IN THE HIGH COURT OF THE REPUBLIC OF SINGAPORE

[2018] SGHC 149

Suit No 1089 of 2017
(Summonses Nos 5611 and 5650 of 2017)

Between

MILLENNIUM PHARMACEUTICALS, INC

… *Plaintiff*

And

DRUG HOUSES OF AUSTRALIA PTE LTD

… *Defendant*

GROUNDS OF DECISION

[Civil Procedure] — [Injunctions]

[Civil Procedure] — [Pleadings] — [Striking out]

[Patents and Inventions] — [Infringement] — [Health Products (Therapeutic Products) Regulations 2016 (S 329/2016)]

TABLE OF CONTENTS

Millennium Pharmaceuticals, Inc
v
Drug Houses of Australia Pte Ltd

[2018] SGHC 149

High Court — Suit No 1089 of 2017 (Summonses Nos 5611 and 5650 of 2017)
Mavis Chionh Sze Chyi JC
28 March; 5 April 2018

27 June 2018

Mavis Chionh Sze Chyi JC:

Introduction

1 By Suit No 1089 of 2017 ("Suit 1089"), Millennium Pharmaceuticals, Inc ("the Plaintiff"), which is the registered proprietor of Singapore Patent Nos SG 151322 and SG 182998 ("the Plaintiff's Patents"), brings an action against Drug Houses of Australia Pte Ltd ("the Defendant") seeking, among other things: (a) a declaration that the Defendant had, in omitting to declare the Plaintiff's Patents when applying for and obtaining registration of its therapeutic product under Therapeutic Product Registration No SIN15243P ("the Defendant's Product"), made a declaration to the Health Sciences Authority ("the HSA") that contains a statement that is false or misleading in a material particular or omits to disclose any matter that is material to its application to register its product; (b) a declaration that the Defendant's performance of the acts for which registration of the Defendant's Product has been obtained would infringe the Plaintiff's

Patents; and (c) an injunction to restrain the Defendant from infringing the Plaintiff's Patents.[1]

2 In Summons No 5611 of 2017 ("SUM 5611"), the Plaintiff applied for an interlocutory injunction to restrain the Defendant from performing any of the acts for which the Defendant had obtained registration of its product.[2] In Summons No 5650 of 2017 ("SUM 5650"), the Defendant cross-applied to strike out the Plaintiff's Statement of Claim on the ground that it disclosed no reasonable cause of action.[3] I heard both summonses on 28 March 2018. On 5 April 2018, I dismissed the Plaintiff's application in SUM 5611 for an interlocutory injunction, and allowed the Defendant's striking-out application in SUM 5650 in part, striking out certain passages in the Statement of Claim. On 26 April 2018, I granted the Plaintiff's application in Summons No 1764 of 2018 ("SUM 1764") for leave to appeal against my decision in SUM 5611.[4] The Plaintiff has appealed against my decision in both SUM 5611 and SUM 5650. Accordingly, I set out below the grounds of my decision.

Background

3 As the statutory framework for the registration of therapeutic products forms an important part of the background to these proceedings, I will first summarise the key components of this framework before setting out the facts leading to the dispute.

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1 Statement of Claim dated 24 November 2017, p 5, prayers (1)–(3).

2 Summons No 5611 of 2017 dated 7 December 2017, para 1.

3 Summons No 5650 of 2017 dated 11 December 2017, para 1.

4 Summons No 1764 of 2018 dated 12 April 2018, para 1.

The statutory framework for the registration of therapeutic products

4 Therapeutic products are one of the categories of health products regulated under the Health Products Act (Cap 122D, 2008 Rev Ed) ("the HPA"): see para 3 of the First Schedule to the HPA. The system of registration put in place for health products generally is set out in Part VII of the HPA, with the detailed requirements in relation to the registration of therapeutic products being set out in Part 5 of the Health Products (Therapeutic Products) Regulations 2016 (S 329/2016) ("the TPR"). The HSA is the agency responsible for overseeing the registration process.

5 In gist, successful registration of a therapeutic product with the HSA indicates that the HSA has evaluated the product for compliance with the statutory requirements for, (*inter alia*) the quality, safety and efficacy of the product and the presentation of the product in the light of its formulation, composition or design specification and intended purpose: see s 33(2) of the HPA. The HSA must in particular be satisfied that the overall intended benefits to a user of the therapeutic product outweigh the overall risks associated with its use; and that based on the formulation, manufacturing process controls, specifications and shelf life of the product, and its stability under the recommended storage conditions, the product is suitable for its intended purpose, and any risk associated with its use is minimised: reg 22 of the TPR.

6 Under reg 23(2) of the TPR, unless the HSA otherwise determines, the applicant seeking to register a therapeutic product must at the time of the application make a declaration stating (a) whether a patent under the Patents Act (Cap 221, 2005 Rev Ed) ("the PA") is in force in respect of the therapeutic product; and (b) whether the applicant is the proprietor of the patent. If the applicant is not the proprietor of the patent in respect of the therapeutic product

and there is such a patent in force, the applicant must further state in its declaration, *inter alia*, whether the proprietor has consented to or has acquiesced in the grant of the registration of the applicant's therapeutic product; or whether, in the applicant's opinion and to the best of its belief, the patent is invalid or will not be infringed by the doing of the act for which registration is sought: reg 23(3)(*b*) of the TPR.

7 According to the Plaintiff (and the Defendant does not dispute this), an applicant seeking to register a therapeutic product may make one of the following four types of declarations:[5]

(a) A "Category A1" declaration, which means that no patent is in force in respect of the therapeutic product to which the application relates.

(b) A "Category A2" declaration, which means that a patent is in force in respect of the therapeutic product to which the application relates, and the applicant is either the proprietor of the patent, or if it is not the proprietor of the patent, the proprietor has consented to or acquiesced in the grant of the registration.

(c) A "Category A3" declaration, which means that a patent is in force in respect of the therapeutic product to which the application relates, the applicant is not the proprietor of the patent, the proprietor has not consented to nor acquiesced in the grant of the registration, and the applicant is requesting for registration to be granted after the patent expires. An application with a Category A3 declaration may not be made earlier than 18 months before the patent expires.

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5 Constance Yeung's first affidavit dated 5 December 2017, exh CY-3, pp 180–181.

(d) A "Category B" declaration, which means that a patent is in force in respect of the therapeutic product to which the application relates, the applicant is not the proprietor of the patent, the proprietor has not consented to nor acquiesced in the grant of the registration, and in the applicant's opinion and to its best belief, the patent is invalid or will not be infringed by the doing of the act for which registration is sought.

8 Under reg 23(5) of the TPR, where the applicant is not the proprietor of a patent under the PA that is in force in respect of the therapeutic product, the HSA "may require the applicant to serve … on the proprietor of the patent, a notice in the form specified on the [HSA's] website" if:

(a) the applicant has declared that, in its opinion and to the best of its belief, the patent is invalid or will not be infringed by the doing of the act for which registration is sought; or

(b) the HSA considers it appropriate in any particular case for the applicant to do so.

9 Anyone seeking to manufacture, import or supply a therapeutic product is also required to apply to the HSA for the appropriate licence, as the licensing system is activity-based, and the type of licence issued by the HSA depends on the specific type of activity the applicant seeks to carry out: see, *eg*, Parts 2 and 3 of the TPR for the requirements in relation to the manufacture and import as well as the supply of therapeutic products respectively.

The dispute

10 The Plaintiff is a company incorporated and based in the United States of America, whereas the Defendant is a company incorporated in Singapore.[6]

11 The Plaintiff's Patents, which expire on 24 March 2025, are process patents which relate to certain processes for the manufacture of the active ingredient Bortezomib, an anti-cancer drug.[7] They are not patents in respect of the active ingredient Bortezomib itself.[8] The Defendant has asserted (and the Plaintiff does not dispute) that the specifications for the Plaintiff's Patents make it clear that the protected inventions are an improvement over other processes, and that apart from the processes disclosed in the Plaintiff's Patents, there exist other processes for the manufacture of Bortezomib which may either not be patented or for which patents may have expired.[9]

12 The Plaintiff does not manufacture, market or supply Bortezomib in Singapore. It has granted an exclusive licence to Johnson & Johnson Pte Ltd ("Johnson & Johnson") in Singapore. The terms of this licence agreement were not put in evidence in the hearing before me. The Plaintiff has asserted – and the Defendant has not denied – that the public hospitals in Singapore hold an annual tender for the supply of Bortezomib, and that up until now, Johnson & Johnson has been awarded the tender "by default as it would be the sole participant in the tender with an existing Therapeutic Product Registration No. in respect of Bortezomib".[10]

13 On 26 May 2017, the Defendant obtained approval from the HSA for the registration of a therapeutic product described as "Bortezomib – Actavis Powder for Solution for Injection 3.5mg/vial" under Therapeutic Product Registration No SIN15243P (*ie*, the Defendant's Product).[11] According to the Defendant, it

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6 Statement of Claim, paras 1 and 2.

7 Yeung's first affidavit, para 4.

8 Baey Yam Khuang's affidavit dated 12 January 2018, para 16.

9 Baey's affidavit, paras 14 and 15 and exh BYK-2; Yeung's first affidavit, exh CY-1.

10 Yeung's first affidavit, para 20.

"does not manufacture Bortezomib or utilise the processes disclosed in [the Plaintiff's] Patents" in the making of its product.[12]

14 The Plaintiff was not served with any notice under reg 23(5) of the TPR.[13] The Plaintiff has also not seen the declaration made by the Defendant under reg 23(2) ("the Defendant's Declaration"), and does not know what the declaration says. The Defendant's Declaration was not produced in evidence in the hearing before me.

15 Sometime in June 2017, the Plaintiff found out about the Defendant's registration of its therapeutic product. On 4 July 2017, the Plaintiff's lawyers wrote to the Defendant asking the Defendant to confirm whether it had declared the Plaintiff's Patents in making the application for registration, and also requesting a copy of the Defendant's Declaration.[14]

16 On 31 July 2017, the Defendant's lawyers replied, stating that the Plaintiff's Patents were "not relevant" to the Defendant's Product because the Defendant's Product "does not use the processes disclosed in the [Plaintiff's] Patents". They asserted that there was accordingly no necessity to provide the Plaintiff with a copy of the Defendant's Declaration, and that the Defendant's Product "does not infringe the [Plaintiff's] Patents".[15] At the same time, the Defendant's lawyers stated that subject to the Plaintiff signing a non-disclosure agreement, the Defendant was willing to furnish documentation describing the

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11 Yeung's first affidavit, exh CY-2.

12 Baey's affidavit, para 15 and exh BYK-2.

13 Yeung's first affidavit, para 11.

14 Yeung's first affidavit, para 14 and exh CY-5.

15 Yeung's first affidavit, para 15 and exh CY-6, paras 2 and 3.

process utilised in respect of the Defendant's Product "in order to facilitate the resolution of the matter".[16]

17 Pursuant to a non-disclosure agreement signed by the Plaintiff and the Defendant in October 2017, the Defendant provided certain documentation to the Plaintiff for the purpose of allowing the Plaintiff to determine whether the process utilised in respect of the Defendant's Product infringed the Plaintiff's Patents.[17]

18 On 24 November 2017, the Plaintiff commenced Suit 1089 against the Defendant.

The applications in SUM 5611 and SUM 5650

19 On 7 December 2017, the Plaintiff brought SUM 5611, seeking an interlocutory injunction to restrain the Defendant from performing any of the acts for which the Defendant had obtained registration of its product.

20 On 11 December 2017, the Defendant brought SUM 5650, seeking to strike out the Statement of Claim in Suit 1089 on the basis that it disclosed no reasonable cause of action pursuant to O 18 r 19(1)(*a*) of the Rules of Court (Cap 322, R 5, 2014 Rev Ed) ("the ROC").

21 Regarding the interlocutory injunction application, it was common ground, pursuant to the test set out by the House of Lords in *American Cyanamid Co v Ethicon Ltd* [1975] AC 396 ("*American Cyanamid*") (at 407–408),[18] that the Plaintiff had to show firstly that there was a serious question to be tried, and

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16 Yeung's first affidavit, exh CY-6, para 4.

17 Constance Yeung's second affidavit dated 25 January 2018, para 9.

18 Plaintiff's Bundle of Authorities ("PBOA"), Tab 9.

secondly, that the balance of convenience lay in favour of granting the interlocutory injunction.

22 As for the striking-out application, the parties' arguments before me focused on whether a reasonable cause of action was disclosed in the following claims by the Plaintiff:

(a) the claim for a declaration that the Defendant's Declaration, in omitting to declare the Plaintiff's Patents, contains a statement that is "false or misleading in a material particular or omits to disclose any matter that is material to the Defendant's application" to register its product ("the Material Falsehood Declaration Claim");

(b) the claim for a declaration that the Defendant's performance of the acts for which registration of the Defendant's Product has been obtained would infringe the Plaintiff's Patents ("the Prospective Infringement Declaration Claim"); and

(c) the claim for an injunction to restrain the Defendant, whether acting by its directors, officers, employees, servants or agents, or any of them or otherwise howsoever, from infringing the Plaintiff's Patents ("the Injunction Claim").

23 In addition, the Defendant argued that certain passages of the Statement of Claim had alleged *actual* infringement by the Defendant ("the Actual Infringement Declaration Claim"), and that these passages should be struck out because the Plaintiff conceded that there had been no actual infringement of its patents by the Defendant.

24 I note that the issue of whether – for the purpose of the Defendant's striking-out application – the Plaintiff's claims disclosed a reasonable cause of action was intertwined with the issue of whether – in the context of the Plaintiff's injunction application – there was "a serious question to be tried". Clearly, a party will not be able to satisfy the court that there is a serious question to be tried unless he establishes that he has a reasonable cause of action.

Issues to be determined

25 In the light of the arguments presented, the issues that arose for my determination were:

(a) regarding the Plaintiff's interlocutory injunction application in SUM 5611:

(i) whether there was a serious question to be tried in Suit 1089; and

(ii) if so, whether the balance of convenience lay in favour of granting the interlocutory injunction; and

(b) regarding the Defendant's striking-out application in SUM 5650, whether there was a reasonable cause of action in respect of the following claims by the Plaintiff (see [22] above):

(i) the Material Falsehood Declaration Claim;

(ii) the Prospective Infringement Declaration Claim;

(iii) the Injunction Claim; and

(iv) the Actual Infringement Declaration Claim.

26 Given my observation at [24] above, I will first deal with the Defendant's striking-out application before addressing the Plaintiff's interlocutory injunction application.

My decision

The striking-out application in SUM 5650

27 There was no dispute that the threshold to be met for striking-out was that the claim "must be obviously unsustainable, the pleadings unarguably bad and it must be impossible, not just improbable, for the claim to succeed"; also, that an application to strike out under this head of O 18 r 19(1) solely concerned issues of law and did not involve affidavit evidence: *Singapore Civil Procedure 2018* vol I (Foo Chee Hock JC gen ed) (Sweet & Maxwell, 2018) ("*Singapore Civil Procedure*") at paras 18/19/6 and 18/19/10.

28 In my judgment, the Material Falsehood Declaration Claim disclosed a reasonable cause of action, while the Prospective Infringement Declaration Claim, the Injunction Claim and the Actual Infringement Declaration Claim all disclosed no reasonable cause of action. I therefore allowed the striking-out application in part. To that end, I ordered the following paragraphs at p 4 of the Statement of Claim to be struck out:

> 12 The Plaintiff avers that the act(s) for which registration of the Product has been obtained (under Therapeutic Product Registration No. SIN15243P) would infringe one or more of Claims 1 to 56 of Singapore Patent No. 151322 and one or more of Claims 1 to 8 of Singapore Patent No. 182998.
>
> 13 The Plaintiff is at present unable to give full particulars of the Defendant's actual and/or threatened infringements of the Patents and the acts thereof until after discovery and/or interrogatories, but will seek relief at the trial of this action in respect of each and every actual and/or threatened infringement and act.

> 14 The Defendant's actual and/or threatened infringements of the Patents cause, and will continue to cause, the Plaintiff to suffer loss and damage.
>
> 15 Unless the Defendant is restrained, the Defendant infringes (or threatens to infringe) the Patents, and will continue to infringe (or threaten to infringe) the Patents.

I also ordered the following prayers at pp 5 and 6 of the Statement of Claim to be struck out:

> …
>
> (2) A declaration that the Defendant's performance of the acts(s) for which registration of the Product has been obtained would infringe Singapore Patent Nos. SG 151322 and SG 182998;
>
> (3) An injunction to restrain the Defendant, whether acting by its directors, officers, employees, servants or agents, or any of them or otherwise howsoever, from infringing Singapore Patent Nos. SG 151322 and SG 182998;
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> (4) An order for the delivery up or destruction upon oath of all infringing articles or any article in which the Product is inextricably comprised, in the Defendant's possession, power, custody, or control;
>
> (5) An inquiry as to damages with such damages to be assessed, or alternatively, at the Plaintiff's option, an account of profits and an order for payment of all sums due;
>
> (6) Interest pursuant to Section 12 of the Civil Law Act (Cap. 43) or under the equitable jurisdiction of the Court;
>
> …

The Material Falsehood Declaration Claim

29 In making the Material Falsehood Declaration Claim, the Plaintiff relied on reg 24(1)(*a*)(ii) of the TPR as providing a cause of action in respect of the making of any false declarations under reg 23(2). According to the Plaintiff, reg 24(1)(*a*)(ii) read with reg 23(2) of the TPR mandate that an applicant must make a truthful and accurate declaration as to the existence and validity of any patent in respect of its therapeutic product, such that should the applicant fail to do so,

an affected patent holder has a cause of action entitling it to seek declaratory relief pursuant to reg 24(1)(*a*)(ii). The Defendant argued that this claim should fail because: (a) the Plaintiff lacked *locus standi* to seek declaratory relief pursuant to reg 24(1)(*a*)(ii); (b) the Plaintiff had pleaded insufficient facts in the Statement of Claim in respect of this claim; and (c) it was impermissible for civil courts to grant a declaratory order that constitutes a declaration on the criminal consequences of one's conduct, which was what a declaration that a material falsehood had been made in a reg 23(2) declaration would amount to.

30 I accepted the Plaintiff's submissions and rejected the Defendant's submissions on this issue. Given however that this aspect of my decision is not under appeal, I do not propose to repeat the reasons that I have already furnished in the brief oral grounds provided to parties on 5 April 2018.

The Prospective Infringement Declaration Claim

31 In the Prospective Infringement Declaration Claim, the Plaintiff sought a declaration that the Defendant's performance of the acts for which it had obtained registration of its therapeutic product "would infringe" the Plaintiff's Patents.

32 At the hearing before me, it was common ground that the Defendant's application to register its therapeutic product did not constitute an infringing act *vis-à-vis* the Plaintiff's Patents, and that no infringing act had actually been committed by the Defendant to date. The Plaintiff expressly conceded that it did not rely on any cause of action in patent infringement under the PA, and had no quarrel with the Defendant's argument that a patent infringement action would have required particulars of past infringing acts: see ss 66 and 67 of the PA and O 87A r 2(2) of the ROC; see also *AstraZeneca AB (SE) v Sanofi-Aventis Singapore Pte Ltd* [2012] SGHC 16 ("*AstraZeneca*") at [20]–[23] and [30].[19]

Instead, the Plaintiff relied on reg 24(1)(*a*)(i) of the TPR and, alternatively, the inherent jurisdiction of the court, both of which it argued could provide the basis for a separate and independent cause of action in prospective infringement outside of the PA framework. I will address both arguments in turn.

(1) Regulation 24(1)(*a*)(i) of the TPR

33 The Plaintiff contended that it had a cause of action in prospective infringement under reg 24(1)(*a*)(i) of the TPR. As counsel for the Plaintiff cited *AstraZeneca* as the authority for this proposition, I set out below in some detail the facts and the decision in that case.

34 *AstraZeneca* was a decision of an assistant registrar ("AR") of the High Court in 2012. By way of background, the plaintiff in *AstraZeneca* was the owner of a patent for which the claimed invention comprised two elements: an active ingredient (Rosuvastatin Calcium) and a stabiliser. The defendant applied to the HSA for product licences in respect of three products: Rosucard Film-coated Tablet 10mg, Rosucard Film-coated Tablet 20mg, and Rosucard Film-coated Tablet 40mg. As this was prior to the enactment of the TPR, the statutory provisions governing the registration of drugs and other "medicinal products", as defined in s 3 of the Medicines Act (Cap 176, 1985 Rev Ed) ("the MA"), were found in what was then Part II of the MA. Part II established a statutory framework for the issuance of product licences in respect of medicinal products which was similar to the present system of registration of therapeutic products set out in Part 5 of the TPR. Section 12A of the MA was the forerunner to what is currently reg 23 of the TPR (see *AstraZeneca* at [29]). Under s 12A(2) of the MA, the party applying for a product licence had to make a declaration stating *inter alia* whether a patent under the PA was in force in respect of the medicinal

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19 PBOA Tab 10.

product to which its application related, and if there was such a patent which the applicant itself was not a proprietor of, whether the proprietor had consented to or acquiesced in the grant of the product licence, or whether in the applicant's opinion and to the best of his belief, the patent was invalid or would not be infringed by the doing of the act for which the licence was sought (which corresponds to regs 23(2) and 23(3) of the TPR).

35 The defendant in *AstraZeneca* made a declaration stating that: (a) a patent was in force in respect of its Rosucard products; (b) the defendant was not the proprietor of the patent; and (c) it believed the patent would not be infringed by the doing of the acts for which the product licence was sought. The defendant was then requested by the HSA to serve a notice on the plaintiff pursuant to s 12A(3) of the MA (which corresponds to regs 23(5) and 23(6) of the TPR). The plaintiff filed a suit against the defendant. This had the effect of triggering a 30-month moratorium against the processing of the defendant's licence application pursuant to s 12A(5) of the MA read with reg 5B(3) of the Medicines (Licensing, Standard Provisions and Fees) Regulations (Cap 176, Rg 6, 2000 Rev Ed) ("the MR") (which corresponds to regs 23(8) and 23(9) of the TPR). In its statement of claim, the plaintiff prayed for, *inter alia*, a declaration that the defendant's performance of the acts for which a product licence was sought would infringe the plaintiff's patent, and an injunction to restrain the defendant from infringing the patent.

36 The import of s 12A of the MA became the key issue in contention in *AstraZeneca* because the plaintiff in that case stated that it was not taking out a patent infringement action under the PA and that it relied instead on s 12A of the MA for its cause of action. The plaintiff took the position that s 12A gave rise to a cause of action separate and independent from a patent infringement action under the PA. The defendant, on the other hand, argued that s 12A merely

provided a notification mechanism whereby a patentee would be informed of any application for a product licence which related to its patent, and that any action to protect its patent would still have to be by way of patent infringement proceedings under the PA. Before the AR, the defendant applied to strike out the statement of claim.

37 In finding for the plaintiff, the AR agreed with the plaintiff that it could not have proceeded under the PA because "it is a fundamental feature of a patent infringement action under the [PA] that there be a *past* act of infringement" [emphasis in original] (at [30]). Conversely, s 12A of the MA, read with reg 5B and the Sixth Schedule of the MR, "contemplates the taking out of an action for *prospective* infringement – the patent will be infringed" [emphasis in original] (also at [30]). In the AR's view, these legislative provisions (at [32]):

> … reflect Parliament's intention to allow a patentee to take out an action pursuant to those provisions fairly clearly. Section 12A(3) of the [MA] allows the HSA to require an applicant for a product licence to serve a notice in a prescribed form to the patentee. The form … informs the patentee that the HSA may grant the licence to the applicant unless the patentee applies "for a court order restraining the act for which the licence is applied for or a declaration by a court or the Registrar of patents that the patent will be infringed by the doing of that act." Reading the provisions holistically, it is, in my view, apparent that the legislature intended for an independent cause of action to be provided pursuant to these provisions.

38 I pause at this point to note that the AR's decision in *AstraZeneca* does not appear to have been appealed against. *AstraZeneca* has been cited and relied upon by parties in other cases: see, *eg*, *Genetech Inc and others v Celltrion Healthcare Singapore Pte Ltd*, Suit No 786 of 2017 (Summons No 4555 of 2017) (27 December 2017).[20]

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[20] Defendant's Bundle of Authorities (SUM 5650/2017), Tab 9.

39 Before me, both parties accepted as the starting point for their arguments the AR's view that patent infringement actions under the PA could not be sustained unless there was a *past* act of infringement as defined in s 66 of the PA. I too agreed broadly with the reasoning set out in *AstraZeneca* at [20]–[23]. The drafting of various provisions in the PA indicates that the legislature was clear as to the distinction between *past* acts of infringements and *prospective* acts of infringement: see, *eg*, s 77(2)(*a*) of the PA, where reference is made both to "acts in respect of which proceedings were threatened *constitute* … an infringement of a patent" and acts which "if done, *would constitute* an infringement of a patent" [emphases added]. The fact that s 67, which enables a patentee to bring civil proceedings for patent infringement and enumerates the reliefs it may seek, is drafted so as to reference *past* infringement also indicates a conscious legislative decision that patent infringement claims under the PA should be founded on *past* acts of infringement.

40 The view that patent infringement actions under the PA must be founded on *past* acts of infringement is also supported by the provisions of O 87A r 2(2) of the ROC. Order 87A deals with how proceedings under the PA are to be brought. As the AR in *AstraZeneca* pointed out (at [22]), O 87A r 2(2) expressly provides that the plaintiff in a patent infringement action under the PA must serve with his statement of claim "particulars of the infringement relied on, showing which of the claims in the specification of the patent are alleged to be infringed and giving at least one instance of each type of infringement alleged". In this regard, the corresponding commentary in *Singapore Civil Procedure* notes that although it "is made clearly obligatory to name some definite instance of the general type of article of the sale, use or manufacture of which the plaintiff complains", the "instances of alleged infringement in the particulars of infringement are not required to be exhaustive" (at para 87A/2/6, citing *Towa*

Corp v ASM Technology Singapore Pte Ltd and another [2017] 3 SLR 771 at [136]).

41 Having found that the plaintiff in *AstraZeneca* had no cause of action under the PA, the AR went on to hold that it could rely on a separate cause of action in *prospective* infringement based on s 12A of the MA read with its accompanying subsidiary legislation. Again, I found the AR's analysis in this respect (at [24]–[30]) sensible and well-reasoned. However, it did not assist the Plaintiff here. Whilst the terms of s 12A of the MA correspond closely to those of reg 23 of the TPR, the immediate difficulty which confronted the Plaintiff in its attempt to rely on *AstraZeneca* was the absence of a reg 23(5) notice in the present case. This meant that there was no triggering of the mechanism provided in reg 23 for the patentee to be notified of and to challenge the registration application.

42 Evidently the Plaintiff recognised this difficulty, because its written submissions stated that its cause of action in prospective infringement was *based on reg 24(1)(a)(i) of the TPR*.[21] However, its submissions did not go on to explain how, in these circumstances, *AstraZeneca* might assist its case. As noted earlier, in *AstraZeneca* the finding of a cause of action in prospective infringement independent of the PA rested on the statutory language of s 12A of the MA. Section 12A, read with the relevant subsidiary legislation, envisaged the proprietor of a patent applying within 45 days of a s 12A(3) notice for a declaration that its patent is valid or "will be infringed" by the doing of the act for which the licence is sought. In the same vein, reg 23(8)(*a*)(ii) of the TPR envisages the proprietor of a patent applying within 45 days of a reg 23(5) notice for a declaration that its patent is valid or "will be infringed" by the doing of the act for which the licence is sought. There is no reference to the PA in s 12A of

[21] Plaintiff's written submissions dated 14 February 2018, para 28.

the MA or in reg 23 of the TPR. As the AR noted in *AstraZeneca*, "section 12A of the [MA] does not envisage the taking out of a patent infringement action under the [PA]" (at [30]). In contrast, reg 24(1)(*a*)(i) of the TPR, which the Plaintiff relied on, expressly contemplates a scenario in which a court (or Registrar or Deputy Registrar of Patents) has determined that the doing of an act authorised by the registration "*infringes* a patent *under the Patents Act*" [emphasis added]. When reg 23(8) and reg 24(1)(*a*)(i) are read side by side, it is clear that the former provision contemplates *prospective* infringement whereas the latter contemplates a scenario in which there has been *actual* infringement justifying infringement action under the PA.

43 When asked about this difference, counsel for the Plaintiff said that the Defendant was "reading too much" into the difference in the statutory language of reg 24(1)(*a*)(i) as against that of reg 23(8)(*a*)(ii), and that the word "'infringes' can encompass prospective infringement". No authority was cited for this proposition, and with respect, I did not see how it could be correct. There is nothing in the drafting of reg 23 and reg 24 – or indeed, in the TPR as a whole – to suggest that the words "infringes" and "will be infringed" are to be used interchangeably. Indeed, given that the words "will be infringed" already appear in the TPR (reg 23(8)(*a*)(ii)), it would be chaotic if the word "infringe" were also capable of being understood to mean "will be infringed".

44 In any event, the word "infringes" in reg 24(1)(*a*)(i) is expressly used in conjunction with the words "under the Patents Act". The Plaintiff had conceded from the outset that patent infringement actions under the PA would not be sustainable unless they featured a past act of infringement. Even on the Plaintiff's own case, therefore, it made no sense to read the phrase "infringes a patent *under the Patents Act*" in reg 24(1)(*a*)(i) as encompassing cases of prospective infringement.

45 The Plaintiff argued that reg 24(1)(*a*)(i) should be given a broad construction so as to give effect to Parliament's intention to create a pro-patentee regime. The authority relied on for this proposition appeared to be *AstraZeneca* at [47] and [48]. I disagreed with the Plaintiff' argument. Those remarks in *AstraZeneca* related to the AR's view that a patentee who filed proceedings within 45 days of a s 12A(3) notice should not be required to "plead facts to support its allegation that its patent will be infringed" (at [47]). They did not provide support for the proposition that the word "infringes" in reg 24(1)(*a*)(i) should be understood to mean the same thing as the words "will be infringed". As Andrew Phang Boon Leong J (as he then was) noted in *Nation Fittings (M) Sdn Bhd v Oystertec plc and another suit* [2006] 1 SLR(R) 712 (at [27]):

> … the favoured approach nowadays (and rightly so …) is a purposive approach that is exemplified not only by the case law but also by s 9A(1) of the Interpretation Act itself (Cap 1, 1999 Rev Ed). Indeed, a purposive approach towards the statutory text does not ignore the literal meaning of the text by any means but, rather, complements it by ensuring that the purpose and intent of the statutory text itself is achieved and that any strained and, a fortiori, absurd result is avoided. I should reiterate that *the court's interpretation should be consistent with, and should not either add to or take away from, or stretch unreasonably, the literal language of the statutory provision concerned*. In other words, the literal statutory language constitutes the broad framework within which the purpose and intent of the provision concerned is achieved. It is imperative, to underscore the point just made, that this framework is not distorted as the ends do not justify the means. …
>
> [emphasis added]

The Plaintiff's suggestion that the word "infringes" in reg 24(1)(*a*)(i) be read interchangeably with "will be infringed" would, in my view, "stretch unreasonably" the literal statutory language of the provision.

46 Moreover, if reg 24(1)(*a*)(i) were to be construed as encompassing prospective acts of infringement, this would in my view render largely

ineffectual the framework established under reg 23. Regulation 23 has put in place a clearly defined process whereby a patentee may – upon service of a reg 23(5) notice – obtain a 30-month moratorium on an application for therapeutic product registration by following the steps detailed in reg 23(8) and complying with the stated 45-day timeline. Pursuant to reg 23(9), if the patentee fails to obtain within the 30-month moratorium period a declaration that its patent is valid or will be infringed by the doing of the acts for which the therapeutic product registration is sought, the HSA may register the therapeutic product without further notice to the patentee. If reg 24(1)(*a*)(i) were to be construed as creating another cause of action for prospective infringement *separate from and in addition to* the cause of action under reg 23, it would mean that the patentee who alleges prospective infringement but who fails to act before the 45-day deadline or fails to obtain the necessary declaration during the 30-month moratorium gets a second bite of the cherry even after registration. The potential repercussions are widened when we note that reliance on reg 24(1) is not restricted to patentees but is expressly open to "any interested person". It does not seem to me credible to suggest that it must have been the legislature's intention to create another separate cause of action for prospective infringement which would render largely pointless the framework already provided in reg 23. The Plaintiff could not point to any material which supported such a suggestion.

47 Finally, the Plaintiff argued that if its claim for prospective infringement were to be struck out, it would signal that a patentee pharmaceutical company was completely "impotent" to protect its patent when a generic acted "dishonourably" in failing to make a truthful patent declaration in its application for therapeutic product registration. I did not think this was an accurate depiction of the present state of the law. As observed earlier, the TPR allow for a patentee to pre-emptively halt registration of a therapeutic product via the prospective infringement regime under regs 23(5) and 23(8) – but assuming the patentee is

unable for some reason to halt registration, it can still bring patent infringement proceedings under the PA if, pursuant to the registration, the successful applicant does any act which infringes the patent. Nor will a false or misleading patent declaration go unsanctioned: the patentee can still get the registration cancelled under reg 24(1)(*a*)(ii) if it can obtain a court determination on the false or misleading declaration. Furthermore, the applicant who makes a false patent declaration may be prosecuted for an offence under reg 25 of the TPR and subjected to criminal sanctions. In short, there was no basis for the submission that a patentee pharmaceutical company would be completely helpless if a generic failed to declare its patent.

(2) The inherent jurisdiction of the court

48 The Plaintiff's written submissions stated that it relied on the court's inherent jurisdiction as an alternative basis for a cause of action in prospective infringement. Apart from a cursory mention of the "Court's inherent jurisdiction" in its written submissions,[22] however, nothing else was said by the Plaintiff in the course of the hearing. The Plaintiff did not elaborate – nor did it cite any authorities – on the basis for invoking the court's inherent jurisdiction in this case. No arguments were made by the Defendant either on this issue. Nevertheless, as I indicated to parties when issuing my decision, I did consider whether the claim for a declaration of prospective infringement could be sustained on the basis of what was pleaded in the Statement of Claim – and did not find it to be the case.

49 In *AstraZeneca*, the AR opined that apart from s 12A of the MA (read with the accompanying subsidiary legislation) affording the plaintiff a cause of action for prospective infringement outside of the PA, the plaintiff's statement

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22 Plaintiff's written submissions, para 28.

of claim "may be able [to] sustain an action for a declaration of future infringement under the inherent jurisdiction of the court" (at [36]). In expressing such an opinion, the AR referred (at [37]) to s 18 read with para 14 of the First Schedule of the Supreme Court of Judicature Act (Cap 322, 2007 Rev Ed) ("SCJA"), which empower the High Court to make binding declarations of right. Reference was also made (at [39]) to the judgment of Lord Diplock in *Gouriet v Union of Post Office Workers and Others* [1978] AC 435,[23] in which it was held that a party applying for declaratory relief need not have a subsisting cause of action or a right to some other relief: "[i]t is when an infringement of the plaintiff's rights in the future is threatened or when, unaccompanied by threats, there is a dispute between parties as to what their respective rights will be if something happens in the future, that the jurisdiction to make declarations of right can be most usefully invoked" (at 501). The AR further alluded to the decisions in *Nokia Corp v Interdigital Technology Corp* [2007] FSR 23 ("*Nokia*") and *Wyko Group Plc v Cooper Roller Bearings Co Ltd* [1996] FSR 126 ("*Wyko*") as establishing that the court had the inherent jurisdiction in patent cases to grant declarations of infringement or non-infringement pertaining to prospective events, provided firstly that the "question must be a real and not a theoretical question; the person raising it must have a real interest to raise it; he must be able to secure a proper contradictor, that is to say, someone presently existing who has a true interest to oppose the declaration sought" (at [40]).

50 I make two points in relation to the above observations. Firstly, I do not think there is any magic to invoking the court's inherent jurisdiction to grant declaratory relief in the context of patent cases. The general principle, that the "essential touchstone" for any exercise of the court's inherent jurisdiction is that of "need", must continue to apply in such cases as it does to all other cases where

[23] Defendant's Supplementary Bundle of Authorities ("DSBOA"), Tab 2.

parties seek to rely on this inherent jurisdiction: see *Wee Soon Kim Anthony v Law Society of Singapore* [2001] 2 SLR(R) 821 at [27]. The requirement stated in cases such as *Wyko* for the party seeking declaratory relief to show a "genuine interest" in raising the question appears to me to be simply another way of expressing the general principle. Thus, in *Nokia*, for example, where the respondent ("Nokia") sought declarations that certain patents of the appellant ("InterDigital") did not cover that which it was essential to use for complying with the internationally agreed 3G standard for mobile phones, it was acknowledged by both parties that Nokia did not have a licence from InterDigital, and that if the patents were truly essential for the 3G standard, then Nokia needed one and was at that stage "technically infringing". On that basis, it can hardly be gainsaid that Nokia had a "need" for the declarations sought. The English Court of Appeal had no difficulty holding that Nokia had shown a "real commercial reason" for seeking the declarations. InterDigital's appeal against the High Court's refusal of its application to set aside the proceedings and/or to enter summary judgment was accordingly dismissed. Conversely, in *Wyko*, the plaintiff – who wished to start manufacturing roller bearings and associated products which would closely match the defendant's products – sought declarations of non-infringement of the defendant's copyright in respect of some of the parts it wanted to manufacture. The court noted that: (a) the plaintiff had yet to manufacture any items which might be said to infringe; (b) it had not identified any particular copyright; (c) in the absence of some allegedly infringing product, none was capable of being identified; and (d) the defendant had not as yet asserted any claim (a mere reservation of rights in inter-solicitor correspondence being insufficient for this purpose). On these facts, the plaintiff was held to have failed to demonstrate any basis for the grant of declaratory relief.

51 Secondly, assuming as a general proposition of law that the court may in exercise of its inherent jurisdiction grant a declaration of prospective infringement, a plaintiff who seeks to rely on this inherent jurisdiction must plead sufficient facts to provide basis for its exercise. This is why we see the court in *Wyko*, for example, scrutinising the plaintiff's statement of claim "in order to see the precise case which they seek to put" (at 130–132). In the present case, the Statement of Claim asserts that: (a) the Plaintiff has patents over processes for the manufacture of Bortezomib; (b) the Defendant has registered a therapeutic product containing Bortezomib as an active ingredient; and (c) the acts for which registration has been obtained "would infringe one or more" of the 64 claims of the Plaintiff's Patents.[24] It is not disputed, however, that the making of an application for registration *per se* is not an infringing act: see *The Upjohn Company v T Kerfoot & Co Ltd* [1988] FSR 1 at 6.[25] The Plaintiff concedes in its Statement of Claim that it can give no particulars of any actual and/or threatened infringements of its patents "until after discovery and/or interrogatories".[26] Whilst the Plaintiff alleged that the Defendant had participated in the 2017 tender thrown by Singapore public hospitals for the supply of Bortezomib,[27] this was not pleaded in the Statement of Claim, nor was leave sought at any stage to amend the Statement of Claim so as to plead this. Indeed, at the date of the hearing before me on 28 March 2018, the Plaintiff did not dispute that the Defendant had not supplied its therapeutic product in Singapore.[28] Given the

24 Statement of Claim, paras 3–6 and 12.

25 DSBOA, Tab 4.

26 Statement of Claim, para 13.

27 Yeung's first affidavit, paras 24–28; Yeung's second affidavit, para 12(b).

28 Although various aspects of the Plaintiff's affidavit evidence on the Defendant's alleged participation in the 2017 public hospitals' tender were to my mind unsatisfactory, these did not factor in the consideration of SUM 5650, since the ground relied on for striking-out was that of no reasonable cause of action under O 18 r 19(1)(*a*) of the ROC. The unsatisfactory aspects of the affidavit evidence are separately dealt with in the consideration of SUM 5611 below (see [69] and [78] below).

"most exceptional" nature of the court's inherent jurisdiction (*Wellmix Organics (International) Pte Ltd v Lau Yu Man* [2006] 2 SLR(R) 117 at [81]), and the courts' repeated reminder that the "circumstances must be special" to justify its exercise (*Roberto Building Material Pte Ltd and others v Oversea-Chinese Banking Corp Ltd and another* [2003] 2 SLR(R) 353 at [17]), I do not see how – even with the low threshold applicable at the striking-out stage – the pleadings disclose a "need" for the court to exercise its inherent jurisdiction to grant a declaration of prospective infringement.

52 In coming to the above view, I note that the AR in *AstraZeneca* seemed at one point to suggest that for the court to exercise its inherent jurisdiction to grant the kind of declaration envisaged under s 12A of the MA (read with its accompanying subsidiary legislation), the fact that the defendant had applied for a product licence *per se* sufficed to demonstrate a "real commercial question to be answered" and the plaintiff's "real interest" in raising it (at [43]). I also note, however, that firstly, the AR's suggestion was made in the context of s 12A of the MA, and that secondly, he acknowledged his comments were purely *obiter*, since the plaintiff in *AstraZeneca* had not invoked the court's inherent jurisdiction (at [44]). In any event, having regard to the reasons set out in the preceding paragraph, I would respectfully disagree with his suggestion.

53 For the reasons set out above, I held that the Prospective Infringement Declaration Claim disclosed no reasonable cause of action and was obviously unsustainable.

The Injunction Claim

54 Next, the Plaintiff's Statement of Claim sought an injunction to restrain the Defendant from infringing its patents. As noted earlier, the Plaintiff conceded that this was not a case where any infringing act had actually taken place, and

that its claim for an injunction was only premised on a cause of action in *prospective* infringement arising either from regulation 24(1)(*a*)(i) of the TPR or from the court's inherent jurisdiction (see [32] above). Accordingly, for the reasons that I have set out earlier in rejecting the Prospective Infringement Declaration Claim (at [31]–[53] above), I found that this claim disclosed no reasonable cause of action and was obviously unsustainable.

The Actual Infringement Declaration Claim

55 Finally, aside from the alleged cause of action in *prospective* infringement, the Statement of Claim also asserted *actual* infringement by the Defendant: see, *eg*, paras 13–15 of the Statement of Claim. The Defendant pointed out in its written submissions that the claim of actual infringement is baseless because the Plaintiff has not pointed to and cannot point to any infringing act by the Defendant. Indeed, as noted earlier, the Plaintiff conceded that: (a) this was not a case where any infringing act had taken place; (b) the Plaintiff was not claiming actual infringement under the PA. As such, the claim of actual infringement in the Statement of Claim – as well as the associated prayers for an order for the delivery up or destruction of infringing articles and an inquiry into damages (or alternatively an account of profits) – were plainly unsustainable.

The interlocutory injunction application in SUM 5611

56 I now turn to the Plaintiff's application in SUM 5611 for an interlocutory injunction to restrain the Defendant from performing any of the acts for which registration of the Defendant's therapeutic product was obtained.

57 To succeed in this application, the Plaintiff had to show firstly that there was "a serious question to be tried"; and secondly, that "the balance of

convenience [lay] in favour of granting" the interlocutory injunction: *American Cyanamid* at 407–408.

58 In my judgment, the Plaintiff failed to satisfy either limb of the *American Cyanamid* test. I therefore dismissed the Plaintiff's application for an interlocutory injunction.

Serious question to be tried

59 On the first limb of the *American Cyanamid* test, I held that the "serious question to be tried" must relate to the right for which the Plaintiff has sought protection from injury.

60 In so far as the Plaintiff appeared to suggest in its arguments in SUM 1764 (when seeking leave to appeal against my decision in SUM 5611) that the first limb of the *American Cyanamid* test can be satisfied so long as a valid cause of action is found in respect of *any* right asserted in the statement of claim, regardless of what that right might be, I do not think the suggestion is correct as a matter of principle. As Lord Diplock held in *American Cyanamid* (at 406), "[t]he object of the interlocutory injunction is to protect the plaintiff against injury by violation of his right for which he could not be adequately compensated in damages recoverable in the action if the uncertainty were resolved in his favour at the trial". To put it somewhat colloquially, when the court asks of a plaintiff "what do you seek to injunct the defendant from doing", the "flip-side" of that question must be "what right do you seek to protect from injury by the defendant". It does not make sense for the court to injunct a defendant from doing specific acts without knowing what rights of the plaintiff's those specific acts are alleged to injure.

61 In the context of the present application, the "serious question to be tried" must therefore be one which related to the Plaintiff's alleged right to protection from prospective infringement of its patents. In this connection, the Plaintiff has conceded that there has been no actual infringement of its patents by the Defendant (see [32] above), and I have indeed so found (at [55] above). I have also found that the Plaintiff had no reasonable cause of action for prospective infringement of its patents (at [31]–[53] above). In the circumstances, I was of the view that the Plaintiff could not satisfy the first limb of the *American Cyanamid* test. To quote Lord Diplock again, this time from his judgment in *Siskina (Owners of cargo lately laden on board) and Others v Distos Compania Naviera SA* [1979] AC 210 ("*The Siskina*") (at 256):

> … A right to obtain an interlocutory injunction is not a cause of action. It cannot stand on its own. It is dependent upon there being a pre-existing cause of action against the defendant arising out of an invasion, actual or threatened by him, of a legal or equitable right of the plaintiff for the enforcement of which the defendant is amenable to the jurisdiction of the court. The right to obtain an interlocutory injunction is merely ancillary and incidental to the pre-existing cause of action. …

Although *The Siskina* concerned an application for a *Mareva* injunction, the principle articulated by Lord Diplock in the aforementioned passage is of general application, having been applied, for example, by Hoffmann J (as he then was) in *Associated Newspapers Group Plc v Insert Media Ltd and Others* [1988] 1 WLR 509 (at 514–515).

The balance of convenience

62 In the event that I was wrong about the Plaintiff's ability to satisfy the first limb of the *American Cyanamid* test, I also proceeded to consider the second limb of the test, that is, whether – assuming it could cross the threshold of

"serious question to be tried" – the Plaintiff was able to show that the balance of convenience lay in favour of granting it the interlocutory injunction.

63 The governing principles in this respect are set out in Lord Diplock's judgment in *American Cyanamid*. For ease of reference, I reproduce the relevant passages (at 408–409) below:

> … the court should first consider whether, if the plaintiff were to succeed at the trial in establishing his right to a permanent injunction, he would be adequately compensated by an award of damages for the loss he would have sustained as a result of the defendant's continuing to do what was sought to be enjoined between the time of the application and the time of the trial. If damages in the measure recoverable at common law would be adequate remedy and the defendant would be in a financial position to pay them, no interlocutory injunction should normally be granted, however strong the plaintiff's case appeared to be at that stage. If, on the other hand, damages would not provide an adequate remedy for the plaintiff in the event of his succeeding at the trial, the court should then consider whether, on the contrary hypothesis that the defendant were to succeed at the trial in establishing his right to do that which was sought to be enjoined, he would be adequately compensated under the plaintiff's undertaking as to damages for the loss he would have sustained by being prevented from doing so between the time of the application and the time of the trial. If damages in the measure recoverable under such an undertaking would be an adequate remedy and the plaintiff would be in a financial position to pay them, there would be no reason upon this ground to refuse an interlocutory injunction.
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> It is where there is doubt as to the adequacy of the respective remedies in damages available to either party or to both, that the question of balance of convenience arises. It would be unwise to attempt even to list all the various matters which may need to be taken into consideration in deciding where the balance lies, let alone to suggest the relative weight to be attached to them. These will vary from case to case.
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> Where other factors appear to be evenly balanced it is a counsel of prudence to take such measures as are calculated to preserve the status quo. If the defendant is enjoined temporarily from doing something that he has not done before, the only effect of the interlocutory injunction in the event of his succeeding at the trial is to postpone the date at which he is able to embark upon a course of action which he has not previously found it necessary to undertake; whereas to interrupt him in the conduct of an

> established enterprise would cause much greater inconvenience to him since he would have to start again to establish it in the event of his succeeding at the trial.
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> Save in the simplest cases, the decision to grant or to refuse an interlocutory injunction will cause to whichever party is unsuccessful on the application some disadvantages which his ultimate success at the trial may show he ought to have been spared and the disadvantages may be such that the recovery of damages to which he would then be entitled either in the action or under the plaintiff's undertaking would not be sufficient to compensate him fully for all of them. The extent to which the disadvantages to each party would be incapable of being compensated in damages in the event of his succeeding at the trial is always a significant factor in assessing where the balance of convenience lies; and if the extent of the uncompensatable disadvantage to each party would not differ widely, it may not be improper to take into account in tipping the balance the relative strength of each party's case as revealed by the affidavit evidence adduced on the hearing of the application. This, however, should be done only where it is apparent upon the facts disclosed by evidence as to which there is no credible dispute that the strength of one party's case is disproportionate to that of the other party. …

64 The Plaintiff contended that damages would not provide it with an adequate remedy in the event of its succeeding at the trial, for the following reasons. Firstly, it alleged that the Defendant had participated in the 2017 tender thrown by Singapore public hospitals for the supply of Bortezomib.[29] According to the Plaintiff, the supply to public hospitals constituted 85% of the "multi-million dollar market for Bortezomib in Singapore".[30] Previously, the Plaintiff's exclusive licensee in Singapore – Johnson & Johnson – had been the sole supplier to the public hospitals. The Defendant's entry into this market would, according to the Plaintiff, result in a "devastating decimation of the Plaintiff's (or its exclusive licensee's) market share for Bortezomib": the Defendant "would be able to supply the Defendant's Product at a significantly lower price than the Plaintiff's (or its exclusive licensee's) own product for Bortezomib … because

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29 Yeung's second affidavit, para 12(b).

30 Yeung's first affidavit, para 20.

the Defendant does not have to recoup the extensive research and development expenditure and marketing costs incurred by the Plaintiff and/or its exclusive licensee".[31]

65 Secondly, the Plaintiff alleged that the "negative repercussions" of the Defendant's conduct were on a "global" scale and "incalculable" because if the Singapore courts denied the Plaintiff an interlocutory injunction against the Defendant, other generic drug companies "in Singapore and elsewhere" would also "apply for and obtain therapeutic product registration for their generic Bortezomib products without declaring the Patents and notifying the Plaintiff, leading to incalculable losses for the Plaintiff around the world and an adverse impact on the Plaintiff's global patent management".[32]

66 The Defendant neither confirmed nor refuted the allegation that it had participated in the 2017 public hospitals' tender. However, it asserted that damages would be an adequate remedy for the Plaintiff if it succeeded at trial. Firstly, the Defendant pointed out that the Plaintiff's Patents were in respect of a number of processes for the manufacture of the active ingredient Bortezomib, but the Plaintiff itself was not marketing or selling Bortezomib in Singapore. Instead, Johnson & Johnson held the product licence for the drug "Velcade" which contained the active ingredient Bortezomib, and Johnson & Johnson was the one marketing and selling Velcade in Singapore.[33] Indeed, according to the product licence obtained from the HSA by Johnson & Johnson, the Plaintiff was not even the manufacturer of Velcade: two European companies – BSP Pharmaceuticals SpA and Pierre Fabre Medicament Production – were listed as the manufacturers.[34] Johnson & Johnson was not a party to the present

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31 Yeung's first affidavit, paras 21 and 36(1)(a).

32 Yeung's first affidavit, para 36(1)(b).

33 Baey's affidavit, para 23 and exh BYK-4.

proceedings, and no affidavit evidence had been procured from any of its representatives. In the two affidavits filed in these proceedings, the Plaintiff had omitted to disclose the terms of its relationship with Johnson & Johnson. There was also no evidence of the terms of the licensing agreement or of what losses, if any, the Plaintiff would suffer in the event of Johnson & Johnson losing the contract to supply to the public hospitals. In the circumstances, and absent any other evidence from either the Plaintiff or Johnson & Johnson, the Plaintiff's "best case" could "only be limited to a cut of revenue / royalty payments from Johnson & Johnson['s] … sales", which was a loss that was "easily quantifiable and would be adequately remedied by damages at trial".[35]

67 Secondly, the Defendant contended that even if the Plaintiff could claim to suffer wholly and directly the loss of the contract to supply to the public hospitals, such contract was for a defined and limited period of one year. The Defendant contended that the loss of the contract to supply to public hospitals was clearly capable, therefore, of being quantified in monetary terms, which made damages an adequate remedy for the Plaintiff in the event it succeeded at trial.[36]

68 Finally, as to the Plaintiff's allegation about "incalculable" repercussions on its "global patent management", the Defendant contended that the allegation was purely speculative, as there was no evidence of the alleged link between the grant (or refusal) of an interlocutory injunction in Singapore and the strength of protection enjoyed by any patents they might hold in other jurisdictions.[37]

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34 Baey's affidavit, exh BYK-4.

35 Baey's affidavit, para 31(c).

36 Baey's affidavit, para 29.

37 Baey's affidavit, para 30.

69 I noted that in Constance Yeung's first affidavit dated 5 December 2017 ("Yeung's first affidavit"), it had been stated that "[b]ased on past experience", the outcome of the 2017 public hospitals' tender "could be announced anytime in the period between early December 2017 and mid-December 2017".[38] Nothing further was said, however, about the outcome of the 2017 tender in Constance Yeung's second affidavit dated 25 January 2018 ("Yeung's second affidavit") and at the hearing before me on 28 March 2018. On my querying the Plaintiff's counsel about the outcome of the 2017 tender, the only response I received was that there was "[n]o outcome as yet *at the time of [Yeung's] second affidavit*", *ie*, as of 25 January 2018. No further information was provided as to whether the outcome of the 2017 tender had been made known between 25 January 2018 and 28 March 2018. This was, with respect, unfortunate. What it left me with – in so far as the issue of the contract to supply to public hospitals was concerned – was that as at 28 March 2018, the Plaintiff conceded that there was no evidence of the Defendant having supplied Bortezomib in Singapore, and the Plaintiff did not dispute the Defendant's assertion that the contract was in any event for a defined and limited period of one year.

70 As to the terms of the Plaintiff's relationship with Johnson & Johnson, the Plaintiff's counsel replied that it would not make a difference because it was "up to [the] patentee-owner how to exploit its invention, including through licensing", and what was important was that the "generic's entry will slash prices and it affects the patentee too. The boat has been rocked, and you cannot calibrate [the] price to its original point". Plaintiff's counsel cited the four cases in the Plaintiff's supplementary bundle as authorities in which interim injunctions were granted on the basis that the generic's entry would slash prices and cause unpredictable and incalculable damage. Further, he contended that I should hold

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38 Yeung's first affidavit, para 26.

it against the Defendant that it had failed to take steps under s 78 of the PA to obtain a declaration of non-infringement before registering its therapeutic product.

71 I will address first the Plaintiff's reliance on the cases in its supplementary bundle of authorities. In each of these cases, detailed – indeed, voluminous – evidence was produced by the parties on the issue of adequacy of damages. In each case, it was only after a careful analysis of the evidence available that the court concluded that damages would be an inadequate remedy for the claimants in the event of their success at trial, and that the balance of convenience favoured the grant of an interlocutory injunction.

72 In *Leo Pharma A/S and Another v Sandoz Ltd* [2008] EWCA Civ 850,[39] for example, the claimant-patentee Leo owned the patent for the monohydrate of a vitamin D analogue called calcipotriol. Leo was itself selling the patented product as an ointment under the trademark Dovonex and as a combination product containing calcipotriol monohydrate with a steroid under the trademark Dovobet. Evidence was adduced to show that these products made up 45% of Leo's turnover in the UK. Evidence was also adduced to show that the defendant Sandoz – a "substantial player in the generic pharmaceutical market" with "considerable marketing powers" – had already launched a generic calcipotriol cream, and that whilst the total sales figure for Sandoz's product over a four-month period was relatively modest, this was not surprising because Sandoz had launched its product on an unusually small scale for a generic company and had been selling at a price which was of the order of Leo's price. The first-instance judge concluded, after reviewing the evidence, that Leo could not be entirely compensated in damages and granted it an interlocutory injunction against Sandoz. In particular, Leo's evidence showed that in effect 70% of the market

[39] Plaintiff's Supplementary Bundle of Authorities ("PSBOA"), Tab 1.

for this cream could be open to generic competition because 70% was for prescriptions use in the generic name rather than in Leo's trademark. Neither the first-instance judge nor the English Court of Appeal had any difficulty in accepting Leo's evidence that a competitor such as Sandoz would want to get that 70% of the market and that the only way it could do so was to market at a price less than Leo's (at [11]). Leo's evidence was that Leo could not be clear as to what it would do once Sandoz cut its price: there would be instead "a great field of speculation" (at [16]). There were also "further heads of uncertain damages" in this case, such as the effect on the price of Leo's products in Spain (at [17]). In all, the Court of Appeal held that the exercise of discretion by the first-instance judge revealed "[no] error of principle" in the assessment of the evidence (at [25] *per* Jacob LJ), and "was entirely justified *on the material before him*" [emphasis added] (at [27] *per* Mummery LJ).

73 *SmithKline Beecham Plc v Generics UK Ltd* [2001] EWHC 563 (Pat)[40] concerned the patent held by the claimant SmithKline Beecham ("SB") for a particular form of paroxetine hydrochloride which they sold in hemihydrate form under the trademark "Seroxat". SB's evidence showed that Seroxat was their top-selling drug. The defendants Generics UK Ltd ("Generics") intended to launch a product called paroxetine. The evidence showed that: (a) they had been considering the market for this drug since 1997, some four years prior to the proceedings; (b) they appeared to have done some research on the patent position; and (c) they had obtained market authorisation without informing SB.[41] There was also evidence that there were parallel imports of SB's product from sister companies in Europe, for which there was a floor price because these sales were by SB abroad.[42] On the other hand, SB had also recently entered into a

40 PSBOA, Tab 4.

41 PSBOA, Tab 4, p 1.

42 PSBOA, Tab 4, p 6.

supply agreement with a well-known generic supplier called Norton, pursuant to which SB intended to make available its product in generic form to Norton, with the latter being free to sell to others at a price of their own choosing.[43] Jacob J found, on the evidence before him, that if Generics entered the market too:[44]

> … [t]here will be price competition between the parallel importers who cannot go any lower, Norton who can go as low as they like, and the defendants. The price will be chased down. The effect of that chasing down may well be to force the patentees to lower their prices too … The potential effect of the entry into the market of the defendants will be to cause a price spiral.

Jacob J also held that in this case, he had to consider the effect on Norton:[45]

> They are free to enter the generic market with product other than that bought from the patentees. The evidence indicates that they were close to doing it, one way or another, with a product within the patent or without … If the price is chased down, Norton might switch from the patentees to someone else.

74 Jacob J therefore found on the evidence that if no injunction were granted, SB would "very probably suffer price loss and loss of market share. Undoubtedly, the amounts involved will be very substantial sums indeed. Quite what they would be would be impossible to calculate".[46] Whilst he accepted that the defendants' damages were "also unquantifiable", the "order of damage to [SB] was likely to be a good deal greater than that to [Generics]".[47] Additionally, in arriving at the decision to grant SB an interlocutory injunction against Generics, Jacob J noted that: (a) Generics had known "for a long time" about the patent; (b) Generics had known as early as 1997 "that if the patentees would cause trouble they would [take action]"; and (c) there were a number of things

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43 PSBOA, Tab 4, p 2.

44 PSBOA, Tab 4, pp 7–8.

45 PSBOA, Tab 4, p 8.

46 PSBOA, Tab 4, p 9.

47 PSBOA, Tab 4, p 10.

Generics could have done, but that they chose not to do it.[48] He found this to be a relevant factor, adding that this was "not a case where [Generics] could say, on the material they had, it was certain not to fall within the claims": although they had materials from their supplier and from experiments by their sister company in Australia which suggested that was so, they had not taken steps to obtain details of the experiments themselves.[49]

75 *SmithKline Beecham Plc and Another v Apotex Europe Limited and Others* [2003] EWCA Civ 137 ("*Apotex*")[50] again featured Smithkline Beecham's UK patent for the particular form of paroxetine hydrochloride sold in hemihydrate form under the trademark "Seroxat". The claimants were Smithkline Beecham Plc and GlaxoSmithKline (UK) Limited (collectively, "SB"), who were the proprietor and the exclusive licensee of the patent respectively. They sought an interlocutory injunction to restrain the defendants Apotex Europe Limited ("Apotex") from making and selling hydrochloride anhydrate. The injunction was granted by the first-instance judge. On appeal, Apotex contended that any infringement, even if established at trial, would result in no unquantifiable loss. The Court of Appeal examined the evidence before it in considering the issue of adequacy of damages. Aldous LJ (with whom Carnwath LJ and Sir Christopher Staughton agreed) noted, *inter alia*, that in addition to Apotex, there were three other companies with stocks of generic paroxetine hydrochloride which were already packaged, licensed and ready for immediate sale and distribution (at [36]). Aldous LJ also observed that Apotex accepted that if they or any other generic company entered the market, SB would not only lose substantial sales, but the price would also "collapse", and SB's prices would be "severely eroded" (at [32], citing the decision of the first-

48 PSBOA, Tab 4, pp 11–13.

49 PSBOA, Tab 4, pp 12–13.

50 PSBOA Tab 3.

instance judge). Where parties differed was on the question of whether SB had sufficient market power to reinstate prices at the existing levels (at [37]). Considering the conflicting evidence produced by the parties on this, Aldous LJ held that the first-instance judge was entitled to conclude that damages would not be an adequate remedy for either SB or Apotex because there was "no clear case to conclude that it would be easier to assess the damages due to SB if no injunction was granted than it would be to assess the damages to Apotex under the cross-undertaking of damages if an injunction was wrongly granted" (at [38]). Finally, Aldous LJ also found that having found damages to be an inadequate remedy for both SB and Apotex, the first-instance judge was entitled to find that Apotex knew at least a year before the proceedings that SB would likely seek to injunct the sale of their product – this was a case where "Apotex walked into the situation that they find themselves in with their eyes open to the risk that they were taking" (at [39]–[40]). The Court of Appeal therefore upheld the first-instance decision to grant the interlocutory injunction.

76 In *Merck Sharp & Dohme Corporation and another v Glenmark Pharmaceuticals* FAO (OS) 190/2013,[51] the High Court of Delhi went through a similar process of examining the evidence adduced before deciding that an interim injunction against the defendant Glenmark Pharmaceuticals ("Glenmark") would remove the possibility of irreparable harm to the claimant-patentee Merck Sharp & Dohme ("MSD") as well as maintain the public interest involved. The court found it relevant first of all that the evidence showed a "strong case of infringement" and that it was especially in such cases that courts should be mindful of the interest in enforcing the Indian Patents Act, 1970 (at [85]). The court noted that the price differential between MSD's drug and Glenmark's infringing drug was 30%, a significant portion of which was due to

[51] PSBOA, Tab 2.

the customs duty that MSD had to pay. On the other hand, whilst there was a well-established principle in Indian jurisprudence that the courts must consider the public interest in ensuring access to drugs, in this case the price difference between MSD's and Glenmark's commercial products was not so startling as to compel the court to infer that allowing Glenmark to sell its drug at depressed prices would result in increased public access to the drug (at [82]). The court considered the offer made by MSD to compensate Glenmark for loss of earnings if MSD's suit for infringement of its patent were to be dismissed, and concluded that such an undertaking sufficed to ensure not only that Glenmark would (if successful) be able to return to the market without any handicap, but also compensate it at market value for the period for which it was excluded (at [86]).

77 I have gone through the four cases raised by the Plaintiff in some detail in order to demonstrate that in all these cases, the court's decision to issue or uphold an interlocutory injunction against the defendant-generic in each case was based on a careful review of the evidence adduced. None of these cases establishes a general proposition of law that in every pharmaceutical case where a patentee is pitted against a generic, the damage suffered by the patentee if denied an injunction pending trial will *inevitably and automatically* be found to be "incalculable". The position is perhaps best put in *Cephalon, Inc and Others v Orchid Europe Limited and Generics (UK) Ltd (t/a Mylan)* [2010] EWHC 2945 (Pat) ("*Cephalon*") (an authority brought to my attention by the Defendant's counsel during the hearing) by Floyd J, who stated (at [49]–[51]):

> There have been a number of cases where interim injunctions have been granted in cases concerning patented pharmaceuticals and generic competition where the court has concluded that the loss likely to be suffered by the patentee would be larger and more unquantifiable than the loss to the generic. Mr Carr [counsel for the claimants] reminded me of *SKB v Generics* (23rd October 2011) [(*ie*, the case referred to above)] at 11 lines 7-10; *SKB v Apotex* [2003] FSR 30 and *Abbott v Ranbaxy* (19th November 2004). In each case a significant factor

> has been the fact that the generic competition was likely to produce price cutting, and that restoring those prices to the full monopoly level after success at trial could cause the patentee to lose goodwill.
>
> A second theme which has emerged from the cases is that a factor in the balance of convenience may be that the generic company which is threatening to come on the market has taken no steps to "clear the way". Given that the launch of a pharmaceutical cannot be achieved overnight, and requires the obtaining of marketing approval after the submission of data, it has been said that a generic company which does not also take steps to ensure that it is not arguably infringing the relevant patents should not be able to rely subsequently on the resulting uncertainty. This was said in *SKB v Apotex* (above) at [65]–[68] and on appeal by Aldous LJ at [2003] FSR 31 at [38]–[40].
>
> *These are certainly considerations which, depending on the evidence, may be material in particular cases. There is a danger however in treating them as principles of law. Whether they apply at all in any given case and whether, if they do, they outweigh other factors is to be decided on the evidence.*
>
> [emphasis added]

78 In the present case, the Plaintiff laid great emphasis on the importance of the market for supply to public hospitals, claiming that it represented 85% of the Singapore market for supply of Bortezomib. However, as I noted earlier (at [69] above), no evidence was adduced as to the outcome of the 2017 public hospitals' tender, which had constituted one of the chief reasons for the Plaintiff seeking an urgent *ex parte* interlocutory injunction in early December 2017. As I have also noted (at [32] above), when queried at the hearing on 28 March 2018, the Plaintiff admitted that this was not a case where it was relying on actual infringing acts by the Defendant. In any event, even assuming that the Defendant had been awarded the 2017 public hospitals' tender, the Plaintiff did not dispute the Defendant's assertion that any such contract would only be for the specific, limited period of one year. Additionally, since 85% of the local market is supplied via an annual tender jointly conducted by the public hospitals in

Singapore,[52] the revenue and the profits from supplying the lion's share of the market were readily quantifiable.

79 I did bear in mind the possibility of an argument being made that the damage resulting from the loss of the 2017 tender was not limited to the contract price and that a supplier which lost its monopoly position in one year might never be able to get prices back to the monopoly level in following years. Critically, however, there was no evidence adduced before me which could have provided some basis for making such a supposition. There was no basis for me to accept the sweeping argument that because the courts in the above four cases had accepted that the generic's entry in those cases meant an irretrievable downward price spiral, so too the present Plaintiff must be assumed to face an irreversible price crash and correspondingly, incalculable damage. As the Defendant rightly pointed out, there have after all been other cases where the courts have declined to find that a generic's entry presaged an irreversible price crash. In *Cephalon*, for example, Floyd J found the evidence before him insufficient to show "irreversible price erosion" (at [62]). He noted in particular that: (a) the claimants Cephalon, Inc ("Cephalon") had previously dealt with competition from parallel importers of modafinil by giving discounts to pharmacy chains; (b) the evidence showed Cephalon to be able to raise their prices in relation to modafinil after lowering them temporarily; and (c) there was no suggestion that Cephalon experienced any significant loss of goodwill when they did so (at [61]–[66]).

80 Further, in assessing the impact of any entry by the Defendant into the local market, it must be remembered that the present Plaintiff is not the party selling Velcade in Singapore, nor is it the manufacturer of Velcade.[53] It was on this basis that the Defendant's Baey Yam Khuang had asserted in his affidavit

52 Yeung's first affidavit, para 20.

53 Baey's affidavit, exh BYK-4.

dated 12 January 2018 ("Baey's affidavit") that any loss suffered by the Plaintiff if it succeeded at trial must at best be "limited to a cut of revenue / royalty payments from Johnson & Johnson['s] … sales".[54] In fact, in one of the cases cited by the Plaintiff, *ie*, *Apotex*, Aldous LJ had astutely observed that "[i]n cases where the patentee is not a manufacturer, the patentee will normally only be able to establish that he has lost that which he would have charged for use of his invention, namely a reasonable royalty" (at [8]). This did *not* mean that infringement might not cause a patentee loss exceeding a reasonable royalty: the extent of recovery in each case would "depend upon the facts and the normal considerations of causation and remoteness" (also at [8]). In this case, it was telling that not only had Yeung's first affidavit been silent on the terms of the Plaintiff's agreement with Johnson & Johnson, but Yeung's second affidavit – which was filed in response to Baey's affidavit – also made no response to the critical assertion by Baey that the Plaintiff's loss was at best limited to a cut of the revenue or royalty payments from Johnson & Johnson's sales. All that Yeung's second affidavit did was to repeat in vague and general terms that "damages would not be an adequate remedy for the Plaintiff".[55]

81 As to the Plaintiff's allegation about "incalculable" repercussions on its "global patent management", this was again only a general allegation which was not substantiated by any evidence of the "global" issues faced by the Plaintiff.

82 Lord Diplock's judgment in *American Cyanamid* made it plain that "[i]f damages in the measure recoverable at common law would be an adequate remedy and the defendant would be in a financial position to pay them, no interlocutory injunction should normally be granted, however strong the plaintiff's case appeared to be at that stage" (at 408). For the reasons set out

54 Baey's affidavit, para 31(c).

55 Yeung's second affidavit, para 28.

above, I found that the Plaintiff had failed to show that damages would be an inadequate remedy for it in the event it succeeded at trial. On the evidence available, the Defendant was not unjustified in saying that the Plaintiff's damage in the event of success at trial was limited to a reasonable royalty. I therefore concluded that even if the Plaintiff were able to show a "serious question to be tried", damages would be an adequate remedy for it if it succeeded at trial after being denied an interlocutory injunction.

83 As I found that damages would be an adequate remedy for the Plaintiff in the event it succeeded at trial, I did not find it necessary to consider the Plaintiff's argument that the Defendant should have acted first to obtain a declaration of non-infringement under s 78 of the PA before registering its therapeutic product.

84 The Defendant had in its affidavit put on record its willingness to pay any damages awarded to the Plaintiff at trial, and also exhibited documentary evidence of its financial ability to do so.[56] The Plaintiff did not dispute nor did it put forward any submissions on the Defendant's financial ability to pay any award of damages. There was thus no reason to doubt the Defendant's ability to pay any damages awarded at trial.

Conclusion

85 For all the reasons set out above, I allowed in part the Defendant's application for striking-out in SUM 5650, ordering that paras 12–15 at p 4 of the Statement of Claim as well as prayers (2)–(6) at pp 5 and 6 of the Statement of Claim be struck out, and fixed costs at $5,000 (all in) to be paid by the Plaintiff to the Defendant. As for the Plaintiff's application in SUM 5611 for an

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[56] Baey's affidavit, exh BYK-1.

interlocutory injunction, I dismissed the application and fixed costs at $7,000 (all in) to be paid by the Plaintiff to the Defendant.

Postscript: Plaintiff's submissions on a *quia timet* injunction in SUM 1764

86 At the hearing on 26 April 2018 of SUM 1764 (the Plaintiff's application for leave to appeal against my decision in SUM 5611), the Plaintiff cited a number of authorities on the issuance of *quia timet* injunctions to make the point that "a Plaintiff may be entitled to an injunction (*ie*, a *quia timet* injunction) against a Defendant, even though an infringement has not taken place but is merely feared or threatened, so long as a valid cause of action exists".

87 The Defendant did not have the opportunity of dealing with the Plaintiff's submissions and the supporting authorities cited in this regard,[57] as these were not put forward in the course of the substantive hearing on 28 March 2018. In any event, I did not think these further submissions and authorities would have assisted the Plaintiff at the substantive hearing. It did not appear to me that the Defendant disputed the possibility – in principle – of an injunction being issued to prevent an *anticipated* (as opposed to an *actual*) infringement. The principles by which it is decided whether an injunction should be granted or refused are not different merely because relief is sought *quia timet*. As noted in I C F Spry, *The Principles of Equitable Remedies*: *Specific Performance, Injunctions, Rectification and Equitable Damages* (Sweet & Maxwell, 9th Ed, 2014) (at p 389):

> … [t]he equitable remedy of injunctions has been moulded to fit many purposes, and various classifications have been developed, according to the particular distinctions that happen to be in question. It is important to note that precisely the same general principles are applied by court of equity whatever the nature of the particular injunction that is sought may be.

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[57] Outline of Plaintiff's Oral Submissions in SUM 1764/2018, p 4.

88 In other words, the Plaintiff still had to be able to show, on its summons for interlocutory injunction, that there was a "serious question to be tried" and that damages would not be an adequate remedy for it in the event it succeeded at trial. Indeed, it appeared to me that the Plaintiff accepted this since it alluded to a *quia timet* injunction being available to protect a plaintiff from a feared or threatened infringement "so long as a valid cause of action exists". I would also add that the authorities are clear that a plaintiff who seeks a *quia timet* injunction "takes upon himself the burden of proving that it is reasonably certain that what the defendant is threatening and intending to do will cause imminent and substantial damage to the plaintiff": see *Royal Insurance Co Ltd v Midland Insurance Co Ltd* (1908) 26 RPC 95 at 97 *per* Cozens-Hardy MR. This was something which, on the evidence before me, the Plaintiff clearly failed to do (see [77] to [81] above).

Mavis Chionh Sze Chyi
Judicial Commissioner

Suhaimi bin Lazim, Chiong Song Ning and Yan Chongshuo (Mirandah Law LLP) for the plaintiff;
Kang Choon Hwee Alban, Tan Lijun and Marcus Lim (Bird & Bird ATMD LLP) for the defendant.