

Hamburg District Court

Ref.: 315 O 28/24



Interim injunction

In the matter

- 1) **Biogen GmbH**, represented by the Managing Director, Carl-Zeiss-Ring 6, 85737 Ismaning, Germany

- Applicant re 1) -

- 2) **Biogen Netherlands B.V.**, represented by the Managing Director Alexander Johannes den Har- tog, Prins Mauritslaan 13, 1171 LP Badhoevedorp, The Netherlands

- Applicant re 2) -

Counsel for 1 and 2:

Rechtsanwälte **Sträter**, Kronprinzenstraße 20, 53173 Bonn, Gz.: 00136/23 DI/DI

against

STADapharm GmbH, Stadastr- 2-18, 61118 Bad Vilbel

- Defendant -

Authorised representative:

Lawyers **Preu, Bohlig & Partner, Munich**, Leopoldstraße 11a, 80802 Munich, Germany, ref. no.: 010095-23/PCZ/KBR

the Regional Court of Hamburg - Civil Chamber 15 - by the presiding judge at the Regional Court Harder, the judge at the Regional Court Dr Lauritzen and the judge Neumann on 16 April 2024:

1. **By way of an interim injunction** - for reasons of urgency and without an oral hearing - the defendant is **prohibited from** being imprisoned for up to six months (maximum fine of EUR 250,000.00 in each individual case; maximum imprisonment of two years in total) in order to avoid a fine to be determined by the court for each case of infringement and in the event that this cannot be collected,

in the course of trade for the purposes of competition, the finished medicinal products

dimethyl fumarate Stada enteric-coated hard capsules in the strengths 120 mg and 240 mg and/or to place them on the market and/or to advertise them and/or to have them advertised.

2. Orders the defendant to pay the costs.
3. The amount in dispute is set at € 67,000,000.00 (sixty-seven million euros).

Reasons:

With regard to the facts of the case, reference is made to the application dated 9 February 2024, the documents submitted with it and the other mutual written submissions.

The formal requirements for the issuance of this preliminary injunction are met. The matter is urgent for the applicants, even if the presumption of urgency of Section 12 (1) UWG does not apply in the present case, as no "claims based on this law" (sc . of the UWG) are correctly asserted - as will be explained in relation to the merits. Urgency within the meaning of Sections 935, 940 ZPO exists if there is an objectively justified risk that a change in the status quo could frustrate or impede the realisation of the applicants' rights by means of a judgment obtained in the main proceedings, including its enforcement (*Becker in: Anders/Gehle, ZPO, 82nd edition 2024, Section 935 para. 6*). The applicants have made it credible that the defendant has been offering the generic Stada 120 mg and 240 mg enteric-coated hard capsules in the Lauer tax since 1 April 2023, which is why their continued marketing protection is at risk and waiting until a decision on the merits would have serious adverse effects on their legal interests, since the marketing protection expires on 3 February 2025 in any case and no (legally binding) judgment can be obtained until then. Although the applicants (only) filed this application on 9 February 2024, they did not pursue the proceedings too hesitantly (cf: BGH GRUR 2017, 1017 (1022) - *Raltegravir*). The applicants have credibly demonstrated that the defendant - unlike other competitors - respected the ten-year marketing protection in favour of the applicants. The further (and last) year of marketing protection, which only began on 2 February 2024 and is the subject of the present proceedings, represents

This constitutes a new circumstance that revives the urgency (cf: Han- seatisches Oberlandesgericht Hamburg, judgement of 11 August 2005, Ref.: 5 U19/05, para. 25, cited in juris - *Startguthaben*).

Contrary to the opinion of the defendant, the applicant under 1) also has standing for the injunctive relief sought. The defendant rightly points out that Article 14(11) of Regulation (EC) No 726/2004 refers to the authorisation holder as the holder of the marketing protection right. However, the Chamber shares the legal opinion of the applicants that a generics manufacturer who places a generic product on the market before the expiry of the marketing protection, contrary to Art. 14 para. 11 Regulation (EC) 726/2004 or Section 24b para. 1 sentence 2 AMG, can be held liable both by the rights holder and by the company that holds exclusive marketing rights (sc . the applicant re 1)). The distributor can assert its own claim for injunctive relief and, if applicable, damages.

The application is successful on the merits and the interim injunction is to be issued as requested.

Although the parties to the proceedings are competitors, the claim for injunctive relief does not arise from Sections 3a, 3, 8 UWG in conjunction with Art. 14 (11) Regulation 726/2004 or

§ Section 24b para. 1 sentence 2 AMG, as the applicants believe. According to Section 3a UWG, only anyone who violates a statutory provision that is also intended to regulate market behaviour in competition in the interests of market participants and the violation is likely to significantly impair the interests of competitors, other market participants or consumers is acting unfairly. In this sense, Art. 14 para. 11 Regulation 726/2004 and Section 24b para. 1 sentence 2 AMG do not constitute *market* behaviour rules. Rather, they are market *access* regulations that prevent companies from entering the market regardless of market behaviour (BGH, judgement of 10 November 2022, ref.: I ZR 16/22, para. 20, cited in juris - *Stickstoffgenerator*). These include, among other things, economic governance standards that define the framework conditions of competition or are intended to keep certain companies out of certain markets in order to protect companies operating in a certain market from unwanted competition (BGH, judgement of 8 November 2018, ref.: I ZR 108/17, para. 27, cited in juris - *Deutschland-Kombi*). Art. 14 para. 11 of Regulation 726/2004 and Section 24b para. 1 sentence 2 AMG are intended (for a time) to prevent so-called "competition restrictions".

protect originators from unwanted competition. This is because Section 24b para. 1 sentence 2 AMG, which implements Art. 14 para. 11 Regulation 726/2004, grants the originator - in this case the applicants - a period of protection during which it can exclusively use and commercialise the knowledge it has gained (see *Heßhaus* in: Spickhoff, Medizin- recht, 4th edition 2022, Section 24b, para. 3). In this way, the legislator creates a practical concordance between the legitimate interests of the prior applicant in an exclusive market position and the interest in the use of already acquired medical and pharmacological knowledge for third parties (ibid, para. 2). Finally, Art. 14 para. 11 Regulation 726/2004 and Section 24b para. 1 sentence 2 AMG do not have a dual function. In addition to their *market* access function, they do not also fulfil a function regulating market *behaviour*. It is true that such provisions may also be covered by Section 3a UWG (see BGH, judgement of 25 April 2002, ref.: I ZR 250/00 -, BGHZ 150, 343-353, para. 21, cited in juris - *Elektroarbeiten*). In the present case, the standards infringed by the defendant have no further competitive protective function beyond (temporary) market exclusivity.

The injunctive relief follows from Sections 823 para. 2 BGB, Art. 14 para. 11 VO 726/2004 and Section 24b para. 1 sentence 2 AMG, Section 1004 para. 1 BGB by analogy. The provisions of Art. 14 para. 11 VO 726/2004 and § 24b para. 1 sentence 2 AMG constitute protective laws within the meaning of § Section 823 para. 2 BGB (cf. *Nack/Kühne* in: GRUR Int. 2018, 1152 - *The marketing exclusivity under pharmaceutical law: an unrecognised IP right?*). Marketing exclusivity does not merely confer a subjective public right, but an absolute right in the sense of a specific industrial property right under pharmaceutical law (GRUR Int., loc. cit.). The applicants can invoke this property right, as marketing protection for their medicinal product still exists until 3 February 2025. Pursuant to Art. 14 para. 11 Regulation 726/2004 and Section 24b para. 1 sentence 2 AMG, the medicinal product Tectifera has been protected for eleven years since 3 February 2014, i.e. until 3 February 2025. In this respect, the European Commission's implementing decision of 2 May 2023 has a binding effect on the Chamber. According to Article 2 of the same decision, "*on t h e basis of the scientific elements in Annex IV to this Decision [...] the marketing protection pursuant to Article 14(11) of Regulation (EC) No 726/2004 shall be extended for the additional year. The marketing protection shall expire eleven years after the entry into force of Implementing Decision C(2014) 601*

final of the Commission on 3 February 2014 ." The implementing decision is an administrative act which, in principle, has the effect of establishing the facts, on the basis of which authorities, courts and public law entities not involved in the administrative procedure must also base their own decisions on the regulation made in the administrative act without examining the content of the correctness of the regulation made therein, whereby the factual effect of the administrative act generally begins with its adoption and not only with its incontestability or finality (BGH, judgement of 04.08.2020, Ref.: II ZR 174/19 -, BGHZ 226, 329-349, para. 35, cited from *juris*). The effect of the facts is limited by the nullity of the administrative act (OLG Frankfurt, judgement of 08.07.2021, ref.: 6U 126/20, para. 35, cited in *juris* - *Hustensaft*). In the case of legal acts of an institution of the European Union, the principles underlying the decision of the ECJ, judgement of 22 October 2010, case no. C 304/09, cited in *juris* - *Zuckerfabrik Süderdithmarschen* and *Zuckerfabrik Soest* , namely (1.) the existence of serious doubts as to the validity of the act, (2.) the risk that the implementation of the act would cause serious and irreparable damage, (3.) the consideration of the Union's interest and (4.) compliance with the decisions of the European courts. In the opinion of the ECJ, the defendant is in any case not threatened with serious and irreparable damage, as it could suffer financial damage in the event of enforcement of the European Commission's implementing decision of 2 May 2023, but this could be compensated (see order of the Vice-President of the Court of First Instance of 2 February 2024, para. 92, Annex AST 8d). The Chamber agrees with this legal understanding. Insofar as the defendant refers to a decision of the Finnish licensing authority of 19 March 2024, this is not relevant for the present decision due to the recorded European legal requirements. The defendant violated the applicants' right to marketing protection pursuant to Section 24b (1) sentence 2 AMG and Art. 14 (11) Regulation 726/2004 by including their preparations in the Lauer-Taxe before its expiry and thus placing them on the market. As the defendant has not issued a cease-and-desist declaration with a penalty clause in response to the applicants' warning, there is a risk of repetition.

The costs result from Section 91 (1) sentence 1 ZPO, the determination of the value in dispute is based on the plausible information provided by the applicant (Section 51 (2), (4) GKG).

Notice of legal remedies:

An objection can be lodged against the interim injunction. The objection is not subject to a time limit.

The objection is to the

Hamburg District Court
Sievekingplatz 1
20355 Hamburg

to raise.

The objection must be lodged in writing by a lawyer.

An appeal may be lodged against the determination of the value in dispute if the value of the object of the appeal exceeds 200 euros.

The complaint must be lodged within **six months** with the

Hamburg District Court
Sievekingplatz 1
20355 Hamburg

to insert.

The time limit begins when the decision on the merits of the case becomes final or the proceedings are otherwise settled. If the amount in dispute has been determined later than one month before expiry of the six-month period, the appeal may still be lodged within one month of service or informal notification of the determination decision. In the case of informal notification, the decision is deemed to have been published on the third day after posting.

The appeal must be lodged in writing or by declaration for the record at the registry of the aforementioned court. It may also be declared for the record before the registry of any local court; however, the deadline is only met if the record is received by the above-mentioned court in good time. The co-operation of a lawyer is not required.

Legal remedies can also be submitted as an **electronic document**. A simple e-mail does not fulfil the legal requirements.

Legal remedies submitted by a lawyer, a public authority or a legal entity under public law, including the associations formed by it to fulfil its public duties, must be submitted **as an electronic document**, unless this is temporarily impossible for technical reasons. In this case, transmission shall remain permissible in accordance with the general provisions, whereby the temporary impossibility must be substantiated at the time of the substitute submission or immediately thereafter. The electronic document must be submitted upon request.

Electronic documents must

- be provided with a qualified electronic signature of the person responsible or
- signed by the person responsible and submitted via a secure transmission channel.

An electronic document bearing a qualified electronic signature of the person responsible may be transmitted as follows:

- on a secure transmission channel or
- to the court's electronic court and administrative mailbox (EGVP) set up for the receipt of electronic documents.

Reference is made to Section 130a (4) of the Code of Civil Procedure with regard to secure transmission channels. With regard to the other requirements for electronic communication with the courts, please refer to the Ordinance on the Technical Framework Conditions for Electronic Legal Transactions and on the Special Electronic Mailbox for Public Authorities (Electronic Legal Transactions Ordinance - ERVV) as amended and to the website www.justiz.de.

Harder

Presiding judge at
the regional court

Dr Lauritzen

Judge
at the district court

Neumann

Judge



For the accuracy of the transcript
Hamburg, 17.04.2024

Heinelt, JAng
Clerk of the Registry

Document signed
by: Heinelt, Justice of the Free and
Hanseatic City of Hamburg
on: 17.04.2024 10:44

