AstraZeneca AB (SE) *v* Sanofi-Aventis Singapore Pte Ltd
[2012] SGHC 16

Case Number : Suit No 416 of 2011 (Summons 5001/2011/M)

Decision Date : 19 January 2012

Tribunal/Court : High Court

Coram : Chan Wei Sern Paul AR

Counsel Name(s) : Lee Ai Ming, Alvin Lim and Sandeep Menon (Rodyk & Davidson LLP) for the plaintiff; Vignesh Vaerhn, Eunice Lim and Tan Lijun (Allen & Gledhill LLP) for the defendant.

Parties : AstraZeneca AB (SE) — Sanofi-Aventis Singapore Pte Ltd

Patents and Inventions – Infringement

Civil Procedure – Pleadings – Striking Out

19 January 2012 Judgment reserved.

Chan Wei Sern Paul AR:

1 By Summons 5001 of 2011 ("SUM 5001"), the defendant seeks to strike out the plaintiff's Statement of Claim (Amendment No. 1) and prays for the plaintiff's claim in this action to be wholly dismissed. At the heart of this matter lies the import of section 12A of the Medicines Act (Cap 176, 1985 Rev Ed) ("Medicines Act"), a provision enacted in 2004 to enable Singapore to fulfil part of its obligations arising from the United States-Singapore Free Trade Agreement.

Background

2 Both the plaintiff and the defendant are companies which engage in the research, development, manufacture and commercialisation of healthcare products, including medicines. The former is incorporated in Sweden, the latter Singapore. The plaintiff is also the owner of Singapore Patent No. 89993 ("the Patent"). The full title of the invention for which the Patent was granted is "Pharmaceutical Compositions Comprising a HMG COA Reductase Inhibitor". Claim 5 of the specification of the Patent states the essence of the invention in the following terms:

> 5. [The plaintiff] present as a feature of the invention
>
> (1) A pharmaceutical composition comprising the Agent [chemically defined earlier in the specification but which we may for present purposes simply term as Rosuvastatin Calcium] as an active ingredient and an inorganic salt in which the cation is multivalent.
>
> (2) The use of an inorganic salt in which the cation is multivalent as a stabilising agent in a pharmaceutical composition comprising the Agent.

In other words, the invention is composed of two elements, an active ingredient (Rosuvastatin Calcium) and a stabiliser. Significantly for this application, the stabiliser consists specifically of "an inorganic salt in which the cation is multivalent".

3 On 1 April 2011, the defendant submitted its applications to the Health Sciences Authority ("HSA") for product licences in respect of the following products:

(a) Rosucard Film-coated Tablet 10 mg;

(b) Rosucard Film-coated Tablet 20 mg; and

(c) Rosucard Film-coated Tablet 40 mg.

For ease of reference, these shall henceforth be called the "Proposed Products". According to section 5 of the Medicines Act, a product licence is required to: (a) sell, supply or export any medicinal product; (b) procure the sale, supply or exportation of any medicinal product; or (c) procure the manufacture or assembly of any medicinal product for sale, supply or exportation.

4 In its application forms, the defendant openly declared that these were applications where:

(a) a patent was in force in respect of the Proposed Products;

(b) the defendant was not the proprietor of the patent;

(c) the proprietor had not consented to nor acquiesced in the grant of the product licences; and

(d) in the opinion and to the best belief of the defendant, the patent would not be infringed by the doing of the act for which the licences were sought.

The defendant further elaborated that the proprietor of the patent was the plaintiff and that the relevant patent was indeed Singapore Patent No. 89993.

5 By way of a letter, the HSA subsequently requested the defendant to serve a notice to the plaintiff using a form set out in the Sixth Schedule to the Medicines (Licensing, Standard Provisions and Fees) Regulations (Cap 176, S 74, 2000 Rev Ed) ("the Regulations"). This the defendant did in a notice dated 19 April 2011 ("the Notice"). In the Notice, the defendant informed the defendant that applications for product licences have been made to the HSA in respect of the Proposed Products and further stated that:

2. In [the defendant's] opinion and to the best of [its] belief, the [Patent] will not be infringed by the doing of the act for which the licence is sought. The basis of [its] opinion is: [the defendant's] proposed composition does not comprise an "inorganic salt in which the cation is multivalent" as set out in the patent claims.

3. Unless an application is made, within 45 days from the date of this Notice is served on you, for a court order restraining the act for which the licence is applied for or a declaration by a court of the Registrar of Patents that the [Patent] will be infringed by the doing of that act, the HSA may proceed to grant the licence.

Pursuant to Section 12A(5) of the Medicines Act read with regulation 5B(3) of the Regulations, the effect of the plaintiff making the application as stated in paragraph 3 of the Notice within the 45-day period would be that a 30-month stay on the processing of the product licence applications would be enforced by the HSA.

6 On 10 June 2011, the plaintiff filed its original Statement of Claim, the practical effect of which was to set in place the 30-month moratorium. There was some dispute over whether the action was commenced within the 45-day period but it appeared that the HSA has accepted that it was and this point was not material in the present application. The Statement of Claim was subsequently amended. In its final form, the plaintiff prays, *inter alia*, for:

a) a declaration that the defendant's performance of the following acts in Singapore will infringe the Patent:

i. disposal of the defendant's Products;

ii. offer to dispose of the defendant's Products;

iii. using the defendant's Products;

iv. importing the defendant's Products;

v. keeping whether for disposal or otherwise of the defendant's Products.

b) 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 No. SG89993.

The only basis for these prayers appears to be the allegation that the stated acts "will infringe claims 1 to 27 of the Singapore Patent No. SG89993 if carried out by the Defendant in Singapore". No Particulars of Infringement was filed for the plaintiff did not think it necessary for an action of this kind.

7 The defendant thereafter sought further particulars of the plaintiff's Statement of Claim. This request was considered to be wholly misconceived by the plaintiff and was for that reason rejected. On 4 November 2011, the defendant then filed SUM 5001 pursuant to O. 18, r. 19 of the Rules of Court (Cap 322, R 5, 2006 Rev Ed) ("ROC") to, as stated earlier, strike out the action. The defendant's application is supported by a lengthy affidavit but the plaintiff chose not to file an affidavit in response.

The parties' cases

The defendant's case

8 Initially, the defendant proceeded on the assumption that the plaintiff is taking out a patent infringement action pursuant to sections 66 and 67 of the Patents Act (Cap 221, 2005 Rev Ed) ("the Patents Act"). In order to rely upon these sections for an action of patent infringement, the defendant argued that the patentee is required to provide at least one instance of a past infringement. Without a history of infringement, any action pursuant to section 67 is doomed to failure. In the present action, it is common ground between the parties that *the defendant has not yet committed any act which could be said to amount to an infringement of the Patent.* The only act which the defendant could be said to have performed in respect of the Proposed Products in Singapore was to apply for product licences. This in itself was not an infringing act on the authority of *The Upjohn Company v T. Kerfoot & Co. Ltd.*[1988] FSR 1 ("*Upjohn v Kerfoot*"). For this reason alone, it was submitted that the plaintiff's claim should be dismissed.

9 It was also suggested that the purpose of the plaintiff's action is merely to institute the 30-month stay on the processing of the product licence applications for the Proposed Products. Alternatively, the defendant also opined that the plaintiff is attempting to obtain confidential information regarding the Proposed Products for the plaintiff's own purposes. The plaintiff's action is, in short, not a *bona fide* action.

10 During the hearing, the court was informed by the plaintiff that it is not taking out a patent infringement action pursuant to the Patents Act. Rather, the plaintiff is relying upon the section 12A of the Medicines Act for its cause of action. To this argument, the defendant submitted that section 12A of the Medicines Act did not provide for a cause of action separate and independent from a patent infringement action under the Patents Act. The defendant opined that the provision in the Medicines Act merely provides for a notification mechanism whereby a patentee would be informed of any application for a product licence which related to its patent. However, any action to be taken out should still be made pursuant to the Patents Act. The defendant pointed out that unlike section 67 of the Patents Act, the Medicines Act did not specifically give a patentee the right to commence civil proceedings.

11 In any case, the defendant also argued that even if section 12A of the Medicines Act contemplated an action separate and independent from a patent infringement action under the Patents Act, a mere disbelief of the defendant's explanation for non-infringement of the plaintiff's patent is insufficient to sustain an action.

The plaintiff's case

12 Before the court, it was clarified on behalf of the plaintiff that the plaintiff is not taking out a patent infringement action under the Patents Act. In fact, it was conceded that the plaintiff has no evidence that the defendant had committed an act of infringement. Such evidence, it was agreed, is necessary to sustain a patent infringement action. Instead, the plaintiff explained that the plaintiff's action is based on section 12A of the Medicines Act which, in his view, provides a separate and independent cause of action. According to the plaintiff, section 12A of the Medicines Act entitles the plaintiff to test the possibility of *future* infringement of the Patent on the assumption that the defendant will carry out the acts for which the product licences were sought. It is, therefore, pre-emptive in nature.

13 Although it was not explicitly stated on affidavit, it soon became clear that the only reason why the action was commenced is because the plaintiff did not believe that the defendant's composition did not contain a stabiliser which comprised "an inorganic salt in which the cation is multivalent". The plaintiff pointed out that the Proposed Products shares the same active ingredient with the invention for which the Patent was granted, namely Rosuvastatin Calcium. Counsel for the plaintiff submitted that, to the best of the plaintiff's knowledge, it is impossible to use Rosuvastin Calcium without utilising a stabiliser which comprised an inorganic salt in which the cation was multivalent. Unfortunately, no affidavit was filed to aver to that effect. It was argued that the section 12A of the Medicines Act entitles the plaintiff to test the defendant's claim by having the defendant reveal the exact composition of the Proposed Products in discovery. For this reason, it was argued that the action should not be prematurely terminated.

The court's decision

14 The defendant's application is made on the basis that the Statement of Claim (Amendment No. 1):

(a) discloses no reasonable cause of action;

(b) is frivolous or vexatious; and/or

(c) is otherwise an abuse of the process of the court.

15 The law regarding striking out of pleadings is not disputed. I need only be brief. The standard which must be satisfied before pleadings can be struck out was set out in the Court of Appeal case of *Gabriel Peter & Partners (suing as a firm) v Wee Chong Jin and oths*, [1997] SLR(R) 649, which reads, *inter alia*:

> 18 In general, it is only in plain and obvious cases that the power of striking out should be invoked. This was the view taken by Lindley MR in *Hubbuck & Sons v Wilkinson, Heywood and Clark* [1899] 1 QB 86 at p 91. It should not be exercised by a minute and protracted examination of the documents and facts of the case in order to see if the plaintiff really has a case of action. The practice of the courts has been that, where an application for striking out involves a lengthy and serious argument, the court should decline to proceed with the argument unless, not only does it have doubts as to the soundness of the pleading, but in addition, it is satisfied that striking out will obviate the necessity for a trial or reduce the burden of preparing for a trial.

In *Tan Eng Khiam v Ultra Realty Pte Ltd* [1991] 1 SLR(R) 844, G P Selvam JC explained the court's reluctance to summarily strike out a claim (at [31]) as follows:

> …This is anchored on the judicial policy to afford a litigant the right to institute a bona fide claim before the courts and to prosecute it in the usual way. *Whenever possible the courts will let the plaintiff proceed with the action unless his case is wholly and clearly unarguable…* [Emphasis added.]

16 In order to determine if the plaintiff's action discloses no reasonable cause of action, it is necessary to consider the following two issues:

(a) Whether section 12A of the Medicines Act contemplates a cause of action separate and independent from a patent infringement action under the Patents Act.

(b) If the first issue is answered in the affirmative, whether the cause of action contemplated in section 12A of the Medicines allows for a patentee to maintain an action solely on the basis that it does not believe the reason for non-infringement proffered by the defendant.

I will deal with those issues first before turning to the question of whether the plaintiff's action is frivolous, vexatious or an abuse of the process of the court.

Whether section 12A of the Medicines Act contemplates a cause of action separate and independent from a patent infringement action under the Patents Act

17 This is a critical issue as the defendant's submissions revolved around the premise that section 12A of the Medicines Act is merely didactic in nature and does not provide for an independent cause of action. To the defendant, the section 12A of the Medicine Act merely allows for a patentee to be notified when an application for a product licence is filed, the subject matter of which is "in respect of" his patent: see sub-sections 12A(2) and (3) of the Medicines Act. Should a patentee wish, thereafter, to commence an action for patent infringement, he must do so, so the defendant submitted, pursuant to the Patents Act. As a result, it is necessary for the plaintiff to plead at least

one instance of past infringement in order for his statement of claim to disclose a reasonable cause of action. The plaintiff, as stated earlier, takes the view that the section 12A of the Medicines Act contemplates a cause of action separate and independent from a patent infringement action under the Patents Act.

18 To discern whose view is correct, it is necessary to appreciate the nature of the relevant provisions.

A patent infringement action under the Patents Act

19 In order for a patentee to succeed in a patent infringement action pursuant to the Patents Act, two essential features must be made out. One of these would be the fact that the alleged infringing product falls squarely within the claim of the patent. To ascertain if this feature has been made out, a two-step process is involved. As Lord Upjohn explained in *Rodi & Wienenberger AG v Henry Showell Ltd* [1969] RPC 367 ("*Rodi*") (at p. 391):

> …the court must ascertain what the essential integers of the claim, this remains a question of construction and no general principles can be laid down…Secondly, the essential integers having being ascertained, the infringing article must be considered. To constitute infringement the article must take each and every one of the essential integers of the claim. Non-essential integers may be omitted or replaced by mechanical equivalent; there will still be infringement. I believe this states the whole substance of the 'pith and marrow' theory of infringement.

In short, the alleged infringing product must contain the pith and marrow of the claim of the patent.

20 Further, and equally importantly, the patentee must also prove that the infringer has committed – and not merely will commit – an act of infringement as defined in section 66 of the Patents Act. Where the invention is a product (as it is in the present case), section 66 sets out as follows:

> **66.**-(1) Subject to the provisions of this Act, a person infringes a patent for an invention if, but only if, while the patent is in force, he does any of the following things in Singapore in relation to the invention without the consent of the proprietor of the patent:
>
> (a) where the invention is a product, he makes, disposes of, offers to dispose of, uses or imports the product or keeps it whether for disposal or otherwise;
>
> …

There appears to be no provision of an action for *prospective* infringement – notably the word "infringes", not the phrase "will infringe", is used.

21 The fact that the there must have been a past act of infringement before a relief for patent infringement will be granted may also be discerned from section 67 of the Patents Act which provides for the available reliefs:

> **67.**-(1) Subject to this Part, civil proceedings may be brought in the court by the proprietor of a patent in respect of any act alleged to infringe the patent and (without prejudice to any other jurisdiction of the court) in those proceedings a claim may be made –
>
> (a) for an injunction restraining the defendant from any *apprehended* act of infringement;
>
> (b) for an order for him to deliver up or destroy any patented product in relation to which the

patent *is infringed* or any article in which that product is inextricably comprised or any material and implement the predominant use of which has been in the creation of the infringing product;

(c) *for damages in respect of the infringement*;

(d) *for an account of the profits derived by him from the infringement*; and

(e) for a declaration that the patent is valid and *has been infringed* by him.

[Emphasis added.]

To my mind, the words in italics suggest that all of the reliefs that avails a patentee for a patent infringement are only available when there has been a past instance of infringement.

22 This understanding of a patent infringement action under the Patents Act is further fortified by O. 87A, r. 2(2) of the Rules. That provision mandates that:

[t]he plaintiff in such [a patent infringement] action 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**. [Emphasis added.]

23 In light of the above, it cannot be gainsaid that a patent infringement action brought pursuant to section 67 of the Patents Act requires the satisfaction of two equally fundamental requirements:

(a) the alleged infringing product must fall squarely within the claim of the patent; and

(b) there must have been a past act of infringement as defined in section 66 of the Patents Act.

For ease for future reference, I shall refer to the former as the "theoretical infringement" requirement and the latter as the "practical infringement" requirement.

Section 12A of the Medicines Act

24 In my view, section 12A of the Medicines Act contains at least three key features.

25 First of all, a declaratory regime is established. By section 12A(2) of the Medicines Act, an applicant for a product licence must declare whether "a patent under the Patents Act is in force in respect of any medicinal product to which the application relates". If the applicant so declares that there exists such a patent, he must also declare whether he is the proprietor of the patent and, if not, who the proprietor is. Significantly, if the applicant is not the proprietor, the applicant must go on to make either one of two possible declarations:

(a) the proprietor has consented to or has acquiesced in the grant of the licence to the applicant; or

(b) in the applicant's opinion and to the best of his belief, the patent is invalid or will not be infringed by the doing of the act for which the licence is sought.

26 The making of the declaration is a serious matter. This is underscored by the fact that a false declaration is a criminal offence pursuant to section 20 of the Medicines Act and any person guilty of

making a false declaration is liable, upon conviction, to a fine not exceeding $5000 or to imprisonment for a term not exceeding 2 years or to both.

27 In addition to a declaratory regime, section 12A(3) of the Medicines Act also sets out a notification procedure. If the HSA deems it appropriate, the HSA may require the applicant, as it did in the defendant's case, to serve a notice on the proprietor of the patent in a prescribed form and furnish evidence of the service to the HSA. The prescribed form is one found in the Sixth Schedule to the Regulations and states, *inter alia*, that:

> Unless an application is made, within 45 days from the date of this Notice is served on you, 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 –
>
> (a) the patent is valid; or
>
> (b) the patent will be infringed by the doing of [the act for which the licence is sought],
>
> the HSA may proceed to grant the licence.

By way of the declaratory and notification regimes, the registered patents are "linked" to relevant products for which applications for product licences have been sought.

28 It is notable that the notification regime hints at a legal action – it refers to "an application for a court order... that the patent is valid or the patent will be infringed by the doing of [the act for which the licence is sought]". This is the action that the plaintiff seeks to take out. The question to answer is whether the legislative regime refers to an existing cause of action or sets out a new, independent cause of action.

29 Finally, section 12A of the Medicines Act delineates two circumstances, amongst others stated in the Medicines Act, under which the HSA may grant a product licence: see subsections 12A(5) and (6) of the Medicines Act. These are as follows:

> (a) The proprietor of the patent has not, within 45 days from the date of the notice served on him by the applicant, instituted an application for a restraining order or a declaration as stated in the notice *and* informed the HSA, by way of written notice, that such an application has been made.
>
> (b) The proprietor of the patent has made the application referred to in the notice but no such order or declaration has been obtained within 30 months of the making of the application.

Thus, the outcome of the legal action contemplated in section 12A(3) of the Medicines Act, read with section 5B and the Sixth Schedule of the Regulations, materially affects the ability of the applicant to obtain a product licence after the 30-month moratorium.

Compatibility of section 12A of the Medicines Act and a patent infringement action under the Patents Act

30 From the foregoing analysis of the relevant provisions in the Patents Medicines Acts, it is my view that section 12A of the Medicines Act does not envisage the taking out of a patent infringement action under the Patents Act. The incompatibility of the two is clear. Section 12A of the Medicines Act, read with section 5B and the Sixth Schedule of the Regulations, contemplates the taking out of

an action for *prospective* infringement - "the patent will be infringed". However, a patent infringement action under the Patents Act is the converse. As explained earlier, it is a fundamental feature of a patent infringement action under the Patents Act that there be a *past* act of infringement. A future possibility of practical infringement alone is insufficient to sustain a patent infringement action. Without the satisfaction of the *practical* infringement requirement of a patent infringement action, not only is any relief unavailable, the entire action is wholly unsustainable under section 67 of the Patents Act.

31 What the two actions do have in common is the fact that both appear to require the satisfaction of the *theoretical* infringement requirement. In other words, both require the determination of whether the relevant product (the alleged infringing product in the case of a patent infringement action under the Patents Act and the product for which the product licence is sought in the case of section 12A of the Medicines Act) falls squarely within the claim of the patent. In a patent infringement action, this is well-established: see for instance *First Currency Choice Pte Ltd v Main-Line Corporate Holdings Ltd and another appeal* [2008] 1 SLR(R) 335 and *Contour Optik Inc v Pearl's Optical Co Pte Ltd* [2002] SGHC 238. Where section 12A of the Medicines Act is concerned, this may be inferred. The provision operates on the assumption that the practical infringing act will be committed. Thus, in order to determine whether "the patent will be infringed", all that is left to do is to assess the theoretical aspect of the infringement. In fact, from my reading of section 12A of the Medicines Act, this appears to be the whole substance of an action under that provision.

32 The defendant suggested that there is no direct reference to the creation of an independent cause of action of action in section 12A of the Medicines Act. This is unlike the Patents Act where section 67 clearly reads that "...civil proceedings may be brought in court by the proprietor of a patent in respect of any act alleged to infringe the patent..." I believe this sentiment to be overstated. In the first place, section 12A of the Medicines Act does not, by any stretch of the imagination, refer to a patent infringement action under the Patents Act either. Hence, the defendant's main argument that the plaintiff should take out a patent infringement action is equally untenable on this count. More importantly, I take the view that the relevant legislative provisions (section 12A of the Medicines Act, section 5B of the Regulations and the Sixth Schedule of the Regulations) reflect Parliament's intention to allow a patentee to take out an action pursuant to those provisions fairly clearly. Section 12A(3) of the Medicines Act allows the HSA to require an applicant for a product licence to serve a notice in a prescribed form to the patentee. The form is set out in the Sixth Schedule of the Regulations and 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 those provisions.

33 Another way to arrive at the same conclusion is by considering the alternative. If section 12A of the Medicines Act does, in spite of the lack of any wording to that effect, refer a patentee to take out a patent infringement action under the Patents Act, it would be almost impossible for a patentee to obtain a "declaration...that the Patent will be infringed" as contemplated by the provision. This is because it would be almost impossible for a patentee to satisfy the practical requirement of a past infringing act demanded by a patent infringement action in a situation where all the applicant for a produce licence has done is to apply for a product licence. As pointed out by the defendant himself, the case of *Upjohn v Kerfoot* is authority for the proposition that the act of applying for a product licence is not in itself an infringing act. Further, section 66(2)(h) of the Patents Act provides a blanket defence for any preparatory act performed to support that application. The only way, in such a situation, for the patentee to obtain the declaration contemplated by section 12A of the Medicines

Act, read with section 5B and the Sixth Schedule of the Regulations, is if the applicant has committed an infringing act, as defined under section 66 of the Patents Act, which is not protected by any statutory or common law defence. However, if that were the case, there would be no need to sue for a "declaration... that the Patent will be infringed" as provided for in section 12A of the Medicines Act. The patentee may simply take out a patent infringement action under the Patents Act. Since this interpretation of section 12A of the Medicines Act (and its accompanying subsidiary legislation) makes a part of the legislation redundant, it is unlikely that this would have been the interpretation intended by Parliament.

34 To be complete, it appears, in my view, that an action for "a declaration...that...the patent will be infringed" under section 12A of the Medicines Act is incompatible with *any* action provided for in the Patents Act, not just a patent infringement action. For instance, section 78 of the Patents Act provides an avenue for the applicant of a product licence to seek a declaration of non-infringement in respect of future hypothetical events but a patentee does not appear to have the converse right.

35 I therefore agree with counsel for the plaintiff in this respect: section 12A of the Medicines Act, read with its accompanying subsidiary legislation, contemplates a cause of action separate and independent from a patent infringement action under the Patents Act. At the very least, it cannot be said that the plaintiff's case is wholly and clearly unarguable and should be struck out on this point alone.

Inherent jurisdiction

36 In addition, it appears that the plaintiff's Statement of Claim (Amendment No. 1) may be able sustain an action for a declaration of future infringement under the inherent jurisdiction of the court.

37 Generally, it is established law that the High Court has the power to make binding declarations of right whether or not any consequential relief is or could be claimed: see *Tan Ah Thee and another (administrators of the estate of Tan Kiam Poh (alias Tan Gna Chua), deceased) v Lim Soo Foong* [2009] 3 SLR(R) 957 ("*Tan Ah Thee*"). This power is provided for in section 18, read together with the First Schedule, of the Supreme Court of Judicature Act (Cap 322, 2007 Rev Ed), which reads:

> **Powers of the High Court**
>
> **18.**-(1) The High Court shall have such powers as are vested in it by any written law for the time being in force in Singapore.
>
> (2) Without prejudice to the generality of subsection (1), the High Court shall have the powers set out in the First Schedule.
>
> **FIRST SCHEDULE**
>
> **ADDITIONAL POWERS OF THE HIGH COURT**
>
> **Reliefs and remedies**
>
> **14.** Power to grant all reliefs and remedies at law and in equity, including damages in addition to, or in substitution for, an injunction or specific performance.

However, that the court possesses such a power does not mean that it should be exercised in every instance. Rather, the power is to be exercised within the boundaries outlined in *Salijah bte Ab Latef v*

Mohd Irwan bin Abdullah Teo [1995] 3 SLR(R) 233 (at [16]):

> Firstly, the jurisdiction of the court to make a declaration of right is confined to declaring contested legal rights, ***subsisting or future*** , of the parties represented in the litigation. Secondly, the remedy being a discretionary one, it will not be granted to a plaintiff if it would not give him 'relief' in any real sense, *ie* relieve him from any liability of disadvantage or difficulty. Thirdly, the power to make a declaratory judgment is confined to matters which are justiciable in the High Court. Finally, it has been held that there is nothing in O 15 r 16 which enables the court to make a declaration in a matter in which its jurisdiction is excluded by a statute which gives exclusive jurisdiction to another tribunal. [Emphasis added.]

38 To the best of my understanding, this general position of law fairly reflects that of patent law as well. With regard to patent law, it is established that the court has the inherent jurisdiction to grant declarations of infringement or non-infringement that pertains to prospective events. The caveat is that the prospective events cannot be purely hypothetical; instead, there must be a "real commercial interest" in obtaining the declaration: see *Nokia Corp v Interdigital Technology Corp* [2007] FSR 23 ("*Nokia*").

39 There was, in antiquity, some suggestion that it is a requirement before a declaration of right is granted for the defendant to have asserted a claim of right: see *Re Clay, Clay v Booth* [1919] 1 Ch 66 ("*Re Clay*"). However, the law has since moved on and the modern position was eloquently set out by Lord Diplock in *Gouriet v Union of Post Office Workers* [1978] AC 435 (at p. 501):

> The power to grant a declaration is discretionary; it is a useful power and over the course of the last hundred years it has become more and more extensively used—often as an alternative to the procedure by way of certiorari in cases where it is claimed that a decision of an administrative authority which purports to affect rights available to the plaintiff in private law is ultra vires and void. Nothing that I have to say is intended to discourage the exercise of judicial discretion in favour of making declarations of right in cases where the jurisdiction to do so exists. But that there are limits to the jurisdiction is inherent in the nature of the relief: a declaration of rights.
>
> The only kinds of rights with which courts of justice are concerned are legal rights; and a court of civil jurisdiction is concerned with legal rights only when the aid of the court is invoked by one party claiming a right against another party, to protect or enforce the right or to provide a remedy against that other party for infringement of it, or is invoked by either party to settle a dispute between them as to the existence or nature of the right claimed. **So for the court to have jurisdiction to declare any legal right it must be one which is claimed by one of the parties as enforceable against an adverse party to the litigation, either as a subsisting right or as one which may come into existence in the future conditionally on the happening of an event.**
>
> The early controversies as to whether a party applying for declaratory relief must have a subsisting cause of action or a right to some other relief as well can now be forgotten. It is clearly established that he need not. Relief in the form of a declaration of right is generally superfluous to a plaintiff who has a subsisting cause of action. **It 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. But the jurisdiction of the court is not to declare the law generally or to give advisory opinions; it is confined to declaring contested legal rights. subsisting or future, of the parties represented in the litigation before it and not those of anyone else.**

[Emphasis added.]

40 In this regard, mention must be made of *Wyko Group Plc v Cooper Roller Bearings Co Ltd*, [1996] FSR 126 ("*Wyko*"). In *Wyko*, the court adopted three guidelines first laid down by Lord Dunedin in *Russian Commerical and Industrial Bank v British Bank for Foreign Trade*, [1921] 2 AC 438 (at 448) in its determination of whether to grant a declaration of non-liability as follows:

> 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.

The first and third of these guidelines were held not to be satisfied in *Wyko*, a copyright case. In particular, the claim was founded on hypothetical circumstances rather than an existing set of facts. Further, it was held that the defendant had no true interest in opposing the declaration and that he had merely taken part in a theoretical debate (in the inter-solicitor correspondence).

4 1 *Nokia* is an example of a case in which it was found that the plaintiff had a "real commercial reason" for seeking a declaration of non-infringement even though the patentee-defendant did not make a claim against the plaintiff. In that case, the plaintiff, Nokia Corporation, sought declarations that thirty patents owned by the patentee-defendant, Interdigital Techonology Corporation, were not required to comply with the internationally agreed 3G standard for mobile phones. At first instance, the court refused the defendant's application to set aside the proceedings on the ground that the court had no jurisdiction. This decision was upheld on appeal. Jacob L.J. explained (at [19]):

> ... Nokia have a manifest and real commercial interest in a decision of the kind sought. They are "technically infringing" if they are wrong...

42 The case recent of *Nokia Oyj v IPCOm GmbH & Co KG* [2010] EWHC 3249 appeared to have muddied the waters slightly by seemingly suggesting that the court's inherent jurisdiction to grant declarations does not include the power to grant declarations about future events. However, I do not believe that that is a proper understanding of the case. It is paramount that, when distinguishing between a declaration sought under section 71 of the UK Patents Act and one under the court's inherent jurisdiction, Mr Justice Lewison had this to say (at [6]):

> There are at least three features of section 71 which distinguish it from the court's inherent jurisdiction to grant declarations. First, section 71 enables the court to grant declarations about **future hypothetical** events. The ability to make declarations is triggered merely by a proposal to do something. That proposal need not even have got as far as a settled intention. [Emphasis added.]

That the court will not grant declarations pertaining to events that are both future *and hypothetical* is consistent with the law as set out by an established line of cases, some of which have been cited above. However, the situation is far different if the relevant events are prospective but *real*.

43 In short, the court may have the power to grant the kind of declaration envisaged under section 12A of the Medicines Act, read with section 5B and the Sixth Schedule of the Regulations, pursuant to its inherent jurisdiction. In a case such as the present, there appears to be a real commercial question to be answered. Given that the defendant has gone to the trouble of applying for product licences in respect of the Proposed Products from the HSA, it can hardly be said that the issue between the parties is a purely hypothetical one. Indeed, the defendant has declared to the the HSA that it intends to perform certain acts which, from the plaintiff's perspective, will infringe the

plaintiff's patent. Further, the plaintiff has a real interest to raise the question; if it did not do so, the defendant may have already obtained the product licences from HSA upon application. Further, in order to prevent the defendant from being granted the product licences after the 30-month moratorium, a determination on the dispute must be obtained. For the same reasons, it cannot be gainsaid that the defendant has a true interest to oppose the application sought.

44 Given that the plaintiff did not pursue this avenue, however, I am loath to make any decided finding thereon; nor is it necessary for me to do so given my earlier decision that section 12A of the Medicines Act provides for an independent cause of action. I am hence satisfied to leave this point to be determined on an occasion when the court has the benefit of full arguments.

Whether the cause of action contemplated under section 12A of the Medicines Act allows for a patentee to maintain an action solely on the basis that it does not believe the reason for non-infringement proffered by the defendant

45 Even if section 12A of the Medicines Act does provide for an independent cause of action, it remains to be decided what facts must be pleaded to sustain that action. In the present case, the Statement of Claim filed by the plaintiff is a fairly simple one. The plaintiff simply recounted facts regarding the defendant's application for product licences and alleged that:

> 7. The Plaintiff contends the following acts for which the product licenses referred to in paragraph 4 are sought, namely (a) disposal of the Defendant's Products; (b) offer to dispose of the Defendant's Products; (c) using the Defendant's Products; (d) importing the Defendant's Products; and (e) keeping whether for disposal or otherwise of the Defendant's Products; will infringe claims 1 to 27 of Singapore Patent No. SG8993 if carried out by the Defendant in Singapore.

At this point, the plaintiff, of course, has no actual knowledge of the composition of the Proposed Products. All that it knows of the Proposed Products – they contain Rosuvastatin Calcium and do not utilise "an inorganic salt in which the cation is multivalent" – was learnt through the defendant's self-disclosure. The plaintiff essentially seeks to have the defendant reveal the composition of the Proposed Products in order for the defendant's claim of non-infringement to be tested.

46 As may be expected, the defendant takes objection to this. The defendant suggests that it is generally incumbent upon a plaintiff to prove its case. This should be done by, *inter alia*, pleading relevant facts. In the present case, it is pointed out that the plaintiff did not allege any facts in support of its allegation of potential patent infringement. The plaintiff has also refused to provide particulars on the basis that there are no acts of infringement being alleged. As a result, the writ fails completely. The plaintiff's claim, the defendant contends, has no facts to stand on and is doomed to failure at the outset.

47 In my view, there is a disputed fact – whether the Proposed Products contain "an inorganic salt in which the cation is multivalent". It is of course true that the plaintiff is, currently, unable to plead any fact that would support its allegation that the Proposed Products do contain that essential ingredient. Nevertheless, this state of affairs, I believe, is precisely the scenario that the drafters of section 12A of the Medicines Act had envisioned the provision to apply to. The legislative provisions make this clear. After being served with the notice under section 12A(3) of the Medicines Act, a patentee is given only 45 days to take out the section 12A application. In that space of time, it would be impossible for the patentee to discover the composition of the applicant's products, particularly so when the applicant was not forthcoming. To expect the plaintiff, at the point of filing its pleadings, to be able to plead facts to support its allegation that its patent will be infringed would

be unrealistic and not in conformity with the spirit and intent of the relevant legislative provisions.

48 This position is admittedly pro-patentee for an applicant for a product licence is virtually forced to reveal the composition of its products upon the taking out of an action by the plaintiff. Until that point, no application for striking out of the plaintiff's case is tenable. However, this is not a position which the court has adopted. Rather, this is a position that Parliament has taken through the enactment of the relevant statutory regime. The court is not free to depart from the statutory regime contemplated in the enactment of section 12A of the Medicines Act and its accompanying subsidiary legislation.

49 It is also ventured that this reading of the legislation puts the defendant's products at risk. Should the Proposed Products not contain "an inorganic salt in which the cation is multivalent" as declared by the defendant, the defendant would have revealed its trade secrets, so to speak, to the plaintiff. The plaintiff may then take advantage of this for its own commercial benefit. After all, at this point in time, the Proposed Products are not protected by a patent yet. However, the risk may be mitigated. While it is true that the defendant will have to reveal the composition of its products, there are ways provided by the court's procedures and rules which will allow the defendant to protect itself. For instance, applications may be made for confidential information to be restricted to certain persons or for the plaintiff to be made to undertake not to use the information for purposes outside of the court action. Such applications are not entirely new.

Frivolous, vexatious or otherwise an abuse of process

50 In its application to strike out the plaintiff's Statement of Claim (Amendment No. 1), the defendant also alleges that the action is frivolous, vexatious or otherwise an abuse of process. Before me, this allegation was not pursued with as much force as the allegation that the Statement of Claim (Amendment No. 1) discloses no reasonable cause of action but it must be dealt with in any case. In support of this latest allegation, the defendant argues that:

(a) the original Writ and Statement of Claim was riddled with elementary mistakes such as misstating the name and address of the plaintiff;

(b) there are other patents owned by the plaintiff to which the Proposed Products also relate and for which additional notices were served but the plaintiff has not commenced any action against the defendant in respect of those patents;

(c) the plaintiff could not have known what patents it owned related to the Proposed Products for it did not know of the composition of the Proposed Products;

(d) the plaintiff, following the commencement of this action, sought for discovery of documents that were overly intrusive and onerous;

(e) the plaintiff's associated company has had its statement of claim in a Canadian case struck out for lack of material facts in its pleadings; and

(f) the plaintiff have been found guilty of patent misuse in other jurisdictions.

51 Taken holistically, I am not of the view that these allegations, even if true, necessarily leads to the conclusion the plaintiff is pressing upon the court – that the plaintiff does not sincerely believe that its patent will be infringed and is simply instituting the action to delay the defendant's applications from being approved or to obtain confidential information belonging to the defendant.

While it is true that the plaintiff's associated company has had its statement of claim struck out in *AstraZeneca Canada Inc v Novopharm Limited* 2009 FC 1209, it is not at all clear to me that an action similar to the one contemplated under section 12A of the Medicines Act was taken out. Its probative value is therefore low. Nor I am persuaded that the present action is the latest in the plaintiff's attempts to abuse the patent system. In the result, there is insufficient evidence to prove that the plaintiff's present action is frivolous, vexatious or otherwise an abuse of the court's process.

Conclusion

52 In the circumstances, the application is dismissed. I will hear parties on costs.

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