

IN THE HIGH COURT OF JUDICATURE AT MADRAS

DATED: 08.09.2005

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THE HONOURABLE MR. JUSTICE D. MURUGESAN

O.A. Nos. 544 to 546 of 2005

in

C.S. No. 456 of 2005

Wockhardt Ltd.

... Applicant

Vs.

Hetero Drugs Ltd. and Ors.

... Respondents

JUDGMENT

D. Murugesan, J.

O.A. NO. 544 of 2005

1. This original application praying that this Hon'ble, Court be pleased to grant an order of Ad-interim injunction restraining the respondents, their directors, partners, servants, agents, dealers, distributors, retailers or assigns and each of them from in any way infringing the Patent No. 188847 of the Applicant or in any way using a process which infringes the said Patent No. 188347 of the applicant in the manufacture of any pharmaceutical and medicinal product/process or in any other manner whatsoever, pending disposal of the suit.

O.A.NO. 545 of 2005 This Original Application praying that this Hon'ble Court be pleased to grant an order of Ad-interim injunction restraining the respondents, their directors, partners, servants, agents, dealers, distributors, retailers or assigns and each of them from in any way infringing the EMR No. EMR/1/03 of the applicant or in any way using any composition which infringes the said EMR

No. EMR/1/03 by manufacture, sale distribution and marketing of NADIDERM, Nadifloxacin 1% cream or any other Pharmaceutical and medicinal product under any trade mark or branch name in any other manner whatsoever, pending disposal or the suit.

O.A.NO. 546 of 2005 This Original Application praying that this Hon'ble court be pleased to grant an order of Ad-interim injunction, restraining the respondents, their servants, agents, dealers, distributors, retailers or assigns and each of them from manufacturing, marketing or in any way using any composition which contains between 0-1 to 10% by weight of Rs. (+)-9-fluoro-8-(4-hydroxy-1-piperidyl)-5-methyl-6,7-dihydro-1-oxo-1H, 5H-benzo (1J) quinolizine-2-carboxylic acid or S-(-)-fluoro-8-(4-hydroxy-1-piperidyl)-5-methyl-6,7-dihydro-1-oxo-1H, 5H-benzo (ij) quinolizine-2-carboxylic acid and sodium salts, potassium salts, salts with organic basic compounds and other pharmaceutically acceptable salts or such compounds in admixture with a pharmaceutically acceptable carrier as described and claimed in said patent No. 188847 and EMR No. EMR/1/03 pending disposal of the suit.

These original applications are coming on this day before this Court for hearing, the court made the following order;

O.A. Nos. 544 to 546 of 2005 in C.S. No. 456 of 2005 The applicant is the plaintiff company. The first respondent is the defendant company, the second respondent is the marketer and the third respondent is the dealer of the products of the first respondent company. Prior to India becoming a signatory to the TRIPS agreement, the Patents Act, 1970, as it stood originally, contemplated only a process patent in respect of medicinal preparations. After the TRIPS agreement, the patent laws were amended by introducing a provision for grant of a product patent as well. The amendment came into force with effect from 1.1.2005. In the interregnum period, a transitory provision in Chapter IV-A was introduced whereby an exclusive marketing right (EMR) was granted to an applicant. For grant of EMR, an applicant (i) must have a process patent; (ii)

must have a valid manufacturing licence. The EMR granted would be valid for a period of five years or until the product patent is granted or rejected.

2. On 8.5.2000, the applicant applied for process patent for benoquinilozines on the ground that the applicant had invented the admixture composition. The process patent was granted to the applicant on 6.6.2003, of course, with effect from the date of application viz., 8.5.2000. The said process patent is renewed from time to time and is still valid and subsisting. The applicant also applied for product patent under Section 7, which was treated as mailbox application under Section 5(2) on 28.3.2002. The applicant also obtained the manufacturing licence for Nadifloxacin 1% cream on 27.4.2002 from the Drugs Controller General of India. The applicant started manufacturing the pharmaceutical preparation Nadifloxacin 1% cream. The terms of the transitory provision of Section 24-A, the applicant was granted EMR for a period of five years on 15.12.2003 upto 16.7.2008 and the grant of EMR was also informed to the Drugs Controller General. By the grant of EMR, the applicant started marketing Nadiflovacin 1% cream. The application for product patent is still pending.

3. In the meantime, the first respondent company applied for manufacturing licence adopting US patent 1981 and Japan patent 1983 to manufacture Nadifloxacin 1% cream under the trade mark NADIDERM. The Drugs Controller General granted manufacturing and marketing licence to the first respondent company for Nadifloxaion 1% cream based on US patent by an order dated 14.9.2004. Pursuant to the order of the Drugs Controller General, the first respondent company started manufacturing and marketing Nadifloxacin 1% cream.

4. Questioning the order of the Drugs Controller General granting manufacturing and marketing licence in favour of the first respondent company, the applicant filed a writ petition before the Delhi High Court. The Delhi High Court directed the Drugs Controller General to afford an opportunity to the applicant before granting any further licence for Nadifloxacin 1% cream. The first respondent

company also filed a writ petition before the Mumbai High Court for suspension/cancellation of the EMR granted to the applicant. The said writ petition is still pending. In these circumstances, the applicant has approached this Court with the present suit for a judgement and decree of (a) permanent injunction restraining the respondents from in any way infringing the Patent No. 188847 of the applicant or in any way using a process which infringes the said patent; (b) permanent injunction restraining the respondents from in any way infringing the EMR granted to the applicant or in any way using any composition which infringes the said EMR by manufacture, sale, distribution and marketing of NADIDERM Nadifloxacin 1% cream; (c) permanent injunction restraining the respondents from manufacturing or in any way using any composition which the applicant invented for manufacturing of Nadifloxacin 1% cream. Pending the above suit, similar orders of ad-interim injunction were asked in the above criminal applications. By an order dated 31.5.2002, this Court had granted interim injunction in O.A. Nos. 544 of 2005.

5. I have heard Mr. A.L. Somayaji, learned Additional Advocate General and Mr. P.S. Raman, learned Senior Counsel for the applicant and Mr. R. Krishnamurthy, learned Senior Counsel for the first respondent, Mr. S. Ramasubramanian, learned Counsel for the second respondent and Mr. K.M. Santhanagopalan, learned Counsel for the third respondent.

6. The respective learned Counsel had elaborately argued on the law of process patent, product patent as well on the manufacturing licence including the grant of EMR. On a similar challenge, a learned single Judge of this Court in the decision in "Nevertis AG and Anr. v. Adarsh Pharma and Anr. 2004 (29) PTC 108 (MAD)", while considering the scope of EMR, held "that the grant of EMR is only by way of an interim measure and the same is granted to an applicant who has filed the patent claim. The learned Judge also held that though Section 24-A of the Patents Act, 1970 specifically excludes the operation of Section 12(1) of the act alone, inasmuch as the said section provides for an examination under Section 13, the requirements of Section 13 also shall stand excluded for

the purpose of Chapter IV-A of the Act. The learned Judge also held that in view of the above exclusion of not only Section 12(1) but also Section 13, Section 64(1)(e) of the Act cannot be pressed into service to invalidate the EMR." Based on the above findings, the learned Judge proceeded to decide the issue and ultimately the applications for interim injunction were allowed. That order was questioned before a Division Bench and the Division Bench in the decision in "Intas Laboratories Private Limited, Ahmedabad and Anr. v. Novartis A.G., Schwarzwaldallee 215 represented by its Power of Attorney Retushka Negi and Ors. 2005 (1) MLJ 309", held that it will not be proper for the Court to decide the issue arising out of interim orders as the same would render the suit itself infructuous leaving nothing for the trial and that any view, opinion or finding expressed in that regard would automatically be binding on the learned single Judge in the trial, directed eschew of the findings of the learned single Judge with reference to the validity of EMR. The Division Bench also directed that the issue should be decided only within the parameters of the balance of convenience and public interest in question.

7. Keeping the above judgement in mind, the issue in the original applications has to be considered. Though the original applications for injunction are to be considered on the basis of the balance of convenience as well the public interest in question, this Court would also be competent to find out a prima facie case for grant of interim order. Hence, I am inclined to discuss the submissions on the issue, only to find out first as to whether any prima facie case is made out by the applicant. As on today, the applicant has got the process patent for benoquinilozines and claims that it is an invented admixture composition. The applicant has also applied for product patent and the same is still pending. The applicant also obtained the manufacturing licence for Nadifloxacin 1% cream and the applicant was also granted with EMR upto 16.7.2008, the above facts are not in dispute. Whether the EMR granted to the applicant is valid or not is not a matter for this Court to adjudicate and decide, as the grant of EMR is not questioned before this Court by the first respondent company. Admittedly, the

first respondent company has filed a writ petition before the Mumbai High Court questioning the EMR granted to the applicant and the Mumbai High Court has not granted any interim order. Hence, the EMR granted in favour of the applicant is still in force. The process patent given in favour of the applicant is also not questioned by the first respondent company and the same is also in force. Equally the applicant had also obtained the manufacturing licence for Nadifloxacin 1% cream on 27.4.2002 and that the said manufacturing licence is also in force. For the grant of EMR, as already referred to, an applicant should have a process patent, should have filed a product patent application and should have a valid manufacturing licence. All the above three conditions are satisfied by the applicant. From the above it is seen that the applicant, by virtue of the grant of EMR coupled with the grant of manufacturing and marketing licence, is entitled to manufacture and market Nadifloxacin 1% cream. The question as to whether the applicant has obtained the process patent, manufacturing and marketing licence as well the EMR on the basis of the a new invention as defined under Section 2(1) is not a matter to be decided at this stage. Whether the Nadifloxacin 1% cream is an invention as defined under Section 2(1) or is not an invention under Section 3(d) & (e) is not a matter to be decided by this Court at this stage as it should be decided at the time of trial. Any finding on the said issue will have a direct effect in the trial.

8. Per contra, the case of the first respondent company is that it had obtained manufacturing and marketing licence to manufacture NADIDERM from the Drugs Controller General on 14.9.2004. The grievance of the applicant is that the first respondent company had copied the composition contained in the applicant's patent and EMR. A specific allegation that the first respondent company had wrongly and illegally infringed the patent and EMR of the applicant and thereby is causing irreparable loss and injury which cannot be compensated in terms of value is made. The question as to whether the first respondent company has infringed the patent of the applicant by copying the same composition contained in the applicant's patent and EMR cannot also be

decided at this stage. However, to come to a prima facie satisfaction, the affidavit of one of Chandrashekar Mainde employed as Head-Formulation-Domestic Business in the applicant company needs a reference. It is seen from the said affidavit that the preparation of Nadifloxacin 1% cream is different from process US patent. On the other hand, it is the specification of the first respondent company that the first respondent company had been given the manufacturing and marketing licence for Nadifloxacin 1% cream based on US patent 1981 and Japan patent 19S3. Whether the first respondent company are manufacturing the Nadifloxacin 1% cream by copying the composition contained in the applicant's patent and EMR cannot also be gone into in detail at this stage, as it would be determining the claims of the parties, which should be done only in the trial. It is also relevant to note that the challenge to the manufacturing licence given to the first respondent company by the Drugs Controller General is questioned by the applicant before the Delhi High Court and the said order has not been stayed. In the circumstances, it would not be proper to restrain the first respondent company from manufacturing and marketing the NADIDERM on the strength of the order on the Drugs Controller General dated 14.9.2004. Prima facie, I am of the view that considering the fact that the applicant claims that it had invented the admixture composition for manufacturing Nadifloxacin 1% cream and it is the case of the first respondent company that the manufacturing and marketing licence granted for NADIDERM is not on the basis of the admixture composition of the applicant but is only by adopting the US patent and Japan patent, I am convinced that the first respondent cannot be enjoined from manufacturing and marketing the NADIDERM on the strength of the manufacturing licence given by the Drugs Controller General on 14.9.2004. Insofar as the balance of convenience as well having obtained the manufacturing licence, the first respondent company is entitled to manufacture and sell the NADIDERM cream. It is also relevant to note that the challenge to the said manufacturing licence at the instance of the applicant before the Delhi High Court is still pending and no order restraining the first respondent company from

manufacturing NADIDERM cream on the basis of the manufacturing licence was passed.

9. For all the above reasons, I am of the considered view that the injunction granted should be vacated. Accordingly, the interim order of injunction is vacated and the O.A. Nos. 544 and 545 of 2005 are dismissed. For the same reason, O.A. No. 546 of 2005 is also dismissed.