Novartis AG and another *v* Ranbaxy (Malaysia) Sdn Bhd
[2012] SGHC 253

Case Number : Suit No 150 of 2011

Decision Date : 28 December 2012

Tribunal/Court : High Court

Coram : Lee Seiu Kin J

Counsel Name(s) : Tony Yeo, D K Rozalynne PG Dato Asmali and Dora Tay (Drew and Napier LLC) for the plaintiff; Daniel Koh (Eldan Law LLP) (instructed) and Andrew Quirk (foreign counsel from Mirandah Law LLP) for the defendant.

Parties : Novartis AG and another — Ranbaxy (Malaysia) Sdn Bhd

Patents and inventions

28 December 2012 Judgment reserved.

Lee Seiu Kin J :

1 This is an application brought by the plaintiffs for leave to amend the claims in Patent No SG120119 ("Patent") pursuant to O 87A r 11(6) of the Rules of Court (Cap 322, R 5, 2006 Rev Ed) and s 83 of the Patents Act (Cap 221, 2005 Rev Ed)("the Act").

Background Facts

2 The first plaintiff, Novartis AG, is the registered proprietor of the Patent, and the second plaintiff is its exclusive licensee. The defendant, Ranbaxy (Malaysia) Sdn Bhd, opposes the application made by the plaintiff.

3 The defendant, a pharmaceutical company, seeks to import for marketing in Singapore products known as Starval Tablets, of various compositions, which relate to the plaintiffs' Patent. The defendant was obliged under s 12A(3)(*a*) of the Medicines Act (Cap 176, 1985 Rev Ed) ("Medicines Act") to serve its applications made to the Health Sciences Authority for product licences on the first plaintiff. The purpose of the notices was to inform the plaintiffs that the products which the defendant intended to import for marketing in Singapore could potentially infringe the plaintiffs' Patent, and that the plaintiffs ought to commence the necessary action before the High Court within 45 days to assert its rights under the Patent and to obtain the necessary relief from the court, failing which the relevant product licences would be granted to the defendant. Shortly after the receipt of the requisite notice, the plaintiffs commenced this suit, asserting, *inter alia*, that if the licences sought were granted, and the defendant's products were imported and marketed in Singapore, the Patent will be infringed. Thus, the plaintiffs seek declarations of infringement with respect to the Patent. The defendant asserts, *inter alia*, in its defence and counterclaim, that the Patent is invalid because the invention it discloses has been anticipated by the prior art. In particular, two pieces of prior art have been relied upon, and they shall be referred to as DA1 and DA2 respectively for the purposes of this judgment.

4 In response, the plaintiffs seek to amend the Patent claims to "enhance clarity, to highlight the inventive contributions of the Patent and to reduce the number of claims" [note: 1], as well as to "further distinguish the claims in [the Patent] from the matter disclosed in the ... references ... cited

by the Defendant in its Defence and Counterclaim and Particulars of Objections". [note: 2]

5 In the application as filed in Singapore, it is stated in the Patent specifications that the invention relates to: [note: 3]

> ... pharmaceutical preparations, which comprise an AT_1 receptor antagonist or an AT_2 receptor modulator, respectively, or a pharmaceutically acceptable salt thereof, for the treatment of conditions or diseases associated with the increase of AT_1 receptors in the sub-epithelial area or increase of AT_2 receptors in the epithelia.

It is also claimed that the invention may be used for the treatment of: [note: 4]

> ... obstructive airways diseases ... chronic obstructive pulmonary disease, such as bronchitis, e.g. chronic bronchitis and emphysema, likewise from asthma, cystic fibrosis, interstitial lung disease, invasive lung and invasive breast cancer, pulmonary vascular disease, and increased resistance to airflow during forced expiration, any such treatment may also be associated with the treatment of hypertension as well as both non-smokers and smokers; for the treatment of specific forms of lung conditions and diseases; for the treatment of adults respiratory distress syndrome (ARDS); for reducing the proliferative capacity of the epithelium invasive cancer, for the treatment of sepsis syndrome, lung injury forms, such as pneumonia, aspiration of gastric content, chest trauma, shock, burns, fat embolia, cardiopulmonary bypass, O_2 toxicity, haemorrhagic pancreatic, interstitial and bronchoalveolar inflammation, proliferation of epithelial and interstitial cells, collagen accumulation, or fibrosis.

6 The proposed amendments are marked up against the claims of the application as filed, as follows [note: 5] :

> 1. A compressed tablet comprising valsartan in free form as the only active agent; and more than 30% of microcrystalline cellulose and 2 to 10% of crospovidone, both by weight based on the total weight of the core components of ~~said~~ the compressed ~~form~~ tablet.
>
> 2 . ~~A~~ The compressed tablet according to claim 1 comprising up to 65% of microcrystalline cellulose.
>
> ~~3. A compressed tablet according to claim 1 or 2 comprising less than 13% of crospovidone.~~
>
> ~~4. A compressed tablet comprising valsartan in free form and microcrystalline cellulose wherein the weight ratio of valsartan to microcrystalline cellulose is from 2.5 : 1 to 0.3 : 1.~~
>
> ~~5~~ 3. ~~A~~ The compressed tablet according to any one of claims 1 to ~~4~~ 2 comprising 20 to 65% of valsartan.
>
> ~~6~~ 4. ~~A~~ The compressed tablet according to any one of claims 1 to ~~5~~ 3 comprising 20 to 360 mg of valsartan.
>
> ~~7~~ 5. A compressed tablet, comprising 20 to 65% of valsartan in free form as the only active agent, by weight based on the total weight of the core components of the compressed tablet, 31 to 65% of microcrystalline cellulose by weight based on the total weight of the core components of the compressed tablet, 2 to 10~~13~~% of crospovidone by weight based on the total weight of the core components of the compressed tablet.

~~8. Use of the solid oral dosage form according to any one of claims 1 to 8 in the manufacture of a medicament for the treatment of conditions or diseases associated with the increase of AT1 receptors in the sub-epithelial area.~~

At the hearing, counsel for the parties agreed that the dispute really relates to whether amendments to claims 1 and 5 are permissible, because the amendments to the other claims as seen above are consequential to those amendments. The following matters are also not disputed:

(a) valsartan is an active agent for which a separate patent subsists;

(b) microcrystalline cellulose is an exigent which, when used in a certain dosage, improves the performance of valsartan as the active agent;

(c) crospovidone is a drug distegrant which will break up the drug inside the human digestive system; and

(d) the Patent relates to how valsartan, a known active agent, is delivered to and absorbed by the human body, and not the compound of valsartan.

The law on amendment of patent claims

Amendment shall not add matter to the patent application as filed

7 Before turning to the issues arising out of the present application, it is necessary to first set out the legal principles which govern the amendment of patent specifications. The plaintiff's application is brought pursuant to s 83(1) of the Act, which provides that:

Amendment of patent in infringement or revocation proceedings

83. —(1) In any proceedings before the court or the Registrar in which the validity of a patent is put in issue, the court or, as the case may be, the Registrar may, subject to section 84, allow the proprietor of the patent to amend the specification of the patent in such manner, and subject to such terms as to the publication and advertisement of the proposed amendment and as to costs, expenses or otherwise, as the court or Registrar thinks fit.

Thus, the court has discretion to grant leave to amend the specifications of a patent. However, such discretion is subject to s 84(3) of the Act, which provides that:

(3) No amendment of the specification of a patent shall be allowed under section 38(1), 81 or 83 if it —

(*a*) results in the specification disclosing any additional matter; or

(*b*) extends the protection conferred by the patent.

For the purposes of the present application, only s 84(3)(*a*) is germane.

8 In determining whether the amendments to a patent's specifications would disclose additional matter, the applicable test is that which has been laid down in the oft-cited case of *Bonzel (T) and anr v Intervention Limited and anr (No 3)* [1991] RPC 553 ("*Bonzel*") at p 574, as follows:

… The task of the Court is threefold:

(1) To ascertain through the eyes of the skilled addressee what is disclosed, both explicitly and implicitly in the application.

(2) To do the same in respect of the patent as granted.

(3) To compare the two disclosures and decide whether any subject matter relevant to the invention has been added whether by deletion or addition. The comparison is *strict* in the sense that subject matter will be added unless such matter is *clearly and unambiguously disclosed in the application either explicitly or implicitly*.

[emphasis added]

The test laid down in *Bonzel* has been endorsed in three local cases, namely, *FE Global Electronics Pte Ltd and others v Trek Technology (Singapore) Pte Ltd and another appeal* [2006] 1 SLR(R) 874 at [24] ("*FE Global*"), *Martek Biosciences Corp v Cargill International Trading Pte Ltd* [2011] 4 SLR 429 ("*Martek*") at [81] and *Main-Line Corporate Holdings Ltd v DBS Bank Ltd* [2012] 4 SLR 147 at [73] ("*Main-Line*"). The *Bonzel* test has been further elaborated upon in a subsequent English case, *European Central Bank v Document Security Systems Incorporated* [2007] EWHC 600 at [97]–[102]:

97. A number of points emerge from [the *Bonzel*] formulation which have a particular bearing on the present case and merit a little elaboration. First, it requires the court to construe both the *original application and specification to determine what they disclose*. For this purpose the claims form part of the disclosure ... though clearly not everything which falls within the scope of the claims is necessarily disclosed.

98. Second, it is the court which must carry out the exercise and it must do so *through the eyes of the skilled addressee*. Such a person will approach the documents with the benefit of the *common general knowledge.*

99. Third, the *two disclosures must be compared to see whether any subject matter relevant to the invention has been added.* This comparison is a strict one. Subject matter will be added unless it is clearly and unambiguously disclosed in the application as filed.

100. Fourth, it is appropriate to consider what has been disclosed both expressly and implicitly. Thus the addition of a reference to that which the skilled person would take for granted does not matter: *DSM NV's Patent* [2001] R.P.C. 25 at [195]-[202]. On the other hand, it is to be emphasised that this is not an obviousness test. A patentee is not permitted to add matter by amendment which would have been obvious to the skilled person from the application.

101. Fifth, the issue is whether subject matter relevant to the invention has been added. In case *G1/93, Advanced Semiconductor Products*, the Enlarged Board of Appeal of the EPO stated (at paragraph [9] of its reasons) that the idea underlying Art. 123(2) is that that an applicant *should not be allowed to improve his position by adding subject matter not disclosed in the application as filed, which would give him an unwarranted advantage and could be damaging to the legal security of third parties relying on the content of the original application.* At paragraph [16] it explained that whether an added feature which limits the scope of protection is contrary to Art 123(2) must be determined from all the circumstances. *If it provides a technical contribution to the subject matter of the claimed invention then it would give an unwarranted advantage to the patentee. If, on the other hand, the feature merely excludes protection for part of the subject*

matter of the claimed invention as covered by the application as filed, the adding of such a feature cannot reasonably be considered to give any unwarranted advantage to the applicant. Nor does it adversely affect the interests of third parties.

102. Sixth, it is important to *avoid hindsight*. Care must be taken to consider the disclosure of the application through the eyes of a skilled person who has not seen the amended specification and consequently does not know what he is looking for. This is particularly important where the subject matter is said to be implicitly disclosed in the original specification.

[emphasis added]

Undue delay on the plaintiff's part in applying for amendment

9 If the amended specifications do not result in the specifications disclosing additional matter, the court has discretion to allow the amendment. In exercising the court's discretion, the court may consider various factors, including whether there was undue delay in taking out an application for leave to amend. In *Smith Kline & French Laboratories Limited v Evans Medical Limited* [1989] 1 FSR 561 ("*Smith Kline*") at 569 (endorsed in Singapore in *FE Global*), the factors to be taken into account by a judge when exercising the discretion to allow or disallow a proposed amendment of a patent were outlined by Aldous J as follows:

(a) whether the patentee has disclosed all the relevant information with regard to the amendments;

(b) whether the amendments are permitted in accordance with the statutory requirements;

(c) whether the patentee delayed in seeking the amendments (and, if so, whether there were reasonable grounds for such delay);

(d) whether the patentee had sought to obtain an unfair advantage from the patent; and

(e) whether the conduct of the patentee discouraged the amendment of the patent.

10 In determining whether the court ought to exercise its discretion against the grant of leave to amend on ground of undue delay, it was held in *Matbro Limited v Michigan (Great Britain) Limited and Another* [1973] RPC 823 at 833, lines 30-34 ("*Matbro*") that:

... mere delay is not, of itself, necessarily sufficient to justify refusal of amendment. There must have been or be likely to be some detriment to the respondents or to the general public caused by such delay before it can be an effective bar to relief.

Thus, where there is undue delay on the part of the plaintiff in applying to amend the patent specifications, the court may decide in the circumstances, to exercise its discretion against the grant of leave to amend. It has been accepted in the local case of *Trek Technology (Singapore) Pte Ltd v FE Global Electronics Pte Ltd and others and other suits* [2005] 3 SLR(R) 389 at [76] – [77], by Lai Kew Chai J, that a patentee ought to act expeditiously from the time he discovers the relevant prior art. The patentee seeking leave to amend must satisfy the court, based on the facts and circumstances, that the patentee acted reasonably and without undue delay. It was held that mere knowledge of some prior art did not mean that the plaintiff ought to amend its patent, but was entitled to take the advice of patent agents on whether amendment was necessary, and if so, the form of amendment required.

11 In exercising the court's discretion, it is imperative to bear in mind the Court of Appeal's remarks on appeal in *FE Global* (see above at [8]) at [31]:

> We agree that the modern context in which patents are registered must be taken into account when considering whether amendments should be allowed. The present practice in Singapore is that skilled examiners examine and scrutinise patent applications and if there is a negative patent examination report, it is in the patent file at the Intellectual Property Office of Singapore and is open for public inspection. Lai J was thus entitled to say at [67] of his judgment that as examination reports are available for public inspection, adverse parties are able to evaluate the validity and strength of patents which have been filed and they are "less likely to be surprised (and consequently prejudiced) by subsequent amendments which may be sought by the patentee, even if this takes place in the course of patent litigation". *As there is little scope for abuse when patent applications for patents are filed nowadays, we agree that a more lenient approach towards amendments is now called for.*
>
> [emphasis added]

The issues raised

12 The issues raised in this application relate to the application of the principles highlighted above at [7]–[11], and they are:

> (a) whether the various amendments to the patent claims as set out above at [6] add matter to the application as filed; and
>
> (b) if the answer to the first issue is in the negative, whether there was undue delay on the part of the plaintiff in taking out the present application which justifies the refusal of leave to amend.

In addressing the first issue, it is necessary to first deal with the preliminary issues which have been raised by both the plaintiffs and the defendant, *viz*, whether the plaintiffs' expert, Professor Geoffrey David Tovey ("Professor Tovey") and defendant's expert, Mr Morten Garberg ("Mr Garberg") are sufficiently qualified to give their opinions as experts.

Whether the amendments to the patent claims add matter to the application as filed

Threshold issue: whether the experts are sufficiently qualified

13 It has been raised as a preliminary issue, that the defendant's expert witness, Mr Garberg, is insufficiently qualified, being a patent agent who has a degree in chemistry but no practical experience in the formulation of tablets. Furthermore, being aged 19 as at the priority date of the Patent, the plaintiffs submitted that Mr Garberg would be ignorant of the prevailing common general knowledge. I understand the objection taken to relate to Mr Garberg's ability to shed light on what a person skilled in the art would understand from the disclosures made by the Patent, and his ability to testify in relation to tablet formulation. The plaintiffs also submitted that due to Mr Garberg's limited practical knowledge, his evidence should either be disregarded completely, or little weight ought to be attached to his evidence. [note: 6]

14 It is trite that evidence may be tendered of expert opinion on matters relating to "scientific, technical or other specialised knowledge" which is likely to assist the court under s 47(1) of the Evidence Act (Cap 97, 1997 Rev Ed) ("EA"), from experts who are persons with "scientific, technical

or other specialised knowledge based on training, study or experience" (see s 47(2) of the EA).

15 In proceedings such as the present, the court may be assisted by expert witnesses who may provide their opinions on the extent of disclosures made to the notional addressee skilled in the art by the patent application as filed, and the patent application as amended. Experts may also assist in informing the court on the common general knowledge which persons skilled in the art would possess as at the priority date of the patent. This is because it is trite that in construing a patent, the court must bear in mind that the notional addressee of a patent is a person skilled in the art. As explained by Aldous LJ in *Lubrizol Corp and another v Esso Petroleum Co Ltd and others* [1998] RPC 727 at 738, lines 25 to 31:

> Patent specifications are intended to be read by persons skilled in the relevant art, but their construction is for the Court. Thus the court must adopt the mantle of the notional skilled addressee and determine, from the language used, what the notional skilled addressee would understand to be the ambit of the claim. To do that it is often necessary for the Court to be informed as to the meaning of technical words and phrases and what was, at the relevant time, the common general knowledge; the knowledge that the notional skilled man would have.

According to Judith Prakash J in *Ng Kok Cheng v Chua Say Tiong* [2001] 2 SLR(R) 326 ("*Ng Kok Cheng*") at [21], a person skilled in the art is by definition someone who:

> (a) possesses common general knowledge of the subject matter in question;
>
> (b) has a practical interest in the subject matter of the patent or is likely to act on the directions given in it; and
>
> (c) whilst unimaginative is reasonably intelligent and wishes to make the directions in the patent work.

"Common general knowledge" has been defined in *British Thomson-Houston Company Ld v Stonebridge Electrical Company Ld* (1916) 33 RPC 166 at 171 line 7 to mean:

> the information which at the date of the Patent in question is common knowledge in the art or science to which the alleged invention relates, so as to be known to duly qualified persons engaged in that art or science …

16 In *Ng Kok Cheng*, it was accepted by one of the witnesses, a patent attorney, that he was not a person who has practical interest in the subject matter, *viz*, the design and making of locks, and therefore could not be considered an expert who can assist in informing the court in relation to a person skilled in the art. Further, in *ASM Assembly Automation Ltd v Aurigin Technology Pte Ltd and others* [2010] 1 SLR 1 (at [6]), it was held by the High Court and accepted by one of the witnesses, that a patent lawyer from an "American intellectual property firm that was responsible for prosecuting [the plaintiff's] United States Patent" could not be considered an expert and that his views were "not relevant to issues pertaining to the views of a person skilled in the art" of design and manufacture of solder ball placing apparatuses. However, the above two cases should not be regarded as stating an immutable rule that patent attorneys are in all cases, incapable of informing the court in relation to the knowledge of a person skilled in the art. In *Main-Line*, Andrew Ang J accepted the evidence of the plaintiff's expert, a qualified patent attorney based in Dublin, Ireland, and has represented and advised the plaintiff on matters relating to its patent since the priority date of the patent. Andrew Ang J also accepted that the defendant's expert, a European and German patent attorney practising in Germany, with a specialisation in intellectual property law, was sufficiently qualified to testify as an

expert witness. On the facts however, his evidence was regarded as unhelpful due to his evasiveness on key issues.

17 In my view, patent attorneys with specialisations in relation to certain types of inventions are capable of assisting the court in relation to the disclosures made in patent specifications, on the construction of the ambit of the claims, and on their experience concerning the relevant art, (see also *V-Pile Technology (Luxembourg) SA and others v Peck Brothers Construction Pte Ltd* [1997] 3 SLR(R) 981 and *Main-Line*). The usefulness of the patent attorney's evidence however depends on the nature of his experience in relation to the relevant art and the nature of the issues raised. Thus, as the defendant has rightly submitted, Mr Garberg's lack of practical experience in tablet formulation does not *per se* mean that Mr Garberg is unable to assist the court, since Mr Garberg can and does comment on matters which relate to his expertise as a patent attorney who often acts for companies relating to pharmaceutical patents in matters before the European Patent Office, and who is capable of learning about the prevailing common general knowledge as at 1998 with some research and study in the course of his work relating to patents for pharmaceutical products. [note: 7] I do not think that it is an immutable rule or a necessary condition that a witness giving an opinion as expert must always have practical experience in the field of the invention. However, as can be seen from the ensuing discussion, due to the nature of the issues raised, Mr Garberg's evidence is at best of limited utility.

18 Interestingly, the defendant in turn alleged that the plaintiffs' expert, Professor Tovey's evidence should also be disregarded as he has no practical experience in relation to whether an amendment to patent would add matter, and has never given expert evidence on a related issue before. The defendant submitted that little weight should be attached to Professor Tovey's evidence as he is unfamiliar with matters relating to patent drafting. This objection can be dismissed swiftly. First, as mentioned above at [15], the task of assessing whether matter will be added by a patent amendment belongs to the court, and that determination may be made with the assistance of experts. Second, Professor Tovey, an expert who has spent more than 35 years working in research and development on a wide range of dosage forms for new molecular entities and product line extensions, is clearly a person skilled in the relevant art, and is in a position to inform the court on what a notional skilled addressee would understand to be the scope of the disclosure of the patent application as originally filed, the scope of the claims in the amended specifications, in the light of prevailing common general knowledge. It is not necessary, in my view, for Professor Tovey to be familiar with the drafting of patents.

Valsartan in free form

19 I turn now to the Patent claims proper. Valsartan in "free form" relates to the existence of valsartan on its own as a compound, and not as a component of a larger compound with another molecule in the form of a salt. [note: 8] In relation to the amendment to claim 5 of the Patent to specify that valsartan is to be free form, the plaintiffs submitted that it is clear from claims 1 to 4 that the invention claimed is expressly stated to relate to valsartan in free form, and such clarity extends to claim 5, which is essentially only a sub-set of claim 1. [note: 9] Furthermore, the application as filed contains examples of the invention which specifies the possible compositions of the product with specified weights of valsartan, *eg*, 80mg. These compositions would be meaningless if the specified weights given were of valsartan in salt form because different types of salts formed with valsartan would contain different amounts of valsartan in free form. [note: 10] As a consequence, a person skilled in the art would find it difficult to follow the examples and arrive at an effective product. Thus, a person skilled in the art would read references to valsartan in the specifications in the application as filed, as disclosing valsartan in free form.

20 The defendant referred to Dr Arvind Kumar Bansal's ("Dr Bansal") opinion in his affidavit that the use in claim 5 of the word "comprising" in making reference to valsartan discloses the teaching of the use of valsartan in the form of a salt. I also understand the defendant's argument to be that since it was not clearly and unambiguously disclosed explicitly that valsartan had to be in free form and could not take the form of a salt, to narrow the claims to specify that valsartan is to be in free form would in and of itself add matter.

21 However, the defendant's argument ignored the fact that the teaching of the use of valsartan in free form has been disclosed in the application as filed. It is true that the specifications do make mention of the possibility of valsartan taking the form of a salt, in the following paragraph [note: 11] :

> WO 97/49394 (the content of which is incorporated herein by reference, especially (but not limited to) the subject matter as claimed) discloses compressed solid oral dosage forms e.g., by compaction of valsartan (optionally in salt form) optionally combined with hydrochlorothiazide (HCTZ). In WO 97/49394 the preferred range of cellulose is given as 10 to 30%, e.g., 21%, for valsartan/HCTZ compositions and 5% Valsartan alone ...

However, from the quotation above, it is apparent that the teaching of valsartan in free form is more than clearly disclosed, amongst the options of valsartan in salt form and combined with hydrochlorothiazide. Furthermore, on a plain reading of claims 1 to 4 in the application as filed, it is clear beyond doubt that the teaching of valsartan in free form has been disclosed. The defendant's own experts did not appear to dispute that these disclosures have been made clearly and unambiguously in claims 1 and 4. [note: 12] The amendment of the claim 5 to specifically remove the possibility of valsartan taking the form of a salt from the ambit of the patent restricts the scope of the invention claimed. This cannot, in my view, amount to added matter, without evidence that the narrowing of claim 5 in the manner sought by the plaintiffs introduces new matter of inventive significance. As the defendant's own expert, Dr Bansal has stated, regardless of whether valsartan takes the form of a salt or free form, the effective amount of valsartan is the only material factor towards the performance of the invention disclosed in the Patent specifications. [note: 13]

Valsartan in free form as the only active agent

22 The plaintiffs argued that the proposed amendments to disclose that valsartan in free form is to be the *only* active agent in claims 1 and 5 have been clearly and unambiguously disclosed in the original specifications which disclose the invention of tablets comprising valsartan as *the* active agent, save for one instance of mention of a substance known as hydrochlorothiazide as a possible active agent. In all of the examples given in the specifications (see for example, below at [29]), only valsartan featured as an active agent, and specific weights of valsartan have been given in the examples, of compositions of the invention, which cannot be meaningful unless references to valsartan are understood as references to valsartan in free form as the only active agent.

23 The defendant submitted that the specifications do not expressly disclose the teaching that valsartan is to be included in free form as the *only* active agent. In particular, claim 1 in the application as filed has disclosed an invention of a compressed tablet *comprising* valsartan and more than 30% of microcrystalline cellulose. The defendant submitted that it is open to a person skilled in the art would interpret the patent specifications, in light of the common general knowledge as at the priority date of the patent, as disclosing an invention *comprising* valsartan as one of many possible active agents. In support, the defendant adduced the evidence of its expert, Dr Bansal, who has spent more than seven years doing research and development on pharmaceutical products. Dr Bansal stated that a person skilled in the art would regard the word "comprises" used in the claims in the

application as originally filed, as open-ended in nature, and therefore admitted the possibility of the inclusion of other active agents. Particularly, Dr Bansal pointed to p 23 of the specifications which claims a monopoly over [note: 14] :

> The invention also provides the use of an AT_1 receptor antagonist or an AT_2 receptor modulator, respectively, *or a pharmaceutically acceptable salt thereof*, for producinq a pharmaceutical preparation for the treatment of conditions or diseases associated with the increase of AT_1 receptors in the sub-epithelial area of increase of AT_2 receptors in the epithelia.
>
> [emphasis added]

Dr Bansal stated that this paragraph is worded in general terms and admit the possibility of various active agents. Mr Garberg and Dr Bansal both also stated that references to "Valsartan drug substance" in examples 7 to 11 of the patent specifications are vague enough to include valsartan in salt form. I understand the defendant's submission to be that the amendment would introduce an inventive concept that is not expressly disclosed in the patent application as filed, *viz*, that valsartan in free form is to be the only active agent, and not any other substance or salt.

24 The defendant also submitted that on the basis of Mr Garberg's first report [note: 15] , the amendment seeks to "extract":

> ... the feature that there are no other active agents than Valsartan present from the examples, and then combining this with more general disclosure from the description. The resulting amended claims are therefore "hybrids" between (i) the specific disclosure of the examples and (ii) the general disclosure of the original claims.

The defendant further relied on Mr Garberg's second report [note: 16] , where he stated that he is "not of the opinion that specific examples can generally be used as a basis to support patent claims at a higher level of generality".

25 The question of whether matter would be added by the amendment is to be answered by the court, having regard to what would be understood by a notional address skilled in the art. The plaintiffs do not dispute that the patent specifications do disclose that valsartan may be used in conjunction with another substance, hydrochlorothiazide, as an active agent, as follows [note: 17] :

> WO 97/49394 (the content of which is incorporated herein by reference, especially (but not limited to) the subject matter as claimed) discloses compressed solid oral dosage forms e.g., by compaction of valsartan (optionally in salt form) optionally combined with hydrochlorothiazide (HCTZ). In WO 97/49394 the preferred range of cellulose is given as 10 to 30%, e.g., 21%, for valsartan/HCTZ compositions and 5% Valsartan alone ...

Parties are also not disputing that the word "comprises" connotes a non-exhaustive list. What parties disagree upon is whether the narrowing of the patent claims to expressly restrict the claim to only that of valsartan as the only active agent adds matter to the claims, in the light of all the disclosures made in the specifications in the application as filed. I am of the view that the teaching of the use of valsartan as *the* active agent, quite apart from hydrochlorothiazide or any other substance, has been clearly and umambiguously from plain reading of the specifications, including the original claims 1 and 5 in the application as filed, and the examples of preferred embodiments of the invention. It is undisputed that the examples listed in the specifications of preferred compositions consisted of

valsartan in free form as the only active agent. [note: 18]

26 Even if the specification admits of the possibility of valsartan being used in conjunction with other active ingredients, I am unable to see how an amendment to limit the scope of the patent claims to claim a monopoly over an invention consisting of valsartan as the only active agent would add matter, as the plaintiffs are clearly restricting the scope of monopoly claimed. There is nothing in the evidence which suggests that the use of only valsartan as an active agent discloses anything new to a person skilled in the art. Thus, I am unable to see how the restriction of claims to free form valsartan as the only active agent adds anything to the disclosure which has already been made.

27 In an analogous case, *Martek*, the court was concerned with an invention of infant formula with a blend of two microbial oils. Prior to this invention, infant formulae contained other types of microbial oils to deliver the desired effects. An application was brought by the plaintiff to amend the patent claims to claim a monopoly over infant formula with a blend of *only* DHA and ARA. This preferred embodiment of the infant formula invention could be found in an example, which describes a composition of oil blend of DHA and ARA. Tay Yong Kwang J held that the amendments would not add matter, because the example had already disclosed an infant formula consisting of a blend of *only* DHA and ARA. Similarly, in the present case, the proposed amendments relate to matter which has already been disclosed in the examples given of preferred embodiments. In the premises, I find that no new matter has been added.

2 to 10% of crospovidone

28 The proposed amendments to claims 1, 3 and 5 would have the effect of limiting the disclosed proportion of crospovidone from 2-13% to 2-10%. The plaintiffs argued that the composition of the invention comprising 2-10% of crospovidone has been clearly and unambiguously disclosed in the patent specifications for the following reasons. The patent specifications specifically give the example of a tablet comprising 2 to 10% of cropovidone, as follows [note: 19] :

> In a further embodiment the solid oral dosage form of the invention comprises less than 13% of crospovidone, e.g., 2 to 10%, by weight based on the total weight of the core components of the solid oral dosage form.

29 Embodiments of the invention containing the proportion of crospovidone of 2 to10% have also been disclosed in the examples 7, 8, 9 and 11 in the application as originally filed. The material portions of the examples with which we are concerned as stated in the specifications are [note: 20] :

> **Formulation Examples from the [Patent]**
>
> NOTE: percentage figures are given first as % core mass (without coating) and second as % total mass (including coating), i.e., (% core/% whole)

Example	Valsartan drug substance(mg)	Micro-crystalline cellulose (mg)	Crospovidone (mg)	Colloidal anhydrous silica (mg)	Magnesium stearate (mg)
7(tablets)	80.00 (51.61% core weight)	54.00 (34.84%)	15.00 (9.68%)	1.50 (0.97%)	3.00 + 1.50 (2.90%)
8(tablets)	160.00 (51.61% core weight)	108.00 (34.84%)	30.00 (9.68%)	3.00 (0.97%)	6.00 + 3.00 (2.90%)

9(tablets)	40.00 (51.61%/49.20%)	27.00 (34.84%/33.21%)	7.50 (9.68%/9.23%)	0.75 (0.97%/0.92%)	1.50 + 0.75 (2.90%/2.77%)
11(tablets)	320.00 (51.61%/50.31%)	216.00 (34.84%/33.96%)	60.00 (9.68%/9.43%)	6.00 (0.97%/0.94%)	12.00 + 6.00 (2.90%/2.83%)

30 The defendant argued that various other portions of the specifications contain contrary teachings in relation to the composition of crospovidone, and thus the teaching of 2 to 10% crospovidone was not clearly and unambiguously disclosed on the face of the application as filed. In particular, examples 1, 2, 3, 4, 5 and 6 given in the specifications are of embodiments which contain more than 10% crospovidone. Hence, it would be unfair to allow the plaintiffs to now select the particular examples which suit their purpose at this stage of the proceedings.

31 Indeed, there are also portions of the specifications which differ in relation to the proportion of crospovidone. The specifications also disclose "the preferred range of [crospovidone] is given as 10 to 20%, *eg* 13%. [note: 21] Proportions of crospovidone in excess of 10% have also been disclosed in examples 1 to 3 and 10, and the claim as amended is not "representative" of the plaintiffs' invention. [note: 22] However, that is not the test which the court has to apply. The test which the court has to apply is whether the amendments would add matter to the disclosure which has already been made of the invention which is the subject of the application as originally filed. At no point did the defendant inform the court as to what exactly is the nature of the added matter which would be added to the disclosure.

32 This amendment would lead to a narrowing, not expansion, of the scope of the patent. The defendant relied on the case of *Merck & Co Inc's Patents* [2004] FSR 16 ("*Merck*"), where it was held that while deletion of portions of the patent claims have the effect of narrowing the scope of invention claimed, such deletion can nevertheless add matter to a patent. Thus, in *Merck*, the patentee claimed a monopoly over a drug for the treatment of urolithiasis and for inhibition of bone re-absorption, which contains 70mg alendronate, to be taken by way of any number of doses. In an application to amend, the plaintiffs sought leave to delete portions of the claim to clarify that the 70mg dose was to be delivered in a single dosage, to avoid anticipation by prior art which was to be administered in 10mg daily doses for the treatment of osteoporosis and 40 mg for the treatment of Paget's disease. The consequence of that amendment was that the inventive significance of the quantity in a single dose for the treatment of particular ailments was disclosed by the amendments, and that constituted the addition of matter to the patent application. In contrast, in the present case, the defendant has not raised any evidence of the added inventive significance resulting from the narrowing of the claim in relation to the percentage composition of crospovidone, such as the better delivery of or absorption by the body of valsartan. I am thus of the view that the narrowing of the scope of claim 5 as well as the amendments to claims 1 and 3 in relation to the percentage of crospovidone do not add any matter.

Whether the combination of teachings would add matter

33 The plaintiffs also argued that the exact combination of various teachings disclosed in the amended claims, have been disclosed in various parts of the specifications, *ie*, the teachings of 20-65% valsartan with 31-65% microcrystalline cellulose and 2-10% crospovidone, and also in various examples, and thus no new matter is added.

34 The defendant submitted that the combination of various teachings disclosed in various parts of the specifications, *eg*, the teaching of the combination of 20-65% valsartan with 31-65%

microcrystalline cellulose and 2-10% crospovidone, while disclosed in examples 7, 8, 9 and 11 of the specifications, were not disclosed clearly and unambiguously in the specifications of the patent application as filed, and thus, if the amendments were allowed, matter would be added. The defendant argued that the amendments to give added significance to this particular combination of components offend the principle against intermediate generalisation, thereby constituting added matter which could not be learned from the specifications of the Patent application as filed. The defendant asserted that the plaintiffs may not "pick and choose" from the specifications below to arrive at the present claims as amended:

> In a further aspect, the invention relates to a solid oral dosage form comprising
>
> 20% to 65% of valsartan
>
> 31% to 65% of microcristalline cellulose
>
> 2 to 13% of crospovidone
>
> A typical composition may comprise:
>
> 20% to 65% of valsartan
>
> 31% to 65% of microcristalline cellulose
>
> 2 to 10% of crospovidone
>
> 1 to 10% of magnesium slearate
>
> 0.5% to 5% of colloidal anhydrous silica

Intermediate Generalisation

35 The concept of intermediate generalisation has been recognised, particularly in the recent years, in decisions delivered by the European Patent Office and in certain decisions delivered by the English Courts (see *Fosroc International Limited v W R Grace & Co-Conn* [2010] EWHC 1702; *Vector Corporation v Glatt Air Techniques Ltd* [2007] EWCA Civ 805). The text of Cornish, Llewelyn and Aplin, *Intellectual Property Patents, Copyright, Trade Marks and Allied Rights* (7th Ed, 2010, Sweet & Maxwell) (*Cornish*) at p 178 (4-32)-(4-33) provides a good explanation of the concept of intermediate generalisation:

> In many cases the aim of an amendment is to cut down the scope of what is claimed, because a piece of prior art is discovered which makes the original claim cover unjustifiably broad territory ... In a classic example, the broadest claim originally related to a tool for crimping together electrical wires and connectors, which had a ratchet and pawl device to prevent premature release of the tool before crimping was complete. In order to side-step prior art, the patentee was allowed to add to this a device that was mentioned in the description incidentally as an additional feature – a stop designed to prevent crimping from going too far. Within this general principle, it is permissible to change a product claim to a claim to its use …
>
> In the crimping tool case, if the stop device had not originally been mentioned, to add it by amendment would in most circumstances be barred as "extending" the matter disclosed. The

same would probably apply if originally a particular kind of stop was mentioned and the amendment sought to refer to all kinds of stop. Again, suppose that stops were mentioned in general and the amendment sought to refer to one particular kind of stop. It may be objected that this is to give prominence to something not previously pointed up in the description. If so the proposed amendment will be classed as an "intermediate generalisation" and disallowed as a departure from the governing principle that the patentee must disclose the essential features of his invention from the application onwards. *The test overall is whether the skilled man would learn from the amended specification anything about the invention which he could not learn from the unamended specification.*

[emphasis added]

36 The above quotation should not be understood as standing for the proposition that it shall in all circumstances be impermissible to amend the specifications of a patent to narrow the scope of the invention claimed to the examples listed in the specifications as filed. The distinction between acceptable narrowing of claims originally expressed as generalisations of various examples and narrowing of claims which would add matter has been well elucidated by Pumfrey J in *Palmaz's European Patents (U.K.)* [1999] RPC 47 at 71 lines 2 to 8:

If the specification discloses distinct sub-classes of the overall inventive concept, then it should be possible to amend down to one or other of those sub-classes, whether or not they are presented as inventively distinct in the specification before amendment. The difficulty comes when it is sought to take features which are only disclosed in a particular context and which are not disclosed as having any inventive significance and introduce them into the claim deprived of that context. This is a process sometimes called "intermediate generalisation".

Thus, the question ultimately, is whether the amendment which seeks to disclose a specific feature disclosed in the specifications of a patent but not the original claims would introduce a new inventive concept to which inventive significance was never attached previously in the specifications.

37 The concept of "intermediate generalisation" is now firmly entrenched as part of English law. In *LG Philips LCD v Tatung* [2007] RPC 21, the English Court of Appeal specifically rejected the argument that the principle of intermediate generalisation was an unhelpful and illegitimate concept as it was not to be found in the English Patents Act or the European Patent Convention. It was held that the test laid down by the Enlarged Board of the European Patent Office in this regard has merely developed the law by superimposing policy over what had been perceived by the English courts as purely a matter of principle.

38 However, the policy-oriented rules applicable in England by virtue of the European Patent Convention should not be unthinkingly adopted in Singapore without an examination of its compatibility with the local statutory regime. The distinction between the statutory frameworks binding upon the European Patent Office and the local courts have been recognised by Andrew Ang J in *Main-Line* at [50] – [52]:

50 Given that the statutory matrices and prevailing administrative practices in Singapore clearly differ from those in Europe, the mere fact that the EPO has come to a different conclusion from our Court of Appeal, certainly does not mean that this court should regard itself to be free to depart from the ... Court of Appeal decision...

52 A few pertinent observations may be made on the English position... The first observation is obvious, but nevertheless worth stating: not being party to the European Patent Convention, our

courts, unlike the English Courts, are not bound to give consideration to EPO decisions. *At best, the reasons of the EPO for coming to a particular conclusion may only be said to be of persuasive value to our courts.*

[emphasis added]

39 I am of the view that the principle of intermediate generalisation appears to be subsumed under the test of added matter. This is because the question which the test of intermediate generalisation seeks to answer is simply whether a person skilled in the art would learn something new which has not hitherto been disclosed in the patent specifications (see *Cornish*, above at [35]). In *Merck* (see above at [32]), Andrew Morritt VC has succinctly stated that the question is not whether an amendment would widen or restrict the scope of the claim, and the "right question is whether the proposed amendment would result in the specification disclosing additional matter" (at [48]). This is precisely the test which the court has to apply under s 84(3) of the Act.

Application to the facts

40 It is clear from the specifications in the application as filed, that the original claim 5 has been disclosed, and the "typical composition" which is disclosed, is the amended claim 5. I am of the view that the precise combination of the three components as amended does not disclose new matter which was not previously disclosed. I am unable to accept the defendant's argument that the skilled addressee would need to "mix and match" to generate a "hybrid" which is not apparent from the patent specifications and therefore does not clearly and unambiguously disclose the invention. All three components have been disclosed in the specifications as part of the "typical composition" of the plaintiffs' invention. It is clear that the following disclosure more than encompasses the present amended claims, which is a narrower claim:

In a further aspect, the invention relates to a solid oral dosage form comprising

20% to 65% of valsartan

31% to 65% of microcristalline cellulose

2 to 13% of crospovidone

41 The defendant made much of the fact that the "typical composition" as disclosed in the specifications also comprises teachings of magnesium slearate and colloidal anhydrous silica which have been omitted in the patent claims. In my view, nothing turns on this. The plaintiffs are perfectly entitled to leave out the last two components if they wish. I am unable to see any inventive significance raised by this omission. The plaintiffs are perfectly entitled to have a claim which is expressed more generally than the specifications which contain details as to embodiments of the claimed invention. As stated in *Terrell on the Law of Patents* (17th Ed, 2011, Sweet & Maxwell) at p 489 (15-22):

The claims of an application or specification themselves constitute a separate disclosure, but they are not disclosures of the detail of how a product may be constructed to achieve the aims of the invention, which is why not all products within the ambit of a claim are disclosed. The fact that a claim in the patent as granted would cover embodiments not disclosed in the application, therefore, does not mean that there is added matter, since a patentee need not limit his claim to all the details of his disclosure …

42 Furthermore, the components of magnesium slearate and colloidal anhydrous silica do not have inventive significance to the notional addressee skilled in the art. In any event, examples 7, 8, 9 and 11 clearly disclose the specific composition which is the subject of the amended claim 5. I accept the evidence of Professor Tovey, the plaintiffs' expert who is experienced in the field of tablet manufacture, that magnesium slearate and colloidal anhydrous silica are non-essential as they relate to colour and film coating, which affect a patient's convenience and product elegance, and not the performance of the invention. [note: 23]

43 Thus, I am of the view that none of the proposed amendments would add matter which has not already been disclosed in the application as filed.

Whether there was undue delay in taking out the present application

44 Having decided that the proposed amendments to the Patent claims would not add matter to the Patent specifications, I now turn to the issue of whether I should exercise my discretion in favour of refusing leave to amend on the ground that the plaintiffs had unduly delayed the taking out of this present application. The defendant contended that the plaintiff could have taken out this application much earlier:

(a) in 2006, when prior art DA2 was cited in opposition proceedings before the European Patent Office in relation to the grant of the European patent for the same invention; or

(b) in 2009, when prior art DA1 was cited in invalidation proceedings concerning the European patent for the same invention which resulted in the plaintiffs voluntarily amending their specifications filed with the European Patent Office.

The defendant argued that the plaintiffs should have taken out this amendment application upon seeing the prior art in 2009 which would necessitate an amendment, instead of waiting until after the defendant served its notices on the plaintiffs in 2011. The delay in taking out this application constituted the taking of unfair advantage of the Patent, which justifies the court's refusal of leave to amend.

45 The plaintiffs contended that in 2006, they prevailed in the challenge on the ground of anticipation by prior art DA2, and hence they correctly decided not to amend. In relation to the second challenge in 2009, the plaintiffs contended that between September 2009 and July 2011, they had proposed the inclusion of disclaimers to overcome the objections of third parties, and that the process of resolving the matter had been ongoing, even up until the point when the defendant served its notices on the plaintiffs in Singapore in January 2011. [note: 24] The plaintiffs also submitted that it would not be reasonable to expect the plaintiffs to amend their specifications for patents filed worldwide the moment prior art has been raised in one jurisdiction. The plaintiffs had to ascertain that amendments were required and that proposed amendments were viable before commencing action for amendments. That was the reason why the plaintiffs decided to wait for the amendments to the plaintiffs' European patent in relation to the same invention to be granted before proceeding in other jurisdictions. However, that plan was thwarted because the plaintiffs had to put forward proposed amendments to the Intellectual Property Office of Singapore as early as 5 August 2011 (before the plaintiffs finally resolved the grant of the amendments to the European patent on 19 August 2011), as triggered by the defendant's activities in filing for product licences. The plaintiffs were made aware that the prior art DA1 and DA2 would be raised in Singapore only after the defendant filed its defence in April 2011. Within a few months thereafter, *ie*, on 5 August 2011, the plaintiffs gave the defendant notice of its intention to take out the present application. Thus the plaintiffs argued that they were

not guilty of undue delay.

46 I am of the view that there was no undue delay or reprehensible conduct on the part of the plaintiffs. I think it is not fair to state that the plaintiffs were responsible for undue delay because they did nothing in relation to the Singapore Patent after becoming aware of prior art DA1 as early as 2006, given that the plaintiffs believed they would, and actually did prevail in the opposition proceedings at the European Patent Office. As for the plaintiffs' awareness of prior art DA1 since as early as September 2009, I am satisfied that the plaintiffs' response thereafter is perfectly acceptable. The fact that the European Patent Office proceedings raised prior art which necessitated an application to amend the specifications of the European patent in relation to the same invention did not necessarily mean that the plaintiffs ought to immediately take out an application to amend in Singapore. It was perfectly reasonable for the plaintiffs to endeavour to first prosecute the amendment in Europe, and then take out an application in Singapore after obtaining the ruling upon its amendment application, when the necessity arose. In a turn of events, it turned out that the defendant's notices served under the Medicines Act accelerated the process by requiring the plaintiffs to amend their claims arising out of the defendant's counterclaim. I note that notice was given of the plaintiffs' intention to take out this present application soon after the defendant pleaded DA1 as prior art which would have anticipated the Patent.

47 For completeness, I should deal with the defendant's argument that the plaintiffs have taken advantage of the wider claims of the Patent, as the plaintiffs' have commenced infringement proceedings on wider claims than the amended claims. However, I do not see how this is unfair in any way. As mentioned above at [3], the notices served pursuant to s 12A(3) of the Medicines Act required the plaintiffs to commence an action for the necessary relief within 45 days after the service of notices by the defendant to avert the grant of product licences to the defendant after the expiry of the 45-day period. Thus, the plaintiffs cannot be expected to wait until after the grant of leave to amend to commence an action for declaration of infringement. The defendant's objection that the plaintiffs' application was made to avoid invalidation in the light of the cited prior arts is neither here nor there, because that in and of itself is not an objection which is sustainable on the principles of law relating to amendment of patent specifications (see above at [7]–[11]).

48 At the end of the day, it must be emphasised that a patentee must act expeditiously in taking out an application to amend its patent claims upon discovering relevant prior art. Any delay in taking out an application to amend must be capable of explanation, and the patentee cannot persist in refusing to amend its patent specifications in an unamended and suspect form despite becoming aware of prior art. However, the court ought to bear in mind, as stated by the English High Court in the case of *Matbro* (at p 834 lines 5-16), that it is necessary to:

> ... draw a clear distinction between instances where a patentee knows of prior art which he genuinely, and quite properly in the circumstances, thinks is irrelevant, and other instances where, though he learns of or has been warned of objections which are available against his patent as a result of prior art, yet he takes no steps to put his specification right by way of amendment, or still worse, knowingly persists in retaining it in the unamended and suspect form. In the latter cases delay is culpable because potential defendants and the general public are entitled to plan their activities on the assumption that the patentee, though warned, has decided not to amend. If the patentee, by his conduct, lulls the public into a false sense of security he cannot thereafter be allowed to change his mind and ask for amendment, or at any rate without adequate protection being granted to the public.

In my view, the present case does not fall within the latter category. In line with the "lenient" approach (see above at [11]) towards the allowing of amendments to patent specifications even

during the course of proceedings, I see no reason to refuse the amendments sought.

Conclusion

49 In the circumstances, prayer 1 of the plaintiffs' application is granted in terms. I order the parties to appear before the Registrar for directions in relation to the amendment of pleadings. I will hear parties on the question of costs.

[note: 1] the plaintiffs' closing submissions filed on 25 July 2012, para 18

[note: 2] plaintiffs' statement of reasons as referred to in the defendant's closing submissions filed on 7 September 2012 at para 11

[note: 3] specifications in Dr Richard Anthony Mabyn Ross's affidavit dated 15 June 2012 at p 33

[note: 4] *Ibid* at p 49

[note: 5] plaintiffs' closing submissions annex A

[note: 6] para 61 of plaintiffs' closing submissions

[note: 7] defendant's written submissions at p 148

[note: 8] Garberg, NE, day 2 p 40 at lines 9 - 13

[note: 9] plaintiffs' closing submissions at pp 32 – 33

[note: 10] plaintiffs' closing submissions at pp 30 – 33

[note: 11] plaintiff's closing submissions annex B

[note: 12] bundle of transcripts, day 2 p 40 line 31 to p 41 line 20, day 3 p 5 line 5 to p 6 line 3.

[note: 13] bundle of transcripts, day 3 p 24 line 28 to p 25 line 4.

[note: 14] Dr Richard Anthony Mabyn Ross' affidavit dated 15 June 2012 at p 34

[note: 15] first report in Mr Garberg's affidavit filed 15 June 2012 at p 31, para 49

[note: 16] second report in Mr Garberg's affidavit filed 11 July 2012 at p 5 para 10

[note: 17] Dr Richard Anthony Mabyn Ross's affidavit dated 15 June 2012 at p 35

[note: 18] bundle of transcripts, day 2 p 46 lines 18 to 21 and day 3 p 8 lines 9 to 14

[note: 19] Dr Richard Anthony Mabyn Ross's affidavit dated 15 June 2012 at p 35

[note: 20] plaintiff's closing submissions filed 7 September 2012 at annex C

[note: 21] p 24 of the Patent specifications at annex B of plaintiffs' closing submissions

[note: 22] Mr Bansal's affidavit filed on 11 July 2012 at para 19; see defendant's closing submissions at p 63

[note: 23] Professor Tovey's second affidavit, filed on 11 July 2012, p 11 para 22.

[note: 24] affidavit of Denis Barbier filed 15 June 2012 at paras 37 – 50.

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