A Swiss and a Miss: The Future of Swiss-style Patents in Singapore

I. Executive summary

1. In the recently-decided case of *Warner-Lambert Company LLC v Novartis (Singapore) Pte Ltd* [2017] SGCA 45, the Court of Appeal ("**CA**") addressed a number of novel issues in Singapore patent law. The dispute between the two pharmaceutical companies was based on Novartis' potential infringement of Warner-Lambert's patent. This patent (filed in 1997) claimed a monopoly over the use of a substance, pregabalin, for the treatment of pain (the "Patent"). In 2015, Novartis applied for regulatory approval to market pregabalin products for other treatments which it claimed were not presently covered by the Patent. In response, Warner-Lambert asserted that to do so would infringe Warner-Lambert's Patent. Novartis countered that the Patent was invalid in any event because it claimed a monopoly over methods of treatment of the human or animal body ("method of treatment" claims), which are not allowed under Singapore's patent law.

2. In response to Novartis' defence, Warner-Lambert sought to amend the Patent in the High Court ("**HC**");[1] the proposed amendments were the specific subject of this stage of the legal action. The HC dismissed Warner-Lambert's application to amend the Patent, stating that: (a) 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,[2] and (b) granting the amendments would extend the Patent's scope of protection.[3] Warner-Lambert appealed the HC's decision to the CA. The CA agreed with the HC on both issues and dismissed Warner-Lambert's appeal against the lower court's refusal to permit amendment of the Patent.

3. In addition, the CA took the opportunity to make some observations on two novel but related issues in Singapore patent law, despite not having had the benefit of full

David Lim, 4th-Year LLB Student, Singapore Management University's School of Law. This work would not have been possible without the invaluable contribution and editing of Professors Ong Ee Ing and David Llewellyn of Singapore Management University.

[1] *Warner-Lambert Co LLC v Novartis (Singapore) Pte Ltd* [2016] 4 SLR 252.
[2] *Id*, at [113].
[3] *Id*, at [89].

arguments from the parties on those issues. The CA's observations are nevertheless instructive as to how future cases may be decided. The issues were: (a) whether second and subsequent medical uses of known substances are patentable; and (b) whether Singapore recognises the legitimacy of "Swiss-style" claims. In its observations, the CA found it highly likely that Singapore's Patents Act permitted the patentability of second and subsequent medical uses of known substances.[4] If this was so, it might be sufficient for inventors of such uses to formulate their patent claims as "purpose-limited product claims". Thus, the CA suggested that "Swiss-style" claims (ie as a process of manufacture of a known substance for the purpose of a new therapeutic use) might not be necessary at all.[5]

II. Material facts

4. Warner-Lambert filed the application for what became the Patent in July 1997; it was granted in May 2000 (although the 20-year term for patent protection starts from the date of filing). At the time of Warner-Lambert's patent application, Singapore operated a self-assessment patent application system, whereby the burden was on the applicant to certify the invention's compliance with the requirements for patentability set out in the Patents Act.

5. Warner-Lambert had applied for the Patent under the Patent Cooperation Treaty, an international patent treaty to which Singapore is a signatory. Under this treaty, an applicant files a single patent application; this application then may be accepted or denied according to the rules of each signatory country. In May 1998, through an International Preliminary Examination Report from the European Patent Office acting as an International Preliminary Examining Authority under the Patent Cooperation Treaty, Warner-Lambert was informed that the claims in the application, which were expressed as a "method of treatment", might not be patentable in some countries. Nonetheless, it proceeded with its application in Singapore and the Patent was granted. Despite amending the equivalent patent in some other countries to deal with the defect, Warner-Lambert did not apply to amend the Patent in Singapore.

---

[4] *Warner-Lambert Company LLC v Novartis (Singapore) Pte Ltd* [2017] SGCA 45 at [88].
[5] *Id*, at [89].

6. In 2015, Novartis applied to the Singapore Health Sciences Authority for licences for certain pregabalin products, stating in its applications that marketing of such products would not infringe Warner-Lambert's patent. As a result, Warner-Lambert commenced legal action, seeking a declaration that the Patent would be infringed by Novartis if the licenses were granted. Novartis countered that the Patent was invalid as it claimed a method of treatment of the human or animal body, which is expressly prohibited by the Patents Act.

7. In August 2015, Warner-Lambert applied to the HC to amend the Patent to cure the alleged problem. In these amendments, Warner-Lambert conceded that the Patent was invalid because the claims were for a "method of treatment" of the human body. It therefore framed its amendments as "Swiss-style" claims instead, ie as the use of pregabalin in the manufacture of a medicine for a specified (and novel) therapeutic use.

8. Novartis challenged the amendments before George Wei J in the HC. The HC decided that: (a) Warner-Lambert's failure to act to amend the Patent until 2015 constituted an undue and unreasonable delay;[6] and (b) the proposed amendments would extend the protection conferred by the Patent, contrary to section 84(3)(*b*) of the Patents Act.[7] The application to amend was refused.

9. Warner-Lambert appealed to the CA on the grounds that the HC had erred in finding (a) undue delay and (b) that the proposed amendments extended the scope of protection of the Patent.

[6] *Supra*, n. 2 at [113].
[7] *Id*, at [89].

III. Issues on appeal

A. Was there undue delay by Warner-Lambert in amending its patent?

10. The CA held that (a) there had been undue delay by Warner-Lambert in seeking amendments to the Patent,[8] and (b) there was no reasonable explanation for such delay.[9] This was because Warner-Lambert took more than a decade to seek the amendments, even though it knew or ought to have known that the form of claims in the Patent was problematic (ie, it had actual or constructive knowledge of the underlying problem).[10]

11. Under the Patents Act, the court's power to allow amendments is a discretionary one. Relevant factors to consider in the exercise of the court's discretion include whether the patentee delayed in seeking the amendments, and whether there are reasonable grounds for such delay. In deciding whether there has been undue delay, the court will consider the time that elapsed between the point at which an applicant first had actual or constructive knowledge of the need to amend, and the time at which the amendment was sought. This need not necessarily be long to be considered an undue delay, but a lengthy delay will strongly indicate unreasonableness.[11]

12. Warner-Lambert asserted that the threshold of actual or constructive knowledge required should be a high one; further, that its knowledge of the need to amend the Patent did not meet this threshold because it did not receive any legal advice alerting it to such a need. As such, it argued, its delay in applying for the amendments was not undue or unreasonable.

13. The CA did not accept this. It held that (a) the threshold of knowledge required should be a low one, in order to ensure the timeliness of patent amendments;[12] (b) constructive, rather than actual, knowledge of the invalidity of a patent was sufficient to start the

[8] *Supra*, n. 5 at [55].
[9] *Id*, at [56].
[10] *Id*, at [40] and [53].
[11] *Id*, at [42].
[12] *Id*, at [45] – [50].

clock running for amendments;[13] and (c) Warner-Lambert had constructive knowledge that "method of treatment" claims could not be patented in Singapore and therefore that the Patent was invalid.[14] Prior to the grant of the Patent, Warner-Lambert had received a report notifying it that "claims directed to methods of treatment of the human or animal body by therapy might be found inadmissible in some patent systems". In fact, soon after receiving this notification, Warner-Lambert took steps to amend its corresponding European patent applications for pregabalin from "method of treatment" claims to "Swiss-style" claims. However, it did not do so for the patent filed in Singapore. Furthermore, Warner-Lambert had applied to amend various other patents in Singapore from "method of treatment" claims to "Swiss-style" claims, but failed to do so for the Patent. Indeed, these actions led to the conclusion that Warner-Lambert had actual knowledge of the invalidity of the Patent. As such, Warner-Lambert's failure to act on this knowledge expeditiously amounted to unreasonable delay that was not properly explained.

B. Did the Amended Claims extend the patent's scope of protection under the original patent?

14. The CA held that the amendments sought would clearly have been an extension of the scope of protection accorded by the Patent.[15] Under section 84(3)(*b*) of the Patents Act, an amendment will not be allowed where it extends the protection conferred by a patent.[16]

15. The CA drew a distinction between patents obviously invalid in totality (such as those excluded from patentability by the Patents Act because they are "method of treatment" claims), and patents which are potentially invalid because they may have been anticipated by prior art.[17] Where a patent is obviously invalid, an amendment application must fail. However, patents that are only potentially invalid may be amended, ie narrowed, to avoid being anticipated by prior art. The Patent, being a

[13] *Id*, at [48].
[14] *Id*, at [53].
[15] *Id*, at [66].
[16] Singapore Patents Act (Cap 221, 2005 Rev Ed) s 84(3)(*b*).
[17] *Supra*, n. 2 at [62]. "Prior art" refers, generally, to publicly available evidence that an invention is not new. See Singapore Patents Act (Cap 221, 2005 Rev Ed) s 14(2).

"method of treatment" claim, was obviously invalid. As such, the proposed amendments must be disallowed.

16. The CA also considered whether Warner-Lambert's amendment application, which re-formulated its claim from a "method of treatment" claim to a "Swiss-style" claim, extended the scope of protection conferred by the Patent. It held that the proposed amendments sought to protect a process of manufacture, while the original claims only protected a method of treatment, and as such the amendments sought would provide an extension of the scope of protection conferred by the Patent.[18]

IV. Novel issues

17. The CA also gave guidance on two novel points of law not necessary for its decision. It discussed (a) whether second and subsequent medical uses of known substances are patentable, and (b) whether Singapore should recognise the validity and legitimacy of "Swiss-style" claims.

18. On (a): the first medical use of a substance (eg where Medicine A is developed for the treatment of Ailment P) is generally patentable. However, some jurisdictions disallow patenting of the same substance for subsequent medical uses (eg where Medicine A is later discovered to also treat Ailment Q). The CA observed that section 14(7) of the Patents Act appears to support the patentability of second and subsequent medical uses of known substances in Singapore.[19]

19. On (b): "Swiss-style" claims are formulated as a process of manufacture of a known substance for the purpose of a new therapeutic use.[20] They are designed to avoid (i) an inventor of a subsequent use of a known substance being unable to claim patent protection over the subsequent use because the known substance is part of the "prior art", and (ii) the statutory exclusion of claims that deal with a "method of treatment" of the human or animal body. The CA noted that in view of the previous observation – that second and subsequent medical uses of known substances might be patentable in

[18] *Id*, at [74].
[19] *Id*, at [81].
[20] *Id*, at [80].

Singapore – "Swiss-style" claims might be not necessary at all. Instead, it might suffice to formulate such claims as "purpose-limited product claims", such as "Medicine A for the treatment of Ailment Q".[21]

20. The CA clarified that these were merely observations, as determination of these novel points was not necessary for this appeal. Moreover, the CA did not have the benefit of having full arguments from the parties on these novel issues.

A. Protection of subsequent medical uses

21. In considering whether second and subsequent medical uses of a known substance could be protected under the Patents Act, the CA first noted the broad public interest in incentivising the research and development of new therapeutic uses of known substances through the granting of patent protection for such uses.[22] However, there was a conceptual difficulty with recognising a new therapeutic use of a known substance as a patentable claim: since a known substance forms part of the prior art, the known substance cannot be patented by the inventor of the new use. The only novelty rests in the new use for the known substance. (As the HC noted in its judgment, in general new uses of a known substance are not given patent protection.) The CA suggested that this difficulty could be alleviated by giving a wider interpretation to section 14(7) of the Patents Act.[23]

22. Section 14(7) states, in part: for a (later) invention consisting of a substance or composition for use in a method of treatment of the human body, the fact that the substance or composition is part of a prior invention shall not prevent the (later) invention from being considered to be new "if the use of the substance or composition *in any such method*" is also new.[24] The position adopted by UK courts is that the words "any such method" mean that once one medical use of a substance or composition is known, claims to second and subsequent uses lack novelty and hence cannot be granted patent protection.

---

[21] *Id*, at [81].
[22] *Id*, at [82].
[23] *Id*, at [84].
[24] Singapore Patents Act (Cap 221, 2005 Rev Ed) s 14(7).

23. However, the CA considered another way of interpreting section 14(7), which was more in keeping with the "ordinary meaning" and purpose of that provision. It suggested that the provision did protect any use, first or subsequent, which was not anticipated by prior art. Therefore, even if a substance itself has been patented, if a new medical use for that substance is later discovered, that new use is also itself patentable. Thus, the CA found it "highly persuasive" that section 14(7) supported the patentability of second and subsequent medical uses of a known substance.[25]

24. The CA further observed that if that were so, it might be sufficient for applicants who wished to patent a second and subsequent medical use of a known substance to file claims in the form of "Compound X for use in the treatment of disease Y", ie a "purpose-limited product claim". Thus "Swiss-style" claims might not be necessary at all.[26]

B. Validity of "Swiss-style" claims

25. The CA considered that, while there was no reason to disagree with the validity of "Swiss-style" at this stage, they were "merely a novel and perhaps questionable way of getting around [the problems raised by] s 14(7) of the Patents Act".[27]

26. The "Swiss-style" claim was developed in Europe to overcome perceived legal difficulties in recognising new uses of known pharmaceutical products.[28] "Swiss-style" claims are neither product claims nor "method of treatment" claims. Instead, they are claims to a *process of manufacture* of a substance for the purpose of a new therapeutic use of the known substance. The validity of "Swiss-style" claims has been recognised in various jurisdictions, including the UK, and by the European Patent Office. They are also presently allowed by the Intellectual Property Office of Singapore.[29]

---

[25] *Supra*, n. 2 at [88].
[26] *Id*, at [89].
[27] *Id*, at [96].
[28] *Id*, at [91] – [92].
[29] See Intellectual Property Office of Singapore, "Examination Guidelines for Patent Applications at IPOS" at para 2.67.

V. Legal implications

27. The case has a number of important implications for future patent cases.

28. First, it serves as a timely reminder that applications for patent amendments should be made expeditiously: undue delay may result in adverse consequences for patent holders.

29. Secondly, patent holders should be careful when drafting any amendments to their patents, to ensure that the amendments do not extend the scope of protection previously granted by the original patent.

30. Thirdly, patent owners should note that the courts are unlikely to grant amendments where the claim as originally filed is obviously invalid, such as when its subject matter is specifically non-patentable by statute (eg a "method of treatment" claim in Singapore).

31. Finally, the CA tentatively observed that the Patents Act could support the patentability of second and subsequent medical uses of known substances. If that were so, it might then suffice for inventors of such uses to frame their patent claims as "purpose-limited product claims". While not denying the validity of "Swiss-style" claims, the CA suggested that their use was questionable.