IN THE HIGH COURT OF THE REPUBLIC OF SINGAPORE

[2016] SGHC 106

Suit No 390 of 2015
(Summons No 4136 of 2015)

Between

WARNER-LAMBERT COMPANY LLC

… *Plaintiff*

And

NOVARTIS (SINGAPORE) PTE LTD

… *Defendant*

JUDGMENT

[Patents and Inventions] — [Industrial application]
[Patents and Inventions] — [Novelty]

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v
Novartis (Singapore) Pte Ltd

[2016] SGHC 106

High Court — Suit No 390 of 2015 (Summons No 4136 of 2015)
George Wei J
23 November 2015

26 May 2016 Judgment reserved.

George Wei J:

Introduction

1 This dispute revolves around a pharmaceutical patent ("the patent") owned by the plaintiff, a well-established pharmaceutical company. The central issue before me is whether the plaintiff should be granted leave to amend the patent under s 83(1) of the Patents Act (Cap 221, 2005 Rev Ed) ("the Act"). For reasons that will be set out in this judgment, I dismiss the plaintiff's application for leave to amend its patent.

Background

The patent

2 The patent claims a monopoly over the use of pregabalin for the treatment of pain. Under the patent, the plaintiff manufactures and distributes

the product known as "Lyrica" which has pregabalin as its active ingredient. Lyrica is approved by the Health Sciences Authority ("the HSA") for use in treating, *inter alia*, neuropathic pain and chronic pain disorders including fibromyalgia.

3 The patent was filed on 16 July 1997 and was granted in Singapore on 23 May 2000. Since patents in Singapore are protected for a term of 20 years from the date of filing the application (s 36 of the Act), it follows that the patent is approaching the end of its term of protection. Apart from this patent, the plaintiff owns equivalent patents in other jurisdictions. In particular, it is relevant to note that the plaintiff's patents in Australia, Europe and Singapore were derived from an international application filed on 16 July 1997.

The material events

4 On 23 March 2015, the plaintiff received notice of the defendant's applications to the HSA for product licences in respect of pregabalin products. The notification was made pursuant to s 12A(3)(*a*) of the Medicines Act (Cap 176, 1985 Rev Ed). In the notice, the defendant alleged that the patent would not be infringed by the doing of the acts for which the product licences were sought.

5 On 21 April 2015, the plaintiff commenced an action against the defendant seeking *inter alia* a declaration that its patent would be infringed by the doing of the acts for which the product licences were sought. Thereafter, the plaintiff notified the defendant of its intention to apply to amend the patent on 5 May 2015.

6 On 2 June 2015, the defendant filed its defence and counterclaim in which it counterclaimed for a revocation of the patent on the basis that the

patent is and always has been invalid for the reason that it claims a monopoly over methods of treatment of the human or animal body, which are not patentable in Singapore.[1]

7 The plaintiff's proposed amendments were subsequently advertised on 29 June 2015, as required under O 87A r 11(1) of the Rules of Court, and the defendant filed its notice of opposition to the application to amend on 24 July 2015. On 26 August 2015, the plaintiff filed this application to amend the claims in its patent. It is clear that the application is the plaintiff's attempt to address the claim that the patent as granted is and always has been invalid for claiming a monopoly over methods of treatment.

The amendments

8 In essence, the amendments pertain to a change from a claim to a method of treatment to a "Swiss-style" claim in the following generalised form: "the use of compound X in the manufacture of a medicament for a specified (and new) therapeutic use Y".

9 The proposed amendments are marked up against the claims of the patent as granted:

> 1. Use ~~A method for treating pain comprising administering a therapeutically effective amount~~ of a compound of Formula I

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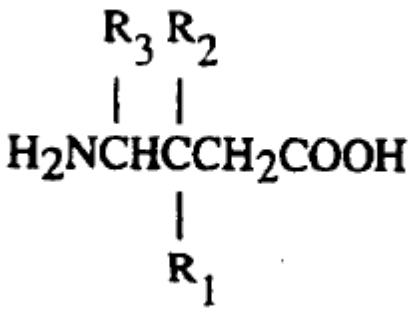
[1] Defence and Counterclaim, para 23.



or a pharmaceutically acceptable salt, diastereomer, or enantiomer thereof wherein

R1 is a straight or branched alkyl of from 1 to 6 carbon atoms, phenyl, or cycloalkyl of from 3 to 6 carbon atoms;

R2 is hydrogen or methyl; and

R3 is hydrogen, methyl, or carboxyl

in the preparation of a medicament for treating pain in ~~to~~ a mammal ~~in need of said treatment~~.

2. ~~A method~~ Use according to Claim 1 wherein ~~the compound administered is a compound of Formula I wherein~~ R3 and R2 are hydrogen, and R1 is -(CH2)0-2^{-i} C4H9 as an (R), (S), or (R,S) isomer.

3. ~~A method~~ Use according to Claim 1 wherein the compound ~~administered~~ is named (S)-3-(aminomethyl)-5-methylhexanoic acid and 3-aminomethyl-5-methyl-hexanoic acid.

4. ~~A method~~ Use according to Claim 1 wherein the pain ~~treated~~ is inflammatory pain.

5. ~~A method~~ Use according to Claim 1 wherein the pain ~~treated~~ is neuropathic pain.

6. ~~A method~~ Use according to Claim 1 wherein the pain ~~treated~~ is cancer pain.

7. ~~A method~~ Use according to Claim 1 wherein the pain ~~treated~~ is postoperative pain.

8. ~~A method~~ Use according to Claim 1 wherein the pain ~~treated~~ is phantom limit pain.

9. ~~A method~~ Use according to Claim 1 wherein the pain ~~treated~~ is burn pain.

> 10. ~~A method~~ Use according to Claim 1 wherein the pain ~~treated~~ is gout pain.
>
> 11. ~~A method~~ Use according to Claim 1 wherein the pain ~~treated~~ is osteoarthritic pain.
>
> 12. ~~A method~~ Use according to Claim 1 wherein the pain ~~treated~~ is trigeminal neuralgia pain.
>
> 13. ~~A method~~ Use according to Claim 1 wherein the pain ~~treated~~ is acute herpetic and postherpetic pain.
>
> 14. ~~A method~~ Use according to Claim 1 wherein the pain ~~treated~~ is causalgia pain.
>
> 15. ~~A method~~ Use according to Claim 1 wherein the pain ~~treated~~ is idiopathic pain.

Analysis and Decision

10 The present application is governed by s 83 of the Act. For the avoidance of doubt, the Registrar's general power to allow the specification of the patent to be amended under s 38 of the Act is inapplicable in cases like the present where there are pending proceedings before the court in which the validity of the patent has been put in issue. In such cases, the application to amend must be brought under s 83 of the Act. I note in passing that there are similar provisions set out in s 75 of the UK Patents Act 1977 which extends to proceedings where validity could have, but was not, put in issue: see *CIPA Guide to the Patents Act* (Paul G Cole gen ed) (Sweet & Maxwell, 7th Ed, 2011) ("*CIPA Guide*") at para 75.03.

11 The law on the amendment of patent specifications under s 83 of the Act is clear and well-established. The court's power to amend a patent is circumscribed by s 84(3) which precludes amendments resulting in the specification disclosing any additional matter or extending the protection conferred by the patent. Further, any amendments must satisfy the "base-line criteria" set out in s 25(5) of the Act which provides, *inter alia*, that the claims are to be clear and concise: *Trek Technology (Singapore) Pte Ltd v FE Global*

Electronics Pte Ltd and other and other suits [2005] 3 SLR(R) 389 ("*FE Global (HC)*") at [52]. At the end of the day, the court has a general discretion to allow or disallow the proposed amendments and the exercise of this discretion is guided by the factors outlined in *Smith Kline & French Laboratories v Evans Medical Limited* [1989] FSR 561 ("*Smith, Kline and French Laboratories Ltd*") at 569.

12 I turn now to the defendant's main grounds of opposition which I will examine in the following order.

(a) The proposed amendments, if adopted, would be futile as the amended patent would nonetheless fail to satisfy the requirements for patentability, namely, novelty, inventive step and industrial application.

(b) The proposed amendments fall afoul of s 84(3) of the Act because they result in: (i) the disclosure of additional matter; and (ii) the extension of the protection conferred by the patent.

(c) The court should exercise its discretion to reject the proposed amendments because:

(i) there has been an unreasonable delay in seeking the proposed amendments;

(ii) the plaintiff is seeking to obtain an unfair advantage from the patent which it knew is and always has been invalid; and

(iii) the plaintiff has failed to make full disclosure of all relevant matters in relation to the proposed amendments.

13 For completeness, I note that the defendant has reserved its rights to file submissions on two issues after the parties have filed their respective expert evidence for the trial of the main action.[2] The issues pertain to: (a) whether the amended claims lack novelty and inventiveness; and (b) whether the amended claims are unclear and imprecise. However, for reasons that will become apparent, it will not be necessary to visit these issues.

Whether the amendments would be futile

14 The defendant resists the proposed amendments on the basis that the amended patent would nonetheless fail to fulfil the requirements for patentability, namely, the requirements of novelty, inventive step and industrial application. It is essential, however, to first resolve a logically anterior issue: whether the validity of the amended patent should be considered alongside the pre-requisites before the court grants leave to amend the patent.

15 This issue was recently considered in the case of *Ship's Equipment Centre Bremen GmbH v Fuji Trading (Singapore) Pte Ltd and others and another suit* [2015] 4 SLR 781 ("*Ship's Equipment*"). In that case, the defendants opposed, *inter alia*, the plaintiff's proposed amendment to the first claim of its Singapore Patent SG110370 on the basis that the amended patent would still be invalid. Lee Seiu Kin J rejected this ground of opposition, holding that the defendant's approach puts the proverbial cart before the horse and should not be accepted where the issue of validity was scheduled to be heard after the applications to amend the patents (at [19]).

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2 Defendant's Skeletal Submissions, para 3.03.

16 The parties have also referred me to the following comments made by the learned authors of *Terrell on the Law of Patents* (Richard Miller, Guy Burkill, Colin Birss & Douglas Campbell, *Terrell on the Law of Patents* (Sweet & Maxwell, 17th Ed, 2010) at para 15-44):

> It is not the normal procedure to attack the validity of a patent as it is proposed to be amended (other than in the course of other proceedings in which validity is in issue), and it has been held that it is not permissible when deleting claims to allege that the remaining unamended claims should never have been granted.
>
> However the court or Comptroller will not allow an amendment which is sought to strengthen the validity of the patent ***if the amendment still clearly leaves the patent invalid or if what remains is so small as not to warrant the grant of a patent.***
>
> Where validity is in issue in the same proceedings, and the proposed amended claims are held to be still invalid, the court may either formally allow the amendment but then find the amended patent invalid and order its revocation, or it may refuse leave to amend on the basis that the amendment is pointless and simply revoke the patent in its existing form. Given that the court has a wide discretion as to costs in either event, the difference appears to be one of form only.
>
> [emphasis added in bold italics]

17 A few key points emerge from the passage above. First and foremost, it is not the normal procedure to attack the validity of a patent as it is proposed to be amended. The court may, however, decide issues of validity where validity is put in issue in the same proceedings. Second, the court will refuse an amendment if it clearly leaves the patent invalid or if what remains is so small as not to warrant the grant of a patent. These comments largely cohere with the approach taken by the court in *Ship's Equipment* but appear to go one step further by suggesting that the court disallow the proposed amendment in cases where it is clear that the amendment is pointless.

18 I agree with the view espoused in *Ship's Equipment* that it is inappropriate for issues of validity to be heard together with the hearing to amend the patent. Even if, as opined by the learned authors of *Terrell on the Law of Patents*, the court may refuse an amendment where the amended patent would still be clearly invalid, this is not the case here. Quite the contrary, it is far from clear, on the material before me, whether the amended patent would be invalid and the assistance of expert evidence would be necessary to help the court in arriving at a decision on the matter. Both parties have indicated their intention to adduce expert evidence in relation to the validity of the proposed amendments. It will thus be more expedient to leave such issues to the trial of the action in which they can be more adequately ventilated. The defendant will not be prejudiced since it will have ample opportunities to challenge the validity of the proposed amended claims after this application is disposed of.

19 For completeness, I shall address the defendant's reliance on two cases that were cited in the footnotes accompanying the excerpt from *Terrell on the Law of Patents*. The first is the case of *Texas Instruments Ltd v Hyundai Electronics UK Ltd* (1999) 22(12) IPD 22116 (Ch D (Patents Ct)) ("*Texas Instruments*") and the second case is *Richardson-Vicks Inc's Patent* [1995] RPC 568 ("*Richardson-Vicks*"). The defendant claims that these cases stand for the proposition that the court may visit issues of validity in deciding whether to allow amendments to the patent.

20 In *Texas Instruments*, an infringement action was brought and the defendant counterclaimed for the revocation of the patent in suit. After the court heard the infringement action and before judgment, the parties settled their differences but remained at issue as to whether the amendment of the patent in suit should be allowed and, if it was, as to the patent's validity (see [2]). In *Richardson-Vicks*, the application to amend and the petition for

revocation came up for hearing together. The application to amend (in an attempt to save the patent) was made in the revocation proceedings. After hearing evidence, Jacob J (as he then was) *allowed* the amendments but proceeded to grant the petition to revoke the patent.

21 Both *Texas Instruments* and *Richardson-Vicks* may be readily distinguished from the present case as both cases concerned the situation in which the application to amend and the petition for revocation were before the court. In contrast, the matter before me concerns an application to amend the patent *before* the hearing of the substantive infringement action in which the defendant is challenging the validity of the patent. Whilst the application to amend under s 83 of the Act and the counterclaim for revocation have arisen in the course of the *same* infringement proceedings, the amendment application has been heard much in advance of the trial unlike the situation in the aforementioned cases.

22 Before leaving this issue, I add that I reject the defendant's contention that as long as it has included objections to the validity of the patent in its notice of opposition, it is entitled to be heard on the issue of validity. Although the court may have regard to the grounds raised in the notice of opposition in determining whether an amendment should be granted, it does not necessarily follow that the court has to make a conclusive determination on *all* matters raised in the notice of opposition, including those that are legally irrelevant. For instance, it has been held that it is not permissible when amending a patent by deleting claims to allege that the remaining unamended claims should never have been granted: *Chiron Corp v Organon Teknika Ltd (No 11)* [1995] FSR 589.

23 To briefly conclude, I am of the view that this is *not* the appropriate forum to reach a decision on the validity of the amended patent. This is an issue which should await determination at a more appropriate juncture when it can be more conveniently and thoroughly examined. To be clear, even if there is some residual power to refuse an amendment where the amendment is "pointless", this must be limited to cases where the reason is clear and obvious. This is far from the case on the facts before me.

Whether the proposed amendments fall afoul of s 84(3) of the Patents Act

24 The court's discretion to grant leave to amend patents post-grant is qualified by s 84(3) which precludes such amendments if they: (a) result in the specification disclosing any additional matter; or (b) extend the protection conferred by the patent.

25 The defendant contends that the amendments proposed by the plaintiff fall afoul of both limbs of s 84(3). The plaintiff, on the other hand, submits that since the defendant did not include s 84(3)(*a*) as a ground of opposition in the Notice of Opposition, the objection on the basis of disclosure of additional matter does not arise. I will return to this point later.

26 Before turning to examine the objections in respect of each limb of s 84(3), it is important to first have a broad understanding of Swiss-style claims. As the name suggests, Swiss-style claims were developed in Europe and the UK. Even though such claims may be less relevant today in those jurisdictions because of legislative developments and the introduction of the European Patent Convention 2000 ("the EPC 2000"), a considerable body of European and UK case law exists on the scope and interpretation of Swiss-style claims. An overview of the basic principles governing such claims will be helpful in shedding light on their nature, which will in turn help inform the decision as to

whether the proposed amendments result in added matter or an extension of protection. I note also that Singapore has modelled much of its current patent legislation on equivalent provisions of the UK Patents Act 1977. For that reason, the teaching of the European and UK patent decisions on Swiss-style claims and related pharmaceutical inventions, whilst not binding, will nevertheless be instructive.

Pharmaceutical inventions and patent law

27 The objective of the patent system is to benefit the public as a whole by encouraging and supporting the development of science, industry and the arts. Amidst calls for and against monopoly, the patent regime rests on a carefully calibrated balance between competing interests. This balance may be found in the imposition of requirements that must be fulfilled before patent protection will be granted (such as enabling disclosure, novelty, inventive step and industrial application) as well as the exclusion of certain "things" from the patent system altogether. The present application directly engages (a) the requirement of novelty; and (b) the method of treatment exclusion.

The requirement of novelty

28 It is trite law that in order to qualify for patent protection, the invention must be novel in the sense that the claimed invention does not form part of the state of the art. The rationale underpinning this requirement is clear — granting patents for inventions that are already known would encumber industry with constraints upon the use of information without any sufficient return: see William Cornish, David Llewelyn & Tanya Aplin, *Intellectual Property: Patents, Copyrights, Trademarks & Allied Rights* (Sweet & Maxwell, 8th Ed, 2013) ("*Cornish, Llewelyn & Aplin*") at para 5-03.

29 That having been said, "inventions" are not confined to new tangible products. An invention may simply be wrapped around a new process such as a new method of producing a known compound. In such a case, the scope of the subject-matter of the patent is the new "method of production" as opposed to the compound that is produced. In other cases, the invention may be wrapped around a new use (or method of use) of a known substance so as to achieve some new useful end result. Many other permutations can and do arise.

30 The focus here is on new uses of known substances. In the pharmaceutical industry, the discovery of a new therapeutic use for a known drug or compound lies behind many new medical products. Even if serendipity assists with an initial lead, the cost of the follow-up research and development is likely to be considerable. The inventor cannot, in such a case, assert protection over the product *per se*. The compound or drug is known and already a part of the prior art. What is new is the use of the compound or drug for a new medical indication such as where a known compound used to treat angina is later found to have utility in treating erectile dysfunction. To stand a chance of success, the claims must be directed at the new use. Thus, where the novelty resides in new uses for old materials/compounds, the requirement of novelty is satisfied by claiming the new use in the form of a *process* patent instead of a *product* patent.

The method of treatment exclusion

31 It is not uncommon for patent systems to exclude methods of treatment from its domain. It has been rightly observed that the limitation rests on a legal fiction that methods of treatment and diagnosis are not capable of industrial application. Thus, it is commented in William Cornish, *Intellectual Property:*

Omnipresent, Distracting, Irrelevant? (Clarendon Law Lectures 2002) (Oxford University Press, 2004) at p 11 that the fear of adverse impact on the health system lies at the heart of the exclusion of methods of medical treatment. The real reason is that it is not in the interest of the public to have methods of treatment and diagnosis controlled by a few: Ng-Loy Wee Loon, *Law of Intellectual Property of Singapore* (Sweet & Maxwell, 2nd Ed, 2014) ("*Ng-Loy Wee Loon*") at para 30.1.69. In the same vein, in *CYGNUS/Diagnostic method* (G 1/04) [2006] EPOR 15, the Enlarged Board of Appeal of the European Patent Office ("EPA") identified the exception as being based on socio-ethical and public health considerations: the practice of medicine by various professionals needs to be carried on without them having to consider whether a patent licence is necessary for any method of treatment (at [4]).

32 In Singapore, the method of treatment exclusion is statutorily embodied in s 16(2) of the Act which deems methods of treatment to be incapable of industrial application. Section 16 of the Act reads:

> **Industrial application**
>
> **16.**—(1) Subject to subsection (2), an invention shall be taken to be capable of industrial application if it can be made or used in any kind of industry, including agriculture.
>
> (2) An invention of a method of treatment of the human or animal body by surgery or therapy or of diagnosis practised on the human or animal body shall not be taken to be capable of industrial application.
>
> (3) Subsection (2) shall not prevent a product consisting of a substance or composition from being treated as capable of industrial application merely because it is invented for use in any such method.

33 The purpose of s 16(2) is to exclude from the patent system inventions that comprise a method of treatment of the human or animal body. The

provision is carefully and precisely crafted. The method of treatment (be it surgery, therapy or diagnosis) must be practised on the human or animal body. However, s 16(3) clarifies that any *product* that was invented for use in the method of treatment is not caught by the exclusion. The intention is clear — the medicinal product that was invented for use in the method of treatment may be patented provided that it fulfils all the other requirements of the patent system (such as enabling disclosure, novelty, inventive step and industrial application). For instance, a drug invented to be used in a treatment plan for Parkinson's disease is not caught by s 16. Therefore, the practical effect of the method of treatment exclusion is to "compel" would-be patentees in the area of medical research to focus their claims on the product that is invented for use in the treatment. I note in passing that s 16 of our Act is *in pari materia* with s 4A of the UK Patents Act 1977 (as amended in 2004).

The twin perils of the requirement of novelty and the method of treatment exclusion

34 The combined effect of the requirement of novelty and the method of treatment exclusion has created particular problems for would-be patentees in the pharmaceutical industry. Prior to the UK Patents Act 1977, the basic rule was that novelty could not be claimed for an old substance by limiting the claim to a new use however inventive the new use may be: *Actavis UK Ltd v Merck & Co Inc* [2009] 1 WLR 1186 ("*Actavis*") at [14]. In other words, the old substance lacked novelty whatever the new use. One solution was to direct the claim at a new method of using the substance.

35 In the field of medicine, the problem was that a claim to a new method of using the substance to treat a medical condition was equivalent to a claim to a *method of treatment* which was excluded from patentability: Phillip Grubb & Peter Thomsen, *Patents for Chemicals, Pharmaceuticals and Biotechnology:*

Fundamentals of Global Law, Practice and Strategy, (Oxford University Press, 5th Ed, 2010) ("*Grubb & Thomsen*") at pp 258–259. Another alternative was to direct the claim towards a pharmaceutical composition containing the desired active ingredient. In such cases, however, the question of novelty of the pharmaceutical composition had to be carefully examined: *Grubb & Thomsen* at p 259.

36 If the claimed invention was unpatentable either for a lack of novelty of the substance (even given its new use) or for falling within the method of treatment exclusion, the perceived problem to society was that there was no incentive to investigate whether an old substance had a medical use. Indeed, as Jacob LJ pointed out in *Actavis* at [17], not even a first medical use for an old substance would be worth researching, let alone a second or third medical use.

37 Change came with the European Patent Convention 1973 ("EPC 1973") which permitted the first medical use discovered for an old substance to be patented. For a first medical use of this nature, Art 54(5) of the EPC 1973 provided that the compound was to be treated as being new for the purpose of the requirement of novelty, thus permitting "use-bound" product claims. Such a claim did not fall foul of the prohibition against methods of treatment since the products used in the method, though not novel in the absolute sense, were treated as novel as regards a first use as a medicament (*Actavis* at [26]). Equivalent provisions were subsequently adopted in the UK (s 2(6) of the UK Patents Act 1977) as well as in Singapore (s 14(7) of our Act). For convenience, s 14 (7) provides:

> In the case of an invention consisting of a substance or composition for use in a method of treatment of the human or animal body by surgery or therapy or of diagnosis practised on the human or animal body, the fact that the substance or composition forms part of the state of the art shall not prevent the invention from being taken to be new if the use of the

> substance or composition in any such method does not form part of the state of the art.

38 I pause here to observe that outside of s 14(7) and a first *medical* use for a known substance, the general question of whether the discovery of a new use for a known substance is sufficient to confer novelty on that substance for the new use remains unanswered. Whilst this issue awaits an appropriate case for determination in Singapore, I note that in *Actavis* at [18] the English Court of Appeal cited *Mobil Oil III/Friction reducing additive* (G 2/88) [1990] EPOR 73 as standing for the view that the use of X as a friction reducing additive in a lubricant composition for engines was new even though use of X in such a composition for the purpose of rust inhibition was known and part of the prior art.

39 The question then arises: what of the researcher who discovers a second medical use for the same compound or substance? In such a case, Art 54(5) of the EPC 1973 (or the equivalent provisions) does not apply because they are confined to cases where a first medical use is found for a known substance. To avoid the novelty objection, it would still be necessary to claim a method of using the compound to treat the new disease indication. Such a claim, as explained earlier, would fall afoul of the method of treatment exclusion. In *Actavis*, the court at [19], agreeing with the EPA's judgment in *Eisai/Second medical indication* (G 5/83) [1979–1985] EPOR B241 ("*Eisai*"), stressed that a claim to the use of a compound for therapeutic treatment is "confined to the step of treatment" (*Eisai* at [18]) and so was unpatentable. This lacuna in patent law in respect of second and further medical uses persisted until the introduction of Swiss-style claims.

Swiss-style claims

40 The generalised form of Swiss-style claims is "the use of compound X in the manufacture of a medicament for a specified (and new) therapeutic use Y". Such claims were conceived to afford patent protection to second medical indications by steering clear of the twin perils of lack of novelty and the preclusion of methods of treatment: *Actavis* at [7]. The Swiss-style claim is not a claim to a method of treatment — the critical point of a Swiss-style claim is that simply making a substance for administration is not the same as administration or treatment. Further, the new therapeutic use is regarded as conferring novelty on the process of manufacture: see *Actavis* at [27] and *John Wyeth and Brothers Ltd's Application and Schering AG's Applications* [1985] RPC 545. However, the fiction (implicit) behind the finding of novelty in the method of manufacture on the basis of a new therapeutic use is readily apparent.

41 Swiss-style claims have had a chequered history in patent law and have not been hitherto considered by the courts in Singapore. They were at first regarded with a degree of measured scepticism but were eventually first accepted in Europe by the Swiss Patent Office — hence the name: *Cornish, Llewelyn & Aplin* at para 5-67. The legitimacy of this practice was subsequently affirmed by the EPA in *Eisai*. Thereafter, Swiss-style claims were rapidly adopted in the pharmaceutical industry even though uncertainty remained over details such as whether a mere change in the dosage regime was sufficient to confer novelty.

42 The complicated position reached in Europe (*ie*, the use of Swiss-style claims to cover second and subsequent medical uses) was simplified by the EPC 2000. Art 54(5) of the EPC 2000 clarified that the novelty requirement

does not operate to exclude the patentability of any substance or composition for use in a method of treatment provided that the use is not in the state of the art. This new provision thus extended the same purpose-limited product claim that was previously only permitted for first medical uses to cover second and further medical uses.

43 The effect of Art 54(5) of the EPC 2000 was considered at length by the EPA in the case of *ABBOTT RESPIRATORY/Dosage regime* (G 2/08) [2010] EPOR 26 ("*Abbott Respiratory*"). The EPA held that since the loophole in the EPC 1973 had been closed, the reason for Swiss-claims had disappeared. The Swiss-style claim was described at [7.1.1] as an "adequate but exceptional" solution to the loophole. That being so, the EPA concluded that "where the subject matter of a claim is rendered novel only by a new therapeutic use of a medicament, such a claim may no longer have the format of a so called Swiss-type claim as instituted by the [*Eisai* decision]" (at [7.1.3]). In setting out its decision, the EPA acknowledged that many patents had already been granted and many applications were pending based on the Swiss-style claim. For that reason, the EPA made it expressly clear at [7.1.4] that the "abolition" of the Swiss-type claim formula did not have any retrospective effect.

44 Put simply, the effect of Art 54(5) of the EPC 2000 is to do away with the Swiss-style claim in favour of an alternative use-bound product claim for second and further medical uses. While the intention of the legislators of the EPC 2000 was to close the loophole in respect of the patenting of second and further medical uses *without extending protection beyond the legal status quo* (*ie*, the protection afforded by Swiss-style claims), it seems that the practical effect of Art 54(5) has been to broaden the protection accorded to second medical uses.

45 In *Abbott Respiratory*, the EPA acknowledged that Art 54(5) of the EPC 2000 went beyond simply codifying the result of the *Eisai* decision. The court accepted that "[i]t appears that the rights conferred on the patentee by the claim category under Art 54(5) EPC are likely broader, and could, in particular, lead to possible restrictions on the freedom of medical practitioners to prescribe or administer generics" (at [6.5]). That being said, the EPA acknowledged that its powers were limited and that, in view of the clear provisions of Arts 53(c) and 54(5) of the EPC 2000, it had no power to broaden or reduce in a praetorian way the scope of these provisions.

46 In the same tenor, in Sigrid Sterck & Julian Cockbain, "Purpose-limited pharmaceutical product claims under the revised European Patent Convention: a camouflaged attack on generic substitution?" (2010) 1 IPQ 88, it was observed at pp 91–92 that the scope of protection conferred on second medical uses has been broadened by a shift from protecting second medical indications through a purpose-limited claim to the *process* for making a drug to a purpose-limited claim to the *drug itself*. The difference in scope of protection according to the learned authors is set out in the following hypothetical at p 92:

> Let us take the (fictional) example of "Exprin", a compound first known for its pretty colour, then found to be useful taken in 20mg tablets for curing malaria, then later found to be useful in doses of 20mg for lowering blood pressure, then later still to be more useful in doses of 40mg for lowering blood pressure.
>
> Under EPC 1973, the *inventor of the malaria application* could obtain a patent to "Exprin for use in medicine". The freedom of action of the physician or pharmacist is unaffected—Exprin had previously not been available in a medically approved form, so there is no generic to substitute with. After the patent expires, generic versions for the treatment of malaria could reach the market and be used legitimately.
>
> Under EPC 1973, the *inventor of the first blood pressure application* could obtain a patent for "the use of Exprin for the

> manufacture of a medicament for use in treatment to reduce blood pressure". The physician treating blood pressure now has a new drug in her arsenal and her position is clearly improved. Generic Exprin might be available, but only from companies expressly advertising their product as for use in treating malaria. The physician or pharmacist does have the option to substitute without infringing (as, if the generic is manufactured for treating malaria and not blood pressure, the Swiss type patent claim in the patent of the inventor of the first blood pressure application is not infringed by her actions).
>
> Under EPC 2000, however, the first blood pressure inventor could obtain a patent for "Exprin for use in treating blood pressure", i.e. for a *product* as such rather than for a process for its manufacture. If the physician or pharmacist substitutes generic Exprin under the new legal regime, she will infringe.
>
> With the *second blood pressure invention* (i.e. the finding that Exprin in doses of 40mg is more useful for lowering blood pressure than in doses of 20mg), the question arises as to whether its inventor can obtain a patent with *dosage regime* claims, i.e. claims to either "the use of Exprin for the manufacture of a medicament to be given in 40mg doses in the treatment of blood pressure" or to "Exprin for use in 40mg doses for treating blood pressure". With the first of this claims, the Swiss type claim of EPC 1973, substitution with generic 20mg tablets for blood pressure would neither infringe nor be seen to be risky. With the second type of dosage regime claim, the product per se claim of EPC 2000, substitution *would* infringe.
>
> [emphasis in original]

47 Section 2(6) of the UK Patents Act 1977 was repealed in 2004 and replaced by s 4A which corresponds to Arts 53(c), 54(4) and (5) of the EPC 2000. Further, the UK Intellectual Property Office has subsequently indicated that Swiss-style claims in UK-filed patent applications will be objected to as lacking clarity, and that patentees of new and pending patent applications would be required to amend their claims to the new claim formulation: see UK Intellectual Property Office, "Examination Guidelines for Patent Applications relating to Medical Inventions in the Intellectual Property Office" (May 2013) at para 97. Following these developments, it can be said that the patent regime

in Europe and the UK has become friendlier to second and subsequent medical uses of known substances.

48 In the area of pharmaceutical inventions, Singapore does not have an equivalent to Art 54(5) of the EPC 2000. Our Act dates back to 1994 and its provisions were modelled after the then existing provisions of the UK Patents Act 1977 with "necessary modifications" made, a point that was noted in *Genelabs Diagnostics Pte Ltd v Institut Pasteur* and another [2000] 3 SLR(R) 530 and *Ng Kok Cheng v Chua Say Tiong* [2001] 2 SLR(R) 326.

49 In Singapore, the question as to how ss 14(7), 16(2) and 16(3) of our Act are to be interpreted has not directly arisen for consideration. In particular, the question as to whether a second medical use for a known substance is patentable has not arisen for consideration in Singapore. That said, whilst the courts have yet to pronounce on the validity of Swiss-style claims, the patent registry supports the view that such claims are valid. The Examination Guidelines for Patent Applications at IPOS (dated 14 February 2014) (the "IPOS" Guidelines), which provide guidance on the acceptable drafting forms of Swiss-style claims state:

> 8.42 The following forms of "second medical use" claims are allowable:
>
> (1) The use of compound X in the manufacture of a medicament for the treatment of medical condition Y – Typical form of Swiss-type claim.
>
> (2) The use of compound X for the manufacture of a medicament for the therapeutic and/or prophylactic treatment of medical condition Y
>
> (3) The use of compound X in the manufacture of an anti-Y agent in a package together with instructions for its use in the treatment of medical condition Y
>
> (4) The use of compound X in the preparation of an anti-Y agent in ready-to-use drug form for treating or preventing medical condition Y.

50 It is not necessary for me to make a determination on the legitimacy of Swiss-style claims under our Act. Whilst this is an important question, it is best answered at a more appropriate juncture where the question arises for consideration. The question (put broadly) that is before me is whether it is right to allow an amendment of the existing patents claims, which are directed towards methods of treating pain by administering a therapeutically effective amount of the disclosed compound, to claims that are directed to the use of the same compound to prepare a medicament for treating pain. This requires a determination of, *inter alia*, whether the proposed amendment discloses additional matter or extends the protection conferred by the patent.

Whether the proposed amendments disclose additional matter

51 The defendant submits that applying the above principles to the facts of the present case, it is clear that the proposed amendments would result in the disclosure of additional matter, namely *the use of compounds of Formula I in the preparation of a medicament*.[3] This, so the argument goes, was not the subject matter disclosed in the application as filed.

52 Whilst the plaintiff has submitted that this ground of objection is not available to the defendant as it was not included in the notice of opposition, a brief discussion is still warranted. For the avoidance of doubt, an objection based on "additional matter" is not the same as an objection based on "extension of protection." Patent specifications serve the purpose of disclosing the invention in a manner that is clear and complete for the invention to be performed by a person skilled in the art. The claims, on the other hand, define the matter for which the applicant seeks protection: s 25(5)(*a*) of the Act.

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[3] Defendant's Written Submissions, para 7.11.

Whilst these are and remain independent heads of attack, an analysis of what matter if any has been added may be helpful to determining what (and whether) the scope of protection has been extended. In any case, I make clear at the outset that it is immaterial whether this ground of objection has been properly raised, as it fails in any event.

Analysis

53 No amendment to the claim is allowed if it results in the specification disclosing additional matter: s 84(3)(*a*) of the Act. The rationale underlying this rule is 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 upon the content of the original application: *Advanced Semiconductor Products/Limiting feature* (G 1/93)[1995] EPOR 97 at [9].

54 The crux of the issue is not whether the scope of the monopoly has been expanded, which is a matter properly left to be determined under s 84(3)(*b*). Instead, the overall test is whether the skilled addressee would learn from the amended specification anything about the invention which he could not learn from the un-amended specification: *Cornish, Llewelyn & Aplin* at para 4-33. This test was formulated by Aldous J in *Bonzel and another v Intervention Ltd and another (No 3)* [1991] RPC 553 at 574 ("the Bonzel formulation"):

> … The decision as to whether there was an extension of disclosure must be made on a comparison of the two documents read through the eyes of a skilled addressee. 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 proposed to be amended].
>
> (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. …

55 This test was later endorsed and applied by the Court of Appeal of Singapore in *FE Global Electronics Pte Ltd and others v Trek Technology (Singapore) Pte Ltd and another appeal* [2006] 1 SLR(R) 874 ("*FE Global (CA)*") at [24] and applied by the High Court in *Novartis AG and another v Ranbaxy (Malaysia) Sdn Bhd* [2013] 2 SLR 117 ("*Novartis AG*") at [8].

Decision

56 In my judgment, the shift in the claim from a method of treatment to a Swiss-style claim for "the use of a compound of Formula I in the manufacture of a medicament" does not create or disclose any "added matter." Accordingly, the proposed amendments are not precluded by s 84(3)(*a*) of the Act.

57 The existing claims (as granted) are directed towards a method of treating pain by the administration of a therapeutically effective amount of the disclosed compound. The therapeutically effective amount of the disclosed compound is *the medicament* in the language of Swiss-type claims. Bearing that in mind and also the fact that the skilled addressee would appreciate that the Swiss-style claim owes its expression to the manner in which patent law has evolved to protect second medical indications, amending the existing claims to reflect "the use of a compound of Formula I in the manufacture of a

medicament" does not add any technical aspect to the invention that is protected by the patent. In other words, as was observed by Floyd LJ in *Warner-Lambert Company LLC v Actavis Group PTC EHF* [2015] RPC 25, the skilled person would understand that it is necessary for the (Swiss-style) claim to include a manufacturing step to ensure that the claim does not touch the doctor, and fall afoul of the method of treatment exclusion (at [119]).

58 Moreover, the skilled addressee looking at the original claims would realise that the medicament comprising the therapeutically effective amount of the disclosed compound would have to exist. Thus, he or she would regard the manufacture of the medicament as clearly and unambiguously disclosed as a matter of necessary implication even though the existing claim is directed at the method of treatment. That said, while the common general knowledge in the art has to be taken into account when assessing the implicit disclosure of the original application, this does not mean that obvious (as opposed to implicitly disclosed) subject-matter can be added to the original disclosure: *CIPA Guide* at para 76.11.

59 For the foregoing reasons, I take the view the proposed amendments do not fall within the preclusion set out in s 84(3)(*a*) of the Act.

Whether the proposed amendments extend the protection conferred by the patent

60 The defendant relies on s 84(3)(*b*) as a further ground of objection to resist the plaintiff's amendment application. There are two planks to the defendant's case in this regard. *First*, the defendant argues that the plaintiff is attempting to extend the protection of the patent – which is prohibited by s 84(3)(*b*) of the Act – by changing the category of the claim from a method of *treatment* to a method of *manufacture*. *Second*, the defendant argues that the

proposed amendments result in the deletion of the crucial step of "administering a therapeutically effective amount of a compound" and thus results in a broadening of the scope of the existing claim as granted.

61 Although it may appear from the defendant's arguments that there are two distinct issues that arise for consideration, both may be subsumed under the question of whether the amendment from a method of treatment claim to a Swiss-style claim extends the protection conferred by the patent. This is because the deletion of the step of "administering a therapeutically effective amount of a compound" is the necessary consequence of the conversion of a method of treatment claim to a Swiss-style claim.

Analysis

62 The crux of the inquiry is *whether the ambit of the protection conferred by the patent will be extended by the proposed amendments*. As such, it is important not to be unnecessarily side-tracked by the change in the category or subject matter of the claims in the patent. It would be permissible to re-formulate a product claim to a use claim if the result is to cut down the scope of what is protected: *Cornish, Llewelyn & Aplin* at para 4-32. For instance, in *Vifor Medical AG v Fresenius AG and another* (T 134/95) (22 October 1996), a patent had been granted in respect of a "container for medical use". The protection conferred related to the apparatus and after amendment, became a use claim, covering only the use of the container and no longer protecting the apparatus. The amendment was allowed on the basis that the change in category had limited the scope of protection.

63 Therefore, the decision as to whether the scope of protection has been extended cannot be decided on a formalistic basis. A mere change from a

process claim to a method of use claim or a use-bound product claim does not compel the decision that the scope has been extended. It is always necessary to have regard to the claims as a whole. A good test is to ask whether something that fell outside the scope of the claims (properly interpreted) and hence not an infringing act on its own now falls within the claims such that it becomes an infringing act ("the Infringement Test"): *Terrell on the Law of Patents* at para 15-41.

64 To properly apply the Infringement Test, it is necessary to compare the totality of protection established by the patent before and after the amendment, and not the scope of protection within the wording of each single claim as granted: *Cytoplasmic male sterile plants/ENZA ZADEN* (T 579/01) (30 June 2004) at [9]. The test was stated in like terms in *Ship's Equipment* (at [24]):

> Section 84(3)(*b*) of the Patents Act mandates that the amendment of the specification of a patent shall not be allowed if it "extends the protection conferred by the patent". In order to determine if the scope of protection of the patent has been extended, one must examine and compare the totality of the claims before and after the proposed amendments. The extension of the scope of an individual claim *per se* is not objectionable if it does not result in the extension of the protection of the patent: Richard Miller et al, *Terrell on the Law of Patents* (Sweet & Maxwell, 17th Ed, 2011) ("*Terrell*") at para 15-41, citing *Siegfried Demel v Jefferson* [1999] FSR 204 at 213.

65 To effect the comparison, the starting point must always be the claims of the patent in question. Where relevant and necessary, it is also legitimate to consider the accompanying specifications to inform the interpretation of the claims. That said, where the words of the claim are clear and unambiguous, it is not permissible to put a gloss on or expand the claims by relying on the statement in the specification: *First Currency Choice Pte Ltd v Main-Line Corporate Holdings Ltd* [2008] 1 SLR(R) 335 at [24]. Further, the court will adopt what is termed a "purposive approach" when construing the patent

claims. This approach was endorsed by *FE Global (CA)* at [14] in which the Court of Appeal took the view that the purposive approach balances the rights of the patentee and those of third parties.

66 With these basic principles in mind, it will be useful to review decisions in which Art 123(3) of the EPC (the equivalent of s 84(3)(*b*) of our Act) has been examined. For the avoidance of doubt, Art 123(3) of the EPC 1973 and the EPC 2000 can be treated as similar for our present purposes notwithstanding the slight differences in their wording.

67 I begin with *KU Leuven Research & Development v Sedaxnyl SpA and others* (T 495/10) (3 July 2012) ("*Leuven Research*"), a decision of the Technical Board of Appeal of the European Office ("the Board"). There, the relevant claims of the granted patent provided:

> **Claim 1**
>
> A feed additive comprising at least 20% w/w of low molecular weight arabinoxylans having a molecular mass between 414 and about 52,800 Da.
>
> **Claim 12**
>
> The use of arabinoxylans or materials containing arabinoxylans for the manufacture of a feed additive according to any one of claims 1 to 11.
>
> **Claim 21**
>
> A method for improving the weight gain and/or feed utilisation of monogastric animals, which comprises incorporating into the feed of said animals 1 to 50g of low molecular weight arabinoxylans per kg of feed, said low molecular weight arabinoxylans having a molecular mass between 414 and about 52,800 Da.

68 The patentee applied to amend the patent by combining the above claims. The amended claim read as follows:

> Use of arabinoxylans or preparations or materials containing arabinoxylans for the manufacture of a feed additive for monogastric animals, said feed additive comprising at least 20% w/w of low molecular weight arabinoxylans having a molecular mass between 414 and about 52,800 Da, and said feed additive used at 1 to 50g of said low molecular weight arabinoxylans per kg of feed, for improving the weight gain and/or feed utilisation of monogastric animals.

The Board observed preliminarily that the amended claim was drafted as a Swiss-style claim to steer clear of the preclusion of methods of treatment. The opposition division had found that the previous "method" claims covered a method of treatment of the human or animal body by therapy (at [3.1]—[3.4]).

69 The Board held that the amendment did not extend the protection conferred by the patent as granted. Claim 12 (as granted) claimed *generally* the use of arabinoxylans or materials containing arabinoxylans for the manufacture of a feed additive according to claims 1 to 11. The amended claim, in contrast, narrowed the subject-matter of claim 12 (as granted) by: (a) specifying that the process was "for monogastric animals … for improving the weight gain and/or feed utilisation of monogastric animals"; and (b) prescribing the amount of the feed additive required (*ie*, at 1 to 50g of said low molecular weight arabinoxylans per kg of feed) (at [4.4]). Thus, although the amended claim was broader than claim 21, it was significantly narrower than claim 12 and therefore did not have the effect of broadening the scope of protection under the patent but restricted it instead. The amendment was thus held to be permissible under Art 123(3). Here, I pause to comment that the outcome of *Leuven Research* is consistent with the point made earlier that, in deciding whether the scope of protection of the claims has been extended, it is necessary to look at the claims in totality before and after the proposed amendment.

70 I note that it was also argued in *Leuven Research* that the patent protection was extended as the granted claims were directed at non-therapeutic methods whereas the amended claims were re-cast as second medical uses claims (which were therapeutic methods). This contention was rejected (at [4.5]) and the Board held that the granted claims, by not specifying the intended use, could be said to have embraced any use and, therefore, had already embraced therapeutic use. The Board also observed in passing that a method claim was not allowed where the claimed subject matter embraces inseparable therapeutic and non-therapeutic effects. In such cases, the drafting of the claim as a Swiss-type claim ensures therefore that in so far as the inseparable therapeutic method is concerned, the claim does not infringe Article 53(c) of the EPC 2000 (at [3.4.1]).

71 In *EI du Pont de Nemours and Company v Hoechst Aktiengesellschaft* (T 619/88) (1 March 1990), the Board allowed an amendment of claim from "process" to "use of compound in process". The original patent claimed a monopoly over:

> A process for preparing a tetrafluoroethylene polymer which comprises the suspension polymerization of tetrafluoroethylene in the presence of an ionic radical initiator in an aqueous medium containing an aliphatic, substantially non-telogenic carboxylic acid to obtain a precipitated tetrafluoroethylene polymer, characterized in that said polymerization is carried out at a temperature of between 50°C and 100°C and at a pressure of between10 x 10^5 and 50 x 10^5 Pa in an aqueous medium containing an aliphatic, substantially non-telogenic carboxylic acid of 1 to 6 carbon atoms and having a -logK between 1.5 and 10.0 in an amount between 25 and 2500 ppm, based on the weight of water present.

72 The applicant proposed to amend the claim as follows:

> The use of an aliphatic, substantially non-telogenic carboxylic acid of 1 to 6 carbon atoms and having a –logK between 1.5 and 10 to reduce the formation of adhesions which would

> otherwise form in a polymerizer equipped with a rotating internal agitator providing vigorous agitation during the suspension polymerization of tetrafluoroethylene to provide a precipitated tetrafluoroethylene polymer, the suspension polymerization being carried out in the presence of an ionic radical initiator in an aqueous medium containing between 25 and 2500 ppm of said non-telogenic carboxylic acid based on water present, and at a temperature of between 50 and 100°C and at a pressure of between 10 x 10^5 and 50 x 10^5 Pa.

The purpose of this amendment was to make it clear that the subject-matter of the patent in suit was directed to a process on an industrial scale, unlike the prior art cited which was basically concerned with experiments on laboratory scale.

73 It was held that the proposed amendment did not extend the protection conferred by the patent. The Board considered the proposed amendment to involve only a change of form and ruled that the formulation of the amended claim as a use claim did not represent a true change of claim category since it referred to the same use of the acid as defined in the original claims relating to a suspension polymerization process (at [2]).

74 In *Composition for contraception/Bayer Schering Pharma AG* (T 1635/09) (27 October 2010), the application involved the conversion of a use claim to a Swiss-style claim. The issue before the Board was whether the reformulation of a claim for the "use of an oral dosage form comprising… for contraception…" into a claim for the "use of a combination product which comprises … to produce an oral… dosage form for contraception…" extended the protection of the patent (at [14.2]).

75 The crucial question was whether the Swiss-style claim was to be regarded as (a) for the use of a substance or mixture of substances (*ie*, composition) for a specific purpose; or (b) the manufacture of a medicament:

at [14.2]. The Board held that the Swiss-style claim only encompassed the latter, that is, the preceding manufacture of that product.

76 The intention behind Swiss-style claims was to avoid the method of treatment exclusion. For this reason, the Board reasoned that Swiss-style claims could not correspond in content to a use claim in which a substance or composition is used to achieve a given effect; if so, they would fall squarely within the method of treatment exception under Art 53(c) of the EPC 2000. Put simply, the Board drew a clear line between (a) claims for the use of the substance for a specific purpose; and (b) Swiss-style claims covering the preceding step of manufacturing the substance for such use. The effect of this analysis was that the conversion of the claim for the use of a substance or mixture of substances for a specific purpose into a Swiss-style claim was held to result in an extension of the scope of protection.

77 It is also noteworthy that in reaching this decision, the Board emphasised yet again that account must be taken of the granted claims (eight "use" claims and 11 product claims) as a whole in assessing whether the scope of protection had been extended (at [14.1]). In the present case, I note that the 15 (granted) claims raised before me are all directed to method of treatment. The amendments seek to convert all 15 claims into the Swiss form.

Decision

78 Having considered the wider history and legal backdrop surrounding the development of this area of patent law as well as the claims of the patent in question, I am of the view that the manufacture of the medicament is not an activity that falls within the ambit of the patent as originally granted. Accordingly, the proposed amendments would have the effect of extending the protection conferred by the patent and should not be allowed.

79 The question mandated by s 84(3)(*b*) of the Act is whether the amendment extends the protection conferred by the patent. This can only be determined by examining the scope of the invention for which the patent was granted. The focus is on the subject-matter of the granted patent which is delineated by the claim: s 113 of the Act. Apart from the claims, it is also proper to have regard to the specification and claims bearing in mind the purposive approach to interpretation which needs to be adopted: *CIPA Guide* at para 76.21. Where on a non-literal interpretation of the original claims, it is clear that the intended meaning is in fact the meaning set out in the amended claim, then it cannot be said the scope of protection is extended.

80 In the present case, I am unable to see how, on a purposive basis, the claims were in fact intended to cover the use of the disclosed compound to manufacture a medicament (as opposed to its administration in treatment). The difference between the scope of the invention claimed by the granted claims and the amended claims is immediately apparent upon a closer look at the rights stemming from the respective claims.

81 The exclusive rights conferred on a process patent are infringed in the circumstances set out in ss 66(1)(*b*) and (*c*) of the Act which read:

> 66.—(1) Subject to the provisions of this Act, a person infringes a patent for an invention if, but only if, while the patent is in force, he does any of the following things in Singapore in relation to the invention without the consent of the proprietor of the patent:
>
> (*a*) …
>
> (*b*) where the invention is a process, he uses the process or he offers it for use in Singapore when he knows, or it is obvious to a reasonable person in the circumstances, that its use without the consent of the proprietor would be an infringement of the patent;
>
> (*c*) where the invention is a process, he disposes of, offers to dispose of, uses or imports any product

> obtained directly by means of that process or keeps any such product whether for disposal or otherwise.

82 Applying s 66(1)(*b*), a defendant will infringe the *granted* claims if he offers or provides treatment of pain in Singapore by administering a therapeutically effective amount of the disclosed compound. In contrast, the defendant will infringe the *amended* claims under s 66(1)(*b*) if he uses the disclosed compound in a process to manufacture the medicament for treating pain. He will also be infringing the amended claims under s 66(1)(*c*) if he disposes, uses, or imports a product obtained directly from that manufacturing process. It follows, therefore, that the amendment would extend the scope of the protection conferred by the patent.

83 To explain this in a slightly different way, although the claims refer to the medicament (in terms of a therapeutically effective amount of the disclosed compound), they are directed to the method of treatment *viz* the administration. The amended claims, which claim a method of manufacture, represent a shift away from the method of treatment. Whilst broadly connected by the same final objective (of treating pain), the granted claims and the amended claims are targeted at different activities — the latter covers the making of the compound for the purposes of administration (to treat pain) whereas the former covers only the follow-on act of administration of the compound to treat pain. Since the plaintiff, in the patent as granted, had chosen to stake its claim on the administration of the compound for treating pain, and not the preceding manufacturing process that produced the compound for that use, it should not now be permitted to extend the protection conferred by the patent by bringing into its ambit the step of manufacturing the medicament.

84 In coming to my decision, I note in passing two recent English decisions on the interpretation of Swiss-style claims. Whilst these cases were not raised by counsel, a few passing comments are appropriate. The first is *Warner-Lambert Company LLC v Actavis Group PTC EHF* [2015] EWCA Civ 556 ("*Warner Lambert CA*"). The second is *Warner-Lambert Company LLC v Actavis Group PTC EHF* [2015] EWHC 2548 ("*Warner-Lambert HC*").

85 In *Warner Lambert CA* which was decided in May 2015, the English Court of Appeal dealt with a question of construction of a patent in Swiss form, that is, a claim to use of a compound in the production of a medicine for use in a particular therapeutic indication. The patent, in fact, concerned the same medicament in the present dispute before me. The question was described as important as it concerned the scope of protection to be afforded to an important class of inventions in the pharmaceutical field namely discovery of new uses for known medicines (at [1]). The Court of Appeal affirmed that Swiss claims were a form of process claim. The main issue was what amounted to infringement of a patent with a Swiss form claim.

86 At [113], Floyd LJ stated that primary infringement turned on construing the claim said to be infringed: what would the skilled reader of the patent understand the patentee to be using the language of the claim to mean. The difficult issue was whether any mental element was required for an act to fall within use of the compound to produce a medicine *for* a new therapeutic use. To put the matter loosely: what sort of "*mens rea*", if any, was built into the Swiss claim? At [118], the English Court of Appeal found that the technical subject matter of the claim was the making pregabalin for patients to whom it will be intentionally administered for treating pain but yet falls short of including the step of actually using pregabalin for treating pain. This is the

technical contribution of the patentee. That being so, the skilled reader would understand that the claim as involving a *link* between the act of manufacture and the ultimate intentional use of the drug by the end-user to treat pain. The difficult question to determine concerned the required link built into the scope of the invention protected by the Swiss-style claim. After considering various interpretations, Floyd LJ concluded that "there was no reason why the skilled reader would conclude that the word "for" implied "subjective intent" (at [127]). Instead, the skilled reader would understand that the manufacturer "who knows (and for this purpose constructive knowledge is enough) or could reasonably foresee that some of his drug will intentionally be used for treating pain, is making use of the patentee's inventive contribution".

87 Following the decision of the Court of Appeal, the matter returned to Arnold J (*inter alia*) on the question as to whether there was infringement. In coming to his decision, a broad range of issues was discussed including whether the decision on interpretation of Swiss claims in *Warner-Lambert CA* (which was an interlocutory appeal) was binding. Whilst, Arnold J took the view that it was not binding (the question before the Court of Appeal being concerned with the assessment of the balance or risk of injustice and interim relief), he accepted that as a fully considered and unanimous decision, it should be followed unless he was entirely convinced that the decision was wrong. Nevertheless, the difficulties inherent in the test or approach taken by the Court of Appeal were apparent. Arnold J pointed out that the Court of Appeal in reaching its conclusion commented that simply manufacturing pregablin for patients to whom it is to be administered for non-patented indications is not within the technical subject matter of the claim (at [627]). Yet on one interpretation of the decision, if it was a foreseeable consequence that some of his drugs would be intentionally administered for the treatment of pain, then *all* of that manufacturer's acts of manufacturing pregablin would be

infringing acts even though it was foreseeable that the remainder of its pregablin would be administered for the treatment of non-patented indications.

88 As a result, Arnold J held that the correct interpretation of Floyd LJ's decision was that the act of intentional administration lay at the heart of the claimed invention. Viewed in this light, the test could not be a simple matter of foreseeability. This was, however, not the end of the matter. The question remained: whose intention was relevant: the prescribing doctor; the dispensing pharmacist; the patient or some combination? The right answer was by no means obvious. At the end of the day, Arnold J preferred the view that it was the intention of the doctor to specifically prescribe generic pregablin that was most relevant (although the intention of the pharmacist might also come into play) (at [636]). The intention of the patient was irrelevant. The relevant date for establishing the intention (the mental element) was the date of manufacture. On the facts, Arnold J concluded that it was not foreseeable to Actavis that its generic product would be intentionally administered for the treatment of pain save in a small number of exceptional cases, by medical professionals, that were proper to regard as *de minimis* (at [671]). The reason was not simply because the labelling of the generic product did not refer to treatment of pain (so-called skinny labelling) but because Actavis had notified the superintendent of pharmacists that the generic product was not licensed for treatment of neuropathic pain.

89 Earlier, I made the point that the validity of Swiss-style claims and their proper interpretation (over the scope of the subject-matter protected) and infringement have not been authoritatively determined yet in Singapore. The *Warner-Lambert* litigation in the English courts illustrates the problems and difficulties that arise with interpreting Swiss-style claims. In particular, the nexus between the manufacture and the intentional administration for

treatment has proven tricky. This is not simply a matter of determining whether there has been an act of primary infringement. It is essential to the determination as to what is the technical contribution (or subject matter) that falls within the scope of the claim and protected by patent registration. Nevertheless, it is clear that the subject matter of a Swiss-style claim is different from a claim that is directed towards a method of treatment by administering the compound. The technical subject-matter and contribution over which protection is claimed is ostensibly different.

90 Before leaving this issue, I observe in passing that in determining whether the scope of the patent has been extended, one is *not* entitled to take into account secondary or indirect infringement. It is trite law that patent infringement is a tort (breach of statutory duty) and like any tort, liability can extend to other parties who may not be directly liable for the infringing act. In the UK, extensive provisions on what is sometimes called "secondary infringement" are set out in s 60(2) of the UK Patents Act 1977. This provision states:

> Subject to the following provisions of this section, a person (other than the proprietor of the patent) also infringes a patent for an invention if, while the patent is in force and without the consent of the proprietor, he supplies or offers to supply in the United Kingdom a person other than a licensee or other person entitled to work the invention with any of the means, relating to an essential element of the invention, for putting the invention into effect when he knows, or it is obvious to a reasonable person in the circumstances, that those means are suitable for putting, and are intended to put, the invention into effect in the United Kingdom.

91 Unlike the UK, Singapore has not legislatively provided for indirect or secondary patent infringement, preferring to leave the matter to be governed by the common law position on joint tortfeasorship on proof of a common design to procure or actually participate in acts of infringement: Susanna H

Leong, *Intellectual Property Law of Singapore* (Academy Publishing, 2013) at para 19.054.

92 It would not be appropriate to take into account acts that could amount to secondary infringement when ascertaining whether the protection conferred by the patent has been extended by the proposed amendments. The inquiry entails a comparison of *the scope of protection* conferred by the claims in the patent *before* and *after* amendment. Acts that attract accessorial liability, by their very nature, do not fall within the scope of such claims and should therefore be disregarded for the purposes of determining whether the scope of monopoly conferred by the patent has been enlarged by the proposed amendments.

Whether the court should exercise its discretion to allow the proposed amendments

93 The court has a general power to allow or refuse amendments provided that they are permitted under the Act and that no circumstances arise which would lead the court to refuse them. The rationale of the discretion to refuse an application to amend was succinctly summarised in *Ship's Equipment* (at [133]):

> To sum up, it is important to bear in mind the underlying rationale of the discretion to refuse an application to amend. This is well explained by Aldous LJ in *Kimberly-Clark Worldwide Inc v Procter & Gamble Limited* [2000] FSR 235 at 248 as the "desire to protect the public against abuse of monopoly". Pumfrey J in *Instance* at [37] described it as "a desire to ensure that patentees do not obtain an advantage which is unfair from their failure to amend" and went further to consider that it may be "to punish patentees for the unreasonableness of their conduct even when no advantage has in fact been gained".

94 As a corollary to the desire to protect the public against an abuse of monopoly, courts are generally more accepting of amendments designed to assist in the enforcement of a valid claim as opposed to those designed to validate an invalid one. The reason for this difference in attitude was explained by Wilmer LJ in the English Court of Appeal's decision of *Van der Lely NV v Bamfords Ltd* [1964] RPC 54 at 76. Where a claim has been found to be valid, the patentee has made good his claim to monopoly rights to that extent. But where a claim has been found to be invalid, the patentee has failed; and it may well be said that no good reason exists why he should be accorded a second chance. The point was reiterated by Aldous J in *Chiron Corp v Organon Teknika Ltd* (No 7) [1994] FSR 458 at 460. Thus, when exercising the discretion to allow amendments, attention must be paid to the nature of the amendments sought. That said, as discussed later, there is no principle of law that an amendment intended to address a ground of invalidity is to be rejected simply for that reason.

95 I pause to note that the patent regime draws a distinction between amendments to patent specifications and claims in a pre-grant as opposed to post-grant situation. In *Cornish, Llewelyn & Aplin*, it is stated at para 4-31:

> … If the claims are amended during application, they must not notionally add something new to the description in the body of the specification. … Moreover the amended claims have still to satisfy the basic rules that they must be clear and concise, be supported by the description and satisfy the requirement of unity of invention. … Amendments that are themselves sought after grant may not alter the claims so as to extend scope of protection…

A similar point is made in the *CIPA Guide* at para 76.06: the broadening of claims is permitted *pre-grant* provided this does not add subject-matter to the specifications. In Singapore, a general power to amend the application before grant is set out in s 31 of the Act. This includes the right of the applicant to

amend the application of his own volition. However, post-grant amendments under ss 38(1), 81 and 83 will not be allowed if it results in the specification disclosing additional matter or extends the protection conferred by the patent: s 84(3) of the Act.

96 Returning to the present case, the defendant argues that the proposed amendments are barred by reason of: (a) an unreasonable delay on the part of the plaintiff in taking out this application; and (b) the unfair advantage that the plaintiff is seeking by way of this application. I would note also that the instant case falls within the category of cases designed to validate an invalid claim, which courts are said to be less willing to accept (although there is no principle of law that such amendments are not permitted).

Whether there was an unreasonable delay on the part of the plaintiff

The parties' arguments

97 The defendant asks this court to reject the proposed amendments because there has been an unreasonable delay of at least 14 years in seeking the amendments. To this end, the defendant argues that the plaintiff, despite being clearly aware at various stages that the patent was invalid, chose not to amend the patent even though it had ample opportunities (pre-grant and post-grant) to do so. Such knowledge, it is argued, may be inferred from the following.

> (a) In February 1998, the plaintiff obtained an International Preliminary Examination Report ("IPER") which stated that: "[c]laims directed to methods of treatment of the human or animal body by therapy might be found inadmissible in some patent systems." This led

to the plaintiff's amendment of the original claims in its European application from method of treatment claims to Swiss-style claims.

(b) The plaintiff had already applied to amend some of its Singapore patents pre-grant from method of treatment claims to Swiss-style claims many years prior to the commencement of the present dispute.

Singapore Publication No.	**Date of Entry into National Phase**	**Date of Amendment**	**Relevant Amended Claims and Granted Claims**
82798	6 Aug 2001	3 Feb 2005	Granted claim 6 and amended claim 6
113743	10 Jun 2005	20 Jun 2007	All claims
120646	22 Mar 2006	23 Oct 2008	All claims

The earliest amendment was made as early as 2005. As such, the plaintiff was aware or ought to have been aware as early as 2005 that the granted claims were not capable of industrial application. The plaintiff had at least nine years to pursue an amendment to the patent.

(c) The plaintiff admitted that it received advice from its legal counsel, around March 2015, that under Singapore law, method of treatment claims are not taken to be capable of industrial application under s 16(2) of the Act. Despite the advice, the plaintiff proceeded to

file the writ of summons for this suit on 21 April 2015 without an application to first amend the patent.

98 The plaintiff, on the other hand, contends that there has not been any unreasonable delay by the plaintiff in seeking the proposed amendments. Its case is that it was never alerted to s 16(2) of the Act and that there was neither any challenge by any third party to the patent nor any threatened or actual infringement of the patent, which would give rise to an occasion for the plaintiff to seek advice on the enforcement, strength and validity of the patent.[4] The plaintiff adds that it took the following steps expeditiously to apply for the proposed amendments once it was alerted to the need to do so:[5]

(a) 23 March 2015: Plaintiff received notice of the defendant's applications dated 9 March 2015.

(b) 21 April 2015: Plaintiff commenced the present suit (*ie*, Suit No. 390 of 2015).

(c) 22 April 2015: Expiry of 45-day prescribed under s 12A of the Medicines Act for the plaintiff to commence action seeking a declaration of infringement.

(d) 5 May 2015: Plaintiff gave notice to the Registrar of Patents and the defendant of its intention to amendment the Patent.

Decision

99 It goes without saying that an application for patent amendment must be made expeditiously and the patent proprietor is not entitled to sit on its

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4 Plaintiff's Written Submissions, at [65].

5 Plaintiff's Written Submissions, at [68].

hands after discovering the need for amendment. The point was clearly made in the case of *Novartis AG* (at [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. …

100 The point was made in similar terms in *Smith, Kline and French Laboratories Ltd*. Aldous J emphasised (at 569) that it is in the public interest that the amendment is sought promptly and that in cases where a patentee delays for an unreasonable period before seeking amendment, it will not be allowed unless the patentee shows reasonable grounds for his delay. Such grounds, it was held, include cases where a patentee believes that amendment was not necessary and had reasonable grounds for that belief. This statement of law was upheld by the English Court of Appeal and subsequently applied in cases such as *Kimberley Clark Worldwide Inc v Procter & Gamble Ltd (No 1)* [2000] RPC 422.

101 There are a few points that may be gleaned from the case law. First and foremost, for the delay to be considered undue, the period of the delay need not be long provided that there is no plausible explanation for the delay. In *Instance v CCL Label Inc* [2002] FSR 27 ("*CCL Label*"), the proposed amendments were refused on the basis of, *inter alia*, an inexplicable delay. Pumfrey J opined that after counsel's advice was received, a period of two months would have been more than adequate to formulate an amendment. But the applicant did not do so until over a year later and Pumfrey J found there to be no satisfactory explanation for the delay. This unexplained delay thus formed one of the bases on which the amendments were disallowed.

102 Second, a delay may not be held against the applicant if it is able to provide a reasonable explanation for the delay. Guidance as to what may constitute a reasonable explanation can be found in *Ship's Equipment*. There, the defendant contended that the claim in question might have been invalid as early as November 2010 when the decision of the Opposition Division of the European Patent Office ("the EPO") was released in relation to the corresponding European patent. Notwithstanding that, the plaintiff only published its notice of intention to amend more than two years later, claiming that it was entitled to wait for the final outcome of the appeal to amend the patent. But despite this reason given, the plaintiff went ahead with its application to amend the patent before the outcome of the appeal was released.

103 The court rejected the explanation that the plaintiff was waiting for the final outcome of the appeal before the EPO before deciding whether to amend the patent as purely an afterthought and that there was no reasonable explanation for the delay. In coming to this conclusion, the court distinguished the cases of *Novartis AG* and *FE Global (HC)* (at [148]):

> … In *Novartis*, the plaintiffs genuinely believed that they would prevail before the EPO in 2006 and therefore did not amend the Singapore patent. Later, in 2009, when the EPO proceedings raised prior art which necessitated an application to amend the European patent, the court found that it was "perfectly reasonable" for the plaintiffs to proceed with the amendment in Europe, and then apply in Singapore "after obtaining the ruling upon its amendment application, when the necessity arose". This is different from the present case where the Plaintiff had sought and obtained the amendments to the European Patent as early as 10 November 2010, but having done so, took no steps to amend the corresponding 370 Patent in Singapore. It is also apparent that the Plaintiff did not genuinely think that they would prevail without the amendments to the 370 Patent for they would have otherwise proceeded without applying for the Proposed Amendments. Further, *FE Global (HC)* can also be distinguished on the facts. There, the delay was justified by the time taken for the

> consultation with the patent agents from the various jurisdictions. That was not the case here.

104 Third, the appropriate juncture to question whether the amending party has been guilty of an unreasonable delay is the time it was first made aware of the need to amend.

105 The question that naturally arises is this: what is the extent and quality of the knowledge required by the amending party to start the clock running? This issue was squarely addressed in the Australian decision of *CSL Limited v Novo Nordisk Pharmaceuticals Pty Ltd (No 2)* [2010] FCA 1251 ("*CSL Limited*"). After a thorough survey of the key Australian and English authorities relevant to the issue, Jessup J held that an applicant's actual or constructive knowledge of the need to amend should, in appropriate circumstances, suffice to disentitle the applicant to the favourable exercise of the court's discretion (at [76]). A patentee who has been exposed to facts from which it was, or reasonably ought to have been, apparent to him or her that a claim might well be invalid unless amended, but nevertheless brings a late application to amend, is no position to say that there was, on the earlier occasion, no "need" to amend simply because it had not then been conclusively established that the claim was in fact invalid. That said, Jessup J recognised that all will depend upon the extent and quality of the applicant's appreciation (actual or constructive) of the circumstances from which a need to amend is said to arise, and from the nature of those circumstances themselves.

106 It is also useful to look briefly at the factual matrix in *CSL Limited* which is broadly analogous to the present case. There, the patentee held similar patents in multiple jurisdictions and examiners in multiple jurisdictions expressed the view that the claim in question should not be granted because of

what was substantially the same prior art in each case. The applicants' explanation was that they had never received advice from its attorneys anywhere in the world that once a particular amendment is made to a patent in any particular jurisdiction, there is some benefit or gain to be had in reviewing the entire portfolio with the amendment in mind. This explanation was rejected by Jessup J. It was held that the applicants had been put squarely on notice that its claim was problematic, and thus the absence of any evidence of professional advice contrary to the opinions expressed by the examiners in fact counted against the applicants. The examiners' opinions, in the court's view, imposed upon the applicants at least the obligation to obtain such advice in relation to the patent in suit (at [79]).

107 I fully agree with the approach in *CSL Limited*. To set the standard at the patentee's actual knowledge of the invalidity of the patent in question would be, in my view, too lenient an approach. There are sound policy reasons why it should not be so. By successfully registering a patent, the patentee is representing to the public that he has a valid claim. Where he has reason to suspect that his claim cannot be supported, the law must encourage and incentivise sensible behaviour on his part by requiring him to act with reasonable dispatch and diligence in identifying, and thereafter curing the invalidity. A more lenient approach, on the other hand, would only encourage dilatory conduct and wilful blindness on the part of patentees, and cause invalid patents to remain on the patent register for a longer than necessary period of time. It is apposite to keep in mind Lord Normand's dicta in *Raleigh Cycle Co Ltd v Miller (H) & Co* [1951] AC 278 in which he alluded to the need to "take into account the public interest which is injured when invalid claims are persisted in so that inventors are legitimately warned off the area of the art ostensibly monopolised by the claims" (at 281).

108 Before turning to assess the plaintiff's extent and quality of knowledge in respect of the need to amend the patent in the present case, I note that the patent at hand was sought and granted at a time when a self-assessment system was in place in Singapore. As stated at para 29.4.8 of *Ng-Loy Wee Loon*:

> … Under this system, it was not the Registrar of Patents who decided whether the patent applicant was eligible to proceed to grant. Instead, it was the patent applicant who decided whether to make a request for the grant of patent. When the patent applicant decided to request for grant and this request was received by the Registrar of Patents, the patent would be granted if a few matters had been complied with. These matters did not include the fulfilment of the patentability criteria of novelty, inventive step and industrial application. The premise underlying this self-assessment system was that patent applicants would exercise good judgment and proceed to request for grant of patent only if the examination report was a positive one, that is, a report that indicated that the subject-matter of the application satisfied all the patentability criteria. …

109 Under the self-assessment system, it behoved the plaintiff to make informed and considered decisions before proceeding to grant. A granted patent is a property right which is monopolistic in nature. The registration system and the register of patents, whilst concerned with meeting the needs of inventors and their backers, is also very much concerned with the interests and needs of society as a whole. This self-assessment system was departed from on 14 February 2014 in favour of a positive grant system under which a patent is only granted if the examination report is positive on all patentability criteria.

110 Bearing in mind that the self-assessment system placed a responsibility on the plaintiff to have regard to the validity of the patent before grant, I am of the view that there were sufficient facts to put the plaintiff on notice as to the possible defect in its patent such that it was obliged to at least seek legal advice on the matter.

111 As noted above, as early as February 1998, the plaintiff obtained an IPER which stated that: "[c]laims directed to methods of treatment of the human or animal body by therapy might be found inadmissible in ***some patent systems***" [emphasis added in bold italics]. It is also important to point out that the IPER was issued in relation to the international application on which the patent in suit was based. Subsequently, the plaintiff applied to amend its European application from methods of treatment claims to Swiss-style claims, but did not do the same in relation to its application in Singapore. In any case, even if the overseas amendment applications are to be dis-regarded, it is still pertinent to note that the plaintiff had previously amended its other Singapore applications from method of treatment claims to Swiss-style claims in 2005, 2007 and 2008, well before the present application was taken out.

112 The plaintiff must have been apprised of the reason for those amendments and understood that methods of treatment are precluded from patent protection in Singapore. Given that the plaintiff is a well-established pharmaceutical company that conceivably owns a good number of patents similar to the one at the heart of this dispute, it must have appreciated that the same preclusion would likely extend to the other patents in its portfolio, including the patent in suit. Thus, just as in *CSL Limited*, the circumstances behoved the plaintiff to seek out appropriate legal advice in relation to its patents for their compliance with patentability requirements. But it did not do so.

113 In view of the above, I reject the proposed amendments on the basis that there has been undue and unreasonable delay on the part of the plaintiff in taking out this amendment application. The plaintiff had ample opportunity to amend its patent pre-grant and post-grant, and its inaction has not been adequately explained save for a denial that there was legal advice alerting it to

the need to amend. Its assertion that it had no occasion to seek advice on the enforcement, strength and validity of the patent[6] does not advance its case at all.[7] As was held in *CSL Limited*, the patentee, as the person who has access to all the relevant information, should not wait until a challenge is made by a third party in whatever form of proceedings may be appropriate in a particular jurisdiction (at [80]).

114 For completeness, I will briefly address the defendant's contention that the plaintiff has not been completely forthright in its application to amend. The basis for this contention is the plaintiff's alleged failure to disclose certain facts which indicate that it had been put on notice much earlier that its claimed invention might have been invalid. These facts include the IPER (see [104] above), and the plaintiff's applications to amend the claims of the corresponding European and UK patents. I am not inclined to place much weight on this alleged non-disclosure since the plaintiff's case is that it was never alerted to the need to amend the patent in suit prior to the commencement of these proceedings. Naturally, it would not have deemed it necessary to disclose events relating to other patents overseas which, in its view, did not undermine this case. Therefore, there is no reason for the court to infer from this omission that the plaintiff *intended* to mislead or conceal certain facts that were adverse to its application.

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6 Plaintiff's Written Submissions, at [65].

7 Plaintiff's Written Submissions, at [65].

Whether the plaintiff is seeking to obtain an unfair advantage

The parties' arguments

115 The defendant alleges that the plaintiff commenced proceedings despite knowing that the patent needed to be amended to address its validity and, consequently, is seeking to obtain an unfair advantage at the defendant's expense.[8] The defendant also suggests that this knowledge on the plaintiff's part that the patent is and always has been invalid indicates that the application was made to avoid invalidation.

116 The plaintiff denies seeking an unfair advantage and argues that it had to commence infringement proceedings first before applying for the amendments because of the timeline stipulated by s 12A(3) of the Medicines Act. Further, as the court in *Novartis AG* stated unequivocally, the objection that the application to amend the patent was made to avoid invalidation is not an objection sustainable on the principles of law relating to the amendment of patents (at [47]).

Decision

117 A patentee who seeks to obtain an unfair advantage from a patent which he knows, or should have known, needed to be amended will not be allowed to amend. In *Smith, Kline and French Laboratories Ltd* at 569, the example is given of a patentee who threatens an infringer with his unamended patent after he knows or should have known of the need to amend. Reference was also made to the decision of *Autoliv Development AB's Patent* [1988] RPC 425 ("*Autoliv Development*") in which the patentees knew that the amendment was necessary to avoid prior art, but sent out letters threatening

[8] Notice of Opposition, at [3.04].

alleged infringers. What is noteworthy about *Autoliv Development* is that the court also considered the four-year delay in seeking the amendment in arriving at the conclusion that the patentees were attempting to obtain an unfair advantage.

118 Similar conduct attracted the reproach of Pumfrey J in *CCL Label* in which the patentee commenced various proceedings to assert its claim after the need to amend had been identified. The patentee did not inform the defendants in those proceedings that the claim could not be defended but would have to be amended or partially revoked. The court considered the patentee's conduct to be a factor that justified its refusal to exercise its discretion to permit the amendment (at [39]).

119 I am satisfied that the plaintiff's conduct here does not attract reproach in the manner described in the above cases. I accept the plaintiff's point that it had to commence the proceedings before the expiry of the 45 days stipulated in s 12A(3) of the Medicines Act, and could not afford to await the grant of leave to amend the patent before commencing infringement proceedings. Following the commencement of these proceedings on 21 April 2015, the plaintiff applied to amend the patent in less than two weeks. Thus, given that the plaintiff had acted swiftly to cure the invalidity, it cannot hardly be said that it was attempting to secure an unfair advantage at the defendant's expense.

120 I am also not prepared to accept the defendant's argument that the plaintiff was attempting to seek an unfair advantage by attempting to validate an invalid claim. In this regard, I am in agreement with Lee Seiu Kin J's holding in *Novartis AG* that an objection that the plaintiffs' application was made to avoid invalidation is neither here nor there because this in and of itself

is not an objection which is sustainable on the principles of law relating to the amendment of patent specifications. It is no answer to an amendment application to argue that the amendment, if granted, would cure an invalid claim and result in an extension of patent protection since the original invalid claim conferred no protection in the first place. My view in this regard comports with that expressed by the learned editors of the *CIPA Guide* at para 76.21:

> … It has been suggested in (1980–81) 10 *CIPA* 316 and 403 that the words "extends the protection conferred by the patent" can only apply to a valid claim, as an invalid claim would confer no protection, with the result that allowable amendment would be limited to combining an invalid claim with the whole of one or more sub-claims. If true, this would preclude the curing of invalidity by incorporating into the claims a feature of any specific sub-claim. It would also preclude amendment to a generalisation intermediate between the scope of the invalid claims and that of the valid ones. This argument was run in *Tickner v Honda* BL C/68/01, noted I.P.D. 25020, it being contended that if claim 1 of the patent were invalid, the introduction of a claim narrower than the original claim 1 but broader than any of the sub-claims would result in the protection conferred by the patent being extended (the original claim 1, being invalid, conferring no protection). That argument was rejected, the court saying that "like patents themselves, the EPC and the Act must be construed purposively", but the proposed amendment was nevertheless found objectionable: see §76.12, above. Thus it should probably be assumed that the reference to "the protection conferred" relates to the terms of the specification and claims as these stand immediately before amendment, irrespective of the validity of the unamended claims.

121 Accordingly, I found no merit in the contention that the plaintiff was attempting to obtain an unfair advantage by seeking the proposed amendments. Nevertheless, as explained above, I was persuaded to disallow the application to amend on the basis that the plaintiff's conduct was nevertheless unreasonable given the lengthy delay in applying for the amendments.

Conclusion

122 In the area of health, medicine, disease, illness and infirmity, it is unsurprising that the question of the role and function of patent law in promoting the research and development of new medicines, products useful in diagnosis, treatment and surgery (such as new imaging technology) and treatment therapies has long thrown up tricky questions which, at the heart, engage the policy and purpose of patent law. For instance, the development of modern biotechnology on the back of the huge advances in genetics have increased the intensity and range of questions as to what can or should be protected by patent law. Such concerns, whilst not immediately apparent in the present case, form the backdrop against which the issues in this application should be considered.

123 In the present application, the question before me concerned the exercise of the court's power to grant an amendment post-grant so as to re-focus a claim for a method of treatment claim to one over the use of the disclosed compound to manufacture a medicament for treating pain (*ie*, a Swiss-style claim). It was not necessary for me to make any decision on the validity of Swiss-style claims. Nevertheless, I note the comment of Arnold J in *Warner-Lambert HC* that the Swiss form claim, whilst accepted, was a "piece of judicial law making" which "fudged some of the difficult issues" (at [90]). Indeed, Floyd LJ in *Warner-Lambert CA* at [54] also referred briefly to the criticisms of Swiss form claims including the point that if the idea was that the Swiss form claim protects a doctor from being sued for infringement, it was hard to see how that was in fact so. A Swiss form claim being a form of process patent is also infringed by anyone who uses or disposes of the direct product of the process. The frustration felt by Floyd LJ is self-evident in his quotation of a statement by Lord Nicholls of Birkenhead in *Sempra Metals Ltd*

(formerly Metallgesellschaft Ltd) v Inland Revenue Commissioners [2008] 1 AC 561 at [51] that "legal rules which are not soundly based resemble proverbial bad pennies: they turn up again and again". Floyd LJ observed also that thirty years after the confirmation of Swiss claims in *Eisai*, the courts in UK and Europe were still "working on how to deal with the fall-out from that case" and that "it would have been better if doctors had been provided with a defence or the restriction on methods of treatment repealed altogether" (at [55]).

124 Statuory developments have of course taken place in the UK and Europe (following the introduction of the EPC 2000); but even so, the scope of patents for second medical use remains tricky. It is evident that problems may arise over the scope of liability of the various parties who may be involved in the production, labelling, supply and distribution of the medical compounds. As noted, some countries, whilst recognising the public interest in allowing doctors to treat patients without fear of patent infringement, prefer to allow method of treatment claims whilst providing medical practitioners with robust defences. Ultimately, the question as to the extent to which Singapore patent law should support method of treatment claims is a matter that can only be addressed by Parliament.

125 To briefly conclude, I have found that the proposed amendments are impermissible by dint of s 84(3)(*b*) of the Act because they extend the protection conferred by the patent. Further, this case is in my view an appropriate one in which the court should exercise its discretion to disallow the amendments because they were sought after a lengthy and inexplicable delay. For these reasons, the application to amend the patent in suit is dismissed with costs to the defendant (to be taxed or agreed).

126 As a post-script, the court would also like to place on record its appreciation for counsel's assistance and helpful submissions.

George Wei
Judge

Stanley Lai Tze Chang, SC, Gloria Goh En-Ci and Clara Tung Yi Lin (Allen & Gledhill LLP) for the plaintiff;
Suhaimi Bin Lazim and Chow Jian Hong (Mirandah Law LLP) for the defendant.