Intas Laboratories Pvt. Ltd. And Anr. vs Novaritis A.G., Schwarzwaldallee, ... on 20 December, 2004

Equivalent citations: 2005(1)CTC27

Author: P.D. Dinakaran

Bench: P.D. Dinakaran, S.R. Singharavelu

ORDER

P.D. Dinakaran, J.

1. These appeals are directed against the common order dated 28.4.2004 made in O.A.No. 13/2004 and A.No. 1218 of 2004 in C.S.No. 5 of 2004; O.A.No. 14 of 2004 & A.No. 1076 of 2004 in C.S.No. 6 of 2004; O.A.No. 15 of 2004 and A.Nos. 841, 842 and 843 of 2004 in C.S.No. 7 of 2004; O.A.No. 16 of 2004 and A.Nos. 844, 845 and 846 of 2004 in C.S.No. 8 of 2004; and O.A. No. 17 of 2004 and A.Nos. 847, 848 & 849 of 2004 in C.S.No. 9 of 2004 filed by the respondents herein/plaintiffs in the respective suits, wherein the learned single Judge made absolute the order of ex parte injunction dated 20.01.2004 made in O.A.Nos. 13 to 17 of 2004 in C.S.No. 5 to 9 of 2004 in favour of the respondents/plaintiffs in each of the suits and dismissed the applications filed by the appellants/defendants to vacate the ex parte order of injunction dated 20.1.2004 in each of the suits.

2. The respondents/plaintiffs filed the above suits, viz., C.S.Nos. 5 to 9 of 2004 against the appellants herein/defendants in the suit for a common relief, namely:

> (a) for a decree of permanent injunction restraining the respective defendants, their directors, their partners, servants, agents, licensees, and distributors and anyone claiming through them from manufacturing, for sale, distributing, selling, marketing and/or exporting their and cancer drug composed of "Beta-Crystalline form of Imatinib Mesylate" under the mark/name "IMATIB","IMALEK","IMANIB","ZOLETA" and "TEMSAN" respectively or any other brandname/mark or otherwise; so long as the Exclusive Marketing Right granted by the Controller of Patents on 10.11.2003 under EMR No. 002 and notified in the Official Gazette on 13.12.2003 is subsisting;
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> (b) for a direction to the respective defendants to render a true and faithful account of the profits made by the defendants by selling the anti cancer drug being the "Beta-Crystalline form of Imatinib Mesylate" under any mark or otherwise by a preliminary decree;

(c) for a decree that the entire stock of the impugned drug in the custody or possession of each defendant be forthwith seized and kept in the custody of the Hon'ble Court or the custody thereof be handed over to the plaintiffs' and/or their representatives/ agents.

3.1. The common case of the respondents/plaintiffs in all the suits is that:

(i) India, as a member of World Trade Organisation and by virtue of it's agreement on trade related aspects of intellectual property rights (TRIPS AGREEMENT), is under an obligation to consider granting product patent in all fields, including medicines and drugs with effect from 1.1.2005;

(ii) by way of an interim measure, till the product patent application is taken up for consideration, provision is made in the Patents Act for granting Exclusive Marketing Rights (hereinafter referred to as 'EMR');

(iii) the first plaintiff filed a patent application in India on 17.7.1998 for the product patent referred to above;

(iv) the first plaintiff filed an application in a convention country, i.e., Australia on 16.7.1998 claiming patent for the identical product;

(v) marketing approval to sell the identical product was granted in Australia on 13.8.2001 followed by the proceedings dated 28.2.2002, by which, the patent product was granted in Australia;

(vi) on 4.12.2001, marketing approval for an identical product was granted in India in favour of the second plaintiff by the Drug Controller General;

(vii) on 27.3.2002, the plaintiff filed an application with the patent office Kolkata for an "EMR" for the patent product and "EMR" was granted on 10.11.2003;

(viii) "EMR" confers an exclusive right to sell or distribute the drug referred to earlier for a period of five years or till an order is passed in the patent claim in India either way, whichever is earlier; and

(ix) the Drug Controller of India had given marketing approval to the second plaintiff for the drug in question by order dated 5.12.2002 valid for the period from 1.1.2003 to 31.12.2005 and the defendants, either in their capacity as the manufacturer or distributor, are infringing the rights of the plaintiffs, given under the "EMR", by dealing with the same drug.

3.2. It was thus contended by the respondents/plaintiffs that they have obtained a valid EMR from the authorities concerned; the balance of convenience lies in their favour; the element of public

interest has also been taken care of for supply of free GLIVEC medicine by the programme called as GIPAP programme and therefore, if injunction is not granted, the respondents/plaintiffs would suffer irreparable loss.

3.3. Incidentally, it was also contended by the respondents/plaintiffs that, assuming if any public interest suffers on account of the price determined by the authority, the Central Government alone can, by notification, pass appropriate directions exercising the power conferred under Section 24-D(2) of the Patents Act.

4. Pending the above suits, the respondents/plaintiffs sought for an order of interim injunction, which is identical in all the Original Applications and based on the above pleadings, the learned Single Judge, granted ex parte injunction on 20.1.2004, as modified by an order dated 26.2.2004.

5. Aggrieved by the grant of ex parte interim injunction by order dated 20.1.2004, as modified by the order dated 26.2.2004, the appellants/ defendants filed applications to vacate the order of ex parte injunction dated 20.1.2004.

6.1. The suits were resisted by the appellants/defendants as follows:

(i) The first plaintiff filed a patent claim in "US" on 28.4.1994 titled "Pyrmidine derivatives and processes for the preparation thereof, priority for this application was claimed from "Swiss" patent application filed on 1.4.1992;

(ii) this patent was granted by "US" on 28.5.1996 disclosing "Mesylate Salt of Imatinib";

(iii) for the same invention, the plaintiff filed a patent claim in "Canada" on 1.4.1993 basing again the priority on the "Swiss" patent application referred to earlier;

(iv) "Canada" granted patent on 26.11.2002;

(v) no patent for "Imatinib Mesylate" was ever filed in India and therefore, there is no question of the plaintiffs entitled to any protection on the basis of any patent that may still subsist abroad for "Imatinib" per se or for the "Mesylate Salt of Imatinib";

(vi) no patent can be granted, if the said subject matter was claimed elsewhere, before the priority date claimed in India;

(vii) the first plaintiff filed a patent application in India on 17.7.1998 titled "Crystal modification of a N-Pheny - 2 - Pyrimidineamine derivative process for it's manufacture and it's use;

(viii) for this application, the priority date is 18.7.1997 Switzerland;

(ix) on the date of filing the patent application in India, Switzerland was not a convention country and it was notified as a convention country only on 28.9.1998 and therefore, no patent can even be granted in India to the invention referred to above;

(x) the first plaintiff obtained a patent in Australia based on the priority on the "Swiss" patent application of July 18, 1997;

(xi) the "EMR" issued in this case does not disclose the specific substance claimed in the Australian patent, on which it is based;

(xii) the "EMR" granted is vague and indefinite;

(xiii) the first plaintiff is trying to create a monopoly and to take the entire profits out of the sale of drugs covered under the "EMR", adversely affecting the interest of the patients in India;

(xiv) the cost of one capsule marketed by the plaintiffs is Rs. 1,700 whereas the cost of the drug in question sold by the Indian manufacturer averages less than Rs. 100 per capsule;

(xv) taking the price tag, the cost of the plaintiffs' product per year would be approximately Rs. 25 Lakhs while the same would be Rs. 1-1/2 lakhs for an Indian drug;

(xvi) India being a poor country, many cannot afford to buy the plaintiffs' product and ultimately, they would die untreated;

(xvii) the plaintiffs have to establish that the "EMR" was validly granted and it is being infringed;

(xviii)appropriate tests have never been carried out in Australia in relation to "Beta-Crystalline form of Imatinib Mesylate" and therefore, granting marketing approval without conducting tests in Australia is not valid;

(xix) here also, the permission to import "Imatinib Mesylate" to India was not granted to the first plaintiff but only to the second plaintiff; and (xx) the "EMR" holder and the import licence holder must be the same and that not being the case here, the injunction must be vacated.

6.2. The appellants/defendants thus contended that in a suit complaining infringement of a patent, in the instant case the EMR, the plaintiffs must make out a strong and prima facie case for the issue of a temporary injunction. Since a serious controversy exists as to whether or not the invention claimed by the respondents/plaintiffs is a new one or a new manufacture or whether or not the

invention involves any new inventive skill having regard to what was known or used prior to the date of the patent, it may not be just and proper to pass an order of interim injunction restraining the appellants/defendants from pursuing their normal business activities.

7. After hearing both sides, the learned Single Judge, by order dated 28.4.2004 finding that the balance of convenience lies in favour of the respondents/plaintiffs in each of the suits and that the public interest had also be taken care of by the GIPAP programme, made absolute, the order of ex parte injunction granted on 20.01.2004 and dismissed the applications filed to vacate the ex parte injunction. Hence, the above appeals.

8. We heard the elaborate arguments made on both sides, reiterating the contentions that were made before the learned Single Judge and we have given careful consideration to the same.

9. The main contention of the appellants/defendants is that the EMR obtained by the respondents/plaintiffs in each of the suits is not in accordance with the provisions of the Patents Act, 1970, as the conditions imposed under Section 24-B of the Patents Act, 1970 have not been satisfied by the respondents/plaintiffs and therefore, they are not entitled for an order of interim injunction with respect to the patent till it is five years old. In this regard reliance was placed on the decision in V. Manicka Thevar v. M/s. Star Plough Works, and Niky Tasha India Pvt. Ltd. v. M/s. Faridabad Gas Gadgets Pvt. Ltd., 1984 PTC 87. It is also contended that the GIPAP programme is not sufficient to protect the public interest and the same is nothing but self-serving.

10. On behalf of the respondents/plaintiffs, it was contended that as long as the EMR obtained by the respondents/plaintiffs from the authorities concerned under the provisions of the Patent Act, 1970, which is valid for five years or till the disposal of the patent application one way or other/ whichever is earlier, and until the same is revoked under due process of law, the right conferred under EMR in favour of the respondents/plaintiffs shall not be interfered with or infringed by the appellants/defendants in any manner; and in any event, since the GIPAP Programme takes care of the public interest, the appellants/defendants cannot have any grievance in that regard, and even if any public interest is involved with reference to the determination of the price of the suit product, they are at liberty to move the Central Government for necessary directions invoking the power of the Central Government conferred under Section 24-D(2) of the Patents Act, 1970.

11. From the above rival contentions made by either side on the validity of the EMR granted in favour of the respondents/plaintiffs in each of the suits, we are of the considered opinion that it would not be proper for us to decide the said issue in appeals arising out of interim orders as the same would render the suit itself infructuous leaving nothing for the trial, as any view, opinion or finding expressed in that regard would automatically be binding on the learned Single Judge in the trial. We are, therefore, inclined to eschew any of the findings of the learned Single Judge with reference to the validity of the EMR granted in favour of the respondents/plaintiffs in each of the suit and to test the order under appeal dated 28.4.2004 only within the parameters of the balance of convenience and public interest in question.

12.1. Since the learned Single Judge, based on the materials placed before him and exercising his discretion, arrived at the finding that the balance of convenience lies in favour of the respondents/plaintiffs, stressing more on the EMR granted in favour of the respondents/plaintiffs under Section 24-B of the Patents Act, 1970, the validity of which has to be tested only in the trial in the suits, we find it difficult to interfere with the same.

12.2. However, the contentions advanced on behalf of the appellants/defendants with respect to the public interest deserves serious concern as the public interest should not be made to suffer on account of legal battle between the trading parties, particularly in the case of supply of medicines for Chronic Myeloid Leukaemia.

13.1. In response to the concern expressed by this Court in the public interest, Mr. Habibulla Basha, learned Senior Counsel, of course based on the telephonic instructions from the respondents/plaintiffs, fairly came forward to relax the conditions imposed in the GIPAP programme in the public interest. Accordingly, the learned Senior Counsel for the respondents/ plaintiffs gave an undertaking to the following effect, pending disposal of the suit:

> (a) the respondents/plaintiffs would supply Beta-Crystalline form of Imatinib Mesylate freely to all the patients, who are suffering from Chronic Myeloid Leukaemia and are earning less than Rs. 3,36,000 per month;
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> (b) in the case of patients suffering from Chronic Myeloid Leukaemia, who are entitled for insurance for Chronic Myeloid Leukaemia, any amount which falls short of insurance policy shall be met by the respondents/plaintiffs;
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> (c) similarly, in the case of patients suffering from Chronic Myeloid Leukaemia, who are covered under reimbursement scheme, any amount falling short of reimbursement shall be met by the respondents/plaintiffs; and
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> (d) "Beta-Crystalline form of Imatinib Mesylate" medicine required for the patients, who are diagnosed as suffering from Chronic Myeloid Leukaemia by whichever hospital, shall be supplied by the respondents/plaintiffs to the hospitals as per their requirement; and the hospitals while placing such orders shall also inform the respondents/plaintiffs, the amount that would be met by the insurance company (reimbursing authority) and the amount to be met by the respondents/plaintiffs.

13.2. However, Mr. Habibulla Basha, learned Senior Counsel appearing for the respondents/plaintiffs sought time till 22.12.2004 to enable the respondents/plaintiffs to file an affidavit of undertaking to the above effect.

14. Recording the undertaking of the learned Senior Counsel made on behalf of the respondents/plaintiffs, we confirm the order of interim injunction dated 28.4.2004 of the learned Single Judge granting time to the respondents/ plaintiffs till 22.12.2004 to file an affidavit to the above effect before the Registry, and pending disposal of the suits,

(i) the respondents/plaintiffs would supply Beta-Crystalline form of Imatinib Mesylate freely to all the patients, who are suffering from Chronic Myeloid Leukaemia and are earning less than Rs. 3,36,000 per month;

(ii) in the case of patients suffering from Chronic Myeloid Leukaemia, who are entitled for insurance for Chronic Myeloid Leukaemia, any amount which falls short of insurance policy shall be met by the respondents/ plaintiffs;

(iii) similarly, in the case of patients suffering from Chronic Myeloid Leukaemia, who are covered under reimbursement scheme, any amount falling short of reimbursement shall be met by the respondents/plaintiffs;

(iv) "Beta-Crystalline form of Imatinib Mesylate" medicine required for the patients, who are diagnosed as suffering from Chronic Myeloid Leukaemia by whichever hospital, shall be supplied by the respondents/plaintiffs to the hospitals as per their requirement; and the hospitals while placing such orders shall also inform the respondents/plaintiffs, the amount that would be met by the insurance company reimbursing authority) and the amount to be met by the respondents/plaintiffs;

(v) the parties are at liberty to agitate their respective contentions before the learned single Judge and the same shall be considered on merits, independently, without any reference to any of the views expressed by the learned single Judge in the order dated 28.4.2004 or being infringed by any of the observations made hereunder;

(vi) the respondents/plaintiffs shall also file a report in compliance of the above arrangement every month before this Court in the suit as to the supply of medicines;

(vii) the parties are at liberty to move the learned single Judge or My Lord, the Honourable Chief Justice for expeditious disposal of the suits;

(viii) if any difficultly arises in implementing the above arrangement, either of the parties are at liberty to move this Court by appropriate applications, if they are so advised; and

(ix) all the original side appeals are disposed of accordingly. No costs. Consequently, the connected C.M. Ps are closed.