AstraZeneca AB (SE) *v* Sanofi-Aventis Singapore Pte Ltd
[2013] SGHCR 7

Case Number : Suit No 416 of 2011 (Summons No 471 of 2013)

Decision Date : 15 March 2013

Tribunal/Court : High Court

Coram : Justin Yeo AR

Counsel Name(s) : Mr Alvin Lim and Mr Sandeep Menon (Rodyk & Davidson LLP) for the plaintiff; Mr Jason Chan, Mr Melvin Pang and Ms Anna Toh (Amica Law LLC) for the defendant.

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

Patents and Inventions – Infringement

Civil Procedure – Pleadings – Further & Better Particulars

15 March 2013

Justin Yeo AR:

1 This is an application by Sanofi-Aventis Singapore Pte Ltd ("the Defendant") pursuant to O 18 r 12 and O 87A r 2 of the Rules of Court (Cap 322, R 5, 2006 Rev Ed) ("Rules of Court"), for an order that AstraZeneca AB (SE) ("the Plaintiff") provides further and better particulars of the Plaintiff's Statement of Claim (Amendment No 1) ("the Application").

Background

2 The Plaintiff is the proprietor of Singapore Patent No SG 89993 ("the Plaintiff's Patent"). The title of the invention for which the Plaintiff's Patent was granted is "Pharmaceutical Compositions Comprising a HMG COA Reductase Inhibitor". The "feature of the invention" is specified on page 2 of the Plaintiff's Patent specifications as:

> (1) A pharmaceutical composition comprising the Agent [a pharmaceutical composition defined on page 1 of the Plaintiff's Patent specifications, which may simply be referred to as *rosuvastatin*] 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.

3 It is also stated on the same page that while the pharmaceutical composition can be both in the form of a tablet or powder, "[p]referably the pharmaceutical composition of the invention is a tablet".

4 The Plaintiff's Patent contains a total of 27 claims. It is not necessary, at this point in time, to set out all the claims. It suffices to note that Claim 1 of the Plaintiff's Patent covers a "pharmaceutical composition" used to treat high cholesterol, comprising:

> (a) *rosuvastatin* as the active ingredient; and

(b) an inorganic salt in which the cation is multivalent (but which is neither *hydrotalcite* nor synthetic *hydrotalcite*, and the counter anion to the inorganic salt is not a phosphate) ("the Inorganic Salt").

5 On 1 April 2011, the Defendant submitted applications to the Health Sciences Authority ("HSA") for product licenses in respect of its *Rosucard* Film-coated Tablets in 10mg, 20mg and 40mg dosage forms (collectively referred to as "the Defendant's Products"). On 26 April 2011, the Plaintiff was served with a Notice to Proprietor of Patent pursuant to s 12A(3)(a) of the Medicines Act (Cap 176, 1985 Rev Ed) ("the Medicines Act") by the Defendant, notifying the Plaintiff that the Defendant had submitted the applications to the HSA as mentioned above.

6 On 10 June 2011, the Plaintiff commenced the present action seeking a declaration of infringement that the disposal, offer to dispose, use, import and keeping of the Defendant's Products will infringe all 27 claims of the Plaintiff's Patent if carried out by the Defendant in Singapore. The practical effect of the commencement of the present action was to set in place the 30-month moratorium on the processing of the product licence applications for the Defendant's Products (see s 12A(6) of the Medicines Act read with regulation 5B(4) of the Medicines (Licensing, Standard Provisions and Fees) Regulations (Cap 176, S 74, 2000 Rev Ed)).

7 The Plaintiff subsequently filed an amended Statement of Claim (Amendment No 1) dated 5 July 2011. The Defendant then applied to strike out the action on several grounds, including that the Statement of Claim (Amendment No 1) pleaded no act of infringement by the Defendant, and therefore disclosed no reasonable cause of action under the Patents Act (Cap 221, Rev Ed 2005) ("the Patents Act"). The Plaintiff argued that the present action was based on a separate and independent cause of action created by s 12A of the Medicines Act, which did not require an act of infringement to have been committed.

8 The striking out application was heard in December 2012, and the written decision of *AstraZeneca AB (SE) v Sanofi-Aventis Singapore Pte Ltd* [2012] SGHC 16 ("*AstraZeneca*") was rendered thereafter. In brief, the court held that s 12A of the Medicines Act contemplated a cause of action *independent* from a patent infringement action under the Patents Act, and only required a *prospect of infringement* to be established. The court also found that the Plaintiff's disbelief of the Defendant's opinion (*viz*, that the Defendant's Products did not infringe the Plaintiff's Patent) was sufficient to sustain the action under s 12A of the Medicines Act. Consequently, the action was not struck out.

9 The Plaintiff subsequently took out an application for discovery of the Product Descriptions of the Defendant's Products, arguing that it needed the Product Descriptions to know how the Defendant could be infringing the Plaintiff's Patent. On 24 August 2012, the court allowed the application, and the Defendant has since provided the Plaintiff with discovery of the Product Descriptions of the Defendant's Products. These descriptions disclosed the chemical composition of the Defendant's Products and the amount and weight of the active pharmaceutical ingredients and excipients therein.

10 On 14 December 2012, the Defendant's solicitors requested for further and better particulars from the Plaintiff by way of a letter of request. The Plaintiff's solicitors responded that the Defendant was not entitled to the particulars sought, as they were of the view that the requests related to issues of construction of the Plaintiff's Patent. The Defendant thereafter brought the Application, seeking the further and better particulars stated in their letter of request.

Legal principles regarding particulars in patent infringement claims

11 At the hearing of the Application, both parties seemed content to proceed on the basis that the Rules of Court related to pleadings (and the particularity thereof) applying to actions under the Patents Act apply likewise to actions under the Medicines Act. I saw no reason to disagree with this view, and therefore proceeded on this basis.

Particulars of pleadings under the Rules of Court

12 It is trite that particulars of pleadings serve, *inter alia*, to inform the other side of the nature of the case that has to be met, so as to prevent the other side from being taken by surprise at trial, and also to enable the other side to know what evidence it oughts to prepare for trial (see *Singapore Civil Procedure 2013* vol 1 (G P Selvam gen ed) (Sweet & Maxwell Asia, 2013) at para 18/12/2). These particulars also serve to ensure clarity and precision of the issues and to avoid the expense of subsequent measures to remedy insufficiently particularised pleadings (*Singapore Court Practice 2009* (Jeffrey Pinsler SC gen ed) (LexisNexis, 2009) ("*Singapore Court Practice*") at para 18/12/1).

13 As such, where pleadings are inadequate, O 18 r 12(3) provides that:

> The Court may order a party to serve on any other party particulars of any claim, defence or other matter stated in his pleading, or in any affidavit of his ordered to stand as a pleading, or a statement of the nature of the case on which he relies, and the order may be made on such terms as the Court thinks just.

14 Patent actions, like any other action, have to contain pleadings which are properly particularised (*Singapore Court Practice* at para 87A/2/2). O 18 r 12 applies just as much to a patent action as to any other action, and therefore, the court has power to order parties to give particulars of their pleadings upon such terms as the court thinks just (*ibid*).

15 However, in addition to the usual particulars given under O 18 r 12, for patent infringement claims, O 87A r 2(2) requires that a specific type of particulars must be given. O 87A r 2(2) provides:

> The plaintiff in such an 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]

16 O 87A r 2(2) does not define the extent of "particulars of the infringement" that must be given. In this regard, it is necessary to turn to the principles enunciated in case law regarding the "office" of particulars of infringement (a term borrowed from *Wenham Co Ltd v Champion Gas Lamp Co Ltd and Todlenhaupt and Co* [1891] 8 RPC 22 ("*Wenham*") at 24 *per* Chitty J) in patent infringement claims.

The office of particulars of infringement in patent infringement claims

17 The determination of whether the particulars given by a patentee in a patent infringement claim sufficiently perform the office required of particulars of infringement involves, as will shortly be evident, questions of fact that turn on the unique circumstances of each case. However, the legal principles governing the office of particulars of infringement, as set out in (especially English) case law, have changed over the years. The following sections attempt to examine in some detail the changes and developments in the office of particulars of infringement in patent infringement claims. As the application of the legal principles to the facts is crucial for context and also for tracing developments in this particular area of law, the facts of the cases and the judicial analyses of the same will be set out at some length.

The traditional position in English law

18 Traditionally, a patentee is not ordered to give particulars of the construction which the patentee proposes to put on the patent claims (*Singapore Court Practice* at para 87A/2/2 and *The White Book Service 2013: Civil Procedure* (Rupert Jackson LJ gen ed) (Sweet & Maxwell, 2013) ("*UK White Book 2013*") at para 18.1.5).

1 9 *Wenham* is the *locus classicus* of the position just mentioned. In *Wenham*, the plaintiff had a patent specification consisting of four claims. By their particulars of breaches, the plaintiff alleged that the defendants had infringed the patent by using or applying for their own profit in or to gas lamps or lanterns certain mechanism or arrangements being the same or substantially the same as the mechanism described in the specifications, and claimed in the four claims (*Wenham* at 23, lines 16-20). The High Court found that the particulars thus framed sufficiently performed the office required of particulars of breaches, the object being to tell the defendants what the plaintiff says he has done in infringement of the patent (*Wenham* at 24, lines 28-31). The court noted the defendant's "plausible argument" that getting more particulars will enable the defendants to limit the nature of the evidence raised as well as to limit the nature of the objections to the validity of the patent, but held that the defendants had no right to ask the plaintiff to put a definite construction upon the specification at that point in time (*Wenham* at 24, lines 33-38). As such, the court found that the particulars were sufficient, and dismissed the application for further particulars.

20 Applying the same principles, a different result was reached on the facts of *Marsden v Albrecht and Albrecht* (1910) 27 RPC 785 ("*Marsden*"). In *Marsden*, the Court of Appeal was faced with a situation in which the plaintiff, by his original particulars, in substance said "You have infringed all the four Claims of this Patent" (*Marsden* at 788, lines 4-5). In particular, it was alleged that the defendant had infringed Claim 1 of the patent ("a claim for a process which consists in taking a particular article, namely a certain perforated templet, which is described, and doing a certain act, namely, rubbing through the perforations of a material, and the characteristics of that material are mentioned; it must be one capable of strongly adhering to the cloth, when treated in a given manner") (*Marsden* at 788, lines 25-30). The plaintiff had given further particulars by stating "Over the lays thus perforated colouring or marking materials, capable of adhering to the cloth, were spread so as to transfer the patterns marked on the lays to the cloth beneath"; the words "capable of adhering to the cloth" were further added to the particulars on the direction of the first instance Judge (*Marsden* at 788, lines 35-39).

21 The Court of Appeal noted that the issue was whether the plaintiff had sufficiently identified the acts done by the defendants which the plaintiff says constitute an infringement of the plaintiff's patented process. The particulars sought by the defendants were, in effect, for the plaintiff to answer the question "What acts do you say that I did which constitute an infringement of the process described in your first Claim?" (or "What acts, do you say, we have done, which you are coming into Court to prove, and which you will then say are an infringement of your Claim?") (*Marsden* at 788, lines 45-51). The Court of Appeal went on to note that although the plaintiff did not have to construe his patent, he was bound to inform the defendants of sufficient particulars such that the defendants would know the case that he was going to make (*Marsden* at 788, lines 52-54). In this regard, it was "not enough" for the plaintiff to state simply "you have infringed the process described in my first Claim"; instead, the plaintiff "ought to condescend to describe the manner in which the acts which he alleges to be infringement were carried out" (*Marsden* at 789, lines 1-3).

22 In *Aktiengesellschaft Für Autogene Aluminium Schweissung v London Aluminium Company, Limited* [1919] 2 Ch 67 ("*Aktiengesellschaft*"), Paragraph 1 of the plaintiffs' particulars of breaches read, in part, "the defendants have infringed each of the letters patent referred to in the statement

of claim by the use in this country for welding objects made of aluminium of fluxes made in accordance with the descriptions in the complete specifications of each of the said letters patent and as claimed in all the claiming clauses thereof". Swinfen Eady MR noted (at 74), after reading paragraph 1 of the plaintiffs' particulars, that "[t]here are no particulars and no details at all. In my opinion that paragraph does not amount to a particular of any breach whatever." Warrington LJ agreed, stating (at 78):

> Paragraph 1 of the particulars of breaches here is in my opinion no particular at all. It is true that it complies with r. 16 to the extent of stating that the defendants have infringed the claims of both the specifications, there being only one claim in each, but except for that it gives no particulars at all. *It condescends to no date and no place, to nothing except a general allegation in expanded terms that the defendants have infringed the plaintiffs' patents*. Just put oneself in the position of a defendant coming to trial on such an allegation. *He has no information at all, and it would be quite impossible for him to meet and deal with some instance of which the plaintiff might adduce evidence*. He would have *no information which would enable him to prepare his witnesses for meeting any case which the plaintiffs might make*. It seems to me, therefore, that para. 1 of the particulars of breaches is wholly insufficient.
>
> It has been suggested, and it is true, that para. 1 does comply with r. 16 by specifying the claim which is said to be infringed; … [But] [t]he Plaintiff is still under the obligation imposed by r. 13 to *give the defendant such information as will enable him to know the case which is going to be made against him at the trial*.
>
> [emphasis added]

23 It is clear from *Aktiengesellschaft* that the function of particulars of breaches is to point out to the defendant what specific act on his part was complained of so as to prevent surprise at trial. On that basis, the court found that it was insufficient to make a general allegation that the defendants have infringed the patents without condescending to give any detail or any particular of the breach.

24 *Marsden* was applied in the Canadian case of *J K Smit & Sons of Canada Ltd v Fastcut Bits Ltd* [1949] 9 CPR 138 ("*Smit*"). Citing the portions quoted in [21] above, the Ontario Supreme Court held that the particulars furnished by the plaintiff did not meet the requirements set out by *Marsden*. In paragraph 1 of the particulars, the plaintiff had stated that the defendant had followed certain steps in the manufacture of diamond drill bits. The court found this insufficient, and held that the plaintiff "should say how it alleges these steps infringe the claims in the Patent mentioned in… the statement of claim…" (*Smit* at 141).

Developments in English law from the 1930s to the 1950s

25 In 1936, the UK Rules of the Supreme Court were amended in an attempt to make a plaintiff define the ambit of his claims at an early stage (see the unreported decision of *Mars Incorporated v Azkoyen SA and Others* (27 February 1991) ("*Mars*"), which details such a development). The amended O 53a r 21A(2) required the parties to deliver:

> … statements signed by counsel setting out all the contentions whether of fact or law (including contentions as to the *construction of the specification* or other documents) upon which the parties respectively intend to rely. [emphasis added]

26 As such, in cases such as *Fraser v Simpsons (Piccadilly) Ltd and Platinum Products Ltd* 54 RPC 199, the court ordered the patentee to deliver a statement referring to every claim alleged to be

infringed of the patent, *inter alia* specifying the integers alleged to be comprised in each claim and identifying parts of the products with the corresponding integers specified in the claim.

Developments in English law from the 1950s onward

27 There was some discontent with the rule requiring parties to construct their claims. In *Unifloc Reagents Ltd v Newstead Colliery Ltd* (1943) 60 RPC 165 ("*Unifloc Reagents*") at 191, Bennett J noted that while it was initially thought that an exchange of statements at an early stage of a patent action would enable the real issues to be discovered thus shortening the trial, the said statements often added to the length of the trial and the expense of patent litigation. Similarly, in *Terrell and Shelley on the Law of Patents* (Sweet & Maxwell, 9th ed, 1951) at p 355 (as cited in *Mars*), it was stated that:

> The rule as originally drafted contemplated the exchange of 'statements' setting out the substantial issues between the parties, which statements, it was hoped, would result in a saving of expense at the trial. In several cases elaborate orders for this purpose were made and it has been discussed whether the statements should necessarily be reciprocal. *But experience has shown that the effect of these statements is merely to increase the length of the trial and it is unlikely they will be ordered in future*. [emphasis added]

28 In recognition of the difficulties caused by the rule, the UK Rules of the Supreme Court were subsequently amended in 1954 to delete the provision for the exchange of statements (see *Mars*).

29 In *Lux Traffic Controls Limited v The Staffordshire Public Works Company Limited* [1991] 4 RPC 73 ("*Lux*"), the Patents Court had occasion to consider the issue relating to further and better particulars of patent infringement. Aldous J emphasised that it was "well settled that particulars will not be ordered of construction of a patent claim", citing *inter alia* the cases of *Wenham* and *Marsden* (*Lux* at 75, lines 34-40). The court also helpfully explained the rationale for the return to the traditional position, and reiterated that *Wenham* should apply (*Lux* at 75, lines 43-48):

> About forty years ago orders were made that parties should serve details of the construction of the claims that they were going to rely on. *The experience of the court was that this led to considerable expense, time and energy being wasted*. The learned pleaders took *considerable time* and with their *considerable skill pleaded the construction of the claims in alternative forms*. It turned out that the *interests of justice were not advanced* by such orders and they were discontinued.
>
> The practice of this court has recently changed, in that there is exchange of statements of expert witnesses a number of weeks before trial; this ensures that the parties are not taken by surprise. Also in most cases there is exchange of all witness statements. In the present case the defendant submits that the particulars requested should be given now so that its witnesses can turn their minds to the particular points in issue.
>
> I have come to the conclusion that *the statements made by Chitty J. are just applicable today as they were when they were made* and it would be quite wrong to order any particulars of construction of the claim.
>
> [emphasis added]

30 Indeed, on a close reading of *Lux*, Aldous J appeared to take a position that was possibly even more restrictive than the traditional position; he opined, albeit *obiter*, that it was "doubtful" that

particulars would be ordered *even if* the request was "drafted in a way that would avoid the plaintiff having to construe [the claim]", adding that (*Lux* at 76-77):

> One of the advantages of the system of exchanging all witness statements is that the parties are not taken by surprise and there is plenty of time to analyse the other party's case. Thus it is important that the pleadings should raise and limit the issues between the parties, but their cost of production should not escalate. *Increase in costs at the pleading stage places an unnecessary burden upon litigants who in many cases settle the dispute before trial*. Thus the present system is designed to ensure that the pleadings define and limit the issues so that the parties can prepare their cases for trial. This is aided by exchange of witness statements. Thus nobody is taken by surprise on the day of the trial. [emphasis added]

31 About a month later, Aldous J rendered the unreported decision of *Mars*. In *Mars*, the defendant had sought further particulars based on reference to words of the patent claims, seeking that the plaintiffs should identify either parts or values which are said to be embodied in defendant's allegedly infringing apparatus. Aldous J reiterated his view that the position taken in *Wenham* (*viz* that claim construction would not be ordered at the stage of particulars of pleadings) was the "correct practice", and emphasised three reasons for such a view:

> First, it is *not easy for a plaintiff to put a precise construction upon his claims until all the facts are before the court*. Under the present practice, witness statements are exchanged, and therefore it is normally possible for a plaintiff to construe his claims during the opening of the action.
>
> Secondly, orders making a plaintiff define the ambit of the claims by serving a statement to that effect have proved to be disastrous. *They lead to the drafting of long and complicated documents*, and discussions as to the meaning of those documents, thereby *increasing the cost of patent actions*.
>
> Thirdly, if the true construction finally relied on was not pleaded in such statements, then applications to amend were made which, subject to costs, were normally allowed. Thus little, if anything, was gained.

32 Aldous J also cited the decision in *Unifloc Reagents* (see [27] above) and went on to emphasise that:

> Ever since 1954 the practice has been that *no particulars will be ordered which will require the plaintiff to set out his construction of the claims of his patent*. That practice is, I believe, properly founded, and it would be wrong to go back to the procedure which existed between 1936 and 1954 which had to be abandoned. [emphasis added]

33 On the facts of *Mars*, Aldous J found that the defendants were seeking particulars which required the plaintiffs to set out their construction of their claims, and therefore made no order on the application.

34 The cases cited thus far illustrate that, traditionally (and with the exception of the intervening period of 1936 to 1954), the standard practice in patent infringement cases was that patentees were not generally ordered to give particulars requiring them to construe their patent claims. Even where particulars were ordered, such as in *Marsden* and *Smit*, the courts were keen to reiterate that the patentees did not have to construe their respective patents. This has led some commentators to opine that it is "unusual" for particulars clarifying patent construction to be ordered (see *Blackstone's*

Civil Practice 2013 (Stuart Sime & Derek French *gen ed*) (Oxford University Press, 2012) ("*Blackstone's Civil Practice 2013*") at para 30.2). Indeed, as alluded to above (at [30]), the court in *Lux* may have gone even further than the traditional position, opining that particulars may not be ordered *even if* the request was drafted in a way to avoid any form of claim construction.

Recent trends towards provision of information at an early stage

35 More recently, however, there has been evidence of a trend towards the provision of information at an early stage (see Brian Cordery *et al*, *Review of Patent Cases in the English Courts in 2008* at 16), and that the position stated in *Lux* is no longer an "invariable rule" (see *Blackstone's Civil Practice 2013* at para 30.2).

36 The case of *Novartis AG, Ciba Vision AB v Johnson & Johnson Medical Limited* [2008] EWHC 293 (Pat) ("*Novartis*") is especially instructive in this regard, and will be analysed at some length.

37 In *Novartis*, the Patents Court ordered the provision of particulars in response to the defendant's request for information concerning the construction of the patent in the suit. Floyd J recognised the traditional position (citing *Lux*) that patentees would not be ordered to give particulars of the construction which they propose to put on the claims, but went on to note that *Lux* was decided prior to the introduction of the UK Civil Procedure Rules ("CPR"), and relied upon very old authorities such as *Wenham*. In this regard, it should be noted that Rule 63.6 of the CPR, read with para 4.1 of the UK Practice Direction 63, is very similar to O 87A r 2(2) of the Rules of Court.

38 On the facts of *Novartis*, the defendants sought particulars of the construction of the plaintiffs' claims *inter alia* because the defendants intended to carry out experiments to demonstrate that the plaintiff's patent did not deliver what it claimed (*ie* that the patent claims were insufficient), and that there was obviousness based on examples in the prior art (*Novartis* at [8]). The defendants argued that until they knew about how the patent claims were constructed, they would not know how to design their experiments, and that this would lead to wasted costs if it transpired – at the exchange of expert reports – that there were additional characteristics of the material to be tested (*Novartis* at [12]). The plaintiffs contended that it would not be right at a relatively early stage of the proceedings to require them to commit to what characteristics must be tested, that the necessary detail will emerge in expert reports, and that it is not for the plaintiffs to tell the defendants how to design their experiments (*Novartis* at [13]).

39 Floyd J opined that "[e]xperiments raise different questions", and noted that the cost of experiments, as well as the failure of experiments to illuminate the precise issue in dispute, were common criticisms made of patent litigation in the UK (*Novartis* at [14]). He accordingly made an order for the plaintiffs to state whether they will contend at trial that the skilled addressee would understand a certain term of art ("ophthalmically compatible") to have a particular specified meaning (*Novartis* at [15]). He also ordered the plaintiffs to define what was meant by "prescribed period of wear", so that the defendants would be aware of the period for which the experiments had to be conducted (*Novartis* at [16]). He noted that it would not be satisfactory for the defendants to have to repeat experiments for a longer period depending on what the plaintiffs contended at trial, and that it was not burdensome for the plaintiffs – being proprietors of the patent – to state what they will contend is meant by "prescribed period of wear" (*Novartis* at [16]). Adopting a similar approach with similar reasons, Floyd J also ordered the plaintiffs to provide particulars on several other claims, so as to clarify what was meant by *inter alia* "extended periods of wear", "oxygen permeation in an amount sufficient to maintain corneal health", "ion and water permeation", *etc* (*Novartis* at [17]-[22]). Floyd J also ordered the plaintiffs to provide particulars on "whether at trial the claimants will contend that in order to determine whether an ophthalmic lens falls within the claims of the Patent it is necessary

to carry out a clinical assessment of the behaviour of the lens in the eye", finding that despite the fact that the answer may not be a straight "yes" or "no", it would nonetheless be a useful request to have answered at this stage (*Novartis* at [23]).

40 Regarding the requests on (a) whether the respective clinical assessments included measurement of a specific parameter; and (b) identification of the criteria to be applied to distinguish a positive value of that parameter from a null or negative one, Floyd J found that it was appropriate to order the plaintiffs to answer the former (regarding what measurements have to be made), but not the latter (*Novartis* at [26]). In Floyd J's view, the latter request is to be debated by experts in due course, rather than at the stage of pleadings (*Novartis* at [26]).

41 With regard to requests on whether the examples stated in the patent were alleged to fall within the patent claims, Floyd J ordered the plaintiffs to identify the examples which were outside the patent claim (*Novartis* at [29]-[32]). However, Floyd J did not allow the request for the plaintiffs to state "which of the lenses have been assessed clinically in humans and over what period of wear", as he was of the view that this would be a "very substantial" exercise that was inappropriate at the pleading stage (*Novartis* at [33]-[34]).

42 With regard to requests on the commercial success of the plaintiffs' products, Floyd J ordered the plaintiffs to state which claims in the patent were contended to cover each brand of commercial lenses; however, he made no order for the plaintiffs to state which of their commercial lenses were made in accordance with the examples in the patent as this request went too far and was of dubious value (*Novartis* at [35]-[37]).

Summary

43 It appears, therefore, that the English developments in this particular area of the law may be summarised as a series of movements, beginning from the *traditional position* (where the office of the particulars of infringement clearly did *not* permit any form of claim construction), to the position where particulars of infringement, including those that involve claim construction, were mandated by subsidiary legislation, back to the traditional position (and, indeed, a position possibly more restrictive than the traditional position, as envisaged in *Lux* albeit *in obiter*), and finally to the *modern position* (where, in exceptional cases, the office of the particulars of infringement may extend to claim construction depending on the facts of the case).

The legal position in Singapore

44 In view of the paucity of case law in Singapore setting out the role of the office of particulars in patent infringement claims, English case law would be persuasive given the similarity of the regimes. However, even then, there does not appear to be any firm authority in the UK regarding how the traditional and modern positions interplay.

45 There are competing considerations which underlie the tension between the two positions. On one hand, underlying the approach in *Novartis* is the clear desire to narrow issues and save litigation costs, particularly – on the facts of *Novartis* at least – with regard to *expensive biomedical experiments*. In *Novartis*, the court found it necessary that the plaintiffs to order answers to certain requests for particulars in order to ensure that the defendant's clinical trials were conducted on the correct basis. It was unsatisfactory to allow the plaintiffs to identify the characteristics for testing only at the stage of experts reports, as such an approach may require the defendants to perform experiments again at that stage, and may also have led to the defendants investing significant resources into performing immaterial experiments.

46 On the other hand, there are difficulties with adopting the *Novartis* approach as a general approach to *all* patent infringement claims (see *Lux* and [29] above). While there may be benefit in ordering early construction of what a claim means, the experience of the English courts from 1937 to 1954 was that parties would attempt to put forward a plethora of alternative claim constructions, eventually resulting in immense wastage of time and energy of all involved.

47 In my view, the approach propounded in *Novartis* should be applied only in certain exceptional circumstances. Indeed, Floyd J was careful to emphasise that the *Novartis* decision was based on the unique facts of the case; the spectre of the immense costs of misdirected and inadequate experiments, coupled with the fact that it would not be burdensome for the plaintiffs to answer some of the requests, undoubtedly motivated Floyd J's departure from the traditional approach which had held sway in English law for (at least) a century.

48 I am of the view that the considerations in *Novartis* are equally pertinent to the present case, and that the *Novartis* decision would therefore be highly persuasive. First, like in *Novartis*, the present case involves a pharmaceutical patent, and – as is often the case in claims involving such patents – the precise patent infringement(s) may not be easily observable without the conduct of experiments. Second, the experiments just alluded to are often very costly, and an absence of particularisation at an early stage may result in the wasted costs of misdirected and inadequate experiments. Third, it should be noted that the present case involves a patent infringement claim under the Medicines Act. All that is required to trigger the 30-month moratorium is an action for *prospective* infringement (*contra* a *past* act of infringement, as is required for claims under the Patents Act) (see *AstraZeneca* at [30]; and see [6] above and [71] below). For all the reasons stated in this paragraph, in my view, the provision of more particulars at an earlier stage of the proceedings may be necessary in cases such as the present.

49 I turn now to consider the Defendant's requests for further and particulars of the Plaintiff's patent infringement claim.

Application to the facts

50 There are three points to note, at the outset, before considering the individual requests made in the Application.

51 First, in the present case, paragraph 7 of the Statement of Claim (Amendment No 1) simply repeats all the acts of infringement found in the Patents Act. Paragraph 7 of the Statement of Claim (Amendment No 1) reads:

> 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. SG 89993* if carried out by the Defendant in Singapore. [emphasis added]

52 It is evident that the said paragraph does not provide any detail to aid the Defendant in identifying how the Defendant's Products are alleged to infringe the claims of the Plaintiff's Patent.

53 Second, and as mentioned above, the Defendant has already provided the Plaintiff with discovery of the Product Descriptions of the Defendant's Products (see [9] above). As such, the Plaintiff is in a position to analyse the chemical composition of the Defendant's product in order to

decide how it would be proceeding with the present patent infringement claim. Indeed, I note that in the written submissions filed for the relevant discovery application, counsel for the Plaintiff had represented that the Defendant's product and process descriptions for the Defendant's Products were:

> … clearly relevant to ascertain whether the Defendant's [Products] falls within the claims 1 and 24 of the Plaintiff's [Patent]. The product description will ascertain whether the Defendant's [Products] (which undeniably contains Rosuvastatin) covers the pharmaceutical composition comprising the active ingredient and an inorganic salt in which the cation is multivalent as per claim 1 of the Plaintiff's patent. The process description will similarly ascertain whether the Rosucard product was made from the method claimed in claim 24 of the Plaintiff's [Patent]. …

54 Therefore, insofar as some of the particulars sought by the Defendant concern whether the Defendant's Products had infringed the Plaintiff's Patent in some way, the Plaintiff is not placed in a position where it will be impossible to provide those particulars. Indeed, it was precisely for the purposes of ascertaining what the Defendant's Products contained in order to mount its case for infringement that the Plaintiff had sought discovery of the Defendant's Products.

55 Third, it should also be noted that at the hearing of the Application, counsel for the Plaintiff lamented that but for the Application, expert reports could have been filed and exchanged by January 2013. According to him, the expert has been on "stand by", but "has not actually done the work". In my view, if the expert has been on stand by and has been ready to provide the necessary input (by January 2013, which was two months prior to the hearing of the Application), this, coupled with the fact that the Plaintiff had successfully obtained discovery of the Defendant's Products (for the specific purpose, I would add, of analysing the same for purposes of infringement), would suggest that the granting of some of the requests would not be overly burdensome for the Plaintiff.

56 Against the backdrop set out above, I summarise the Defendant's seven requests for further particulars as follows:

(a) Request 1 seeks identification and further particulars of how each of the 27 claims will be infringed, and for the Plaintiff "to identify the specific component(s)/characteristic(s) of the Defendant's products that reads on each element of each claim identified";

(b) Request 2 seeks identification and further particulars of the Inorganic Salt and "specifically the definition adopted by the Plaintiff";

(c) Request 3 seeks identification and further particulars of whether the Inorganic Salt is "directed solely to performing a stabilising function";

(d) If Request 3 is in the affirmative, then Request 4 seeks identification and further particulars of the "specific condition(s) against which the [Inorganic Salt] stabilises";

(e) Request 5 seeks identification and further particulars of the "pharmaceutical composition" identified in claims 1, 3 to 19, 24 and 27 of the Plaintiff's Patent, specifically whether the composition "includes a coating thereof";

(f) Request 6 seeks identification and further particulars of the "pharmaceutical tablet" identified in claim 2 of the Plaintiff's Patent, specifically whether the tablet "includes a coating thereof"; and

(g) Request 7 seeks further particulars of the means by which the Inorganic Salt "is incorporated into the compound", and specifically, "whether the method of incorporation is that of admixture".

Request 1

57 Request 1 will be allowed. In my view, it is insufficient for the Plaintiff to simply state that all 27 claims have been infringed. Taking Claim 1 for example, Claim 1 claims at least 6 different elements, *viz* (a) a pharmaceutical product; (b) in the form of a composition; (c) comprising a specific chemical structure, or a pharmaceutically acceptable salt thereof as the active ingredient; and (d) an inorganic salt in which the cation is multivalent, but provided (e) that the inorganic salt is not a hydrotalcite or synthetic hydrotalcite; and (f) the counter anion to the inorganic salt is not a phospate. It was pointed out to me by counsel for the Defendant that Claim 1 was a very *broad* class of claims – it is, in effect, describing a class of salts, with some exclusions, rather than reference to a *specific* salt or material. Yet, the Plaintiff has not informed how Claim 1 is infringed, despite obtaining discovery.

58 I am aware that there is no objection to the patentee stating that he relies on all the claims in his patent (*Haslam & Co v Hall* (1887) 4 RPC 203 at 206, as cited in *Singapore Court Practice* at para 87A/2/2). However, in my view, this should not absolve the Plaintiff from informing the Defendant of the case against him. It would be highly onerous for the Defendant to prepare to meet every possible case against it on each of the 27 claims. This would, it is imagined, involve – amongst other things – painstaking investigation into the prior art relating to each of the 27 claims.

59 Counsel for the Plaintiff forcefully argued that Request 1 essentially requires the Plaintiff to construe its claim. This would not be a knock-down argument, in light of the reasons stated and the position taken in *Novartis*.

60 That said, in my view, even under the traditional position, Request 1 should be allowed. In this regard, it would be recalled that in *Marsden*, the patent at issue covered a series of acts to be done sequentially, as part of which colouring materials of particular characteristics would be spread onto cloth and then passed between rollers heated with gas flames, which served to cause the colouring materials to adhere strongly to the cloth. The plaintiff pleaded that the defendant had done the series of acts, but failed to particularise whether the colouring materials allegedly used by the defendant had the particular characteristics described in the patent, and whether the defendant was alleged to have treated the colouring materials in the manner described in the patent for the purpose of fixing the colouring materials onto the cloth. The court noted that it was insufficient for a plaintiff to set out generally the process allegedly used by the defendant, and simply state that the process infringed the plaintiff's patent, and required the plaintiff to particularise whether it was alleging that the defendant's process used the materials defined in the patent at issue and whether the materials were used in the manner described in the patent at issue. Similarly, in *Smit*, the court held that the defendant had to state *how* it alleged the defendant's manufacturing steps infringe the claims in the plaintiff's patent. Although counsel for the Plaintiff pointed out that the patents in *Marsden* and *Smit* were *process* patents (*contra* some of the claims in the present case, which involved a *product* patent), I do not think that this would be a material distinguishing factor.

Request 2

61 Request 2 will not be allowed. Request 2 requires the Plaintiff to, *inter alia*, define the Inorganic Salt. This appears to me to be the work suited for expert evidence at a later stage of the proceedings, and is not necessary at the stage of pleadings. Ultimately, these will be issues to be defined by experts, and submitted for final determination at trial. I note that *Novartis* may suggest

that a plaintiff can be ordered to define the terms in his patent claims. However, in my view, the definition of the Inorganic Salt in the present case can be distinguished from the definitions of "ophthalmically compatible" and "prescribed period of wear" in *Novartis*. These latter terms involved parameters that were broad, vague and plausibly subjective, and that would directly affect the experiments to be conducted by the defendant in *Novartis*; the same cannot be said of the definition of the Inorganic Salt in the present case.

Requests 3 and 4

62 With regard to Requests 3 and 4, counsel for the Plaintiff pointed out that there was no reference to any "stabilising function" in the Plaintiff's Patent claims. This, he submitted, should mean that Requests 3 and 4 – which are based on the premise that the Plaintiff's Patent claims a "stabilising function" – cannot be granted.

63 While I understand that the Plaintiff should not be made to limit his claim at an early stage, and *a fortiori* based on limitations that are not apparent on the face of the claims, I note that the "stabilising function" appears to have been put in issue in the proceedings. First, the specification on page 2 of the Plaintiff's Patent indicates that the Inorganic Salt is incorporated "as a stabilising agent". Second, the Plaintiff has represented that it is "a stabiliser which comprised an [Inorganic Salt]" that infringes the claims of the Plaintiff's Patent. Third, counsel for the Plaintiff confirmed during the hearing of the Application that it is true that the "inventive step" for the Plaintiff's patent is the stabilising function, but there is no need for the Plaintiff to specify the same. Fourth, the court in *AstraZeneca* had noted that the only reason for the action was because "the [P]laintiff did not believe that the [D]efendant's composition did not contain a stabiliser which comprised an [Inorganic Salt]" (*AstraZeneca* at [13]).

64 Depending on whether it is the Plaintiff's case that the inorganic salt in the Defendant's Products performs a stabilising function, the Defendant will have to decide whether to conduct experiments to determine if the Defendant's inorganic salt indeed has a stabilising function. While there is no explicit reference to a stabilising function within the Plaintiff's Patent claims, for the reasons stated in [63] above, the Defendant may be put through unnecessary costs and expense due to vagueness as to whether the experiments should include measurement of a specific parameter (*viz*, the "stabilising function"). I therefore allow Requests 3 and 4. I am fortified in my decision in this regard by the decision in *Novartis* on a similar point (see [39]-[40] above).

Requests 5 and 6

65 Requests 5 and 6 are mirrored requests regarding the terms "pharmaceutical composition" and "pharmaceutical tablet" respectively. Each of these requests has two components: (a) the definition of the term in question; and (b) whether the term in question includes a "coating" thereof.

66 I do not think that it is necessary for the Plaintiff to define what is meant by the terms, *inter alia* because the Defendant has not shown that he requires such definitions to know the case against it. However, as for whether the terms in question include a "coating" thereof, I am of the view that this part of the requests is "inclusive" in nature – it merely seeks particulars on whether the Plaintiff's claim *includes* a "coating". I therefore find it difficult to see how the request for such particulars requires the Plaintiff to limit its claims.

67 I therefore allow Requests 5 and 6 only insofar as they relate to whether the term in question includes a "coating" thereof.

Request 7

Request 7

68 Request 7 relates to Claims 24 and 27 of the Plaintiff's Patent. Claims 24 and 27 of the Plaintiff's Patent claim "[a] method of producing a stabilised pharmaceutical composition which comprises *incorporating* an [Inorganic Salt]" [emphasis added]. Counsel for the Plaintiff conceded that some examples of admixtures were given, but that the claims did not limit incorporation to be by way of admixture.

69 Similar to Request 2, Request 7 appears to me to be the work suited for expert evidence at a later stage of the proceedings, and is not necessary at the stage of pleadings. It does not appear appropriate to require the Plaintiff to define whether the method of incorporation is that of admixture. Furthermore, the process of admixture was neither referred to on the face of the claims, nor has it been put in issue akin to the "stabilising function". As such, Request 7 will not be allowed.

Conclusion

70 By way of a parenthetical concluding observation, where a claim has serious consequences to the public and to a defendant's legitimate business, as a matter of good practice, the plaintiff should be required to give proper particulars of its claim. This principle is established in actions for breach of confidence, where the courts have held that extra care must be taken to ensure "clear particularisation" (*John Zink Co Ltd v Wilkinson* [1973] RPC 717, followed in *Chiarapurk Jack v Haw par Brothers International Ltd* [1993] 2 SLR(R) 620, and *Ocular Sciences Ltd v Aspect Vision Care Ltd* [1997] RPC 289 ("*Ocular Sciences*")). This is because, *inter alia*, courts are careful to ensure that such claims are not used to oppress and harass competitors (*Ocular Sciences* at 359).

71 Although the precise scheme for patent actions differs from that regarding actions for breaches of confidence, the same concerns and considerations should apply. Indeed, such concerns are recognised, in part, in the form of remedies against groundless threats of patent infringement. In my view, these concerns apply *a fortiori* to actions taken out under the Medicines Act, because such actions trigger a stay on the processing of product licences for medicinal products for a period of 30 months from the date of the commencement of the action, based simply on *prospective* infringement (see [6] and [48] above). The availability of the moratorium, whilst possibly intended to encourage settlement of patent infringement claims before the allegedly infringing products enter the market, can be used to delay the manufacture, importation and sale of medicinal products by competitors of the patentee, and may further have the effect of hindering public access to the competitor's products. Accordingly, the modern position as embodied in *Novartis* is, for the reasons alluded to throughout this judgment (and, in particular, at [47]-[48] above), patently applicable to cases such as the present.

72 Returning to the Application, I have allowed Requests 1, 3, 4, as well as 5 and 6 (both in part). Counsel for the Plaintiff requested for, to which counsel for the Defendant consented, 14 days to file and serve the particulars related to the allowed requests, and I so order.

73 I will now hear parties on costs.

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