(2004) 12 BOM CK 0043

In the Bombay High Court

Case No : Notice of Motion No. 293 of 2004 in Suit No. 261 of 2004

Novartis AG and Another — APPELLANT

Vs

Mehar Pharma and Another — RESPONDENT

Date of Decision : 23-12-2004

Acts Referred:
Patents Act, 1970 — Section 24B

Citation : (2005) 3 BomCR 191 : (2005) 30 PTC 160

Hon'ble Judges : D.K. Deshmukh, J

Bench : Single Bench

Advocate : Divyanshu Dave, Nitin Sen and Rajesh Gajaria, instructed by Gajaria and Co, for the Appellant; Ravi Kadam and V.R. Dhond, instructed by S.R. Legal, for Defendant No. 1 and Aspi Chinoy, instructed by S.R. Legal, for Defendant No. 2, for the Respondent

Judgement

D.K. Deshmukh, J.—The plaintiffs have moved the present Notice of Motion in the suit seeking reliefs in terms of prayers (a) and (b) thereof, inter alia, seeking a restraint order against the Defendants from manufacturing for sale, sell, marketing and exporting their anti cancer drug composed of the "B-crystalline form of imatinib mesylate salt"'' under the brand name "VEENAT" or any other brand name till such time the exclusive marketing rights granted in favour of the plaintiffs on November 10, 2003 and gazetted on December 13, 2003 subsists. The plaintiffs also seek an order of appointment of a court receiver in terms of prayer (e).

2. The plaintiffs submit that they are the holders of Exclusive Marketing Rights (hereinafter referred to "EMR") granted under Chapter IV-A of the Patents Act, 1970 (hereinafter referred to "the Act"). Section 24B of the Act deals with grant of EMR.

It is submitted that since the plaintiffs have been granted in EMR, akin to a patent right by an expert statutory authority, i.e. the Patent Office, the plaintiffs are entitled to the temporary injunction. The Patent Office deliberated on the

matter for one and a half years and carried out an intense examination of the matter before the EMR was finally granted. The plaintiffs rely on statutory illustration (e) of Section 114 of the Evidence Act, 1872 which says that that Court may presume that judicial and official acts have been regularly performed.

3. It is further submitted that under the EMR granted on November 10, 2004, the plaintiffs have the following exclusive rights i.e., "Now, therefore the said applicant is hereby granted, subject to the provisions of the law for the time being enforce, the exclusive right to sell or distribute the B-CRYSTALLINE FORM OF IMAITNIB MESYLATE IN ITS DOSES FORMS as approved by appropriate authority, in India by their agents or their licensees."

The exclusive right abovesaid shall stand terminated at the end of five years from the date of grant of exclusive marketing right, or on the date of grant of patent or on the date of rejection of application for the grant of patent in India, whichever is earlier. In respect of this very right the Hon''ble High Court of Madras granted an order of ex-parte injunction in favour of the plaintiffs in Suit Nos. 5-9 of 2004. Subsequently by a detailed order dated April 28,2004, the High Court of Madras has confirmed the aforesaid order of the ex-parte injunction and has been pleased to grant interim injunction pending the suit pending before that High Court restraining the Defendants herein from infringing the EMR in any manner. Further the plaintiffs submit that although the said judgment and order has been appealed in Appeal No. O.S.A. No. 170 of 2004, the operation and implementation of the said Order by the Division Bench of the Madras High Court has not been stayed. The plaintiffs are, therefore, entitled to an Order or injunction from this High Court against the present defendants. The plaintiffs further submit that the EMR gives an exclusive right all over India and if the Hon''ble High Court of one State has restrained the defendants, it would be just and proper that this Hon''ble High Court may also injunct the present defendants accordingly. Undisputedly the two actions are identical, being proceedings against similarly situated defendants and relying on the same evidentiary material which establishes the identical nature of the impugned drugs of all the defendants, regardless of jurisdiction.

4. Until the amendments made by the Patents (Amendment) Act, 1999, only a Process Patent was granted for a medicine or a drug. Old Section 5 was renumbered as Section 5(1) and Sub -clause (2) was added by the Patents (Amendment) Act, 1999 and Product Patent for a medicine or a drug can now be applied for and it may be granted u/s 5 (2) in the manner provided under Chapter IV (A).

5. The plaintiffs submit that denial of an Order of injunction in the present notice of motion will certainly be against the will of our Parliament as expressed in sections 24A to 24F of Chapter IV A read with Sub-section (2) of Section 5.

It is submitted that a combined reading of these provisions clearly make it clear that the holders of EMR are entitled to be protected by an Order of injunction

against the infringers in terms of Chapter XVIII of the Act particularly in terms of Section 108 thereof it is further submitted that the plaintiffs have adduced evidence along with the plaint to show a prima facie case and establish that the defendants'' "VEENAT" is infringing the EMR granted to the plaintiffs in respect of their drug GLIVEC.

6. It is submitted that the defendants have not disputed the factum of infringement. The plaintiffs submit that there is no objection-from the defendants even after almost one year of the filing of the suit to the averments made in paragraphs 23 to 25, amongst other paragraphs.

Their case is that the patent granted in 31 countries of the world and which resulted in grant of EMR ought not to have been granted because they contend that the Plaintiff No. 1 is earlier 1993 invention allegedly disclosed the beta crystalline form of imatinib mesylate. In this regard, the Plaintiffs submit as under:

(a) At the prima facie stage, this Court need not to go into this aspect because the Certificate of EMR together having been gazetted on December 13, 2003 coupled with the fact that 31 patent jurisdictions worldwide have granted patents on the drug in question, which fact clearly support an Order of injunction.

(b) The patent application for beta crystalline form of imatinib mesylate clearly cites the earlier 1993 invention in the beginning. The 1993 invention was for imatinib per se, and not for imatinib mesylate, let alone the beta crystalline form of imatinib mesylate. Had the beta crystalline form of imatinib mesylate been disclosed, the Plaintiff No. 1 would never have been successful in securing patents in 31 of the 50 countries till date.

(c) Without prejudice to the above, this action is for infringement of an EMR. It is not an action for infringement of a Patent. In the normal case of a patent an application is made u/s 7, a provisional specification followed by complete specification is submitted u/s 9. The specification shall be in the manner provided u/s 10. A request for examination of the application for a Patent may be made u/s 11 (B) Thereupon a claim for Patent is taken up for examination u/s 12.

(d) By virtue of Section 12 (l)(c), the Examiner shall report the result of the investigations made u/s 13. u/s 13, the examiner is required to investigate whether or not the invention claimed has been disclosed earlier or more precisely, "Anticipated by prior publication". Thus, it is only by virtue of Section 12(l)(c) read with Section 13 that the question of "Anticipation by prior publication" arises for consideration.

(e) In the case of Product Patents for a medicine or a drug, Section 5 (2) contains a non obstinate clause and stipulates that the claim for Patent shall be dealt with in the manner provided in Chapter IV (A). The first part of Section 24 (A) prohibits the Controller from referring the application u/s 5 (2) for examination u/s 12 (1) until December 31, 2004. By applying such prohibition,

the claim for a Patent made u/s 5 (2) cannot be examined in the light of Section 12(l)(c) read with Section 13. Therefore, the inescapable conclusion is that there is no question of examination whether or not there has been "Anticipation by prior publication". It is submitted that "Anticipation by publication" is dealt with in Sections 29 to 34, and these provisions are not attracted to an application u/s 5 (2), because Section 12 (l)(c) and Section 13 are excluded.

(f) In the case of an application for grant of EMR u/s 24B, the examiner has to make a report on two matters only, namely,

(i) whether the invention is not an invention in terms of Section 3; and

(ii) whether the invention is an invention for which no Patent can be granted in terms of Section 4.

Hence, for the purpose of grant of EMR, the claim for a product Patent for a medicine or drug u/s 5 (2) can be examined u/s 3 and Section 4 and no other aspect or issue in regard to the claim can be examined at this stage. Section 3 provides what are not inventions. Section 4 provides that no Patent shall be granted in respect of an invention relating to Atomic Energy. The claim for Patent made by the Plaintiff is not hit by either Section 3 or Section 4.

(g) The plea taken u/s 3(d) by the Defendants is false and misconceived. The prohibition u/s 3(d) is only in respect of a known substance. The substance in question, i.e. beta crystalline form of imatinib mesylate was neither known nor invented until the Plaintiff No. 1 was successful in inventing the same in the late 1990''s. Indeed, this is evidenced by the fact that the Defendant claims to have come in the market only in January 2003. Had the beta crystalline form of imatinib mesylate been known since 1993, it could have reverse engineered the 1993 invention and come to the market sooner, if not before the Plaintiff No. 1 invented the beta crystalline form-of imatinib mesylate. However, the Defendants had to wait until the Plaintiffs launched the commercial embodiment of the substance under the brand name GLIVEC before they could make their impugned drugs.

(h) Any further examination of the underlying patent examination will result in examining a black-box/mail-box application, which exercise is prohibited by the Legislature in terms of Section 24-A

7. Nevertheless, the plaintiffs further submit the entire attempt on the part of the defendant to oppose the Notice of Motion and grant of an order of injunction is based upon the specious plea, namely that the research in respect of beta crystalline form of imatinib mesylate is not an invention and is not based on an inventive step. The plaintiffs submit that the expression "invention" and "inventive steps" respectively have been defined in Sub-sections 2(i)(j) and 2(1)(ja) respectively. A combined reading of these definitions make it clear that an invention is a new product and/or process involving inventive steps, that is a feature that makes the invention not obvious to a person skilled in the art and

capable of an industrial application. It is he plaintiffs know that the beta crystalline form of imatinib mesylate is a new product and a process involving inventive step and is capable of having been translated into an industrial application. The beta crystalline form of imatinib mesylate was researched and founded upon inventive steps, which was not obvious to any person other than the plaintiffs and certainly not to the defendants. It is this feature that has made the invention patentable to the exclusion of all others.

8. Further, the Plaintiffs submit that they have adduced sufficient evidence in the form of affidavits of experts to establish, at least prima facie, that beta crystalline form of imatinib mesylate is indeed a new product and/or process involving inventive steps. As against the evidence adduced by the plaintiffs, the defendants have not adduced by evidence much less an evidence of any experts to show that the beta crystalline form of imatinib mesylate is not a new product and/or process involving an inventive step. The only evidence adduced by the defendants is a certificate of IICT Hyderabad, Annexure D5 of the affidavit of Uday Trivedi. The aforesaid certificate does not in any manner dilute the claim of the plaintiffs in respect of. the invention. On the contrary, the certificate at page 170 only concludes as follows:

"The results show that in over 8 experiments performed under various conditions varying the nature of solvent, only the beta crystal form of imatinib mesylate is significantly produced invariably."

Dr. Suffer in is affidavit mentioned above at page 34 the beta crystalline form of imatinib mesylate to IICT and the same was revealed in the analysis. In short, the existence of "beta"; which was unknown to the world till the plaintiffs succeeded in their research sometime during the late 90''s stands established and reconfirmed by this very certificate and it does not show that beta crystalline form of imatinib mesylate is not a new pro have admittedly come into market at best in January 2003, much after the plaintiffs had introduced their GLIVEC in the market in 2002. It is submitted that the defendants'' contention, to the effect that beta crystalline form of imatinib mesylate not a new product or process involving inventive steps is merely a submission unsubstantiated by any evidence, much less any expert evidence.

9. The plaintiffs further submit that legal proceedings instituted by the plaintiffs against the very second defendant, i.e. Natco Pharma Limited, the manufacturer and distributor of "VEENAT" in England alongwith its have been compromised by the said second defendant, who has also given an undertaking not to export and sell "VEENAT" in UK. It is submitted that while the English proceedings were instituted on behalf of the plaintiffs for infringement of sister company Natchem (the first Defendant therein), their Patent No. EP (UK) 0 564 409 in respect of the 1993 invention for imatinib per se, by their solicitor''s letter dated March 5, 2004, the Plaintiffs specifically reserved their right to institute proceedings for infringement of their patent in respect of "B-crystalline form of imatinib Mesylate" being protected in England under Patent No. EP (UK) 0 998 473.

The Defendant''s undertaking covers both the aforesaid patents. If this be so, the defendants cannot now be possibly be allowed to "continue to infringe the plaintiffs EMR in India, when the products are same as in England. It is submitted that the defendants have acted dishonestly and, therefore, need to be restrained by this Hon''ble Court from continuing to act so and infringe the just, legal and statutory rights of the plaintiffs.

10. It is submitted that this is prima facie a stage, such a contention ought not to be accepted, particularly when the plaintiffs'' patent in respect of this very product and/or process has been registered in 31 jurisdictions worldwide. However, before granting the EMR, as mentioned above, the Controller of Patents had conducted a detailed enquiry spread over one and a half years and had referred the matter to the Examiner. The Controller had satisfied himself about the claims of the plaintiffs in terms of the statutory requirements u/s 24-A and B. It is submitted that the Drug Controller of India had granted necessary license/ permission in respect of GLIVEC thereby recognizing the drug to be a useful drug in the market. The plaintiffs, therefore, submit that there is overwhelming and clinching evidence on record to substantiate their case that beta crystalline form of imatinib mesylate is a new product and/ or process involving inventive steps. The Plaintiffs are, therefore entitled to an order of injunction as prayed for.

11. It is submitted that the balance of convenience is in favour of the plaintiffs. It is further submitted that it will cause grave and irreparable damage and injury to the plaintiffs, if an injunction order is denied. As revealed in the plaint and affidavits filed, the Plaintiffs have spent decades of research and millions of dollars in research in inventing and developing the drug. They have also obtained 31 patents in respect of the same and an EMR in India after much effort and time. None of the Defendant companies have voluntarily withdrawn their impugned drugs as a result of which the Plaintiffs have been constrained to enforce their precious statutory grant in a Court of Law. The Plaintiffs will suffer grave and irreparable harm to their reputation and standing if they are incapable of enforcing their statutory rights. The Plaintiffs will be discouraged from their resolve to develop even more innovative and useful drugs for the betterment of patients worldwide in case their right is not enforced.

12. The plaintiffs submit that in matters of intellectual property, particularly infringement of statutory rights like trade mark, copyrights, patents and designs, the Court is, prima facie, required to see where there is an infringement or not. If there is an infringement, then an order of Injunction must follow. The defendants'' contention that the plaintiffs damage can be compensated since the plaintiffs value the some in terms of money value is irrelevant in matters of infringement. It is submitted that in any case the plaintiffs having been granted an EMR as per the statutory scheme, their prayers for specific relief ought not to be denied.

13. It is submitted that keeping in mind the fact that the plaintiffs have spent millions of dollars in research and development and the conduct by the

defendants public interest demands that it be protected. It is submitted that this Court apart from being the Court of law is also a Court of equity. Therefore, the process of this Court ought to come to the aid of a person who conducts research and brings into existence new and innovative products for the betterment of the society at large. Conversely, the Court cannot come to the aid of infringer who wants to steal upon such research and capitalize in clear profiteering motives.

14. The Plaintiffs are successfully running a free programme called Glivec International Patients Assistance Programme (GIPAP) in 70 nations, including India. In India, approximately 3000 patients are enrolled under the programme till date. On the other hand, the Defendant is not pleading the interest of the public. It is a manufacturer who has stolen the Intellectual Property of the Plaintiffs. Plaintiff No. 1 has spent millions of dollars to research and invent the drug. The Defendant No. 2 is pleading a private, commercial interest without any basis in law or equity. The balance of convenience lies in favour of the Plaintiffs. If the reliefs prayed for by the Plaintiffs are granted by this Hon''ble Court, the EMR will remain a paper right. Rather, this Court by granting the specific reliefs as prayed for will honour the TRIPS Agreement and the provisions of the Patents Act in consonance with India''s obligations under the TRIPS Agreement and the provisions of the Patents Act without jeopardising public interest.

15. The defendants oppose grant of reliefs sought by the plaintiffs by this Notice of Motion. At the outset, it is submitted that the suit filed by the plaintiffs relates to a specific form of intellectual property, viz. exclusive marketing rights which is like a patent. A patent right is different is nature, scope and legal effect from other forms of intellectual property such as trade marks and copyright. A patent can be granted for an industrially useful invention, which is novel and not part of the public domain. Once granted a patent confers on the patentee, the exclusive right to prevent others from making, using, offering for sale or importing the patented product in India. No product patent for a medicine can be granted under the law at present, although an application may be filed.

16. Whilst registration of trade marks and copyright in one country has a persuasive value in another, patent and design rights are statutory creatures, territorial in nature and dependent only on specific registration in each country. Registration of patent rights in one country does not automatically confer protection in other countries nor does it have any persuasive value. Registration in each country may be obtained only after passing the tests prescribed in each country. Without registration, the invention or design in question enters the public domain in that country and the public would be free to copy and use the same. Thus, registration of a patent or a design in one country is not a sine qua non for protection of those rights in another country. If this were otherwise, one patent or design right obtained in one country would have been valid all over the world. The EMR granted to the plaintiffs vide order dated 10th November 2003 is an interim right akin to a patent and derivative thereof.

17. It is submitted that the Government of India by Patent (Amendment) Act,

1999 dated 1st June 1999 amended the Patents. Act, 1970 and enacted retrospectively its provisions enabling the grant of ''Exclusive Marketing Rights'' (EMR). The said provisions have however been enacted in utter disregard of the constitutional restrictions giving rise to a draconian creature, untrammelled by any constitutional restraints, as would be evident from the following:-

(a) Unlike a patent application, processing of an EMR application is shrouded in a cloak of secrecy. No member of the public has any right to inspect the file or to file any objections whatsoever in respect thereof. There are no provisions prescribed in this behalf which enable any member of the public to see the file or take inspection of the same.

(b) Unlike a patent application, there is no clear and unambiguous provision as to how the EMR applications would be examined, providing opportunity to hear the applicants, appeal from the Controller''s order etc.

(c) Even after such an EMR is granted, no person from the public may seek revocation of the same on grounds of lack of novelty and inventiveness or any other grounds of non-patentable subject-matter. Unlike patents, the trade and public have no right to file revocation suo motu. There is no clue regarding the Forum where to file revocation (whether before the Appellate Tribunal, High Court, Supreme Court, WTD etc.) what is the time limit within which the revocation may be filed, grounds of revocation etc.

(d) Unlike patent applications, there is no procedure for filing pre-grant opposition, even implied, by the trade and public. There is no provision for appeal from the Patent Controller''s order.

(e) The duration of an EMR is effective for five years from the date of grant or till the date of grant of patent or rejection of patent, whichever is earlier and, during its subsistence, it confers a complete monopoly in the hands of the applicant to sell or distribute the article or substance covered by it to the exclusion or all others and in negation of any public health or public interest considerations. It is material to note that an EMR grantee enjoys such an unfettered monopoly, even though its product patent application is pending and may be rejected after 1st January 2005 whenever examined. Even distribution through channels of charity is hit by the anti-competitive and monopolistic effects of the EMR grant. It is submitted that the TRIPS contemplates provisions for ''Exclusive Marketing Rights, whereas the Amendment Act, 1999 travels beyond and provides for an Exclusive Marketing Right which enables its grantee to sell, market and distribute the products. Thus, the Act confers unfettered superior rights on the EMR grantee. Pertinently, Parliament has not amended Section 5(1) and the prohibition on grant of product patent for medicines and substances having medicinal use continues. Hence, an anomalous situation exists where EMR right is granted in anticipation of grant of a patent which until amendment of Section 5(1) can never be granted.

(f) The aforesaid reasons, inter alia, it is clear that the EMR created under the impugned act is a draconian creature, and untrammelled by any constitutional restraints, it threatens and has in fact threatened the very fabric of constitutional guarantees and freedoms which constitute the very foundation of our Republic. Thus, the EMR has been granted under unusual circumstances and must be considered in that background.

18. It is submitted that raising the aforesaid concerns, defendant No. 2 has challenged the constitutional validity of the Patents (Amendment) Act, 1999 in the Hon''ble High Court of Delhi by way of writ proceedings bearing writ petition Nos. 9081-82/2003 filed on December 18, 2003.

19. It is further submitted that the title of the plaintiffs is under challenge in these proceedings since the said title suffers from the following infirmities and has been obtained by the plaintiffs by playing fraud on the Patent Office. The same is borne out by the following facts:-

a. EMR has been granted for a known molecule :- EMR may only be granted for a product which is new and no obvious to a skilled person and which has been invented after Ist January 1995. No EMR may be granted for product in public domain. In the present case, the plaintiffs'' EMR is based on an Indian application No. 1602/MAS/98 filed on 17th July 1998 in which the plaintiffs had falsely disclosed that the earlier patents in this field of technology had disclosed only pyrimidine compounds and not its salt form and now it had discovered a beta crystal form of the sale of one of the aforesaid compounds. The sale form of the said compound is already disclosed by a Canadian patent bearing No. 2093203 dated 1st April 1993 in claim 29 which is reproduced hereinbelow:-

"29. N-(5(4(4- methylpiperazino-methyl)- benzoylamido)-2-methyl-phenyl) -4-(3-pyridyl) -2-pyrimidine-amine or a pharmaceutically acceptable salt thereof according to claim 1."

The said claim discloses very clearly the compound as well as its salt. It is submitted that the beta crystal form is the dominant and stable form and manifests itself (under normal conditions) during the process of preparation of the said salt by methods known in the public domain. Therefore, the beta crystals are inherent in and disclosed by the said Canadian Patent. Hence, there has been no invention post 1.1.1995 as contemplated by the Act.

The technical information of the aforesaid Canadian patent became public knowledge insofar as India is concerned way back in 1993 and any person could use, manufacture or sell these compound/salts, including Imatinib mesylate, freely in India thus, the EMR granted to the plaintiffs is for a product which is a known molecule prior to 1995.

The plaintiffs had full knowledge of the fact that the compound claimed in the Indian application is a known compound existing in the public domain and yet, filed a patent for the same and obtained EMR by misleading the Patent Controller

to believe that it was a new molecule.

b. It is submitted that the said EMR has been granted without any scrutiny since :

(i) Section 24B of the Act requires the relevant patent application to be filed in a ''convention country''. The plaintiffs allege that this requirement is satisfied by the filing of a Swiss Application. However, since Switzerland was not a convention country under the Act at the time of filing the Indian application, this condition has not been met.

(ii) Section 24B of the Act requires the Patent application and EMR application relate to the same product. In this case, EMR approval relates to the compound imatinib mesylate (i.e. the pyrimidine derivative). The EMR approval does not relate to the beta crystal form of imatinib mesylate. which is the subject-matter of a Swiss Application, the 98 Australian application and the 98 Indian application that was relied upon for grant of the EMR. Since all the applications relate to different products, it is clear that this condition has also not been met.

(iii) Section 24B also stipulates that the same applicant obtain patents in convention country, marketing approval in convention country and in India. In the instant case, the Drug Controller''s approval has been obtained by plaintiff No. 2, the Australian Drug Controller''s approval has been obtained by yet another entity-Novartis Australia Pty and EMR has been applied for by plaintiff No. 1. Thus, since all acts have not done by the same entity as contemplated under the act, this condition has also not been met.

(iv) Section 24B of the Act further require ''tests'' or clinical trials to be performed in the country in which the relevant patent application was filed. On information and belief, no clinical trials have been conducted in any country with respect to the beta crystal form of the pyrimidine derivative imatinib mesylate after 1995.

It is clear that none of the conditions prescribed for grant of EMR were satisfied by the plaintiffs and as such, the grant of EMR to the plaintiffs is contrary to law and without application of mind and deserves to be revoked. The plaintiffs misled the Patent Office into believing that all conditions for grant of EMR had been satisfied and obtained the said order by device and design.

20. It is submitted that the drug which is the subject-matter of EMR is an anti-cancer drug. It is a life saving drug and the only drug in the market capable of combating blood cancer. There is no cure for this deadly disease and this is the only recommended drug. The prescribed dose is 4 capsules of the drug per day and the treatment is for life, not any short period.

Nearly 30,000 patients are afflicted by this deadly disease in India. nearly 19,000 have succumbed to this disease in the last 5 years for various reasons. About 10 patients die every day. The demand for this drug in the market is over 30 lakh capsules per month, which cannot be met by any single entity, including the plaintiffs for various reasons including lack of effective distribution network and

infrastructure. On account of the injunction orders obtained by the plaintiffs, most of the avenues of availability of the said anti-cancer drug have been choked and there is already a shortage of the said life-saving drug in the market.

Defendant No. 2 is the largest supplier of this anti-cancer drug in the market and any adverse order which may be passed by this Court would completely stifle all avenues of supply of this life-saving drug and leave the patients at the mercy of the erratic and costly supply by the plaintiffs.

It is submitted that the drug of the plaintiffs costs Rs. 1000 whereas the drug as sold by the defendants costs about Rs. 90. The cost for an average patient works out to Rs. 4000 per day if he were to be prescribed the imported version of the plaintiff and would work out to Rs. 300 per day if he were to use the drug of the defendants. It is submitted that the patients can ill-afford such high priced imported versions of the drug as sold by the plaintiffs and they do not have the manufacturing facility to manufacture the said drug whereas defendant No. 2 has got state of arts, international standard manufacturing facilities.

If the defendants are also restrained from manufacturing and marketing their anti-cancer drug in the market, it would cause great prejudice to public health and public interest and create a grave public health crisis with disastrous consequences.

21. It is submitted that the plaintiffs have not made out any prima facie case for grant of injunction. It is relevant to note that the plaintiffs do not manufacture the said anti-cancer drug in India, it is imported from Switzerland; whereas the defendants manufacture and sell the product all over India. The total sales of the defendant''s anti-cancer drug in the last couple of years exceeded Rs. 10 crores and several crores worth of anti-cancer drug is in the pipeline. Further the anti-cancer drug of the defendants is being used by more than thirty thousand patients.

It is submitted that if the injunction as prayed for by the plaintiffs is granted, all the patients would be deprived of medication and would be left high and dry. Furthermore, the defendants have made substantial investments in the research and development of the said anti-cancer drug. A vast number of employees have been deployed for this project. In other words, the defendants have a running business which would be adversely affected, if the injunction as prayed for is granted.

22. It is submitted that the defendants also run charity programmes in which several hundred of patients are enrolled and are receiving medication. If the injunction is granted, the patients would be left with no alternative but to switch over to an expensive and unaffordable medication or if they cannot afford it, stop all medication. Thus, the plaintiffs have no prima facie case and the balance of convenience is heavily tipped in favour of the defendants. If no injunction is granted, the plaintiffs will not suffer any harm or injury, whereas if the injunction is granted, the defendants business as well as patients rights would be seriously

jeopardized. The resulting damage and injury cannot be compensated in monetary terms.

23. It is submitted that the order of EMR was issued 10th November 2003 and the plaintiffs have waited for three months to institute suits against various parties including the defendants, which clearly demonstrates the lack of urgency in the matter. The defendants'' product was launched on 1st January 2003 and is in the market since last one year.

24. From the rival submissions, it is clear that grant of EMR is a step in the direction of grant of patent. The plaintiffs have clearly stated so. According to them, grant of EMR is a akin to grant of patent. However, according to the plaintiffs, as the EMR has been granted by the authorities after due scrutiny, there is a presumption in relation to its validity and therefore, at the interim stage, the Court should go by that presumption" However, the settled law in relation to the validity of the patent granted by the authorities, which obviously is on a higher level than EMR, appears to be otherwise. A Division Bench of the Delhi High Court has considered the law on the point in its judgment in the case of Niky Tasha India Pvt. Ltd. v. Faridabad Gas Gadgets Pvt. Ltd. 1984 PTC 87. In paragraph 9, the Division Bench of the Delhi High Court observes thus :-

"9. In England, as in India, it is open to a plaintiff at any time after the institution of the suit to move for an interlocutory injunction to prevent the defendant from infringing his design between then and the date of trial in Smith v. Grigg Ltd. (1924) 41 RPC 149, it was held that same principles apply to the case of a designs are applicable in the case of a patent. The plaintiff must show that he has a prima facie case, both that his design is valid and that it has been infringed by the defendant. The mere fact that the plaintiff is in possession of a patent or of a registered design is not of Use If necessarily prima facie evidence of validity. On the contrary, where it appears that the design has only recently been registered, and where it appears that there is a substantial issue to be tried, an interlocutory injunction will not be granted. (Russel-Clarke, page 121)."

The Division Bench thereafter refers to several decisions of the English Courts. In paragraph 11, it observes thus:-

"11. I take it to be well settled, both in India and in England, that an interlocutory injunction will not normally be granted where damages will provide an adequate remedy should the claim succeed. Further more, I have always understood the rule to be that the Court will not grant an interlocutory injunction unless satisfied that there is a real probability of the plaintiff succeeding on the trial of the suit, where the design is of a recent date, as in this case, no injunction should be granted. More so, when there is a serious question as to the validity of the design to be tried in the suit and an application for cancellation has been made. Where a person is entered as a proprietor of a registered design, that is under the Act no conclusive proof that the plaintiff is the proprietor of the design, but only a prima facie evidence that he is the proprietor. The plaintiff has

this advantage that if no evidence at all is given then the certificate is sufficient evidence that he is the proprietor, Mohammad Abdul Karim Vs. Mahammad Yasin, ."

25. Thus, the settled law appears to be that in relation to a patent, the Court will not grant an interlocutory injunction unless satisfied that (a) there is a real probability of the plaintiffs succeeding on the trial of the suit, and (b) where the patent is of a recent date, no interim injunction should be granted. More so, when there is a serious question as to validity of the patent raised by the defendants to be tried in the suit.

26. Insofar as the present case is concerned, it is an admitted position that the EMR has been granted only in the month of November 2003. Therefore, it has been granted recently. Therefore, in order that the plaintiffs become entitled to the grant of a temporary injunction , I have to consider whether in this suit, the defendants have raised a serious question as to the validity of the EMR that has been granted in favour of the plaintiffs.

27. Perusal of various grounds that have been raised by the defendants to indicate that the grant of EMR in favour of the plaintiffs is not valid, appear to my mind, to raise serious questions as to the validity of the EMR granted in favour of the plaintiffs. For example, it is clear from the application filed in Canada for patent by the plaintiffs on 1st April 1993 that the salt form of the said compound is disclosed in that application. In paragraph 10 of the plaint, the plaintiffs have stated thus:

"10. Plaintiff No. 1 through its continued research and development was successful in inventing a particular form of methanesulfonic acid addition salt of a particular ''Pyrimidineamine Derivatives (Imatinib Mesylate)'' in crystal form. The said crystals were found to be in two forms Alpha (a) and Beta (B) crystalline form, Alpha form is Characterized by needle shaped crystals and is hygroscopic. In this form the crystals are particularly not well suited to pharmaceutical formulation as solid doses form because their physical properties e.g. their flow characteristics are unfavourable. On the other hand, the beta crystals are non-needle shaped and found to be thermodynamically more stable at temperatures below 140 C and are less hygroscopic. The beta form thus stores better and is easier to process and guarantees a constant quality of the final drug product. It is more useful as a therapeutic agent for the retardation of tumours and cancer cells. The beta crystalline form is being produced and sold on a commercial basis after conducting exhaustive clinical trials and obtaining all the requisite approvals in various countries. This invention for the B crystalline form of Imatinib Mesylate is titled Crystal Modification of N-Phenyl-2-pyrimidineamine Derivative, Processes for its manufacture and its Use."

28. A comparison of what is stated in the application submitted by plaintiffs in Canada for the patent in 1993 and the contents of paragraph 10, in my opinion, definitely raises a serious question as to whether the product in relation to which

EMR has been granted is really a new product or not. In paragraph 8 of the plaint, the plaintiffs describe the invention as B crystalline form of Imatinib Mesylate. In paragraph 10, the plaintiffs admit that Imatinib Mesylate crystals were found to be in two forms - Alpha (a) and Beta (B). Alpha was needle shaped. Beta was found to be thermodynamically stable and was prepared for use in pharmaceutical preparations. Perusal of the application submitted by the plaintiffs in 1993 for patent in Canada shows that the plaintiffs have disclosed the compound as well as its salt. Beta crystals are clearly disclosed in the application. Therefore, in my opinion, apart from other challenges, this challenge can definitely be said to be serious insofar as the validity of EMR granted is concerned and if that be so, in terms of the law that appears to be settled referred to above, the EMR being of recent origin, the plaintiffs would not be entitled to the temporary injunction sought. It is further to be seen here that in the present case, it cannot be said that even if the plaintiffs ultimately succeed, the loss or injury that may be caused to the plaintiffs is not incapable of being compensated in terms of money. Indeed, in the plaint, the plaintiffs have worked out loss suffered by them and have in fact sought a monetary decree in relation thereto. In my opinion, the aspect of balance of convenience has also to be answered in favour of the defendants, especially because the drug in relation to which EMR is granted is a anti-cancer drug, is a life saving drug and the plaintiffs do not manufacture the drug in India but import it from foreign country. The defendants have stated that the demand of capsules is over 30,00,000 per month. This does not appear to have been disputed by the plaintiffs. It is clear that the demand of this drug in India is very large, it is a life saving drug. The defendants manufacture the drug in India. The plaintiffs do not manufacture the drug in India. They state that they will import required quantity of the drug from a foreign country. Therefore, the plaintiffs will rely entirely on the international transport system for making the drug available in India in required quantity. In case interim injunction is granted in favour of the plaintiffs, the manufacturing and marketing network of the defendants so far as the drug is concerned would be dismantled. If due to any problem, the plaintiffs cannot make available the drug in required quantity in India, it obviously will be disastrous for the patients. This consequence is foreseeable, therefore in my opinion, the Court should not pass any interim order which may possibly lead to such a situation. In my opinion, the aspect of the difference in price of the product of the plaintiffs and the defendants also cannot be ignored, especially at the stage of considering the question whether the plaintiffs are entitled to any interim relief.

29. So far as the order passed by the Madras High Court is concerned, I have gone through the order carefully. With due respect to the Hon''ble Madras High Court, I find that the Madras High Court has not properly considered the settled law in the matter of grant of temporary injunction in relation to a patent of recent origin and, therefore, I am not inclined to agree with the view that has been taken by the Madras High Court. In my opinion, therefore, the plaintiffs are not entitled to the temporary injunction sought by them. In my opinion, the

interest of the plaintiffs can be safeguarded by directing the defendants to maintain accounts of the trade that they carry on in respect of their drug in question during the pendency of the suit and submit an undertaking to this Court undertaking therein to pay damages as may be awarded by this Court in case this Court decrees the suit in favour of the plaintiffs as also to maintain faithful accounts of their trade in the drug in question during the pendency of the suit. It is accordingly so ordered. Notice of Motion is disposed of. The defendants to submit the undertaking within four weeks from today.

Parties to act on the copy of this order duly authenticated by the Associate/ Personal Secretary of this Court as true copy. Certified copy expedited.

