

IN THE HIGH COURT OF JUDICATURE AT MADRAS

DATED: 28.04.2004

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THE HONOURABLE MR. JUSTICE R. BALASUBRAMANIAN

C.S. Nos. 5 to 9 of 2004

Novartis AG and another

... Plaintiffs

Vs.

Adarsh Pharma and another

... Defendants

ORDER

R. Balasubramanian, J.

1. In all the original applications an ex parte order of injunction was granted by this Court on 20.1.2004. To vacate that ex parte order in each suit, the aggrieved party has filed an application. This application to vacate the injunction stands accompanied by two applications having successive numbers, namely one to stay the operation of the "Exclusive Marketing Rights", hereinafter for brevity referred to as "EMR" and the other, to implead the authority, which granted the "EMR", as a party to the suit. Of course, it must be noticed that in C.S.No. 5/2004 and C.S.No. 6/2004, there is no such application to stay the operation of the "EMR" and to implead the authority, which issued the said "EMR", as a party to the suit. The authority, which issued the "EMR", had filed a counter stating that "EMR" was justifiably granted. In the context of this Court deciding to hear the original applications, where an ex pane order of injunction was granted and the applications filed to vacate the interim order, Mr. Lakshmi Kumaran learned counsel appearing for the defendants in the last three suits, where applications were filed to stay the operation of the "EMR" and to implead the authority, which issued the "EMR", as a party to the suit, submitted, on

instructions from his clients, that he is not interested in prosecuting all those applications. Accordingly A.Nos. 842 and 843/2004 in C.S.No. 7/2004 and A.Nos. 845 & 846/2004 in C.S.No. 8/2004 and A.Nos. 848 & 849/2004 in C.S.No. 9/2004 stand dismissed as not pressed. This means, this Court is now called upon to decide as to whether any case is made out to continue the order of interim injunction granted or should it be vacated? Mr. P. Chidambaram learned senior counsel and Mr. Habibullah Badsha learned senior counsel appeared for the plaintiffs in the suit and in the applications for injunction. Mr. Arvind P. Datar learned senior counsel appeared for the aggrieved party in C.S.Nos. 5 & 6/2004 while Mr. V. Lakshmi Kumaran learned counsel appeared for the aggrieved party in C.S.Nos. 7 to 9/2004.

2. Taking into account the stage at which this case is poised for a decision (interlocutory stage), I am of the opinion that it is enough if the sum and substance of the case of the respective parties are set out hereunder. In fact, pleadings is complete in C.S.Nos. 7 to 9 of 2004 i.e., the written statement is also filed. To set out the entire pleadings at length (the pleadings at the interlocutory stage runs to several pages) at this stage would be a futile exercise, since it forms part of the record and the Court can always refer to it. The sum and substance of the plaintiffs' case at this interlocutory stage is as follows:

"The first plaintiff is a "Swiss" company and the second plaintiff is its subsidiary in India; the first plaintiff invented a particular form of Methanesulphonic acid addition salt of a particular pyrimidineamine derivatives (Imatinib Mesylate in crystal form), hereinafter referred to as the "invention"; the crystals are in two forms namely, "Alpha" and "Beta"; in the manufacture of the drug in question, "Beta" crystalline form is used; the product so invented is "Beta Crystalline form of Imatinib Mesylate", hereinafter referred to as the "product"; the first plaintiff had filed applications in 1997 to 2000 for the said product patent in several countries and in some countries, patent had been granted and in the other countries, patent is still pending; India, as a member of World Trade Organisation and by virtue of its 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; 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 ("EMR"); the first plaintiff filed a patent application in India on 17.7.1998 for the product patent referred to above; the first plaintiff filed an application in a convention country i.e., Australia on 16.7.1998 claiming patent for the identical product; 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; 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; 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; "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; 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."

On the above stated facts, the plaintiffs sought for an injunction and it was accordingly granted ex parte on 20.1.2004, which underwent a slight modification on 26.2.2004.

3. The defendants' case is summarised as hereunder:

"The first plaintiff filed a patent claim in "US" on 28.4.1994 titled "Pyrimidine derivatives and processes for the preparation thereof; priority for this application was claimed from "Swiss" patent application filed on 1.4.1992; this patent was granted by "US" on 28.5.1996 disclosing "Mesylate Salt of Imatinib"; 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; "Canada" granted patent on 26.11.2002; no patent for "Imatinib Mesylate" was ever filed in India and therefore there is no question of the plaintiffs being 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"; no patent can be granted, if the said subject matter was claimed else where, before the priority date claimed in India; 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 its manufacture and its use"; for this

application, the priority date is 18.7.1997 Switzerland; 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; therefore no patent can ever be granted in India to the invention referred to above; the first plaintiff obtained a patent in Australia based on the priority on the "Swiss" patent application of July 18, 1997; the "EMR" issued in this case does not disclose the specific substance claimed in the Australian patent, on which it is based; the "EMR" granted is vague and indefinite; 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; 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; 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; India being a poor country, many cannot afford to buy the plaintiffs' product and ultimately, they would die untreated; the plaintiffs have to establish that the "EMR" was validly granted and it is being infringed; the plaintiffs are lacking in good faith; the "EMR" is not validly granted for the reasons stated in paragraph Nos. 43 to 50 of the written statement; the marketing approval in Australia for the drug in question was not given to the first plaintiff but to M/s. Novartis Pharmaceuticals Australia Private Limited, hereinafter referred to as "Novartis Australia"; appropriate tests have never been carried out in Australia in relation to "Beta crystal form of Imatinib Mesylate"; therefore granting marketing approval without conducting tests in Australia is not valid; here also, the permission to import "Imatinib Mesylate" to India was not granted to the first plaintiff but only to the second plaintiff; however, "EMR" is granted to the first plaintiff; the "EMR" holder and the import licence holder must be the same and that not being the case here, the injunction must be vacated; the subject matter of the "EMR", the patent application in Australia and India and the marketing approval in Australia and India are not the same; patent and marketing approvals were given for different substances in Australia; the plaintiffs have misled this Court that they got the Australian patent and the marketing approval for an identical substance, to the one claimed in the "EMR"; the applicants' right under the "EMR" is not infringed for the reasons stated in paragraphs 65 to 76 of the written statement; principles of natural justice has been violated in this case while granting the "EMR" to the first plaintiff and the plaintiffs are lacking in good faith."

4. The arguments advanced by Mr. P. Chidambaram learned senior counsel appearing for the plaintiffs in some of the suits are summarised as hereunder:

"Under Section 24-A of the Act, the application for patent has to be referred to an examiner only for compliance of Sections 3 and 4 of the Act. Section 24-A excludes the operation of Section 12 of the Act. If the operation of Section 12 is excluded, then the investigation under Section 13 regarding anticipation by publication also stands excluded. Therefore, examining the application for patent under Sections 12 and 13 read with Sections 29-34 does not arise at all at the stage of examining the application for patent, in the context of considering the application for the grant of exclusive rights. In other words, the requirements of Sections 3 and 4 of the Act alone have to be taken into account by the examiner, to whom the application for patent is referred to and if that report is not adverse to the applicant, who filed the claim for patent, then the exclusive right to sell must follow, subject to Section 24-B. Of course, when the patent claim is taken up for consideration, the usual procedure, which includes the procedure contemplated under Sections 12 and 13 of the Act, would have to be followed. All the conditions of Section 24-B(1)(a) of the Act stands fully established. The patent claim is made by the same person in Australia and in India namely, the first plaintiff. The patent claim in Australia stands granted to the first plaintiff. It may be true that the marketing approval in Australia stands granted to the subsidiary of the first plaintiff company in Australia, on the basis of which "EMR" was granted to the parent company itself. Likewise, in this case also, marketing approval is also granted in favour of the subsidiary company of the first plaintiff in India namely, the second plaintiff. The parent company namely, the first plaintiff and the subsidiary company namely, the second plaintiff are a single economic unit. Therefore, holding of marketing approval by the subsidiary company would amount to the parent company itself holding the same. "EMR" is granted in India to the first plaintiff. If the case is tested on the basis of a single economic unit, the first plaintiff company having a patent and an "EMR" in Australia and its subsidiary in Australia having a marketing approval right cannot be held to be in violation of the requirements of the Indian Law regarding the grant of "EMR". Here also, the second plaintiff is holding a marketing approval right while the first plaintiff is having an "EMR". On the same principle as referred to above regarding the Australian company, this Court must hold that there is no violation in granting the "EMR". Even otherwise, from the relevant provisions of law applicable regarding granting marketing approval right under the Drugs and Cosmetics Act and the relevant provisions of law under the Patents Act to grant an "EMR", it is seen that there is no legal bar for the agent of a principal holding a marketing approval on the basis of which the principal himself getting an "EMR". The patent claim in India and the patent claim in Australia alone must be considered to fix the identity of the article. The grant by the convention country, which may be for

the patent claim itself or for any modified claim and therefore comparing the patent grant, while exercising power under Section 24-B of the Act, is un-called for. While comparing the identity of the article between the Australian patent claim and the Indian claim or even considering the patent grant in Australia with the patent claim in India, the essential features of both alone should be taken into account, which is called as pith and marrow theory. If so done, it is easily seen that the essential features of the drug patent in Australia and the patent claim for the drug in India are the same. The balance of convenience is heavily loaded in favour of the plaintiffs. The Parliament itself had made enough provisions in the Act itself to meet public interests."

Mr. Habibullah Badsha learned senior counsel advanced his arguments with equal force. Since the arguments of the learned senior counsel is overlapping on the arguments of Mr. P. Chidambaram learned senior counsel summarised above, with respect, I am of the opinion that the arguments of Mr. Habibullah Badsha learned senior counsel need not be stated once again.

5. Mr. Lakshmi Kumaran learned counsel appearing for the defendants in some of the suits and Mr. Arvind P. Datar learned senior counsel appearing for the defendants in some of the other suits submitted their arguments, which are on the following lines:

"Patent cannot be granted to the first plaintiff, since imatanib "mesylate, in short "IM", was disclosed in the US, Canadian patent based on 1992 priority and no such right was ever claimed in India. Patent claim must also fail on the basis of claiming a wrong priority, the subject matter of the patent already standing disclosed. The statutory requirements of Section 24-B of the Act are not fulfilled. Patent applicant, person holding an "EMR" and the person holding the marketing approval, must be the same person both in India and in the convention country. In other words, the submission is that, the Swiss company should file the patent claim in India and Australia; it should apply for the marketing approval in India and Australia and it should only hold the "EMR" in India and Australia. In the case on hand, in India, the Swiss company is not holding the marketing approval and likewise, in Australia, it is not holding it. Therefore, the "EMR" falls to the ground. On facts in the case on hand, the single economic unit theory is of no avail. The subsidiary company has a separate legal entity. Identical article or substance should be the subject of the patent application in India; the patent application and the grant of patent in the

convention country; the marketing approval to sell in India issued by the authority specified by the Central Government and the grant of "EMR". In this case, there is no identity of article or substance in the above records. Therefore "EMR" is not validly granted. Subject matter of patent claim in India stands disclosed and therefore the patent claim in India must be rejected. Learned counsel for the defendants also submitted that there is no presumption of validity of the "EMR" under the Act and therefore, once the validity of the "EMR" is challenged, the party, who is holding it, should discharge the burden of proof that it is validly granted and this Court even at this stage, can decide the validity of the "EMR" one way or the other. Defences available under Section 64 of the Act can enter the mind of this Court while the validity or otherwise of the "EMR" is decided. By applying the principle of anticipation by previous publication (see Section 13 of the Act), the patent claim has to be rejected. The above referred to ground is available under Section 64(1)(e) of the Act. Section 24-A of the Act does not exclude the application of Section 13 of the Act. Therefore, Section 13 squarely applies to the case on hand. Active Pharmaceutical Ingredient (API) in the label of the drug marketed by the plaintiffs indicate it as "imatanib in the mesylate form". Therefore the statement made in the pleading that API is the "Beta crystalline form of imatinib mesylate" is incorrect. The patent claim in India and the patent grant in Australia are totally different. The subject matter of the patent stands already disclosed in India by the principle of anticipation. The second plaintiff is a separate legal entity and therefore each of the plaintiff should be treated as a separate legal entity and not as a single economic unit. As already stated, the substance in the patent application in India; the patent application and the patent granted in the convention country; the marketing approval given in India and the application for granting the "EMR" in India is not identical. No tests at all were carried out in Australia before granting the marketing approval. There is no prima facie case in favour of the plaintiffs for getting an order of injunction. The balance of convenience is also in favour of the defendants. The test report relied upon by the plaintiffs, compares the alleged infringing product with the plaintiffs' commercial product and it is impermissible. On the contrary, the product of the defendant must be compared with the product in the patent claim. The "EMR" itself is of a recent origin and therefore a mere challenge to its validity would disable this Court from granting an order protecting such rights."

Mr. Arvind P. Datar learned senior counsel appearing for some of the contesting defendants would submit, besides adopting the arguments of Mr. V. Lakshmi Kumaran learned counsel, that the "EMR" being of a recent origin, injunction

cannot be granted. It is his further submission that there is no presumption in the Patents Act regarding the validity of the "EMR" and therefore, this Court can go into the validity of the "EMR".

6. Going by the submission made by the learned counsel on either side, it is clear to my mind that construction of Section 24-A and 24-B of the Act primarily arise for consideration at this stage. Prior to Amending Act 17/1999, product patent was impermissible in India. Till the Amending Act was brought into force, process patent alone was permissible. By the Amending Act, existing Section 5 was converted into Section 5(1) (dealing with process patent) and by the amendment a new section was brought in by inserting Sub-section (2) to Section 5 of the Act (dealing with product patent). This sub-section enables a patent claim to be dealt with in the manner provided in Chapter IV-A, without prejudice to the other provisions of this Act. Normally, when patent claim is made, it must go through the provisions contained in Chapters III and IV. By making this special provision, the Legislative intent is very clear that, without going through the regular procedure, the patent claim can be looked into for the limited purpose of considering the application for grant of an exclusive right under Chapter IV-A. It is not in dispute that product patent claim has to be taken up for consideration only after the expiry of 31.12.2004 as per the agreement arrived at, as a result of India being a Member of the World Trade Organisation. In other words, patent claim cannot be taken up for consideration in India till 31.12.2004. As already stated, by the special provision made in Sub-section (2) of Section 5 of the Act, the patent claim for a limited purpose mentioned in Chapter IV-A of the Act can be looked into before the expiry of 31.12.2004 itself. Section 12 of the Act provides for examination of the patent claim. It contemplates the procedure to be followed in examining the patent claim, which includes the result of investigation to be made under Section 13. Section 24-A postpones such examination of the patent claim till 31.12.2004. While postponing the examination of patent claim till 31.12.2004 for consideration, Section 24-A provides for referring the application for patent to an examiner, when an

application for grant of an exclusive right to sell is received by the Controller. Section 24-A of the Act states that such a reference is for getting a report from the examiner as to whether the invention is not an invention within the meaning of the Act in terms of Section 3 or the invention is an invention for which no patent can be granted in terms of Section 4. Reading Section 24-A(1) as a whole, the following conclusions are inevitable:

- (a) Referring the patent claim for examination under Section 12(1) of the Act stands postponed till 31.12.2004;
- (b) If an application for grant of an exclusive right to sell has been made, then
 - (i) the Controller shall refer the application for patent to an examiner for his report;
 - (ii) such examination is for the limited purpose of finding out whether the patent claim is not an invention within the meaning of Section 3 of the Act; and
 - (iii) whether the patent claim is an invention, for which no patent could be granted in terms of Section 4 of the Act?

When the reference of the patent claim to an examiner for making his report is confined to the requirements of Sections 3 and 4 of the Act alone, there is no scope, in my considered opinion, for examining the said patent claim on the basis of any of the other provisions of the Act, which may stand attracted when the patent claim is taken up for consideration on merits after 31.12.2004.

7. Lengthy arguments have been advanced by Mr. V. Lakshmi Kumaran learned counsel appearing for the contesting defendants that Section 24-A of the Act excludes the operation of Section 12(1) of the Act only for the purpose of Chapter IV-A; there is no such exclusion of Section 13; under Section 13 the principle of anticipation by previous publication and by prior claim are to be investigated; the ground mentioned in Section 13, if found against the patent claim, would be a ground under Section 64(1)(e) of the Act and when there are materials on record to show that there was prior publication of the claim, the

patent claim is liable to be rejected; since that ground is made available as a ground to invalidate the "EMR", this Court would be in a position to set aside the "EMR" itself. In this context, the learned counsel would submit that the defences available for revocation of patent are equally available to revoke the "EMR" and for this purpose, he relies upon Section 24-E of the Act. Learned counsel is right in his submission in this regard namely, defences available to revoke the patent are also available as defences to revoke the "EMR". Relying upon Section 24-F of the Act, the learned counsel would also submit that there is no warranty to the validity of the grant of "EMR" and therefore, the burden is on the first plaintiff to prove the validity of the grant. As already stated, the grant of "EMR" is by way of an interim measure. "EMR" is granted to an applicant, who has filed the patent claim. Though Section 24-A specifically excludes the operation of Section 12(1) of the Act alone, inasmuch as Section 12(1) of the Act provides for an examination under Section 13, it is only logical to hold that consequent to the exclusion of Section 12(1) from the purview of Chapter IV-A, the requirements of Section 13 also stand excluded for the purpose of Chapter IV-A. If that is so, application by previous publication or by prior claim has no relevancy while examining the patent claim in the context of deciding to grant or not to grant an "EMR". The patent claim is under scrutiny under Chapter IV-A for a limited purpose. Section 24 of the Act begins with the following words:

" 'Subject to the provisions contained in this Act' and then the grounds available for revocation of the patent grant are mentioned. Therefore it is clear that the grounds made available in Section 64 of the Act would normally be available so long as there is no other provision which excludes the operation of the same. Since I have already held that Section 24-A of the Act not only excludes Section 12 but also Section 13 (reasons for the same given earlier), there is no point in saying that the defence enumerated in Section 64(1)(e) can still be pressed into service at this stage to invalidate the "EMR". Therefore I hold that search for anticipation by previous publication and by prior claim (Sections 13 and 29 to 34) is not attracted and therefore the arguments advanced by Mr. V. Lakshmi Kumaran learned counsel on this point stand rejected. For the reasons stated above I hold that the requirements of Section 24-A stand fully complied with and there is no infringement of that section.

8. Let us now go to Section 24-B of the Act. Under Section 24-B(1)(a) of the Act, the procedural requirements to be complied with are as hereunder:

"Before filing a claim for patent in India in respect of an invention made whether in India or in a country other than India, the applicant should have filed claim for the same invention in a convention country on or after 1.1.1995. There is no dispute that before the filing of the patent claim in India on 17.7.1999, the first plaintiff had filed his patent application for an identical article in Australia on 16.7.1998 in Patent Application No. 89759/1998, such application having come to be filed after 1.1.1995. In other words, after 1.1.1995 and before filing the patent claim in India, the first plaintiff had filed an application in a convention country namely, Australia. The date of filing of the patent claim in Australia and the date of filing of the patent claim in India are not disputed by the learned counsel appearing for the defendants and their dispute is on other points, about which, I will refer later in this order. The next part of the procedural requirement is that the convention country ought to have given the patent and the approval to sell or distribute, etc., on the basis of appropriate tests conducted on or after 1.1.1995 and such granting should have been after making the patent claim in India. On 13.8.2001, marketing approval was granted in Australia, which is definitely after the filing of the patent claim in India. The convention country in Australia had also granted the patent to the first plaintiff on 28.2.2002. From the last two dates mentioned above, it is seen that the convention country had granted the marketing approval and patent only after 17.7.1998 i.e., after the patent claim was filed in India. On 4.12.2001, the Drugs Controller General (India) granted permission to the second plaintiff to import the drug under Rule 122-A of the Drugs and Cosmetic Rules, subject to certain conditions. On 10.11.2003, the Controller of Patents granted the "EMR" to the first plaintiff.

9. From the above noted events, it is prima facie seen that the plaintiffs have satisfied all the requirements of Section 24-B of the Act, on the basis of which, the Controller of Patents had granted the "EMR". But the submission of Mr. V. Lakshmi Kumaran learned counsel appearing for the defendants is that, though filing the relevant documents in India and in the convention country are made on the dates specified, yet for the following reasons, the "EMR" has to be invalidated, since it does not satisfy the other requirements of the above referred to section on the following grounds:

(a) No patent can be granted for "Imatinib Mesylate" as "Imatinib" is the popular name of a chemical substance, which was identified in early 90's. "Imatinib" is converted into its salt by reaction with an acid and the salt so produced is known as "Imatinib Mesylate". US patent filed on 28.4.1994 was granted on 28.5.1996 and the Canadian patent filed on 1.4.1993 was granted on 26.11.2002. Both these patents claim priority to the date 3.4.1992, the date of Swiss patent application. The product is also disclosed in several journals. Therefore in India priority is wrongly claimed on the basis of the priority date 18.7.1997 - filing in Switzerland. Switzerland was not a notified convention country on 17.7.1998 when the first plaintiff filed the patent claim in India and it was notified as such only later on. On account of choosing a wrong priority as stated above namely, filing before the Swiss Authority, the patent stands disclosed in India.

(b) The person, who files the patent application in India should not only file a patent application and get a patent in the convention country, but the same person should also get the approval in the convention country. But on the facts of this case, in the convention country, the same person has not obtained the patent and the marketing approval. The patent is in the name of the first plaintiff while the approval in the convention country is in the name of Novartis Pharmaceuticals Australia Pty. Limited. In the case on hand also, the person, who files the patent in India, should have the marketing approval in his name. But in this case, the marketing approval is given in the name of the second plaintiff.

(c) The substance in the patent application in India; in the patent application and the patent grant in the convention country; in the marketing approval granted in the convention country; in the marketing approval granted by the Central Government and in the application for the grant of an "EMR" in India, should be the identical article or substance. In all the above applications in the case on hand it is not so.

(d) No appropriate tests were carried out in Australia.

10. I have already held that since Section 24-A of the Act excludes the operation of Section 12(1) of the Act and by implication Section 13 also standing excluded, meaning thereby, Sections 29 to 34 would also stand excluded for the present, I am of the opinion that the grant of "EMR" cannot be attempted to be invalidated on the ground of previous publication or by prior claim covered by Sections 13 and 29 to 34 of the Patents Act. Therefore, I reject the argument advanced by Mr. V. Lakshmi Kumaran learned counsel on ground (a) for the present. Let me now apply my mind to the defence raised on ground (b) referred to above. It speaks about an applicant filing a patent claim in India; filing an application for the same invention in a convention country and getting the patent and approval to sell in the convention country, after filing a patent claim in India. If the argument advanced by Mr. V. Lakshmi Kumaran learned counsel appearing for the defendants is to be accepted on the construction of Sub-clause (a) of sub Section (1) of Section 24-B of the Act, then unless the person is the same in the patent claim in India; patent claim in Australia and in the marketing approval given in Australia, the applicant in India for a patent claim is not entitled to get an "EMR". In my opinion, this argument does not appear to be sound. The question is, whether the word "applicant" referred to in sub Section (1) of Section 24-B of the Act necessarily excludes any other person, other than the applicant, for getting an approval on behalf of the applicant? Sub-clause (a) of Sub-section (1) of Section 24-B is mandatory in only one aspect namely, the applicant being the same in the patent claim in India and the patent claim in the convention country. The section states, where a claim for patent has been made and the applicant - the word applicant herein refers to the person, who filed the patent claim in India, has to file the application for the same invention in a convention country. Therefore it is clear that the applicant in the patent claim in India and the applicant in the patent claim in Australia must alone be one and the same. There is no dispute in this case that the first plaintiff is the applicant in the patent claim in India as well as in the convention country. Sub-clause (a) for the present purpose can be divided into two parts namely, Part I, a patent claim in

India being filed and the applicant therein filing an application for the same invention in the convention country and Part II, the patent and the approval to sell or distribute, etc in that country (convention country) has been granted. Part II of Sub-clause (a) spells about receipt of the patent and the approval to sell in the convention country. Who should file an application for an approval to sell in a convention country, is not prescribed in Sub-clause (a) of Sub-section (1) of Section 24-B of the Act. If the applicant in the patent claim in India has filed the patent claim in the convention country, then, according to me, it satisfies the requirement of the above referred to provision. It is needless to state that a patent can be granted only to the applicant. When this section is silent as to who should apply for the marketing approval in Australia, then in my opinion, it is not possible to read the section as requiring the applicant in the patent claim in India and in the convention country also, being the person in the application for marketing approval in the convention country. Therefore, it depends upon the law prevailing in Australia, On the issue namely? whether the applicant for the patent claim in the convention country should be the applicant in the application for marketing approval, no provision of law requiring the same is brought to the notice of this Court. Going by the fact that in the convention country the marketing approval was given to Novartis Pharmaceuticals Australia Pty. Limited, who is not the applicant in the patent claim itself and until the contrary is shown, substantiated by a provision of law, it cannot be said that the patent standing in the name of the applicant and the marketing approval standing in the name of a person other than the applicant in the patent claim in the convention country, would violate Sub-clause (a) of Sub-section (1) of Section 24-B of the Act. In my opinion, only one thing is certain on reading the above referred to provision of law namely, the applicant in the patent claim in India; the applicant in the patent claim in Australia and the grantee in Australia must be one and the same. In this case, it stands established.

11. Let me see what is the requirement of law in this country to apply for marketing approval? There is no provision in the Patents Act to grant marketing

approval and as to who should apply for the marketing approval. To understand this, Section 24-B of the Act must be read with the beginning words of the section, excluding Sub-clauses (a) and (b), with the last paragraph in the said section. If it is read, it shows that the applicant has received the approval to sell or distribute the article or substance from the authority specified in this behalf by the Central Government. If such an approval is received by the applicant and if he satisfies the requirements of Section 24-B(1)(a) of the Act, then "EMR" should follow. What is the meaning that should be attached to the section as referred to above to be read excluding Clauses (a) and (b)? Does it mean that the applicant in the patent claim alone should have the approval in his own name? Does it mean that the applicant in the patent claim alone should apply for the marketing approval? My answer is an emphatic "no". The reasons are not far behind to see. Reading Section 24-B(1), excluding Sub-clauses (a) and (b), it is clear what the section says is that the applicant has received the approval to sell..... from the authorities specified in this behalf by the Central Government. Under Rule 40 of the Patents Rules 2003, once an application for an exclusive right to sell is made to the Controller (Patents Controller), then the Controller shall notify the filing of the application in the Official Gazette and to the authority of the Central Government that is responsible for the grant of approval to sell. Therefore reading Section 24-B(1) of the Act as indicated above and Rule 40 together, it is clear that the authority to issue a marketing approval is not an authority under the Patents Act. Under the provisions of the Patents Act, once a marketing approval is received by the applicant, then as rightly contended by Mr. P. Chidambaram learned senior counsel appearing for the plaintiffs, the Patent Controller puts the seal of approval on it. Only to that limited extent, the marketing approval is put up on the table of the Patent Controller. The Patent Controller's job is on the other aspects namely, whether the application for the grant of "EMR" satisfies the requirements of law as referred to earlier? Therefore, once it is clear that the grant of the marketing approval is not within

the domain of the Patent Controller, one must necessarily look into the provision of law which deals with that.

12. Rule 24 of the Drug and Cosmetic Rules as it stood upto 31.12.2002 and as it stands today, are the relevant Rules, which deal with the situation. The said rule is in Part IV of the Drug and Cosmetic Rules. The definition of "manufacturer" is defined in Rule 21 (d). The definition was brought into the Rules with effect from 1.1.2003. It defines a "manufacturer" as a person who is a company or a unit or a Body Corporate or any other establishment in a country other than India..... The first plaintiff satisfies this definition. Under Rule 122-A, no new drug shall be imported, except under and in accordance with the permission granted by the Licencing Authority as defined in Clause (b) of Rule 21. The licence to be so granted should be in either Form 10 or Form 10-A, the former relating to drugs excluding those specified in schedule X and the latter in respect of drugs specified in Schedule X. Part IV of the Rules deals with import and registration. There are various schedules containing description of drugs. Rule 24 as it originally stood states that an application for import licence in respect of schedule "C" or "C (1)", excluding those specified in Schedule X, shall be made in Form 8 and in respect of the drugs specified in Schedule X in Form 8-A. Under the old Rule, the said application has to be filed by the manufacturer's agent in India. Under the Rule as it stands today, an application for drugs, excluding those specified in Schedule X has to be made in Form 8 and for the drugs specified in Schedule X, in Form 8-A. The words in the old Rule namely, "drugs specified in Schedule "C" or "C(1)" has been omitted. Under the new rule, an application can be made by the manufacturer himself..... or by the manufacturer's agent in India, either having a valid wholesale licence for sale or distribution of drugs under these Rules. The difference between the old Rule and the new Rule is that, under the old Rule, the manufacturer's agent alone was authorised to apply for an import licence while under the new Rule, the manufacturer also is entitled to apply for an import licence, on the conditions stated therein. Form 8 and 8-A, as they stood originally and as they stand today,

at the foot of it show the person applying for the licence as the manufacturer's agent in India. Rule 122-A prescribes an application for grant of a permission to import a new drug in Form 44. Reading Rule 24 as it stood then; Rule 24 as it stands today and Rule 122-A of the Rules, it is clear that in respect of the drugs covered under Rule 24 (both old and new), the application for import should be made in the form prescribed in that Rule only and in respect of drugs not covered under Rule 24 (both old and new), the application has to be in Form 44 as provided for under Rule 122-A. There is no dispute that the drug concerned in this case is covered under Rule 24 as it stood then and as it stands today. But however, issuing an import licence is only under Rule 122-A in Form 45 or Form 45-A. The second plaintiff has such a permission given by the Licencing Authority in this regard by its proceedings dated 4.12.2001. That was valid for a period of two years and the second plaintiff is again having another such approval for a period of two years commencing from 1.1.2003 and expiring with 31.12.2005. I have already found that neither in the Patents Act nor in the Patents Rules, there is any amended provision as to who must apply for the marketing approval in India when a patent claim is filed in India by the inventor. Therefore, this Court has to necessarily look into the Drug and Cosmetic Rules alone to find out the person authorised to apply for such marketing approval, otherwise called as an import licence. Since under the Drug and Cosmetic Rules referred to above, the manufacturer's agent stood recognised as the only authority to apply for an import licence upto 31.12.2002 and the manufacturer himself coming to be recognised, besides his agent, from 1.1.2003 to apply for an import licence, it is clear that the second plaintiff, applying for an import licence, is not in violation of Rule 24 of the Drug and Cosmetic Rules.

13. Admittedly, in this case the second plaintiff alone had applied for an import licence/marketing approval. Is he an agent of the first plaintiff or the plaintiffs constitute a single economic unit? Admittedly, the first plaintiff is holding 50.93% shares in the second plaintiff company, the remaining belonging to the Indian public. An affidavit sworn to on 30.3.2004 is on record, which affirms the

position that the first plaintiff is the parent company of the second plaintiff and the first plaintiff is the parent company of Novartis Pharmaceuticals Australia Pty. Limited. The affidavit also discloses that the acts of the second plaintiff is entirely under the direction and control of the first plaintiff and that the second plaintiff imports the drugs manufactured by the first plaintiff for distribution in India. The case of the plaintiffs is that they constitute a single economic unit. In support of such a plea, Mr. P. Chidambaram learned senior counsel relied on the judgments , Volume 74, Company Cases 543, Volume 88 Company Cases 213, Volume 89 Company Cases 785, 1978-1 LLR 225, 1976 (3) All England Reports 462 and Gower on Principles of Modern Company Law 4th Edition Pages 112 and 137. Mr. V. Lakshmi Kumaran learned counsel appearing for the defendants would oppose these submissions by stating that each of the plaintiff is a separate legal entity by themselves and therefore the principle of lifting the corporate veil to treat both the plaintiffs as a single economic unit is not attracted to the case on hand. The facts available in the case laws cited on behalf of the plaintiffs as referred to above are totally different from the facts available in this case and therefore those case laws would not apply. The House of Lords in their judgment Woolfson v. Strathclyde, Regional Council, distinguished DHN Food Distributors' case, 1978 SLT 159, wherein it was held that the subsidiary is different from the holding company. Learned counsel for the defendants relied on the judgment Buckinghamshire County Council v. Secretary of State for the Environment, Transport and Regions and Anr., 2001(1) BLR 38, Kapila Hingorani v. State of Bihar, , LIC of India v. Escorts, and Skipper Construction Company, to contend that the principle of single economic unit, on facts of this case, does not stand established. Mr. Arvind P Datar learned senior counsel, supporting the arguments of Mr. V. Lakshmi Kumaran learned counsel, cited the following judgments in the above regard namely, Spencer & Company Limited v. CWT, AIR 1965 Madras 359, CWT v. Spencer & Company Limited, , Adams v. Cape Industrials Plc, 1990 BCLC 479. In Re. Pollypeck International Plc, 1996 (1) BCLC 428. I perused the judgments. The Court of Appeal in Adams'

Case held that "there is no general principle that all companies in a group of companies are to be regarded as one. On the contrary, the fundamental principle is that, each company in a group of companies (a relatively modern concept) is a separate legal entity possessed of separate legal rights and liabilities". This judgment of Court of Appeal discusses the entire case laws, including the one rendered in DHN Food Distributors' Limited Case. In the DHN case, the following is stated:

"We all know that in many respects a group of companies are treated together for the purpose of general accounts, balance sheet and profit and loss account. This is especially the case when a parent company owns all the shares of the subsidiaries, so much so, that it can control every movement of the subsidiaries. These subsidiaries are bound hand and foot of the parent company and must do just what the parent company says."

Then the DHN case proceeded to hold that the companies involved in that case are a single economic unit. In DHN case, again the following is found stated on the concept of single economic unit:

"This is a case in which one is entitled to look at the realities of the situation and to pierce the corporate veil. I wish to safeguard myself by saying but so far as this ground is concerned, I am relying on the facts of this particular case. I would not, at this juncture, accept that in every case where one has a group of companies, one is entitled to pierce the veil. But in this case, the two subsidiaries were both wholly owned, further, they had no separate business whatsoever. Thirdly, in my judgment, the nature of the question involved is highly relevant namely, whether the owners of this business have been disturbed in their possession and enjoyment of it?"

Therefore, it is clear that the concept of a single economic unit is an accepted position in law and whether a group of companies constitute a single economic unit, depends on the facts of each case. The Court can investigate the relationship between the parent company and the subsidiary in this regard. On facts, I find, as already stated, that the affidavit sworn to on 30.4.2004 and filed before this Court show that the second plaintiff was incorporated in India as the subsidiary of the first plaintiff, to meet the requirements of law in India. The

affidavit also shows that the second plaintiff is under the control of the first plaintiff and it only imports the drugs manufactured by the first plaintiff and distributes the same in India. The second plaintiff is not shown to be carrying on any other business activities of its own. I have already noted that in the second plaintiff company, the first plaintiff has 50.93% shares and the remaining, with the Indian public. I am not, for a minute, saying that the first plaintiff holding major shares in the second plaintiff company would not put an end to the corporate character of the second plaintiff (See *Spencer & Company Limited Case*, AIR 1965 Mad. 359). As already stated, whether the companies in a group can be characterised as the single economic unit or not, depends on the facts of each case. In *Gower's Principles of Modern Company Law*, it is found stated as follows:

"As we have seen, it has become a habit to create a pyramid to interrelated companies, each of which is theoretically a separate entity but in reality, part of one concern represented by the group as a whole. The separation of the group into distinct companies is not necessarily in any way improper. It may well be the most economical and most convenient arrangement when the concern carries on a number of separate business or when it is desirable to distinguish between the manufacturing and the marketing part of enterprise or between trade in its various products."

"It is still possible and indeed usual, for a public company to carry on business through subsidiary operating private companies."

From the above passage, it is seen that the practice of creating an apex company with a number of subsidiary companies is held to be not impermissible and in fact, such an organisational set up for the purpose of business related activities is found to be permissible. The first plaintiff's case is that, the second plaintiff imports the drugs manufactured by the first plaintiff and distributes the same in India. *Palmer's Company Law* (25th Edition) gives, with reference to case laws, twelve instances where the corporate veil was lifted. Instance No. 3 is "in certain matters pertaining to the law of taxation, particularly where the question of controlling interest is in issue." The Supreme Court in the judgment *L.I.C. v.*

Escorts, and in *State of U.P. v. Renusagar Power Co.*, , examined in depth the circumstances under which the corporate veil can be lifted. In *New Horizon and Anr. v. Union of India and Ors.*, Volume 89 (1997) C.C.785 the following stands stated:

"Nevertheless, this did not preclude treating, say, a subsidiary as the agent or the alter ego of its parent, provided the facts of the case justified such a conclusion. However, it would seem that the facts would have to reveal a very high degree of control by the parent over the subsidiary before a Court would conclude that an agency relationship had been established."

In *Renusagar Power Co. Case*, on lifting the corporate veil, the Supreme Court said as follows:

"It is high time to reiterate that in the expanding of horizon of modern jurisprudence, lifting of corporate veil is permissible. Its frontiers are unlimited. It must, however, depend primarily on the realities of the situation. The aim of the legislation is to do justice to all the parties. The horizon of the doctrine of lifting of corporate veil is expanding."

14. Mr. V. Lakshmi Kumaran learned counsel, relying on the judgment of the Supreme Court in *Kapila Hingorani v. State of Bihar*, submitted that lifting the corporate veil should not be attempted in each and every case for the mere asking and the same should be done only when the corporate entity is abused for an unjust and inequitable purpose. According to him, only when such a factual situation exists, the Court should not hesitate to lift the veil and look into the realities so as to identify the persons, who are guilty and liable therefor. Learned counsel would add that such is not the situation here and therefore each of the plaintiff should be treated as a separate legal entity. Learned counsel took me through the judgment of the Court of Appeal in *DHN Case* and the judgment of House of Lords in *Woolfson's Case* to submit that the House of Lords did not approve the law laid down in *DHN case*. A perusal of the judgment in *Woolfson's case* shows that the House of Lords distinguished the judgment in *DHN Food Case* on facts. On going through the judgment of the Apex Court in *Kapila Hingorani's Case* referred to supra, it is not possible to agree with the

submission made by Mr. V. Lakshmi Kumaran learned counsel that only when the corporate entity is abused for an unjust and inequitable purpose, the Court should lift the corporate veil. A careful reading of the judgment referred to above shows that the Supreme Court did not unsettle the twelve instances given in the 25th Edition of Palmer on Company Law, where the corporate veil can be lifted. Therefore, as already stated, I am not inclined to agree with the submission made by Mr. V. Lakshmi Kumaran that only when the corporate entity is abused for an unjust and inequitable purpose, the Court should not hesitate to lift the veil. As could be seen from the various judgments cited at the Bar, the Court can investigate the relationship between the parent company and the subsidiary company and lifting the corporate veil depends on the facts of each case. I have already applied my mind to the materials on record, which evidences the relationship between the first plaintiff and the second plaintiff. On the facts observed by me in that context, I am of the opinion that the plaintiffs can be treated as one single economic unit. Section 24-B(1) of the Patents Act only contemplates the applicant receiving the approval to sell or distribute the article, from the authority specified in this behalf by the Central Government. I have already held that the plaintiffs constitute a single economic unit and that the second plaintiff applying for and getting a marketing approval is as good as the first plaintiff himself applying for the same and getting it. Reading of Section 24B(1) of the Act only contemplates the applicant, who had filed the patent claim, receiving the marketing approval. Inasmuch as, the provisions contained in the Drug and Cosmetic Rules enables the manufacturer's agent to apply for marketing approval, which provision stands modified with effect from 1.1.2003 to enable the manufacturer also to apply for marketing approval, on the facts of this case, I hold that the marketing approval applied for and obtained by the second plaintiff cannot be said to be in infringement of any Statutory requirement, either under the Patents Act (24-B(1)) or under any provision of the Drug and Cosmetic Rules. This conclusion of mine is strengthened, as rightly contended by Mr. P. Chidambaram learned senior counsel appearing for the

plaintiffs, by Section 24-B(1) permitting the use of exclusive right to be given to the applicant under the Patents Act to be exploited by himself, his agents or licencees, etc..... In the context of the exclusive right given under the Patents Act to the applicant being permitted to be exploited by the applicant himself, his agents or licencees, etc.....would help this Court to understand the requirement of the section, when it says the applicant has received the approval to sell, to mean that the marketing approval can be obtained by the applicant himself or anybody claiming under him.

15. Let me now address myself to the arguments advanced by Mr. V. Lakshmi Kumaran that unless the substance in the patent claim in India; in the patent claim and in the patent grant in the convention country; in the approval to sell in the convention country; in the approval to sell granted in India and in the grant of "EMR" is the same, the "EMR" should be invalidated. For this proposition, the learned counsel heavily relies upon Section 24-B of the Act. A reading of Section 24-B(1)(a) of the Act mandatorily requires that before filing a patent claim in India, the applicant ought to have filed an application for the same invention claiming identical article or substance in the convention country. A perusal of the claim in India and in the convention country, which are on record, do show that they are, for the identical article or substance. The first requirement of Section 24-B(1)(a) of the Act is that the claim in the Indian patent and the claim in the patent filed in the convention country must be the same and this stand satisfied in this case. The second requirement of the above referred to section is, grant of the patent in the convention country and the approval to sell or distribute the article or substance, etc., in the convention country. Learned counsel for the defendants would submit that the expression "the article or substance" means the article or substance disclosed in the patent claim in India and in the convention country. His further submission is that, the article or substance for which the patent and the approval to sell was granted by the convention country, is not the same as the patent claim in India and in the convention country. Mr. P. Chidambaram learned senior counsel appearing for

the plaintiffs would submit, by taking me through the patent granted in Australia, that the grant is in respect of twelve claims and every claim relates to "Beta crystals of Imatinib mesylate". Learned senior counsel would also state that under the provisions of the Patents Act, the patent, as claimed, can be granted for all the claims or for modified claims or the patent can be granted only for some of the claims. In the convention country, patent was granted for twelve claims and each claim relates to "Beta crystals of Imatinib Mesylate". The marketing approval in the convention country is also in respect of the same article or substance. The patent claim in India is also in respect of the same article or substance. Therefore, this Court, at this stage, has to go only by the records shown where the article or substance is disclosed. To say that the article or substance concerned in the records are not identical, oral evidence by way of expert's evidence is necessary, which will arise only during trial. Examiner to whom the Controller had referred the patent claim under Section 24-A (examiner should be an expert) had gone into this identity, on the basis of which the "EMR" had come to be granted. The Patents Controller had also filed an affidavit stating that the "EMR" is validly granted. All official acts, unless the contrary is shown, should be presumed to have been taken in accordance with law. The Authority in the convention country had given a certificate about the identity of the substance being the same in the patent and "EMR" granted by them and in the patent claim in India. Therefore, in the absence of oral evidence before Court for or against, on the identity of the article or substance, at this stage the Court should not venture to go into that issue. These submissions made by Mr. P. Chidambaram learned senior counsel, appeal to me and accordingly they are accepted. This Court is not an expert to decide the identity of the substance on pleadings and materials alone, in the absence of expert's evidence. Therefore I hold that, going by the prima facie materials, I hold that the article or substance is identical in all the legal documents prescribed under Section 24-B(1)(a) of the Act.

16. The validity of the patent grant in the convention country and the marketing approval given by it is attacked on yet another ground namely, they have not

been given after conducting appropriate tests in that country. Again, it is a matter for oral evidence to explain what are the appropriate tests conducted and the manner and method in which they were conducted. On pleadings alone, the said issue cannot be decided. The very act of the convention country in granting the patent and the marketing approval implies that the same had been granted, after conducting appropriate tests. The contrary can be shown only on evidence during trial. The other submission made by Mr. V. Lakshmi Kumaran learned counsel is that the drug of the defendants is shown to have been compared with the commercial product of the plaintiffs and it is impermissible in law. According to him, the product marketed by the defendants should be compared with the drug disclosed in the patent claim in the convention country. But I see from the reports made available by the plaintiffs that the product marketed by the defendants had been compared with the drugs under the Australian Patent and in the Indian Patent application. (See the affidavit of Dr. Michael Mutz) In any event, at this stage namely, interlocutory stage, this Court would not be in a position to go deep into that issue, especially when there is no oral evidence before Court to give a decision in favour of either of the parties. Therefore, going by the apparent tenor of the records made available by the plaintiffs in this regard, I am not inclined to hold at this stage that the comparison is bad in law. The arguments advanced by Mr. V. Lakshmi Kumaran learned counsel for the defendants, based on the Information Technology Act, 2000, on the unsigned report on the scientific tests stated to have been conducted, have been answered by an affidavit sworn to by Dr. Michael Mutz. As against the test reports relied upon by the plaintiffs, the contesting defendants rely upon the test conducted by Dr. A. Ramanan, Associate Professor of IIT at Delhi. That report, as pointed out by Mr. P. Chidambaram learned senior counsel for the plaintiffs, while showing that reasons are not clear as to how the plaintiffs' expert arrived at the conclusion that the product marketed by the defendants is infringing the plaintiffs' product, does not indicate as to what are the characteristics of the product marketed by the defendants. To a question put to Mr. V. Lakshmi Kumaran learned counsel on

the characteristics of his clients' product, the learned counsel fairly stated that "Beta crystalline form" is related to the drug marketed by them. But however, he would hasten to add that, going by the patent grant given in the convention country, the percentage of crystals in their drug is far below the percentage mentioned in the patent grant in the convention country and therefore the defendants marketing such drug with a low percentage of "Beta crystals" shall not be taken to be an infringement of the "EMR". Mr. P. Chidambaram learned senior counsel in this context would submit that applying the "pith and marrow" principle, also called as "Doctrine of Equivalents", the Court should find that "Beta crystals" are related to both the drugs and it is enough, without reference to the difference in percentage of the presence of such "Beta crystals", to hold that there is an infringement. Mr. V. Lakshmi Kumaran learned counsel for the contesting defendants would submit that the Courts have given up the "pith and marrow" principle long before and the "Doctrine of Purposive Construction" should be applied and if it is applied, the infringement theory falls to the ground. To apply the above doctrine, the plaintiffs have to plead facts and they are absent. There is also no evidence on their side. Therefore the same cannot be applied. "Doctrine of Equivalents" also is another theory, which can be applied while comparing the drugs. For that theory also, there must be pleading by the plaintiffs, which is also wanting in this case. Therefore the plaintiffs are not entitled to the relief of injunction. Again, I state that at this interlocutory stage, the Court is not called upon to go deep into these issues and arrive at a finding one way or the other. Inasmuch as the Court has to go only by prima facie materials at this stage, taking into account the statement made at the Bar that the drug marketed by the defendants contains "Beta crystals" though in a lower percentage, it is clear to my mind that there is an infringement, especially when the invention claimed by the plaintiffs is "Beta crystalline form of Imatinib Mesylate". "Beta crystal form is the invention claimed by the first plaintiff and it is related to the drug marketed by them in the name of "Imatinib Mesylate".

17. Going by the balance of convenience and public interest, it is not disputed at the Bar that the infringing product of the defendants has come to be marketed only after the plaintiffs' introduced their product in the market. The plaintiffs have an "EMR" valid for a period of five years or till the disposal of the patent claim one way or the other, whichever is earlier and the Statute protects such rights. I have already held, on prima facie materials, that the plaintiffs have established the validity of the "EMR". When the Statute protects such rights, in my opinion, the balance of convenience loses its significance, especially when the parties in opposition do not have a legal ground in their favour at this stage. As far as public interest is concerned, the Patents Act itself had taken that into account. Under Section 24-D of the Act, the Central Government, on being satisfied that it is necessary or expedient in public interest to allow the sale of the drug by a person other than a person in whose favour the "EMR" is granted, it can do so. Under Sub-section (2) of Section 24-D of the Act, the Government has a right, having regard to the public interest involved, to fix the price, determined by an authority specified by it in this behalf, at which the "EMR" holder should sell the said product. Section 24-D of the Act, in my opinion, is a complete answer to the arguments advanced by Mr. V. Lakshmi Kumaran learned counsel that public interest would be affected, if the "EMR" is to be sustained. The case relied upon by the learned counsel for the defendants that unless a very strong case for trial is established by the plaintiffs no injunction should be granted pending trial, relates to a case where a mandatory injunction was asked for. Therefore that judgment, on facts, is not applicable to the case on hand where a prohibitory injunction is asked for. In all cases where prohibitory injunction is asked for, the well-known principle of prima facie case, balance of convenience and irreparable loss would be the prime materials, on which the Court must consider the application. In *Morgan Stanley Mutual Fund v. Kartick Das*, , the Supreme Court laid down the following factors, which should weigh with the Court while a request for an ex parte injunction comes up for consideration:

- "(a) Whether irreparable or serious mischief will ensue to the plaintiff;
- (b) whether the refusal of ex parte injunction would involve greater injustice than the grant of it would involve;
- (c) the Court will also consider the time at which the plaintiff first had notice of the act complained so that the making of improper order against a party in his absence is prevented;
- (d) the Court will consider whether the plaintiff had acquiesced for some time and in such circumstances it will not grant ex parte injunction;
- (e) the Court would expect a party applying for ex parte injunction to show utmost good faith in making the application;
- (f) even if granted, the ex parte injunction would be for a limited period of time;
- (g) general principles like prima facie case, balance of convenience and irreparable loss would also be considered by the Court."

This has been quoted with approval by the latter judgment of the Supreme Court . In the judgment *Wander Ltd. v. Antox India P. Ltd.*, 1990 (Suppl.) SCC 727, arising under the Trade and Merchandise Marks Act, 1958 while the interlocutory application for injunction came up for consideration, the Court held as follows:

"(1) Usually, the prayer for grant of an interlocutory injunction is at a stage when the existence of the legal right asserted by the plaintiff and its alleged violation are both contested and uncertain and remain uncertain till they are established at the trial on evidence. The Court, at this stage, acts on certain well settled principles of administration of this form of interlocutory remedy which is both temporary and discretionary. The interlocutory remedy is intended to preserve in status quo, the rights of parties which may appear on a prima facie case. The Court also, in restraining a defendant from exercising what he considers his legal right but what the plaintiff would like to be prevented, puts into the scales, as a relevant consideration whether the defendant has yet to commence his enterprise or whether he has already been doing so in which latter case considerations is somewhat different from those that apply to a case where the defendant is yet to commence his enterprise, are attracted."

Learned counsel for the contesting defendants would submit that since the "EMR" is of a recent origin and once a challenge to the validity of the same is

made, this Court should not ordinarily grant an injunction. For this purpose, the learned counsel relied upon a judgment of this Court in the case *P. Manickka Thevar v. Star Plough Works*, which was followed by the Kolkata High Court in the judgment *Hindustan Lever v. Godrej Soaps Limited*, , where this Court had held that when a patent is of a recent origin, the Court should not grant an injunction. We are now concerned in this case with the validity of the "EMR", the period of which is only five years as the outer limit and determinable prior to that, if the patent claim is disposed of one way or the other. The Statute protects the exclusive marketing right in favour of the grantee for the full period of five years. Therefore, to agree with the submission made by the learned counsel for the contesting defendants that for a period of six years atleast no injunction should be granted protecting the rights of the "EMR" holder, has really no meaning, since the period of the validity of the "EMR" itself is less than six years. In the judgment of this Court referred to above, the learned Judge has held as follows:

"In a suit complaining of infringement of a patent the plaintiff must make out a strong prima facie case for the issue of a temporary injunction. If from the objections raised by the defendant it is clear that a serious controversy' exists as to whether or not the invention claimed by the plaintiff 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, Courts will not grant an interim injunction restraining the defendant from pursuing his normal business activity. An interim injunction will not be granted if the defendant disputes the validity of the grant. If the patent is new and its validity has not been established in a judicial proceeding till then, and if it is endeavoured to be shown that the patent ought not to have been granted under the provisions of Section 26 of the Patents and Designs Act, 1911, the Court will not interfere by issuing a temporary injunction."

Therefore it is clear from the above that the learned Judge has never said that if the patent is of a recent origin and if it is less than six years old, no injunction at all should be granted. On the other hand, the learned Judge had recognised the power of the Court to grant an interim order, if facts made available warrant such an order being passed. The learned Judge relied upon the statement of law in

Terrells on Patent, 9th Edition that a patentee should show undisturbed possession and enjoyment of the patent at least for a period of six years before the controversy arose. The learned Judge had also said that Courts have always taken a patent as a recent origin one, if it is less than six years old. Nowhere, this Court had said that when a patent is of a recent origin, the Court should never grant an injunction. In the case on hand, I have already held that prima facie materials are in favour of the applicants/plaintiffs. I have also already noted that the defendants started marketing their product, which is shown to be an infringement, only after the plaintiffs' started marketing the product in India. Therefore, on the principles laid down by the Supreme Court in the judgments referred to above and taking into account the facts available in this case as noted earlier, the plaintiffs have definitely made out a prima facie case for confirming the order of injunction already granted in their favour. Balance of convenience also stands heavily loaded in favour of the plaintiffs and if an injunction is not granted, they would suffer an irreparable loss. I have already stated on the element of public interest, if at all it arises on the facts of this case, that there are provisions in the Act itself for the Government of India to take care of it and do remedial measures. The arguments advanced by Mr. V. Lakshmi Kumaran learned counsel that the plaintiffs are guilty of coming to Court with unclean hands, which would disentitle them from getting the relief of injunction, on facts, do not appeal to me at all. The fact that the second plaintiff invited one or more of the defendants to come to the negotiating table and the challenge to their "EMR" is pending on the Delhi High Court (these facts are not disclosed either in the plaint or in the affidavit of the plaintiffs) would not by themselves amount to the plaintiffs suppressing material facts, which, if disclosed, would enable this Court to approach the problem from a different angle. There is no doubt that any relevant material touching upon the controversy between the parties, which may or may not influence the decision making process of this Court, if burked, may be put up against the party guilty of such suppression. The two instances referred to above, in my considered opinion, would have no relevance at all in deciding

the controversy between the parties. A number of case laws, other than the ones referred to in this order, have been cited before this Court by the learned senior counsel on either side. Inasmuch as, I have arrived at my conclusions on prima facie materials and on the point of law decided, supported by the judgments referred to in this order, I have not set out in detail the other case laws and considered it in this order. Consequently, I am inclined to make absolute the order dated 20.1.2004 granting injunction as prayed for in all the original applications and as a result thereof, all the original applications would stand allowed as prayed for and all the applications filed to vacate the injunction would stand dismissed.