(2009) 07 DEL CK 0023

In the Delhi High Court

Case No : IA 1509 of 2008 in CS (OS) 227 of 2008

B. Barun Melsungen AG and Others — APPELLANT

Vs

Mr. Mohinder Paul and Another — RESPONDENT

Date of Decision : 02-07-2009

Acts Referred:
Civil Procedure Code, 1908 (CPC) — Order 39 Rule 1, Order 39 Rule 2
Patents Act, 1970 — Section 64(1)

Citation : (2009) 40 PTC 593

Hon'ble Judges : S.N. Dhingra, J

Bench : Single Bench

Advocate : Arun Jaitley, Pravin Anand, Binny Kalra and Taapish Joshi, for the Appellant; Rohit Aggarwal, for D-1, Shailen Bhatia, Vandena Nathan, Ekta Nayar and Amit Jain, for the Respondent

Final Decision : Dismissed

Judgement

Shiv Narayan Dhingra, J.—plaintiffs filed this suit for permanent injunction against defendants since defendants had brought out a product in the market as MEDIFLON SAFETY. It is alleged that this product of the defendants infringes the plaintiffs'' Patent No. 210062. The claim of plaintiffs patent No. 210062, as given in the plaint and in the documents filed mainly concerns claim No. 21 of the patent application filed by plaintiffs on 18th August 1998 and granted on 17th September 2007. It is described as under:

Claim 21: An IV catheter assembly comprising:

a needle having a needle shaft and a needle tip, the needle shaft comprising a portion of increased diameter proximal from the needle tip;

. a housing having a cavity formed therein;

. a needle guard disposed within the cavity, the needle guard comprising a proximal wall having first and second end portions and an opening therein, through which the needle shaft extends, and a resilient arm extending distally

from the first end of the proximal wall, the resilient arm comprising a radically extending member at the distal end thereof, the needle guard being moveable with respect to the needle between a ready position and a protective position; . wherein, when the needle guard is in the ready position, the resilient arm is held biased away from the needle shaft by contact between the radially extending member at the distal end of the resilient arm and the needle shaft, and the housing holds are first and second end portions of the proximal wall of the needle guard in an orientation relative to the needle allowing the needle shaft to pass through the opening in the proximal wall and maintain the needle guard in the ready position; and

. wherein when the needle guard is in the protective position the resilient arm is no longer biased outwards and the radially extending member at the distal end thereof blocks the needle tip, the portion of the needle shaft of increased diameter engaging with the proximal wall of the needle guard to prevent the needle guard from moving from the protective position.

2. It is submitted by the plaintiffs that the above patent of the plaintiffs is in respect of IV catheter, a device through which intravenous fluids are administered. The invention made by plaintiffs addressed a problem that persisted in existing catheters. The problem being that immediately after withdrawal of needle from the patient''s vein, the healthcare worker had to place the exposed needle tip at a nearby location and address the tasks required to be accomplished on withdrawal of the needle. At this juncture, the exposed needle tip used to create a danger of accidental needle prick, making the health care workers vulnerable to transmission of various dangerous blood-borne pathogens transmitting diseases including AIDS and Hepatitis (paragraph 9 of the plaint). Based on this invention, plaintiffs were marketing their products under the name Vesofix Safety. As per the plaintiffs, the core of plaintiffs'' invention was that it provided a protective guard on the tip of the injection needle which while drawing out from its catheter engages with the needle tip by detaching and shielded it during removal, thus ensuring that the handler is never exposed to the needle tip.

3. The defendants in their written statement stated that the claim made by the plaintiffs regarding invention, as set out in paragraph 9 of the plaint was false as a safety IV catheter was a well-known product in the market and various companies had introduced safety IV catheter to protect health workers from accidental needle pricks and the plaintiffs falsely claimed that it was plaintiff who invented a device to protect the healthcare workers from the risk of accidentally having pierces of the needle of IC catheter. The defendants in support of this plea mentioned about the US Patent, Specification No. 5599310, a patent specification of M/s Johnson & Johnson Medical Inc filed on 7th June 1995 and granted on 4th January 1997. It is submitted by defendants that even the language of specification of Johnson & Johnson was plagarised by the plaintiffs. It is submitted that plaintiffs'' entire claim was tainted with dishonesty and malafide.

Apart from making the submissions that the so-called invention allegedly made by the plaintiffs was not at all an invention and the grant of patent was wrong and invalid, it is also submitted by defendants that there was no similarity between the products of defendants'' and the patent of plaintiffs or the products of the plaintiffs. It is also submitted that plaintiffs were guilty of material concealment and the suit filed by plaintiffs was liable to be rejected.

4. The defendants have distinguished between the products /patent of plaintiffs and their own products. On the basis of this distinction, it is submitted that the working of the two products was entirely different. There was no infringement of plaintiffs'' patent and there was no overlapping between the two products. The concept, idea, the principle and the technology of the two products was entirely different. It is also submitted that the entire claim of plaintiffs regarding its patent was hollow and the patent of the plaintiffs was liable to cancelled under the provisions of Section 64(1) (e) and (f) of the Patents Act, 1970. Defendants also filed counter claim suit to this effect. The defendants informed the court that they had applied for registration of the design of their own safety IV catheter with Patent Office on 19th February 2007 and 29th March 2007 and the same were registered under numbers 208450 and 209167. It is submitted that the technology being used by the plaintiffs and the defendants was totally different. While the plaintiffs had a safety device riding on the needle which claps the needle tip on retraction, the defendants'' product had a metal strip fixed in housing which blocks the passage of needle on retraction. The metal strip was having a separate seat and does not ride the needle in the manner as in the products of the plaintiffs.

5. It is submitted by counsel for plaintiffs that the registration of a patent creates a monopoly in favour of the plaintiffs. Since the patent of plaintiffs was registered, there was a strong presumption in favour of plaintiffs about its validity and the Court cannot presume invalidity of the patent at the time of disposing of an application under Order 39 Rules 1 & 2 of Civil Procedure Code. The plaintiff has only to establish that there was a violation of the plaintiffs patent by defendants and in case plaintiffs succeed in establishing this, the plaintiffs were entitled to an interim injunction. It is submitted that the intent and purpose of patent laws is to encourage scientific research, new technology and industrial progress. The exclusive use or right to sell the products based on the patented inventions stimulates new inventions and encourages the companies to invest in developing new products and new technology. The Courts should, therefore, always protect the registered patent.

6. Regarding prior art and prior design, it is submitted that a new patent is granted even for an inventive step in the existing process or product. It may be that the safety IV catheter was already available in the market or was a well known product, but the patent of plaintiffs involved a new inventive step capable of industrial application and that is why the plaintiffs were granted patent. The specifications as stated in claim 21 of the application made by plaintiffs to patent

office fully described the invention and its operative use and method by which it is to be performed. Under law it was required of the plaintiffs to disclose the best method of performing the invention as known to them. Merely because there was overlapping or similarity between the claims of the plaintiffs and an earlier patent registered in USA would not make the patent of the plaintiffs as a prior art, thus the defence raised was baseless. It is argued that while considering the patent of the plaintiffs, the Court has to look into the true nature of specification and claims regarding innovation and evaluate the inventive step. Where an infringement is committed by a person and the infringement falls within the claim of plaintiff, it is no defence to say that it involves ingenuity. The Court has to construe the claims of plaintiffs to find out infringement without reference to the body of specification and reference to the specification is needed only if there was an abnormity or difficulty in construction of the claims in question. It is submitted by the plaintiffs that plaintiffs have prima facie established that the product of the defendants was nothing but a copy of the plaintiff''s patented claim and thus defendants have infringed the claim of plaintiff. Since the patent of plaintiffs was a registered patent, the plaintiffs had a prima facie case and since products of the defendants was nothing but a copy out of the plaintiff''s patented claim, therefore, the balance of convenience lied in favour of the plaintiffs and since plaintiff had made huge investments in making the invention, the plaintiffs shall suffer irreparable loss and injury in case defendants were not restrained from marketing the products based on the plaintiff''s patent.

7. In order to understand the plaintiff''s case, it is to be understood as to what is the alleged invention or inventive step made the by the plaintiffs. plaintiffs filed detailed specifications, before the Patent''s Office. A perusal of these specifications would show that the plaintiffs intended to address the problem of safety of health workers using IV catheter into the patient''s vein in their own way. A normal IV catheter being used prior to 1995 contained a plastic tube enveloping a needle so as to puncture the tissues of a patent. This needle so enveloped by a plastic tube would enter the tissues of the patent and after this process the needle used to be withdrawn and the plastic tube used to remain positioned inside the patient''s arm or other place wherever the fluid was to be inserted into the patient''s body. Since the healthcare workers after piercing the tissues with the help of needle had to withdraw the needle and pay attention immediately to fix the fluid into the IV catheter and check that there was no reverse flow of blood or other related problems, the needle used to be thrown on the floor or kept aside. The tip of the needle being sharp, sometime used to prick the health care workers accidentally or as a matter of chance. Hence, the healthcare workers ran a risk of getting infected from those patients who were suffering from infectious diseases like AIDS etc. In order to address this problem, the pharmaceutical companies devised a method so that when the needle was withdrawn from the patient''s body/tissues, the tip of the needle gets covered automatically at the time of withdrawal itself so that there was no chance of accidental pricking of the needle into the body of the health care workers, even if

the needle used was thrown on the floor. The plaintiff''s patent application is also one in lines of other patented products of similar nature. It is not disputed by the plaintiff that there were many other similar patented products. The plaintiffs in the replication referred to different patents cited by the defendants as prior art and tried to distinguish their own patent from other patents. The patents so referred by the plaintiffs and defendants are US Patent No. 5584810 (Brim Hall), US Patent No. 54237666 (Dicesare), US Patent No. 5135504 (Mclees, US Patent No. 5053017 (Chamuel), US Patent No. 5215528 (Purdy). The plaintiffs have given a table showing that how their patent and other patents differed and explaining that there was an innovative step involved in the plaintiffs'' patent.

8. Turning to the claim of plaintiffs, it cannot be said that plaintiffs got a novel idea of producing safe I.V. needles. This idea had already taken shape and various patents had been filed in US and other countries. Claim No. 21 describes IV catheter assembly of the plaintiffs sought to be patented. The first part of claim No. 21 is a needle having a needle shaft and needle tip. The needle shaft has an increased diameter proximal to the needle tip. Obviously the needle shaft and needle tip are all prior art and the plaintiffs cannot claim to have invented the same. The plaintiffs claim of innovative step seems to be in providing increased diameter near the needle tip. The next claim of plaintiffs is a housing at end of catheter. The housing is a place where something is housed or placed. Housing is not an invention of the plaintiffs. No unconventional or new design of housing has been given in the patent application showing that housing was an invention. The third step given in claim is that needle guard is positioned in the cavity of housing and this needle guard is so positioned in the housing that it allows needle to move through an opening in the proximal wall so long as the portion of increased diameter does not reach there. When the increased diameter reaches at the opening, the arm of needle guard closes at the tip. Thus the tip becomes safe for the healthcare workers as now it cannot prick the healthcare workers. When the needle is withdrawn, this needle guard get detached from the housing and moves along with the needle and the needle can be thrown anywhere without the danger of its pricking somebody. The invention of the plaintiff thus lies in devising a needle guard so located in the housing rear portion of catheter that the moment the needle is withdrawn from the body of the patient and, it passes through the catheter''s rear portion where the guard is located, the guard covers the tip of the needle and sticks there with the help of increased diameter covering the tip of the needle.

9. The plaintiff demonstrated the working of its invention with the help of power point in the Court whereas the defendants demonstrated the difference in functioning of its own devise and that of plaintiffs with the help of actual catheters by bringing the plaintiff''s products and the its own products in the Court.

10. It is contended by plaintiff that plaintiffs'' product demonstrated in the Court by defendants was a double metal strip locking devise and it does not show the

design of single metal strip device has also got registered by the plaintiffs and the single strip device being used by the defendants was nothing but a copy of the patent of the plaintiffs in this respect.

11. As discussed above, the invention which the plaintiff claimed provides single strip or double strip guard in the cavity of catheter''s rear portion, termed by plaintiff as a housing, and when the needle is withdrawn from catheter guard, detaches itself from the housing and gets attached to the needle due to increased diameter. The guard presently being used by the plaintiffs is a nose shaped crossed metal strip with a hole on the rear part. The defendant''s device provides a separate plastic unit where the needle guard, a single L-shaped metal strip, is located. This metal strip cannot be detached from the housing. The housing holds the metal strip in plastic clips firmly and when the needle comes out of the catheter, this housing also gets detached from the catheter and the metal strip in the housing holds the needle into the housing itself and the housing cannot be taken out. The result is whereas the device of plaintiffs provides a detachable metal guard, the device of defendants provides a plastic housing with L-shape metal strip which does not allow the needle to move out of the housing and the housing gets stuck to the needle tip resulting into the safety of the healthcare workers. The plastic housing is covered from all sides and even if the metal strip is not of L-shape but is of only a small metal washer type, the purpose would be served. Making it an L-shape only seems to have ensured that in case housing gets crushed under somebody''s boot, still the needle would not prick someone. There is no doubt that there is an increased diameter/ bulge in both the cases. In case of plaintiff, the bulging has been provided by increasing the diameter of needle near tip while in case of defendant the bulging has been provided by not increasing diameter of entire needle but by compressing type bulge on two opposite sides.

12. I have also seen the other products in the market placed before the Court like BDTVC with Patent No. 0554841. This also has a housing similar to that of defendant but the needle gets stuck in the housing because of a thin plastic film attached to rear part of needle so that when needle is withdrawn, the plastic film does not allow it to come out of housing. The length of this plastic film is less than the length of the needle resulting into the needle not coming out fully of the housing. Thus, the idea of getting the needle within the housing was not of the plaintiff or of the defendant. This idea was already existing. The defendants, instead of providing a plastic film, provided a metal strip with a hole whose diameter was slightly higher than that of the needle diameter but less than the bulging portion of the needle, resulting into the needle not coming out of the housing.

13. The plaintiffs'' alleged invention relates to a metal guard covering needle point. US Patent No. 5584810 dated 17th December 1996 is also in respect of the needle point guard assembly. It describes the invention as under:

The present invention relates to a needle point guard assembly that can be slid

relative to the needle so the sharp distal tip of the needle point is safely shielded inside the needle point guard assembly. When the sharp distal tip of the needle is safely shielded inside the needle point guard assembly, the needle point guard assembly lockingly engages the needle to prevent re-exposure of the sharp distal needle tip.

14. Similarly in US Patent No. 5423766, the safety device is described as under:

The safety shield of the subject invention includes a guard that is slidably mounted on the needle cannula for movement between a proximal position where the distal tip of the needle cannula is readily accessible and a distal position where the sharply pointed distal tip of the needle cannula is safely enclosed. The guard maybe plastic, but may include a metallic member securely engaged or retained therein. The metallic member maybe biased against the needle cannula for sliding movement with the cap along the needle cannula. However, after sufficient movement of the guard distally along the needle cannula, the metallic member will pass the distal tip of the needle cannula. The metallic member will then be biased into a position for protectively coveting the distal tip of the needle cannula and preventing a return or proximal movement of the guard.

15. The US Patent No. 5135504 of 4th August 1992 describes the invention as under:

In order to satisfy the objects of the invention and improve upon the prior art, a simple needle tip guard has been devised which in its initial position resides entirely inside the hub of a standard catheter. The needle initially passes completely through the guard. The presence of the needle dips and the end of the guard flared out and thereby retained inside the hub until needle is withdrawn from the catheter. At that time a slightly widened portion of the needle tip catches the guard, forcing the end of the guard to close over the tip and pulling the guard from the hub.

16. It is apparent from the above description of prior inventions and similar many more inventions that increasing the diameter or slightly widening a portion of the needle tip was not a new invention. Hence the inventive step, as claimed by plaintiffs, was not in fact a new step. Similarly, providing of a safety guard to cover the needle tip was also not an inventive step but it was a prior known step. Thus, the so called invention of plaintiff is in fact a prior art and was well known to the players of the field. It cannot be said that there was a real inventive step or invention made by plaintiff.

17. The object of most of the pharmaceutical manufacturers after 90''s had been to develop such IV catheter which were safe for the health workers. This concern had already gained momentum and the object was achieved by various devices and modes. Every company came up with different devices. The mechanism followed by plaintiffs was to provide a safety metal guard which got fixed firmly at the tip of the needle and got detached from its location/position inside the

housing when the needle was withdrawn. Many other companies had devised methods of securing the needle within the housing itself by different methods e.g. by providing plastic film or by a washer with increased diameter of the needle near the tip or by providing a metallic strip within the housing with increased diameter of the needle. The defendants'' device uses a metallic L-shape arm fixed within the housing with the result that housing remains tagged at the needle tip firmly securing the needle tip within it. In the products of plaintiff there is no separate housing and the metallic safety guard is housed within the rear increased portion of IV catheter which served as a housing. In case of defendants, the housing is detachable one. The principle on which the catheters work is the same and there can be no patent of the principle. The patent is only of the process of securing the needle tip. The plaintiffs process has not been copied by defendants and it is different from the process of securing the needle tip by the plaintiffs.

18. In view of foregoing facts, I consider that prima facie it is not a case of infringement of plaintiffs'' patent by defendants. The defendants had devised its own mode and methods of securing the needle tip as many other pharmaceutical companies devised the similar methods. Since I find that there is no prima facie case in favour of the plaintiffs, this application under Order 39 Rules 1 & 2 CPC is hereby dismissed. CS(OS) 227/2008

List on 12th August 2009.

