CASE UPDATE

The Court of Appeal refused to allow the amendment of invalid patent claims from methods of treatment to Swiss-style

10 August 2017

For any queries relating to this article, please contact:

Tan Tee Jim, *S.C.*
tanteejim@leenlee.com.sg

Authors:
Tan Tee Jim, *S.C.*
Eugene Lau

Lee & Lee
50 Raffles Place
#06-00 Singapore Land Tower
Singapore 048623
Tel: +65 6220 0666

Introduction

1. In *Warner-Lambert Company LLC v Novartis (Singapore) Pte Ltd* [2017] SGCA 45 ("**Warner-Lambert**"), the Singapore Court of Appeal (the "**SCA**") refused to exercise its discretion to allow the appellant to amend its method of treatment claims to Swiss-style claims because of undue delay in filing the amendment application.

2. The SCA also considered if the amendments would extend the scope of protection of the appellant's patent as well as the law on subsequent medical uses and Swiss-style claims under the Patents Act ("**PA**").

Facts

3. The case concerned a patent for a method of treating pain through the use of a substance known as pregabalin (the "**Patent**"). Prior to the expiry of the Patent in July 2017, the respondent applied to the Health Sciences Authority for product licences for pregabalin products and stated in the application that the products would not infringe the Patent. The appellant then commenced a suit against the respondent seeking, amongst other reliefs, a declaration that the Patent would be infringed by the products. It also filed an application for leave to amend the Patent.

4. The High Court dismissed the amendment application on the grounds that there had been undue delay in making the amendments and, at any rate, the amendments would extend the scope of the protection conferred by the Patent.

5. The SCA upheld the dismissal. In doing so, it provided valuable guidance on the law on amendment of a patent under the PA.

Amendment under s 83, PA

6. Post-grant amendments, in the midst of court proceedings, are governed by s 83, PA. The power to grant such amendments is a discretionary one. The SCA held that the factors to be considered in exercising the discretion 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.

7. As regards factor (c), the court would consider:

(a) The particular circumstances of each case, such as the length of the delay and the patentee's explanation for the delay;

(b) Whether the patentee could provide a reasonable explanation for the delay; and

(c) Whether the patentee had constructive knowledge of its patent's potential invalidity.

8. In the *Warner-Lambert* case, there was a delay of more than a decade before the appellant applied to amend the Patent. This was despite the fact that it knew of the potential invalidity of the Patent, as the International Preliminary Examination Report had alerted that the claims in the Patent were "directed to methods of treatment of the human or animal body by therapy [which] might be found inadmissible in some patent systems". The SCA found that the appellant had not provided any reasonable explanation for such a lengthy delay, other than the bare assertion that it did not receive any legal advice that it needed to amend the Patent. This finding was sufficient to dispose of the appeal. Nevertheless, the SCA also considered the issue of allowable amendment under s 84(3), PA.

Amendment under s 84(3), PA

9. This provision mandates that no amendment of a Patent is allowed if it

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

(b) extends the protection conferred by the patent.

10. The SCA held that the method of treatment claims in the Patent was obviously invalid under the PA. This being the case, a strict approach towards an application to amend the Patent was justified because the appellant had unjustifiably obtained a monopoly for several years and the onus had been on it to ensure compliance with the requirements of the PA. The appellant attempted to amend the Patent to re-formulate the claims as relating to the manufacture of a medicament for treating pain. This was held by the SCA to be extending the protection conferred by the Patent.

11. Currently, the Singapore patent regime has a "positive-grant" system whereby applicants may submit the full search and examination report issued by a foreign patent office and the Intellectual Property Office of Singapore would make a positive determination on whether the patent application complies with the patentability requirements of the PA. This system is more rigorous than the preceding self-assessment system in examining and allowing claims. Consequently, the SCA opined that the strict approach would affect only a small number of patents granted under the "positive-grant" system.

Swiss-style claims

12. Prior to the emergence of these claims, there were difficulties in patenting new uses of known pharmaceutical products under product claims or as a method of treatment claims due to statutory exclusions.

13. Swiss-style claims are claims to a process of manufacture of a medicament for the purpose of the new therapeutic use of a known compound of a pharmaceutical product. The courts in the UK and Europe have affirmed the validity of such claims as the appropriate form to frame claims over second medical uses.

14. In Singapore, s 14(7), PA provides that:

> "In the case of an invention consisting of a substance or composition for use in the 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".

15. The SCA held that this provision allowed the patenting of second and subsequent uses of a known substance. It said that there really was no need to resort to Swiss-style claims under the PA and a purpose-limited product claim might be sufficient to obtain a patent, such as a claim in the following form: "Compound X for use in the treatment of disease Y".

Concluding remarks

16. The SCA's judgment provides timely guidance on the law on amendment of a patent in Singapore. It is now clear that a patentee must not only not delay amending its patent if it knew or ought to have known that the patent may be invalid but must also ensure the proposed amendment is allowable under s 84(3) in light of the strict approach towards amending an invalid patent. The SCA's advice that Swiss-style claims are not really necessary in Singapore is also salutary.

About Lee & Lee

Lee & Lee is one of Singapore's leading law firms being continuously rated over the years amongst the top law firms in Singapore. Lee & Lee remains committed to serving its clients' best interests, and continuing its tradition of excellence and integrity. The firm provides a comprehensive range of legal services to serve the differing needs of corporates, financial institutions and individuals. For more information: visit www.leenlee.com.sg.

The following partners lead our departments:

Kwa Kim Li
Managing Partner
kwakimli@leenlee.com.sg

Quek Mong Hua
Litigation & Dispute Resolution
quekmonghua@leenlee.com.sg

Owyong Thian Soo
Real Estate
owyongthiansoo@leenlee.com.sg

Tan Tee Jim, *S.C.*
Intellectual Property
tanteejim@leenlee.com.sg

Adrian Chan
Corporate
adrianchan@leenlee.com.sg

Louise Tan
Banking
louisetan@leenlee.com.sg