Warner-Lambert Company LLC *v* Novartis (Singapore) Pte Ltd [2017] SGCA 45

Case Number	: Civil Appeal No 121 of 2016
Decision Date	: 01 August 2017
Tribunal/Court	: Court of Appeal
Coram	: Sundaresh Menon CJ; Chao Hick Tin JA; Andrew Phang Boon Leong JA; Judith Prakash JA; Tay Yong Kwang JA
Counsel Name(s)	: Stanley Lai Tze Chang, SC, Gloria Goh En-Ci and Clara Tung Yi Lin (Allen & Gledhill LLP) for the appellant; Prithipal Singh s/o Seva Singh, Suhaimi Bin Lazim and Chow Jian Hong (Mirandah Law LLP) for the respondent; and Professor David Llewelyn (School of Law, Singapore Management University) as amicus curiae.
Parties	: WARNER-LAMBERT COMPANY LLC — NOVARTIS (SINGAPORE) PTE LTD

Patents and Inventions – Industrial application

Patents and Inventions – Novelty

[LawNet Editorial Note: The decision from which this appeal arose is reported at [2016] 4 SLR 252.]

1 August 2017 Judgment reserved

Tay Yong Kwang JA (delivering the judgment of the court):

Introduction

1 This appeal arises from an ongoing dispute in Suit 390 of 2015 ("Suit 390") between two large pharmaceutical companies, Warner-Lambert Company LLC ("Warner-Lambert") and Novartis (Singapore) Pte Ltd ("Novartis"). The subject matter of Suit 390 is a pharmaceutical patent owned by Warner-Lambert which claims a monopoly over the use of a substance known as pregabalin for the treatment of pain ("the Patent"). Under the Patent, Warner-Lambert manufactures and distributes the product "Lyrica" in Singapore. "Lyrica" is approved by the Health Sciences Authority ("the HSA") for use in treating ailments which include neuropathic pain and chronic pain disorders, including fibromyalgia. The Patent was filed on 16 July 1997 and granted in Singapore on 23 May 2000. Its twenty-year statutory protection therefore expired on 16 July 2017.

2 On 23 March 2015, Warner-Lambert received notification of Novartis' applications to the HSA for product licences for pregabalin products, pursuant to s 12A(3)(*a*) of the Medicines Act (Cap 176, 1985 Rev Ed). In the notification, Novartis claimed that the Patent would not be infringed by the acts for which the product licences were sought. On 21 April 2015, Warner-Lambert commenced Suit 390 seeking, among other relief, a declaration that the Patent would be infringed by Novartis if it did the acts for which the product licences were sought. On 5 May 2015, Warner-Lambert informed Novartis of its intention to amend the Patent.

3 On 2 June 2015, Novartis filed its defence and counterclaim seeking revocation of the Patent on the ground that the Patent was invalid as it claimed a monopoly over methods of treatment of the human or animal body, something impermissible under Singapore's patent law. One of the requirements of a patent is that it is capable of industrial application. However, s 16(2) of the Patents Act (Cap

221, 2005 Rev Ed) provides:

> (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.

4 On 26 August 2015, Warner-Lambert applied by Summons 4136 of 2015 ("SUM 4136") for leave to amend the Patent pursuant to s 83(1) of the Patents Act. The amendments aimed to cure the invalidity in the Patent's granted claims ("the Granted Claims") which clearly contradicted s 16(2) of the Patents Act.

5 The High Court judge ("the Judge") dismissed Warner-Lambert's application to amend the Patent. He was of the view that the amendments, if granted, would extend the scope of protection of the Patent. He also held that there had been undue delay by Warner-Lambert in seeking the amendments which warranted the exercise of the court's discretion to disallow the amendments. The Judge's decision is reported as *Warner-Lambert Co LLC v Novartis (Singapore) Pte Ltd* [2016] 4 SLR 252 (the "Judgment"). On 1 August 2016, Warner-Lambert was granted leave by the Judge to appeal against his decision to dismiss SUM 4136 "insofar as it relate[d] to [his] findings that the amendment would extend the protection conferred by the patent under Section 84(3)(*b*) of the Patents Act and that the court should exercise its discretion to disallow the amendments because they were sought after a lengthy and inexplicable delay".

6 Having considered the parties' written and oral submissions and those of Professor David Llewelyn from the School of Law, Singapore Management University as *amicus curiae*, we agree with the Judge's decision and dismiss Warner-Lambert's appeal. This appeal also raised certain issues in patent law which have not been considered by the Singapore courts. These issues relate to the protection of subsequent medical uses of known substances and the validity of "Swiss-style" claims under the Patents Act. Although the determination of these issues is not necessary for this appeal, we take the opportunity in this judgment to make our observations on these issues.

Background Facts

The method of treatment exclusion

7 As mentioned above, method of treatment claims are excluded from patentability by s 16(2) of the Patents Act which deems such claims incapable of industrial application, a requirement for patentability under s 13(1) of the Patents Act. The rationale behind the method of treatment exclusion has been set out clearly by the Judge at [31] to [33] of the Judgment as follows:

> *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…

…

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).

8 As helpfully pointed out by the *amicus curiae*, "a 2014 study by the International Association for the Protection of Intellectual Property, known as AIPPI (Association Internationale pour la Protection de la Propriété Intellectuelle), reported that "method of human treatment" claims are permitted only in the USA, Australia and Russia". [note: 1]

The Patent

9 Before delving into the details of the Patent, it is useful to look at the registration system in place at the time the Patent was filed and granted in Singapore. At the time of Warner-Lambert's application in 1997, Singapore's patent system was a self-assessment system under the Patents Act (Cap 221, 1995 Rev Ed). In this self-assessment system, the Intellectual Property Office of Singapore (IPOS) did not conduct an independent search and examination to determine if the invention was patentable, *ie*, that it fulfilled the three requirements of novelty, inventive step and industrial application. Instead, the burden was on the applicant to self-certify the patent's compliance with the patentability requirements under the Patents Act. A summary of the self-assessment system is provided at para 29.4.8 of Ng-Loy Wee Loon, *Law of Intellectual Property of Singapore* (Sweet & Maxwell, 2nd Ed, 2014) ("*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*… [emphasis added]

10 The reason for having a self-assessment system was explained by then Minister for Law, Professor S Jayakumar, during the Second Reading of the Patents Bill (see *Singapore Parliamentary Debates, Official Report* (21 March 1994) vol 62 col 1446):

> In order to ascertain patentability, an invention has to undergo a search and examination process. We have decided to avoid the substantial investment in building up full-fledged search and examination capabilities in Singapore, and therefore search and examination reports furnished by designated Foreign Patent Offices and International Search and Preliminary Examinations Authorities under a treaty known as the Patent Cooperation Treaty will be accepted.

11 At the time of Warner-Lambert's application in 1997, it was also possible to obtain patent protection in Singapore via an international application made pursuant to the Patent Cooperation Treaty (the "PCT"), to which Singapore is a contracting state. A brief summary of the steps to file an international application is set out at paras 29.4.10 to 29.4.12 of *Ng-Loy Wee Loon*:

> [29.4.10] A national/resident of the PCT member country may file a single application ('PCT application') with a single office (e.g. the patent office of his country of origin or the International Bureau at the WIPO) in one language and with one set of fees in one currency. This PCT application is subject to an international search, which results in an 'international search report' (ISR) citing the prior art relevant to the invention, and/or a non-binding 'preliminary international report on patentability') (IPRP) that looks at whether the invention satisfies the international patentability criteria (novelty; inventive step; industrial application). All this takes place during what is called the 'international phase' of the application.
>
> [29.4.11] With the ISR and/or IPRP in hand, the patent applicant is in a better position to decide whether it is worth his while to continue prosecuting his application in a particular PCT country (or countries). If he decides to do so, his PCT application is said to 'enter the national phase' of the country. His application is examined by the patent office of this country in accordance with the domestic patent law, and it is ultimately this national patent office which decides whether to grant a patent for this invention.
>
> [29.4.12] If the patent applicant decides to continue prosecuting his PCT application in Singapore, he must file the necessary documents with the Registrar of Patents at IPOS within a certain period of time. In the Patents Act, this application is described as an 'international application for a patent (Singapore) which has entered the national phase in Singapore'. This application is treated as an application filed under the Patents Act. However, this applicant has an additional option when he requests for examination or supplementary examination: he may also choose to rely on the ISR and/or IPRP issued under the international phase.

12 On 14 February 2014, the self-assessment system was replaced by a "positive-grant" system which remains in force today. In the "positive-grant" system, IPOS makes a positive determination on whether the patent application complies with the patentability requirements of the Patents Act. To a large extent, the international application process described above remains available to applicants today. Prospective applicants may submit the full search and examination report issued by a foreign patent office for the same invention and IPOS will only conduct a limited supplementary examination. However, pursuant to the Patents (Amendment) Act 2017 (No 18 of 2017), which was passed by Parliament earlier this year on 28 February 2017, such a process will no longer be available to applicants from the planned date of 1 January 2020 when IPOS will conduct the examination of all applications before grant.

13 Warner-Lambert filed the Patent on 16 July 1997 under an international application

(PCT/US1997/012390). [note: 2] On 4 May 1998, Warner-Lambert obtained an International Preliminary Examination Report ("IPER") from the European Patent Office acting as an International Preliminary Examining Authority ("IPEA") under the PCT. The IPER obtained by Warner-Lambert stated in relation to the industrial applicability of the Patent at item 1.4 that "[c]laims directed to methods of treatment of the human or animal body by therapy might be found inadmissible in some patent systems". [note: 3]

14 On 23 May 2000, despite the statement made in the IPER in relation to the industrial applicability of the Patent, Warner-Lambert proceeded to have the Patent granted with effect from 16 July 1997 (the priority date of the application). Until SUM 4136 was filed on 26 August 2015, Warner-Lambert did not make any application to amend the Patent and the Patent has remained on the register in the form that it was originally granted. As patents in Singapore are protected for a term of 20 years from the date of filing pursuant to s 36 of the Patents Act, the Patent expired on 16 July 2017.

Novartis' application for product licenses

15 On 23 March 2015, Warner-Lambert received notices of Novartis' applications to the HSA dated 9 March 2015 for product licences in respect of pregabalin products pursuant to s 12A(3)(*a*) of the Medicines Act. [note: 4] Section 12A of the Medicines Act provides the procedure for drug manufacturers to obtain a product licence when the HSA takes the view that the medicinal product in question may relate to the subject matter of an existing patent. Section 12A(3)(*a*) of the Medicines Act requires the applicant for such product licences to notify the proprietor of the existing patent of its application for a product licence by issuing a notice in a prescribed form:

> (3) The licensing authority may, if the applicant has declared that in his opinion and to the best of his belief the patent is invalid or will not be infringed by the doing of the act for which the licence is sought, or if the licensing authority considers it appropriate in any particular case, require the applicant to do the following within such time as the licensing authority may determine:
>
> (*a*) serve on the proprietor of the patent a notice in the prescribed form of his application;
>
> …

16 In the notices, Novartis sought product licences in respect of three formulations of "Pregabalin Sandoz Capsules" and stated that it was of the view that its intended products would not infringe the Patent as they were not for the indications of treatment covered by the Patent.

The commencement of Suit 390

17 On 21 April 2015, Warner-Lambert commenced Suit 390 against Novartis seeking, among other relief, a declaration that its Patent would be infringed by the doing of the acts for which the product licences were sought. On 5 May 2015, Warner-Lambert notified Novartis of its intention to apply to amend the Patent.

18 On 2 June 2015, Novartis filed its defence and counterclaim to Suit 390. Novartis counterclaimed for a revocation of the Patent on the basis that it was invalid for the reason that the Granted Claims were claims on method of treatment of the human or animal body, which are not patentable in Singapore pursuant to s 16(2) of the Patents Act.

19 Warner-Lambert advertised its proposed amendments on 29 June 2015, as required under O 87A r 11(1) of the Rules of Court (Cap 322, R 5, 2014 Rev Ed). On 24 July 2015, Novartis filed its notice of opposition to the proposed amendments. On 26 August 2015, Warner-Lambert filed SUM 4136 to amend the claims in the Patent.

The proposed amendments

20 It is undisputed that the proposed amendments ("the Amended Claims") are meant to address the invalidity of the Granted Claims as they are method of treatment claims. Warner-Lambert accepts that the Granted Claims as they stand are invalid and this may be seen from the Statement of Reasons (at paras 3 to 5) in its application under SUM 4136. There, Warner-Lambert states that (a) the current claims are method of treatment claims and (b) method of treatment claims are not allowed because of s 16(2) of the Patents Act:

> 3. The proposed amendments are to amend the current claims in the Patent which are currently drafted as method of treatment claims to Swiss-style claims (or second medical use claims), which are accepted under Singapore law. The Examination Guidelines for Patent Applications 2015 issued by the Intellectual Property Office of Singapore (version April 2015) ("Examination Guidelines") clearly state that Swiss-style claims are permitted.
>
> 4. At Sections 8.40 and 8.41 of the Examination Guidelines, it is stated that claims that read as, *inter alia*, "A method of treating…" are not allowable since they are construed as methods of treatment which are not industrially applicable under Section 16(2) of the Act, and "amendment to acceptable medical use claims format should be sought for claims of these types". It is then stated in Section 8.42 of the Examination Guidelines that "second medical use" claims in the form of, *inter alia*, "the use of compound X in the manufacture of a medicament for the treatment of condition Y – Typical form of Swiss-type claim" is allowable.
>
> 5. The proposed amendments to the claim of the Patent to amend the current method of treatment claims to Swiss-type claims are consistent with Singapore law that permits patentees to make Swiss-type claims for second medical uses.

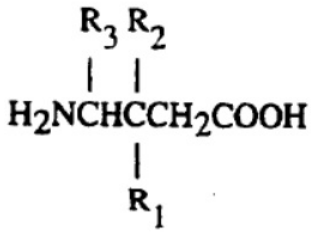
21 The Amended Claims are in the form of Swiss-style claims. Swiss-style claims are patent claims which follow the general formulation:

> The use of compound X in the *manufacture* of a medicament for a specified (and new) therapeutic use Y.

Being claims over the use of a compound for the purpose of manufacturing as opposed to a method of treatment, Swiss-style claims attempt to avoid the method of treatment exclusion under s 16(2) of the Patents Act.

22 The proposed amendments as marked up against the Granted Claims are as follows: [note: 5]

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



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.

1 3 . ~~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.

The proceedings below

23 The Judge heard SUM 4136 on 23 November 2015. Before the Judge, Novartis' opposition to the proposed amendments was three-fold:

(a) First, the amendments, if adopted, would be futile as the amended claims would fail to satisfy the requirements for patentability under the Patents Act, namely, novelty, inventive step and industrial application.

(b) Second, the proposed amendments would fall afoul of s 84(3) of the Patents Act because they resulted in the disclosure of additional matter and the extension of the protection conferred by the Granted Claims.

(c) Third, the court should exercise its direction to reject the amendments because:

(i) there had been an unreasonable delay on the part of Warner-Lambert in seeking the proposed amendments;

(ii) Warner-Lambert had enjoyed an unfair advantage from the Patent; and

(iii) Warner-Lambert had failed to make full disclosure of all relevant matters in relation to the proposed amendments.

24 On 26 May 2016, the Judge dismissed Warner-Lambert's application to amend the Patent on two grounds. First, the Judge held that the proposed amendments would have the effect of extending the protection conferred by the Patent, in contravention of s 84(3)(*b*) of the Patents Act. [note: 6] The Judge found that while both the Amended Claims and the Granted Claims were "broadly connected by the same final objective of treating pain", [note: 7] the former covered the making of the compound for the purpose of administration while the latter only covered the act of administration of the compound to treat pain and not the preceding manufacturing process that produced the compound for that use.

25 Second, the Judge found that there was undue and unreasonable delay on the part of Warner-Lambert in taking out SUM 4136. The Judge held that Warner-Lambert had ample opportunity to amend the Patent pre-grant and post-grant and its inaction had not been adequately explained. [note: 8]

26 The Judge also found that:

(a) the Amended Claims did not result in the disclosure of additional matter; [note: 9] and

(b) Warner-Lambert was not seeking an unfair advantage by attempting to validate an invalid claim. [note: 10]

Arguments on appeal

27 Warner-Lambert's appeal rested on two grounds:

(a) First, it contended that the Judge erred in finding that the Amended Claims extended the

scope of protection of the Patent; and

(b) Second, it contended that the Judge erred in finding that there was undue delay in bringing the amendments.

28 In respect of the Judge's finding that the Amended Claims extended the scope of protection of the Patent, Warner-Lambert submitted the following:

(a) First, Warner-Lambert contended that the skilled reader, on a purposive reading, would understand that the essential feature of the Granted Claims and Amended Claims was the new therapeutic use of pregabalin rather than the step of manufacturing pregabalin. As such, it submitted that there would be no extension of protection because the Granted Claims and Amended Claims protect the same invention, *ie*, the use of pregabalin to treat pain.

(b) Second, Warner-Lambert contended that s 84(3) of the Patents Act should be read purposively such as not to preclude amendments which did not alter the nature of the underlying invention but simply converted a claim from an invalid form to a valid form.

(c) Finally, Warner-Lambert argued that there are strong policy reasons for considering secondary infringement when determining whether the scope of protection has been extended. In that regard, Warner-Lambert argued that allowing the amendments would not add infringing acts but merely transform secondary infringement into primary infringement.

29 In relation to the issue of undue delay, Warner-Lambert submitted that the level of knowledge required to disentitle the patentee to the opportunity to amend the patent is high. Warner-Lambert contended that the Judge had given insufficient regard to the extent to which the self-assessment regime, under which the Patent was registered, placed the risk and responsibility of identifying and removing potentially invalid patents from the Register on both the patentee and potential adverse parties, rather than primarily on the patentee. On this basis, Warner-Lambert submitted that it was not unreasonable to give notice of its intention to amend the Patent on 5 May 2015, having first received legal advice on the requirements of a valid patent under Singapore law in March 2015. Warner-Lambert argued that this conformed with case law showing that the court regards the time for unreasonable delay as starting to run once the patentee has received professional advice that the patent is problematic.

30 In response, Novartis contended that the Judge correctly refused the amendments on the basis that they extended the scope of protection of the Patent. Novartis submitted that the step of manufacture, which was not protected under the Granted Claims, would now be protected by the Amended Claims. The step of manufacture in the Amended Claims was an extension because it covered an entirely different subject matter from the Granted Claims which were exclusively methods of treatment claims. Novartis further argued that the step of manufacture constituted an essential feature of the Amended Claim and could not be characterised as an insignificant inclusion, given its importance in avoiding the method of treatment exclusion and its link with the end-use of pregabalin in treatment.

31 With respect to the issue of undue delay, Novartis contended that the Judge correctly exercised his discretion to refuse the proposed amendments because Warner-Lambert failed to amend the Patent expeditiously, despite having been made aware of the risk of invalidity. Novartis relied on the following facts to support its contention:

(a) Warner-Lambert was notified of potential issues arising out of the method of treatment

exclusion by the IPER; and

(b) Warner-Lambert had amended the Patent's corresponding European applications as well as other method of treatment patents in Singapore to Swiss-style claims.

32 Novartis also contended that Warner-Lambert had not offered any reasonable explanation for the delay save for the bare assertion that it was not sufficiently advised of the risk of invalidity of the Patent. On the whole, Novartis submitted that given the public interest in expeditious amendments and the burden placed on patentees by the self-assessment system in ensuring that the requirements of patentability were fulfilled before grant, it was unacceptable for Warner-Lambert to delay rectifying the defect or seeking legal advice in relation to the Patent's potential invalidity.

Applicable principles relating to amendments under s 83

33 There are two issues in this appeal:

(a) Whether the proposed amendments to the Patent would extend the scope of protection conferred by the Patent, in contravention of s 84(3)(*b*) of the Patents Act; and

(b) Whether the Court should exercise its discretion to refuse the amendments on the ground that Warner-Lambert had delayed for an unreasonable period before seeking to make the amendments.

34 Post-grant amendment of patents, when parties are in the midst of court proceedings, are governed by s 83 of the Patents Act:

Amendment of patent in infringement or revocation proceedings

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

35 Section 84(3) of the Patents Act limits the court's power to allow an amendment of a patent's specification in the following manner:

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

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

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

The amendments sought must also satisfy the "base-line criteria" provided in s 25(5) of the Patents Act (see *Trek Technology (Singapore) Pte Ltd v FE Global Electronics Pte Ltd and other and other suits* [2005] 3 SLR(R) 389 at [52]). Section 25(5) of the Patents Act states as follows:

(5) The claim or claims shall –

(*a*) define the matter for which the applicant seeks protection;

(*b*) be clear and concise;

(*c*) be supported by the description; and

(*d*) relate to one invention or to a group of inventions which are so linked as to form a single inventive concept.

36 It is clear from the language of s 83(1) that the power to allow an amendment of patent specifications is a discretionary one (see *Ship's Equipment Centre Bremen GmbH v Fuji Trading (Singapore) Pte Ltd and others and another suit* [2015] 4 SLR 781 ("*Ship's Equipment*") at [125]). Hence, even if the amendment does not disclose additional matter or extend the protection conferred by the patent, the court retains the general discretion to refuse an amendment application. The rationale of this general discretion was reiterated by Lee Seiu Kin J in *Ship's Equipment* at [133]:

> …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 Proctor & Gamble Limited* [2000] FSR 235 at 248 as the 'desire to protect the public against abuse of monopoly'. Pumfrey J in *Instance* 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".

37 The factors to be considered in the exercise of this discretion were set out by Aldous J (as he then was) in *Smith Kline & French Laboratories Limited v Evans Medical Limited* [1989] FSR 561 ("*Smith Kline & French Laboratories Ltd*") at 569, endorsed by this Court in *FE Global Electronics Pte Ltd v Trek Technology (Singapore) Pte Ltd and another appeal* [2006] 1 SLR(R) 874 ("*FE Global*") at [29] and applied by the High Court in *Novartis AG and another v Ranbaxy (Malaysia) Sdn Bhd* [2013] 2 SLR 117 at [9] ("*Novartis AG v Ranbaxy*"). These factors are:

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

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

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

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

(e) Whether the conduct of the patentee discourages the amendment of the patent.

38 Where the exercise of judicial discretion is called into question, an appellate court would be slow to substitute its decision for that of the lower court. The standard for overturning a judge's exercise of discretion is a "high one" even though appeals are by way of rehearing: see *TDA v TCZ and others* [2016] 3 SLR 329 at [25] cited by this Court in *Ceramiche Caesar SpA v Caesarstone Sdot-Yam Ltd* [2017] SGCA 30 at [21]. The circumstances for overturning a judge's discretion are set out by this Court in *Lian Soon Construction Pte Ltd v Guan Qian Realty Pte Ltd* [1999] 1 SLR(R) 1053 at [34]:

> It is trite law that an appeal against the exercise of a judge's discretion will not be entertained unless it be shown that he exercised his discretion under a mistake of law, in disregard of

> principle, under a misapprehension as to the facts, or that he took account of irrelevant matters, or the decision reached was "outside the generous ambit within which a reasonable disagreement is possible"…

The standard of review prescribed above has been applied by this Court in *Tjong Very Sumito and others v Chan Sing En and others* [2011] 4 SLR 580 at [21] and *Westacre Investments Inc v The State-Owned Company Yugoimport SDPR* [2009] 2 SLR(R) 166 at [17].

39 Having reiterated these established principles, we now consider the Judge's exercise of discretion in refusing Warner-Lambert's amendment application and the issue of whether the amendments would extend the scope of the Patent's protection.

Whether there has been undue delay in seeking the amendments

40 We consider the issue of undue delay first. The Judge's holding that there was undue delay on the part of Warner-Lambert in seeking the amendments was entirely justified on the facts. The delay was for more than a decade. There was no reasonable ground to excuse the long delay. In our view, it certainly could not be due to lack of financial resources.

41 As stated at [37(c)] above, whether the patentee delayed in seeking the amendments and, if so, whether there was a reasonable explanation for such delay are factors to consider in the exercise of the court's discretion. This is because the patentee should not be entitled to stand idle after discovering the need for amendment: see *Novartis AG v Ranbaxy* at [48] (in the context of the discovery of relevant prior art):

> 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 …

42 In deciding what amounts to an undue delay, the court considers the particular circumstances of each case, such as the length of the delay as well as the applicant's explanation for the delay. A period need not be long to be considered an undue delay. For example, in *Instance v CCL Label Inc* [2002] FSR 27, the court found that a delay of one year amounted to an undue delay as a period of two months, after receiving counsel's advice, would have been sufficient to formulate an amendment. However, a delay spanning many years would indicate strongly that it was an unreasonable one.

43 The court also considers whether the applicant is able to provide a reasonable explanation for the delay. This is also a fact-specific inquiry. An example of a case where the court found a reasonable explanation is *Novartis AG v Ranbaxy*. In that case, the court accepted the plaintiffs' explanation that despite being challenged on the patent's validity on the ground of prior art, they genuinely believed that they would prevail before the European Patent Office in 2006 and therefore did not take steps to amend the Singapore patent. In 2009, when the European Patent Office proceedings raised prior art which necessitated an application to amend the European patent, the court also 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 should be contrasted with the case of *Ship's Equipment*, where the court rejected the explanation provided. There, the plaintiff published its notice of intention to amend its Singapore patent more than two years after the decision of the Opposition Division of the European Patent Office was released in relation to the corresponding European patent. In explaining

the delay, the plaintiff argued that it was entitled to wait for the final outcome of the appeal to the Appeal Board of the European Patent Office before deciding whether to amend the patent in Singapore. Lee J dismissed the plaintiff's explanation as an afterthought and held that there was therefore no reasonable explanation for the delay. This was based on the fact that the plaintiff in that case, unlike the plaintiff in *Novartis AG v Ranbaxy*, had sought and obtained the amendments to the corresponding European patent much earlier but having done so, took no steps to amend the Singapore patent.

The threshold of knowledge

44 The parties disagreed over the requisite level of knowledge of the need to amend. Novartis contended that the patentee does not need to have actual knowledge of the invalidity of the patent before he is put on notice of the need to amend and that constructive knowledge of matters which cast suspicion on the validity of the patent is sufficient to put the patentee on notice. Warner-Lambert accepted that there is no strict rule that actual knowledge is required and that constructive knowledge that the patent "may well be" invalid could suffice in appropriate circumstances. However, Warner-Lambert contended that the threshold of actual or constructive knowledge sufficient to disentitle the patentee the opportunity to amend the patent is still a high one. Accordingly, Warner-Lambert submitted that the Judge set too low a threshold for the "extent and quality of knowledge required to start the clock running". Warner-Lambert further contended that a lenient approach ought to be adopted as the self-assessment system (which was in place at the time the Patent was granted) placed the burden of rectifying or removing potentially invalid patents from the patent register on both the patentee and the public jointly.

45 In determining the requisite threshold of knowledge, the Judge adopted the approach taken by Jessup J in *CSL Limited v Novo Nordisk Pharmaceuticals Pty Ltd (No 2)* [2010] FCA 1251 ("*CSL Limited*"). In *CSL Limited* at [76], after considering the key Australian and English authorities, 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.

46 In *CSL Limited*, CSL Limited and Monash University, proprietors of an Australian patent in respect of an invention for a stabilised growth hormone and a method of preparation, commenced infringement proceedings against the defendant, Novo Nordisk Pharmaceuticals Pty Ltd ("Novo"). Novo cross-claimed for a declaration of invalidity and patent revocation on the grounds of lack of inventive step and of novelty. CSL Limited and Monash University then sought to amend the Australian patent by inserting a statement into Claim 1 of the patent that specified the pH of the formulation and removing the pH requirement from Claim 7. CSL Limited and Monash University held similar patents in other jurisdictions and the examiners in multiple jurisdictions had expressed the view that the claim in question should not be granted because of the existence of certain prior art. The patentees' explanation for the delay in bringing the amendment was that they had never received advice from their attorneys that once a particular amendment was made to a patent in any particular jurisdiction, there was some benefit or gain to be had in reviewing the entire portfolio with the amendment in mind.

47 The patentees' explanation was rejected by Jessup J who held that the patentees had been put squarely on notice that their claim was problematic and the absence of any evidence of professional advice contrary to the opinions expressed by the examiners counted against the applicants. The examiners' opinions, in Jessup J's view, imposed upon the applicants at least the obligation to obtain advice in relation to the patent in question (at [79]).

48 We agree with the Judge's view that constructive knowledge of a patent's potential invalidity is

sufficient. As rightly stated by the Judge at [105] of the Judgment, "[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". In our judgment, ensuring the timeliness of patent amendments upholds the public interest in "preventing unworthy inventions and products from monopolising the market" (*Martek Biosciences Corp v Cargill International Trading Pte Ltd* [2011] 1 SLR 1287 at [37]). Such an approach would also "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": see *Raleigh Cycle Co Ltd v Miller (H) & Co* [1951] AC 278 at 281.

49 Further, under the self-assessment system, Warner-Lambert was under an obligation to make a considered decision before proceeding to obtain a grant of the Patent. The fact that the system was a self-assessment system at the time of grant should not give patentees the liberty of taking a lackadaisical approach in ensuring that their patent claims in the register comply with the requirements of patentability under the Patents Act. This is especially so as the grant of the Patent allowed Warner-Lambert to enjoy a monopoly in the supply and sale of pregabalin in Singapore despite the clear invalidity of the Granted Claims. Adopting a lenient approach as advocated by Warner-Lambert "would only encourage dilatory conduct and wilful blindness on the part of patentees, and cause invalid patents to remain on the register for longer than necessary". [note: 11]

50 We find that Warner-Lambert's reliance on this Court's remarks in *FE Global* (at [31]) (set out below) for a "lenient approach" to be adopted is misplaced:

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

51 The above passage states that adverse parties are less likely to be surprised by amendments due to the availability of examination reports for public inspection in the context of modern patent registration. The lenient approach does not translate into a duty on the public or potential adverse parties, who may not have the resources or knowledge, to police the patent register. It certainly does not lessen Warner-Lambert's primary duty of ensuring patentability in the first place under the self-assessment system.

52 Finally, we agree with the Judge that 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". [note: 12]

Application to the facts

53 The evidence shows that Warner-Lambert knew or ought to have known that the Patent was

problematic but chose not to take any steps to find out more or to amend the Patent. This is evinced by the following events:

(a) In February 1998, the IPER received by Warner-Lambert 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". [note: 13] In our view, this would have alerted Warner-Lambert to the possibility that the Patent could be invalid in some countries.

(b) On 14 December 1998, Warner-Lambert filed the Patent's corresponding European application (No. 97932617.0-2107) with an accompanying amendment to the claims from method of treatment claims to Swiss-style claims. [note: 14] This showed that Warner-Lambert had begun to take steps in other jurisdictions to remedy the potential invalidity arising from the method of treatment exclusion in some patent systems but failed to do the same for the Patent here.

(c) At various times in 2005, 2007 and 2008, Warner-Lambert applied to amend the following Singapore applications pre-grant from method of treatment claims to Swiss-style claims but did not apply to amend the Patent:

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

This indicates that Warner-Lambert was aware of the method of treatment exclusion under s 16(2) of the Patents Act as it was prompted to take action to make pre-grant amendments to other patents but did not do the same for the Patent.

54 The abovementioned circumstances lead to the conclusion that Warner-Lambert had actual and/or constructive knowledge that:

(a) Method of treatment claims were precluded from patentability in Singapore.

(b) The Patent was wholly invalid as it contained exclusively method of treatment claims.

55 On this basis, we agree with the Judge that it was incumbent on Warner-Lambert to apply to amend the Patent at the earliest possible opportunity or, at the very least, to seek legal advice in relation to the issue. In our judgment, Warner-Lambert's failure to act on this knowledge expeditiously amounted to unreasonable delay.

56 We also find that Warner-Lambert's failure to amend has not been properly explained save for the bare assertion that it did not receive any legal advice alerting it to the need to amend. Warner-Lambert claimed that it was never alerted to the method of treatment exclusion contained in s 16(2) of the Patents Act and asserted that there was neither any challenge by any third party to the validity of the Patent nor any threatened or actual infringement of the Patent which would give rise to the need to seek legal advice on the validity, strength and enforcement of the Patent.

57 We reject Warner-Lambert's explanation. First, Warner-Lambert has not adduced any evidence before the Judge and this Court on the nature and extent of the advice that it received from 1997 until the present proceedings. The various incidents leading up to the present appeal ought to have put Warner-Lambert on notice of the potential invalidity of the Patent (see [53] above). Further, given that Warner-Lambert is an established pharmaceutical company with a sizeable patent portfolio, we find that it was more likely than not that it was aware of the method of treatment exclusion in s 16(2) of the Patents Act and that it recognised the need to amend the Granted Claims.

58 Second, even though the Patent was sought and granted at a time when a self-assessment system was in place in Singapore, it was incumbent on Warner-Lambert to be responsible for the validity of the Patent in the Register. The monopoly rights that Warner-Lambert enjoyed as a result of the grant of the Patent dictated that it should not stand idle and wait for challenges to validity or for infringement before it reviewed the validity of the Patent.

59 Third, accepting Warner-Lambert's explanation would defeat the policy objectives behind s 83(1). As pointed out by Novartis, if a patentee is put on notice only when it receives clear advice that its patent is problematic, patentees would be free to delay amending their patents by simply not taking advice.

60 For the reasons stated, we find that the Judge was right to disallow the proposed amendments on the basis that there was unreasonable delay on the part of the Warner-Lambert in taking out the amendment application. We defer to the Judge's exercise of discretion as there is nothing whatsoever to show that it was wrongly exercised. Even if we were inclined to exercise the discretion anew, we would not have differed from the Judge.

Whether the amendments extend the scope of protection of the Patent

Amendment of obviously invalid patents

61 We now address the second issue in this appeal. The *amicus curiae* set out a related legal problem in this manner:

> …it is by no means clear that an applicant, who failed to make such an amendment pre-grant and instead chose to inform IPOS under the self-assessment system that it should be granted a patent in respect of the invention that was not patentable and thereby secured such a grant, should be permitted post-grant to revisit that by way of amendment.

62 In our judgment, when a patent granted under the self-assessment system is obviously invalid in its totality (as is the case with the Granted Claims here) and such invalidity is attributed solely to the patentee, it seems artificial to even consider whether the proposed amendments extend the protection conferred by that patent. Although all amendment applications concern some level of invalidity arising from a granted patent, there is a clear difference between the situation where a patent is obviously invalid and a situation where a patent is potentially invalid on the ground that it may have been anticipated by prior art or otherwise. In the latter scenario, the amendment is sought to clarify the claims to ensure their continued validity. Therefore, potential invalidity of the patent should not be an impediment to amendment because the claims in the patent are, on their face, deserving of at least some degree of protection. However, when the patent is obviously invalid because it fails to meet even the threshold criteria for patentability, for example, where all the claims are method of treatment claims, such invalidity would be fatal to any amendment application. This is because the granted patent confers no protection whatsoever and the amendment application is seeking to validate that which was not valid from the beginning. In such a case, the court should

exercise its discretion to disallow the amendment. If an amendment were allowed in such a situation, the patentee would obtain protection by relation back when there was no protection to begin with.

63 This strict approach is justified because the patentee who proceeds to obtain an obviously invalid patent under the self-assessment system buys himself an effective monopoly over the subject matter once the patent is entered into the register. The onus is therefore on the patentee to ensure compliance with the requirements in the Patents Act under the self-assessment system.

64 The strict approach should apply where the patent in question is obviously invalid, as in the present case. Arguably, the same approach should also apply to the obviously invalid claims in cases where the patent contains some valid and some obviously invalid claims. In any case, such an approach would affect only a small number of patents since any patent application containing claims similar to the Granted Claims which is made under the present "positive-grant" system would either be rejected or be amended into an acceptable form before grant.

65 As the Granted Claims, being method of treatment claims, are obviously invalid, we would also disallow the amendments sought by Warner-Lambert on this ground.

66 The above analysis is sufficient to disentitle Warner-Lambert from amending the Patent. Nevertheless, for completeness, we consider the approach taken by the Judge in finding that the Amended Claims extended the scope of protection of the Granted Claims. The Judge rightly observed that this issue concerns whether the amendments from method of treatment claims to Swiss-style claims extend the protection conferred by the Patent.

67 The scope of inquiry in an amendment application under s 83(1) of the Patents Act was recently considered by the High Court in *Ship's Equipment*. Similar to the present case, *Ship's Equipment* concerned a patentee's application to amend an existing patent in the midst of infringement proceedings. One of the grounds of the defendants' opposition was that the amended patent would be invalid. Lee J (at [19]) rejected this ground of opposition and held as follows:

> With respect, no matter how persuasive one might consider an EPO decision to be, the validity of a Singapore patent is ultimately a question for the Singapore courts to decide. The Defendants' contention would inevitably require that this court decide on the validity of the 370 Patent before it can determine whether the Proposed Amended Claim 1 should be allowed. This puts the proverbial cart before the horse. Such an approach should not be accepted in the present case where the issue of validity is scheduled to be heard after SUM 2455/2013 and SUM 2458/2013 have been decided. As such, it is necessary to proceed with the examination of the validity of the Proposed Amendments.

68 The above approach appears sensible because the question of the validity of a patent generally requires the assistance of expert evidence, which may not be available at the hearing of the amendment application. As such, the court is not apprised of sufficient evidence at that stage of proceedings to determine whether the patent when amended is invalid or not. The words "examination of the validity of the Proposed Amendments" mentioned in the last sentence of the quotation above refer to the inquiry as to whether the amendments disclosed additional matter or extended the scope of protection of the patent as opposed to whether the amended claims under the patent fulfilled the requirements of a patentable invention under the Patents Act. This is clear from the paragraphs that follow the quotation.

69 The Judge's approach in the present case (at [23] of the Judgment) reflects that of Lee J in *Ship's Equipment* with the slight qualification for "clear and obvious" cases:

> 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.

This is consonant with the view espoused by *Terrell on the Law of Patents* (Richard Miller, Guy Burkill, Colin Birss & Douglas Campbell, (Sweet & Maxwell, 17th Ed, 2010) at para 15-44) that while "[i]t is not the normal procedure to attack the validity of a patent as it is proposed to be amended", "the court…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".

70 In our judgment, as a practical measure, where the amended claims would be obviously invalid, even in the absence of expert or technical evidence, the court may exercise its discretion to disallow the amendment. However, this does not apply to the amendments sought in the present case. The Amended Claims, if allowed, will not leave the Patent obviously invalid because the validity of Swiss-style claims, which has been upheld in jurisdictions such as the UK and Europe in the context of legislation similar to ours, has yet to be considered by the Singapore Courts.

71 The *amicus curiae* agrees with the approach taken by the Judge: [note: 15]

> The process provided by the PA for post-grant amendments of claims requires consideration only (apart from the requirements of section 84(3)) of whether the amendments cure the invalidity giving rise to the amendment: it does not require consideration of whether the claims as amended are valid and they may subsequently be found invalid for reasons unconnected with the particular application for amendment… On this issue (which is the subject of the first question posed by the Honourable Court), subject to the practical point I raise in the next paragraph, I respectfully endorse and cannot usefully add to the views and reasoning of the Trial Judge (see Judgment at [14]-[23]).

72 The Judge applied the established legal principles and correctly identified that the "crux of the inquiry is *whether the ambit of the protection conferred by the patent will be extended by the proposed amendments"* [emphasis in original]. In essence, this is an exercise of interpreting the claims purposively: [note: 16]

> 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.

73 The Judge was also correct to observe that an amendment application that seeks to re-formulate a claim from one type of claim to another, for instance, from a product claim to a method of use claim, may be permitted if the scope of protection is not extended. An example of where such a change was allowed is the case of *Vifor Medical AG v Fresenius AG and another* (T 134/95) (22

October 1996). There, a patentee had been granted a product claim in respect of a "container for medical use". The patentee applied for the product claim to be amended into a use claim, which covered only the use of the container. The Technical Board of Appeal of the European Office ("the Board") allowed the amendment on the basis that the change in category resulted in reduction of the scope of protection rather than in extension.

74 The ambit of protection conferred by a patent is demarcated in s 66 of the Patents Act. Acts that would infringe process claims like the Granted Claims here, assuming they are valid, are set out in s 66(1)(*b*) and (*c*) of the Patents Act:

> 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.

We agree with the Judge that the manufacture of the medicament for the purpose of treating pain, as stated in the Amended Claims, is not an act that falls within the ambit of protection of the Granted Claims. The Amended Claims protect the manufacture while the Granted Claims protect the method of treatment. As manufacture was not within the original scope of protection, there would clearly be an extension of the scope of protection if the amendments were allowed. Therefore, Warner-Lambert's submissions (summarised at [28] above) that the Amended Claims and the Granted Claims protect the same invention could not be correct. In contending for a purposive reading of s 84(3) such that it would not preclude the substitution of the Granted Claims with the Amended Claims because the latter would not alter the nature of the underlying invention, Warner-Lambert appears to be advocating that any amendment to the Patent claim, however worded, would not change the scope of protection of the Patent so long as the claim relates to the product in issue. In our view, such a contention cannot be correct. It would effectively make nonsense of the prohibition against method of treatment claims in s 16 of the Patents Act which precisely prohibit the framing of claims as method of treatment claims.

75 The case of *Composition for contraception/Bayer Schering Pharma AG* (T 1635/09) (27 October 2010) ("*Bayer Schering*") which was cited by the Judge at [74] of the Judgment supports such an interpretation of the scope of the Granted and Amended Claims. *Bayer Schering* involved a similar application to amend a use claim into a Swiss-style claim. The issue before the Board was whether the amendment of a claim for the "use of an oral dosage form comprising … for contraception …" into a Swiss-style 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]). The Board was of the view that Swiss-style claims encompassed only the manufacture of a medicament and not the use of the compound for a specific purpose. Accordingly, the Board held 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. The Board also stated that if they did, then they would fall afoul of the method of treatment exception under Art 53(c) of the European Patent Convention 2000.

76 The recent UK Court of Appeal decision in *Warner-Lambert Company LLC v Actavis Group PTC EHF* [2015] EWCA Civ 556 ("*Warner Lambert CA*") offers some guidance as to the scope of protection of Swiss-style claims. The main question posed to the English Court of Appeal in *Warner Lambert CA* was the question of what amounted to infringement of a Swiss-style claim. The English Court of Appeal held at [118] that the technical subject matter of the Swiss-style claim was the *making of pregabalin for patients to whom it will be intentionally administered for treating pain* but fell short of including the *step of actually using pregabalin for treating pain*. As such, the skilled reader's construction of the essential feature of the Amended Claims involves a link between the act of manufacture and the ultimate intentional use of the drug by the end-user to treat pain, rather than the new therapeutic use of the drug itself (which is the essential feature of the Granted Claims).

77 Lastly, we agree with the Judge that secondary or indirect infringement should not be considered in determining the scope of the protection of the Granted Claims. The Judge's findings on this issue are at [90] to [92] of the Judgment:

> 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.

78 We see no reason to disagree with the Judge's reasoning.

Our observations on the novel issues

79 Having disposed of the main issues in this appeal, we now turn to make some observations on the novel issues that arise in the present case. These issues are identified by the Judge at [49] of the Judgment:

> 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 Judge went on to say at [50] and reiterated at [123], that it was not necessary for him to make a determination on the legitimacy or validity of Swiss-style claims under the Patents Act.

80 Swiss-style claims were described by the Judge as having the generalised form of "the use of compound X in the manufacture of a medicament for a specified (and new) therapeutic use Y" (at [40] of the Judgment). The Judge explained that 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. We will discuss Swiss-style claims in greater detail towards the end of this judgment.

81 Without having had the benefit of full arguments from the parties on these two related issues (the scope of s 14(7) of the Patents Act read in conjunction with s 16, and the validity of Swiss-style claims), we make two tentative observations:

(a) The Patents Act appears to support the patentability of second and subsequent medical uses of known substances.

(b) Although Swiss-style claims may offer a valid way of framing claims for second and subsequent medical uses of a known substance, a purpose-limited product claim may also suffice.

Protection of subsequent medical uses under the Patents Act

82 There is a broad public interest in providing incentives and patent protection over new therapeutic uses of known substances. In this regard, we refer to the view expressed in *Schering AG's Application* [1971] RPC 337 at 341:

> It is no doubt sensible that a person who is able to produce a substance which, for example, would cure or prevent cancer should, subject to safeguards, be offered a limited monopoly as a reward, and the possibility of such monopoly protection has undoubtedly resulted in an enormous investment in research in the medical field. If this position is accepted, it is a little difficult to see why someone who by research effort devises a new method of using a known substance to achieve equally beneficial results should be denied patent protection.

83 The conceptual difficulty with recognising new therapeutic uses was explained by the Judge in the present case at [30] of the Judgment:

> 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.

84 This issue may not pose too much difficulty if s 14(7) of the Patents Act is given a wider and purposive interpretation. In our view, the provision recognises new uses of known substances as long as the new uses do not form part of the state of the art. It provides:

> (7) 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.

The *amicus curiae* submitted that the effect of s 14(7) is that "if pregabalin formed part of the state of the art at the time of grant of the subject patent this would not in itself prevent the use of pregabalin in a method of human treatment (for pain) from being novel and complying with one of the three requirements conditions of patentability" under the Patents Act. This statement appears to be premised on the first use of the known substance. If so, as we explain subsequently, we think the provision goes further than merely conferring patentability on the first use.

85 In England, the equivalent provision, s 2(6) of the UK Patents Act 1977 (c 37) (UK) ("the UK Patents Act 1977"), has been interpreted as protecting only the first medical use of known substances. Such an interpretation stems from the use of the words "any such method" in the second last line of s 14(7). The words "any such method" mean that once one therapeutic use is known, claims to further therapeutic uses lack novelty. This reasoning was espoused in *obiter dicta* in *John Wyeth and Brothers Ltd's Application and Schering AG's Applications* [1985] RPC 545 ("*John Wyeth's and Schering's Applications*"). In that case, Falconer J (in delivering the judgment of the court) stated at 565 that:

> …we think the better view would be that a claim in the Swiss form to an invention directed to the use of a known pharmaceutical to manufacture a medicament, not in itself novel, for a second or subsequent and novel medical use would not be patentable as lacking the required novelty. It has to be recognised that it would have been a simple matter to provide for the patenting of such an invention directed to a second medical use by the omission of the word "any" in section 2(6), if it had been the intention of the legislature that a novel second or further use of a known pharmaceutical should be patentable.

86 In our view, there is another way of interpreting s 14(7) of the Patents Act which accords more with the ordinary meaning and is in keeping with the purpose of that provision. In its ordinary meaning, s 14(7) of the Patents Act does protect any use, first or subsequent, which is not part of the state of the art. Hence, the substance or composition may be well known but if a new use for it is found, unknown until the time the invention is disclosed, the invention will qualify within the meaning of the words "the invention is new" in s 13(1)(*a*) of the Patents Act. By this line of reasoning, even if pregabalin had been in use for the past twenty years to treat ailment P only, the knowledge that it could now also be used for the treatment of ailment Q would make the second use novel. If further uses are devised in future, those uses will likewise be novel. In our opinion, finding a new use for a known substance is no less novel and innovative than finding the substance itself. It may even happen that the new use will revolutionise the particular industry or area of knowledge.

87 The words "any such method" in the latter half of s 14(7) refer to "a method of treatment of the human or animal body by surgery or therapy or of diagnosis practised on the human or animal body" in the earlier half. However, that in no way prevents s 14(7) from bearing the meaning that we

have just stated. The same sequence of words also appears in s 16(2) and (3) (see below) and the meaning we have given to these words in s 14(7) is consonant with their meaning in s 16(2) and (3).

88 We therefore find it highly persuasive that s 14(7) enables the patenting of second and subsequent uses of a known substance. If this is correct, then inventors really do not need to resort to Swiss-style claims, which, as the Judge described aptly at [40] of the Judgment, involve a "fiction (implicit) behind the finding of novelty in the method of manufacture on the basis of a new therapeutic use".

89 If s 14(7) of the Patents Act does cover second and subsequent medical uses of known substances, then a purpose-limited product claim may be sufficient to obtain a patent and Swiss-style claims may not be necessary at all. A purpose-limited product claim could take the following form:

> Compound X for use in the treatment of disease Y

Such a claim is not precluded by s 16(2) of the Patents Act because of the qualification in s 16(3). Section 16 reads:

> (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.

Swiss-style claims

90 Swiss-style claims were developed in Europe to overcome the perceived legal difficulties in recognising new uses of known pharmaceutical products. These difficulties were:

> (a) The inventor of the new use of a known pharmaceutical compound is unable to assert patent protection over the pharmaceutical compound in the form of a product claim because the compound is known and already a part of the prior art.
>
> (b) The inventor of the new use of a known pharmaceutical compound is also unable to patent the use of the compound as a method of treatment claim due to statutory exclusions.

91 According to European jurisprudence, Swiss-style claims offer a means to overcome these difficulties because they are neither product claims nor claims to a method of treatment. Instead, Swiss-style claims are claims to a process of manufacture of a medicament for the purpose of the new therapeutic use of the known compound. Courts in jurisdictions such as the UK and Europe with provisions that were *in pari materia* or similar to those in the Patents Act have affirmed the validity of Swiss-style claims as the appropriate form to frame claims over second medical uses.

92 In Europe, Swiss-style claims were first recognised in the decision of the European Patent Office Enlarged Board of Appeal ("the Enlarged Board") in *Eisai/Second medical indication (G 5/83)*

[1979–1985] EPOR B241 ("*Eisai*"). In *Eisai*, the Enlarged Board interpreted Arts 52(4) and 54(2) of the European Patent Convention 1973 ("EPC 1973"), which are similar to ss 16(2) and 14(7) of the Patents Act, in the context of Swiss-style claims. There, the Enlarged Board held that while a method of treatment claim was prohibited, a Swiss-style claim was permitted (at [12] and [19]). The Enlarged Board also found that the patent in question fulfilled the requirement of novelty despite the fact that the compound was a known compound and that the process of manufacture was not novel. The Enlarged Board reasoned that in the context of a Swiss-style claim, the "new and non-obvious use of the known product constitutes the invention".

93 The English Courts recognised the validity of Swiss-style claims in *John Wyeth's and Schering Applications*. There, the court (at 567) adopted the Enlarged Board's approach in *Eisai* and recognised that "in a Swiss type of use claim directed to the use of a known pharmaceutical in the manufacture of a medicament, not novel in itself, for a novel second (or subsequent) therapeutic use, the required novelty of the claimed process may be found in the new second (or subsequent) therapeutic use".

94 It should, however, be noted that there are certain practical difficulties in recognising Swiss-style claims and enforcing them in infringement actions. As observed by Floyd LJ in *Warner-Lambert Company LLC v Generics (UK) Ltd (trading as Mylan) and others* [2016] EWCA Civ 1006 at [187]:

> …[t]he law is struggling on the one hand to give the patentee a proper reward for his contribution to the art by elucidating the new use for the drug, whilst at the same time not excluding the competing manufacturer from making and marketing the drug for its known purpose. The issue is complicated by the interaction with the law relating to, and the practices of the market in, prescription medicines. The solution adopted by this court in Warner-Lambert CoA was an attempt to strike the right balance by not placing insuperable obstacles in the path of the patentee, whilst at the same time recognising in very clear terms that the remedies available for infringement will have to be moulded so as to achieve fair and proportionate relief tailored to the very special circumstances of this type of case.

95 Swiss-style claims are less relevant today in Europe and in the UK because of legislative changes to the European Patent Convention and the introduction of the UK Patents Act 2004, both of which allow patent protection for second or subsequent uses of a substance or composition in a method of human treatment through purpose-limited product claims. Specifically, the UK Patents Act 2004 introduced specific provisions to deal with first medical uses (ss 4A(3)) and subsequent medical uses (4A(4)) separately:

> 4A(3) In the case of an invention consisting of a substance or composition for use in any such method, 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 the state of the art.
>
> 4A(4) In the case of an invention consisting of a substance or composition for a specific use in any such method, 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 that specific use does not form part of the state of the art.

96 Swiss-style claims are allowed by IPOS (see The Examination Guidelines for Patent Applications at IPOS dated 14 February 2014) quoted by the Judge at [49] of the Judgment. While we see no reason to disagree with the validity of such claims at this stage, we think they are merely a novel and perhaps questionable way of getting around what has been perceived to be the meaning of s 14(7) of the Patents Act. If s 14(7) is given the meaning that we have discussed earlier, the need for Swiss-

style claims in Singapore would probably cease.

Conclusion

97 In summary, Warner-Lambert's appeal is dismissed for the following reasons:

(a) First, the Amended Claims should be rejected on the basis of the undue delay by Warner-Lambert in bringing the amendment application.

(b) Second, the Amended Claims extend the scope of protection covered by the Granted Claims.

98 The Judge dismissed SUM 4136 with costs to be taxed or agreed. When he granted leave to Warner-Lambert to appeal, he also ordered that the costs of and incidental to that application be costs in the appeal. In the light of our affirmation of the Judge's decision on both grounds of appeal, it follows that this appeal is dismissed with costs to be taxed or agreed, including the costs of and incidental to the application for leave to appeal.

99 We are grateful to Prof Llewelyn for his time and effort in preparing his written submissions and for his able assistance in court as *amicus curiae*.

[note: 1] Footnote 3 of the amicus curiae's opinion.

[note: 2] Supplementary Core Bundle ("SCB") at pp 84-120.

[note: 3] CB Vol 2 pp117-120.

[note: 4] CB Vol 2 pp 110-116.

[note: 5] Judgment at [9].

[note: 6] Judgment at [78].

[note: 7] Judgment at [83].

[note: 8] Judgment at [113].

[note: 9] Judgment at [56].

[note: 10] Judgment at [120].

[note: 11] Judgment at [107].

[note: 12] Judgment at [104].

[note: 13] CB Vol 2 pp117-120.

[note: 14] SCB at pp 140-142.

[note: 15] Amicus opinion at para 27.

[note: 16] Judgment at [79].