

Pregabalin and Fulvestrant - a comparison of German and English liability regimes for Swiss-type claims in light of current case law¹

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The most recent decision of the Düsseldorf Appeal Court (OLG Düsseldorf) in the legal dispute concerning the active substance *Fulvestrant* (GRUR 2019, 279) is a contribution to concretisation of the new liability criteria which the court clearly formulated for the first time in the “*Östrogenblocker*” decision of 5 May 2017 (GRUR 2017, 1107). According to this decision, the liability of a generic drug manufacturer no longer depends on a “manifest arrangement” (*sinnfällige Herrichtung*) of their products. While German case law is moving away from a narrow interpretation of the scope of protection, the UK Supreme Court case law is heading in the opposite direction. In a dispute over the active ingredient *Pregabalin*, the UK Supreme Court clarified, in its ruling of 14 November 2018, that the manufacturers’ liability does not depend on the foreseeability of the protected use of the compounds, as the previous instance had assumed.

I. Introduction

In recent years, German and European patent courts have been increasingly occupied with patents for a second medical indication. The focus has been on the connection between the formulation of so-called Swiss-type-claims and the resulting scope of protection. The starting point of the case law in Germany, which has meanwhile come to a wide interpretation of the scope of protection - in a patentee-friendly manner -, was the legal action regarding the active substance *Pregabalin*

which came before the Hamburg Regional Court⁴. The proceedings concerned the use of generic *Pregabalin* outside its marketing authorisation (so-called cross-label use) as a result of discount agreements. According to sec. 129 para. 1 sentence 2 and sentence 3 of the German Social Code, Book V (SGB V) the conclusion of such contracts results in generic substitution in pharmacies. The traditional German determination of the scope of protection of Swiss-type claims, by way of manifest arrangement (for example by way of formulation and dosage, packaging, labelling, patient information leaflet and/or Summary of Product Characteristics (SmPC) of the product directed towards the patented use)⁵, made it more difficult for patent proprietors to enforce their industrial property rights. Omitting the patented indication in the instructions for use pursuant to sec. 11a para. 1e Medical Products Act (AMG) (so-called carve-out) seemed to be sufficient to avoid liability. The cross-label applications of generic drugs therefore made it necessary to consider an extended liability criterion in the realm of second medical use patents.⁶

What began with the *Pregabalin* decision by the Hamburg Regional Court, which found the manufacturers liable for indirect patent infringement and attributed to them the substitution of generic drugs by pharmacies⁷, was clarified in the Appeal Court Düsseldorf’s “*Östrogenblocker*” decision of 5 May 2017 as well as in the Appeal Court Düsseldorf’s “*Dexmedetomidin*” decision of 1 March 2018.⁸ However, the liability criterion established here leads

1 A German version of this article “Zwischen Pregabalin und Fulvestrant, Ein Vergleich des deutschen und englischen Haftungsregimes bei Swiss-type claims anlässlich aktueller Rechtsprechung” was published in the journal GRUR 2019, p. 260 et seq.

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4 Hamburg Regional Court, GRUR-RS 2015, 08240 – Rabattvertrag (Discount Agreement).

5 cf. German Federal Court (BGH) GRUR 1977, 652, 653 – Benzolsulfonylharnstoff.

6 In the literature, there has already been demands for a further interpretation of manifest arrangement, see von Falck/Gundt, Commemorative Publication 80 Jahre Patentgerichtsbarkeit (80 Years of Patent Jurisdiction) Düsseldorf, 2016, p. 113, 124.

7 Hamburg Regional Court, GRUR-RS 2015, 08240 – Rabattvertrag (Discount Agreement).

8 Concerning case law development, see Cepl/Paheenthararajah, ‘Durchsetzung von Second-Medical-Use-Patenten nach der “Östrogenblocker” – Rechtsprechung des OLG Düsseldorf’ (2018) GRUR-Prax 225; Schäffner, ‘Der Schutzbereich von Second Medical Use-Patenten II, Entwicklung im Lichte von “Lyrica”, “Pemetrexed”, “Östrogenblocker” und “Verwendungspatent”/“Glasfaser II”’ (2018)

only theoretically to better protection for patent proprietors. With its decision of 5 July 2018, the Düsseldorf Regional Court has shown that the requirements for demonstrating these individual liability criteria can be stringent. The judgment was upheld by the Court of Appeal. The appeal court's decision contains initial clarification on the liability requirement of "sufficient scope of use".

Occasioned by this recent decision of the Düsseldorf Appeal Court, the following discussion first intends to analyse the legal dispute concerning the active substance *Fulvestrant* and concomitant case law developments in the field of second medical use patents (II.). Secondly, it draws a comparison between this recent decision and the latest development in liability criteria in England following the Supreme Court's decision in the *Pregabalin* case (III.).

II. Dispute concerning *Fulvestrant*

The subject of the proceedings was European patent EP 1 272 195 B1. This concerns the use of the active substance *Fulvestrant* in the treatment of resistant breast cancer ("*Use of Fulvestrant in the treatment of resistant breast cancer*"). Claim 1 of the patent reads:

"Use of fulvestrant in the preparation of a medicament for the treatment of a patient with breast cancer who previously has been treated with an aromatase inhibitor and tamoxifen and has failed with such previous treatment."

Fulvestrant is a specific anti-oestrogen with a high affinity for oestrogen receptors. Unlike conventional non-steroidal, anti-oestrogens, this active ingredient has no agonistic, oestrogen-like activity and is thus more efficacious in the treatment of breast cancer. This is a so-called "third-line therapy". The patentee, who markets its *Fulvestrant* drug under the name *Faslodex*[®], opposed the offering and marketing of generic medicinal products for therapeutic use in the patient group claimed by the patent.

1. Düsseldorf Appeal Court, Decision of 5 May 2017

What first caused a stir in this lawsuit complex was the Appeal Court Düsseldorf's "*Östrogenblocker*" decision

handed down on 5 May 2017. Here the court upheld the Düsseldorf Regional Court's rejection of the patent proprietor's application for an interim injunction, citing lack of urgency.⁹

In these proceedings, the Appeal Court for the first time expressly stated its position on new liability criteria in the field of second medical use patents, which in the opinion of the Court resulted from a dogmatically stringent application of the German Federal Court's (BGH) earlier case law. The court pointed out that the BGH had already clarified in its "*Kollagenase I*"¹⁰ decision and, at the very latest, in its judgment in the "*Pemetrexed*"¹¹ case that manufacturing use claims should be treated as purpose-limited product claims.¹² Due to the limited protection of the substance as a result of the purpose limitation, a direct utilisation of the use patent can only exist if the product being offered or marketed has the requisite therapeutic purpose. This could be done actively in the form of a manifest arrangement. However, there is no limitation to this form of infringing activity. To establish infringement of second medical use patents, it is only important that the necessary purpose-limitation for the protected active substance is ensured. In this context, the court formulated the following new liability criteria¹³:

1. The product must be suitable for the patented purpose.
2. The distributor must take advantage of circumstances which, in a manner similar to an active manifest arrangement, ensure that the product being offered or marketed is used for the specified therapeutic purpose. This requires a sufficient and not only occasional use, as well as the relevant knowledge or at least disregard of such knowledge by the supplier acting in bad faith.

In the opinion of the court, a manifest arrangement is unnecessary, especially if even external conditions, such as those present in the case of cross-label use, already leads to a patented therapeutic use of the product.¹⁴

The court also based its "*Dexmedetomidin*" decision on this extended liability criterion.¹⁵

GRUR 449; Schneider/Lindenthal. 'Erweiterer Haftungsmaßstab bei Second Medical Use Patenten – und jetzt?' (2018) PharmR 461.

9 Düsseldorf Appeal Court, GRUR 2017, 1107 – Östrogenblocker; see annotations on the judgment by Neuhaus, GRUR 2017, 1111.

10 German Federal Court GRUR 2014, 461 – Kollagenase I.

11 German Federal Court GRUR 2016, 921, 926 – Pemetrexed.

12 Düsseldorf Appeal Court, GRUR 2017, 1107, 1109 – Östrogenblocker.

13 Düsseldorf Appeal Court, GRUR 2017, 1107, 1110 (para. 39) – Östrogenblocker.

14 Ibid

15 Düsseldorf Appeal Court. 'Zum Schutzzumfang und zur Verletzung sogenannter zweckgebundener Stoffschutzpatente im Pharmabereich – Anmerkung zu OLG Düsseldorf, Urteil vom 01.03.2018 - I - 2 U 30/17' (2018) PharmR 306 – Dexmedetomidin; see the commentary by Czertitz/Thewes, PharmR 2018, 433.

2. Düsseldorf Regional Court, Judgment of 5 July 2018

After the patentee's immediate appeal before the Appeal Court concerning their request for an interim injunction had failed, it pursued its claim in a principal action. However, the Düsseldorf Regional Court saw no infringing activity in the market presence of generic compounds and therefore dismissed the patentee's action.¹⁶

In its reasoning for the decision, the Regional Court for the first time applied the Appeal Düsseldorf's new liability criterion described above. In particular, the parties disputed the criterion concerning sufficient scope of use. The Regional Court based its decision on an interpretation of the patent claim according to which the unsuccessful treatment could be either a palliative or an adjuvant¹⁷ breast cancer therapy.¹⁸ However, it could not be established that the contested embodiment was used to a sufficient extent in palliative therapy after failure of treatment with both *Tamoxifen* and an aromatase inhibitor. The court found that the data provided by the patentee to substantiate sufficient scope of use was not conclusive. Another argument against the frequency of use of *Fulvestrant* is the fact that a new class of active substances for the treatment of breast cancer had in the meanwhile been approved in Europe, as a result of which the guideline recommendations for the early detection, diagnosis, treatment and aftercare of breast carcinoma were also changed. In particular, the extension of market authorisation for Faslodex[®] to include the use of *Fulvestrant* as a monotherapy and as a combination therapy in combination with *Palbociclib* is evidence of a departure from previous use practices.¹⁹

3. Düsseldorf Appeal Court, Judgment of 9 January 2019

With its judgment of 9 January 2019, the Appeal Court upheld the Regional Court's decision to the effect that a sufficient scope of use could not be proven by the patentee.²⁰ In doing so, the Senate addressed for the first time the question of the exact extent to which preparation-free usage must take place to give rise to

liability. In the case of cross-label use, it cannot be that only a use which exclusively or almost exclusively concerns the patented use is relevant for liability. Rather, the decisive factor must be the certain knowledge or disregarding knowledge that the marketing of the medicinal product will actually lead to patent-compliant prescribing and usage of the product. It is a matter for the court to decide (i) that there has been patent-compliant use to a sufficient extent and (ii) that the generic company could not have been completely unaware of this fact. The probability of such a judicial finding increases with the number of patent-compliant use cases that have demonstrably occurred.

As a further liability scenario, the Senate cited the following circumstance: the particular outstanding benefits of the patented use compared to other therapeutic purposes would have to practically demand use of the medication in accordance with the patent.²¹ In the case of prescription-only medicines, the prescription practice decides which is billed within the content of the resources available to the doctor when prescribing. Experience has clearly shown that the physician would prescribe individual drugs only on the basis of the particular SmPC. In the case of skinny labelling, a generic medication would therefore also not be prescribed in the patented field.²²

Although it was no longer important in the present case, the Senate in its final analysis pointed out one more difficulty in the area of liability without manifest arrangement. The absence of manifest arrangement would have an effect on the necessary recurrence risk with regard to injunction liability. In the case of a manifest arrangement, every single case of infringement, even an initial and single infringement, would generally underscore the threat of future recurrence. However, if the distributor has not carried out any preparatory measures and if its liability is only tied to an actual prescribing practice corresponding to the protected mode of use, an injunction will only be considered if also at the time of the oral proceedings a liability-relevant prescribing routine can still be determined. In the case of a changing prescribing practice, an injunction would be precluded, since in this case the reference point is not

16 Düsseldorf Regional Court, judgment dated 5.7.2018 – 4c O 46/17, BeckRS 2018, 15431; see on this decision, the article by Schneider/Lindenthal. 'Erweiterter Haftungsmaßstab bei Second Medical Use Patenten – und jetzt?' (2018) PharmR 461, 463.

17 Adjuvant therapy begins after the breast cancer has been surgically removed and is carried out only as an accompanying measure to surgical procedure. Palliative therapy begins with a manifest tumour, usually at the metastatic stage.

18 Düsseldorf Regional Court, judgment dated 5.7.2018 – 4c O 46/17, BeckRS 2018, 15431; concerning the parallel proceeding, see Düsseldorf

Regional Court judgment dated 5.7.2018 – 4c O 10/18 BeckRS 2018, 15603.

19 Düsseldorf Regional Court, judgment dated 5.7.2018 – 4c O 46/17, BeckRS 2018, 15431.

20 Düsseldorf Appeal Court, GRUR 2019, 279 – Fulvestrant. Regarding the parallel proceeding, see Düsseldorf Appeal Court, GRUR-RS 2019, 182.

21 Düsseldorf Appeal Court, GRUR 2019, 129 (para. 44).

22 Ibid (para. 45).

the infringer's behaviour, but rather the prescribing practice as an external condition.²³

4. Evaluation

The decisions of the Düsseldorf Regional Court and the Appeal Court make it clear that the patentee-friendly developments with regard to the classification of the Swiss-type claims as purpose-limited product claims and the departure from a rigid adherence to a manifest arrangement as a form of infringement, do not automatically lead to simpler patent enforcement. The reasons for this are both factual and legal in nature.

Through the suitability and sufficient scope of use criteria, the Appeal Court Düsseldorf has introduced balancing considerations into the question of infringement, which must be fleshed out in order to avoid legal uncertainty. The Regional Court's decision has made it clear that especially sufficient scope of use calls for substantiated evidence. It is incumbent upon the patentee to provide such concrete evidence. In the case of *Fulvestrant* this was not achieved.

Some legal uncertainty has been caused by extending the liability criteria in the area of injunctive relief with respect to what constitutes the requisite risk of recurrence. In the case of manifest arrangement, the mention of the patented indication in the patient information leaflet or the SmPC, for example, may constitute a risk of recurrence. If, however, the liability of generic manufacturers is predicated on external circumstances, the Appeal Court rightly points out that such circumstances are outside the manufacturer's direct sphere of influence. Substitution of medicinal products is carried out in the pharmacies on the basis of sec. 129 para. 1 sentence 2, sentence 3 SGB V. Exclusion of substitution can only occur by the attending physician checking the "aut idem" box on the respective prescription. However, generic manufacturers have no contractual relationship with physicians on the basis of which they could exert influence.²⁴ Nonetheless, by entering into discount agreements or participating in so called "open-house" procedures, manufacturers can at least indirectly influence the ultimate substitution in the pharmacy in favour of their products. A risk of recurrence could be inferred from the fact that such contracts will be entered into again in the future, without there being market segmentation between patented and patent-free indications, including additional

information to physicians from the health insurance funds regarding the patented-protected indications.²⁵ But this too can only apply to the case of the original prescription practice. Accordingly, the patent proprietor, in asserting their protective rights, in addition to proving suitability and a sufficient scope of use of the infringing compound, must also prove that there will be sufficient medical use for it in the future. Ongoing contractual arrangements for discount agreements in which no distinction is made between patent-free and patent-protected indications could be a possible indication of this.

III. The judgment of the UK Supreme Court in the matter of *Pregabalin* of 14 November 2018

The Appeal Court Düsseldorf's "Östrogenblocker" and "Dexmedetomidin" decisions also received attention in the *Pregabalin* proceedings before the UK Supreme Court. The court's decision of 14 November 2018 ended the legal dispute over European patent EP 0 934 061 B1 which protects the use of *Pregabalin* for the manufacture of a pharmaceutical composition for the treatment of (neuropathic) pain. The Supreme Court upheld the decision of the lower courts and confirmed the invalidity of claims 1 and 3 of the patent.²⁶ In Germany too, the patent in the meanwhile has been declared invalid by the Federal Patent Court.²⁷

The UK Supreme Court addressed the question of infringement only in the context of an *obiter dictum* from which it can be deduced that the court does not intend to follow Germany's patentee-friendly jurisprudential line, as appeared to be the case from the earlier Court of Appeal decision.

1. Swiss-type claims as purpose-limited process claims

The common reference point for the critical analysis of all three instances was claim 3, which is formulated as a Swiss-type claim. In the opinion of the English courts, this form of claim is a *purpose-limited process claim*, according to which it is not the product itself that is protected, but rather the manufacturing process. In this case, the question of infringement is assessed in accordance with Art. 60 para. 1 lit. c of the Patents Act

23 Ibid (para. 46).

24 cf. Schwarzer/Dörries. Düntheit schützt (nach wie vor) vor Strafe nicht (2018) Intellectual Property, 2nd edition, June 2018, p. 24, 27; Kühnen, Handbook of Patent Infringement, 11th edition 2019, cap. A para. 382.

25 See also the decision of the Düsseldorf Appeal Court Public Procurement Division, judgment dated 11.5.2016, VII-Verg 2/16, BeckRS 2016, 13255.

26 [2018] UKSC 56, para. 54, 121.

27 Federal Patent Court, judgment dated 24.1.2017 – 3 Ni 3/15.

1977²⁸, which stipulates strict liability both for the manufacturer of the product and for third parties (such as wholesalers or pharmacists).

The protection covers the manufacture of the product for the purpose of treating neuropathic pain. In the English version of the claim, this purpose-limitation arises from the formulation “*preparation of a pharmaceutical composition for treating (neuropathic) pain.*” The court decisions focused on the accurate interpretation of the word “*for*” and the related question as to what kind of internal attitude (“*mental element*”) is required to prove the liability of the generic manufacturer.

In the course of the legal dispute in the UK, this question gave birth to three different tests from the individual courts, on the basis of which the liability of generic manufacturers should be measured: the High Court’s “*subjective intention*” test, the Court of Appeal’s “*foreseeability*” test and the Supreme Court’s “*outward presentation*” test.

a. The Court of Appeal’s “*foreseeability*” test

While the High Court had argued in favour of demanding a subjective intention on the part of the manufacturer to establish liability²⁹, the Court of Appeal focused on a much broader liability criterion, and in this context formulated a “*foreseeability*” test. A first step in assessing the liability of a generic manufacturer would depend on whether the manufacturer knew or could have foreseen that at least some of the prescriptions written generically for *Pregabalin* for the treatment of pain would lead to the dispensing of a generic medicinal product. If knowledge or at least foreseeability could be affirmed, the second step would be to verify whether the manufacturer has taken all reasonable steps within its power to prevent the generic medicinal product from being used for the treatment of pain.³⁰ The court rejected the German “*only packaging will do*” approach (meaning liability as a result of manifest arrangement) as being too narrow.³¹

28 Art. 60 Abs. 1 lit. c Patents Act 1977: “Subject to the provisions of this section, a person infringes a patent for an invention if, but only if, while the patent is in force, he does any of the following things in the United Kingdom in relation to the invention without the consent of the proprietor of the patent, that is to say where the invention is a process, he disposes of, offers to dispose of, uses or imports any product obtained directly by means of that process or keeps any such product whether for disposal or otherwise”.

29 [2015] EWHC 72 (Pat), para. 100, 111.

30 [2016] EWCA Civ 1006, para. 205 et seq.

b. Supreme Court: “*outward presentation*” or “*subjective intention*”

The Supreme Court did not accept the Court of Appeal’s broad interpretation of the scope of protection for Swiss-type claims for a number of reasons. On one side, the test was found to be arbitrary with regard to the liability of third parties, such as pharmacists, since the reference point for their liability would also be foreseeability on the part of the manufacturer.³² Moreover, it was always foreseeable that despite reasonable preventive measures a small proportion of the generic *Pregabalin* medicinal products would be dispensed for the patented indication. Given this fact, all these products would be patent infringing. Consequently, any subsequent dealing with these products would justify liability pursuant to Art. 60 para. 1 lit. c Patents Act, thereby de facto extending patent protection for the patent-free indications.³³

With the second step of the “*foreseeability*” test, whereby the mental element could be negated by taking reasonable steps, the Court of Appeal had created a non-statutory defence to infringement. However, the Supreme Court noted that this is the task of the legislator.³⁴ Ultimately, the Court of Appeal’s test was found to be also legally uncertain and practically unworkable. It is not clear what steps manufactures had taken to prevent the dispensing of their products for the patented use and whether a court would consider such measures to be reasonable.³⁵

The Supreme Court also clearly distanced itself from the most recent development within German case law, whereby, particularly with the Appeal Court Düsseldorf’s “*Östrogenblocker*” decision, an extended standard of liability has now been put into practice. The Supreme Court drew attention to the different classification of Swiss-type claims within the two legal systems. While, in English case law, Swiss-type claims are classified as purpose-limited *process* claims, under German case-law they are treated as purpose-limited *product* claims.³⁶ Moreover, the court ignores the German system of prescribing and dispensing medicinal products, the regime for patent infringements or the market conditions within which a fair balance has to be struck.³⁷

31 Ibid, para.191 et seq.

32 [2018] UKSC 56, para. 79, 86.

33 Ibid, para. 79.

34 Ibid, para. 81.

35 Ibid

36 Ibid, para. 85, 168.

37 Ibid, para. 168.

Against this background, Lord Sumption and Lord Reed stated their preference for an “*outward presentation*” test.³⁸ In their view, neither the subjective nor the objective intention of the manufacturer were relevant to the question of infringement. The only decisive factor is how the product is presented after its manufacture. In addition, the contents of the patient information leaflet should be taken into account. The “*outward presentation*” test is thus similar in meaning to the German liability criterion of manifest arrangement.³⁹ This interpretation has the argument of legal certainty in its favour, and in particular strikes a fair balance between the public interest in rewarding the invention by allowing the patentee to exploit his monopoly and the public interest in the free use of the invention in the non-patent-protected area.⁴⁰

Lord Mance agreed in principle with this approach. However, he left open whether there could be cases in which a generic manufacturer would have to positively exclude the patent-protected use by a notice.⁴¹ Liability could result from the fact that a manufacturer does not make it sufficiently clear that its product is not intended for the patented purpose. In this context, he referred to Kühnen’s⁴² approach, who had previously discussed the manufacturer’s obligation to affix a warning on the product.⁴³ Lord Briggs and Lord Hodge picked up on the “*subjective intention*” test formulated by the High Court.⁴⁴ The patent proprietor could provide an evidence of a subjective intention, especially by objective evidence of conduct like patient instruction leaflets.⁴⁵ Against this background there appears to be only a marginal difference between this interpretation and the “*outward presentation*” test.

2. Evaluation

The route adopted by the Supreme Court takes the practice back to the beginnings of a European development, which initially seemed to tend uniformly towards an extended standard of liability in the area of Swiss-type-claims. The courts recognised the weaknesses associated with the use of the manifest arrangement where skinny labels are used, especially with the cross-label-use of generic drugs. In England, the Court of Appeal

responded by establishing the “*foreseeability*” test, which also gained acceptance in the Dutch jurisdiction.⁴⁶

With the Supreme Court’s decision, the recent increasingly patentee-friendly development in Europe has now come to an abrupt end. Despite the fact that the statements made on the question of infringement did not play a role in the dispute and should therefore be viewed with caution with regard to their significance for future proceedings, they make it abundantly clear that proof of foreseeability of an infringing use of the products will not suffice to establish liability on the part of the manufacturer. As a result of this ruling, patent owners in the UK will have to face considerable challenges in the future in the enforcement of their property rights, especially in the sphere of complex cross-label-use scenarios.

Even if the criticism of the “*foreseeability*” test is justified, particularly in view of the vague requirements for the manufacturer’s preventive steps, it would have contributed to a uniform European case law to be wished for in the area of liability as far as second medical use patents are concerned. For patentees, this test would have been particularly advantageous, because it is easier to prove foreseeability than to prove subjective intention as required by the High Court. Furthermore, the “*foreseeability*” test could have been the starting point for a concretisation of the required preventive measures. The German courts are also currently faced with the task of clarifying the recently created extended liability criteria, in order to provide also the manufacturers with guidelines. At any rate, clarity is currently provided to the extent that, according to German case law, a skinny label can no longer preclude liability.⁴⁷ The Court of Appeal’s “*foreseeability*” test would have had the same result. The Supreme Court’s decision has reopened this question once again and its answer will ultimately depend on the route the English courts will follow in the coming years. If the “*outward presentation*” test formulated by Lord Sumption and Lord Reed is maintained, there is strong evidence that skinny labelling can effectively exclude liability on the part of the manufacturer. The Supreme Court certainly recognised this weakness in the “*outward presentation*” test.

38 Ibid, para. 84 et seq.

39 Ibid, para. 83 et seq.

40 Ibid, para. 84.

41 Ibid, 213 et seq.

42 Presiding Judge at the Appeal Court Düsseldorf.

43 Kühnen (Fn. 24), cap. A, para. 382.

44 Supreme Court, judgment dated 14.11.2018, [2018] UKSC 56, para. 172.

45 Ibid, para. 167, 172 et seq.

46 Hoge Raad, judgment dated 3.11.2017, file ref.: 15/04934 RM/EE (ECLI:NL:HR:2017:2807), – Merck/Teva; Rechtbank Den Haag,

judgment dated 5.4.2017, file ref.: C/09/469148 / HA ZA 14-770

(ECLI:NL:RBDHA:2017:3430) – Sun/Novartis. See on this the comparative law review by Zorr, The scope of protection of patents for a second medical indication in the case of a cross-label use, p. 91 et seq.

47 Cepl/Paheentharajah. ‘Durchsetzung von Second-Medical-Use-Patenten nach der ‘Östrogenblocker’ – Rechtsprechung des OLG Düsseldorf’ (2018) GRUR-Prax 225, 227; Schwarzer/Dörries. Dünneheit schützt (nach wie vor) vor Strafe nicht (2018) Intellectual Property, 2nd edition, June 2018, p. 26 et seq.

However, in its view, it has to be tolerated that generic manufacturers, by labelling the product for one area of application but marketing it for another, could exploit the narrow protection provided by this test. In the court's opinion, it is not only the patentee's interests that should be taken into account. Moreover, these difficulties would arise directly from the inherent limitations of Swiss-type claims.⁴⁸ Finally, the Supreme Court called upon the legislature to address such issues.⁴⁹ It remains to be seen whether this appeal will be heard.

IV. Conclusion

What began with the Hamburg Regional Court's "Pregabalin" decision in 2015 changed course as a result of the "Kollagenase I" and "Pemetrexed" decisions by the BGH and has now been concretised and consolidated by the Düsseldorf Courts. The consequences of this case law for manufacturers have increasingly been discussed in the literature. In particular, there is

discussion taking place about active preventative measures, such as notifications to health insurance providers and physicians, including patent notices in pharmaceutical databases or placing warnings on packaging.⁵⁰ While the focus here is already on the legal consequences of liability, the Appeal Court Düsseldorf, in its most recent decision, raised the previous question of a risk of recurrence in the case of a new prescribing practice. Second medical use patents in the form of Swiss-type-claims will therefore continue to provide sufficient food for discussion in the future. Against this background, it would have been desirable, for both patent proprietors and generic manufacturers, to have a single liability criterion applicable to a European patent in Germany and England; these being the two most relevant patent jurisdictions in Europe. However, in view of the UK Supreme Court's *Pregabalin* ruling, at the moment a convergence of liability systems seems unlikely.

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48 Supreme Court, judgment dated 14.11.2018, [2018] UKSC 56, para. 86.

49 Ibid.

50 See Ceppl/Paheentharajah. 'Durchsetzung von Second-Medical-Use-Patenten nach der "Östrogenblocker" – Rechtsprechung des OLG Düsseldorf' (2018) GRUR-Prax 225, 227; Kühnen (Fn. 24), cap. A para. 382; Neuhaus, GRUR 2017, 1111; Schäffner. 'Der Schutzbereich von

Second Medical Use-Patenten II, Entwicklung im Lichte von "Lyrica", "Pemetrexed", "Östrogenblocker" und "Verwendungspatent"/"Glasfaser II" (2018) GRUR 449, 454; Schneider/Lindenthal. 'Erweiterter Haftungsmaßstab bei Second Medical Use Patent – und jetzt?' (2018) PharmR 461, 463 et seq.; Zorr (Fn. 46), p. 207 et seq.