4b O 43/24

Pronounced on 02.27.2025

Beihof, judicial employee
acting as recording clerk of
the court registry

Regional Court of Düsseldorf

IN THE NAME OF THE PEOPLE

Judgment

In the civil matter

of **Ellodi Pharmaceuticals, L.P.**, represented by the managing director John Fraher, Suite 200, 325 Sentry Parkway, Building 5 West, PA 19422 Blue Bell, United States,

Claimant,

Legal representatives: Osborne Clarke, Innere Kanalstraße 15, 50823 Cologne,

against

Dr. Falk Pharma GmbH, represented by the managing directors Philipp Argast, Dr Kai Pinkernell, Dr Andreas Rascher and Torben Zachmann, Leinenweberstraße 5, 79108 Freiburg,

Defendant,

Legal representatives: Rechtsanwälte rospatt Rechtsanwälte PartGmbB, Emanuel-Leutze-Straße 11, 40547 Düsseldorf,

Dr. Falk Pharma v. Ellodi Pharmaceuticals
IPR2025-00054
Dr. Falk Pharma Ex. 1121

the 4b Civil Chamber of the Regional Court of Düsseldorf, following the oral hearing of February 13, 2025, by the Presiding Judge at the Regional Court Dr Voß, the Judge at the Regional Court Dr Schröder and the Judge Dr Janich,

has decided as follows:

I. The action is dismissed.

II. Upon the counterclaim of the defendant and counterclaimant it is declared

1. that the "Settlement Agreement" of 29/06–03/07/2022 does not prohibit the defendant and counterclaimant from initiating or conducting inter partes review (IPR) proceedings against US protective rights of the claimant

   which belong to the same patent family as a patent in a European country which is a contracting member state of the European Patent Organization and which relates to Jorveza (Budesonide ODT) and/or APT-1011 (Fluticasone propionate ODT), including such patents that concern (i) corticosteroids for treating inflammatory diseases of the gastrointestinal tract, (ii) corticosteroids for treating eosinophilic oesophagitis, (iii) budesonide, fluticasone, flunisolide, ciclesonide, mometasone, beclomethasone, toxicortol, or their salts, esters or solvates, for treating eosinophilic oesophagitis and/or (iv) methods

   for their manufacture or use;

2. that the claimant and counter-defendant is obliged to compensate the defendant and counterclaimant for all loss caused and yet to be caused to it by the initiation of US proceedings 1:24-cv-01392 before the US District Court for the Eastern District of Virginia, Alexandria Division.

III. The costs of the proceedings are borne by the claimant.

IV. The judgment is provisionally enforceable against the provision of security in the amount of 110% of the sum to be enforced in each case.

Facts

The claimant asserts claims against the defendant in relation to so-called “inter partes review” proceedings (hereinafter: IPR proceedings) initiated before the US Patent and Trademark Office (hereinafter: USPTO) against the US patent with publication number US 8,771,729 B2 (hereinafter: US ’729). By way of counterclaim the defendant seeks, via an intermediate declaratory action, a declaration that it cannot be prohibited from initiating IPR proceedings and, via a declaratory action, a declaration that it has claims for damages against the claimant due to further proceedings pursued by the claimant before a US court.

The parties are pharmaceutical companies and competitors in the field of products for the treatment of eosinophilic oesophagitis. The claimant is the developer of an orally disintegrating tablet containing fluticasone propionate and designated “APT-1011”. The defendant markets in Europe a product under the name “Jorveza”, which is an orally disintegrating tablet with the ingredient budesonide. Both preparations are dosage forms of corticosteroids used to treat inflammatory diseases of the gastrointestinal tract, primarily the upper gastrointestinal tract, in particular the oesophagus.

Both parties hold several technical protective rights in this technical field, and in the past there were numerous patent and utility model disputes between the parties. The defendant had filed oppositions to patent grants at the European Patent Office (hereinafter: EPO), and vice versa. Similarly, the claimant had pursued claims against

the defendant for patent infringement (Regional Court of Mannheim, ref. 7 O 75/19, concerning EP 2 482 822 B1) and utility model infringement (Regional Court of Düsseldorf, ref. 4c O 10/19, concerning DE20201018594U1). The claimant's patent EP 2 482 822 (hereinafter: EP '822) was declared invalid by the European Patent Office.

To settle the disputes, the parties entered into negotiations, in the course of which, in addition to a so-called "Term Sheet" (exhibit rop2), various drafts of a settlement agreement were exchanged in advance. The parties then concluded a Settlement Agreement on July 3, 2022 (see exhibit K1, with German translation exhibit K1a; hereinafter: Settlement Agreement).

The Settlement Agreement contains, in clause 1.4, a definition of the term "Patent", which reads as follows:

> *"Patent" shall mean any patent application or patent relating to Jorveza (Budesonide ODT) and/or APT-1011 (Fluticasone propionate ODT), including Patents addressing (i) corticosteroids to treat inflammatory disorders of the gastrointestinal tract, (ii) corticosteroids to treat eosinophilic esophagitis, (iii) budesonide, fluticasone, flunisolide, ciclesonide, mometasone, beclomethasone, toxicortol, or salts, esters or solvates thereof, to treat eosinophilic esophagitis and/or (iv) methods of manufacturing or uses of thereof, in any European country that is a contracting member state of the European Patent Organization. This includes all of the following categories of patents and patent applications, and their national equivalents: provisional, utility, divisional, continuation, continuation-in-part, and substitution applications; utility models, re-issue, re-examination, renewal and extended patents, and patents of addition, and any supplementary protection certificates, restoration of patent terms and other similar rights.*

Clause 2.4 contains a *covenant not to sue* with the following content:

Ellodi covenants, on behalf of itself, its Affiliates and its successors and assigns, not to sue the other Party, or its Affiliates (except on the basis of representations and obligations expressly included in this Agreement) or their respective vendors, suppliers, manufacturers, developers, distributors, contractors, partners, hosts, customers and end-users for direct or indirect infringement of a Patent with respect to making, having made, using, selling, offering for sale, or importing Jorveza (Budesonide ODT) in a European country under the jurisdiction of the European Patent Organization. Falk covenants, on behalf of itself, its Affiliates and its successors and assigns, not to sue the other Party, or its Affiliates (except on the basis of representations and obligations expressly included in this Agreement) or their respective vendors, suppliers, manufacturers, developers, distributors, contractors, partners, hosts, customers and end-users for direct or indirect infringement of a Patent with respect to making, having made, using, selling, offering for sale, or importing APT-1011 (Fluticasone propionate ODT) in a European country under the jurisdiction of the European Patent Organization. Upon execution of this Agreement, the covenant not to sue provided in this Agreement shall be irrevocable, and in the event of any accusation of breach of this Agreement, the sole and exclusive remedy available to the accusing Party shall be compensatory damages proximately caused by said breach.

Clause 2.5 governs a non-challenge obligation (*Covenant Not to Challenge*) of the parties, which reads as follows:

Each Party covenants, on behalf of itself, its Affiliates and its successors and assigns, not to challenge the validity, or otherwise pursue any claims, challenges, demands, obligations, liabilities, damages, costs, fees, expenses, actions, causes of action, or suits at law or in equity, related to the validity of the Patents of the other Party as defined above under 1.4. This covenant includes, but is not limited to, filing an opposition or third party observations, in any country under the jurisdiction of the European Patent Organization. Upon execution of this Agreement, the covenant not to challenge provided in this Agreement shall be irrevocable, and in the event of any accusation of breach of this Agreement,the sole and exclusive

remedy available to the accusing Party shall be compensatory damages proximately caused by said breach.

In clause 3.10 the parties agreed to the exclusive local jurisdiction of the Regional Court of Düsseldorf and the application of German law (*Choice of Law and Venue*):

This Agreement shall be governed and construed in accordance with the laws of Germany, without regard to choice-of-law or conflicts of law principles. Each Party hereby consents to the exclusive jurisdiction and venue of the courts in Düsseldorf, Germany, in any action arising out of or relating to this Agreement.

In addition, clause 3.11 further addresses *jurisdiction*:

Any action arising out of, or relating to, any of the provisions of this Agreement shall be brought and prosecuted only and exclusively in Dusseldorf, Germany, or if such court does not have jurisdiction or will not accept jurisdiction, in any court of general jurisdiction in Germany.

In May 2024 a dispute arose between the parties about the scope of the Settlement Agreement, in particular concerning the geographical scope of clause 2.5 (all following, unspecified clauses are those of the Settlement Agreement). At that time the defendant approached the claimant seeking to extend the Settlement Agreement to worldwide application and announced that otherwise it would initiate IPR proceedings before the USPTO with the aim of revoking US ’729.

After no agreement was reached, on 22 July 2024 the defendant filed with the USPTO a petition for IPR against the patent US ’729 for the purpose of examining validity, under Case No. IPR2024-01197. The patent US ’729, of which the claimant is proprietor, is a patent filed on October 1, 2010 which claims the priority of the US *provisional application* 61/247,642 filed on 1 October 2009. EP ’822, filed on 30 September 2010 under (European) application number 10821232.5, similarly claims the priority of this *provisional application*. The underlying PCT application WO 2011/041509 A1

(hereinafter: WO ’509), the European patent EP ’822 and the US patent US ’729 are all members of the same patent family. The invention in each case concerns “orally administered corticosteroid compositions”.

The claimant then initiated proceedings before the US District Court for the Eastern District of Virginia, Alexandria Division (hereinafter: District Court), which comprised a principal action and a motion for a preliminary injunction for breach of the Settlement Agreement. The court there dismissed the motions as inadmissible.

The claimant objects to the IPR proceedings initiated by the defendant before the USPTO. It argues that US protective rights such as US ’729 are also covered by the Settlement Agreement and that the initiation of the IPR proceedings constitutes a breach of the Settlement Agreement.

In its view, clause 1.4 covers not only EP ’822 but also US ’729, which is a national equivalent of EP ’822. The definition encompasses any patent application or patent relating to Jorveza and/or APT-1011 and is not limited to proceedings in countries within the scope of the European Patent Organization. Disputes in those countries were indeed the occasion for concluding the Settlement Agreement, but were not intended to form its territorial boundary.

The claimant applies

I. to order the defendant to withdraw the petition for the conduct of an inter partes review against the US patent with publication number US 8,771,729 B2, filed by the defendant on July 22, 2024 at the United States Patent and Trademark Office under Case No. IPR2024-01197;

II. to declare that the defendant is obliged to compensate the claimant for all damage incurred by the claimant as a result of the initiation of the inter partes review on 22 July 2024 at the United States Patent and Trademark Office against the US patent with publication number US 8,771,729 B2, Case No. IPR2024-01197.

The defendant applies

for the action to be dismissed.

It argues that the US IPR proceedings named by the claimant in the claim application do not fall under clause 2.5 in two respects. First, the proceedings do not concern one of the objects mentioned in that clause, because US ’729 is not a patent in a European state that is a member state of the European Patent Organization, but a US patent. Second, it is not proceedings in a country under the jurisdiction of the European Patent Organization.

The defendant further submits that it has an interest in an intermediate declaratory judgment that, beyond the IPR proceedings at issue here under Case No. IPR2024-01197, it may also bring further IPR proceedings before the USPTO.

It was not obliged, prior to taking a measure which, in the view of one of the contracting parties, is not permitted under the Settlement Agreement, to clarify by way of an action for a declaration before the court competent under clause 3.11 whether this measure was permitted under the Settlement Agreement or not. This applies to any conceivable court proceedings, thus also to applications for interim injunctions.

Moreover, costs were incurred by it—the defendant—through the proceedings set in motion by the claimant before the US District Court for the Eastern District of Virginia. The claimant had no reason to bring court proceedings against the defendant in the USA. For, under clause 3.11, this court here has exclusive jurisdiction for disputes arising out of or

relating to the Settlement Agreement. Against this background the claimant is obliged, pursuant to sections 280(1), 249(1) of the German Civil Code (BGB), to pay damages for breach of contract. The defendant suffered loss through the initiation of the proceedings before the US court because it had to bear the legal costs thus incurred. In US civil proceedings— even in the event of success—reimbursement of legal costs is not provided for.

By way of counterclaim the defendant applies

I. for a declaration that the “Settlement Agreement” of 06.29/07.03.2022 does not prohibit the defendant from initiating or conducting inter partes review (IPR) proceedings against US protective rights of the claimant

which belong to the same patent family as a patent in a European country which is a contracting member state of the European Patent Organization and which relates to Jorveza (Budesonide ODT) and/or APT-1011 (Fluticasone propionate ODT), including (i) corticosteroids for treating inflammatory diseases of the gastrointestinal tract, (ii) corticosteroids for treating eosinophilic oesophagitis, (iii) budesonide, fluticasone, flunisolide, ciclesonide, mometasone, beclomethasone, toxicortol, or their salts, esters or solvates, for treating eosinophilic oesophagitis and/or (iv) methods

for their manufacture or use;

II. for a declaration that the claimant is obliged to compensate the defendant for all loss caused and yet to be caused to it by the initiation of US proceedings 1:24-cv-01392 before the US District Court for the Eastern District of Virginia, Alexandria Division.

The claimant applies

for the counterclaim to be dismissed.

The claimant argues that under clause 3.11 the defendant was obliged, in the event of a disagreement about the interpretation of the Settlement Agreement, first to obtain a judicial clarification.

As to the declaratory action for damages, the claimant argues that there has been no breach of duty on its part. Interim injunction proceedings do not fall within the scope of the Settlement Agreement at all, because they do not bring about a final determination. Moreover, by filing the motion for a preliminary injunction the claimant merely reacted "on the spot", for reasons of effective legal protection and equality of arms in procedure, to the initiation of the IPR proceedings by the defendant in breach of contract.

At the very least the defendant is acting abusively. The defendant behaves inconsistently in that by initiating the IPR proceedings in the USA it itself disregarded the clear jurisdiction agreement in the Settlement Agreement, but now, in the context of the counterclaim, reproaches the claimant for not complying with the same.

Alternatively, the amount of the damages claim should be reduced due to contributory negligence on the part of the defendant.

Grounds for the decision

The action is admissible but unfounded. The counterclaim, by contrast, is admissible and well-founded.

A

The admissible action is unfounded.

I.

The action is admissible.

1.

International and local jurisdiction of the Regional Court of Düsseldorf follows from Article 25 of the Brussels Ia Regulation in conjunction with clause 3.11 of the Settlement Agreement.

a)

The Brussels Ia Regulation applies pursuant to Article 1 thereof. The Hague Convention on Choice of Court Agreements does not take precedence over the applicability of the Brussels Ia Regulation because the USA, where the claimant has its seat, has not ratified that Convention.

b)

Within the meaning of Article 25(1), first sentence, of the Brussels Ia Regulation the parties agreed that a court of a Member State of the Brussels Ia Regulation is to decide on a future dispute arising from a specific legal relationship.

Clause 3.11 contains a jurisdiction agreement under which the Regional Court is to have jurisdiction for all actions arising out of or in connection with the Settlement Agreement. That is the nature of the action here. In the present dispute the claimant seeks, based on the Settlement Agreement, withdrawal of a petition for the conduct of IPR proceedings and a declaration of the defendant's liability for damages on the ground that the petition for the conduct of the IPR proceedings breaches the defendant's obligations under the Settlement Agreement.

c)

The formal requirements under Article 25(1), third sentence, have been met.

d)

Nor does Article 24(4) of the Brussels Ia Regulation preclude the prorogation undertaken here. Under that provision, exclusive jurisdiction applies, for proceedings which have as their object the validity of patents, in favor of the courts of the Member State in whose territory the deposit or registration has been applied for or effected or is deemed to have

been effected by virtue of a Union act or an international convention. The Settlement Agreement does not govern the conduct of such proceedings, but the mutual obligation to refrain from them.

2.

The application under head II is further admissible as a declaratory action pursuant to section 256 of the Code of Civil Procedure (ZPO).

a)

The application seeks a declaration as to a legal relationship.

In principle, subjective rights of all kinds are capable of being the subject of a declaration, including contractual obligations under the law of obligations (MüKoZPO/Becker-Eberhard, 6th ed. 2020, ZPO, section 256, para. 11). Such a relationship is present here. The claimant submits that it has against the defendant, under the Settlement Agreement, a claim for payment of damages due to the initiation of the IPR proceedings in dispute. This is an obligation under the law of obligations.

b)

A legal interest in a declaration is also present.

This is the case where the claimant's right or legal position is subject to a present danger or uncertainty and a declaratory judgment is suitable to remove that danger (MüKoZPO/Becker-Eberhard, loc. cit., para. 39 with further references). A danger regularly lies in the defendant seriously disputing the claimant's right (MüKoZPO/Becker-Eberhard, loc. cit., para. 42 with further references). The defendant denies any breach of its contractual obligations under the Settlement Agreement by initiating the IPR proceedings before the USPTO. As the claimant cannot yet quantify the loss incurred by the IPR proceedings, but the application for performance under head I would clarify questions in dispute between the parties as to the basis of the claim, and without a declaration of the damages claim the limitation of that claim cannot be precluded, the declaratory judgment sought, despite the lack of enforceability in the main, is the most appropriate means to finally clarify the issues in dispute between the parties (cf. MüKoZPO/Becker-Eberhard, loc. cit., para. 47).

II.

The action is unfounded.

The claimant has no claim to withdrawal of the IPR proceedings under clause 2.5 in conjunction with sections 280(1), 249(1) BGB and the principles of natural restitution, or on any other basis. Both the interpretation of clause 2.5 and of clause 1.4, which must be examined incidentally (see below, no. 1), show that the Settlement Agreement did not preclude the initiation of the IPR proceedings. There is no room for a supplementary interpretation of the contract (see below, no. 2). Accordingly, the claimant also has no claim for damages against the defendant.

1.

Pursuant to clause 3.10 the Settlement Agreement is to be interpreted under German law. Accordingly, sections 133 and 157 BGB governing contract interpretation are applicable. These are parallel, in principle equal-rank and complementary provisions which are also to be applied alongside one another in the interpretation of contracts. Both provisions form the methodological basis both for simple (explanatory) interpretation, which primarily focuses on the true intention of the declaring parties, and for supplementary interpretation, which serves to fill gaps in legal transactions, in particular based on normative criteria (MüKoBGB/Busche, 10th ed. 2025, section 133 BGB, para. 20). Contractual provisions and other legal arrangements are to be understood in such a way that they do not amount to a unilateral imposition of interests but allow appropriate consideration of the interests of the respective other party. A comprehensive balancing of the parties' interests is therefore required (MüKoBGB/Busche, 10th ed. 2025, section 157 BGB, para. 7). Moreover, courts may also take into account other external circumstances that reflect the parties' intention from the perspective of an objective observer at the time the contract was concluded (Jauernig/Mansel, 19th ed. 2023, section 133 BGB, para. 3). The burden of pleading and proof for such supplementary facts lies with the party that seeks a contract interpretation deviating from the written wording, if the other party disputes this (Federal Court of Justice (BGH) NJW 1999, 1702, headnote).

The starting point for interpretation is the language of the contract (MüKoBGB/Busche, 10th ed. 2025, section 133 BGB, para. 63). Thus, the English wording of the Settlement Agreement is decisive. This and the fact that the claimant is a US company do not, however, lead to any departure from the interpretative standard under German law applicable here pursuant to clause 3.10. This is merely a circumstance to be taken into account in contract interpretation.

Considering all the circumstances, it follows that the Settlement Agreement does not preclude the initiation of IPR proceedings against a US patent before the USPTO.

The non-challenge obligation set out in clause 2.5 obliges the parties not to contest the other party's patents. The subject of the "non-challenge" is therefore the patents referred to in clause 1.4, which include only the patents in the member states of the EPC.

a)

The first sentence of clause 1.4 defines, first, the material scope by specifying exhaustively which patents with what content are covered by the Settlement Agreement. Second, it already determines the geographical scope of the agreement with the words "*in any European country that is a contracting member state of the European Patent Organization*". It concerns patents in those countries that are member states of the European Patent Organization (hereinafter referred to as "member state"). No restriction is made to national parts of European patents or patent applications, so that simply all patents—including "purely national" ones—in these countries are meant.

The second sentence of this clause states that (the patents mentioned in the first sentence) include all categories of patents and patent applications specified in more detail, as well as their national equivalents. Only the national parts of European patents can be meant by the national equivalents. Admittedly, such clarification would not have been necessary because those national parts already fall under the definition in the

first sentence. After all, the national parts of European patents are each patents in a European country that is a member of the European Patent Organization. This additional and thus superfluous mention of “national equivalents” does not, however, lead to an extension of the scope of the Settlement Agreement to any patents that belong to the same patent family as one of the patents falling directly under sentence 1 of clause 1.4 but were filed in a country that is not a member state of the European Patent Organization.

There is no indication that “national equivalents” could mean patents in states other than the member states of the European Patent Organization referred to in sentence 1 of clause 1.4. Sentence 2 of clause 1.4 begins by stating that “the following categories of patents and patent applications, and their national equivalents” shall be covered. Various categories of patents as well as utility models are then listed, thereby expressly defining the material scope. This is made clear in particular by the mention of utility models, which are not materially equivalent to a patent but are to be covered by the Settlement Agreement. The provision is plainly not designed to extend the geographical scope laid down in sentence 1.

Moreover, that scope would not only be extended beyond what is clearly set out in sentence 1 of clause 1.4 to an indeterminate number of further states, but this would also be inconsistent with the preamble. The preamble expressly refers to several disputes between the parties at that time. These include primarily oppositions filed before the European Patent Office, but also an action for nullity of a utility model concerning a German utility model and patent infringement proceedings before the courts in Mannheim and Düsseldorf. The preamble states that the parties wish to settle these proceedings by agreement. These are therefore all disputes before the EPO or the courts of the member states that were to be settled. By concluding the Settlement Agreement the parties pursued the settlement of these disputes and the prevention of such disputes in the future. They evidently considered it necessary only to create a regulation limited to the member states.

Nor does a different interpretation follow in light of further circumstances. The claimant argues that it is a US company and that the Settlement Agreement is written in English. Therefore, one must think “internationally” and interpret the contract accordingly. Specifically, it submits that the categories of patents and patent applications mentioned in sentence 2 of clause 1.4 exist, in part, only under US patent law. Whether that is indeed the case and to what extent the terminology is also found in connection with patents or patent applications in the member states is irrelevant for contract interpretation. Even if one assumed that it is standard wording under US law, that wording may have been included so that the claimant, as a US company, would find itself reflected in the agreement and be sure that all types of patents or patent applications—familiar to it— in the EPO member states are covered. In no event is the inclusion of such wording—albeit customary under US law—apt to extend the geographical scope of the non-challenge obligation to an indeterminate extent. Against this background there was no obligation for the court to obtain expert advice due to the need to interpret a contract in the English language (cf. BGH NJW 1987, 591 (592) in a case concerning the interpretation of a clause commonly used in international contracts).

Nor does the negotiation history permit the conclusion that the parties mutually proceeded on the basis of a broader scope of the non-challenge obligation. In particular, the so-called *Term Sheet* lists “Europe” under *Territory*, though this was still to be discussed (*Exact list of countries to be discussed*). No binding conclusion can therefore be drawn from it as to the scope of the geographical application. The same applies to the fact that one of the drafts discussed whether the law of the US State of Pennsylvania should apply and jurisdiction be vested “only and exclusively in the United States District Court for the Eastern District of Pennsylvania”. Ultimately, the parties agreed bindingly on the application of German law, so earlier considerations of that nature play no role.

Insofar as the original draft of the Settlement Agreement contained the term “foreign equivalents” in section 1.4 and the parties later replaced this with “national equivalents”, this similarly serves only to underline the parties’ common intention to limit the scope to the member states.

b)

Nor does clause 2.5 lead to a different interpretation. This clause clarifies that the non-challenge undertaking includes the filing of an opposition or third-party observations in a country under the jurisdiction of the European Patent Organization, but is not limited to this. Considered in isolation—irrespective of the question whether and where a comma appears—this clause is not unequivocal to the extent that the absence of limitation could refer to the filing of an opposition or third-party observations, with the result that other than these attacks on validity could also be meant; or the absence of limitation could refer to the geographical scope, with the result that attacks on validity in countries outside the European Patent Organization could also be meant. Alternatively, the absence of limitation might relate to both.

From the context of sentence 1 of clause 2.5, however, it follows that the geographical scope was not intended to be extended without restriction. For sentence 2 of clause 2.5 refers expressly to “*this covenant*”, that is, to the covenant already mentioned in sentence 1. That covenant, in turn, refers solely to the other party’s patents. The scope of that term is— as already established—limited to patents in the member states.

In that regard, the list in sentence 2 of clause 2.5 is to be understood as non-exhaustive to the effect that there may be further means of challenging a patent in the member states, and it was intended to ensure that *all* forms of challenge are excluded.

This is also consistent with clause 2.4 of the Settlement Agreement. The covenant not

to sue states that the parties undertake not to bring actions against the other party in a European country under the jurisdiction of the European Patent Organization. The geographical scope thus exactly matches that of the non-challenge obligation. If one were not to limit the geographical scope of the non-challenge obligation to patents of the member states, but were to limit the scope of the covenant not to sue, this would lead to a contradiction that is not in the mutual interest of the parties. In that case the claimant could proceed against the defendant in countries in which the latter would be prevented from challenging the validity of the respective protective right.

2.

As it corresponded to the clear, common intention of the parties to limit the scope of the Settlement Agreement to patents in the member states, the Settlement Agreement similarly affords no basis, by way of supplementary contract interpretation pursuant to sections 133, 157 BGB, for a claim by the claimant against the defendant to withdraw the IPR proceedings.

B

The counterclaim brought by the defendant is admissible and well-founded.

I.

The counterclaim application under head I is admissible and well-founded as an intermediate declaratory action.

1.

The counterclaim application is admissible.

a)

As set out above under section A I, the court seized is locally and subject-matter competent here as well. For the defendant bases the claims asserted by way of counterclaim on the Settlement Agreement, which contains a valid prorogation in favor of the court seized.

The counterclaim application under head I seeks a declaration of the non-existence of

a legal relationship that is prejudicial for the principal applications. The declarable legal relationship lies in the non-existence of the prohibition on initiating IPR proceedings—namely with regard to the patents materially covered by clause 1.4.

b)

The requisite prejudiciality with regard to the application under head I is also given. By way of an intermediate declaratory action under section 256(2) ZPO, a declaration is sought in pending proceedings as to a prejudicial legal relationship, i.e. a legal relationship on the existence or non-existence of which the decision in the main proceedings wholly or partly depends. Prejudiciality under section 256(2) ZPO replaces the otherwise required legal interest in a declaration under section 256(1) ZPO.

Directly prejudicial for the present proceedings is the defendant's application for a declaration that the conduct of IPR proceedings before the USPTO is prohibited under the Settlement Agreement only insofar as the specific proceedings with Case No. IPR2024-01197 are concerned. For practical grounds it appears appropriate to treat the entire declaratory action in accordance with application I as an intermediate declaratory action (Stein/Roth, 24th ed. 2024, section 256 ZPO, para. 11). This appears particularly appropriate here because, as regards the interpretation of the non-challenge obligation, the IPR proceedings with Case No. IPR2024-01197 are no different from other IPR proceedings.

2.

The counterclaim application under head I is also well-founded. In that respect full reference can be made to the submissions on the action, according to which IPR proceedings before the USPTO are not covered by the Settlement Agreement and are thus not prohibited.

For the sake of clarity the defendant's application was adjusted in the operative part, because in the form recorded in the transcript it was grammatically incorrect. In any event the defendant sought a declaration with regard to the patents that fall materially under clause 1.4. This clarification does not entail any substantive change in scope.

II.

The application by the defendant for a declaration as to the claimant's liability for damages in principle is similarly admissible and well-founded.

1.

The counterclaim application under head II is admissible. The prorogation in favor of the Regional Court of Düsseldorf is effective. This leads to the consequence that the questions of the existence and content of contractual secondary claims arising from this jurisdiction clause are also to be determined by the Regional Court of Düsseldorf (BGH, NJW 2020, 399, para. 21).

2.

The counterclaim application under head II is also well-founded.

As established above under section A I, the Settlement Agreement validly chose German law as the applicable law.

The defendant has a claim against the claimant for damages under section 280(1) BGB in conjunction with clause 3.11 for reimbursement of the costs incurred from the proceedings before the District Court. The claimant undertook to assert claims under the contract exclusively before the Regional Court of Düsseldorf. It culpably breached this duty by bringing the action before the District Court, section 280(1) BGB. Consequently, the claimant must compensate the costs incurred, section 249(1) BGB (BGH, loc. cit., para. 22).

Clause 3.11 creates between the parties an obligation within the meaning of section 280(1) BGB that obliged them to bring actions under the contract exclusively before the Regional Court of Düsseldorf (cf. BGH, loc. cit., para. 24).

An obligation backed by damages to seize a particular court is not only, in principle, legally possible (BGH, loc. cit., paras 25 et seq.), but was also agreed here by clause 3.11. That clause is to be interpreted to the effect that the parties are obliged to bring any action arising out of or in connection with the Settlement Agreement only before the Regional Court of Düsseldorf. Moreover, clause 2.5, at its end, explicitly provides that, in the event of a breach of provisions of the Settlement Agreement, damages may be claimed. There is no indication that this obligation to pay damages should not also apply to a breach of the jurisdiction agreement. Irrespective of that, a separate provision on damages was not necessary, since the jurisdiction agreement itself is to be interpreted as meaning that breach of this duty gives rise to a claim for damages under section 280(1) BGB (cf. BGH, loc. cit., paras 41 et seq.).

The claimant is responsible for its breach of duty. There is nothing to indicate that it could exculpate itself, section 280(1), second sentence, BGB. Where a company such as the claimant consciously agrees to the application of German law, it is, from its objectively recognizable perspective, out of the question that it could rely on not being liable, under the "American rule of costs", for the opponent's costs of legal defense in the event of breaches of the jurisdiction clause (BGH, loc. cit., para. 49). In this respect the claimant acted at least negligently, because it disregarded the care required in the circumstances, section 276(2) BGB, and it must have the fault of its lawyers imputed to it (cf. BGH, loc. cit., paras 55 et seq.).

There is no contributory negligence on the part of the defendant. It had neither a duty nor a secondary obligation, prior to initiating the IPR proceedings, to bring an action for a declaration. Such an action would have been possible for it, but it was not obliged to do so. Since the IPR proceedings initiated by the defendant do not fall under the Settlement Agreement, it was not prevented from initiating those proceedings before

the USPTO and did not therefore have to obtain prior clarification by way of a declaratory action. Nor can the prior out-of-court correspondence give rise to such an obligation.

C

The decision on costs is based on section 91(1) ZPO.

The amount in dispute is set, under sections 45(1), 51(1) of the Court Fees Act (GKG), at EUR 1,500,000.00.

Dr Voß	Dr Schröder	Dr Janich
Presiding Judge at the Regional Court	Judge at the Regional Court	Judge

I, Vlasta Đurina, hereby certify that the attached document is, to the best of my knowledge and belief, a true and accurate translation from German into English:

February 27, 2025 Verdict from *Ellodi Pharmaceuticals, LP v. Dr. Falk Pharma GmbH*, Düsseldorf Regional Court, Case No. 4b O 43/24, Patent Litigation Chamber, Werdener Str. 1, 40227 Düsseldorf, Germany.

I declare under the penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Vlasta Đurina	18 November 2025
Signature	Date

Vlasta Đurina

Name

Translator (MTPE)

Title