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Judgment

COURT OF APPEAL OF THE HAGUE

Civil law

Court case number : 200.314.300/01

Case number court : C/09/625801 KG ZA 22-201

Summary judgment of 15 November 2022

in the case of

Pharmathen Global B.V.

, established in

Amstelveen, appellant,

Advocate: Mr A.A.A.C.M. van Oorschot, Amsterdam,

at

Novartis A.G. ,

based in Basel, Switzerland

defendant,

Advocate: Mr R.M. Kleemans of Amsterdam.

The court will hereinafter refer to the parties as Pharmathen Global and Novartis.

1 Proceedings on appeal

1.1 The course of the appeal proceedings is evidenced by the following documents:

- the summons dated 1 August 2022, by which Pharmathen Global appealed of the judgment of interim relief judge in the District Court of The Hague dated 19 July 2022; Pharmathen Global included its grievances against the judgment in the summons.
- Novartis' response, with exhibits.
- the productions 1-6 and 7-11 submitted by Pharmathen Global on the occasion of the following oral hearing submitted.
- the productions 41-42 submitted by Novartis on the occasion of the oral treatment has submitted.

1.2 An oral hearing was held on 30 September 2022. The lawyers explained the case on the basis of pleadings which they submitted.

1.3 The court of appeal dismisses Pharmathen Global's objection to the exhibits 41 and 42 submitted by Novartis. Although Novartis submitted these productions after the time limit set by the rules of procedure, the court of appeal does not consider this exceeding the time limit in this case to be contrary to due process. Indeed, the productions concern statements in which Novartis' experts mainly respond to the latest productions of Pharmathen Global. The productions could therefore not have been submitted at an earlier stage.

2 Factual background

2.1 The Novartis Group is a global pharmaceutical group that develops, manufactures and markets pharmaceuticals. The Novartis group is headed by Novartis.

2.2 Novartis is marketing an injectable LAR (Long Acting Release) product containing octreotide under the name Sandostatin LAR. Octreotide resembles the body's own hormone somatostatin and it blocks the production of many types of hormones. Octreotide is prescribed in the treatment of various cancer tumours of organs that produce hormones, such as in acromegaly and gastroenteropancreatic neuroendocrine tumours. Microparticles consisting of a biodegradable poly(lactide-co-glycolide) (hereinafter PLG) polymer and octreotide acetate are injected into the muscle by injection. The microparticles slowly release the octreotide into the bloodstream.

2.3 Novartis holds - among others - European patent EP 2 377 519 B1 (hereinafter EP 519 or the Patent) entitled "Pharmaceutical Composition Comprising Octreotide Microparticles". EP 519 was granted on 23 March 2016 on an application dated 18 November 2003 and invokes priority documents GB 0226993, dated 19 November 2002, and GB 0227883, dated 29 November 2002. The Patent is in force until 19 November 2023 and is designed for the Netherlands, Austria, Belgium, France, Germany, Greece, Italy, Liechtenstein, Portugal, Spain, Switzerland, Turkey and the United Kingdom.

2.4 Independent conclusions 1 and 2 of EP 519 read as follows in the original English language version:

1. A process for the production of octreotide acetate microparticles comprising the steps of:

a) mixing octreotide acetate in methanol with methylene chloride containing a dissolved linear poly (lactide-co-glycolide) to form a solution; and

b) emulsifying said solution with the extraction medium, wherein said extraction medium is water or an aqueous buffered solution with a stabiliser.

c) immediately after the formation of emulsion, adding all at once said emulsion to an effective amount of an extraction medium to extract methylene to form said microparticles, wherein said extraction medium is water or an aqueous phase; and

d) collecting and drying the microparticles, e.g. freeze-drying or drying under vacuum.

2. A process for the production of octreotide acetate microparticles comprising the steps of:

a) mixing octreotide acetate in methanol with methylene chloride containing a dissolved linear poly (lactide-co-glycolide) to form a solution; and

b) mixing said solution with high shear stress with a suitable quantity of process medium in the ratio of 1 volume of said solution of step a) with 10 to up to 50 volumes of process medium, wherein said process medium is an aqueous phase.

c) hardening the microparticles by solvent evaporation under stirring; and

d) washing, collecting and drying the microparticles.

2.5 These conclusions, in the uncontested Dutch translation, read as follows:

1. Process for manufacturing octreotide acetate microparticles, comprising the steps of:

a) mixing octreotide acetate in methanol with dichloromethane containing a dissolved linear poly(lactide- co-glycolide) to form a solution; and

b) emulsifying the solution with the extraction medium, where the extraction medium is water or an aqueous buffered solution with a stabiliser.

c) immediately after forming the emulsion in one pass, adding the emulsion to an effective amount of an extraction medium to extract dichloromethane to form the microparticles, where the extraction medium is water or an aqueous phase; and

d) collection and drying of the microparticles, e.g. freeze-drying or vacuum drying.

2. Process for manufacturing octreotide acetate microparticles, comprising the steps of:

a) mixing octreotide acetate in methanol with dichloromethane containing a dissolved linear poly(lactide- co-glycolide) to form a solution; and

b) mixing the high shear stress solution with a suitable amount of process medium in the ratio of 1 volume of the solution from step (a) to 10 to at most 50 volumes of process medium, the process medium being an aqueous phase.

c) hardening of the microparticles by solvent evaporation under stirring; and

d) Washing, collecting and drying the microparticles.

2.6 The Greek company Pharmathen SA (hereinafter Pharmathen Greece) was founded in 1969.

The Pharmathen group now comprises several European pharmaceutical companies in the field of - among others - generic medicines. In September 2015, UK investor BC Partners acquired the Pharmathen Group, followed by the creation of Pharmathen Global on 13 October 2016. On 20 January 2022, the Pharmathen group was acquired by Swiss investor Partners Group.

2.7 Pharmathen Global's filed 2020 financial statements include the following:

Directors' Report

PHARMATHEN GLOBAL BV: Report of the Management

Board 1 Company Overview

(...)

Following the acquisition of Pharmathen in 2015 by funds advised by BC Partners, the strategy of the Group focused on expanding further its international Business to Business (B2B) operations. With this target the Group in 2017 divested its Business to Consumer (B2C) operations and applied a Netherlands-based B2B operating model and structure based on strong relationships with its marketing partners.

As a result, Pharmathen Global B.V. became the leading operating company of the Group, being responsible for setting the strategic targets, deciding on the allocation of the R&D resources of the Group and its commercial policy. It also exploits commercially in the international markets the products developed by the Group by forming long lasting business relationships with leading marketing partners that distribute the products of the Group worldwide. The development of the international business is supported by experienced staff, which is employed by Pharmathen Global B.V. and its subsidiary Pharmathen UK Ltd (based in Hertfordshire, UK).

(...)

1. General information

Activities:

Pharmathen Globa1 B.V. (hereafter "the Company") is a private limited liability company (B.V.) incorporated on 13 October 2016 in the Netherlands. The Company was set up to become the B2B sales and marketing and business development hub of Pharmathen Group for international B2B customers. The Company is also leading all the strategic decision making of the Group with respect to Research and Development of new products, commercial terms and policies and Group investing and financing.

2.8 Within the Pharmathen group, Pharmathen Greece manufactures injectable octreotide LAR products in Greece. In manufacturing these products, Pharmathen SA uses PLGA polymers that it sources from Corbion, called Purasorb® PDLG 5505G (hereinafter Purasorb).

2.9 On 13 March 2019, Pharmathen Greece sued Novartis before the Court of Athens, Greece. In these proceedings on the merits, Pharmathen Greece sought a declaration of non-infringement of EP 519.

2.10 Novartis filed two proceedings against Pharmathen Greece on 16 April 2019 before the interim relief judge at the Athens District Court, Greece. The first procedure is an interim injunction in which Novartis sought - among other things - a preliminary injunction against infringement of the Greek part of EP 519. In the second proceedings, Novartis sought a preliminary injunction against infringement of the Greek part of EP 519 until the oral hearing in the interlocutory proceedings

lawsuit. The claim in the second proceedings was dismissed on 18 April 2019. The claims in the first proceedings were dismissed by judgment of 10 October 2019. In that judgment, the Greek interim relief judge ruled that Pharmathen Greece did not infringe the Greek part of EP 519.

2.11 In the proceedings on the merits instituted by Pharmathen Greece (see section 2.10 below), Novartis subsequently sought to have the dismissive decision in the interim injunction revoked. By judgment of 26 November 2021, the Greek court dismissed Pharmathen Greece's and Novartis' claims on procedural grounds.

2.12 Pharmathen Greeksand obtained market authorisations in the Czech Republic and Germany on 18 November 2021 to market injectable octreotide LAR products under the brand name Okrodin (hereinafter Okrodin). In addition, Pharmathen Greece has submitted applications for market authorisation in France and the UK.

2.13 The Pharmathen Group's Global Product Catalogue 2021 includes - among other things - the following (yellow highlighting added):

Long Acting Injectables

PRODUCT	PHARMACEUTICAL FORM	STRENGTHS	THERAPEUTIC CATEGORY	DOSSIER STATUS
OCTREOTIDE ACETATE	Long-acting injectable	10mg/vial 20mg/vial 30mg/vial	Treatment of acromegaly and control symptoms such as diarrhea or flushing in patients with tumors Treatment of patients with advanced neuroendocrine tumors of the midgut or of unknown primary origin where non-midgut sites of origin have been excluded. Treatment of TSH-secreting pituitary adenomas: • when secretion has not normalized after surgery and/or radiotherapy • in patients in whom surgery is inappropriate • in irradiated patients, until radiotherapy is effective	EU approved
PALIPERIDONE PALMITATE 1M	Long-acting injectable	25mg/syringe 50mg/syringe 75mg/syringe 100mg/syringe 150mg/syringe	Indicated for the treatment of schizophrenia in adult patients	Available Now
PALIPERIDONE PALMITATE 3M	Long-acting injectable	175mg/syringe 263mg/syringe 350mg/syringe 525mg/syringe	A 3-monthly injection, indicated for the maintenance treatment of schizophrenia in adult patients who are clinically stable on 1-monthly paliperidone palmitate injectable product	Under development
PASIREOTIDE	Long-acting injectable	20mg/vial 40mg/vial 60mg/vial	Treatment of patients with acromegaly who have had an inadequate response to surgery and/or for whom surgery is not an option (listed as an orphan indication in EU) Orphan indication in EU only: Treatment of adult patients with Cushing's disease for whom surgery is not an option or for whom surgery has failed	Under Development
RISPERIDONE	Long-acting injectable	12.5mg/vial, 25mg/vial, 37.5mg/vial, 50mg/vial	Acute and chronic schizophrenic psychoses treatment	EU approved
TRIAMCINOLONE ACETONIDE	Long-acting injectable	32mg/vial	An extended-release synthetic corticosteroid indicated as an intra-articular injection for the management of osteoarthritis pain of the knee	Under Development

3 Court proceedings

3.1 Novartis has sued Pharmathen Global and claimed, in summary, that the interim relief judge by judgment, to be declared provisionally enforceable to the extent possible:

(i) will prohibit Pharmathen Global, with immediate effect after service of the judgment, from acting unlawfully, in the countries mentioned in paragraph 40 of the summons, by inducing its subsidiaries (the holder of market licences and their local representatives), or third-party distributors, to infringe permitting, approving, facilitating, promoting, or inducing such infringement, or knowingly profiting from such infringement, in particular by authorising the manufacture, marketing and export of infringing products, or otherwise acting unlawfully vis-à-vis Novartis.

(ii) will prohibit Pharmathen Global from directly or indirectly infringing EP 519 in the Netherlands and the other countries where EP 519 is in force, with immediate effect after service of the judgment.

(iii) Pharmathen Global will direct third parties, including its subsidiary Pharmathen Greece, their local representatives, or third-party distributors to cease and desist from infringing EP 519.

(iv) will order Pharmathen Global to pay an immediately due and payable penalty for each full or partial breach of one or more of the injunctions or prohibitions set out in the judgment (to be imposed, court added) of €1,000,000 for each day or part thereof that the breach continues, or at Novartis' discretion, €250,000 for each breach.

(v) will set the time limit for bringing a claim in the main action under section 1019i of the Code of Civil Procedure ("Rv") at six months after the judgment; and

(vi) order Pharmathen Global to pay the full costs of these proceedings in accordance with Section 1019h Rv, to be paid within fourteen (14) days of the date of the judgment, failing which the aforementioned amount will be increased by the statutory interest as referred to in Section 6:119 of the Civil Code (hereinafter: BW) from the fifteenth day after the date of the judgment until the day of payment in full.

3.2 The interlocutory court largely upheld the claims and ordered Pharmathen Global to pay the costs.

4 Claims on appeal

4.1 Pharmathen has appealed because it disagrees with the verdict. It has raised 19 grievances against the verdict. It wants the court to dismiss Novartis' claims as yet.

5 Assessment on appeal

Grievance 1: urgent interest

5.1 Grievance 1 of Pharmathen Global is directed against the judgment of the interim relief judge on Novartis' urgent interest in the relief sought. This grievance is unfounded for the following reasons.

5.2 First and foremost, when an interlocutory injunction is sought seeking to put an end to acts that are classifiable as systematic infringements of a subjective right, from which the claimant suffers ongoing harm, it is entirely obvious that that party has an urgent interest in its claims. [1] That the measures sought may have far-reaching consequences for Pharmathen Global and Pharmathen Greece and their customers is

insufficient to allow continuation of the infringement. Nor do patients' interests oppose the assumption of an urgent interest, if only because an alternative to Pharmathen Global's LAR products is available.

5.3 The fact that Novartis has known about the alleged infringement by Pharmathen Greece in Greece and Pharmathen Global's role in it since the beginning of 2019 does not mean that Novartis no longer has an urgent interest in the measures claimed. Novartis has argued that it has recently become aware that Pharmathen Greece and Pharmathen Global have expanded or threaten to expand their LAR activities. In that regard, Novartis has pointed out, among other things:

i. a press release dated 19 July 2021 from Partners Group, which talks about 'initiatives to scale the business in Europe' in the context of the announcement of the acquisition of Pharmathen Global's parent company.
ii. Pharmathen Global's 2020 and 2021 financial statements published in July 2021 and June 2022, respectively, which state as targets: 'successful US and EU launch of new class of Long Acting Injectable (LAI) molecules'.
iii. Pharmathen Greece's acquisition of a market authorisation in Germany in early 2022 and its pending applications for market authorisations in the UK and France, among others; and
iv. the publication by Pharmathen Global of a 'Global Product Catalogue 2021' listing the LAR products.

These circumstances, taken together, make the (imminent) extension of the alleged infringement by Pharmathen Greece and Pharmathen Global sufficiently plausible. That extension provides sufficient justification for the circumstance that Novartis commenced these summary proceedings against Pharmathen Global in early 2022 and that it focused only on Pharmathen Greece's activities in Greece through the proceedings in Greece in early 2019.

5.4 The fact that a customer of Pharmathen Greece has been marketing LAR products in 22 European countries since 2019 does not alter the foregoing. That customer is not a party to these summary proceedings.

Grievance 2: duty of truth

5.5 Ground 2 of Pharmathen Global is directed against the opinion of the interim relief judge that the sanction of inadmissibility is too far-reaching for Novartis' alleged breach of the duty of truth. That grievance is unfounded.

5.6 Section 21 Rv states that the parties are obliged to state the facts relevant to the decision fully and truthfully and that if this obligation is not complied with, the court may draw the conclusion it deems appropriate. Pharmathen Global accuses Novartis of failing to mention in the initiating summons that Novartis' claims in the Greek summary proceedings had been dismissed, nor did it submit the summary judgment. The court agrees with Pharmathen Global that Novartis thereby violated Section 21 Rv. However, the court of appeal shares the opinion of the interim relief judge that declaring Novartis inadmissible would be too far-reaching a sanction for that violation. Declaring inadmissible is a very far-reaching decision. The gravity of the infringement does not justify this sanction, also in view of the fact that Novartis did mention the preliminary relief proceedings in the initiating summons and the importance of the said preliminary relief proceedings for the decision in this case is less than Pharmathen Global makes it appear (see paragraph 5.9 et seq.). Pharmathen Global did not argue that a sanction other than a declaration of inadmissibility (or the equally far-reaching sanction of dismissal of the claims) would also be appropriate. The court sees no grounds for this either.

Grievance 3: restructuring

5.7 By grievance 3, Pharmathen Global argues that because of a transfer of the octreotide acetate business to Pharmathen Greece, it no longer has that business itself

performs and also no longer influences the policies of Pharmathen Greece. The court rejects that grievance for the following reasons.

5.8 Pharmathen Global has not made the alleged transfer of business sufficiently plausible given what Novartis has argued. Novartis has referred, inter alia, to a letter dated 25 August 2022 from Pharmathen Global's lawyer in which it expressly states that the restructuring alleged by Phmarmathen Global will not take place before the court hearing in this case and that "the precise functions to be allocated to particular entities is subject to change" (Novartis' production 34B). In addition, Novartis has argued that the new owner of the Pharmathen group, the Partner Group, still reported in a statement dated 24 May 2022 that Pharmathen is 'headquartered basically in the Netherlands' (Novartis' production 37A). In light of this, a statement in which Pharmathen's CFO reported that Pharmathen Greece conducts all activities in respect of octreotide acetate (Pharmathen Global's production 2) and a statement by a Teva employee that Teva purchases the products from Pharmathen Greece (Pharmathen Global's production 27) do not provide sufficient support for the claim that Pharmathen Global no longer conducts activities in respect of octreotide acetate and no longer has any influence on Pharmathen Greece's policy.

Grievance 4: recognition of Greek judgment

5.9 By ground 4, Pharmathen Global argues - in summary - that the Dutch court is bound by Article 36 of the Brussels Ibis Regulation2 by the Greek court's finding that Pharmathen Greece does not infringe. That grievance is partly unfounded and partly well-founded.

5.10 The obligation deriving from Article 36 Brussels Ibis Regulation to recognise judgments given in other Member States means that, in principle, those judgments have the same effect in the State addressed as those judgments have in the State of origin. [3] To the extent that Pharmathen Global has relied on the Greek system of res judicata for judgments, it cannot succeed. The Greek judgment was rendered in proceedings in which Pharmathen Global was not a party. Novartis argued, supported by a statement from its expert Kilimiris (Novartis' production 38), that under Greek law a judgment has res judicata only between the parties in the proceedings that led to the judgment (as in the Dutch regime for res judicata). Pharmathen Global did not dispute this, or did not give sufficient reasons to do so. On the contrary, the expert Ballas engaged by it confirms in his submission that, under Greek law, *res judicata* exists in disputes on the same subject matter between the same parties (Pharmathen Global's production 3, paragraph VII(ii)).

5.11 Pharmathen Global's argument that, notwithstanding the foregoing, it can still invoke res judicata is based on the assumption that Pharmathen Global and Pharmathen Greece can be seen as a single litigant. That assumption is unfounded. As the testimony of the expert Ballas hired by Pharmathen Global confirms, Pharmathen Global and Pharmathen Greece are, also under Greek law, distinct legal entities. In addition, Novartis argued, uncontested, that under Greek law, as under Dutch law, a summary judgment is never res judicata, even between the same parties. For that reason too, the appeal to res judicata cannot succeed. The court will therefore have to form its own opinion on the alleged infringement and is not bound by the opinion of the Greek interim relief judge.

5.12 There is also no violation of the rules of international jurisdiction. The Dutch court has jurisdiction in this case under Article 4 of the Brussels Ibis Regulation because Pharmathen Global is based in the Netherlands. That jurisdiction is cross-border and therefore also extends to Pharmathen Global's actions in the other countries where EP 519 is in force, including Greece and Germany. That the Dutch court would not have had jurisdiction in a case against Pharmathen Greece concerning infringements of the Greek part of EP 519, because it is already the subject of proceedings on the merits between Novartis and Pharmathen Greece, is i r r e l e v a n t . Indeed, Pharmathen Greece is not a party to those proceedings.

5.13 However, Pharmathen Global has also argued that under Greek law, it is not possible for the

effect of a court decision to be set aside by a second court decision, other than by filing an appeal against the first court decision. In other words, second proceedings cannot be used as a disguised appeal of an unfavourable decision in earlier proceedings. Violation of that rule may also occur if the second court decision is directed against a different party from the first decision, but effectively has the effect of setting aside the effect of the first court decision.

5.14 The rule described above was violated in the judgment insofar as the interim relief judge thereby ordered Pharmathen Global to instruct Pharmathen Greece to cease the alleged infringement in Greece. The judgment thus effectively set aside the decision of the Greek court in preliminary relief proceedings rejecting the claim against Pharmathen Greece for an injunction prohibiting infringement in Greece. Otherwise, the rule was not violated. The injunction against Pharmathen Global and the order instructing Pharmathen Greece to cease infringing outside Greece do not conflict with the Greek interim relief judge's decision. This is because that Greek decision does not relate to infringements by Pharmathen Global itself nor to infringements by Pharmathen Greece outside Greece.

Grievance 5: infringement and unlawful conduct

5.15 Ground 5 of Pharmathen Global is directed against the opinion of the court in preliminary relief proceedings that it is plausible that Pharmathen Global is in any way involved in infringement of EP 519 in the countries where the patent is in force and that this is unlawful under Dutch law. That grievance fails for the following reasons.

5.16 First and foremost, the question whether Pharmathen Global infringes must be assessed under the law of the countries for which Novartis claims protection. Indeed, Article 8 of the Rome II Regulation4 requires that the non-contractual obligation arising from an infringement of an intellectual property right shall be governed by the law of the country for which protection is claimed. Thus, not only Dutch law applies. Given the far-reaching (informal) harmonisation of the rights attached to a European patent in the member states of the European Patent Convention, the court below will assume that those rights are the same in all countries. In doing so, the court will use Dutch law as a starting point and discuss other legal systems only if the parties have argued that a different regulation applies under a specific legal system.

5.17 In the court's view, Pharmathen Global is itself responsible for performing the alleged reserved actions in the various member states where EP 519 is in force. Novartis has made it sufficiently plausible that Pharmathen Global is not merely the parent company of Pharmathen Greece, but actually directs or performs reserved actions in relation to the LAR products. In this regard, Novartis pointed out, inter alia, that Pharmathen Global reported the following in its 2020 annual report:

'As a result, Pharmathen Global B.V. became the leading operating company of the Group, being responsible for setting the strategic targets, deciding on the allocation of R&D resources of the Group and its commercial policy. It also exploits commercially in the international markets the products developed by the Group by forming long lasting business relationships with leading marketing partners that distribute the products of the Group worldwide. The development of the international business is supported by experienced staff, which is employed by Pharmathen Global B.V. and its subsidiary Pharmathen UK Ltd (based in Hertfordshire, UK).'

Pharmathen Global has also acknowledged that it has gradually taken up sales from its inception in 2016 (conclusion of reply, paragraph 4). It only states that Pharmathen Greece continued to handle research and development activities and sales in Greece and "certain niche markets" outside Greece. That does not preclude Pharmathen Global from leading those activities.

5.18 In addition, Pharmathen Global has argued that the proposed restructuring provides for the transfer of Pharmathen Global's commercial business to Pharmathen

Greece. As the court of appeal has already ruled above in the context of assessing grievance 3, it is not plausible that this alleged restructuring has already been realised. Given the as yet central and leading role of Pharmathen Global in the commercial exploitation of the LAR products, (also) Pharmathen Global must be held responsible for the alleged reserved actions, even if certain actions were actually performed by Pharmathen Greece.

5.19 Pharmathen Global's defence that the statutory list of acts reserved to the patentee cannot be expanded by invoking the general doctrine of tort, the court can pass over. The foregoing judgment on Pharmathen Global's responsibility does not imply an expansion of the reserved acts listed in the law. It only makes it clear that the responsibility for reserved acts can (also) lie under circumstances with a company other than the company that actually performs the acts.

5.20 A similar judgment follows from Greek patent law, to which both parties refer. Novartis, supported by statements by Greek lawyer Kilimiris, showed that under Greek patent law, the party responsible for the 'productive exploitation' of the patented invention performs a reserved act, even if another party actually performs certain acts. The counterarguments raised by Pharmathen Global, referring to statements made by Greek lawyer Ballas, can be passed by the court. Pharmathen Global and Ballas argue that under Greek law there is no indirect infringement, or at least that indirect infringement and injunctions against intermediaries are only possible if it is established that a third party infringes. However, the court's opinion above is not based on the indirect infringement regime or that for intermediaries.

5.21 Novartis has not argued that Pharmathen Global is acting unlawfully in any other way than by the aforementioned facts, which entail that Pharmathen Global itself infringes. There is therefore no basis for granting the claimed injunction against unlawful conduct, in addition to the claimed injunction against infringement, and Novartis also has no interest in doing so. Given the manner in which Pharmathen Global is infringing, in particular directing Pharmathen Greece, the claimed injunction instructing Pharmathen Greece to cease infringement does constitute an appropriate remedy in addition to the injunction, albeit excluding infringements of the Greek part of EP 519 in order to avoid a clash with the Greek judgment (see 5.14 above).

Grievances 6 to 11: scope of protection

5.22 Grievances 6 to 13 relate to the interim relief judge's finding that Pharmathen Global's conduct falls within the scope of protection of claim 1 of EP 519. Those grievances fail for the following reasons.

5.23 Article 69(1) of the European Patent Convention (hereinafter EPC), which applies here by virtue of Article 2(2) EPC, provides the following on the determination of the scope of protection of a European patent:

The scope of protection of the European patent is determined by the claims. Nevertheless, the description and drawings serve to explain the claims.

The Protocol on the Interpretation of Article 69 EPC associated with Article 69 EPC (the Protocol) reads:

1. Article 69 should not be interpreted as meaning that the scope of protection of the European patent is strictly determined by the literal text of the claims and as meaning that the description and drawings may only serve to eliminate ambiguities that may exist in the claims. Nor should Article 69 be interpreted as if the claims served only as a guideline and as if the scope of protection also extended to what, in the opinion of the person skilled in the art examining the description and drawings, the patentee intended to protect. Instead, the interpretation should take a middle ground between these two extremes, with

provides both equitable protection to the patent holder and a reasonable degree of legal certainty to third parties.

2. In determining the scope of protection of the European patent, appropriate account should be taken of any element equivalent to one defined in the claims.

5.24 In applying Article 69 EPC and the Protocol, the court will apply the two-step approach developed in case law.

5.24.1. The first step of that approach is sometimes referred to as the assessment of 'literal infringement'. In that step, an interpretation of the patent claim is used to determine whether the product or process of a third party complies with all the features of that patent claim. That interpretation does not refer to the extreme referred to in Article 1 of the Protocol, where the scope of protection of the European patent is strictly determined by the literal text of the claim, but to an interpretation of the patent claims in the light of, inter alia, the description and drawings from the perspective of the average person skilled in the art with his knowledge of the prior art (Article 69(1) EPC and the middle of Article 1 of the Protocol). Various points of view may play a role in that interpretation.

5.24.2. If the patent claim cannot be interpreted to mean that all of its features are 'literally' reflected in the product or process, the second step is to determine whether the element that deviates from a feature included in the claim is equivalent to that feature and whether it is appropriate for the product or process to still fall within the scope of protection of the patent for that reason. The second step involves whether, in the perception of the average person skilled in the art, the claims, read in the light of the description and drawings, leave room for equivalents, given, on the one hand, equitable protection for the patentee and, on the other, a reasonable degree of legal certainty for third parties.

5.24.3. In order to answer the above equivalence question positively, it is first required that the deviating element is technically equivalent to the claimed feature. This requirement is met if the product or process with the deviating element also solves the problem solved by the patent and, in that context, the deviating element performs the same function as the claimed feature. This requirement of "technical equivalence" is the basis for the claim of equivalence.

5.24.4. Second, it must be assessed whether, from the point of view of equitable protection of the patentee, it is appropriate to take equivalents into account when determining the scope of protection of the patent. That viewpoint requires that the scope of protection of the patent be proportionate to the contribution that the patent holder has made to the prior art with the patent. In addition to the novelty and inventive step of the variant, to be discussed separately as a fourth requirement below, this means that the invention must have been disclosed in the patent specification in such a way that it would be obvious to the average person skilled in the art to also apply that invention with elements different from the feature of the patent claim. In other words, the patent specification must disclose to the average person skilled in the art with his general professional knowledge a doctrine that may include the application of equivalents.

5.24.5. Thirdly, it must be assessed whether recognition of the claim of equivalence is appropriate in a concrete case given the required reasonable degree of legal certainty for third parties. The fact that the patent claims used wording that does not literally include equivalents is an important circumstance in that context. Given that Article 69 EPC presupposes that the scope of protection of a European patent is determined by the claims, third parties may in principle rely on the wording of the claims, interpreted in the light of the description and drawings, and ambiguity created by the wording of the claims in principle operates to the detriment of the patentee. The fact that the

patent claims have used wording that does not literally include equivalents, however, cannot suffice for a finding that legal certainty for third parties is insufficiently ensured. If it were, reliance on equivalence would be impossible. That outcome would be inconsistent with Article 2 of the Protocol, which requires equivalents to be taken into account in an appropriate manner. Recourse to equivalence should therefore be possible if, despite the specific wording of the conclusions, a sufficient degree of legal certainty is ensured. There is a sufficient degree of legal certainty if the average person skilled in the art understands that the patent claims leave room for equivalents because, for the average person skilled in the art, the doctrine of the patent is clearly broader than the wording of those claims and, in the eyes of the average person skilled in the art, there is no good ground for limiting the scope of protection to application of the feature set out in the claims. Such good cause does not exist only if the average person skilled in the art may assume that part of the protection has been waived.

5.24.6. Fourth, if the defence so warrants, it should be assessed whether the variant is new and inventive compared to the prior art of the patent. Granting protection for non-new or non-inventive products or processes would go beyond what would justify equitable protection for the patentee (also known from the Gillette or Formstein defence, named after two cases of the same name from England and Germany respectively). These aspects must be tested in the context of determining the scope of protection of the patent because the novelty and inventiveness of equivalents is not assessed in grant, opposition and invalidity proceedings.

Grievance 6: no literal infringement 'a linear PLG'

5.25 In the context of assessing 'literal infringement', the parties firstly dispute the interpretation of the conclusion element 'a linear PLG' (linear poly(lactide-co-glycolide)). In this context, there is no dispute that there is a contradiction between linear PLG on the one hand and star PLG on the other. However, the parties differ on the criterion for making that distinction. According to Novartis, whether the PLG is linear or not should be determined by counting the arms of the PLG molecules. Pharmathen Global believes that the linear or non-linear nature of the PLG should be determined by the initiator used in the production of the PLG and, more specifically, that the average subject on the priority date PLG made with glucose as initiator would qualify as star PLG rather than linear PLG within the meaning of EP 519. The court agrees with Pharmathen Global on the literal infringement on this point.

5.26 The key point is that the average person skilled in the art reads the patent with his general professional knowledge. By itself, Novartis has made a sufficiently plausible case that the average person skilled in the art knew by virtue of his general expert knowledge on the priority date that the terms 'linear' and 'star' indicate different structures of the polymer and, more specifically, a different number of arms of the polymer.

5.27 However, it must be assumed that the average subject also knew that, at the priority date, no method was available to accurately determine the number of arms of glucose-produced PLG and that, partly for this reason, people were used to classifying PLG on the basis of the initiator used. Polymers made with an initiator with one free hydroxyl group (or two free hydroxyl groups) were qualified as linear polymers. Polymers made with initiators with three or more free hydroxyl groups, such as the polyol glucose that has five free hydroxyl groups, were classified as star polymers without question. This was because it was assumed that a polymer made with such an initiator contains mainly polymers with more than three arms.

5.28 That this was the general expert knowledge with which the subject read EP 519 on the priority date is confirmed by Novartis' own contentions. Novartis has argued that on the priority date there was no suitable method to determine the number of arms of PLG polymers (preliminary subpoena, paragraph 52, and response brief, paragraphs 195-208)

and that, at the priority date, it was assumed that a star polymer resulted from an application of a certain initiator such as glucose and appropriate reaction conditions (Reply Memorandum, paragraph 162).

5.29 Moreover, that it was common practice to classify a PLG produced with glucose as a star polymer is confirmed by the fact that Novartis was unable to identify a single example of the qualification of a PLG produced with glucose as a linear PLG from the many publications on linear and star polymer that it submitted. Novartis also acknowledges that the Purasorb used by Pharmathen Global is generally classified as star, although some of the polymers in the product are linear (pleading at first instance, paragraph 79).

5.30 That the average subject should read the characteristic 'a linear PLG' in claim 1 of EP 519 according to his general subject knowledge is confirmed by the description of EP 519. The description of EP 519 does not mention a method for determining the number of arms of the PLG, but for the content of the terms linear PLG and star PLG, it refers to the way linear PLG and star PLG were made at the time. For linear PLG, the description refers to conventional preparation methods, as revealed in US 3 773 919, among others. Pharmathen Global has argued undisputedly that that conventional preparation method used an initiator with one free hydroxyl group. The only interpretation that the description gives to the term star polymer is the statement in paragraph [0022] that it may, for example, be a reaction product of an initiator with at least three hydroxyl groups. The same follows from the last sentence of paragraph [0022] of EP 519: 'these star polymer products are disclosed e.g.'. It is not in dispute that the grant history shows that at the end of that sentence the words 'in US patent 5,992,682' were omitted and that the sentence should therefore be read as 'these star polymer products are disclosed e.g. in US patent 5,992,682'. That patent application US 5 992 682 (hereinafter US 682) discloses polymers that are reaction products of an initiator with at least three hydroxyl groups, in particular reaction products of the initiator glucose.

5.31 In addition, paragraph [0022] of the description states that 'the linear polymer of the invention [...] contains less than 5%, or preferably is free from, star polymers'. Pharmathen Global has made it sufficiently plausible that such a high degree of pure linear PLG cannot be achieved with glucose as an initiator. This underlines that glucose-initiated PLG is not 'literally' linear PLG within the meaning of EP 519.

5.32 It is not in dispute that based on the above interpretation of the characteristic 'a linear PLG', the process used by Pharmathen Greece and Pharmathen Global does not literally infringe EP 519. It is established between the parties that in the production of ocreotide acetate microparticles, Pharmathen Greece and Pharmthen Global use a PLG product called Purasorb from Corbion made with glucose as an initiator.

Grievance 6: equivalence of Purasorb and a linear PLG

5.33 Novartis has alternatively invoked equivalence. It argues in this regard that Purasorb is equivalent to a linear PLG within the meaning of EP 519. Pharmathen Global disputes that. The court agrees with Novartis for the following reasons. In this regard, the main point is that, as the court will motivate in the context of assessing grievance 12, Purasorb is a mixture of linear and star-shaped PLG molecules, of which 47% to 72% are linear.

5.34 To answer positively the question whether Purasorb is equivalent to the claimed linear PLG, it is first required that Purasorb is equivalent to a linear PLG within the meaning of EP 519 from a technical point of view. That requirement is met if the process used by Pharmathen Greece and Pharmathen Global also solves the problem the patent solves and, in that context, Purasorb performs the same function as a linear PLG within the meaning of EP 519. In order to assess whether this requirement is met, it must first be established what problem or problems the patent seeks to solve.

5.35 Paragraphs [0002] and [0003] of EP 519 describe that on the priority date, ocreotide acetate microparticles for delayed-release parenteral administration, such as Sandostatin LAR, were made with star PLG. In addition, those paragraphs state that ocreotide acetate microparticles were made in accordance with the teachings of US 5 538 739 (hereinafter US

739), which involves the use of silicone oil and heptane. Paragraph [0004] reports that no linear PLG-based octreotide compositions for delayed-release parenteral administration were on the market at that time. According to paragraph [0005], the invention is a process for manufacturing ocreotide acetate microparticles with similar pharmacokinetic properties to Sandostatin LAR, but made from linear PLG and without silicone oil and heptane. That process is cheaper and easier, according to paragraph [0004] of the description.

5.36 It follows from these paragraphs that the claimed contribution to the prior art includes teaching the average person skilled in the art how ocreotide acetate microparticles with similar pharmacokinetic properties to Sandostatin LAR can be made from linear PLG. That inventive step is exploited insofar as the claimed process steps are used to produce ocreotide acetate microparticles with the linear PLG molecules from the Purasorb mixture. Indeed, based on the patent, the average person skilled in the art knows that if the claimed process steps are used, the presence of 47 to 72% linear PLG in the starting material will result in ocreotide acetate microparticles with similar pharmacokinetic properties to Sandostatin LAR. The fact that Purasorb also contains star-shaped PLG molecules, for which other modes of action were already known by the priority date, does not prevent this. It is not in dispute that application of the process even in the presence of star PLG in the starting material results in ocreotide acetate microparticles that have pharmacokinetic properties comparable to Sandostatin LAR. Nor is it in dispute that the mixture of linear and star PLG molecules in Purasorb performs the same function in that context as the claimed linear PLG, namely 'packaging' the active substance octreotide acetate in such a way as to delay its release into the body.

5.37 The presence of star PLG also does not prevent Purasorb from realising the other advantages of the invention described in paragraphs [0004] and [0005] of EP 519, namely that the microparticles produced by the claimed process are free of impurities in the form of heptane and silicone oil, and that the process is, partly for this reason, cheaper and simpler than the known process for the production of ocreotide acetate microparticles. That the method results in particles free of heptane and silicone oil even with the presence of star PLG in the starting material is not in dispute.

5.38 Regarding the cost and simplicity of the process, Novartis has argued that the average person skilled in the art will understand that these advantages result, inter alia, from the fact that in the known process, star PLG was used that was as pure as possible, i.e. a PLG with as little linear PLG as possible, and that the production and application of more or less pure star PLG is relatively expensive and difficult. In that context, Novartis and its retained expert [expert 1] explained that in order to prevent linear PLG from forming during the preparation of star PLG (and the ocreotide acetate microparticles), it is necessary to meticulously purify the ingredients and carefully control the reaction conditions. The patent shows that, if the claimed process steps are followed, the ocreotide acetate microparticles can also be made with linear PLG and, in that case, it is therefore not necessary to avoid forming linear PLG when preparing the PLG (and the ocreotide acetate microparticles). This advantage is also achieved when working with a mixture of linear and star PLG produced without observing the expensive and complicated measures needed to produce more or less pure star PLG.

5.39 The court considers it sufficiently plausible that the average person skilled in the art would think that in that known method of working, more or less pure star PLG was used, given the fact that on the priority date, it was not known that and how ocreotide acetate microparticles with similar pharmacokinetic properties as Sandostatin LAR could be made on the basis of linear PLG. Therefore, the average subject would think that in the prior art, the formation of linear PLG was avoided as much as possible. Paragraph [0003] of EP 519 reinforces the average subject in that thought. Indeed, that paragraph describes that ocreotide acetate microparticles were produced in the prior art on the basis of 'star polymer' and refers to US 682 in that regard. US 682 claims in claim 1 polyols having at least three arms and a star-shaped structure ('said polyol ester having at least 3 of said hydroxyl groups in esterified form and having a star-shaped structure'). These are pure

star polymers. The fact that another application submitted in parallel to US 682, namely GB 2 145 422, also discloses polyols with less than 3 arms does not make this different. Indeed, EP 519 refers to US 682 and not GB 422. Therefore, the average subject matter expert will consider US 682 and not GB 422, at least in this context, when interpreting the conclusions of EP 519.

5.40 That EP 519 also refers to patent application US 739 cannot, contrary to Pharmathen Global's view, lead to a different opinion. That reference is made not in the context of describing PLG used in the prior art, but in the context of describing microparticle preparation methods using silicone oil and heptane. Therefore, the average subject matter expert will not consult US 739 when explaining the characteristic 'a linear PLG'. Moreover, US 739 explicitly favours the use of star polymers over linear polymers because of favourable properties of star polymers (relatively high molecular weight with relatively short chains) in microparticle production (US 739, column 8, lines 24-34). Thus, even if the average subject would consult US 739 in this context, he is confirmed in the idea that more or less pure star PLG was used at the priority date. The fact that US 739 does not explicitly reveal the measures to be taken to achieve the purity of star PLG does not alter this.

5.41 The court also considers it sufficiently plausible that the production and use of more or less pure star PLG is more expensive and complicated than the production and use of Purasorb. Novartis has explained this, supported by statements from its expert [expert 1] , on the basis of the measures to be taken to prevent the formation of a substantial part of linear PLG. Pharmathen Global has not disputed this, or has not sufficiently disputed it.

5.42 For the sake of completeness, the court points out that the opinion that Pharmathen Greece and Pharmathen Global apply the doctrine of the patent with their process is also supported by the information contained in the grant file. Novartis has shown that this shows that the inventive step behind the words of the claim is not only the use of a linear PLG without the addition of heptane and silicone oil, but also the use of methanol. If not or not sufficiently disputed, it is established that application of methanol instead of water as a solvent for octreotide acetate leads to more homogeneous ocreotide acetate microparticles, regardless of whether the microparticles are made from linear PLG or star PLG. This underlines that Purasorb is an equivalent of a linear PLG in the sense of EP 519.

5.43 It follows from the foregoing that the first requirement for equivalence has been met, namely that the process adopted by Pharmathen Greece and Pharmathen Global also solves the problems underlying the patent and, in that context, Purasorb performs the same function as the claimed linear PLG. The second requirement of equitable protection of the patentee is also met. As considered above, Pharmathen Greece and Pharmathen Global apply the doctrine of the patent by their process and thus realise the benefits associated therewith. This argues in favour of bringing that practice within the scope of EP 519.

5.44 There is also a sufficient degree of legal certainty. The average person skilled in the art will understand that the patent claims leave room for equivalents because, for the average person skilled in the art, the doctrine of the patent is clearly broader than just the use of the claimed linear PLG and includes the use of Purasorb. There is no good reason why that process should nevertheless be excluded from the scope of EP 519. The fact that Purasorb does not literally fall under the characteristic 'a linear PLG' within the meaning of EP 519 is related to the fact that, at the priority date, no method was yet available to accurately determine the degree of branching of PLGs and that PLGs were therefore classified on the basis of the initiator used. However, by the time Pharmathen Greece and Pharmathen Global started applying their methodology, the publication of [... 1] had appeared. In it, [... 1] introduced a method by which the branching degree of PLGs could indeed be determined reasonably accurately and published data on Purasorb, among others, which make it clear that Purasorb contains a significant proportion of linear PLG. In light of this new information and the knowledge that the benefits of the invention could be realised with Purasorb, it was for the

average skilled person sufficiently clear that Purasorb is an equivalent of the linear PLG claimed in EP 519 and that the conduct of Pharmathen Greece and Pharmathen Global therefore falls within the scope of protection of EP 519.

5.45 Pharmathen Global's defence that [... 1] should be disregarded because the priority date is the reference date for assessing infringement is unfounded. In the context of whether a process falls within the scope of protection of the patent, significance may also be given to the knowledge of the average skilled person at the time of the alleged infringement, in particular as to whether there are equivalent elements.

5.46 The fact that paragraph [0022] of the description states that the linear PLG of the invention contains a maximum of 5% star PLG cannot lead to a different judgment on legal certainty. As the interim relief judge also ruled, that limit is not mentioned in the claim and is mentioned in a paragraph describing implementation examples. Also in view of the patent doctrine described above, the average person skilled in the art will understand that a process using less than 5% star polymer is no more than an embodiment of the claimed invention that maximises the cost advantage of the invention. Therefore, the average person skilled in the art will understand that the quoted sentence is not intended to limit the scope of protection conferred by the patent based on the text of the claim and the inventive step disclosed in the description.

5.47 The court understands that, with its ground 13, Pharmathen Global intended to argue that the fourth requirement for equivalence has not been met, namely that the variant of the claimed method is new and inventive compared to the prior art. The court rejects that argument. For the reasons for this opinion, the court of appeal refers to the following assessment of ground 13.

Grievance 7: PLG with two arms is 'linear PLG'

5.48 Ground 7 of Pharmathen Global is directed against the opinion of the court in preliminary relief proceedings that a PLG molecule with two arms is a linear PLG within the meaning of claim 1 of EP 519. Regarding literal infringement, it can be left open whether the grievance succeeds, as the court above has already ruled on other grounds that there is no literal infringement. However, the argument about the number of arms of a linear PLG is also relevant in the context of the plea of equivalence. This is because the amount of linear PLG established above in Purasorb, namely 47-72 mol%, is based on the assumption that a PLG molecule with two arms is a linear PLG.

5.49 The grievance against the judgment on two-armed PLG molecules fails for the following reasons. Novartis has made a sufficiently plausible case that the average person skilled in the art regarded a two-armed PLG molecule on the priority date as a single-chain molecule. It has argued, with reference to the IUPAC definitions, that for the average subject matter expert it would be decisive which classification leads to the simplest representation of the molecule and that a representation in which the PLG molecule with two arms forms one chain is the simplest representation. After all, a PLG molecule with two arms forms one line. Pharmathen Global has not disputed this with sufficient justification. Pharmathen Global does argue that a PLG molecule with two arms contains two chains, namely a main chain and a branch chain, but it has not explained why that is the simplest representation of the molecule or for what other reason the average subject would see the PLG molecule as consisting of two chains.

5.50 Assuming that the average subject sees a PLG molecule with two arms as one chain without branching, that molecule is also a linear polymer in the definitions used by Pharmathen Global. Indeed, Pharmathen Global defines linear polymer as a chain of monomers in one direction without branching (conclusion of reply, paragraph 38). Such a molecule also meets the IUPAC definition of a linear polymer. IUPAC definition 1.32 defines a linear polymer as 'a chain with no branch points intermediate between the boundary units'. As also argued by Pharmathen Global, for two-armed PLG, the average subject will consider the end groups of the two arms to be the 'boundary units' of the molecule. There is no 'branch point' between those end groups. A

Indeed, 'branch point', according to IUPAC definition 1.54, is 'a point on a chain at which a branch is attached'. IUPAC Definition 1.53 defines a 'branch' as 'an oligomeric or polymeric offshoot from a macromolecular chain'. These definitions imply that a 'branch point' exists only if the molecule consists of at least two chains, where one chain is the main chain and the other chain is a branch of the main chain. It follows from the previous consideration that a PLG molecule with two arms does not meet this condition.

5.51 Assuming that the average subject sees a PLG molecule with two arms as one chain, that PLG molecule also does not meet the IUPAC definition of a star polymer. IUPAC definition 1.51 describes a star molecule as 'a macromolecule containing a single branch point from which linear chains emanate'. A PLG molecule with two arms does not meet this definition because, as the court has noted above, such a molecule has neither a branch point nor multiple linear chains.

5.52 Moreover, it is not disputed that one-armed PLG is linear PLG and that Novartis has made it plausible that the average person skilled in the trade on the priority date knew on the basis of his general professional knowledge that two-armed PLG generally has the same properties as one-armed PLG and that, partly because of this, these variants are practically indistinguishable from each other. As the interim relief judge also ruled, that supports an interpretation of the characteristic 'linear PLG' that includes two-armed PLG. Pharmathen Global only countered that U-shaped two-armed PLG has a higher viscosity than single-armed PLG. That argues against classifying that particular variant as linear PLG, but there is no need to take that particular variant into account when interpreting the number of arms studies. Novartis has argued undisputedly that U-shaped PLG already leads to an apparently higher average number of arms than non-U-shaped PLG with one or two arms when examining the average number of arms.

5.53 Moreover, many specialist literature sources cited by Novartis support that the average subject classified two-armed PLG not as star, but as linear PLG at the priority date. Novartis, on the one hand, pointed to several publications that define star or branched polymer as a polymer with three or more arms (the publications included in Novartis' production 27 and the publications mentioned in paragraphs 16-18 of the expert statement of [expert 1] submitted as production 21 by Novartis). For example, (the expert hired by Pharmathen Global) [expert 3] writes in his handbook: 'A distinguishing feature of branched polymers compared to linear polymers is presence of more than two chain ends'. PLG with two arms falls outside that definition. On the other hand, Novartis has cited several examples where two-armed polymers are referred to as linear. For example, [... 1] reports in a publication referred to by both parties: 'the branch standard with two arms, i.e. linear PLGA'.

Grievances 8-11: explanation feature 'dichloromethane containing a dissolved linear PLG'

5.54 Grievances 8-11 by Pharmathen Global challenge the interpretation of the characteristic 'dichloromethane containing a dissolved linear poly(lactide-co-glycolide)'. Pharmathen Global believes that this characteristic is met only if at least 95% of the PLG molecules in the d i c h l o r o m e t h a n e are linear, especially since paragraph [0022] describes that the linear PLG of the invention contains up to 5% star PLG. As far as literal infringement is concerned, it can be left open whether the grievances succeed because the court has already ruled above on other grounds that there is no literal infringement. That the percentage mentioned in paragraph [0022] does not preclude reliance on equivalence, the court of appeal has already ruled above.

Grievance 12: amount of linear PLG in Purasorb

5.55 Grievance 12 of Pharmathen Global is directed against the opinion of the interim relief judge that the PLG product used in the manufacture of the Pharmathen group's LAR products, namely Corbion's product Purasorb, contains a substantial amount of linear PLG. That grievance cannot succeed for the following reasons.

5.56 The court of appeal agrees with the interim relief judge that Novartis has made it sufficiently plausible that Purasorb contains a substantial amount of linear PLG. In this respect, Novartis points to the data on Purasorb mentioned by [... 1] in its 2019 publication, including the fact that the PLG molecules in Purasorb have an average of 2.85 arms. The data provided by Novartis

expert [expert 1] hired on the basis of that data calculated that in Purasorb 72% of PLG molecules are linear.

5.57 Pharmathen Global has countered that reports by [expert 3], [... 2] and the University of Valencia reveal a higher average number of arms at Purasorb than [... 1] . However, Novartis has argued, supported by statements from its experts [expert 2] and [expert 1] , that [... 1] is the most reliable source. In that regard, it has pointed out that [... 1] is a *peer-reviewed* publication, which provides a lot of information about the methodology used, and that the research described by [... 1] was conducted by independent bodies and individuals, including employees of the US FDA. The sources referenced by Pharmathen Global are not *peer-reviewed* publications. In addition, the studies by [expert 3] and the University of Valencia were commissioned by one of the parties and the report by [... 2] contains significantly less data on the methodology followed than [... 1] . In light of this, the court attaches the most value to [... 1] . There is no room for further investigation in the context of these summary proceedings. In addition, starting from the average reported by [... 2], according to Hoogendom's calculations, 47% of PLG molecules are still linear. That too is a significant proportion of linear PLG.

5.58 In addition, Pharmathen Global objects to the way [expert 1] calculated the said percentages. In particular, Pharmathen Global complains about [expert 1]'s assumption that Purasorb contains only PLG molecules with two or five arms. In his submission, [expert 1] explained why he made that assumption roughly. In summary, that explanation means that in an optimal process with glucose as initiator, mainly PLG with five arms is formed in addition to some linear polymers resulting from side reactions. Under less ideal conditions, more side reactions leading to linear PLG will occur, but five-arm PLG and linear PLG remain the main components, according to [expert 1] . Pharmathen Global refuted that explanation by referring to Table 6A of [... 1] , which, according to Pharmathen Global, would show that 5-armed PLG does not or hardly occur in Purasorb. In the court's opinion, that conclusion cannot be drawn from Table 6A of [... 1] . In that table, for a number of PLGs, the calculated number of arms is set off against the molar mass. However, that calculated number of arms is, as [expert 1] explained, an average in each case. Thus, the fact that Table 6A does not or hardly shows any fractions at Corbion where the average number of arms is five does not rule out the possibility that Corbion consists mainly of 5-armed PLG and linear PLG.

5.59 The 10% figure cited by Pharmathen Global with reference to the report of its expert [expert 3] appears to be a poorer approximation of reality. First, this figure is a weight percentage. As linear PLG is generally much lighter than star PLG, the proportion of linear molecules is much higher than the 10% quoted. Second, the percentage concerns only the fractions containing pure linear PLG. Thus, the percentage does not take into account the presence of linear PLG in the fractions consisting of a mixture of linear PLG and star PLG. If these two factors are taken into account, the data used by [expert 3] result in a much higher percentage, according to Novartis a percentage of 76 mol%.

5.60 In addition, Pharmathen Global has argued that a study by the expert Spring it hired did not identify acidic end groups, while the amount of acidic end groups is a measure of the amount of linear PLG. However, Novartis has argued that the 13C NMR method used by Spring is not suitable for determining acidic end groups in polymers. In its response to this criticism, Spring acknowledges that it is difficult to analyse end groups based on the 13C NMR method. In that light, the court attaches more value to the aforementioned data on the proportion of linear PLG.

Grievance 13: application state of the art

5.61 By grievance 13, Pharmathen Global argues - in summary - that a process involving a PLG prepared with glucose as an initiator cannot fall within the scope of protection of claim 1 of EP 519, because if it did, the claim would not be novel in light of the process disclosed in US 739. This argument cannot succeed for the following reasons.

5.62 Novartis expressly did not take Pharmathen Global's submission as an attack on the novelty of EP 519. In response, Pharmathen Global did not take the position that its submission should be so understood. In light of this, the court assumes with Novartis that the validity of EP 519 has not been challenged and that only the scope of protection of EP 519 is at issue.

5.63 Pharmathen Global's argument is based on the assumption that the type of PLG would be the only difference between US 739 and EP 519 practices. That assumption is unfounded. US 739 describes in columns 9 and 10 referred to by Pharmathen Global different methods of microparticle preparation. Pharmathen Global has not shown that all the features claimed in claim 1 of EP 519 are directly and unambiguously revealed there in combination. It only argues that the use of methanol is revealed. For its part, Novartis has pointed to discrepancies. Among other things, it points out that the process described in column 9 uses heptane and silicone oil and does not specifically relate to the preparation of octreotide acetate microparticles. The process described in column 10 uses water as a solvent, at least that column does not directly and unambiguously reveal the use of methanol.

Grievances 14 and 15: infringement by Pharmathen Global

5.64 Grievances 14 and 15 by Pharmathen Global address Pharmathen Global's judgment of infringement. Those grievances do not succeed. It follows from the above that the court of appeal agrees with the interim relief judge that Pharmathen Global infringes EP 519.

5.65 The fact that Novartis has not submitted documents showing in which countries EP 519 is in force does not change this. Indeed, Pharmathen Global has not disputed that EP 519 is in force in the countries mentioned by Novartis.

5.66 The defence that Pharmathen Global does not carry out patent-relevant acts in the countries where EP 519 is in force is unfounded. Based on the scope of protection of EP 519 established above and Pharmathen Global's responsibility over the exploitation of the LAR products, it is not in dispute that Pharmathen Greece applies the claimed process when manufacturing the LAR products in Greece and that Pharmathen Global can be held responsible for it.

5.67 In addition, under EP 519, Novartis can oppose the offering and marketing of the products obtained directly by applying the patented process, such as the LAR products made by Pharmathen Greece. The fact that Pharmathen Greece markets and offers those LAR products in Greece is not in dispute. On that point, too, Pharmathen Global bears an allegation of infringement.

5.68 In addition, Novartis has made a sufficiently plausible case that Pharmathen Global itself has offered the LAR products worldwide through the 'Global Product Catalogue 2021' (Novartis' production 16), which lists the LAR products. Pharmathen Global is listed therein as the publisher. Pharmathen Global's contention that that catalogue is 'no longer used' cannot lead to a different judgment. Indeed, that contention does not alter the fact that Pharmathen Global did publish the catalogue and that, also given Pharmathen Global's position that it is not infringing, there is a threat that it will resume offering it. In addition, Pharmathen Global has not argued that it had already ceased using the catalogue prior to the injunction imposed by the preliminary injunction court, let alone prior to Novartis issuing the initiating summons.

Other grievances

5.69 Pharmathen Global's grievances 16-19 cannot succeed either. The grievances mainly build on the earlier grievances and should therefore be dismissed on the same grounds as those earlier grievances. The grievance against the amount of the periodic penalty payments is unfounded. Pharmathen Global has not substantiated why the maximum determined by the court in preliminary relief proceedings is too high and why a lower amount would also provide a sufficient incentive to comply with the order.

Conclusion

5.70 In conclusion, Pharmathen Global's appeal largely fails. Therefore, the court will largely uphold the judgment. Only the awarded prohibition of unlawful conduct and the awarded order to instruct Pharmathen Greece insofar as they relate to the Greek part of EP 519 will be set aside by the Court of Appeal and rejected by the Court of Appeal again. For the sake of clarity, the court notes that this annulment does not affect the awarded injunction instructing Pharmathen Greece insofar as it related to parts of EP 519 other than the Greek part.

5.71 The court of appeal will order Pharmathen Global, as the unsuccessful party, to pay the costs of the appeal. The Court of Appeal will estimate the costs on Novartis' side at € 100,000 in accordance with the agreement made by the parties. The court of appeal sees no reason to deviate from this agreement.

6 Decision

The court:

6.1 Annuls the interlocutory judgment of the court in preliminary relief proceedings in so far as, under 5.1, it orders Pharmathen to cease unlawful conduct and, under 5.3, orders Pharmathen to instruct Greece to cease the infringement of the Greek part of EP 519, and, adjudicating afresh, dismisses those claims.

6.2 otherwise upholds the judgment.

6.3 orders Pharmathen Global to pay the costs of the appeal, estimated to date at € 100,000 on the part of Novartis, plus statutory interest from 14 days after today until the date of payment in full.

6.4 declares the costs order provisionally enforceable.

This judgment was delivered by P.H. Blok, R. Kalden and A. Kamperman Sanders and pronounced in public on 15 November 2022 in the presence of the Registrar.

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[1] HR 23 January 1998, ECLI:NL:HR:1998:ZC2553 (*Lancôme/Kruidvat*), para 3.3.

[2] Regulation (EU) No 1215/2012 of the European Parliament and of the Council of 12 December 2012 on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters.

[3] Cf. ECJ 4 February 1988, C-145/86, ECLI:EU:C:1988:61 (Hofmann v Krieg).

[4] Regulation (EC) No 864/2007 of the European Parliament and of the Council of 11 July 2007 on the law applicable to non-contractual obligations.