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Proposed Legislative Amendments to Regulation 23

We write to provide an update on the Health Sciences Authority's ("HSA") proposed legislative amendments to Regulation 23 ("Reg 23") of the Health Products (Therapeutic Products) Regulations 2016 ("TPR").

Introduction

Under the patent linkage regime, a generic drug manufacturer who wishes to apply for marketing approval of a generic drug will have to notify the drug registration authorities (i.e., HSA) and the patent holder of its application. There is a "linkage" between the marketing approval of the generic drug sought and patent status of the innovator drug as marketing approval cannot be granted until:

- (a) The patent holder consents or acquiesces to the marketing approval; or
- (b) The patent is invalid or will not be infringed by the marketing approval of the generic drug.

Singapore's patent linkage regime was introduced pursuant to the US-Singapore Free Trade Agreement (6 May 2003) and is statutorily reflected in Reg 23, TPR.

Presently, Reg 23(1), TPR does not specify the categories of patents that constitute patents that are "*in force in respect of a therapeutic product*", for which applicants seeking to register a therapeutic product must declare to the HSA. The HSA has proposed amending Reg 23, TPR to now specify the categories of patents that would be considered to be "*in force in respect of the therapeutic product*" (i.e., patents that must be declared to the HSA). We set out below a comparison table between the present Reg 23, TPR and the proposed amendments thereto:

Present Reg 23, TPR	Amended Reg 23, TPR
Reg 23(1) merely states the HSA must consider whether a patent under the Patents Act is in force in respect of the therapeutic product.	Amended Reg 23(1) will specify that the following categories of patents are " <i>patents that are in force in respect of the therapeutic product</i> ": <ul style="list-style-type: none"> (a) A patent containing a claim for an active ingredient of that therapeutic product (amended Reg 23(1)(a)(i), TPR); (b) A patent containing a claim for a formulation or composition of that therapeutic product (amended Reg 23(1)(a)(ii), TPR); and/or (c) A patent containing a claim for the use of an active ingredient in the manufacture of that therapeutic product for a specific therapeutic, preventive, palliative or diagnostic use (amended Reg 23(1)(a)(iii), TPR). (" Restraining Patents ")
-	New Reg 23(11) will specify a non-exhaustive list of categories of patents to which the amended Reg 23, TPR will not apply to: <ul style="list-style-type: none"> (a) A process patent, other than a process patent that contains a claim for the use of an active ingredient in the manufacture of a therapeutic product for a specific therapeutic, preventive, palliative or diagnostic use (new Reg 23(11)(a), TPR);

	<p>(b) A patent that contains only claims relating to packaging (new Reg 23(11)(b), TPR;</p> <p>(c) A patent that contains only claims relating to metabolites (new Reg 23(11)(c), TPR); and</p> <p>(d) A patent that contains only claims relating to intermediates (new Reg 23(11)(d), TPR).</p>
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Where the applicant’s declaration to the HSA claims invalidity or non-infringement of the patent in force in respect of a therapeutic product, and the applicant is not the proprietor of the patent, the applicant is required to serve notice of the applicant’s application to the HSA, as well as that the applicant considers the patent in issue to be either invalid or not infringed by the therapeutic product for which registration is sought. The proprietor may then, within 45 days of being notified, initiate proceedings which automatically triggers a 30-month freeze against the HSA granting marketing approval in respect of the applicant’s therapeutic product.

The HSA has considered feedback from industry stakeholders that the current therapeutic product registration requirements “lacked clarity and may cause uncertainty on the types of patents that must be listed in the patent declaration, resulting in potential inappropriate use of the mechanism” (see HSA announcement “[Public Consultation on the Proposed Amendments to Regulation 23 of the Health Products \(Therapeutic Products\) Regulations](#)” dated 29 February 2024).

The HSA’s objectives in proposing the above-mentioned amendments to Reg 23, TPR, include:

- (a) Providing clarity to industry stakeholders on the types of patents that must be considered when making an application for registration of a therapeutic product; and
- (b) Minimising any potential indiscriminate use of the mechanism under Reg 23, TPR.

Patents that are in force in respect of the therapeutic products, but which do not fall under the specified categories of Restraining Patents will not be subject to the amended Reg 23, TPR, i.e., the declaration process any longer.

HSA Guidance on Proposed Amendments to Reg 23, TPR

Under the amended Reg 23, TPR, unless the HSA otherwise determines, the applicant for registration must make a declaration stating:

- (a) Whether one or more Restraining Patents are in force in respect of the therapeutic product;
- (b) Whether the applicant is the proprietor of the Restraining Patent;
- (c) If the applicant is not the proprietor, whether:
 - i. the proprietor has consented to or has acquiesced in the grant of the registration;
 - ii. in the opinion of the applicant and to the best of its belief, the Restraining Patent is invalid or will not be infringed by the doing of the act for which registration is sought.

Patents that are in force in respect of the therapeutic product but do not fall within the categories of Restraining Patents are not subject to Reg 23, TPR. Such patents need not be declared to the HSA and therefore, the proprietors need not be notified of the application for therapeutic product registration.

In the HSA announcement “[Summary of Responses to Feedback from Public Consultation on the Proposed Amendments to Regulation 23 of the Health Products \(Therapeutic Products\) Regulations](#)” dated 31 May 2024, the HSA helpfully provided some non-exhaustive illustrative examples of patents that are subject to requirements under the amended Reg 23, TPR:

- (a) A patent that contains a mixture of claims specified in the amended Reg 23(1)(a), TPR and claims specified in Reg 23(11), TPR. For example, a patent containing claims for both an active ingredient of the therapeutic product and its metabolites.

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- (b) A patent containing a claim for the same polymorphic form of an active ingredient of that therapeutic product.

The HSA has also explained circumstances in which a patent would not need to be considered under the amended reg 23, TPR:

- (a) A patent specified in the amended reg 23(1)(a)(i), TPR is in force in respect of a polymorphic form X of the active ingredient. The application is for a polymorphic form Y of the same active ingredient, and the patent claims for polymorphic X of the active ingredient will not be infringed by the act for which the registration of the therapeutic product containing polymorphic form Y is sought.
- (b) A patent specified in the amended reg 23(1)(a)(iii), TPR is in force in respect of indication X of the therapeutic product for which registration is sought. The application for registration is for indication Y, and the patent claims for indication X will not be infringed by the act for which the registration of the therapeutic product is sought in respect of indication Y.

Implications of Amendments to Reg 23, TPR

Although the proposed amendments to Reg 23, TPR, are not yet in force, these proposed changes to the Singapore patent linkage regime are significant ones that will benefit both innovators as well as generic drug manufacturers.

Generic drug manufacturers, as applicants for therapeutic products registration, need only consider if there are Restraining Patents in force in respect of the therapeutic product by reference to the amended Reg 23(1) and also to the new Reg 23(11), TPR.

As for innovators, they will have greater certainty as well over the categories of patents that may be asserted against applicants seeking to register their therapeutic products in Singapore for which patent coverage exists thereby reducing the likelihood of them having to commence litigation proceedings following receipt of a notice under Reg 23, TPR.

Overall, with the added certainty arising from the amendments to Reg 23, TPR, we are also likely to see a significant reduction in the number of legal proceedings being commenced under the Reg 23 regime, which will lead to a saving of time and costs for innovators, generic product retailers/marketers, as well as the Singapore Courts.

Our IP team is very experienced in patent linkage cases and pharmaceutical patent litigation matters. If you would like to speak to us on such matters, please contact our Partner Jevon Louis (jevon.louis@shooklin.com) or Senior Associate Kuek Kai Liang (kailiang.kuek@shooklin.com).

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