such specific averment. There is no averment that the process patent i.e. Indian patent No.190759, or for that matter the 'Mylan process', is being practised/infringed by Natco within the jurisdiction of this Court. This has also to be seen in the context of the fact that there is no denial by the Plaintiffs that there is no manufacture of the GA- second product in Delhi. There is also no denial by the Plaintiffs that Natco has at present its manufacturing facilities only in Hyderabad.

31. Since the suit concerns a process patent, the pleadings as regards the product being sold in Delhi or elsewhere, or the possibility of it being launched in Delhi or elsewhere cannot justify the jurisdiction of this Court. To recapitulate, in para 40 of the plaint it is averred that "The US Court decision leads to an incontrovertible conclusion of infringement of rights of Plaintiffs No. 1 and 2 in IN '759 based on the manufacture of glatiramer acetate by Defendant No.2 for export and sale in the United States." In para 41 it is stated that Natco's act of **manufacturing** the glatiramer acetate product "for sale in the US and elsewhere" amounts to infringement of the process patent. The averment is not that such manufacturing of the product for export to the US and elsewhere is happening or is apprehended to happen within Delhi. In the circumstances, the invocation of Section 48(b) of the Patents Act 1970 by the Plaintiffs to urge that the product obtained as a result of infringement of process is sold or apprehended to be sold in Delhi appears to be misconceived. The fact that Natco may have an office in Delhi or a distributor in Delhi is not relevant given the fact that the subject matter of the suit is a process patent, and the action brought forth is for alleged

infringement of that process for the purposes of export to the US and elsewhere.

32. Further, notwithstanding the legal position that the statements made by the Plaintiffs in the written submissions or list of dates, which do not form part of and are not contained either in the plaint or in the pleadings in the application under Order VII Rule 10 CPC cannot possibly be taken into account by the Court for deciding the application under Order VII Rule 10 CPC, the fact that Natco has obtained an import license from the Central Drug and Standard Control Organization or that it has marketing approval to sell glatiramer acetate in India or that it is already selling 'Glatimer' by the Indian process in Delhi are not relevant as regards the question of jurisdiction in a suit for alleged infringement of a process patent for the purposes of export to the US and elsewhere.

33. The above factors distinguish the present case from the decision in *Bristol Myers Squibb v. V C Bhutada*. There, the issue concerned the apprehension of infringement of a product patent. The Defendants in that case had already obtained approval from the Drug Controller for marketing the product without any restriction as to territory.

34. The Court is satisfied that the plaint in CS (OS) No. 3193 of 2012 fails to make out a case for the Court to entertain the suit within its jurisdiction. Consequently, in exercise of the powers under Order VII Rule 10 CPC, the Court directs the plaint to be returned to the Plaintiffs

for presentation in the appropriate court. IA No. 10390 of 2013 is allowed accordingly, but without any order as to the costs.

IA Nos. 10389 of 2013, 10638 of 2013, 20025 of 2013 and 18788 of 2013

35. In view of the above conclusion, the Court does not consider it necessary to deal with any of the above applications. All questions and contentions raised by the parties are left open to be decided in accordance with law in appropriate proceedings. The suit and pending applications are disposed of in the above terms.

FEBRUARY 28, 2014

dn/tp



S. MURALIDHAR, J.