IN THE HIGH COURT OF MALAYA AT KUALA LUMPUR

(COMMERCIAL DIVISION)

SUIT NO: D5(IP)-22-2374-2008

BETWEEN

1. B. BRAUN MELSUNGEN AG
2. B. BRAUN MEDICAL SUPPLIES SDN BHD ... PLAINTIFFS
(Company No. 56425-H)

AND

1. TERUMO KABUSHIKI KAISHA
2. SUMMIT COMPANY (M) SDN BHD ... DEFENDANTS
(Company No. 007775-T)

JUDGMENT

Introduction

In this action, the plaintiffs are suing the defendants for infringement of Malaysian Patent No. MY-136823-A entitled "Spring Clip as Needle Tip Protection for a Safety Catheter" (the Braun Patent).

The plaintiffs' safety intravenous catheter products, "Introcan Safety", "Vasofix Safety" and "Vasoscan Safety" are claimed to practice the Braun Patent.

The allegedly infringing product is the 1st defendant's safety intravenous catheter known as "Terumo Surshield Surflo 11" (the Terumo Product).

The defendants have raised a defence of non-infringement. In addition, the defendants counterclaim to invalidate for the reason that the invention of the Braun Patent is not a patentable invention under the Patents Act 1983 (the Act).

The safety intravenous catheter product

To make the point under discussion easier to comprehend, it is useful to have an understanding of the product in question. The product that is the subject matter of this action is a safety intravenous catheter (IVC). An IVC is a product or device that is primarily used by health care workers to administer fluids directly into a patient's vascular system. The IVC comprises, among other components, a needle with a tip and a shaft.

The insertion procedure comprises 4 basic steps, namely:

a. The needle tip extending from the catheter tube penetrates the patient's vein;

b. The catheter is inserted into the vein over the needle tip by the health care worker pushing the catheter hub;

c. The health care worker then withdraws the needle leaving the catheter in the vein;

d. The health care worker then fastens the inserted catheter hub to the patient's skin, and connects the open end of the catheter hub to the source of the fluid to be administered into the patient's vein.

After the insertion procedure has been completed and the needle withdrawn from the catheter, an exposed needle tip can lead to an accidental or inadvertent needle stick injury, thereby exposing health care workers to a transmission of a multitude of dangerous blood borne pathogens.

The 1st plaintiff's safety IVC and the Terumo Product are products devised to, among other objectives, automatically cover a needle tip when the needle is withdrawn from the catheter hub, to thereby prevent health care workers from accidentally sticking themselves with the needle tip.

The parties

The 1st plaintiff is B. Braun Melsungen AG, a company incorporated under the laws of the Federal Republic of Germany. The 1st plaintiff has its principal offices at Carl-Braun-Strasse 1, 34212 Melsungen, Federal Republic of Germany.

The 1st plaintiff carries on business as, *inter alia*, manufacturer, distributor, supplier and exporter for the global healthcare market by supplying products for anesthesia, intensive medicine, cardiology, extra corporeal blood treatment and surgery, as well as services for hospitals, general practitioners and the homecare sector.

The 2nd plaintiff is B. Braun Medical Supplies Sdn Bhd, a company incorporated in Malaysia.

The 1st defendant is Terumo Kabushiki Kaisha, a company incorporated in Japan, having its principal offices at 44-1, 2-chome, Hatagaya Shibuya-ku, Tokyo, Japan. The 1st Defendant manufactures and produces for sale a range of medical products including disposable medical products, that is, single-use products to eliminate the risk of infection due to re-use of medical supplies and to provide safety for both patients and medical staff.

The 2nd defendant is Summit Company (M) Sdn Bhd, a company incorporated in Malaysia. The 2nd defendant carries on business as a trading company which mainly supplies products for clinics, hospitals and general pharmaceutical use.

The trial

The trial of this action was heard in this Court on 1.11.2010 to 4.11.2010 and 8.3.2011 to 10.3.2011.

The Plaintiffs' evidence was led through 3 witnesses, namely Kevin Woehr (PW1); Mr Noel J.Akers (PW2) and Mr Lam Chee Hong (PW3).

The defendants called 4 witnesses, namely Mr Kazuhiro Uchida (DWI); Mr Takato Murashita (DW2); Mr Gregory Richard Munt (DW3) and Dr Joseph J. Beaman (DW4).

The plaintiffs' case

A summary of the plaintiffs' case is given here. On 28.11.2008, a patent was granted for the 1st plaintiff's safety IVC, by way of the Braun Patent.

The 1st plaintiff is the owner of a valid granted and subsisting Braun Patent for Spring Clip as Needle Tip Protection for a Safety Catheter and is the manufacturer of the products protected by the said Braun Patent.

The 2nd plaintiff is at all material times, the exclusive licensee in Malaysia of all the intellectual property rights in the products and processes of the 1st plaintiff, including but not limited to patent rights.

It is the contention of the plaintiffs that based on the features and elements of the Terumo Product, the 1st defendant's

infringing product's similarity in use and operational functions can only be achieved by the replication of the structural form, physical and operational feature elements of those claimed in the said plaintiffs' Braun Patent or at least as claimed in Claims 1, 2, 3, 4, 6 and 7 of the said Braun Patent. As a result, the plaintiffs contend that the defendants have committed an act of infringement of the plaintiffs' Braun Patent. The plaintiffs have not, on any occasion previously or now, authorized or consented to the defendants' manufacturing, marketing, distributing, supplying or offering to sell by way of trade of the defendants' Terumo Product.

By reason of the matters aforesaid, it is the contention of the plaintiffs that they have suffered and will continue to suffer loss and damage which are and will be substantial and irreparable unless the defendants, singly or jointly, their agents, servants and/or distributors are prevented and restrained from manufacturing, marketing, offering to sell, selling the 1st defendant's Terumo Product or any other product that infringes the Braun Patent.

Hence, the plaintiffs have, on 23.12.2008, filed the present action against the defendants, claiming, *inter alia*, for a declaration that the Braun Patent is valid and has been infringed by the defendants; an injunction; delivery up order; an inquiry into the damages; aggravated and/or exemplary damages and costs.

The defendants' case

1. Non-infringement

The Terumo Product does not come within the scope of and does not infringe any of the claims of the Braun Patent.

The Terumo Product does not have the following features that are defined in Claim 1 of the Braun Patent:

a. The needle guard (120) has two resilient arms (122, 124) which are urged away from each other by said needle shaft in the ready position;

b. Each arm being provided at the distal end with a distal guard wall (130) positioned on the shaft of the needle (16) in the ready position...";

c. The needle (16) having a segment (138) "slightly proximal to the needle tip, the segment (138) being provided with increased diameter in relation to the needle tip";

d. The needle guard having a rear wall (126) from which the arms (122, 124) extend in a distal direction; and

e. The inner wall of the chamber of the catheter hub is provided with a retaining means in the form of an annular groove by which the needle guard is retained in the catheter hub in the ready position.

Hence, according to the defendants, the Terumo Product does not infringe Claim 1 of the Braun Patent. Since Claims 2 to 7 of the Braun Patent are dependent directly or indirectly on Claim 1, it therefore follows that the Terumo

Product also does not infringe Claims 2 to 7 of the said Patent.

2. The Braun Patent is not new

It is the defendants' case that the Braun Patent is anticipated by International publication WO 99/08742 (international application PCT/EP98/05231) published on or about 25.2.1999. The application for the Braun Patent was purportedly a divisional application (the Application) of application no. P120000497 (the Initial Application), which has a filing date of 11.2.2000. The Application was filed some time in 2004 and claims the priority date of the Initial Application, i.e., 11.2.2000. The plaintiffs filed amendments to the specification of the Application and on those amendments, the Braun Patent was granted. The amendments went beyond the disclosure in the Initial Application. The Braun Patent is therefore not entitled to claim priority of the filing date of the Initial Application. The filing date of the Braun Patent is thus the date in 2004 when the Application was filed. International publication WO

99/08742 disclosed the features claimed by the Braun Patent in 1999 more than a year prior to the filing of the Application in 2004. Therefore, it is the contention of the defendants that the Braun Patent is anticipated by prior art, is not new and not a patentable invention.

3. No inventive step

Moreover, it is the defendants' case that the Braun Patent involves no inventive step in that it was obvious to a person having ordinary skill in the art having regard to any matter which forms part of the prior art as at the priority date of the patent application for the Braun Patent (priority date) –

Particulars

(a) The publication to the public of the following documents prior to the priority date:

(i) U.S. Patent No. 5,135,504 entitled "Needle tip guard" (McLees Patent);

(ii) U.S. Patent No. 5,599,310 entitled “I.V. catheter assembly with automatic cannula tip guard” (Bogert Patent); and

(iii) U. S. Patent No. 4,952,207 entitled “I.V catheter with self-locating needle guard” (Lemieux Patent).

(b) The subject-matter of each of the documents in paragraph (a) above was at all material times common general knowledge to a person skilled in the art.

In the above premises, the defendants counterclaim for –

a. A declaration that the Terumo Product does not infringe and does not come within the claims of the Braun Patent;

b. A declaration that the Braun Patent is and was at all material times invalid; and

c. Damages.

The Braun Patent

Before dealing with specific issues which arise for determination, it is important at this point to understand the scope of the plaintiffs' Braun Patent.

The invention relates to an intravenous catheter comprising a catheter hub attached to the proximal end of a tubular catheter and having a chamber, a needle having a needle shaft and a needle tip, wherein the needle is provided with an increased diameter, and a needle guard retained in a ready position wholly in the chamber of the catheter hub. The needle guard has two resilient arms which are urged away from each other by the needle shaft in the ready position, each arm being provided at the distal end with a distal guard wall positioned on the shaft of the needle in the ready position. The distal guard walls overlap each other in front of the needle tip when the needle guard is in a blocking position.

In the patent document, the abstract of the Braun Patent is declared as follows. There is disclosed an intravenous catheter

comprising a catheter hub (26) attached to the proximal end of a tubular catheter (24) and having a chamber, a needle (16) having a needle shaft and a needle tip, wherein the needle is provided with an increased diameter, and a needle guard (120) retained in a ready position wholly in the chamber of the catheter hub (26). The needle guard (120) has two resilient arms (122, 124) which are urged away from each other by the needle shaft in the ready position, each arm being provided at the distal end with a distal guard wall (130) positioned on the shaft of the needle (16) in the ready position and wherein the distal guard walls overlap each other in front of the needle tip when the needle guard is in a blocking position. The needle shaft has a segment (138) slightly proximal to the needle tip, the segment (138) being provided with an increased diameter in relation to the needle tip. The needle guard (120) has a rear wall (126) from which the arms (122, 124) extend in a distal direction wherein the rear wall (126) includes an opening (134) through which the needle shaft passes. The diameter of the increased diameter segment (138) is greater than that of the opening (134), and

wherein an inner wall of the chamber of the catheter hub (26) is provided with a retaining means in the form of an annular groove (136) by which the needle guard is retained in the catheter hub in the ready position.

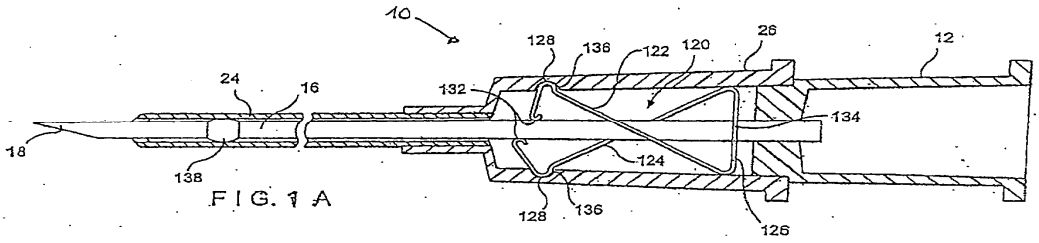


FIG. 1A

The objects of the invention are as follows:

a. To provide a safety IV catheter, which reliably and automatically prevents accidental, inadvertent contact with the needle tip after use.

b. To provide a safety catheter which provides reliable protection to the health care worker against needle sticks without requiring any change in the manner of use of the safety catheter by the worker.

c. To provide a safety IV catheter of the type described which is relatively simple and inexpensive to manufacture.

d. To provide a safety catheter of the type described in which removal of the needle from the needle guard after use is prevented.

Claim 1 of the Braun Patent claims an intravenous catheter, comprising:

i. A catheter hub A;

ii. The catheter hub being attached to the proximal end of a tubular catheter B;

iii. The catheter hub A having a chamber C;

iv. A needle D;

v. The needle having a needle shaft E and a needle tip F;

vi. The needle being provided with an increased diameter G;

vii. A needle guard H;

viii. The needle guard being retained in a ready position wholly within the chamber of the catheter hub;

ix. The needle guard having two resilient arms I, J;

x. The arms being urged away from each other by the needle shaft in the ready position;

xi. Each arm being provided at its distal end with a distal guard wall K, L;

xii. Each distal guard wall being positioned on the shaft of the needle in the ready position;

xiii. The distal guard walls overlapping each other in front of the needle tip when the needle guard is in a blocking position;

xiv. The needle shaft having a segment M provided with an increased diameter in relation to the needle tip;

xv. The segment being slightly proximal to the needle tip;

xvi. The needle guard having a rear wall N;

xvii. The arms extending in a distal direction from the rear wall;

xviii. The rear wall including an opening 0;

xix. The needle shaft passing through the opening in the rear wall;

xx. The diameter of the Increased diameter segment being greater than that of the opening in the rear wall;

xxi. The Inner wall of the chamber of the catheter hub being provided with a retaining means in the form of an annular groove P; and

xxii. The needle guard being retained in the catheter hub in the ready position by the annular groove.

Claim 2 of the Braun Patent depends from Claim 1 and further requires that:

1. The distal end of an arm includes a curved protrusion Q;

2. The curved protrusion extending to the distal guard wall.

Claim 3 of the Braun Patent depends from Claim 2 and further requires that the curved protrusion engages with the annular groove formed in the inner wall of the catheter hub.

Claim 4 of the Braun Patent depends from Claim 1 only and recites as follows: the increased diameter segment of the needle is a bulge R on the needle shaft.

It is to be noted that the plaintiffs do not allege infringement of Claim 5.

Claim 6 of the Braun Patent depends from any of Claims 1 to 5 and further specifies as follows:

1. The distal guard wall terminates in a curved lip S;
2. The curved up engages with the shaft of the needle.

Claim 7 of the Braun Patent depends from Claim 1 only and recites as follows:

1. The device comprises a hinged arrangement T;
2. The hinged arrangement is disposed between the proximal ends of the arms and the rear wall.

Findings of court

It is convenient at this stage of the judgment, I turn first to the defendants' counterclaim to invalidate the Braun Patent.

1. Validity of the Braun Patent

In the first place, as noted earlier, it is the contention of the defendants that the Braun Patent is not new as it is anticipated by the plaintiffs' own European patent international publication

WO 99/08742 (international application PCT/EP98/05231) published on or about 25.2.1999. In this regard, the defendants' argument is that the Braun Patent is not entitled to its status as a divisional patent. According to the defendants, there is no basis in the specification of the parent patent, MY-126024-A, (the Parent Patent) for a needle guard that is not recited as being a "unitary" needle guard. Accordingly, it is the contention of the defendants that the corresponding international patent application no. WO 99/08742, by having a publication date before the actual date on which the application for the Braun Patent was filed, is prior art with respect to the Braun Patent and anticipates all claims of the Braun Patent.

I do not accept this contention. In the first place, section 26B of the Act stipulates that an application may be divided into two or more applications (divisional applications) provided that each divisional application shall not go beyond the disclosure in the initial application. In this regard, in my view, it is an incorrect approach to compare Claim 1 of the Braun Patent to Claim 1 of the Parent Patent. It is the argument of learned

counsel for the plaintiffs that the correct approach is to compare the content of Claim 1 of the Braun Patent with the entirety of the Parent Patent specifications. I find this argument persuasive. Further, there is no reason why Claim 1 of the Braun Patent is required to be directed only to the disclosure of the Parent Patent specification relating to the embodiment shown and described in the specification of the Braun Patent. Instead the claims of the Braun Patent may be directed to subject matter disclosed in any part of the specification of the Parent Patent, including the general description, as well as the disclosure relating to the specific, preferred embodiments set out in the parent specification. In any event, the embodiment disclosed in the Braun Patent is described as a preferred embodiment, and is not to be taken as the only embodiment. The correct position would be that Claim 1 of the Braun Patent may draw on any subject matter that is disclosed in the specification of the Parent Patent. In the Parent Patent document there is a section entitled "Summary of the Invention", there is a general description of the safety IV catheter envisaged in the specification. The IV catheter

is described as having a needle guard. It is important to note that there is no mention of the needle guard being “unitary” in construction. Then, there follows a description of various embodiments of the catheter assembly, in which repeated references are made to the needle guard without mention of it being of “unitary” construction. Accordingly, in my view, there is clear basis in the specification of the Parent Patent to support Claim 1 of the Braun Patent in which the needle guard is recited without being indicated as being “unitary”. It therefore follows that the Braun Patent is fully entitled to its divisional status and to the benefit of the priority date of the Parent Patent. Hence, the defendants’ arguments for lack of novelty having regard to the corresponding international patent application no. WO 99/08742 must fail.

This brings me to the contention of the defendants that Claim 1 of the Braun Patent is invalid for it lacks inventive step. Generally, inventive step denotes a quality of an invention that entails technical advances or improvement as compared to the existing knowledge (see: **SKB Shutters Manufacturing Sdn**

Bhd v Seng Kong Shutter Industries Sdn Bhd and Anor [2011] 4 CLJ 93). Section 15 of the Act states that:

> *" An invention shall be considered as involving an inventive step if having regard to any matter which forms part of the prior art under paragraph (a) of subsection (2) of section 14, such inventive step would not have been obvious to a person having ordinary skill in the art.*

The requirement for inventive step is governed by section 15 of the Act. To meet the criterion, the patentee will have to show that such inventive step would not have been obvious to a person having ordinary skill in the art. The word "obvious" is to be given its plain and ordinary meaning. This was held so in **General Tire & Rubber Co v. Firestone Tyre & Rubber Co Ltd [1972] RPC 457**:

> *We agree, however with what was said by Diplock, LJ. (as he then was) and Willmer, LJ. In the Johns-Manville case [1967] RPC 479 at 93 and 496 deprecating "coining" phrases which may later be suggested to be of general application. "Obvious "is, after all, a much-used word*

and it does not seem to use that there is any need to go beyond the primary dictionary meaning of "very plain". "

The test for obviousness had been laid down in the case of **Windsurfing International Inc v Tabur Marine (Great Britain) Ltd [1985] RPC 59** as follows:

1. First, to identify the inventive concept of the claim in question;

2. Secondly, to identify the notional skilled addressee or person skilled in the art and the relevant common general knowledge of that person;

3. Thirdly, to identify the differences between the state of the art and the inventive concept of the claimed invention;

4. Fourthly, without the benefit of hindsight, to decide whether the differences identified constitutes obvious steps to the notional person skilled in the art.

It is the contention of the defendants that Claim 1 of the Braun Patent is invalid for it lacks inventive step when considering the McLees Patent (US Patent No. 5135504) or the McLees Patent in combination with the Kulli Patent (US Patent No. 4929241). The defendants' case is that the McLees Patent differed from Claim 1 of the Braun Patent in one aspect only, and that is the absence of the annular groove. The defendants took the position that the annular groove is the only thing in Claim 1 of the Braun Patent that is not present in the McLees Patent.

I do not agree. Indeed, as submitted by learned counsel for the plaintiffs, the invention in Claim 1 of the Braun Patent contains 5 features that are not found in the McLees device. These are:

(i) The needle having a segment of increased diameter in relation to the needle tip slightly proximal to the needle tip;

(ii) The needle guard having a rear wall from which the arms extend in a distal direction;

(iii) The rear wall having an opening through which the needle shaft passes;

(iv) The diameter of the segment of increased diameter of the needle being larger than the opening in the rear wall; and

(v) The inner wall of the catheter hub having an annular groove for retaining the needle guard in the catheter hub when in the ready position.

It is the contention of the defendants through the evidence of DW3 that the annular groove in Claim 1 of the Braun Patent is nothing more than a recess used as a retaining means by way of mating or engagement with a projection, such as in the case of a pneumatic hose coupler. Consequently, the defendants contend that it forms part of the common general knowledge of the person skilled in the art, thereby rendering it obvious to a person skilled in the art to modify the McLees device to arrive at the invention in Claim 1 of the Braun Patent. I cannot accept this contention. The plaintiffs have demonstrated during the trial that

in order to incorporate the teaching of the projection engaging with a recess in the pneumatic hose coupler into the McLees device, numerous other steps need to be taken to re-design the McLees device and/or recess and projection before one arrives at the invention in Claim 1 of the Braun Patent. This means that substantial inventive activity need to be undertaken, and these would extend beyond the workshop modifications referred to by DW3. In fact, DW3 had agreed with the plaintiffs' learned counsel, during his cross-examination that at least the following steps must be undertaken before the combination of the McLees device and the recess and projection of a pneumatic hose coupler would result in the invention in Claim 1 of the Braun Patent:

a. Re-design the placement of the projection and recess;

b. Transpose a multipart component into a single part component;

c. Re-design McLees needle to enable the flared needle tip to be pulled proximally of the ends of the distal guard walls; and

d. Modify the manually-activated joint in the pneumatic hose coupler to be become the passive joint in the claimed invention of the Braun Patent.

In my judgment, the defendants have failed to show that the invention of the Braun Patent is obvious when viewed in the light of the actual common general knowledge of the person skilled in the art.

I also reject the contention of the defendants that Claim 1 of the Braun Patent is invalid in light of McLees Patent combined with Kulli Patent. There is merit in the contention of the plaintiffs to the effect that the Kulli Patent does not form part of the common general knowledge of the person skilled in the art. The Kulli Patent is not concerned with IV catheters and is silent about any use of the needle guard in connection with the catheters. In any event, the Kulli Patent was not specifically pleaded in the defendants' claim for invalidation. It is a cardinal principle of pleadings that the parties to an action are bound by their own pleadings. This must be emphasized since this court is not

unconstrained to decide on an action on which no issue has been raised by the parties in their respective pleadings (see: **Yew Wan Leong v. Lai Kok [1990] 2 MLJ 152** and **Ranbaxy (Malaysia) Sdn Bhd v Ei Du Pont De Nemours** and **Company [2011] 1 AMCR 857**). Hence, the defendants are not entitled to rely on Kulli Patent as a ground to invalidate the Braun Patent.

At this juncture, it would be appropriate to provide a summary of my findings up to this point. That is, the Braun Patent is at all material times, valid and subsisting and therefore is enforceable against any other third parties including the defendants. The upshot of all this is that the defendants' counterclaim to invalidate the Braun Patent is wholly unsustainable and must be rejected.

That leaves me to deal with the issues pertaining to the plaintiffs' claim for infringement against the defendants.

Before dealing with this issue, it is useful to be familiar with the defendants' Terumo Product.

The Terumo Product and the Terumo safety device

The Terumo Product is a multiple component, passive IV catheter with a safety device. It is available in a range, varying in terms of needle sizes (18, 20, 22 and 24 gauge), catheter length and the external and internal diameter of the catheter. The safety device is the same for all in the range. The Terumo Product is made up of the following components: (1) the needle; (2) needle hub; (3) catheter; (4) catheter hub; and (5) the safety device.

The safety device of the Terumo Product is made up of multiple components. In particular, it is made up of:

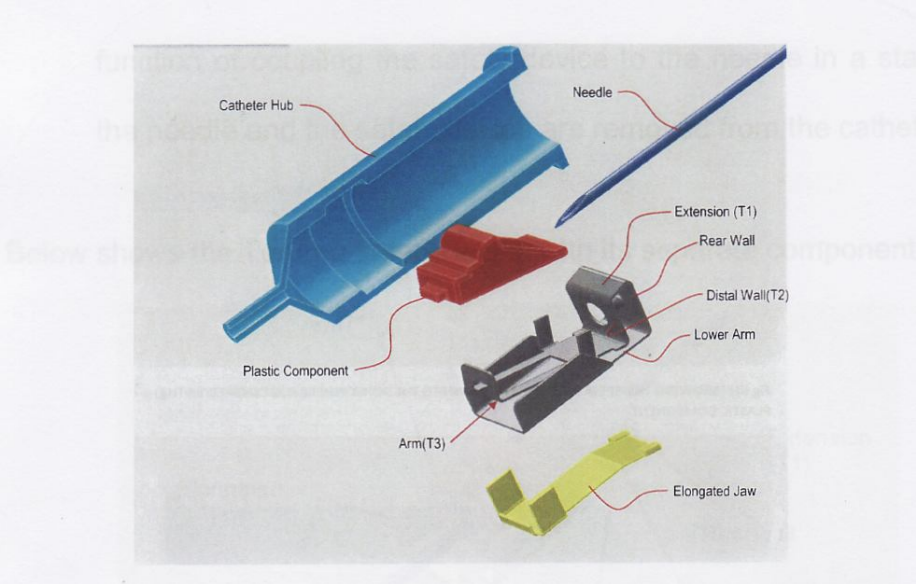
(i) a main body (grey-coloured component) which comprises of a Rear Wall, a Lower Arm (having side protector walls) which extends from the Rear Wall, an Extension (T1), a Distal Wall (T2) extending from the Extension (T1) and an Arm (T3) extending from the Distal Wall (T2);

(ii) a separate piece identified as Elongated Jaw (yellow-coloured component) which is connected to the Arm (T3) via flanges formed at one end of the Elongated Jaw;

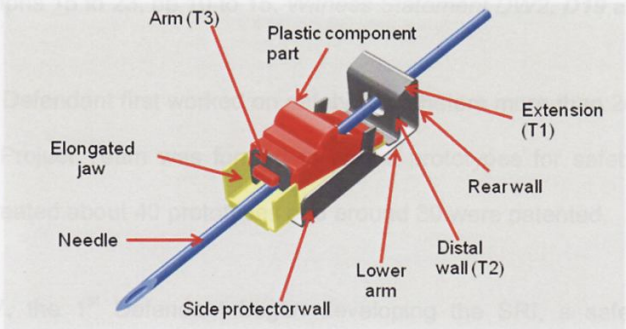
(iii) a plastic component (red-coloured component) mounted on and supported by the Arm (T3). The Arm (T3) has two thin outer straps that hold or support the plastic component; and

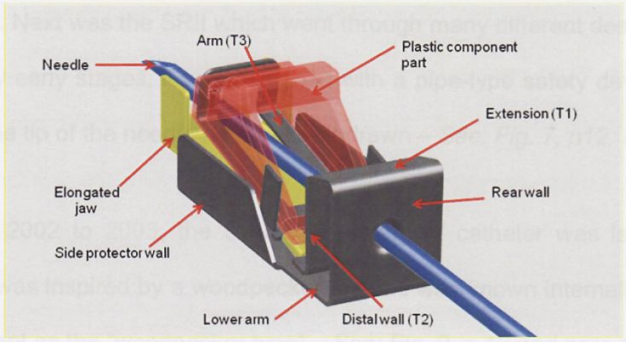
(iv) a Tube that is connected to and extends forwardly from the Rear Wall and receives the needle through the Tube. The Tube performs the important function of coupling the safety device to the needle in a stable way after the needle and the safety device are removed from the catheter hub.

For easy reference, the multiple components of the Terumo safety device are shown below:



Below shows the Terumo safety device with its separate components assembled:





According to the defendants, the Terumo Product is the result of an evolutionary process by the 1st defendant and years of research, development, testing, refining and improvement of the various prototypes and designs of safety devices.

I now turn to address the issue of infringement.

Infringement

Now, the burden at all time is off course borne by the plaintiffs to prove that the defendants' Terumo Product does infringe the claims of the plaintiffs' Braun Patent.

Section 58 of the Act defines patent infringement as follows:

> *Subject to subsections (1), (2) and (3) of section 37 and section 38, an infringement of a patent shall consist of the performance of any act referred to in subsection (3) of section 36 in Malaysia by a person other than the owner of the patent and without the agreement of the latter in relation to a product or a process falling within the scope of protection of the patent.*

As the Braun Patent involves a product patent, the relevant portions of section 36 of the Act are reproduced as follows:

> *"(3) For the purpose of this Part, "exploitation" of a patented invention means any of the following acts in relation to a patent:*
>
> *(a) When the patent has been granted in respect of a product:*
>
> *(i) Making, importing, offering for sale, selling or using the product;*
>
> *(ii) Stocking such product for the purpose of offering for sale, selling or using."*

There is therefore infringement if the acts referred to in section 36(3) of the Act are done without the consent of the patent owner in relation to a product or process falling within the scope of protection of the patent. There can be infringement only if the allegedly infringing product is within the scope of protection of the patent in suit.

The exercise of determining whether patent infringement has occurred involves 2 stages: (a) ascertaining the features or integers of the claim of patent in suit; and (b) ascertaining

whether the alleged infringing product or process falls within the features or integers of the claims of the patent in suit. This is explained in the hallmark case of **Catnic Components Ltd & Anor v. Hill & Smith Ltd [1982] RPC 183** as follows:

> *"To determine whether a claim of a patent has been infringed one must first discover what is claimed. The claim must be construed and analyzed to ascertain what are the features – sometimes called the integers – of the subject matter for which a monopoly is claimed. The claim must be construed in the context of the specification as a whole and in the light of any admissible evidence. It must be read and interpreted as it would be read and interpreted by the notional addressee of the specification, that is to say, a man skilled in the relevant art who has at his disposal the common knowledge in that art at the date of the publication of the specification. When so construed the claim must be analyzed to discover what are the several features of the thing for which a monopoly is claimed. One must next consider the alleged infringement to determine whether it infringes the claim. If the alleged infringement of the claim has all the features of the claim it must infringe the claim, even if it also incorporates other features."*

The scope of the monopoly for which protection is provided is determined by the claims (see: **Electric & Musical Industries Ltd v Lissen Ltd (1939) 56 RPC 23**). A patent claim must be interpreted in the same way and have the same ambit, whether the issue is infringement or validity. A claim can have only one meaning (see: **Amersham International Pic v Corning Ltd & Anor [1987] RPC 53, John Deks Holdings Pty Ltd v Aztec Washer Company [1989] RPC 413**). The claim must be read through the eyes of the notional addressee. In construing a claim, it must be read and interpreted as it would be read and interpreted by the notional skilled addressee of the patent specification, that is to say, a man skilled in the relevant art who has at his disposal the common knowledge in that art at the relevant date (see: **Catnic Components v Hill & Smith [1982] RPC 183, Kirin-Amgen v Hoescht Marion Russell Ltd [2004] UKHL 46, [2005] 1AER 667, SKB Shutters Manufacturing Sdn Bhd v Seng Kong Shutter Industries Sdn Bhd & Anor [2011] 4 CLJ 93** and **Ranbaxy (Malaysia) Sdn Bhd v Ei Du Pont De Nemours and Company [2011] 1 AMCR 857**).

A purposive approach is to be adopted in determining the meaning of the claims. Where the words of the claim are clear, purposive construction does not mean that one can read additional words or features into the claim or to extend or go beyond the definition of the technical matter for which the patentee seeks protection in the claims. In **Bean Innovations Pte Ltd v Flexon [2001] 3 SLR 121**, the patent there was for a device for preventing junk mail from being dropped into mailboxes. One of the essential features of claim 1 was a matrix of orthogonal bars. This was not present in the defendant's product. Counsel for the patentee submitted that the defendant's device and the device of the patent performed the same or similar function, namely, preventing junk mail from being delivered into mailboxes and thus, the patent was infringed. The Court rejected this and ruled -

> *" The essence of the approach urged by counsel is to construe the claim wholly functionally. Clearly this approach is wrong. To construe the claims in the manner urged by counsel would be tantamount to disregarding what is stated in the claims. The clear and unambiguous*

words employed in claim 1 must be given their natural and ordinary meaning.

We should add that the well-known principle that patent claims are to be given a purposive construction does not mean that the court in construing a claim is entitled to disregard the clear and unambiguous words used to describe the essential features of a claim. In Societe Technique de Pulverisation STEP v Emson Europe [1993] RPC 513, 522, Hoffman LJ said:

> *The well-known principle that the patent claim are given the purposive construction does not mean that an integer can be treated as struck out if it does not appear to make any difference to the inventive concept. It may have some other purpose buried in the prior art and even If this is not discernible, the patentee may have had some reason of his own for introducing it….*

Laddie J in Brugger v Medicaid [1996] RPC 635 at 649, having referred to the preceding case quoted above, said:

> *The warning in STEP v Emson cited above has particular relevance here. If the patentee has chosen to define the characterizing part of his claim in narrow terms it is not for the court to rewrite it in broader language simply because it thinks a wider form of wording would have been easy to formulate.*

Even adopting a purposive construction, one cannot write words into a claim that are not there or give a meaning to a term of a claim that is contrary to its language. A caution against blurring the purposive construction approach and the re-writing of a claim was given by Graham J in Rotocorp International v Genbourne [1982] FSR 241 at 255:

> *The authorities establish that if it is clear from the description and claims as a whole that a particular feature is claimed as and must be regarded as essential to the invention, then that is an end of the matter. Either the defendant has taken it or he has not and accordingly he has infringed or not as the case may be.* ”

Coming back to the present case, as I understand the law, upon construction of the claims in the Braun Patent, the Terumo Product will have to be compared to see if it has all the essential integers of the claim. Moreover, the plaintiffs must show that the Terumo Product falls squarely within the claims of the Braun Patent. Unless the Terumo Product contains all the integers of the claim, there is no infringement. To constitute infringement the Terumo Product must take each and every one of the

essentials integers of the claims of the Braun Patent. (see: **Rodi & Wienenberger AG v Henry Showell [1969] RPC 367**).

It is common ground between the parties that Claim 1 is the only independent claim of the Braun Patent. Hence, for there to be any infringement of the Braun Patent, this court must be satisfied that the Terumo Product has all of the features or integers of Claim 1.

It is also common ground between the parties that the following are the 5 features or integers of Claim 1 of the Braun Patent:

1. "… the needle guard has two resilient arms (122,124)."

2. "the needle guard (120) having a rear wall (126) from which the arms (122,124) extend in a distal direction."

3. "the needle guard (120) has two resilient arms (122, 124) which are urged away from each other by said needle shaft in the ready position, each arm being provided at the distal end with a distal guard wall (130)

positioned on the shaft of the needle (16) in the ready position."

4. "Provided with an increased diameter in relation to the needle tip", "… increased diameter segment."

5. "… Wherein an inner wall of the chamber of the catheter hub (26) is provided with a retaining means in the form of an annular groove (136) by which the needle guard is retained in the catheter hub in the ready position."

It is the contention of the defendants that the Terumo Product does not have the features or integers of Claim 1. The defendants' case is that it is not just one feature which is absent but a series of essential features are absent in the Terumo Product. That being so, the plaintiffs' infringement action must fail.

On the other hand, it is the contention of the plaintiffs that each and every feature of Claim 1 of the Braun Patent is found in

the Terumo Product. Hence, according to the plaintiff, the Terumo Product falls within the scope of, and thus infringes, Claim 1 of the Braun Patent.

The critical question then arises: whether the Terumo Product meets all of the features or integers of Claim 1 and therefore infringes the plaintiffs' Braun Patent.

Now, I have read and reviewed in detail the testimonies of all the witnesses, the exhibits and the submissions of both the parties. After much thought and deliberation, I have come to the conclusion that the following 3 essential features in Claim 1 of the Braun Patent are absent in the Terumo Product.

1. Feature 1: "… the needle guard has two resilient arms (122, 124)."

2. Feature 2: "the needle guard (120) having a rear wall (126) from which the arms (122, 124) extend in a distal direction."

3. Feature 4: "… provided with an increased diameter in relation to the needle tip". "… increased diameter segment."

My reasons for so deciding are as follows:

Feature 1

It is beyond dispute that the features of Claim 1 of the Braun Patent include that the "needle guard (120) has two resilient arms". In this regard, it is common ground that in the Terumo Product, the elongated arm is resilient and forms one of the 2 arms of the needle guards. The issue then is whether the other arm, that is, the upper arm T3 satisfies the requirement of being the other resilient arm of the needle guard of the Terumo Product. It is the contention of the defendants that arm T3 is not resilient but functions as a rigid component. I agree with this contention.

DW4 was called by the defendants as an expert witness to testify on what resiliency means and whether the Terumo Product has the feature of two resilient arms. He is a Professor of the

University of Texas and has been the Chair of the Mechanical Engineering Department since 2001. DW4 has extensive experience teaching, reasoning and working in disciplines that are relevant to his testimony given before this court.

He explained that a resilient structure is a structure that stores energy due to elastic strain energy. A structure is resilient if it bends or changes shape in response to the force being exerted on it and springs back to its original position or shape after the force is removed. DW4 explained that just because a structure is a bent shape or moves does not mean that it is resilient. For a structure to be resilient, it must change its shape elastically due to a load and return to its original shape when the load is removed. Just because a structure is made from stainless steel or any other material from which springs can be made does not make it a resilient structure. DW4 said that a person of ordinary skill in the art would understand that such an assumption is not always well founded. In contrast, rigid bodies do not store elastic energy. A structure that retains its shape in response to a force being exerted on it is a rigid body although it

may move in other ways due to force being exerted on it, e.g., to rotate or translate. DW4 explained that for a thing to move or function, it must have energy. Without energy, it cannot function. According to DW4, the same goes for the safety device of the Braun Patent: it must have energy to function. He also explained that when the Braun Patent states that the arms are resilient, it identifies to a person of ordinary skill in the art that the arms are where the functional energy is stored to enable the safety device to operate. This is because it is a basic principle of mechanical engineering that a resilient structure is a structure that stores energy due to elastic strain energy.

An ordinarily skilled person in the art would therefore understand that “resilient” arm in Claim 1 identifies a particular characteristic of the claimed arm. It identifies that the arm be functionally resilient or springs back rather than be functionally rigid and maintaining its shape throughout its operation.

As explained by DW4, it is not possible to determine if a thing is resilient or otherwise by just looking at it. Just because a

thing looks flexible or bendy does not necessarily mean that it functions as a resilient structure. To confirm if a thing or structure is resilient, it is necessary to conduct experiments, preferably controlled experiments, based on how the thing is going to be used in operation.

DW4 conducted 4 tests for the purposes of determining if Arm (T3) of the Terumo Product is a resilient or rigid structure. In conducting his analysis and testing, DW4 used basic and well established engineering principles.

When Tests 1 and 2 were conducted and the needle was withdrawn to transition it from the ready to the blocking position, DW4 found the structures in the Terumo safety device moved as follows:

a. The Arm (T3) remained straight as it moves inward to the blocking position. It therefore functions as a rigid component; and

b. The Distal Wall (T2) and the Extension (T1) function as resilient components which allow for the inward movement of the Arm (T3).

These movements of the structures in the Terumo safety device demonstrated:

a. the Arm (T3) functions as a rigid body and component and not resilient; and

b. The inward movement of the Arm (T3) results from the resiliency in the Distal Wall (T2) and Extension (T1) and is not the result of resiliency in the Arm (T3).

DW4 then conducted Test 3 which was a load test. A simulated load was created by deflecting the protective plastic cover radially outward to a distance similar to the position of the plastic cover when the needle is in the ready position. The deflection was repeated multiple times. DW4 observed that the Arm (T3) remained straight during the load test and that the bottom edge of the plastic protective cover remained straight and

substantially fixed in relation to the edge of the Arm (T3). These demonstrated that the Terumo safety device operates due to resilience in the Distal Wall (T2) and the Extension (T1) and that the Arm (T3) functions as a rigid component.

DW4 also conducted Test 4 which was designed to isolate the various structures in the Terumo safety device to further confirm which structures function as rigid bodies and which function as resilient bodies. The result of Test 4 proves that no functional energy is stored in the Arm (T3). Because there is no functional energy stored in the Arm (T3), it did not move. Rather, the elastic energy is stored in the Distal Wall (T2) and the Extension (T1) and possibly some amount in the Rear Wall. The Arm (T3) could not perform its function as a tip protector if it had to rely on its own elastic energy. There is little or no elastic energy stored in the Arm (T3).

DW4 was cross-examined at length by learned counsel for the plaintiffs. His evidence was severely criticized as unreliable and lack integrity. In this regard, the arguments of learned

counsel for the plaintiffs can be summarized as follows. DW4's protocol was flawed as Tests 1 to 4 were carried out with the plastic component part in place. The images of Test 1 are unclear. Arm (T3) in Test 2 is bowed in the ready position. Because there is a gap between Arm T3 and the straight bottom edge of the plastic component in the ready position and no gap in the blocking position, then, Arm T3 must necessarily be bowed to begin with and thus, it is evidence of the inherent resiliency of Arm T3. The plastic component part has no effect on Arm T3. The movement of the plastic component is caused by the deflection of Arm T3 and not gravity. The Elongated Jaw does not affect Arm T3. Test 4 was "staged" and manipulated to produce the desired results.

In countering these arguments, learned counsel for the defendants pointed out that DW4 has given a very extensive and comprehensive explanation in court regarding the 4 tests he had carried out as can be seen in the notes of proceedings. Learned counsel strongly urged this court to accept the evidence of DW4.

I have carefully scrutinized DW4 evidence, in particular his evidence under demanding and grueling cross examination by learned counsel for the plaintiffs. In my judgment, DW4 is a qualified and experience expert in material analysis. He is a person with practical knowledge in this field. The evidence on which DW4 was called to testify is based on him being a person skilled in the art of the field on material analysis. In my view, DW4 has a sound understanding on the concept and theory of resiliency. So far as the evidence goes, I accept that DW4 had used a very scientific approach in conducting the 4 tests. In my view, his evidence is not successfully contradicted by the plaintiffs' expert witnesses, namely PW1 and PW2. I find myself quite unable to accept the plaintiffs' contention that Tests 1 to 4 carried out by DW4 lack integrity. The plaintiffs' attempts to discredit Tests 1 to 4 have been disproved by DW4 in his extensive and comprehensive explanation and elucidation in court. His evidence is meticulous and plausible. The evidence of DW4 is compelling and there is certainty in his demeanour.

DW4 found the results of Tests 1 to 4 to consistently prove that the Arm (T3) functions as a rigid component; and the release of the stored elastic energy in the resilient components of the Distal Wall (T2) and the Extension (T1) allow the Arm (T3) to move from the ready to the blocking position. According to DW4, the fact that the Arm (T3) moves due to the resiliency of the Distal Wall (T2) and the Extension (T1) does not mean that the Arm (T3) can be characterized as resilient. Arm (T3) is not resilient because there is little or no elastic energy stored in it. I am satisfied that the 4 tests were properly conducted by DW4. I find DW4's evidence to be credible and convincing. I therefore accept his findings as true and accurate.

Furthermore, the evidence of DW2 is consistent with the results of DW4's tests. DW2 is an engineer by profession. DW2 started working for the 1st defendant in 1986 and since then, he has continuously worked on the development and improvement of medical devices. DW2 is the lead inventor of the Terumo Product. He would therefore know the Terumo Product very well including if any particular structure functions as a rigid or resilient

structure. DW2 had also explained that Arm (T3] functions as a rigid structure. When suggested by the plaintiffs' learned counsel that Arm (T3) is resilient, DW2 was categorical in that Arm (T3) is rigid.

I turn next to the plaintiffs' contention that the resilient arm need not be inherently resilient. Now, the wording of Claim 1 of the Braun Patent is clear and unambiguous. It says "…the needle guard has two resilient arms (122, 124)". In the face of this, the plaintiffs urged this court to give it a wide construction so that Claim 1 covers not only inherently resilient arms but also arms which are not resilient but which derive resiliency from another part of the guard, namely the hinged arrangement (125). I am unable to accept this contention.

The plaintiffs contend that "the needle guard has two resilient arms" in Claim 1 is to be broadly construed to also encompass arms which are rigid but which moves due to energy derived from the hinged arrangement. However, nowhere in the plaintiffs' Braun Patent discloses or teaches this to the notional

addressee. There is no mention anywhere of elastic energy being stored in the hinged arrangement or that rigid arms are to move from stored energy in the hinged arrangement. From what is disclosed by the Braun Patent, there is no means by which the notional addressee would understand or be able to appreciate that the arms may be rigid and that the movement of the rigid arms from ready to blocking position will be from elastic energy stored in the hinged arrangement. The teaching the Braun Patent is that the hinged arrangement is a way or joining the resilient arms to the rear wall.

In my judgment, this broad construction urged by the plaintiffs goes against the principles of purposive construction already clearly established by case law. Such an approach would give the plaintiffs a monopoly broader than is intended by law including monopoly to inventions which do not benefit from the Braun Patent but which achieve the same function or purpose as the features of Claim 1 of the said Patent.

In **Kirin-Amgen Inc and others v Hoechst Marion Roussel [2005] 1 AER 667**, the House of Lords held:

> *"Purposive construction does not mean that one is extending or going beyond the definition of the technical matter for which the patentee seeks protection in the claims. The question is always what the person skilled in the art would have understood the patentee to be using the language of the claim to mean. And for this purpose, the language he has chosen is usually of critical importance."*

In **Bean Innovations Pte Ltd and Anor v Flexon Pte Ltd [2001]2 SLR 116**, the Singapore Court of Appeal said:

> "*We should add that the well-known principle that patent claims are to be given a purposive construction does not mean that the court in construing a claim is entitled to disregard the clear and unambiguous words used to describe the essential features of a claim."*
>
> *"Even adopting a purposive construction, one cannot write words into a claim that are not there or give a meaning to a term of a claim that is contrary to its language. A caution against blurring the purposive*

construction approach and the re-writing of a claim was given in Rotocorp International v Gen bourne [1982] FSR 241 at 255:

> *The authorities establish that if it is clear from the description and the claims as a whole that a particular feature is claimed as and must be regarded as essential to the invention, then that is the end of the matter. Either the defendant has taken it or he has not and accordingly he has infringed or not as the case may be."*

In **Free World Trust v Electro Sante Inc. & Ors [2000] 2 S.C.R 1024**, the inventor claimed Infringement by the respondents' device which brings together different components but achieves a comparable result. The Superior Court of Canada rejected the claim and ruled:

> *" I conclude that the appellant's arguments must be rejected. As stated the ingenuity of the patent lies not in the Identification of a desirable result but in leaching one particular means to achieve it. The claims cannot be stretched to allow the patentee to monopolize anything that achieves the desirable result. It is not legitimate, for example, to obtain a patent for a particular method that grows hair on bald men and thereafter claim that anything that grows hair on bald men infringes. "*

For all these reasons, on the facts of the present case, I therefore conclude by saying that in respect of feature 1, the Terumo safety device does not have the feature of two resilient arms as required by Claim 1 of the Braun Patent. The plaintiffs' case that the Arm (T3) comes within Claim 1 is not established. Indeed, Arm (T3) is not resilient and functions as a rigid component.

Feature 2:

Claim I of the Braun Patent states that "the needle guard (120) having a rear wall (126) from which the arms (122, 124) extend in a distal direction".

In my view, the wordings of the claim are such that there must be a direct connection between the rear wall and the arms. In my view, there is no question here of words bearing any exclusive or unusual meaning. While the plaintiffs emphasized the phrase "in a distal direction", one cannot disregard or overlook the words "from which" in Claim 1, which to my mind requires that the arms extend from the rear wall. The court is

not entitled to disregard the clear and unambiguous words used to describe the essential features of a claim. What is not claimed is disclaimed. There is no justification to depart from the unambiguous and grammatical meaning of the claim in question for the purpose of widening the boundaries of the monopoly fixed by the plain words of the claim in the plaintiffs' Braun Patent (see: **Electrical and Musical Industries Ltd v Lissen [1939] 56 RPC 23**).

It cannot be disputed that in the Terumo safety device, the Elongated Jaw is a separate piece and does not extend from the Rear Wall. It is connected to the Arm (73) via flanges formed at one end of the Elongated Jaw. The Arm (T3) also does not extend from the Rear Wall but is connected to the Rear Wall via the Distal Wall (T2) and the Extension (T1). Accordingly, the Elongated Jaw and the Arm (T3) are not arms which have the above feature of Claim 1.

Feature 4

It is important to note that the “increased diameter segment in Claim 1 is in relation to a needle and a needle shaft.

In this regard, it is an established principle that claims are to be construed in the context of the specification as a whole and in light of any admissible evidence (see: **Catnic Components Limited v Hill & Smith Limited [1982] RPC 183**).

A needle shaft has a circular cross-section. In its context of a needle or needle shaft, the word “diameter” in Claim 1 would mean a straight line that passes through the centre of a circle. In Figures 1A and 1B of the Braun Patent, the “increased diameter segment” is also shown to be a bulge with a circular cross-section.

The needle of the Terumo Product has a flattened section. A flattened section does not have a circular cross-section and thus, would not be an “increased diameter segment” within the context or meaning of Claim 1.

Hence, in my view, the Terumo Product does not have the feature of an increased diameter segment.

To conclude, the Terumo Product does not have the features or integers of Claim 1. It is not just one feature but 3 essential features are absent in the Terumo Product. Accordingly, the plaintiffs' infringement action must fail.

It is to be noted that Claims 2 to 7 of the Braun Patent are dependent claims. They are dependent directly or indirectly on Claim 1. Claims 2 to 7 have all of the features of Claim 1 plus the additional feature(s) as identified in each of the respective Claims 2 to 7. Since the Terumo Product does not have all the features or integers of Claim 1, it therefore follows from that there can be no infringement of any of the dependent Claims 2 to 7.

Conclusion

Therefore, to sum it up, my judgment is follows:

a. I allow the plaintiffs' claim for a declaration that the Braun Patent is valid. The rest of the plaintiffs' claim is dismissed.

b. I allow the defendants' counterclaim for a declaration that the 1st defendant's Terumo Product does not infringe and does not come within the claims of the plaintiffs' Braun Patent. The rest of the defendants' counter claim is dismissed.

c. Each party to bear their own costs.

t.t.

(DATO' AZAHAR BIN MOHAMED)
Judge of High Court Malaya
Kuala Lumpur.

29 July 2011.

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