IN THE HIGH COURT OF MALAYA AT KUALA LUMPUR

(COMMERCIAL DIVISION)

SUIT NO.D – 22IP – 46 - 2009

BETWEEN

1. SANOFI-AVENTIS (MALAYSIA) SDN. BHD.
   (Formerly known as Aventis Farma SA (Malaysia Sdn. Bhd.)

2. AVENTIS-PHARMA SA ...PLAINTIFFS

AND

1. FRESENIUS KABI (MALAYSIA) SDN. BHD.
   (Company No. 535495-W)

2. FRESENIUS KABI ONCOLOGY LIMITED
   (Formerly known as Dabur Pharma Ltd) ... DEFENDANTS

GROUNDS OF JUDGMENT

Introduction

1. This action involves a Malaysian Patent MY-118481-A ("the Aventis Patent"). The suit here is by the plaintiffs against the defendants for allegedly infringing the 1st plaintiffs.

2. The plaintiffs' claim is disputed by the defendants. The defendants have also filed a counterclaim that the Aventis Patent is invalid for lack of novelty and/or inventive step pursuant to section 56(2) (a) of the Patent Act 1983 ("The Act").

3. The plaintiffs seek declarations in respect of the alleged in infringements, delivery up of all the defendants' product and damages.

4. The defendants' (Dabur) patent has also been the subject of proceedings in Thailand and Philippines.

The parties

5. The 2nd plaintiff holds the patent rights and other intellectual property rights in the TAXOTERE® products. The 1st plaintiff is at all material times the exclusive licensee of the 2nd plaintiff in respect of the TAXOTERE® product in Malaysia and the registrant of the marketing approval for TAXOTERE® in Malaysia.

6. The 2nd plaintiff patented a process for the manufacture of docetaxel trihydrate in Malaysia under Malaysian Patent No MY-118481-A ("MY'481A Patent"). The filing date of the Aventis Patent is 6.7.1995, and the claimed priority date for this patent is 8.7.1994.

7. This case involves a pharmaceutical process patent. Docetaxel trihydrate is the active ingredient in the drug Taxotere which is used in the treatment of cancer.

8. The 2nd defendant manufactures, in India, a drug called DAXOTEL which it exports to Malaysia. In Malaysia, the 1st defendant is the marketing authorization holder for DAXOTEL.

9. From October 2005 or thereabouts, the 2nd defendant had, through its agent, been importing the product DAXOTEL into Malaysia for distribution and sale; and marketing, distributing, offering for sale and selling DAXOTEL in Malaysia.

10. At the material time, the marketing authorization of the drug DAXOTEL was held by the 2nd defendant's agent, Rohibul Sabri bin Abas.

11. Subsequently, Dabur Pharma Limited was acquired by the 2nd defendant herein and that the marketing authorization of the drug DAXOTEL was transferred to the 1st defendant herein.

The Present Action

12. The Aventis Patent claims, *inter alia*, the process for the preparation of docetaxel trihydrate which comprises crystallizing docetaxel from a mixture of water and an aliphatic alcohol containing 1 to 3 carbon atoms, and then drying the product obtained under defined conditions of temperature, pressure and humidity.

13. The active ingredient in DAXOTEL is also docetaxel trihydrate. This is undisputed and is admitted by the defendants themselves at paragraph 21 of the Defence and counterclaim.

14. The plaintiffs had previously, in Suit No. D5(D1)-22-317-2006 and based upon the Aventis Patent, obtained an interlocutory injunction against the 2nd defendant's predecessor, Dabur Pharma Ltd, and one Rohibul Sabri bin Abas in September 2006 which prohibited them from marketing and distributing DAXOTEL **[see Aventis Farma SA (M) v Rohibul Sabri bin Abbas @ Megat & Anor [2008] 3 MLJ 451].** Upon the acquisition of Dabur Pharma Ltd by the 2nd defendant herein in 2009, the previous suit was discontinued and the present suit commenced. By consent, the parties in the present suit are now bound by the same injunction order.

15. The defendants in this present case claim that they use a process as disclosed in the Dabur US Patent (US Patent No6,838,569 B2). The plaintiffs' claim is that the Dabur Process falls within the scope of the claims of the Aventis Patent, and therefore infringes.

16. At the outset, I wish to state that this has been a difficult case involving a great deal of detailed technical evidence, a lot of documentary evidence and much legal argument. I am most grateful to learned counsels for the plaintiffs and the defendants for their most helpful submissions. I also appreciate the way in which counsels involved prepared the evidence and organized matters during the hearing.

The witnesses

17. The expert evidence in this case was extensive in terms of quantity and impressive in terms of quality. The witnesses were experts in the technical and legal fields.

18. The hearing of these proceedings lasted for seven (7) days, during which I heard evidence from a number of expert witnesses in the scientific and legal fields relating to a number of different issues of facts and expert opinion.

19. The plaintiffs called three (3) expert witnesses :

(1) Martin Howe, QC (PW1)

Martin Howe is an English barrister who was appointed Queen's Counsel (QC) in 1996. He practices in the field of patents and other intellectual property and related fields in the Chambers of Mark Platts-Mills QC which is the specialist of intellectual property chambers in the United Kingdom. Martin Howe QC was called as a legal expert on the UK patent law. His evidence pertained to the UK law on claim construction and he gave an overview of the legal approach the English Courts may take in construing a claim such as that in the present suit.

(2) Professor Yuen Kah Hay (PW2)

Professor Yuen currently is a professor at the School of Pharmaceutical Sciences, University Sains Malaysia (USM) and a research and development consultant with Hovid Bhd, a local public listed pharmaceutical company. PW2 appeared as an expert witness. The purpose of his evidence was to assist the court by providing evidence on how a person skilled in the art would read and understand the specification of the Aventis

Patent and the technical understanding which that skilled reader would bring to the features of the claims. PW2 gave evidence on the technical issues behind the invention of the Aventis Patent, and the effect of the Dabur Process. He also considered the relevant prior art and gave his opinion on the issue of validity (novelty and inventive step).

(3) Timothy Holbrook (PW3)

Timothy Holbrook is a professor of US patent law. His evidence was offered to assist the court in understanding that a grant of the Dabur US Patent is not significant or relevant to the present question of infringement as matters of patentability and infringement are distinct under US patent law.

20. The defendants called six (6) witnesses :

(1) Professor Kevin Burgess (DW1)

Professor Burgess is called as a technical expert witness by the defendants. Currently he is a professor of Chemistry at Texas

University with specialization in synthetic organic chemistry. He gave evidence on, *inter alia,* the various properties of acetonitrile as compared to ethanol, and of the Dabur Process as compared to the claims of the Aventis Patent. DW1 carried out experiments in the second defendant's laboratory in April 2010 in India relating to the Dabur process for the purposes of these proceedings.

(2) George Hamer (DW2)

George Hamer is an English barrister practicing in the field of Intellectual Property and is now working in the Chambers of Thomas Blanco White, Q.C. which is the specialist of intellectual property chambers in the United Kingdom. DW2 was offered by the defendants as an expert of UK law. His evidence relates to the issues of infringement and invalidity under the U.K. law.

(3) Dale Hoscheit (DW3)

Dale Hoscheit, a US Patent attorney, was offered by the defendants to address the issue of the grant of the Dabur US Patent. DW3 said that patentability and infringement issues were not related. He also confirms that a subsequently granted US Patent may still infringe an earlier US Patent.

(4) Pratthrawat Nakaranuruck (DW4)

Pratthawat Nakaranuruck is a Thai lawyer who was called by the defendants to present the Thai Judgment, and to comment on the Thai Opposition Proceedings.

(5) Dr Ramanathan Sankaran (DW5)

Dr Sankaran is the Vice President of Intellectual Property Management of the second defendant company. His evidence introduced the various patent registrations of the defendants, and established that the defendants practice the Dabur process as disclosed by the Dabur US Patent.

(6) Pulak Sarkar (DW6)

Pulak Sarkar is the Manager of Quality Assurance at the plant of the second defendant company in India. He was called to tender the Batch Manufacturing Records and to give evidence on the contents of the same. He testified that there has been no change in the Dabur Process from 2005 to now and explained the discrepancies that existed in the Batch Manufacturing Records.

21. The expert witnesses from whom I heard were all very distinguished. I have briefly summarized their respective careers and have not gone into their many distinguished posts, the very substantial number of publications in journals they have published.

22. I find that all of these witnesses are highly respected experts in the fields in which they professed to practice.

23. Equally, there is no attack on the honesty of any of the experts. However it is alleged against DW1 that he was not as impartial as he is required to be by the Civil Procedure Rules 1984. I consider that allegation

to be baseless. I find that in no way his evidence impugns his expertise or honesty. He certainly did not strike me as so partisan as to lead me to conclude that his evidence should be rejected whenever it conflicted with evidence to other way. On the contrary, on some of the issues on which he was in conflict with PW2, I found his evidence more convincing than his.

Issues

24. The agreed issues which have been expressed by the parties are as follows :

(i) whether the defendants use of the process claimed in the Dabur's US Patent No. 6,838,569 B2 infringes the process claimed in the Aventis Patent;

(ii) whether the defendants have infringed (through its predecessor company) or will infringe the Aventis Patent, respectively, through its previous or its potential future importation, marketing, distribution, use, sale and/or offer for sale of DAXOTEL in Malaysia.

(iii) whether the Aventis Patent is valid and subsisting at all material times.

The Law and Infringement

25. As far, I will deal with the issue of infringement of Aventis Patent first before I deal with the issues of validity of the patent. Reported cases suggest that it is more normal to deal with the issue of infringement before validity.

26. One commits patent infringement by, among others, importing a product that is obtained by means of a patented process. This is provided in section 36(3)(a)(ii) read with section 58 of the Act. There is no requirement that the actual use of the patented process should have occurred within Malaysia, and indeed this is unlikely in the case of an act of importation. Prior to being restrained by injunction, defendants had imported DAXOTEL into Malaysia for sale. In the event that DAXOTEL is found to be produced by a process that infringes the Aventis Patent, the defendants would be liable to the plaintiffs for patent infringement.

27. In order to decide on infringement, the court will have to take the following steps:

(a) Construe the claims the Aventis Patent to determine the scope of protection conferred by the patent. To do this it was agreed by both parties in their written submissions that the court will need to consider the 3 Improver questions as in **Improver Corp. v Remington Consumer Products Ltd [1990] FSR 181**; and then

(a) Analyse the defendants' process (the Dabur process) to determine if such process comes within the claims as so construed.

28. In this present case, it is not disputed between the parties that DAXOTEL contains the active ingredient docetaxel trihydrate which is the end product of the process claimed in the Aventis Patent. Thus, section 36(4) set out below gives rise to a statutory presumption that Dabur is using the process as claimed in the Aventis Patent. The defendants bear the burden of proof (on the balance of probabilities) to rebut this

presumption pursuant to section 36(4) of the Act and to convince this Court that they are using a process other than that claimed in the Aventis Patent.

29. Section 36(4) of the Act states:

> *"For the purposes of this section, if the patent has been granted in respect of a process for obtaining a product, the same product produced by a person other than the owner of the patent or his licensee shall, unless the contrary is proved, be taken in any proceedings to have been obtained by that process".*

30. The process referred to in section 36(4) of the Act is the process as claimed in the granted patent, and those claims may contain a number of features. The presumption has the effect that each of the features of the claim is presumed to have been performed in the making of the product unless the contrary is proved. The purpose of this statutory presumption is to deal with a scenario where a patentee is confronted with a product on the market but has no direct means of adducing evidence about the process used to make that product. Information about that process is much more likely to be in the possession of the person dealing with the alleged

infringing product, who either will know how it was made or at least will be in a position to call upon the supplier to provide that information.

31. In applying this presumption it is necessary for the court to address the following questions:

(a) Have the defendants discharged their burden to prove by credible evidence (on the balance of probabilities) what was the process they use to manufacture DAXOTEL, which contains docetaxel trihydrate; and

(b) If the defendants have not discharged this burden, then the defendants infringe.

The Aventis Patent

32. To determine whether a claim of a patent has been infringed one must first discover what is claimed.

33. The Aventis Patent discloses a process to produce docetaxel trihydrate. Docetaxel itself is an antineoplastic agent prepared by semisynthesis beginning with a precursor extracted from the biomass of yew plants. Docetaxel has anti-cancer properties. The docetaxel compound has various forms including hemihydrate, anhydrate and trihydrate. The Aventis Patent is concerned with the trihydrate form of docetaxel, meaning that there are three water molecules for every docetaxel molecule in this form.

34. The claims of the Aventis Patent are found at page 10 of Bundle C.

Claim 1 of the Aventis Patent reads :

" A process for the preparation of [docetaxel] trihydrate which comprises crystallizing [docetaxel] from a mixture of water and an aliphatic alcohol containing 1 to 3 carbon atoms, and then drying the product obtained under defined conditions of temperature, pressure and humidity".

Claims 2 – 5 of the Aventis Patent then read:

Claim 2:

A process according to Claim 1, wherein the water:alcohol weight ratio is about 2:1;

Claim 3:
A process according to Claim 1, wherein the alcohol is ethanol;

Claim 4:
A process according to Claim 1, wherein the drying is performed at a temperature of about 40°c, at a pressure of between 4 and 7 kPa and in an atmosphere having a relative humidity of about 80%.

Claim 5:
A process according to Claim 1, wherein crystallization is performed in the presence of ascorbic acid.

35. In summary, PW2 explained that the Aventis Patent discloses to the skilled reader a practical process by which trihydrate of doxcetaxel can be made, starting from docetaxel which had been purified. An outline of each of the stages of the Aventis process as explained by PW2 is as follows :

Stage A

Purified docetaxel is dissolved in a solvent (The Examples both use ethanol, i.e. C2 alcohol, while the words of Claim 1 considered further below state the solvent to be an alcohol containing 1 – 3 carbon atoms i.e C1-C3 alcohols)

Stage B

Water is then added to the dissolved docetaxel, and docetaxel is recrystallized from this mixture of solvent and water.

Stage C

The product crystallized out is then dried under defined conditions of temperature, pressure and humidity to produce the trihydrate form.

36. Further, PW2 explained that the Aventis Patent discloses to the reader for the first time :

(a) That docetaxel has a trihydrate form;

(b) That the trihydrate form is stable when stored for long periods of time under humid conditions in contrast to the anhydrous form which is unstable under those conditions, and therefore that it is desirable to make the trihydrate form in order to obtain the benefits of long term stability of the drug in storage;

(c) That the trihydrate form can be manufactured in practice if the process steps are used and if drying is carried out in defined conditions.

The Dabur Process

37. As to the second defendant's process for the manufacture of daxotel, the defendants claim that the process used to make DAXOTEL is that contained in the Dabur US Patent. This is further explained in the evidence of DW1 and DW6.

38. The process described in the Detailed Description of the Dabur process reveals three steps:

Step 1

Step 1 involves purifying crude taxane (which includes docetaxel) by adding the crude compound to a mixture of chlorinated alkane, stirring the mixture, filtering the same under vacuum, and repeating again.

Step 2

Step 2 involves purifying further the taxane obtained from Step 1 by dissolving it in alkyl ketone, cooling, filtering, further adding an alkane

and slowly stirring the mixture, filtering further and drying the material under vacuum.

Step 3

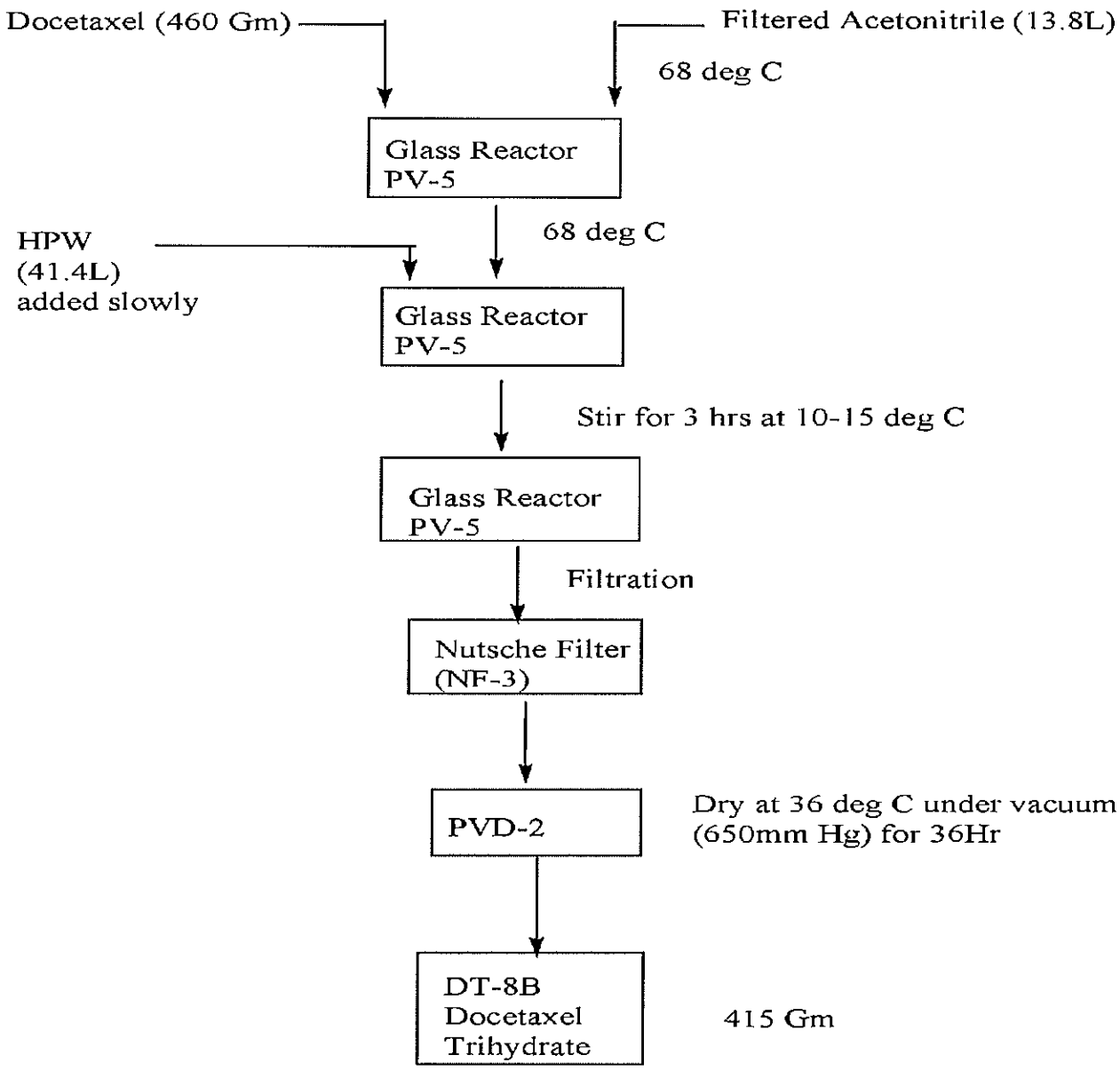
Step 3 states that:

"The taxane obtained in Step 2 is dissolved in an aliphatic nitrile, most preferably acetonitrile... at 50-70°c. To this solution, purified water... is added slowly and then the mixture is stirred further at 10-25°c for 2 – 4 hours. The precipitated material is filtered and then dried at 35-45°c under 650-700 mm mercury vacuum for 36-40 hours with powdering at regular intervals under relative humidity 80-90%."

In relation to Step 3, it is not disputed between the parties that the aliphatic nitrile used in the Dabur Process is acetonitrile.

39. For illustration, a process flow diagram of Step 3 of the Dabur US Patent is produced as follows :

Process Flow Diagram (Fresenius Patent Step 3 of Example II)



40. The plaintiffs contended that step 3 is the stage that corresponds with the process claimed under the Aventis Patent.

General Principles of Patent Construction

41. As emphasized in Simon Thorley et al, Terrel on The Law of Patents (Sweet & Maxwell, 16th Ed, 2006) ("Terrel") at para 6-01, one of the most significant issues in patent litigation is the determination of the true construction of a patent specification, and, in particular, its claim. This is because the monopoly and scope of protection granted by a patent is defined by its claims (see **Electric & Musical Industries Ld v Lissen Ld (1938) 56 RPC 23)**. Once the scope of the claims has been ascertained, the questions of whether the claims are obvious, whether a piece of prior art anticipated the claims and whether there has been an infringement of the patent can then be answered in concrete terms.

42. In ascertaining the true construction of a patent specification, the claims themselves are the principal determinant, while the description and other parts of the specification may assist in the construction of the claims. However, while the claims and the description are to be read together and construed contextually, they are intended to serve different functions. As explained by Laddie J with his customary acuity in **Merck & Co Inc v Generics (UK) Ltd [2004] RPC 31 at [38]** :

> "The purpose of a patent is to convey to the public what the patentee considers to be his invention and what monopoly he has chosen to obtain. These are not necessarily the same. The former is primarily to be found in the specification [ie, the description] and the latter is primarily to be found in the claims."

43. As the necessary background of the words used in the claims may be affected or defined by what is said in the body of the patent specification, the claims should not be viewed independently, but should instead be construed as part of the whole specification (**Rosedale Associated Manufacturers Ld v Carlton Tyre Saving Coy Ld [1960] RPC 59 at 69**). However, it is not permissible to put a gloss on or expand the claims by relying on a statement in the specification. If the claims have a plain meaning, then reliance ought not to be placed on the language used in the body of the specification so as to make them mean something different. Claims must be read and given their ordinary and natural meaning without incorporating extracts from the body of the specification into them.

44. More importantly, the courts have consistently endorsed adopting a "purposive construction" of the claims so as to determine the essential features of an invention. This approach received authoritative judicial affirmation in the seminal decision of the House of Lords in **Catnic**

Components Limited v Hill & Smith Limited [1982] RPC 183, where Lord Diplock said at 242-243:

> *"[A] patent specification is a unilateral statement by the patentee, in words of his own choosing, addressed to those likely to have a practical interest in the subject matter of his invention (i.e. "skilled in the art"), by which he informs them [of] what he claims to be the essential features of the new product or process for which the letters patent grant him monopoly. It is those novel features only that he claims to be essential that constitute the so-called "pith and marrow" of the claim. A patent specification should be given a purposive construction rather than a purely literal one derived from applying to it the kind of meticulous verbal analysis in which lawyers are too often tempted by their training to indulge."*

45. This purposive approach has also been adopted by the court in **Rhone-Poulenc AG Company & Anor v Dilkoride Herbicides Sdn Bhd & Anor [1988] 2 MLJ 323**.

46. The decision in **Catnic** (supra) was reiterated more recently in **Kirin-Amgen Inc v Hoechst Marion Roussel Ltd [2005] RPC 9** ("**Kirin-Amgen**") as constituting the bedrock of all patent construction. Lord Hoffman elaborated on this principle at [32] as follows :

Construction, whether of a patent or any other document, is of course not directly concerned with what the author meant to say. There is no window into the mind of the patentee or the author of any other document. Construction is objective in the sense that it is concerned with what a reasonable person to whom the utterance was addressed would have understood the author to be using the words to mean. Notice, however, that it is not, as is sometimes said, "the meaning of the words the author used", but rather what the notional addressee would have understood the author to mean by using those words. The meaning of the words is a matter of convention, governed by rules, which can be found in dictionaries and grammars. What the author would have been understood to mean by using those words is not simply a matter of rules. It is highly sensitive to the context of, and background to, the particular utterance. It depends not only upon the words the author has chosen but also upon the identity of the audience he is taken to have been addressing and the knowledge and assumptions which one attributes tot hat audience.

47. In **Kirin-Amgen** (supra), the House of Lords define the meaning of purposive construction as follows :

"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. The conventions of word meaning and syntax enable to express our meanings with great accuracy and subtlety and the skilled man will ordinarily assume that the patentee has chosen his language accordingly. As a number of judges have pointed out, the specification is a unilateral document in words of the patentee's own choosing. Furthermore, the words will usually have been chosen upon skilled advice. The specification is not a document inter rusticos for which broad allowances must be made. On the other hand, it must be recognized that the patentee is trying to describe something which at any rate in his opinion, is new; which has not existed before and of which there may be no generally accepted definition. There will be occasions upon which it will be obvious to the skilled man that the patentee must in some respect have departed from convential use of language or included in his description of the invention some element which he did not mean to be essential. But one would not expect that to happen very often."

48. There are three (3) concepts which arise in relation to the issues of patent constructions that an explanation of these concepts is necessary in better understanding how the court would consider these issues. I now turn to discuss these concepts.

The notional skilled person with common general knowledge of the art

49. As I have mentioned above, before the court can decide on the issue of infringement, the Court must embark on an exercise of construction of the patent specification and claims of the Aventis Patent to determine its scope. In doing so, the concept of the notional skilled addressee is central.

50. As stated above, the "audience" whom the patentee is addressing is the person skilled in the art (per Lord Hoffman in **Kirin-Amgen**(supra). As a general rule, the notional skilled person should be taken to be the workman or technician who is aware of everything encompassed in the state of the art and who has the skill to make routine workshop developments, but not to exercise inventive ingenuity or think laterally (per Laddie J in **Pfizer Ltd's Patent [2001] FSR 16** at [62]-[63]. His level of skill will depend on the scope of the subject matter of the patent in question (see **Dyson Appliances Ltd v Hoover Ltd [2001] RPC 26** ("**Dyson v Hoover**"). The notional skilled person is, thus, usually defined according to the qualities which he possesses. As stated in **McGhan**

Medical UK Limited v Nagor Limited Case No CH 1999 1720 (28 February 2001) :

> "This notional person is deemed to posses the common general knowledge of the subject matter in question. It is through the eyes of the skilled addressee that the patent will fall to be interpreted. And it is by the standards of this person that the question of inventive step is to be judged when this topic is addressed in the counterclaim.
>
> A patent is addressed to persons who are likely to have a practical interest in its subject matter or to act on the directions given in it for it to be put into practice. The addressee is deemed to be unimaginative and uninventive but is equipped nevertheless with a reasonable degree of intelligence and with a wish to make the directions in the patent work."

51. The relevant art and the field in which the notional skilled person operates should also be apparent from the patent specification itself (see Terrel (supra) at para 6-32). In the present case, the field of the Invention was stated in the Patent Specification as :

> *" A process for the preparation of [docetaxel] trihydrate which comprises crystallizing [docetaxel] from a mixture of water and an aliphatic alcohol*

containing 1 to 3 carbon atoms, and then drying the product obtained under defined conditions of temperature, pressure and humidity".

52. Aventis contended that PW2 is the appropriate person skilled in the art. I have perused PW2's CV and notes that he may have some knowledge of drug production as a pharmacist but he is not an organic chemist which even PW1 states is the person skilled in the art in this present case. On the contrary DW1 is a Professor in organic chemistry and is therefore more familiar with what happens when an organic solvent is used. It appears for me that from the patent specification, that it would be more appropriate to define the notional skilled person as an organic chemist who had possessed the common general knowledge of the working of solvent chemical.

53. In my view, DW1 job function as a scientist in organic chemistry field provides him with the skill and knowledge of testing chemical solvents and analyses how the solvent works. I take the view that DW1 represents a person skill in the art on matters relating to the issues in the present case. He also has the practical knowledge and experience in the subject matter of the invention in question. He investigated the potential infringement of

claim 1 of the patent in India. Thus, I am clear in my mind that the relevant person skilled in the art in this case would be an organic chemist.

Common general knowledge

54. The skilled addressee is treated as informed with 'common general knowledge', and the extent of this common general knowledge has been discussed in a number of cases. In particular, I would refer to **Beloit Technologies Inc v Valmet Paper Machinery Inc [1997] RPC 489** at page 494 and **Raychem Corp's Patents [1999] RPC 497** at page 503. In the latter case, Laddie J said :

> *"The common general knowledge ... is not limited to material [the nation addressee] has memorized and has at the front of his mind. It includes all that material in the field he is working in which he knows exists, which he would refer to as a matter of course if he cannot remember it and which he understands is generally regarded as sufficiently reliable to use as a foundation for further work or to help understand the pleaded prior art. This does not mean that everything on the shelf which is capable of being referred to without difficulty is common general knowledge nor does it mean that every word in a common text book is either. In the case of*

standard text books, it is likely that all or most of the main text will be common general knowledge'.

55. In the former case, Aldous LJ said [1997] RPC 489 at 494) :

"It has never been easy to differentiate between common general knowledge and that which is known by some. It has become particularly difficult with the modern ability to circulate and retrieve information. ... The national skilled addressee is the ordinary man who may not have the advantages that some employees of large companies may have. The information in a patent specification is addressed to such a man and must contain sufficient details for him to understand and apply the invention .....

It follows that evidence that a fact is known or even well-known to a witness does not establish that fact forms part of the common general knowledge. Neither does it follow that it will form part of the common general knowledge if it recorded in a document."

56. While the patent is to be construed through the eyes of a person (or team of persons) appropriately skilled in the relevant art (or arts), construction is ultimately a matter for the court (see **Lubrizol Corp v Esso**

Petroleum Co. Ltd [1998] RPC 727 at 738 per Aldous LJ). Expert evidence will often be of assistance. **Lubrizol Corp** case was followed by Azahar J (now JCA) in **Ranbaxy Malaysia Sdn Bhd v E.I DU Pont De Numours and Company [2011] 1 LNS 16** and **Kendek Industry Sdn Bhd v Ecotherm (TFT) Sdn Bhd [2010] 2 CLJ 219**).

Prior Art

57. The Prior Art is a term used in section 14 (2) of the Malaysian Patents Act to define what material is taken into account in considering whether an invention is "novel". Novelty is one of the three requirements for an invention to be patentable as provided by Section 11 of the Act, the other two being the requirement of an inventive step and industrial applicability.

58. Section 14(2) provides:

> *14(2) Prior art shall consist of -*
>
> *(a) everything disclosed to the public, anywhere in the world, by written publication by oral disclosure, by use or in any other way, prior to the priority date of the patent application claiming the invention;*

(b) the contents of a domestic patent application having an earlier priority date than the patent application referred to in paragraph (a) to the extent that such contents are included in the patent granted on the basis of the said domestic patent application.

59. The corresponding provisions in s.2 of the United Kingdom Patents Act 1977 are closely similar. They use the term "the state of the art" rather than "prior art", the term "prior art" being of more general application as used in the UK :

2(2) The state of the art in the case of an invention shall be taken to comprise all matter (whether a product, a process, information about either, or anything else) which has at any time before the priority date of that invention been made available to the public (whether in the United Kingdom or elsewhere) by written or oral description, by use or in any other way."

2(3) The state of the art in the case of an invention to which an application for a patent or a patent relates shall be taken also to comprise matter contained in an application for another patent which was published on or after the priority date of that invention, if the following conditions are satisfied, that is to say –

(a) that matter was contained in the application for that other patent both as filed and as published; and

(b) the priority date of that matter is earlier than that of the invention.

60. It is to be noted that the provisions of the two Acts are effectively the same in defining what is the "prior art"/"state of the art". For the purposes of considering "novelty" it covers both material which would have been available to the skilled addressee and also material contained within unpublished pending patent applications. For the purposes of considering "inventive step" the "prior art"/"state of the art" is limited to material which would have been available to the skilled addressee: unpublished pending patent applications are not to be taken into account.

61. The "priority date" of the Aventis Patent is 8 July 1994, based upon a first filing of an application in France. Malaysia, in common with most countries of the world, permits an applicant for a patent in Malaysia to claim priority under the Paris Convention based on the date when the applicant filed a corresponding application in his home country. The Malaysian national application was filed on 6 July 1995 within the permissible 12

month time limit from the first foreign filing in France and is accordingly entitled to the priority date of 8 July 1994 (this has not been disputed by the defendants).

62. The priority date of a patent is a very significant date. It is the date at which the validity of the patent is considered against the prior art available at that date, and more generally the teaching and the contribution to the art made by a patent is to be considered in the light of the common general knowledge of the skilled reader and the available prior art as of that date.

63. Accordingly, for the purposes of this judgment, not only the Colin Patent, but also Holton Patent form part of the prior art in relation to the issue of novelty and the issue of inventive step.

Whether the relevant date for considering patent infringement is the priority date (the publication date) or the date of publication.

64. It is pertinent to note that while the Act provides the priority date for the purpose of invalidity, it did not state what is the relevant date of the prior art for the purpose of assessing patent infringement. In the course of

oral submissions, this issue was rectified by the parties for the court's determination.

65. Relying on the House of Lords decision in **Catnics**' case (supra) and **Improver** case (supra), the plaintiff argued that the relevant date as which to assess infringement is the date of the Aventis Patent publication (1995). Thus, the plaintiffs argued that the Chi Patent, which was published before the date of publication of the Aventis Patent is relevant and should be considered by this court.

66. In this regard, the plaintiffs contended that the Chi Patent shows that :

1. The use of acetonitrile in relation to docetaxel was not new and was already known;

2. It was already known by the industry and the person skilled in the art that acetonitrile, like ethanol, could dissolve docetaxel and that when water was added to the solution, a hydrate form would crystallize out;

3. The Chi Patent suggests that acetonitrile could be used in place of ethanol/C-1C3 alcohol in relation to the process disclosed in the Aventis Patent (or its European equivalent);

4. In any event, the Chi Patent makes it obvious that acetonitrile can be used in place of ethanol/C1-C3 alcohol in the Aventis process.

67. On the contrary, the defendants submitted that in assessing the patent claims, the priority date is to be taken as the relevant date and the Chi Patent which is published after the priority date should not be considered by this court.

68. To answer this question, I refer to the opinion of the plaintiffs' legal expert PW1 and I have carefully perused the notes of proceedings and find that PW1 has stated in his evidence that the relevant date for construing the claims of the patent whether for the purpose of assessing validity or for the purpose of assessing infringement is the same i.e the priority date and

not the publication date which some of the authorities under the old U.K law under the UK Patents Act 1949 suggested.

69. Further, the court finds that PW1 testified that the Durand Patent which was published after the priority date is not relevant for any purpose whether as prior art on invalidity or for the purpose of interpreting the patent in suit. He further clarified that the proper approach is the priority date as clarified by **Biogem v Mediva [1997] RPC 1.**

70. The Encyclopedia of United Kingdom and European Patent Law at paragraphs 3-323 which was referred to by the defendants state that the recent decision of **Kirin-Amgen Inc. v Roche Diagnostics GMBH [2002] RPC 1** seems to make it clear that the patent should be construed at the priority date.

71. Thus, the court finds that there is no common sense in the plaintiffs' arguments that the priority date is only relevant for the issue of invalidity and the publication date should be applicable for the construction of the patent infringement. According to **Bennion on Statutory Interpretation** (fifth edition at page 552), a certain amount of common sense must be

applied in construing statutes. In deed common sense is a quality frequently called for in law generally (see Lord Lane CJ in **R v Rennie [1982] 1 WLR 64** referred to in Bennion).

72. Thus, based on the above reasons, I am of the view that the relevant date for the construction of the patent infringement is the priority date and therefore the Chi Patent is inapplicable and is not relevant.

Interpretation of the Aventis Patent

73. Next, I will deal with the interpretation of the Aventis Patent. It is not disputed between the parties that the invention in the Aventis Patent is the process of obtaining of docetaxel trihydrate by the crystallization of docetaxel from a mixture of water and an aliphatic alcohol containing 1 to 3 carbon atoms followed by drying the product under defined conditions of temperature, pressure and humidity.

74. I shall now deal with the argument of learned counsel for the defendants that using **Catnic's** case, there is no infringement by

defendants of the Aventis Patent. His submission can be summarized as follows:

Step	**Process as claimed in Claim 1 of the Aventis Patent**	**Defendants' Contention**
The Dissolving Step	Docetaxel is dissolved in an **aliphatic alcohol containing 1- 3 carbon atoms**	Docetaxel is dissolved in **acetonitrile**
The Crystallisation Step	Water is added to the dissolved docetaxel, and docetaxel is crystallised from this mixture	Water is added to the dissolved docetaxel, but the docetaxel is **"precipitated"** out. It is not disputed however that the product obtained is crystals
The Drying Step	The product obtained is dried under defined conditions of temperature, pressure and humidity	It is not disputed that temperature and pressure is controlled in the Dabur Process. The Defendants however contend that humidity is not *controlled* in the Dabur Process

75. Further, learned counsel for the defendants submitted that a skilled reader being an organic chemist reading the specification of the Aventis Patent and seeing that the examples and data in the patent specification only relating to methanol being a C2 alcohol and seeing that the claim had

in fact expanded the class of solvents claimed to C1 to C3 alcohols would take it that the patentee here has limited their claim to C1 to C3 alcohols as the patentee has deliberately defined the claim by setting out the solvents that would work. The defendants also argued that there is no issue of the word in the claim being ambiguous and neither do the specifications show anything that will point to the organic solvent to be anything other than a C1 to C3 alcohol.

76. It was pointed out by learned counsel for the defendants that the patentee here did not say "alcohols" or "solvents that would work" or "any organic solvent". The claim very clearly put the limits as to the class of solvents to C1 to C3 alcohols.

77. Learned counsel for the defendants relied on the case of **Merck & Co Inc v Generics (UK) Ltd [2004] RPC 31 (MH 14) (GH 2)** where it was stated at the headnote page 611 :

> "*The wording of the specification is so clear and there is no dispute as to the meaning of the technical terms or esoteric about the chemistry referred to in the specification. In those circumstances, the construction of the patent did not require expert evidence. There was no need for evidence to answer the question*

whether the notional reader would be reasonably confident that the patentee intended to cover the expanded process.

The reader of the patent is entitled to assume that the patentee thought at the time of the specification that he had a good reason for limiting the monopoly to methanesulfonic acid and intended to do so. In those circumstances, to widen out protection was not an act of fairness to the patentee, nor did it give reasonable certainty to third parties"

78. The defendants further submitted that this falls within what Lord Diplock held in **Catnic** where he held (page 243 of the Report) that giving a purposive construction is :

"*whether persons with practical knowledge and experience of the kind of work in which the invention was intended to be used, would understand that strict compliance with a particular descriptive word or phrase appearing in the claim was intended by the patentee to be an essential requirement of that invention so that any variant would fall outside the monopoly claimed, even though it could have no effect on the way the invention worked.*"

79. In this present case, based on the authorities which I have mentioned above, the court must consider the meanings of the chemical terms used in the specification in the light of the expert evidence given by the chemist. In relation to this, the court finds that it has never been contended by either party that there is any dispute over the wording of the specification or as to the meaning of aliphatic alcohol containing 1 to 3 carbon atoms.

80. Both PW2 and DW1 agreed that an alcohol is an organic compound which must contain a hydroxyl group (-OH).

81. Based on the evidence adduced by the parties, the court notes that the three common alcohols clearly falling within the requirement of "an aliphatic alcohol containing 1 to 3 carbon atoms" are methanol CH_3-OH, ethanol CH_3CH_2-OH and 1-propanol $CH_3CH_2CH_2$-OH.

82. Acetonitrile is CH_3CN. It has a cyanide group (-CN), but no alcohol group (-OH) at all. Thus, I am of the view that any chemist would understand a reference to an "alcohol" not to include acetonitrile: its composition is nothing like that of an alcohol, which must have a hydroxyl (-OH) group.

83. To my mind, the wording of the specification and the claims are clear. There is no suggestion that either contain any ambiguities. There is no dispute as to the meaning of technical terms.

84. However, that does not automatically mean that the defendants do not infringe. As it is clear from the discussion in **American Home Product Corp v Novartis Pharmaceuticals UK Ltd [2000] 1 pc 71308**, it is then necessary for the court to pose itself the question characterized by Hoffmann J in **Improver Ltd** (supra). Basing himself on the reasoning of the House of Lords, in **Catnic** Case, Hoffmann J said that the proper approach is as follows :

> *"If the issue was whether a feature embodied in an alleged infringement which fell outside the primary, literal or acontextual meaning of a descriptive word or phrase in the claim ("a variant") was nevertheless within its language as properly interpreted, the court should ask itself the following three questions :*
>
> 1. *Does the variant have a material effect upon the way the invention works? If yes, the variant is outside the claim. If no-*

2. *Would this (i.e. that the variant had no material effect) have been obvious at the date of publication of the patent to a reader skilled in the art? If no, the variant is outside the claim. If yes, -*

3. *Would the reader skilled in the art nevertheless have understood from the language of the claim that the patentee intended that strict compliance with the primary meaning was an essential requirement of the invention. If yes, the variant is outside the claim."*

He added:

On the other hand, a negative answer to the last question would lead to the conclusion that the patentee was intending the word or phrase to have not literal but a figurative meaning (the figure being a form of synecdoche or metonymy) denoting a class of things which include the variant and the literal meaning, the latter being perhaps the most perfect, best-known or striking example of the class."

Improver Questions

85. In **Kirin-Amgen,** the House of Lords has stated that the test may not always be helpful, it has been common ground by the plaintiffs' legal expert witness PW1 and the defendants' legal expert witness DW2 that the test as set out in the **Improver** case would be appropriate to be applied in the present case.

86. In this present case, the fundamental issue that arises is whether the Dabur Process infringe claim 1 of the Aventis Patent. To answer this question, I turn to the 3 Improver Questions, bearing always in mind that they are no more than aids to assist the court to arrive at the proper purposive construction.

First Improver Question – Does the variant have a material effect upon the way the invention works?

87. I now turn to assess the first question. The first question is whether the variant has a material effect upon the way in which the invention works. If it has, the natural assumption is that the variant is not embraced within the patented invention. As I have mentioned, the Aventis process, which is the invention, works on the following premise:

> Docetaxel is dissolved by C1-C3 alcohols. Water is then introduced to the solution to crystallized docetaxel trihydrate, and drying of the crystals is performed under defined conditions of temperature, pressure and humidity.

88. The plaintiffs contended that the Dabur process replicates the Aventis process, save for the use of acetonitrile as a solvent. The material question is whether the use of acetonitrile has any material effect on the way the invention works.

89. In support of its claims that the use of acetonitrile has no effect on the way the invention works, the plaintiffs relied on the evidence of PW2. In this regard, PW2 testified that there are no differences in the way the Aventis and the Dabur processes work based on the following reasons :

(a) Both the processes used organics solvent to dissolve docetaxel;

(b) The solvents do not react with docetaxel;

(c) The solvents are miscible with water;

(d) Miscibility with water is necessary to allow water to be present in the solvent system;

(e) Water has to be present for trihydrate crystals to be formed;

(f) The solvents are not present inside the crystal lattices of docetaxel trihydrate; in other words, both C1-C3 alcohols

and acetonitrile do not prevent water of crystallization from being incorporated into the lattices;

(g) C1-C3 alcohols between themselves have similar properties;

(h) C1-C3 alcohols between themselves also have properties that differ from one another;

(i) The properties that are different (in C1-C3 alcohols) do not play a role in the Aventis process. What is more significant will be the properties that are similar, and these similar properties are those that play a role in the Aventis process.

(j) The similar properties that play a role in the Aventis process allow C1-C3 alcohols to:

1. Dissolve docetaxel;
2. Be miscible with water;
3. Not react with docetaxel;

(k) Acetonitrile also has properties that are similar with, and different from the properties of C1-C3 alcohols;

(l) The properties that are different from C1-C3 alcohols have no material effect on the Aventis process;

(m) The properties of acetonitrile that have a material effect on the Aventis process are within the range of C1-C3 alcohols, e.g the solubility parameter, which the most important feature of the solvents in the process.

90. On the contrary, the defendants submitted that acetonitrile does not work in the same way as it dissolves docetaxel differently. The defendants pointed out that for instance, its hydrogen bonding characteristics enable it to H-bond only to acidic hydrogens in the docetaxel molecule whereas C1 to C3 alcohols will bond with both the oxygen and acidic hydrogen molecules showing the acetonitrile works in a different way than C1 to C3 alcohols. In this regard, the defendant relied on the evidence of DW1 in support of its contention that acetonitrile have a variant effect upon the way the invention works.

91. The issue which then arises for consideration is that although the Aventis Patent is prior art, the person skilled in the art would need to be able to know based on that prior art that the use of acetonitrile would be able to recrystallize docetaxel trihydrate from docetaxel and water.

92. In this regards, DW1 has given evidence that what may be produced could be an oil and amorphous solid or crystal, and if it is a crystal whether the form of the crystal is the desired solvated form of docetaxel trihydrate would be unknown by a person skilled in the art unless he does the experiment and discovers this for himself as was done by Fresenius/Dabur.

93. On this issue, the court finds that even PW2 in his evidence agreed that as a matter of scientific principle one cannot know the solvent molecule of crystallization when a new solvent system is used. In accord with this, even Aventis' own literature states that "modification of the solvent of crystallisation may result in different solvated forms". Therefore, I am of the view that a person skilled in the art even with the knowledge of the Aventis Patent would not know that docetaxel trihydrate will form.

94. On the characteristics of the respective solvents, it was accepted by the experts on both sides that there are similarities in the properties between C1 to C3 alcohols but there are also significant differences. DW1 opinion is that the differences are more significant than the similarities. However what is not disputed is that all the individual properties of the respective solvents act together and so they are not exactly the same

which in fact goes to support the scientific fact that the modification of the solvent may affect what crystal if any is produced. In my view, this must be so, as it is not disputed between the parties that acetonitrile and C1 – C3 alcohols are different solvents.

95. Therefore in my judgment it would have been obvious to a person skilled in the art that the use of acetonitrile (being the variant) would have a material effect on the invention and so there is no infringement.

96. It must be emphasised that DW1 explained that acetonitrile is a different solvent to C1 – C3 alcohols, as based on the various properties such as the different hydrogen bonding characteristics, dipole moment, dilelectric constant, acidity in terms of pKa values and C1 to C3 alcohols being polar protic solvents whereas acetonitrile being polar aprotic solvents, melting points, auto ignition temperature and different azeotropic conditions. DW1 also testified that these factors are to be taken together like a soccer team and so when the new solvent is used you would never know how it would work.

97. Thus, the conclusion that can be drawn is that difference solvents work in different ways, the fact that when a new solvent is used this uncertainty may manifest itself in whether a crystal is formed or when a crystal is formed the conditions on which they can be formed which can be seen when acetonitrile was used.

98. Further, based on the evidence adduced by the parties, the court finds that crystallization is made to occur under different conditions when C1 to C3 alcohols are used and when acetonitrile is used. Therefore since the solvents are different the conditions must be different. Since acetonitrile is not a C1 to C3 alcohol the differences in conditions will emerge in ways that are unpredictable.

99. On the allegation of the plaintiffs that DW1 only compared acetonitrile to ethanol, DW1 explained that he did so as examples were given only for ethanol in the Aventis Patent. He then gave his analysis for the range of solvents to address PW2's comments. Thus, the court accepts the defendants' argument that it is therefore absurd for Aventis to characterize DW1 testimony as being selective when he selected ethanol as the example as this was in fact pre-determined by the Aventis Patent. It was

not as if DW1 chose to compare acetonitrile with methanol when the Aventis Patent only gave examples from ethanol or chose some characteristics from ethanol and some from another C1 to C3 alcohol when comparing different characteristics. So the comparison was in fact driven by the Aventis Patent and there is no issue of choosing ethanol because it was more favourable.

100. As to the issue of solubility parameter raised by plaintiff, DW1 pointed out that the article quoted by Aventis stated that "The total solubility parameter is made up of three partial or component cohesive interactions namely: dipole-dipole, polar and hydrogen bonding interactions". The evidence has shown that in fact acetonitrile is dipole, polarity, and hydrogen bonding characteristics that are outside the range of C1 – C3 alcohols. It follows that the solubility parameter should also be outside the range of C1 – C3 alcohols.

101. I must emphasize that Aventis could not produce a single reference to support the assertion that any other organic compounds like docetaxel trihydrate would crystallize with the same solvent molecules of crystallization from ethanol/water and from acetonitrile/water. Neither did

they produce a single example where an organic compound (similar to docetaxel trihydrate) crystallized with the same solvent molecules of crystallization from ethanol and from acetonitrile. DW1 searched this, presented the most pertinent references he was able to find in the literature.

Precipitation vs. crystallization

102. With respect to the issue of whether the Dabur process is precipitation or crystallization, DW1 has given evidence that the fast production of crystals is precipitation and the slow production is crystallization. He pointed out that what is referred to is the process and not the end result as contended by the plaintiffs.

103. As to the meaning of precipitation, the defendants referred to 'Sohnel and Garside' at page 42 paragraph 1 of P3 what states "It is best to think of precipitation as embodying a fast crystallization".

104. The mere fact the Dabur Patent describes and uses the word crystallization is not relevant as it has been conceded by Aventis that what is relevant is the comparison of the Aventis Patent with the actual process.

105. In this regards, DW1 explained in detail in his testimony that the point at which crystals precipitated in the Dabur process was a sudden, rapid event:

> *"what I have extracted here are what, in my view, are the key six minutes at the stage where the workers at Fresenius are adding water to the acetonitrile solution. I want you to bear in mind that I have said before that most crystallisations act in the following way:*
>
> *you add the water, and you obtain a clear solution, and then you cool it down and you wait for a long period, and gradually the crystals of the product will form. But the Dabur process, now the Fresenius process, is dramatically different and I think it's different in an exciting way, and you can see it on this video. May I approach my computer to switch on?*
>
> *What we see here is first of all the clear solution of acetonitrile at first and then we can just make out, I think, the water being added to the solution, and as the water hits the solution of acetonitrile, then the local*

concentration of water is quite high. So, temporarily, just for a second,you see the precipitates start to form. As the stirring proceeds and everything equilibrates, then the docetaxel trihydrate redissolves until we reach a point where there's enough water in the solution where the docetaxel trihydrate is no longer soluble and it precipitates out, and you see it going more and more cloudy here, we are reaching that point. And then, quite dramatically I think, it's going to go white and you can see the crystals form in the solution. There we go. It's cloudy now and you can see the crystals form very suddenly when you get to that proportion of ethanol and acetonitrile. I think over a period of 20 seconds you can see the difference between the clear solution and the cloudy one because the crystals are now rattling around in that flask. So the process goes on and the researchers at Fresenius would add more water to squeeze as much docetaxel trihydrate out of the solution as they possibly could, but the conclusion is clear; it happens very, very suddenly that the crystals form."

106. Further, based on the evidence adduced by the parties, the court finds that there is no evidence to show that the Dabur Process comes within the defined conditions of temperature, pressure and humidity as claimed in the Aventis Patent.

107. One other further difference between the Aventis Patent and the Dabur process is the presence of ascorbic acid. The Aventis patent states that "it may be advantageous to perform the crystallization in the present of ascorbic acid" (column 2, lines 23-25). On the other hand, the Dabur Patent does not use ascorbic acid.

108. Thus, based on the above reasons, in my judgment the variant involved in the Dabur process have a material effect on the way the invention works.

2nd Improver Questions - would it have been obvious to a man skilled in the art at the relevant date that the variant would work in the same way

109. I now turn to the 2nd question. The issue is whether in this case it would be obvious to the skilled person at the priority date that substitutes acetonitrile for C1-C3 alcohol would have no material effect on the way the Aventis invention works.

110. In **Improver**, Hoffmann J emphasized that this question did not involve limiting possible infringement to a variant 'which would have suggested itself to the skilled man as an obvious alternative to the thing denoted by the literal meaning'. He went on to say :

> *"In my view the question supposes that the skilled man is told of both the invention and the variant and asked whether the variant would obviously work in the same way. An affirmative answer would not be inconsistent with the variant being an inventive step."*

111. The defendants contended that the answer to the 2nd question is no because the reader of the Aventis Patent, skilled in the art as at the priority date, would not know that the solvent employed by the Dabur would work, he would not know that it would have no material effect upon the way in which the invention in the Aventis would work. Thus, learned counsel for the defendants pointed out the evidence of DW1 support the view that a person skilled in the art as at priority date would not know that the invention would work. According to DW1 different solvents have different properties and most importantly one cannot predict what will form when a different solvent is used as it may be an oil, amorphon substance or crystal and

even it is in the form of crystal different solvent molecules of crystallization may form.

112. On the contrary, learned counsel for the plaintiffs contended that it would be obvious to a reader skilled in the art that acetonitrile would not have a material effect on the way the invention work in the Aventis Patent. The plaintiffs relied on the evidence of PW2 to support its contention.

113. The comparison of the solvent properties of acetonitrile and C1 to C3 alcohols had been dealt above. However, in considering whether the variant had a material effect would have been obvious to a skilled reader would mean the differences between the solvents as discussed above would be considered by the skilled reader in the present case and the issue of whether he thought that because of the differences or similarities the invention are obvious are to be taken into account.

114. I have carefully considered the submissions of learned counsel for the plaintiffs and found it very attractive. However with regrets I am unable to accept his submissions. First and foremost, in my view, it is not obvious

to the skilled reader at the priority date that the use of acetonitrile would not have a material effect on the way the invention works.

115. I take this view based on the evidence above on differences and similarities in the properties of the solvent, the skilled reader knowing that the solvents had different properties would not obviously know that acetonitrile would work.

116. In addition, as I have mentioned above, PW2 and DW1 agreed that it cannot be predicted by the use of the new solvent that docetaxel trihydrate crystals would form without the experimentation and the conditions for it to work being discovered.

117. The basic scientific principles which were agreed to by PW2 and Aventis own reference in "Physicochemical Principles of Pharmacy by AT Florence and D Attwood (Exhibit P8) which states at page 26, Modification of the solvent of crystallization may result in different solvated forms". All this supports the fact that when a new solvent is used it is not obvious what would be the crystal formed (if in fact a crystal is formed). Against this the

courts only have PW2's bare statement without any support from science or references that he is able to predict.

118. Based on the evidence of DW1, it is my view that his evidence has enlightened this court on the technical and scientific properties of alcohol vis-à-vis acetonitrile used in the description of the Aventis Patent and the Dabur Process and on the common general knowledge of the art relating to the issue to be determined by the court. His evidence has gone to establish that even though acetonitrile does have 3 characters in common with C1 to C3 alcohols, but one cannot predict to salvation in the crystals or the solvent molecules of crystallization until you carry out an experiment.

119. In view of the above, I am of the opinion that the answer to the 2nd Improver Question is that it would not be obvious to a skilled person that acetonitrile has no material effect on the way the Aventis invention works, (or in other words to put the statement without the double negative, it would be obvious to a skilled reader that acetonitrile has a material effect on the way the invention works).

3rd Improver Question

120. I now turn to the 3rd question. The issue is whether the reader skilled in the art nevertheless have understood from the language of that claim that the patentee intended that strict compliance with the primary meaning was an essential requirement of the invention. If yes, the variant is outside the claim.

121. Authorities have established that Improver Questions 1 and 2 are primarily questions of fact. Question (3) however is a question of construction for the court itself but in answering this question the Court must have regard to the expert evidence so that it can put itself in the place of the skilled reader of the patent. The question is what the skilled reader would have understood. I set out the views of the rival experts.

122. As I understand it, a central issue in the present case is whether the patentee, by including the phrase 'an aliphatic alcohol containing 1 to 3 carbon atoms', is to be understood as strictly requiring that one of those alcohols must be used as the solvent, or whether the phrase in its context in the Patent is to be understood in a looser sense in which those alcohols

exemplify a wider class of solvents which can be used in place of such an alcohol to achieve the process of the invention.

123. PW2 testified that when he read the Aventis Patent, he took the phrase "C1-C3 alcohols" as intending to include solvents that shared the common properties of C1-C3 alcohols that would allow the invention to work. He did not take the scope of the patent to be limited to only C1-C3 alcohols. He testified that he took this position as the reason the Aventis Patent Claim specifies C1-C3 alcohols and not merely 'alcohol' was to exclude alcohols with a higher carbon atom count, such as butanol, which did not share the similar properties found in the C1-C3 alcohols. In support of his testimonies, PW2 relied on the following facts :

(a) The examples in the patent only speak of ethanol (C2) alcohol. There is no mention of C1 or C3 alcohol. Nonetheless, the claim goes on to expand and to include C1-C3 alcohols. One could see that in expanding out, the patentee was trying to describe a certain class of solvents. The patentee recognized the properties involved and tried to capture this by use of the

phrase C1-C3 alcohols (as opposed to including C4 and C5 alcohols which do not share the same properties required).

(b) C4 and C5 alcohols are excluded even though they share many similar properties to C1-C3 alcohols. This is emphasized by the defendants themselves who have stated that C4 alcohol has more in common with C1-C3 alcohols than acetonitrile has. Why are they excluded? One can only surmise that what is important are the properties that C4 alcohol does not share with C1-C3 alcohols but which C1-C3 alcohols shares amongst themselves. This is what is intended by the Aventis Patent.

124. On the contrary, the defendants submitted that the patentee has his claims to C1 to C3 alcohols and as this can be seen from the evidence that there is nothing in the patent specification to show otherwise. Thus, learned counsel for the defendants argued that it is clear that the reader skilled in the art would understand from the language of the claim that strict compliance was an essential requirement of the invention.

125. In this regard, the defendants contended as follows :

(i) Just from reading the specification of the Aventis Patent it is apparent that the patentee made a clear choice as to the scope of his claim. The patentee did not in claim 1 only claim the use of ethanol (i.e. ethyl alcohol), which was the only organic solvent which is disclosed in the body of the specification to have been used (as can be seen in both examples shown in the specification of the Aventis Patent). Instead, it decided to broaden the scope of the claim to C1 to C3 alcohols. In so doing, the patentee used a word which, to a chemist at least, is an ordinary word of certain scope: "alcohol". It is common ground that an alcohol is an organic compound with contains a hydroxyl group (-OH) and that acetonitrile (which has no such group) is not within the class of "alcohols".

(ii) As a further indication that the patentee considered the width of the claim in relation to the nature of the organic solvent and made a choice to restrict the width of the claim, he also chose to limit the nature of the solvent claimed further, by specifying that the alcohol should be aliphatic

(i.e. the structure of the compound is not in the form of a ring) and should have from one carbon atom (methanol, i.e. methyl alcohol) to 3 carbon atoms (the two forms of propanol, i.e. propyl alcohol). Ethanol (ethyl alcohol) is, of course, an alcohol with 2 carbon atoms, right in the middle of the chosen range.

126. In support of its contention, the defendants referred to the case of **Societe Technique de Pulverisation STEP v Emson [1993] RPC 513 (GH 10)** where the court held the construction exercise "is not an invitation to try and identify the reasons why in point of fact the patentee wrote the claim in the way he did". Further, it was argued that the limitation in the claim is there for a particular purpose that is to allow third parties to safely invent and practice around the invention as it was held in **Beloit v Valment [1995] RPC 705 (GH1)** :

> "... *it must be remembered that it is the patentee who has set out the limits of his monopoly. Moreover, those reading his claims are entitled to see that it has a scope which goes thus far and no further and to design around the patent. There is no such thing as the tort of non-infringement.*"

127. Since it is not disputed between the parties that an alcohol is an organic compound which contains a hydroxyl group (-OH) and that acetonitrile is not within the class of "alcohols", I accept the defendants' argument that Aventis has clearly delineated their limitation here to C1 to C3 alcohols and so the attempt to argue that acetonitrile falls within the Aventis Patent is clearly an attempt to rewrite the claim which cannot be allowed. In **Merck** it was held at page 669 that :

> *"where it was clear that the patentee did not want to obtain protection for particular variants, it was not open to the court to extend the monopoly to cover them. Similarly if a notional skilled addressee could not conclude with reasonable confidence that the inventor wanted a particular embodiment, it had to follow that the patent conveyed the message that the patentee might well have intended to exclude that embodiment".*

128. Construing the claims of the Aventis Patent purposively by reference to the test in **Catnic** and applying the Improver Questions, in my judgment the Dabur Process which uses acetonitrile as the organic solvent and not C1 to C3 alcohols does not infringe the Aventis Patent. Further, the fact that the Dabur Process does not control humidity and has a widely different pressure and is by precipitation and not crystallization also goes to show non-infringement.

129. Hence, my conclusion is that the defendant's process is innovative as experiments needed to be done and the defendant had in fact discovered a new process using acetonitrile to obtain docetaxel trihydrate from docetaxel and water.

Validity

130. The next major issue is whether the Aventis Patent is invalid on the basis of lack of novelty and lack of invention.

131. In gist, the validity of the Aventis Patent is challenged by the defendants on the basis that the claims:

(i) are not novel in that they are anticipated by the publication of Holton, US Patent No. 5229526 entitled "Metal Alkoxides", and the corresponding Malaysian patents i.e. Malaysian Patent No MY-128181-A and MY-109876-A by the Florida State University ("Holton") and therefore do not comply with s.14 of the Patents Act; and

(ii) do not disclose an inventive step (i.e. they are obvious) in the light of the matter disclosed in the Holton Patent and therefore do not comply with s.15 of the Patents Act.

Novelty

132. On this issue, as mentioned above, section 14 of the Act states that a patent is not new if it is 'anticipated' by prior art.

133. First and foremost, it is trite law that where lack of novelty is raised, it must be shown that the claimed invention has been anticipated in a single document. No two or more documents is allowed to be combined or mosaic together. This entrenched principle has been clearly expressed in numerous cases. The learned authors Lionel Bently and Brad Sherman have put it this way in Intellectual Property Law, Second Edition, 2004 at paragraph 3.2.1 of page 449 that:

> *"Another important rule of interpretation is that the information must be drawn from a single document. This means that it is not possible to combine together (or mosaic) separate items in prior art. In a similar vein,*

it is not normally possible to combine elements from within a single document."

134. It is also settled law that for there to be anticipation, there must be an 'enabling disclosure', In **Synthon BV v SmithKline Beecham Plc [2005] UKHL 59 at paragraph 14** , Lord Hoffmann stated that:

> *"In order to make good their case, Synthon had to satisfy the judge on two points. The first was that their application disclosed the invention which had been patented as claim 1. I shall call this requirement 'disclosure'. The second was that an ordinary skilled man would be able to perform the disclosed invention if he attempted to do so by using the disclosed matter and common general knowledge. I shall call this requirement 'enablement'. If both these requirements are satisfied, the invention is not new".*

135. Hence, in order to constitute anticipation, there must not only be a prior disclosure which identifies the subject matter of the patent, but it must also have been disclosed in a way that enables the skilled person to make or obtain it.

136. In relation to the requirement of disclosure, the speech of Lord Westbury in **Hill v Evans (1862) 31 L.J.(N.S.) 457** which was set out by the House of Lords in **Synthon** as follows:

> *"I apprehend the principle is correctly thus expressed: the antecedent statement must be such that a person of ordinary knowledge of the subject would at once perceive, understand and be able practically to apply the discovery without the necessity of making further experiments and gaining further information because the invention can be made useful. If something remains to be ascertained which is necessary for the useful application of the discovery, that affords sufficient room for another valid patent".*

137. The requirement of 'enablement' means that the ordinary skilled person would have been able to perform the invention which satisfies the requirement of disclosure. In the hallmark case **General Tire & Rubber Co v. Firestone Tyre & Rubber Co Ltd [1972] RPC 457**, the requirement of an enabling disclosure was considered in detail. It was held by the English Court of Appeal at 40 of page 485 that:

"If the prior inventor's publication contains a clear description of, or clear instructions to do or make, something that would infringe the patentee's claim if carried out after the grant of the patentee's patent, the patentee's claim will have been shown to lack the necessary novelty, that it to say, it will have been anticipated…

To anticipate the patentee's claim the prior publication must contain clear and unmistakable directions to do what the patentee claims to have invented: Flour Oxidizing Co Ltd v Carr & Co Ltd ((1908) 25 RPC 428 at 457, line 34, approved in B.T.H. Co Ltd v Metropolitan Vickers Electrical Co Ltd (1928) 45 RPC 1 at 24, line 1). A signpost, however clear, upon the road to the patentee's invention will not suffice. The prior inventor must be clearly shown to have planted his flag at the precise destination before the patentee."

138. With the law in mind, I now turn to the defendants' allegation that the Aventis Patent lacks novelty. On the issue of invalidity the onus of proof lies on the defendants **(see Kendek Industry Sdn Bhd v Ecotherm (TFT) Sdn Bhd** (supra). Relying on the evidence of DW1 in summary the defendants submitted as follows :

(i) "Methanol is a C1 alcohol and so the fact Holton recrystalized Taxotere which is the commercial name for docetaxel in general without specifying the form would show that docetaxel trihydrate was formed before the Aventis Patent.

(ii) Following the teaching of the Holton Patent one would produce docetaxel which form was not specified. However the expert witnesses have testified that the product would include docetaxel trihydrate. It does not matter that the patentee at the time did not know the specific form of docetaxel as the inevitable result of the Holton process is now known to produce docetaxel trihydrate."

139. I shall next deal with the various points relied upon by the plaintiffs in support of their case that the Holton Patent is different from the Aventis Patent based on the following grounds :

(i) The Holten Patent does not give any information at all about the conditions under which this recrystallisation occurred, for example there is no information about the ratio of water to methanol, the temperature conditions, the time period over which crystallization was allowed to occur, or even more fundamentally whether crystallization took place as a result of

adding water or by an alternative process such as evaporating off part of the methanol/water solvent system;

(ii) Does not even state in express terms that the crystals were dried. Even if it is accepted that it is implicit that dry crystals were obtained by some means or other, absolutely no information is given about the process by which the crystals were dried or any conditions as to temperature, pressure, humidity or time; and

(iii) Most fundamentally, the Holton Patent does not state that the trihydrate form of docetaxel (taxotere) was obtained.

140. For the reasons which I will give below, with regrets, I reject the arguments of the defendants.

141. It appears to me that between the parties, it is common ground that the Holton Patent does not mention the trihydrate form of docetaxel. In this regards, there is no indication in the Holton Patent whether the

trihydrate form was obtained after crystallization at the end of the process of Example 3.

142. However, DW1 testified even though the Holton Patent does not specifically refer to the trihydrate form, in his opinion, trihydrate crystals were formed. According to him, since the Aventis Patent teaches that docetaxel trihydrate is crystallized from methanol and water, so he see no reason why Holton did not also obtain the trihydrate from this mixture.

143. On this issue, I agree with the plaintiffs' submission that DW1's opinion is clearly based on hindsight. He refers to the Aventis Patent, and because he now knows that the trihydrate form can be crystallized out of a mixture of water and C1-C3 alcohol, he concludes that it was the trihydrate form that was crystallized out of the methanol/ water in the Holton Patent.

144. Based on the evidence adduced by both expert witnesses (PW2 and DW1), to obtain the trihydrate form, the wet material must be dried under certain conditions to ensure whilst the surface residual solvent is removed, the crystals do not lose the water molecules of crystallization.

145. The court finds that it is not disputed by both PW2 and DW1 that the Holton Patent does not specify any conditions for drying. There is no indication as to the temperature, pressure or humidity that is to be used or the time period over which drying occurs. By contrast, the Aventis Patent and the Dabur US Patent do disclose specific range of conditions to be used at the drying stage hence showing that the drying conditions are an important factor in obtaining the trihydrate form.

146. As I have mentioned above, the Aventis Patent discloses a process for producing *docetaxel trihydrate* specifically by dissolving, crystallising out of a mixture of C1-C3 alcohol/ water, and they drying. Although both experts agree that it is possible that a trihydrate form may have appeared during the passing stage when the taxane was recrystallised out of methanol/ water, this is only an intermediate stage. It is not further disputed between the parties that the process is not over yet and the material still has to be dried.

147. Further, both experts have agreed that there are no conditions specified in the Holton Patent for the drying stage. DW1 claims that Holton was 'not stupid' as he puts it, and that he would not have used harsh

conditions to dry the material. On this issue, I accept the plaintiffs' arguments that actually the test is not what Mr. Holton might or might not himself have done, but rather how the notional reader of ordinary skill in the art would put into practice the disclosure of the Holton Patent. It is therefore likely that the skilled reader in implementing this disclosure would use conditions such that it would not have produced a trihydrate, and an anhydrous form would most likely have resulted.

148. Thus, in my view, the person skilled in the art who read the Holton Patent would not be led to perform a process that produces docetaxel trihydrate as there are no conditions specified for either the crystallization or the drying stage. The evidence of both PW2 and DW1 has indicated that drying conditions are important in the formation of the trihydrate form. In the words of the hallmark **General Tire & Rubber Co v. Firestone Tyre & Rubber Co Ltd** (supra) quoted above, there has been no "clear and unmistakable directions", nor is the production of the trihydrate form at the end of the case "inevitable". The last two sentences of the paragraph quoted bears repeating:

"A signpost, however clear, upon the road to the patentee's invention will not suffice. The prior inventor must be clearly shown to have planted his flag at the precise destination before the patentee."

149. It is not disputed that the Holton Patent here has not showed clear instructions that would "inevitably result" in the trihydrate form. Without any indication of the drying conditions, the person skilled in the art would have been left with his own choice of an innumerable set of conditions in which to dry the crystallized material. Any form other than the trihydrate could result. Holton did not 'plant a flag'. The law has shown that a mere 'pointing in the right direction' or a 'signpost' is clearly insufficient to anticipate.

Invention

150. An invention is taken to lack inventive step if it is said to be obvious (section 15 of the Act). The question of inventive step is, simply put, whether a person skilled in the art would find it obvious to arrive at the claimed invention.

151. 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** (supra) as follows:

> *"We agree, however, with what was said by Diplock, L.J. (as he then was) and Willmer, L.J. in the Johns-Manville case [1967] RPC 479 at 493 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"."*

152. 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:

(i) *Firstly, to identify the inventive concept of the claim in question;*

(ii) *Secondly, to identify the notional skilled addressee or person skilled in the art and the relevant common general knowledge of that person;*

(iii) *Thirdly, to identify the differences between the state of the art and the inventive concept of the claimed invention;*

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

153. In identifying the notional skilled addressee or person skilled in the art for purpose of assessing inventive step, it is trite law that such a person is unimaginative and without even a scintilla of inventiveness. On this issue, Azahar J (now JCA) in **SKB Shutters Manufacturing Sdn Bhd v Seng Kong Shutter Industries Sdn Bhd & Anor [2011] 2 MLJ 781** has followed the decision in **Technograph Printed Circuits Ltd v Mills & Rockley (Electronics) Ltd [1972] RPC 346** where at page 795 :

> *"To whom must the invention be obvious? It is not disputed that the hypothetical addressee is a skilled technician who is well acquainted with workshop technique and who has carefully read the relevant literature. He is supposed to have an unlimited capacity to assimilate the contents of, it may be, scores of specifications but to be incapable of a scintilla of invention. 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."*

154. More importantly, the 'person skilled in the art' is essentially a legal role which must and can only be assumed by the court. This has been entrenched in numerous cases and, suffice to say, even in **Windsurfing International Inc v Tabur Marine (Great Britain) Ltd** (supra) at paragraph 45 of page 73:

> *"There are, we think, four steps which require to be taken in answering the jury question. The first is to identify the inventive concept embodied in the patent in suit. Thereafter, the court has to assume the mantle of the normally skilled but unimaginative addressee in the art at the priority date and to impute to him what was, at that date, common general knowledge in the art in question. The third step is to identify what, if any, differences exist between the matter cited as being "known or used" and the alleged invention. Finally, the court has to ask itself whether, viewed without any knowledge of the alleged invention, those differences constitute steps which would have been obvious to the skilled man or whether they require any degree of invention."*
>
> [see **SKB Shutters** case (supra)].

155. DW1 testified that the Holton Patent showed that docetaxel could be crystallized from methanol/ water, and that there could only be four possibilities of what would form.

156. However, as stated above, no conditions for drying are stated in the Holton Patent. The court views that the drying conditions are essential when producing the trihydrate form. If the drying conditions are not suitable, the evidence does not establish that trihydrate form will result.

157. Thus, the court finds that the Aventis Patent was not obvious or lacking in inventive step. Claim 1 of the Aventis Patent is not obvious. Thus, there is no basis for the defendants' counter-claim.

Conclusion

158. For the reasons that I have given, whether the issue of interpretation is viewed as a unitary exercise in identifying proper purposive construction, or whether it is approached through the gateway of the 3 Improver questions, I consider that the claims in the Aventis Patent did not embrace the same process developed by the defendants. Accordingly I find that the

Dabur Process did not infringe the Aventis Patent. Thus, the plaintiff's claim is dismissed with costs. Further, I find that the Aventis Patent is not invalid on the ground of lack of novelty and lack of invention. Hence, the defendant's counter claim is dismissed with costs.

159. With respect to the undertaking to damages, the parties have agreed that damages will be assessed by the court with the plaintiff having the liberty to raise the issue of whether the defendants are entitled to damages during the full period of the injunction.

Hanipah binti Farikullah
Judicial Commissioner
Commercial Court 5

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