B. Braun Melsungen Ag & Ors. vs Rishi Baid & Others on 15 April, 2009

Author: Badar Durrez Ahmed

Bench: Badar Durrez Ahmed

THE HIGH COURT OF DELHI AT NEW DELHI

% Judgment delivered on: 15.04.2009

+ IA 1234/2008 in CS(OS) 186/2008 (u/O 39 R 1 & 2 CPC)

B. BRAUN MELSUNGEN AG & ORS. ... Plaintiffs

- versus -

RISHI BAID & OTHERS ... Defendants

Advocates who appeared in this case:
For the Plaintiffs : Mr Arun Jaitley, Sr Advocate with Mr Praveen Anand, Ms Binny Kalra, Ms Ishani Sahiwal and Ms Taapsi Johri
For the Defendants : Mr Dushyant Dave, Sr Advocate with Mr Pallave Sisodia, Mr Rajesh Bhardwaj, Mr Vaibhav Vutts and Mr Rajeev Ranjan Kumar

CORAM:-
HON'BLE MR JUSTICE BADAR DURREZ AHMED

1.

Whether Reporters of local papers may be allowed to see the judgment ? YES

2. To be referred to the Reporter or not ? YES

3. Whether the judgment should be reported in Digest ? YES BADAR DURREZ AHMED, J

1. The plaintiffs seeks an ad interim injunction restraining the defendants from making, selling, distributing, advertising, exporting, offering for sale and in any other manner dealing in or with safety I.V. catheters / cannulae or other device or apparatus that infringes the subject matter of the plaintiffs registered patent number 210062. The plaintiffs also seeks an ad interim injunction restraining the defendants from manufacturing, selling, offering for sale, distributing, exporting, advertising or dealing in any safety I.V. catheters / cannulae under the trademark „VASOFIX® Safety™ or any other mark which uses the plaintiffs alleged confidential information, know-how, trade secrets, data, technical input, drawings, materials and / or any other resource derived by the

defendants from the plaintiffs.

2. According to the plaintiffs, the plaintiff No. 1 (B. Braun Melsungen AG), which is a company incorporated in Germany, supplies the global healthcare market with products for anesthesia, intensive medicine, cardiology, surgery as well as services for hospitals, general practitioners and the home care sector. The plaintiff No.1 is said to innovate products and services with the object of optimizing working procedures in hospitals and medical practices all over the world and also focuses on improving safety for patients, doctors and nursing staff. The plaintiff No.2 [B. Braun Medical (India) Pvt. Ltd] is a wholly owned subsidiary of B. Braun Medical Industries Sdn. Bhd., which, in turn, is a 100% subsidiary of the plaintiff No. 1.

3. It is alleged that the plaintiff No. 2 launched its state of art production facility at Chennai on 30.01.2007 for the manufacture of products for the healthcare market. The plaintiff No. 1, inter alia, has a product which is an intravenous (I.V.) catheter, which is also known as I.V. cannula, with an injection port and self-activating needle stick protection.

4. According to the plaintiff an I.V. catheter is a device through which intravenous fluids are administered directly into a patient s vascular system. The catheter is inserted into a patient s vein by a healthcare worker by using a handheld placement device which includes a sharp tip needle. The needle is positioned in the interior hollow portion of the catheter with its tip extended slightly beyond the edge of the catheter. The end of the apparatus opposite the needle tip is made up of the needle connected to a needle hub, which is capable of being held by the healthcare worker during the insertion procedure. As stated in the plaint, the insertion procedure contains four basic steps:-

> (1) The healthcare worker inserts the needle and catheter together into the patient s vein;
>
> (2) After insertion into the vein with the needle point, the catheter is forwarded into the vein of the patient by the healthcare worker pushing the catheter with his or her finger;
>
> (3) The healthcare worker withdraws the needle by grasping the hub end (opposite the pointed end) while at the same time applying pressure to the patient s skin at the insertion site with his or her free hand; and (4) The healthcare worker then tapes the now inserted catheter to the patient s skin and connects the exposed end of the catheter (the catheter hub) to the source of the fluid to be administered into the patient s vein.

5. A problem, which was faced in the aforesaid procedure, was that after the withdrawal of the needle from the patient s vein, the healthcare worker, who is at that point of time involved in at least two urgent procedures, had to place the exposed needle tip at a nearby location and address the tasks required to accomplish the needle withdrawal. There was a danger of the exposed needle tip

resulting in an accidental needle stick which left the healthcare worker vulnerable to the transmission of various dangerous blood borne pathogens, including AIDS and hepatitis. The plaintiffs invention of the safety I.V. catheters is said to have solved the problem and results in the prevention of accidental needle sticks. It is stated in the plaint by the plaintiffs that the safety I.V. catheters have been developed by several entities to achieve this result with a protective needle guard for use with a hypodermic needle. It is, however, alleged that patents applied for by several parties were cited and overcome in the plaintiff s patent applications in India and other countries.

6. It has been alleged on the part of the plaintiffs that the prior art safety I.V. catheters exhibited one or more drawbacks and had limited the usefulness and full acceptance by healthcare workers. The plaintiffs product is a safety I.V. catheter in which the needle tip is automatically covered after needle withdrawal to prevent the healthcare worker from making accidental contact with the needle tip. According to the plaintiffs, they enjoy patent protection for the said invention in several countries including India where the patent has been registered under No. 210062 in favour of the plaintiff No. 1 with effect from 18.08.1998.

7. In the course of arguments before this Court, great stress was laid on independent claim 28 of the plaintiffs patent No. 210062. The same reads as under:-

> "Claim 28:
>
> An IV catheter including:
>
> A tubular catheter;
>
> A needle having a needle shaft and a tip, said needle being received within said tubular catheter when in a ready position, the needle comprising a bulge in its shaft;
> A catheter hub attached to the proximal end of said tubular catheter, said catheter hub having a hollow interior enclosed by an interior wall;
>
> said needle being movable between said ready position in which said tip is outside of said catheter hub and a retracted position in which said tip is within the interior of said catheter hub;
>
> a needle guard comprising:
>
> a proximal wall for engaging with the bulge in the shaft of the needle to prevent the removal of the needle from the needle guard;
>
> a distal wall engaged by said needle shaft when said needle is in said ready position;

a section of a transverse segment of said needle guard being urged by said needle shaft into retaining relation within said catheter hub when said needle is in the ready position; said distal wall extending from said transverse segment and engaging the needle spaced from said needle tip when said needle is in said ready position and movable within the interior of said catheter hub to a blocking position distal of said needle tip when said needle is in its retracted position; the engaging of the needle and the urging of said section of the transverse segment into retaining relation with the catheter hub in the ready position being both achieved by engagement of the distal wall of the needle guard with the needle shaft;

said section of said transverse segment being a curved section in retaining contact with the interior wall of the catheter hub, for providing engagement of the needle guard when transitioning from the ready position to the blocking position at a fixed longitudinal position within the catheter hub."

8. The plaintiff No. 1 markets the said safety I.V. catheters in India through the plaintiff No. 2. The plaintiff No. 1 is said to manufacture the product in Malaysia through its subsidiary in that country, namely, B. Braun Medical Industries Sdn. Bhd. The said safety I.V. catheter is being marketed by the plaintiff under the brand „VASOFIX® Safety™ at least since June, 2004 in India and it is allegedly presently sold in over 45 countries throughout the world.

9. The defendant No. 3, namely, Poly Medicure Limited is a company registered in India under the Companies Act, 1956 and the defendants 1 and 2 are the Executive Director and Managing Director in the said defendant No. 3 company. According to the plaintiffs, Poly Medicure Limited has been manufacturing a basic I.V. catheter bearing the brand name „ACCUCATH for and on behalf of the plaintiff No.1 under an exclusive agreement executed on 10.02.2005. It is alleged that under the terms of the said agreement Poly Medicure Limited was authorized to manufacture I.V. catheters as a contract manufacturer, according to the applicable specifications and regulatory conditions prescribed by the plaintiff No.2 and also for packaging and labeling these in accordance with the plaintiff No.2 s specifications. The agreement had an initial validity period of two years and was to continue for a further period of one year unless terminated earlier.

10. It is further alleged that the plaintiffs have been marketing and selling two types of I. V. catheters in India:- „Vasofix® for more than two decades and „VASOFIX® Safety™ , which is the improved safety I.V. catheters, since June, 2004. It is alleged that the plaintiff No. 2 had appointed Poly Medicure Limited as a contract manufacturer to manufacture low cost I.V. catheters under the trademark „ACCUCATH and as a result of which Poly Medicure Limited became aware of the plaintiffs' propriety safety product as mentioned above which was being manufactured in the plaintiff No.1 s Malaysian plant. It is alleged that the defendant No. 1 also visited the said Malaysian unit on at least one occasion.

11. The allegation further is that Poly Medicure Limited was provided with all relevant technical knowledge for manufacture of „ACCUCATH . But, though Poly Medicure Limited was contracted to

manufacture only „ACCUCATH , information provided to it by the plaintiffs aided the said Poly Medicure Limited in manufacturing a safety I.V. catheter also. It is alleged that the defendants have approached the plaintiffs with specific problems faced by them while making the „ACCUCATH catheters and that the plaintiffs have solved these problems by going in depth and providing effective solutions. It is alleged that the plaintiffs had reposed complete trust in the defendants while providing them with sensitive data, processes, trade secrets and confidential information. It is specifically pointed out that the plaintiffs did not authorize or appoint the defendants to be contract manufacturers for the „VASOFIX® Safety™ I.V. Catheter at any point of time. Apparently, the plaintiff No. 2 and the defendants also entered into a confidentiality /secrecy agreement executed in March-April, 2006.

12. It is alleged that in November, 2006 at the international trade show at Dusseldorf in Germany, an officer of the plaintiff No. 1 noticed the defendants booth at the said trade show and it is alleged that one of the defendants representative met the said officer and with a view to impress him, showed a product stated to be a prototype of a safety I.V. catheter. It is alleged that the said officer of the plaintiff No. 1 was not given an opportunity to examine the prototype but was concerned that the same may violate the plaintiff No.1 s intellectual property. He requested for a sample of the prototype but the same was not provided by the defendants.

13. It is then alleged that in the trade show organized in November, 2007, the plaintiffs representative visited the booth set up by Poly Medicure Limited and was given samples of the latter s safety I.V. cannula. The sample was allegedly dissected by the plaintiffs, analyzed and photographed from various angles and, in their opinion, infringed the plaintiffs Indian Patent No. 210062. According to the plaintiffs, the defendants sample, which was labeled as „Safety I.V. cannula under the brand name „Poly Safety , obtained in November, 2007 contained all the elements of claim 28 of Patent No. 210062.

14. According to the learned counsel for the plaintiffs 90% of the defendants safety cannula is ACCUCATH. The relationship between the plaintiffs and the defendants for over four years permitted or allowed the defendants to derive knowledge and expertise in that field. And, after having gained the knowledge, the defendants have come out with their own safety I.V. catheter which carries all the elements as set out in claim 28 of the plaintiffs Patent No. 210062. This is, therefore, a clear violation and infringement of their said registered patent and, therefore, they are entitled to the injunction that they seek straightaway.

15. Mr Arun Jaitley, the learned senior advocate who appeared on behalf of the plaintiffs, submitted that what is relevant in such a case is the patent and not the manifestation of it. He submitted that it is, therefore, necessary to compare the defendants product with the plaintiffs' patent and then ask the question as to whether claim No. 28 is incorporated in the defendants product. If the answer is in the affirmative, then it would be a clear case of infringement and the plaintiffs would be entitled to the injunction. He further submitted that minor additions are immaterial. The essential features,

which collectively amount to an invention, must only be seen.

16. The learned counsel referred to the decision of the High Court of Madras in the case of Bajaj Auto Limited v. TVS Motor Company Limited: 2008 (36) PTC 417. The said decision was pointed IA 1234/2008 in CS(OS) 186/2008 Page No.10 of 35 out to show that there is a difference in the rights of patentees after the amendment to the Patents Act, 1970 which came into effect on 20.05.2003. Going through the said decision, it appears that an argument had been raised that after the amendment to Section 48 of the Patents Act, 1970, the position was that once a patentee files a suit for infringement based on the patent granted to him, it ought to be prima facie presumed to be valid until the same is set aside in the manner known to law either by revocation under any one of the grounds under Section 64 of the Patents Act, 1970 or in any other manner. After analyzing the amendment, the learned Single Judge of the Madras High court was of the view that the difference in the said provision before and after the amendment was that prior to the amendment, the patentee was conferred an exclusive right to use, either by himself or through agents or licencees and also to sell or distribute the inventions in India. The patent to which the patentee was entitled to the exclusive user, related to an article or substance and to a method or process of manufacturing the substance. After the amendment, the right which is conferred on the patentee in respect of the product and in respect of the process is an exclusive right to prevent third parties from using or selling etc. The learned Single Judge came to the conclusion that while ascertaining as to whether a plaintiff has a prima facie case or not, even though no presumption of the validity of the patent can be drawn, , after the amendment, a patent obtained by a party is certainly to be IA 1234/2008 in CS(OS) 186/2008 Page No.11 of 35 given greater significance. It was, therefore, concluded that the patent obtained by the patentee in that case could be given more weight for deciding the prima facie case, however, the onus of „proving the prima facie case about the validity of the patent and its infringement is still on the plaintiff and the amendment to Section 48 by Act 32 of 2002 had not made any significant change on the celebrated principle of prima facie case to be proved by the plaintiff before granting an order of injunction pending disposal of the suit.

17. The learned counsel also referred to the said decision to indicate what are the parameters for examination of the balance of convenience. He referred to paragraph 61 of the said decision wherein the decision of the Court of Appeal in Corruplast Ltd. v. George Harrison (Agencies) Ltd.: 1978 RPC 761 was quoted. It was observed that in every case of this kind, the function of the Court must be to consider which course, either the granting or withholding of an injunction, is the one which is likely to make it easy for the trial court, when the issues in the action have been decided, to adjust the rights of the parties and do justice between them.

18. The learned counsel also referred to the decision of a learned Single Judge (S.K. Kaul, J.) of this Court in the case of J. Mitra & Co. Pvt. Ltd. V. Kesar Medicaments: IA No. 11883/2006 in CS(OS) IA 1234/2008 in CS(OS) 186/2008 Page No.12 of 35 2020/2006 decided on 22.02.2008 with particular reference to the portion of mosaicing. The learned Judge quoted Terrell on Patents (16th Edition, 2006) wherein the concept of mosaicing is explained as under:-

> "The mosaicing of individual documents or prior uses is not permissible, unless it can be shown that the skilled person, confronted with a particular citation, would turn to some other citation to supplement the information from the first. Whether he would do so is a question of fact".

A further reference was made to the decision in Technograph v. Mills and Rockley: (1972) R.P.C 346 where Lord Reid observed:-

> "When dealing with obviousness, unlike novelty, it is permissible to make a „mosaic out of the relevant documents, but it must be a mosaic which can be put together by an unimaginative man with no inventive capacity."

Referring to Bilcare Ltd. v. Amartara Pvt. Ltd: 2007 (34) PTC 419 (Del), the learned Judge noted that as per the legal position set out in the said decision, it would not be a defence to show that various components in the patented product are known separately. The combination of such components may be patentable. The Court concluded that it would not be permissible for a defendant to rely on different documents disclosing different components / features of the product to plead that the product of the patent was known.

19. Mr Arun Jaitley also referred to the following decisions:-

IA 1234/2008 in CS(OS) 186/2008 Page No.13 of 35 (1) K. Ramu v. Adyar Ananda Bhavan Muthulakshmi Bhavan:

> 2007 (34) PTC 689 (Mad.); (2) Wockhardt Limited v. Hetero Drugs Ltd. & Ors: 2006 (32) PTC 65 (Mad.) (DB); (3) Ajay Industrial Corporation, Delhi v. Shiro Kanao of Ibaraki City, Osaka, Japan:
>
> 1983 PTC 245; (4) Telemecanique & Controls (I) Ltd v. Schneider Electric Industries SA: 94 (2001) DET 865 (DB). In this decision, it was observed that undoubtedly a patent creates a statutory monopoly protecting the patentee against any unlicensed user of the patented device. Thus, once a violation is established in a 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. It was also observed that monopoly of the patent is the reward of the inventor. (5) N. R. D. Corporation of India v. D. C. & G. Mills Co. Lt.: AIR 1980 Delhi 132. In this decision, a learned Single Judge of this Court noted that for the grant of temporary injunction, the principles applicable to the infringement of patent actions are that there is a prima facie case, that the patent is valid and infringed, that the balance of convenience is in favor of the injunction being granted and that the plaintiff will suffer an irreparable loss. However, it may be noticed that in this decision itself it is noted that it is also a rule of practice that if a patent is a new one, a mere challenge at the Bar would be quite sufficient for a refusal of a temporary injunction, but if the patent is sufficiently old IA 1234/2008 in CS(OS) 186/2008 Page No.14 of 35 and has

been worked, the court would, for the purpose of temporary injunction, presume the patent to be valid one. If the patent is more than six years old and there has been actual user, it would be safe for the Court to proceed on this presumption. The last decision referred to by the learned counsel for the plaintiffs was the case of American Cyanamid Company v. Ethicon Limited: 1975 RPC 513 wherein it was observed that the object of the interlocutory injunction is to protect the plaintiff against injury by violation of his right for which he could not be adequately compensated in damages recoverable in the action if the uncertainty were resolved in his favour at the trial. It was further observed that the plaintiff s need for such protection must be weighed against the corresponding need of the defendant to be protected against injury resulting from his having been prevented from exercising his own legal rights for which he could not be adequately compensated under the plaintiff s undertaking in damages if the uncertainty were resolved in the defendant s favour at the trial. The court must weigh one need against another and determine where "the balance of convenience" lies.

20. Mr Dushyant Dave, the learned counsel appearing on behalf of the defendants, submitted that the registration of the patent by itself is not sufficient for the grant of an interlocutory injunction. Secondly, IA 1234/2008 in CS(OS) 186/2008 Page No.15 of 35 he submitted that the registration itself is questionable. He also submitted that there was no case made out for an unfair business practice. Mr Dave referred to the agreement dated 17.01.2007 between the defendants and the plaintiff No. 2. He referred to Clause 10.1 of the said agreement which is at page 306 of the documents filed by the plaintiffs and forms part of the non-competition clause. As per the clause 10.1, the parties agreed that they shall not compete with each other in respect of the products except those already being manufactured and marketed by Poly Medicure Limited as listed in Schedule 4 and those in the pipeline as listed in Schedule 5. Serial No. 15 of Schedule 4 clearly indicates "Safety I.V. Cannulas". From this, Mr Dave submitted that it was well within the knowledge of the plaintiffs that the defendants were already engaged in the manufacture of safety I.V. cannulae on the date on which the said agreement was entered into, that is, on 17.01.2007. Yet, the plaint does not mentioned this very crucial and important fact.

21. Mr Dave drew my attention to the report in respect of the Audit which was got conducted by the plaintiffs in the defendants plant between 10th -12th October, 2005. The report is at page 213 of the plaintiffs documents. Clause 2.3.4, which refers to future planned changes, clearly indicates in sub-Clause (4) that the Audit party was aware of "introduction of new products which includes Safety IV Catheter .....". Mr Dave pointed out that as early as in IA 1234/2008 in CS(OS) 186/2008 Page No.16 of 35 October, 2005, the plaintiffs were aware that it was within the future plans of the defendants to manufacture safety I.V. catheters. He submitted that this fact was also not disclosed in the plaint. Mr Dave then referred to Audit report dated 05.10.2007, which is at page 62 of the documents filed by the defendants. In para 1.9.3 (6), it is clearly indicated that "Polymed had launched their safety IVC to the market in the Middle East and Europe since July, 2007". Mr Dave submitted that this fact has also not been mentioned in the plaint. Mr Dave also referred to the documents beginning at page 72 of the defendants document, which is a rate contract of the Government of India, Director of Supplies and Disposals, Shastri Bhawan, 26 Haddows Road,

Chennai- 600006, which prescribes the rate contracts for supply of I.V. cannula valid from 01.07.2007 to 30.06.2008. As per serial Nos. 25, 26, 27, 28, 29, 30 and 31, which pertain to Poly Medicure Limited, safety I.V. cannula is clearly indicated and mentioned therein.

22. Mr Dave then went on to explain the dubious circumstances under which the present patent was obtained. On 27.05.2005, with reference to patent application No. 1857/MAS/98, there is an intimation from the Patent Office at Chennai to De Penning & De Penning that the said application had been found in order for grant. However, letters patent would be issued only after disposal of the pre- grant opposition, if any, under Section 25 (1) of the Patents Act, 1970.

IA 1234/2008 in CS(OS) 186/2008 Page No.17 of 35 On 10.09.2007, a letter was written by the new attorneys of the plaintiff to the Controller of Patents, Chennai with regard to the said patent application No. 1857/MAS/1998. As per the said letter, Form 13 in duplicate to bring on record the change in address of the applicant and the attested copy of General Power of Attorney, were submitted. The said Form 13 indicated that the change of address for service from De Penning & De Penning to Anand and Anand, Advocates. This application was received at the Patent Office on 13.09.2007. The patent No. 210062 in respect of application No. 1857/MAS/98 was granted to the plaintiff No. 1 for the I.V. catheters w.e.f. 18.08.1998. However, the date of the grant was 17.09.2007, as indicated by a copy of the patent certificate, which is at page 2 of the plaintiffs documents. The claim that was granted is set out at pages 3-9 of the plaintiffs documents.

23. However, what is interesting and which has been pointed out by Mr Dave is that on 19.09.2007, that is, after the grant of the patent, on 17.09.2007, an application is sent by the new attorneys of the plaintiffs indicating the desire of the plaintiffs to amend the claims by way of correction and explanation. In the so-called amended claim the original claims 1-54 were sought to be cancelled and the amendments set out were exactly those which form part of the patent granted on 17.09.2007. On the basis of these circumstances, Mr Dave submitted IA 1234/2008 in CS(OS) 186/2008 Page No.18 of 35 that there is certainly something more than meets the eye. Otherwise, how could the claims, which were sought to be amended on 19.09.2007, be part of the patent granted two days earlier on 17.09.2007?

24. The learned counsel further pointed out that at the time of application for the patent the same was made in respect of "spring clip safety I.V. catheter". However, in the complete specifications at page 753 of the defendants documents the title given is "an I.V. catheter". In fact, the patent which has been granted is also for an invention entitled "an I.V. catheter".

25. Based on these and other circumstances, Mr Dave submitted that:-

(i) The plaintiffs have suppressed material facts;

(ii) The grant of the patent in favour of the plaintiff No. 1 is coloured by fraud;

(iii) Injunction cannot be granted in favour of the plaintiff particularly when the patent is new and is seriously objected to;

(iv) The defendants have already commenced production and sale of their safety I.V. cannula and the same is to the knowledge of the plaintiff and, therefore, no injunction can be granted in favour of the plaintiff; and

(v) Mere grant of a patent is not sufficient and, apart from the establishment of prima facie case, the considerations of balance of convenience and irreparable loss have also IA 1234/2008 in CS(OS) 186/2008 Page No.19 of 35 to be looked into before a Court can grant an injunction in favour of the plaintiff.

26. Elaborating on the plea of suppression, Mr Dave submitted that the plaint has been very cleverly drafted in the sense that in paragraph 9 of the plaint, although there is a reference of safety I.V. catheters having been developed by several entities and paragraph 10 of the plaint also makes a reference to prior art safety I.V. catheters, but they have been stated to exhibit drawbacks which have allegedly been removed by the plaintiffs invention. Then, it is alleged, in paragraph 12 of the plaint only the effective date of the patent had been disclosed but not the date of grant. Paragraph 14 of the plaint makes no reference to the 54 claims filed earlier but cancelled subsequently. He also submitted that there is no reference to the fact that Poly Medicure Limited was already a substantial market player in I.V. catheters prior to the agreement dated 10.02.2005. There is also no mention of the fact that the plaintiffs were aware of the defendants manufacturing and selling of safety I.V. catheters as far back as in 2005 and definitely in October, 2007. He submitted that the entire story of the plaintiffs coming to know of the defendants safety I.V. catheters in the trade show in November, 2006 is a compete travesty of truth. He submitted that the cause of action disclosed in the plaint for the grant of an injunction is that the defendants were allegedly yet to commence production and sale of their safety I.V. cannula. This is completely IA 1234/2008 in CS(OS) 186/2008 Page No.20 of 35 belied by their own Audit report mentioned above where it is indicated that Polymed had launched the safety I.V.C in the market since July 2007. He also submitted that the plaint carries no mention of Schedules 4 and 5 of the agreement dated 17.01.2007 which specifically excludes safety I.V. cannulae/ catheters from the non-compete clause. Mr Dave submitted that the entire focus and stress of the plaint is premised on the ground that the defendants are yet to launch and that there is imminent threat of sales being commenced whereas, in fact, the defendants had already commenced manufacture and sale of its safety I.V. cannula much prior to the filing of the suit and that too to the knowledge of the plaintiffs as already indicated above.

27. Mr Dave further submitted that the claims 1-54, which had been advertised and to which objections were invited, were in fact cancelled and the amendments were not at all advertised and the patent was granted in respect of the new claims and, in particular claim 28. Mr Dave also referred to Rules 81 and 82 which clearly indicated that if there were substantial amendments, they ought to be published. He submitted that the post-grant proceedings of making an entirely new claim of a patent in the garb of amendment, is contrary to law, vitiated by fraud, collusion and

irregularities. He submitted that thus there is a strong prima facie case for revocation of amended patent 210062 under IA 1234/2008 in CS(OS) 186/2008 Page No.21 of 35 Section 64 (o) of the Patents Act, 1970. He submitted that the grant of patent in the instant case on 17.09.2007 is on replaced claims 1-28 but termed as additions/ amendments which were filed only on 19.09.2007. This demonstrates the fraud played on the statutory authority and the statute itself. He submitted that the application of 18.08.1998 for the grant of patent was in respect of claims 1-54 all of which were sought to be cancelled only on 19.09.2007 and substituted by claims 1-28 for which the statutory procedure and safeguards could not have been followed. He submitted that there had been no examination of claims 1-28 as mandatorily required to ascertain as to whether the same involved a new invention and even an invention involving an inventive step. He submitted that issues like existence of prior art and existing knowledge / anticipation, conditions precedent for grant of patent, had not even been adverted to. Consequently, he submitted that the grant of patent was void ab initio and the plaintiff can derive no right from the same.

28. Mr Dave also submitted that it is an admitted position that insofar as the ordinary I.V. catheter is concerned, it finds its place in a crowded field with many manufacturers worldwide. He submitted that the essential features of a safety I.V. catheter are (i) Needle guard to cover needle tip when taken out from vein of the patient after use; (ii) Bulge in needle to prevent needle coming out without the needle guard;

IA 1234/2008 in CS(OS) 186/2008 Page No.22 of 35

(iii) Catheter hub to retain the needle guard till use and to release it after use; and (iv) Functional arrangement of these integers. It was contended that the patent obtained by the plaintiff was anticipated and made obvious by prior art and knowledge and as such lacks any inventiveness. As an illustration, he referred to U.S Patent No. 5,135,504 of 04.08.1992 with text and drawing therein. The said patent shows all the features of a safety I.V. catheter. The same have been published and commonly known by several manufacturers world over. The said U.S. Patent No. 5,135,504 is in respect of needle tip guard. The abstract indicates that it is in respect of a guard for the tip of intravenous needle which operates automatically when the needle is withdrawn from the intravenous catheter. The background of the invention which is given in the said U.S. patent under the head „description of the prior art clearly indicates that to help / prevent heath care workers from becoming infected by hepatitis or AIDS or the like from an accidental needle prick, it would be desirable to have a guard which covers the tip of an intravenous needle after use. If further reads that many such guards have been previously disclosed by hypodermic needles and syringes in general but no guard has yet been manufactured specifically when the needle is withdrawn from the catheter. It goes on, obviously it would be desirable to have a guard automatically enclose the sharp end of the needle when it is withdrawn from the catheter, thus, preventing the possibility of infection from an IA 1234/2008 in CS(OS) 186/2008 Page No.23 of 35 accidental needle prick during subsequent handling. Thereafter, the summary of the invention, brief description of the drawings and detailed description of the drawings is given. Ultimately, what is claimed is set out. What is claimed is an intravenous catheter insertion kit and a needle guard comprising, inter alia, a flexible catheter and its attached hub; an insertion needle assembly, the insertion needle having a

slightly flared distal tip such that the needle diameter at the said tip is slightly larger than the uniform diameter proximal of the said tip; and ..... whereby the said enlarged needle diameter captures the said needle tip guard and the needle tip becomes enclosed by the said guard when the said needle is withdrawn from the said hub and catheter.

29. Consequently, it was submitted by the learned counsel that the features as indicated in claim 28 of the plaintiffs patent when read alongside the said U.S. Patent No. 5,135,504 indicate that all the features of a safety I.V. catheter were published, commonly known and applied world over by several manufacturers. The learned counsel also referred to the list of prior art which refers to several U.S. patents and the European Patent.

30. It was also submitted that the safety I.V. catheter of Poly Medicure Limited is quite different in many ways to that of the IA 1234/2008 in CS(OS) 186/2008 Page No.24 of 35 plaintiffs product/ patent. It was pointed out that the needle guard of the Poly Medicure safety cannula is made of pink coloured plastic in an axial position whereas the plaintiffs patent pertains to a steel clip in transverse segment. For the engagement of the needle guard with the catheter hub there is a circumferential recess on the distal end of the needle guard which retains position due to the annular ring on the catheter hub in the product of the defendant as against the curved section on the needle guard and hollow interior wall on the catheter hub of the plaintiff s product. There is no bulge in the defendants safety I.V. catheter but a crimp on the needle to lock with the distal end of the needle guard on retraction. According to the defendants, these features are unique and have been developed by Poly Medicure Limited through its own research and development efforts at its own unit.

31. Mr Dave, therefore, contended that no case for an ad interim injunction has been made out.

32. In rejoinder, Mr Arun Jaitely, the learned senior counsel appearing for the plaintiffs submitted that there is no suppression on the part of the plaintiffs. The suit is for infringement of a patent and all the essential elements, which are necessary for claiming the said relief, have been set out in the plaint. He also reiterated that Section 48 of the Patents Act, 1970 was amended in 2003 and because of the amendment IA 1234/2008 in CS(OS) 186/2008 Page No.25 of 35 an exclusive right has been given to the patentee to prevent a third party from infringing the said patent.

33. As regards the allegation of concealment of material facts, the learned counsel submitted that the plaintiffs did mention prior art. For example, in paragraph 9 of the plaint, the expression „existing safety catheters has been used. So also it is stated that the field of other safety I.V. catheters is a crowded one. It has been pointed out that there are other safety catheters in the market but they have same problems which have been overcome by the plaintiffs invention. With regard to the amendments in the claim application, he submitted that the amendment was only to the claims and not to the specifications, abstract or title. Claims 1-28 have been narrowed down

from 1-54. The additional claim and all the amended claims were linked to the earlier claims. Therefore, further publication was not necessary.

34. With regard to the date of grant of the patent being 17.09.2007 when the amendment application was dated 19.09.2007, he submitted that the date of 17.09.2007 which is mentioned on the certificate is a typographical error. He submitted that what is of relevance in terms of Section 53 is that the term of the patent is from the date of filing. This being the position, there would be no object or reason or purpose behind concealing the date of grant because the term IA 1234/2008 in CS(OS) 186/2008 Page No.26 of 35 of the patent does not run from the date of the grant but from the date of filing. He also submitted that a pre-grant amendment does not require publication. In this regard, he referred to Rule 81 (2) of the Rules. He submitted that it is only a post-grant amendment which requires publication. Therefore, the amendment in this case, being pre- grant no publication was necessary. In this connection, he submitted that the fee for amendments before grant is Rs 2,000/- and after grant is Rs 4,000/-. He submitted, therefore, the fact that the fee to the extent of Rs 2,000/- was paid in terms of serial No. 18 of Schedule 1 itself indicates that the application for amendment had been made pre-grant. From this, the learned counsel submitted that the date of 17.09.2007 on the patent certificate is a typographical error and the application had been made prior to the grant of the patent which was ultimately published on 14.12.2007 vide Section 43 (2) of the said Act.

35. Mr Jaitely submitted that the application for amendment was made on 19.09.2007. The application itself indicates that the patent had not been granted till then. The fees for the pre-grant amendment were paid on 21.09.2007. Apparently, a hearing was conducted on 24.09.2007 and thereafter the patent was granted. The factum of grant of patent was recorded on 03.12.2007 and the same was got published on 14.12.2007. On 19.12.2007 the Patent Registry sent a letter to the plaintiff No.1 with regard to the grant of the patent. All these factors, IA 1234/2008 in CS(OS) 186/2008 Page No.27 of 35 according to Mr Jaitely, lead to the only conclusion that the date of 17.09.2007 mentioned on the patent certificate is a typographical error. He reiterated that no purpose would be served by ante-dating the date of grant of the patent.

36. With regard to the US Patent No. 5,135,504, he submitted that there was no ring in the plaintiffs product and the technology is entirely different. Mr Jaitely reiterated that this was a fit case for grant of an ad interim injunction and the defendant ought to be injuncted as prayed for.

37. I may also note that the learned counsel for the defendants had referred to several decisions. One of them was the decision of the Supreme Court in the case of B. P. Radhe Shyam v. Hindustan Metal Industries: 1979 (2) SCC 511. In that decision the Supreme Court observed that the fundamental principle of Patent Law is that a patent is granted only for an invention which must be new and useful. That is to say, it must have novelty and utility. The Supreme Court further observed that it is essential for the validity of a patent that it must be the inventor's own discovery as opposed to mere verification of what was already known before the date of the patent. Elaborating further on the subject, the Supreme Court observed that it is important to bear in mind that in order to be

patentable an improvement on something IA 1234/2008 in CS(OS) 186/2008 Page No.28 of 35 known before or a combination of different matters already known, should be something more than a mere workshop improvement; and must independently satisfy the test of invention or an inventive step. Mere collocation of more than one integer or things, not involving the exercise of any inventive faculty, does not qualify for the grant of a patent. It is obvious that this decision was cited in the context of prior art. It is directed as a challenge to the validity of the plaintiffs patent No. 210062. This gains relevance in the context of Section 64 of the Patents Act, 1970 which deals with revocation of patents. Sub-Section (1) thereof provides that subject to the provisions contained in the Act, a patent, whether granted before or after the commencement of the Act, may, on the petition of any person interested or of the Central Government or "on a counter-claim in a suit for infringement of the patent", be revoked by the High Court on any of the grounds specified therein. One of the grounds is that the subject of any claim of the complete specification is not an invention within the meaning of the Act. Another ground is that the invention so far as claimed in any claim of the complete specification is not new, having regard to what was publicly known or publicly used in Indian before the priority date of the claim or to what was published in India or elsewhere in any of the documents referred to in Section 13.

IA 1234/2008 in CS(OS) 186/2008 Page No.29 of 35

38. In the present case the defendants have preferred a counter- claim and sought the revocation of the plaintiffs patent. At this juncture, it was also be pertinent to note Section 107 of the Patents Act, 1970, which relates to defences, etc, in suits for infringement. Sub- section (1) stipulates that in any suit for infringement of a patent every ground on which it may be revoked under section 64 shall be available as a ground for defence. Therefore, all the pleas which may be taken for seeking the revocation of a patent are also available as a defence in an infringement suit.

39. Another decision referred to by the learned counsel for the defendants was that of the Supreme Court in the case of Monsanto Company v. Coramandal Indag Products (P) Ltd : (1986) 1 SCC 642. A specific reference was made to paragraph 6 thereof wherein the provisions of Section 64 (1) (d), (e) and (f) were discussed. The Supreme Court observed that under Section 64(1) (d) a patent may be revoked on the ground that the subject of any claim of the complete specification is not an invention within the meaning of the Act. Under Section 64(e), a patent may be revoked if the invention so far as claimed in any claim of the complete specification is not new, having regard to what was publicly known or publicly used in India before the date of the claim, etc. Under Section 64(l)(f), a patent may be revoked if the invention so far as claimed in any claim of the complete IA 1234/2008 in CS(OS) 186/2008 Page No.30 of 35 specification is obvious or does not involve any inventive step having regard to what was publicly known or publicly used in India or what was published in India before the priority date of the claim. The Supreme Court also observed that to satisfy the requirement of being publicly known as used in Clauses (e) and (f) of Section 64(1), it was not necessary that it should be widely used to the knowledge of the consumer public. It is sufficient if it is known to the persons who are engaged in the pursuit of knowledge of the patented product or process either as men of science or men of commerce or consumers.

40. A reference was also made to the decision of a learned Single judge of the High Court of Bombay in the case of Novartis AG v. Mehar Pharma and Anr.: 2005 (30) PTC 160 (Bom). In the said decision, the learned Judge observed that the settled law appears to be in relation to a patent, that the Court will not grant an interlocutory injunction unless satisfied that (a) there is a real probability of the plaintiffs succeeding in the trial of the suit, and (b) where the patent is of a recent date, no interim injunction should be granted. More so, when there is a serious question as to validity of the patent raised by the defendants to be tried in the suit. A reference was also made to the decision of this Court in Bilcare Limited (supra) wherein this Court observed that the conspectus of the decisions is that it is not sufficient for the grant of an injunction that a patent is registered and the strength IA 1234/2008 in CS(OS) 186/2008 Page No.31 of 35 of the defence including the revocation application have to be looked into. The decision of a Division Bench of this Court in the case of Niky Tasha India Pvt. Ltd v. M/s Faridabad Gas Gadgets Private Ltd:

> AIR 1985 Delhi 136 was also referred to by the learned counsel for the defendants to indicate that normally interlocutory injunctions ought not to be granted where damages would provide an adequate remedy should the claim succeed. In the said decision the Division Bench further observed that the rule with regard to grant of interlocutory injunction is that the Court will not grant such an injunction unless it is satisfied that there is a real probability of the plaintiff succeeding in the trial of the suit. Where the design is of a recent date, as in the case before the Division Bench, no injunction ought to be granted. It is equally so when there is a serious question as to the validity of the design to be tried in the suit and an application for cancelation has been made. It is clear that the case before the Court in Niky Tasha India Pvt. Ltd (supra) was one under the Designs Act but the principles would be equally applicable to the present case which is under the Patents Act.

41. Having examined the arguments advanced by the counsel for the parties and the case law submitted by them, I am of the view that the plaintiffs are not entitled to an ad interim injunction as prayed for by them. It is clear that the registration of the patent per se does not IA 1234/2008 in CS(OS) 186/2008 Page No.32 of 35 entitle the plaintiffs to an injunction. The defendants case is also to be examined and it is only after the entire case as a whole is considered that the Court can come to a decision as to whether the plaintiffs are entitled to an injunction or not. In the present case the patent is a recent one and, prima facie, there is a serious challenge to the validity of the patent. This has been amply demonstrated by the learned counsel for the defendants in the course of his arguments noted above. I have also noted that the revocation of a patent can be sought under Section 64 of the Patents Act, 1970 by a defendant in an infringement suit by way of a counter-claim. The defendants have already preferred such a counter-claim. Apart from this, under Section 107 of the said Act all the pleas available for revocation of a patent are also available as a defence in a suit for infringement. The question of validity of the plaintiffs Patent No. 210062 is not free from doubt at this prima facie stage. There are more reasons than one for entertaining such doubts. One of the most important reasons is the existence of prior art. By way of illustration, I have already referred to U.S Patent No. 5,135,504. In fact, there are other such patents which were placed before this Court and find place in the documents filed by the defendants. Prima facie, the defendants have been able to show that, first of all, the field of I.V. catheters is a crowded one. Secondly, needle guards, in one

form or the other, have been used for decades by several companies. Thirdly, the IA 1234/2008 in CS(OS) 186/2008 Page No.33 of 35 defendants safety I.V. catheter/ cannula is somewhat different from the plaintiffs Patent No. 210062.

42. Another important factor which goes against the plaintiffs is that they did not come clean with the Court because there is no reference in the plaint of the fact that the plaintiffs were already aware that the defendants have started manufacturing and selling safety I.V catheters/ cannulae. The audit reports referred to above, prima facie, specifically point in this direction. The circumstance of safety I.V catheters/ cannulae being excepted from the list of products to which the non-compete clause of the agreement dated 17.01.2007 would apply, has also not been mentioned in the plaint.

43. The rival contentions with regard to the alleged dubious manner in which the patent was granted in favour of the plaintiff No.1 on 17.09.2007 when the application for amendment itself was made on 19.09.2007 is another circumstance which raises serious doubts. It is true that the plaintiffs have tried to explain this by submitting that the date of 17.09.2007 is a typographical error inasmuch as the patent was granted much later. That, however, is a circumstance which will have to be established as a fact in the course of trial. For the present, what is necessary is that the allegation raised by the defendants cannot be thrown out at the threshold.

IA 1234/2008 in CS(OS) 186/2008 Page No.34 of 35

44. For all these reasons, I hold that the plaintiffs have not been able to establish a prima facie case nor is the balance of convenience in favour of grant of an ad interim injunction in their favour. Consequently, the present prayer for an ad interim injunction made by the plaintiffs is rejected. The plaintiffs, however, can be protected as was done in the case of Bilcare Limited (supra) by directing the defendants to keep accounts of the manufacture and sales of the safety I.V. cannula in question during the pendency of the suit and to make the same available to the Court as and when directed by it. It is ordered accordingly.

With these observations, this application is dismissed.

BADAR DURREZ AHMED
(JUDGE)

April 15, 2009
SR

IA 1234/2008 in CS(OS) 186/2008 Page No.35 of 35