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IP Update

Therapeutic product registration could be jeopardised by omitting to disclose a pertinent patent, regardless of whether the omission was wilful

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*Pursuant to the Health Products (Therapeutic Products) Regulations ("**HPR**"), applicants for registration of a therapeutic product with the Health Sciences Authority ("**HSA**") in Singapore must declare whether "a patent is in force in respect of the therapeutic product" ("**pertinent patent**"). This requirement is part of the patent linkage system in Singapore, which ensures that no therapeutic product would be approved before the expiration of the pertinent patent, except with the consent of the owner of the pertinent patent.*

In the recent decision of Millennium Pharmaceuticals, Inc, vs Zyfas Medical Co [2020] SGHC 28, the High Court granted a declaration that Zyfas had omitted to disclose matter that is material to its application for the registration of a therapeutic product, even though Zyfas' omission was not intentional. The declaration would enable Millennium to apply to the HSA to cancel the registration of Zyfas' therapeutic product.

Background

Zyfas applied to register a drug named "Myborte" containing the active ingredient *bortezomib*, which is a cancer drug for the treatment of multiple myeloma and mantle cell lymphoma. Under Regulation 23(2)(a) of the HPR, the applicant for a therapeutic product must declare to the HSA whether "*a patent is in force in respect of the therapeutic product*" ("pertinent patent"), and if so, whether:

1. The owner of the pertinent patent has given consent;
2. The pertinent patent is invalid; or
3. The pertinent patent will not be infringed by the doing of the acts for which the registration is sought.

In making its application, it appears that Zyfas declared that there was no pertinent patent. It also appears that there was no product (or compound) patent for Bortezomib in force in Singapore at the time of the declaration.

Millennium sought a declaration from the court under Regulation 24(1)(a)(ii) of the HPR that Zyfas had omitted to disclose "*matter that is material to the application*". In particular, Millennium pointed to three process patents owned by Millennium which they claimed related to the manufacture of *bortezomib* ("Millennium's process patents").

Decision

The main point for consideration was whether an operative omission under Regulation 24(1)(a)(ii) required that Zyfas knowingly or intentionally omitted to declare Millennium's process patents. Zyfas contended that it did not knowingly or

intentionally omit to declare these patents. At the time of the patent declaration, it appears that Zyfas was of the view that only the product patent, and not process patents, was considered a pertinent patent.

Applying the rules of statutory interpretation, the court found there was nothing in the provision itself requiring the mental element of knowledge or intention to be present. This is consistent with the function of Regulation 24(1)(a)(ii) as an administrative provision, which provides for the process by which a registered therapeutic product could be cancelled. In comparison, the subsequent Regulation 25 which makes explicit reference to mental elements, is offence-creating and prescribes criminal sanctions for false or deliberate suppression of information.

In the course of the proceedings, Zyfas conceded the following:

1. A pertinent patent under Regulation 23(2)(a) of the HPR includes existing process patents in respect of the therapeutic product; and

2. The existence of Millennium's process patents was "a matter that [was] material to the application" for the purpose of Regulation 24(1)(a)(ii).

In light of these concessions and the administrative nature of Regulation 24(1)(a)(ii) (i.e. not requiring mens rea), the court granted a declaration that Zyfas had omitted to "disclose matter that is material to the application".

This declaration would enable Millennium to apply to the HSA to cancel Zyfas' registration for Myborte.

It appears that the decision is now under appeal. It remains to be seen whether the Court of Appeal affirms the High Court's interpretation that Regulation 24(1)(a)(ii) does not require mens rea.

Commentary

The case also raises an important question of what is meant by "a patent in force in respect of the therapeutic product" in Regulation 23(2)(a). Although Zyfas conceded that a pertinent patent would include a process patent, it is unclear what the legislative intent had been. Was it to extend to product/compound patents only, or was it meant to also include process and other patents relating to the manufacturing of the relevant therapeutic product/compound?

In the patent linkage system of the United States, process patents are expressly excluded[1]. Similarly, process patents were excluded from Canada's patent linkage system after the Canadian government amended the Patented Medicines (Notice of Compliance) Regulations in 2006 to exclude patents that do not cover the direct therapeutic application, such as processes or intermediates[2]. The Food and Drug regulations in both the US and Canada have a patent list (e.g. the "Orange Book" in the US), which therapeutic drug applicants can refer to in order to find out what patents must be declared. There is no similar list in Singapore.

Millennium Pharmaceuticals, Inc, vs Zyfas Medical Co is not the only case that has raised the question of the meaning of "a patent in force in respect of the therapeutic product". The issue had previously been raised in Genentech Inc and others v Celltrion Healthcare Singapore Pte Ltd and Millennium Pharmaceuticals, Inc v Drug Houses of Australia Pte Ltd and another. In both these cases, there were no product/compound patents in force at the time the relevant HPR declarations were made by the applicants. The patents which were subsequently asserted were process patents which the patent owners alleged were in relation to the manufacture of the relevant therapeutic product/compound.

In view of these cases, and to simplify the HPR processes, should the HSA and/or the relevant Ministry/Ministries:

a) Clarify the scope of "a patent in force in respect of the therapeutic product"?

b) In particular, clarify whether process patents should be excluded from or included in the relevant HPR processes, bearing in mind that:

   (i) Owners of product/compound patents are already clearly protected under the relevant HPR regime, and

   (ii) Owners of process patents are perfectly entitled to assert their process patents in standard patent litigation in the High Court in the event of infringement of those patents.

c) Put together a database similar to the Orange Book where applicants for therapeutic products can easily check on the status of pertinent patents before making necessary declarations?

It could be argued that excluding process patents from the HPR regime could serve to moderate the impact of the patent linkage system on access to more affordable therapeutic products and medicines in Singapore. As things stand, if an

[1] Code of Federal Regulations, §314.53(b)

[2] Canada Gazette Part II Regulations amending the Patented Medicines (Notice of Compliance) Regulations, 2006, 140 (21): 1503-1525

applicant for a therapeutic product makes a declaration under Regulation 23(3)(b)(ii), the patent owner can then essentially hold up that therapeutic product application for up to 30 months by applying for the relevant declaration or order3.

It would seem fair and reasonable that the patent linkage system should protect the monopoly of owners of original product/compound patents. However, was the system also intended to extend protection to later-filed process or other patents which are related to the original product/compound patent?

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3 Regulations 23(8)(a) & 23(9) of the HPR