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DISTRICT COURT OF THE HAGUE

Team Trade - preliminary relief judge

Case number / role number: C/09/653142 / KG ZA 23-730

interlocutory injunction of 13 September 2023 decision on incidental claims pursuant to art. 223 Rv[1]

in the case of

1. the legal person under foreign law
GRÜNENTHAL GMBH,
Aachen, Germany,
2. **GRÜNENTHAL B.V.,**
at Bunnik,
Plaintiffs in the main action and in the incident,
lawyer: Mr R.M. Kleemans, Amsterdam,

at

1. **TEVA B.V.**,
2. **TEVA NETHERLANDS B.V.,**
3. **PHARMACHEMIE B.V.,**
all of Haarlem, defendants
in the main action,
defendants in the incident,
Advocate: Mr A.A.A.C.M. van Oorschot, Amsterdam.

Plaintiffs will hereinafter be referred to collectively as Grünenthal (female singular) and individually as Grünenthal GmbH and Grünenthal B.V. Defendants will hereinafter be referred to collectively as Teva et al. (female singular) and individually as Teva B.V., Teva Nederland and Pharmachemie.

The case was substantively heard for Grünenthal by Mr Kleemans aforementioned, Mr A.H. van Duijn, lawyer in Amsterdam, and Dr M. Klok, patent attorney, and on behalf of Teva c.s. by the aforementioned Mr Van Oorschot, Messrs O.P. Swens, S. Moonen and M. Hendriks, advocaten te Amsterdam and Drs. J.J.M. Verbart, patent attorney.

1. The procedure

1.1. The conduct of the proceedings is evidenced by:
- The leave of the interim relief judge dated 1 September 2023 to summon in summary proceedings, with determination of a trial schedule and oral hearing on 12 September 2023;

[1] Code of Civil Procedure

- the served summons dated 4 September 2023 with exhibits EP01 to EP36;
- the statement of reply dated 6 September 2023 with exhibits GP01 to GP24;
- Grünenthal's memorandum of reply dated 7 September 2023 with exhibits EP37 to EP39;
- the deed of submission of reactive productions dated 8 September 2023 by Teva et al. with productions GP24 and GP25 (erroneously called GP11 and GP12 in the deed);
- the oral proceedings of 12 September 2023, notes of which were taken by the registrar;
- the pleading notes used by the parties at the hearing, with the understanding that margin numbers 78 to 85 of the pleading from Grünenthal's side have been crossed out because they were not pleaded.

2. The facts

2.1. Grünenthal is part of the Grünenthal Group, a German pharmaceutical company engaged in the development and production of pharmaceuticals, including a drug marketed under the brand name Nebido. Nebido was developed by Bayer AG and its production and sale was acquired by Grünenthal GmbH in 2022. Grünenthal B.V. holds the Dutch marketing authorisation for Nebido.

2.2. Nebido is a medicine with testosterone decanoate as the active substance and is used to treat long-term testosterone deficiency in men (hypogonadism). It is administered (after a start-up phase) once every 10 to 14 weeks by intramuscular (hereafter also IM) injection. The active substance, testosteroneundecanoate (hereafter also TU), is a testosterone ester. This chemical compound is converted in the body into testosterone and a by-product. Nebido, according to the Summary of Product Characteristics (hereinafter SmPC), is presented in an ampoule/injection vial containing 4 ml of solution containing 1000 mg TU (250 mg/ml) dissolved in a carrier of castor oil and the co-solvent benzyl benzoate. Of the latter compound, the medicine contains 2000 mg in total, i.e. 500 mg/ml,

2.3. European patent EP 1 457 208 B9 (hereafter EP 208 or the patent; shortly after grant, the B1 text was improved) for "*Methods and pharmaceutical compositions for reliable achievement of acceptable serum testosterone levels*" in the Dutch translation "*Methods and pharmaceutical compositions for reliable achievement of acceptable serum testosterone levels*" was granted to (a legal predecessor of) Bayer AG on 16 August 2006 for, inter alia, the Netherlands on a 15 March 2004 application, invoking priority of the Danish application DK 200300399 of 14 March 2003. Bayer AG transferred the patent in July 2022 to Grünenthal GmbH, which has been registered in the register of Octrooicentrum Nederland (hereinafter; OCNL) as the holder of the Dutch part of EP 208 since 10 February 2023. The patent expires on 14 March 2024.

2.4. Teva c.s. is part of the Teva Group, an international pharmaceutical company engaged in the manufacture and marketing of generic and innovative medicines.

2.5. On 19 December 2022, a Dutch marketing authorisation with registration number RVG 129459 was issued to Teva B.V. for a generic version of Nebido with the brand name Testosterone Teva. The SmPc of Testosterone Teva is almost identical to that of Nebido. Testosterone Teva is also approved as an ampoule/injection vial with 4 ml solution for injection containing 1000 mg TU in a castor oil carrier
and the co-solvent benzyl benzoate (in an amount of 500mg/ml). Teva c.s. intends to market this product through Teva Netherlands.

2.6. By letters dated 7 February and 12 April 2023, Grünenthal informed Teva B.V. that a market launch of Testosterone Teva would infringe EP 208. Grünenthal asked Teva B.V. to confirm that it will respect EP 208 or to explain why Testosterone Teva does not infringe EP 208. There has been no response to this.

2.7. By judgment of the German Bundespatentgericht of 1 February 2023, the German part of EP 208 was annulled, also in the form of several requests for relief that were before it (departing from the limited claims) for lack of inventiveness. Grünenthal has appealed against this judgment.

2.8. In a letter dated 26 June 2023, the Minister of Health, Welfare and Sport announced that Nebido and Testosterone Teva will be designated as interchangeable medicines on Appendix 1A of the Health Insurance Regulations with effect from 1 October 2023, allowing health insurers to designate either of them as a preferred medicine for sole reimbursement within that cluster of the drug reimbursement system.

2.9. By judgment of the High Court of Justice of England and Wales (Patents Court) on 24 July 2023, the English part of EP 208 was quashed at first instance. The English court concluded:

i) The obviousness attack from von Eckardstein and the documents to which it cross-refers fails.
ii) All the claims of the Patent as proposed to be amended either conditionally or unconditionally are insufficient for lack of plausibility across their scope and therefore invalid.

In that case, the patent as granted and an application for relief were before us.

2.10. By letter of 24 August 2023, Teva B.V., in response to the summons of 7 February 2023, informed Grünenthal that it intends to include Testosterone Teva in the October 2023 update of the G-Standard, which will be published on 19 September 2023, and subsequently offer it in the Netherlands. Teva c.s. argued that this does not constitute an infringement of EP 208, because the Dutch part of EP 208 is invalid due to lack of inventive step and/or post-workability. It referred to the aforementioned German and English rulings.

3. The dispute in the main case

3.1. Grünenthal claims - in summary - in so far as possible enforceable:

1. An injunction to cease and desist (in)direct infringement of EP 208 in the Netherlands, in particular a prohibition to manufacture, offer, put into circulation, use, import or stock Testosterone Teva for that purpose;
2. a prohibition against acting unlawfully towards Grünenthal, in particular by refraining from inducing, permitting, approving, facilitating, promoting, or provoking related entities, third-party distributors and/or intermediaries to infringe, or knowingly profiting from, such infringement, in particular by refraining from approving to use, or making available, its marketing authorisations for Testosterone Teva, or using them itself for infringement;
3. imposition of a penalty of €100,000 for each day (part) that Teva c.s. fails to comply with the injunction and prohibition under 1 and/or 2 or of €10,000 for each infringing product;
4. order Teva et al. jointly and severally to pay the legal costs pursuant to section 1019h Rv, plus statutory interest;
5. setting the time limit under section 1019i Rv at six months.

3.2. Grünenthal bases its claims on the fact that Teva c.s. threatens to infringe EP 208 with its intended market launch of the generic drug Testosterone Teva, which falls within the scope of protection of (in these proceedings limited claims 1, 2 and 5 to 7 of) the Dutch part of EP 208.

3.3. Teva et al. put forward a defence seeking the dismissal of the claims and an order that Grünenthal pay the costs of the proceedings under section 1019i Rv.

4. The dispute in the 223 Rv incident

4.1. Grünenthal claims - in summary - as far as possible enforceable by way of provisional relief for the duration of the proceedings:

1. conditionally (to the extent no final judgement is rendered on or before 29 September 2023): a provisional injunction against infringement in the Netherlands, under penalty;
2. (at the hearing of 12 September 2023 by oral judgment:) an order to remove Testosterone Teva from the G-Standard for the duration of the proceedings, on pain of a penalty of €250,000 for each day (part) that Teva c.s. breaches this order.

4.2. Grünenthal bases its provisional claims on what is stated above in 3.2 is included. It also bases its second provisional claim on the fact that 13 September 2023 at 17:00 is the last opportunity to remove Testosterone Teva from the October 2023 G-Standard. This follows from the G-Standard 2023 production schedule which lists this as the last moment for "submission" of mutations. The balancing of interests in this case means that, pending a ruling in these interim proceedings, the status quo should be maintained.

4.3. Teva et al. put forward a defence seeking dismissal of the claims.

4.4. The parties' contentions are discussed in more detail below, as far as relevant.

5. The review

5.1. The provisional claim under 1 will be dismissed in this partial judgment. Since the interim relief judge (in the main action) will render judgment on 26 September 2023, or at least before 29 September 2023, the condition under which the provisional claim was brought has not been met, nor does Grünenthal have an interest in a provisional injunction.

5.2. The provisional claim under 2 will be (largely) awarded in this partial judgment as expressed in the operative part. This means that the situation that Teva Testosterone is not in the G-standard, and is therefore not offered, will continue, at least until final judgment is rendered in these preliminary relief proceedings. The balancing of interests between the parties is the reason for this, as explained below.

5.3. It is not in dispute that the last opportunity to remove Testosterone Teva from the October 2023 G-Standard is today at 17:00. This follows from the G-Standard production schedule submitted by Grünenthal. Grünenthal argues that its interest in removal lies in the fact that it will immediately suffer irreparable damage as soon as Teva et al include its generic product Testosterone Teva in the G-Standard. As a result of the announcement of the introduction of a generic alternative to Nebido, insurers will want to renegotiate the price immediately. This is all the more true given the Minister's clustering decision mentioned in 2.8 above. The sales value of Nebido will then immediately decrease, given the preference policy and the related established lower price at which the product will be reimbursed and which customers will immediately start to anticipate. This effect, Grünenthal argues, will also occur, albeit possibly to a lesser extent, if its claims in the main proceedings are upheld in these interim proceedings. In that case, Testosterone Teva will no longer be able to be removed from the October 2023 G-Standard, but a 'V' of 'expired' will (have to) be placed after Testosterone Teva in the G-Standard (with or without simultaneous notice to subscribers). The mere fact that it was included therein will, also given the still only short patent term, mean that customers will anticipate Teva Testosterone becoming available. This will lead to price erosion and possible loss of sales.

5.4. Teva et al counter this with its interest in bringing a generic medicine to market as soon as possible, at least before the patent expires in March 2024. If the provisional injunction sought is granted and it is now deprived of the opportunity to include Teva Testosterone in the October 2023 G-Standard, a final judgment dismissing Grünenthal's claims, i.e. a preliminary final judgment that the patent is not valid, will delay that by at least a month.

5.5. Teva c.s., when asked, has not been able to make concrete what damage it will suffer as a result, let alone that it would be irreparable. It appeared at the hearing that there are no concrete indications that third parties are also in the process of obtaining a marketing authorisation for a similar generic product. Following a

final judgment in these interim proceedings, it will be able to have the product included in the November 2023 G-standard; the cut-off date for notification of new products for that update is, according to the Production Schedule G-standard, 3 October 2023 and therefore after the judgment in the main case. If appropriate, it will be able to recover from Grünenthal any damages resulting from a one-month delay.

5.6. The interim relief judge also took into account - with reference to established case-law[2] - that Grünenthal has a very substantial interest in maintaining the status quo, as Testosterone Teva has not yet been included in the G-Standard and is not yet actually on the market. Finally, the circumstance that since February 2023 Grünenthal has made attempts to obtain clarity about the market launch of Testosterone Teva with the aim of stopping it by invoking its patent weighs in the balance. This is not in dispute. Teva c.s. has apparently deliberately chosen not to respond until 24 August 2023, informing Grünenthal that it intends to include Testosterone Teva in the October 2023 update of the G-Standard, with the aforementioned closure for filing mutations today, because it considers the patent to be just now valid. In its own words, Teva c.s. waited so long because it wanted to wait for the aforementioned German and English judgments. Whatever the case, this does not in any case explain why it did not respond at all for six months (even after a reminder in April) and waited another month even after the latest ruling (by the English court).

5.7. On this state of affairs, the balance of interests falls in Grünenthal's favour. Teva et al. will therefore be ordered to have Testosterone Teva removed from the G-Standard of October 2023, which will be published on 19 September 2023, pending the final judgment in these summary proceedings.

5.8. The decision in respect of the costs of the proceedings and in respect of the claims in the main action is stayed until 26 September 2023.

6. The decision

The preliminary relief judge

6.1. orders Teva c.s. to remove (or cause to be removed) Testosterone Teva from the October 2023 G-Standard with immediate effect and in any event **before 17:00 on 13 September 2023**, on pain of forfeiture of an immediately payable penalty payment of €250,000 for each day or part of a day that this prohibition is violated in whole or in part;

6.2. Declares this judgment provisionally enforceable;

6.3. reserves any further decision.

This judgment was rendered by Mr M.E. Kokke and publicly pronounced on 13 September 2023.

[2] E.g. District Court of The Hague 1 March 2017, ECLI:NL:RBDHA:2017:1907 (Lilly v Sandoz)