Cipla Limited vs Novartis Ag & Anr on 9 March, 2017

Author: Badar Durrez Ahmed

Bench: Badar Durrez Ahmed, Sanjeev Sachdeva

THE HIGH COURT OF DELHI AT NEW DELHI

% Judgment delivered on: 09.03.2017

+ FAO(OS) 21/2015 & CM Nos.731/2015, 1288/2015, 2090/2015

CIPLA LIMITED ... Appellant

versus

NOVARTIS AG & ANR ... Respondents

Advocates who appeared in this case:-

For the Appellant : Mr P. Chidambaram, Mr Abhishek Manu Singhvi and Ms Prathibha M. Singh, Senior Advocates with Ms Bitika Sharma, Ms Namrita Kochhar and Mr Harshit Saxena

For the Respondent : Mr Gopal Subramaniam and Mr CS Vaidyanatham, Senior Advocates with Mr Hemant Singh, Ms Mamta Jha, Dr Shilpa Arora, Mr Talha and Ms Anusha

CORAM:-

HON'BLE MR JUSTICE BADAR DURREZ AHMED

HON'BLE MR JUSTICE SANJEEV SACHDEVA

JUDGMENT

BADAR DURREZ AHMED, J

1. The present appeal is directed against the judgment and/or order dated 09.01.2015 delivered by a learned Single Judge of this Court in IA 24863/2015 which was an application under Order XXXIX Rules 1 and 2 of the Code of Civil Procedure, 1908. That application was filed in CS(OS) 3812/2014 which, in turn, had been instituted by the respondents/ plaintiffs. The suit filed by the respondents was one for permanent injunction restraining infringement of patent No. 222346 granted under the Patents Act, 1970 (hereinafter referred to as □the said Act') in favour of the respondent No.1/plaintiff No.1. The suit was also for rendition of accounts/damages, delivery-up etc. The respondent No.1 is a Swiss company and the respondent No.2 is an Indian company. The appellant, of course, is also an Indian company.

2. The entire controversy is with regard to □INDACATEROL' in respect of which the respondent No.1 holds the said patent. The said respondents market the said □INDACATEROL' under the name □ONBREZ'. □INDACATEROL' is a bronchodilator and provides symptomatic relief to persons suffering from chronic obstructive pulmonary disease (COPD).

3. The appellant launched its drug ❑UNIBREZ' in October, 2004. However, a suit was filed by the respondents on 09.01.2015 which was ultimately disposed of on the appellant's undertaking to change the brand name of the drug from ❑UNIBREZ' to ❑NDAFLO'. That was an infringement of trade mark action.

4. The respondents do not manufacture ❑NDACATEROL' in India. In fact, the drug is manufactured by the respondent No.1 in Switzerland and is imported into India and marketed by Lupin pursuant to an agreement dated 22.03.2012.

5. The appellant is aggrieved by the fact that the learned Single Judge has restrained the appellant from, inter alia, using, manufacturing, importing, selling any pharmaceutical products etc. containing ❑NDACATEROL' or ❑NDACATEROL Maleate', alone or in combination with any other compound or Active Pharmaceutical Ingredient (API), which may amount to infringement of the respondent No.1's patent No. 222346. However, this injunction has been granted until the determination by the competent authority of the pleas raised by Cipla for seeking the compulsory licence, if so filed. In case no such application for compulsory licence is filed, the learned Single Judge directed that the injunction would continue during the pendency of the suit. The learned Single Judge also directed that in case the appellant filed such an application and the same was decided in favour of the appellant, it could move an application for modification etc. of the impugned order dated 09.01.2015.

6. The learned counsel for the appellant submitted that by virtue of the impugned judgment and/or order, the appellant cannot market ❑NDACATEROL' in India. It was also submitted that the respondents do not manufacture ❑NDACATEROL' (ONBREZ) in India. Only small quantities are imported catering to a negligible number of patients. Thus, according to the appellant, the respondents are not working the patent in India and consequently, they are not entitled to an injunction.

7. It was contended that Section 48 of the said Act describes the rights of patentees. However, it begins with the words ❑subject to the other provisions contained in this Act . Referring to the said expression, the learned counsel for the appellant submitted that the said rights of patentees under Section 48 would be subject to other provisions in the Act, including Section 83 of the said Act. Section 48 and Section 83 of the said Act are reproduced herein below:-

> ❑48. Rights of patentees.--Subject to the other provisions contained in this Act and the conditions specified in section 47, a patent granted under this Act shall confer upon the patentee --
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> (a) where the subject matter of the patent is a product, the exclusive right to prevent third parties, who do not have his consent, from the act of making, using, offering for sale, selling or importing for those purposes that product in India;

(b) where the subject matter of the patent is a process, the exclusive right to prevent third parties, who do not have his consent, from the act of using that process, and from the act of using, offering for sale, selling or importing for those purposes the product obtained directly by that process in India: □83. General principles applicable to working of patented inventions.--Without prejudice to the other provisions contained in this Act, in exercising the powers conferred by this Chapter, regard shall be had to the following general considerations, namely;--

(a) that patents are granted to encourage inventions and to secure that the inventions are worked in India on a commercial scale and to the fullest extent that is reasonably practicable without undue delay;

(b) that they are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article;

(c) that the protection and enforcement of patent rights contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations;

(d) that patents granted do not impede protection of public health and nutrition and should act as instrument to promote public interest specially in sectors of vital importance for socio-economic and technological development of India;

(e) that patents granted do not in any way prohibit Central Government in taking measures to protect public health;

(f) that the patent right is not abused by the patentee or person deriving title or interest on patent from the patentee, and the patentee or a person deriving title or interest on patent from the patentee does not resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology; and

(g) that patents are granted to make the benefit of the patented invention available at reasonably affordable prices to the public.

8. It was submitted that the general principles applicable to the working of patented inventions stipulated in Section 83 would govern and sit over the rights of patentees indicated in Section 48 of the said Act. By virtue of Section 48 of the said Act, a patentee has the exclusive right to prevent third parties, who do not have his consent, from the act of making, using, offering for sale, selling or importing for those purposes the product in India (in this case □INDACATEROL'). But, according to the learned counsel for the appellant, this right would be subject to the fact that the patent is worked in India on a commercial scale; that the patent is not used by a patentee merely to enjoy a monopoly for the importation of the patented article; that the grant of the patent does not impede protection of

public health and nutrition and that the objective of making the benefit of the patented inventions available in India at reasonably affordable price to the public is fulfilled. In this context, it was submitted that the respondents did not manufacture ☐INDACATEROL' in India and even the importation was of very small quantities. Thus, the said drug ☐INDACATEROL', which was vital for COPD patients, was not available to large sections of the public in India. It was submitted that the non-availability was further aggravated by the fact that the price of the respondents' ☐INDACATEROL' was exorbitant as compared to ☐INDACATEROL' manufactured, supplied and sold by the appellant. It was submitted that while 10 tablets of the respondents' drug were sold for Rs 677/-, 10 tablets of the appellant's drug were priced only at Rs 130/-. In other words, the price of the respondents' product was five times that of the price of the appellant's product.

9. It was also contended on behalf of the appellant that in the grant of an injunction, one of the considerations, which is regarded as the fourth aspect (in addition to prima facie case, balance of convenience and irreparable harm and injury), was that of public interest. Reliance was placed on the decision of a Division Bench of this Court in the case of F. Hoffmann La Roche Limited and Another v. Cipla Limited: 2009 (40) PTC 125 (Del) (DB). In that decision, the Division Bench of this Court while dealing with the issue of public interest, inter alia, observed as under:-

> ☐81. This Court is inclined to concur with the learned single Judge that in a country like India where question of general public access to life saving drugs assumes great significance, the adverse impact on such access which the grant of injunction in a case like the instant one is likely to have, would have to be accounted for. Erlocip is the Indian equivalent produced by the defendant in India as a generic drug manufacturer. It is priced at Rs.1600 per tablet. Even if this does not make it inexpensive, the question of greater availability of such drug in the market assumes significance.
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> 82. In the considered view of this Court, while it may be possible to distinguish the judgment of the US Supreme Court in E Bay as relating to a case of permanent and not temporary injunction, the traditional four factor test identified in the said judgment does assume relevance even at the stage of grant of an interim injunction. Given the nature of the drug, in the instant case, which admittedly is a life saving one, the fourth test identified in E Bay that the grant of an injunction should not result in the public interest being ☐disserved would be relevant.
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> 83. The judgments relied upon by the plaintiffs underscore the approach of determining these questions on a case by case basis. Whether indeed the public interest in the availability of the drug to the public at large is outweighed by the need to encourage research in the invention, would obviously differ from case to case and depend on a host of factors. This Court finds no ground to differ with the reasoning or the conclusions arrived at by the learned Single Judge on this aspect after an analysis of all the relevant factors. (underlining added)

10. In order to substantiate the allegation that the respondents were importing ☐INDACATEROL' in very small quantities, the following chart was referred to:-

> Year Total Quantity No. of patients Total Qty Deficiency Imported marketed 2008 Nil Approx. 1-1.2 Nil 100% crore (based on 1991 census) 2009 Nil Approx. 1-1.2 Nil 100% crore (based on 1991 census) 2010 Nil Approx. 1-1.2 Nil 100% crore (based on 1991 census) 2011 Nil 1.5 crore Nil 100% (based on 2001 census) 2012 53144 Units 1.5 crore 5567 Units 99.96% 2013 53865 Units 1.5 crore 5655 Units 99.96% It was submitted that based on the above table, as one unit translated to 30 tablets, which was one month's supply, the figure of 53,000 divided by 12 (12 months in a year) would come to a figure of a little over 4,000. Thus, according to the appellant, only about 4,000 patients would get the benefit of the drug ☐INDACATEROL' as against 1.5 crore patients. Thus, it was submitted that public interest would not be served if an injunction were allowed to remain against the appellant. We may, at this juncture, however, note that the figure of 1.5 crore patients suffering from COPD is contested by the respondents.

11. A reference was also made to Article 7 of the TRIPS agreement, which reads as under:-

> ☐Article 7: The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations. (underlining added)

12. Similarly, a reference was made to the following extract from the Doha Declaration:

> ☐4. We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all.... (underlining added)

13. And, a reference was made to India's submissions during the GATT negotiations. The relevant extract of which is as under:-

> ☐Standards and Principles concerning the availability, scope and use of Trade Related Intellectual Property Rights (Communication from India, MTN.GNG/NG11/W/37, dated 10.07.1989) ...Working of Patents
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> 9. The experience of developing countries would clearly point to four basic facts: firstly, patents are seldom worked in developing countries, even when it is

techno-economically feasible to do so. Secondly, the working of the patent in the host country leads to saving of scarce foreign exchange (which is a major constraint to the economic development of developing countries) and the lowering of prices of products particularly in critical sectors such as food, pharmaceutical, agro-chemicals and the like. Thirdly, without the working of the patent, there can hardly be any transfer or diffusion of technology and the promotion of industrial activity in the host country..... (underlining added) Various articles were referred to in an attempt to demonstrate that the total burden of COPD in India had more than doubled to about 14.84 million (approximately 1.5 crores) in 2011 from 6.45 million in 1971. All these submissions were made in the context of the public interest argument coupled with the alleged non-working of the patent by the respondents in India.

14. Another decision referred to by the learned counsel for the appellant was that of Franz Xaver Huemer v. New Yash Engineers: 1996 PTC (16) (DB) 232, wherein a Division Bench of this Court had, inter alia, observed as under:-

> 5. In England, it has been accepted more than a century ago that a patentee who does not put his patent for use by the public is not entitled to temporary injunction. In Plympton v. Malcolmson, (1875) LR 20 Eq 37, the plaintiff who claimed to be owner of a patent sought interim injunction to restrain the defendant from making, selling or using an article which was alleged to be an infringement of the plaintiff's patent. The plaintiff's patent was dated 25-5-1865 and the plaintiff filed the bill in 1875 to establish the validity of his patent and to restrain the defendant (who obtained patent on 7-5-1874) from infringing the plaintiff's patent. There was no evidence of actual user of the plaintiff's patent except of recent date. Refusing injunction on the ground of non-user, Sir George Jessel M.R. observed -
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> When a patentee comes to this Court for interim protection on the ground of previous enjoyment, he must show that there has been actual public user of his patent. In this case, there is no evidence of actual user for any number of years. xxxx xxxx xxxx xxxx 9. In 1886 it was initially held by Blodgett, J. in Hoe v. Knap, (1886) 27 F 204, (212) (CC N.D. 111) that a patentee "is bound either to use the patent himself or allow others to use it on reasonable or equitable terms". In Ewart Mfg. Co. v. Baldwin Cycle-chain Co. (1098) 91 Fed 262 (CCP D, Mass) the Circuit Court also declared that where the patentee refused to make the device available for himself or for others was not within the spirit of the Constitution. Under the Constitution, the reason for granting the patent was the desire to promote progress of science and the useful arts, by encouraging authors and inventors. "Patents suppressed were entitled to scant recognition at law, though necessarily to some, but to none whatever is equity". xxxx xxxx xxxx xxxx 27. In his book 'The United States Patent System' (1956), Chapter VIII) relating to 'Suppression of Patents', Floyd L. Vaughan, refers to what Mr. R.H.F. Palgrave, stated in his Dictionary of Political Economy (III, 76). He stated that the granting of a patent may be a hindrance to industrial life of the patentee, who through want of energy or want of means, neglects to work his

> invention, while others, who would be willing and able to do so, are afraid of infringing his rights. Reference is made to Mr. William Robinson's. The Law of Patents For Useful Inventions (65-67) wherein he said that the expectation that the patentee will use his invention is implied in the infringement laws, which protect the legal monopoly of the patentee throughout the entire period during which his monopoly extends. The Corollary of this protection is that the patentee must develop his invention. These views suggest that if the patentee releases his inventions into the market, it will help in further research, improvement and development of better technology. Floyd L. Vaughan finally says (p. 259) that the US laws allow foreigners to take out patents in US merely for the purpose of reserving the US as a market for their patented products; If there is suppression, it will prevent manufacture in US in spite of more favourable factors for production in US.
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> 28. In our opinion, what was said about unused foreign patents and their adverse effect in US, equally applies to foreign patents registered in India but not used.
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> 29. For the above reasons, the plaintiff who has registered patents in India in 1984 but has not used them in India cannot, in equity, seek temporary injunction against the respondent.

Points 1 and 2 are decided accordingly. (underlining added)

15. The decision in the case of Glaverbel S.A. v. Dave Rose and Ors.:

> 2010 (43) PTC 630 (Del) is that of a Single Judge. Bard Peripheral Vascular, Inc. v. C.R. Bard, Inc.: 670 F.3d 1171 which was a decision of the US Court of Appeals for the Federal Circuit was referred to for the argument that instead of an injunction, royalty may be a substitute. It was also contended on the part of the appellant that the view of the learned Single Judge that the Civil Court could not apply the principles of Section 83 was wrong. It was submitted that while considering the question of grant of an injunction, the general principles set down in Section 83 would also come into play and the Civil Court ought to consider those principles.

16. In sum and substance, the argument on the part of the appellant was that public interest was an important aspect while considering the question of grant of an injunction particularly with regard to a drug of the nature of □INDACATEROL' which could be a virtual life saver for patients suffering from COPD. The public interest element is also evident from the vast difference in the price structure of the appellant's drug, vis-a-vis, the respondent's drug which was five times more expensive than that of the appellant. The factum of non-working of the patent in India would also be a serious issue to be considered with respect to the grant of an injunction based on the patent held by the respondents. It was also submitted that the rights of a patentee declared in Section 48 of the said Act were subservient to the general principles stipulated in Section 83 thereof.

17. On the other hand, it was submitted on behalf of the respondents that the fact that they did not manufacture the product in India did not mean that the patent was not being worked in India because sufficient quantities of imports were made which would serve the needs of the patients suffering from COPD. It was also denied by the respondents that the extent of COPD patients was to the tune of 1.5 crore. It was submitted that enough imports were being made which would satisfy the requirements of the COPD patients for ☐INDACATEROL'. It was, therefore, submitted that it was not a case of public interest being disserved in case an injunction was granted. It was also submitted that prima facie the learned single Judge had held the patent to be valid and that has not been challenged, at least not seriously, by the appellant. Therefore, the respondent is entitled to the benefit of Section 48 of the said Act which clearly entitles it to the exclusive right to prevent third parties, who do not have its consent, from the act of making, using, offering for sale, selling or importing ☐INDACATEROL' in India. It was also submitted that the right of patentees under Section 48 was in no manner reduced or circumscribed by the provisions of Section 83, as the latter provision fell under an entirely different Chapter and had an entirely different objective.

18. It was also submitted that the effectiveness and novelty of ☐INDACATEROL', which was a new chemical entity, is already established. In COPD, the air sacs in the lungs are damaged and, therefore, such damage is irreparable. However, the obstruction can be managed. The obstruction in the respiratory system occurs, inter alia, because of inadequate dilation. Such inadequate dilation is treated by drugs known as ☐Agonists. INDACATEROL is one such dilator and is a ☐Beta Agonist'. It functions differently from other inhaled bronchodilators. In the case of INDACATEROL, one dose in the morning is sufficient to manage the patient for 24 hours and it is extremely fast acting in the sense that it provides relief within five minutes. The other inhaled bronchodilators have very short term effects. There is no doubt that INDACATEROL as a drug is of extraordinary utility and quality and that the inventiveness and usefulness of the drug is prima facie established. It was, therefore, submitted that the fact that the appellant manufactured and marketed ☐INDACATEROL' and ☐INDACATEROL Maleate', is prima facie indicative of the infringement on the part of the appellant.

19. It was, therefore, submitted on behalf of the respondents that, while public interest considerations may be a relevant factor in certain circumstances such as in the case of life saving drugs, it cannot by itself outweigh the rights of a patentee in the case of infringement of the patent as provided under the said Act. It was further submitted that the only argument that has been raised on the part of the appellant is that Section 48 is subject to Section 83 and, therefore, the argument of public interest would override the rights of a patentee under Section 48 of the said Act. It was submitted that Section 48 is undoubtedly subject to the other provisions contained in the Act but, Section 83 would have no relevance insofar as the rights of the patentees under Section 48 are concerned. The two provisions operate in entirely different fields. Section 83, according to the learned counsel for the respondents, also begins with the words ☐without prejudice to the other provisions contained in this Act which would imply that it is without prejudice to all the other provisions in the Act which includes Section 48. Secondly, it was submitted that the provisions of Section 83 are not in respect of the rights of the patentees, but to the powers to be exercised by the controllers and other authorities as conferred on them by Chapter XVI of the said Act which relates to Working of patents, Compulsory Licences and Revocation. Therefore, the element of public interest, which is sought to be introduced by the appellant through the route of Section 83 of the

said Act, would not, in any way, impinge upon the rights of the patentees which includes the rights of the respondent in respect of patent No.222346, under Section 48 of the said Act. It was also submitted on behalf of the respondents that the statistics said to have been provided by the appellant with regard to the extent of COPD patients in India is not reliable. References were made to certain articles to suggest that COPD does not include an asthma-like respiratory symptom or chronic bronchitis and, therefore, the number of patients suffering from asthma or chronic bronchitis cannot be considered as part of COPD patients. We may point out at this juncture itself that there are also articles which may tend to indicate that chronic bronchitis is a part of the COPD spectrum and can be considered as surrogate for COPD. However, we need not enter into this controversy and only observe that the number of COPD patients is large.

20. It was also contended that the conduct of the appellant was mala fide. In this context, it was submitted that the appellants not only infringed the respondent's patent, but had also attempted to pass off its INDACATEROL Maleate's inhalation powder under the trademark □ONBREZ which was an imitation of the respondent's trade mark □UNIBREZ . As pointed out above, it led to the filing of a trademark infringement suit [CS(OS) 3356/2014] in which the appellant undertook not to use the mark □UNIBREZ' any further and the suit was decreed in those terms by the order dated 17.11.2014. It was also pointed out that the appellant had submitted an application under Section 66 of the said Act on 22.10.2014 seeking revocation of the patent on the ground of public interest. And, shortly thereafter, it launched its INDACATEROL.

21. In the context of the rights of a patentee and whether imports constitute working of the patent, the learned counsel for the respondents placed reliance on a Division Bench decision of this court in the case of Telemecanique & Controls (I) Limited v. Schneider Electric Industries SA: 2002 (24) PTC 632 (Del) (DB). Specific reliance was placed on the following paragraphs:-

> □30. It has to be appreciated that undoubtedly patent creates a statutory monopoly protecting the patentee against any unlicensed user of the patented device. Thus once a violation is established in case of a registered patent, subject of course, to the patent being used, it will not be permissible to contend that the said patentee is not entitled to an injunction. A monopoly of the patent is the reward of the inventor. It is also to be appreciated that law of the patent is slightly different from the law of copyright and trademark as the patent is granted only for a period of 14 years. It is also relevant to note that in the agreement of technical services dated 28.11.94 there is no mandate for the appellant to provide technical information to the appellant in respect of the manufacture of any other items but the only requirement is that the same can be done if terms and conditions are agreed upon between the parties. If the respondent would have provided D2 range of products to the appellant it would have been entitled to royalty in terms of Clause 6.4 of the said agreement. It is thus difficult to believe, as stated above, that there could be a license to copy and that is a major factor which has weighed with us in deciding the present appeal. It may also be added

> that Section 83 of the Patent Act, 1970 falls under Chapter XVI dealing with the working of patents, compulsory licenses, licenses of right and revocation. Section 83 by its wording refers to the exercise of powers conferred by the said Chapter and thus in view of there being exploitation of the patent in the country by sale of product by the respondent the public is getting the product and is not deprived of its benefit.
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> 31. We would also like to note that while making submissions in rejoinder Mr. Arun Kathpalia, learned counsel for the appellant, sought to make submissions that in view of Section 83 read with Section 90(d) of the Patents Act, 1970 the patent has to be worked out in India by manufacture and not by import. Mr. Kathpalia sought to rely on the commentary of Terrel on the Law of Patent, 13th edition chapter X para 10.07, 10.09, 10.10, 10.13, 10.14 and 10.17. Mr. Kathpalia submitted that same principles would apply in respect of the Indian law and thus in the absence of definition of commercial scale, natural and ordinary meaning should be given to the expression.

He submitted that in terms of the said treaties the general principles set out are that a patentee must manufacture the product in that country and it should not also be mere improvements. We have, however, considered this aspect aforesaid and have come to the conclusion that there is no force in the submission of the appellant. (underlining added)

22. It was also submitted that the decision in E Bay (supra) on the point of public interest was based on the statutes as they existed in the United States. This is not the case in India. With regard to the decision in Hoffman La Roche (supra), it was submitted that injunction was refused because a prima facie case itself was not made out and there was a credible challenge to the validity of the patent. This was coupled with the fact that there was public interest involved because it was a life saving drug. In the present case, the situation is entirely different and, therefore, injunction cannot be refused. It was further submitted that in Novartis AG and Another v. Mehar Pharma and Anr: 2005 (30) PTC (Bom), injunction had been refused because validity of the patent itself was in question. The decision in Baer v. UoI: WP 1323/2013 decided on 15.07.2014 was also not applicable as that was a case of compulsory licensing. The decision in Franz Xaver Huemer (supra) was also distinguishable as that was a case of non-user and the patent not having been worked at all and for that reason injunction had been refused. The facts in the present case are different. Advanced Cardiovascular Systems v. Medtronic Vascular: 579 F. Supp.2d 554(D. Del.2008) was a case of prior licencing arrangements. Thus, it was submitted that none of the cases cited on the part of the appellants came to their aid.

23. A cross-objection (CM No.2090/2015) had also been filed on behalf of the respondent by way of challenge to paragraphs 86 and 132 which limited the injunction until the compulsory licencing was granted.

24. It was reiterated that manufacturing in India is not necessary for the working of a patent. The respondents have patents in several countries and this does not mean that they have to manufacture in each country. All that is required is that the manufacturing facilities must be capable of supplying

worldwide depending on the demand. The manufacturing facility of the respondent in Switzerland was a state-of-the-art facility and was capable of meeting the demand in India. INDACATEROL was being imported through Lupin and marketed in India to satisfy the needs in India and, therefore, there was no requirement for manufacturing the said product in India. It was also submitted that public interest elements are already incorporated in the said Act, such as in Section 66 where a patent could be revoked if it was contrary to public interest. Furthermore, Section 84 provides for compulsory licence where, again, the element of public interest is indicated. Section 85 of the said Act also provides that where a compulsory licence had been granted and after two years thereof, if the patent had not been worked in India or did not serve the public interest, the patent could be revoked. It was, therefore, submitted that for all these reasons, the injunction granted by the impugned judgment ought not to be disturbed.

25. After considering the submissions advanced by the learned counsel for the parties and examining the relevant papers, we are of the view that the injunction granted by the learned single Judge ought not to be disturbed. The reasons for this are the following:-

> First of all, there is no credible challenge to the respondent's patent No.222346. Therefore, prima facie, the respondent is straightaway entitled to an injunction in view of the rights available to it as a patentee under Section 48 of the said Act;
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> Secondly, although Section 48 is subject to the other provisions contained in the Act and the conditions specified in Section 47, this would only have relevance where the other provisions of the Act impinge upon the provisions or the rights of the patentees under Section 48. Section 83 is not one such provision. Section 83 itself is without prejudice to the other provisions in the said Act and, therefore, is also without prejudice to the provisions contained in Section 48 of the said Act. Moreover, Section 83 falls in an entirely different Chapter which deals with the Working of patents, Compulsory Licences and Revocation. Section 83 deals with the general principles and, in fact, enjoins the authorities under the Act, who exercise powers conferred under Chapter XVI to have regard to the general considerations specified in sub-clauses (a) to (g) thereof. The considerations, inter alia, being that patents are granted to encourage inventions and to secure that the inventions are worked in India on a commercial scale and to the fullest extent that is reasonably practicable.
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> Another consideration is that the patents do not impede protection of public health and nutrition and should act as an instrument to promote public interest in sectors of vital importance for socio-economic and technological development of India. Another consideration to which due regard has to be had is that patents are granted to make the benefit of patented inventions available at reasonably affordable prices to the public. But, all these considerations to which regard has to be had, are directed towards the authorities, who exercise powers conferred under Chapter XVI. Those powers, include the grant of compulsory licences under Section 84, the revocation of patents by the controller for non-working of the patents after the grant of a

compulsory licence under Section 85 and other incidental proceedings. It is immediately clear that the provisions of Section 83 do not curtail or circumscribe the rights of the patentees under Section 48, except in the backdrop of compulsory licences and ancillary issues;

Thirdly, we are of the view that it is not at all necessary that for a patent to be worked in India, the product in question must be manufactured in India.

As pointed out in Telemecanique (supra), a patent can be worked in India even through imports. All that is to be seen is that the imports are of a sufficient quantity so as to meet the demands for the product. This is of particular importance in the case of pharmaceutical products. From the presentation of data before us both by the appellant and the respondent in the shape of articles, etc, we cannot make a definitive conclusion as to whether the extent of imports is not sufficient for meeting the demands of COPD patients in India. This would be a matter of evidence which can only be thrashed out in the course of a trial. We may also point out that apart from INDACATEROL, there are other drugs which deal with the management of COPD which are also available in the Indian market.

INDACATEROL also does not fall in the category of a life saving drug, such as a cancer medicine. We have also noted the submission made on behalf of the respondents that sufficient quantities are being imported into India in order to serve the needs of the COPD patients;

Fourthly, even though the question of public interest may be a factor in considering the grant of an injunction, it is only one of the factors which needs to be kept in mind. In any event, in the present case, we do not feel that the appellant has even made out a case that public service would be disserved by the grant of an injunction. On the other hand, the respondents have established a prima facie case in that that patent is valid and, therefore, there is no credible challenge to the validity of the patent. The balance of convenience is also in favour of the respondent. We are also of the view that in case an injunction is not granted in the circumstances, the respondents would suffer irreparable injury as their rights under Section 48 would be seriously impaired in a manner which cannot be restituted by damages. Because of the aforesaid conclusion, we are also not inclined to uphold the cross-objections of the respondents in CM No.2090/2015.

26. In view of the foregoing discussion, no interference with the impugned judgment and / or order is called for. The appeal is dismissed. There shall be no order as to costs.

BADAR DURREZ AHMED, J SANJEEV SACHDEVA, J MARCH 09, 2017 SR/dutt