

Second medical use claims and scope of protection

- A work in progress since 1984

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ABSTRACT

Second medical use patents and their claims do not only represent highly valuable inventions for both originator and generic pharmaceutical companies, but have also been a topic of debate for many years. In particular, this is due to the fact that these inventions were originally not patentable under the European Patent Convention (EPC) in 1973 and thus required a special claim formulation, known as a Swiss-type claim. The later codification of this judge-made law in the course of the revision of the EPC in the year 2000 resulted in a different claim formulation, referred to as EPC 2000 claims. Since then, the impact of these different formulations on the respective scopes of protection conferred by both claim types has been a source of controversy and as such, much discussed. More recently, with the rise of the European-wide patent litigation surrounding Warner-Lambert's patent for a substance marketed as Lyrica®, second medical use claims have also been a hot topic when it comes to infringement. The national courts, which are responsible for the enforcement of patent law in Europe, have thus been faced with the question of the scope of protection conferred by second medical use claims. Concurrently, through their decisions, the national courts also shape the scope of protection.

This article's main focus is how second medical use claims and especially their scopes of protection have developed throughout the years. It will firstly provide a short background on the importance of second medical use inventions and the necessity to allow their patentability. Following this, it will outline the origin of both Swiss-type and EPC 2000 claims while focussing on the differences in their respective scope of protection. Lastly, it will analyse the recent developments in German case law on patent infringement, as well as their impact on the scope of protection of second medical use claims.

1. THE IMPORTANCE OF SECOND MEDICAL USE PATENTS

Second medical indications occur in a number of situations. The case may be that a drug is placed on the market for a first indication and it is discovered through this use that it is also beneficial for the treatment of other illnesses; hence, if a patient has two illnesses and the drug indicated

for one of these has a positive effect on both illnesses. It could also simply be that research is continued on the drug for other therapeutic indications even after it is placed on the market for a first medical indication.¹ Such 'drug repurposing' is a common business strategy employed by pharmaceutical companies to expand the life cycle of a product.² However, further research is also conducted when a target³ is relevant for two indications. In that case, the pharmaceutical company will aim to place the product on the market as soon as they discover positive effects on one indication, in order to be the first ones to enter the market, while still continuing research regarding the second and further indications. Second medical indications can also occur when a first known use is not successful.⁴ It is also imaginable that compounds known for non-medical uses are later discovered to be effective for medical uses, as is the case for e.g. the medicinal use of marijuana.⁵

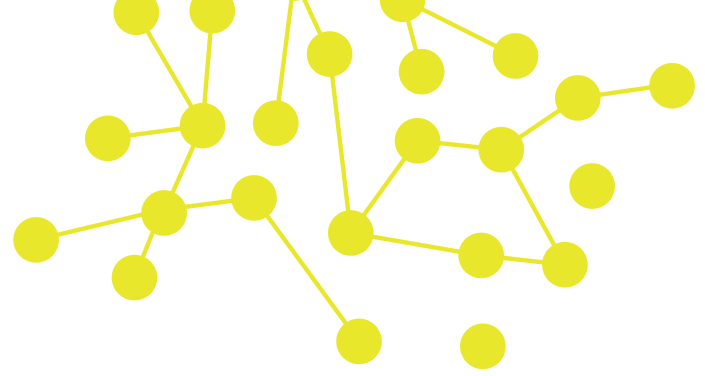
These patents may sometimes be wrongfully perceived as weak patents because the scientific progress may seem minimal to an outside observer due to the abundance of publications concerning the (already known) substance.⁶ However, from an economic perspective, they are valuable inventions that often entail high costs.⁷ As the tolerance and side effect profile of these inventions is typically already known from the first indication product, second medical use products are highly beneficial for patients.⁸ This is the reason why there was a general need in the sector to allow patentability of second medical use inventions in order to promote R&D of such medications.

2. CLAIM CONSTRUCTION OF SECOND MEDICAL USE CLAIMS

As mentioned, second medical use claims and their formulation have come a long way. To assess the differences in the scopes of protection of both Swiss-type and EPC 2000 claims, it is necessary to understand the purpose and origin of the two claim types.

2.1. Swiss-type claims

Swiss-type claims were developed by the Enlarged Board of Appeal (EBA) of the European Patent Office (EPO) in a landmark decision, G 5/83 (*Second medical indication/EISAI*).⁹ This decision circumvented certain patentability exclusions contained in the EPC 1973, which made patenting of second medical use inventions impossible. In doing so, the EBA adopted the practice of the Swiss Federal Intellectual Property Office,¹⁰ according to which second medical use inventions could be protected by a purpose-bound method claim. This claim took the form 'use of a substance or composition for the manufacture of a medicament for a specified (new) therapeutic application' and was referred to as a Swiss-type claim.¹¹



The decision of the EBA in G 5/83 was highly controversial and encountered criticism in particular regarding the ‘fundamental legitimacy’ of Swiss-type claims.¹² Another main point of criticism was that the solution was ill-conceived and did not consider the further implications of this claim format in infringement proceedings. It cannot be denied that the solution reached in G 5/83 was sub-optimal and could not have been intended as a permanent solution. It was an attempt to fit a rule that was intended otherwise to the necessities and demands of the industry.

Prior to this, the German Federal Court of Justice (the Bundesgerichtshof, BGH) developed its own approach to patenting second medical use inventions. In its *Hydropyridine* resolution¹³, it concluded that second medical use inventions should be protected through use claims and argued that the subject-matter of such a claim did not only contain the treatment of the illness in question but also the ‘manifest arrangement’. The concept of ‘manifest arrangement’, which is translated from the German term ‘*augenfällige Herrichtung*’ or ‘*sinnfällige Herrichtung*’ means the arrangement of a medicament for a specific use.¹⁴

2.2. EPC 2000 claims

After judge-made law temporarily solved the issue concerning the patentability of second medical use claims, the reformation of the EPC in the year 2000 came as an opportunity for a more permanent, legislative solution.

A common denominator of all reformation proposals was to provide legal certainty both for the national courts and for those affected by the law. Finally, the EPC drafters agreed to amend Art. 54(5) EPC so that it allowed the patentability of second medical use inventions provided

their use is novel and they fulfilled the additional patentability criteria. To differentiate them from Swiss-type claims, claims granting second medical use patents in accordance with Art. 54(5) EPC 2000 are referred to as EPC 2000 claims. These claims take the (much simpler) format: ‘Substance X for use in the treatment of condition Y’ and are purpose-bound product claims.¹⁵

2.3. The scope of protection of both claim types

The scope of protection of a claim is the crux for the strength of the patent. It is closely interlinked with the infringement of that claim. A patent holder can only enforce the patent and take action against any possible infringers as far as the patent holder enjoys protection. Determining the scope of protection is therefore necessary to provide legal certainty for the following three parties: first, for the patent holder who needs to know what the exclusive right encompasses and what he can prohibit competitors to do; second, for the competitors, who in turn needs to know what they can do and which actions constitute infringement; last, a clear determination of the scope of protection benefits the national courts since they have the exclusive jurisdiction regarding patent infringement.¹⁶ It should also be kept in mind that legal certainty about the scope of protection of a claim benefits the industry as a whole, because this will minimise the risks.¹⁷ Taking the perspective of an innovator pharmaceutical company as an example, it can be assumed that a company is more likely to invest in the costly R&D of a second medical indication medicament, if it feels confident about the scope of the legal protection concerning this medicament.

¹ Mitali Bhagwat, Geetesh Kaushik and Vijaykumar Shivpuje, ‘Second Medical Use Patenting: A Review of Practices Across Different Jurisdictions’ (2016) 21 JIPR 260, 262.

² *Ibid.* 261.

³ “Target” can be defined as the naturally existing cellular or molecular structure involved in the pathology of interest that the drug-in-development is meant to act on.

⁴ Bhagwat, Kaushik and Shivpuje (n 1) 260.

⁵ *Ibid.* 262.

⁶ Andreas von Falck and Miriam Gundt, ‘Die Verletzung von Ansprüchen auf die zweite medizinische Indikation’ in Thomas Kühnen (ed), *Festschrift 80 Jahre Patentgerichtsbarkeit in Düsseldorf* (Carl Heymanns Verlag 2016) 113, 114.

⁷ Frank-Erich Hufnagel, ‘Der Schutzbereich

von Second Medical Use Patentent’ (2014) 2 GRUR 123.

⁸ *Ibid.*

⁹ Case G 5/83 Second medical indication/EISAI [1984], ECLI:EP:BA:1984:G000583.19841205.

¹⁰ Included in the Swiss legal advice of 30 May 1984, cf Jürgen Meier, ‘European Patent Office’ in Jochen Bühling (ed), *Patent Protection for Second Medical Uses* (Wolters Kluwer 2016), 9.

¹¹ Case G 5/83 [19].

¹² Matthew Fisher, ‘Second medical indications and the Swiss-form claim: taming Frankenstein’s monster: Part 1 – solving one problem creates another’ (2017) 39 EIPR 574, 575, with reference to inter alia Julian Cockbain and Sigrid Sterckx, ‘Is the Enlarged Board of Appeal of the European Patent

Office Authorised to Extend the Bounds of the Patentable? – The G-5/83 Second Medical Indication/EISAI and G-2/08 Dosage Regime/ABBOT RESPIRATORY Cases’ (2011) 42 IIC 257, 271.

¹³ BGH NJW 1984, 663.

¹⁴ This concept will be explained in Section 3.1.1 below.

¹⁵ Meier (n 10) 10–11.

¹⁶ Jochen Bühling, ‘Germany’ in Jochen Bühling (ed), *Patent Protection for Second Medical Uses* (Wolters Kluwer 2016), 35, 49.

¹⁷ Matthew Fisher, ‘Second medical indications and the Swiss-form claim: taming Frankenstein’s monster: Part 3 – the Franken-cuckoo comes home to roost’ (2017) 39 EIPR 705, 706.

The scope of protection of both Swiss-type and EPC 2000 claims has been the topic of many discussions in the preparatory works of the EPC, but has also kept courts and researchers busy after the latter came into force in 2007.¹⁸ The main issue is that there is a discrepancy between the reasoning behind EPC 2000 claims and the *de facto* legal effect of these claims. They were introduced as a codification of the jurisprudence at the time (that had created Swiss-type claims), however, as they pertain to a different claim category than Swiss-type claims it is impossible for them to have the same scope of protection.

First and foremost, the scope of protection conferred by a claim is determined by the respective claim itself,¹⁹ and thus by its category. There are two categories of claims,²⁰ which correspond to the two categories of inventions, namely method/process claims on the one hand and product claims on the other. The difference lies in the fact that methods and processes are intangible, whilst products are tangible. As seen above, Swiss-type claims are (purpose-related) process claims and EPC 2000 claims are (purpose-related) product claims. This means that they are governed by different sections of the national patent legislation, which has consequences not only for their scope but also when it comes to infringement.²¹

Initially, both claim types co-existed and could even be combined in the same application. However, in 2010, the EBA of the EPO put an end to Swiss-type claims in their landmark decision G 2/08 (*Dosage Regime/ABBOT RESPIRATORY*).²² The board held that, following a transition period of three months after publication of the decision, second medical indication patents could only be applied for in the format provided in Art. 54(5) EPC.²³ The reasoning behind this was that Swiss-type claims had been invented to remedy a loophole in the EPC 1973, which has now been closed by the new provision of the EPC. As a result, the construct of Swiss-type claims had become redundant, or as the EBA put it: ‘when the reason of law ceases, the law itself ceases’ (*cessante razione legis, cessat et ipsa lex*).²⁴ Of course, the existing patents with Swiss-type claims are still valid until they expire out, which means that Swiss-type and EPC 2000 claims will continue to co-exist until January 2031, possibly even January 2036 if patent extensions due to Supplementary Protection Certificates (SPCs) are factored in.

After considering all these factors, it can be concluded

that, despite the intention found in the *travaux préparatoires* to the EPC, Swiss-type and EPC 2000 claims pertain to different claim categories and thus necessarily have a different scope of protection. The scope conferred by EPC 2000 claims is slightly broader since these are product claims. This finding has been confirmed in numerous EPO court decisions.²⁵ While there is no record that this was borne in mind by the drafters of the EPC, it has to be assumed that their expertise would have enabled them to consider this consequence of choosing a different claim category. The newest developments in the German jurisprudence acknowledge this by assimilating the scope of protection, whereby both types confer the scope of protection as provided by the EPC 2000.²⁶ It should also be noted that by extending the scope of protection, the situation for originator companies, which are typically the holders of second medical use patents, has improved rather than worsened. Therefore, this development is seen as ‘patent holder friendly.’²⁷ On the other hand, it should not be forgotten that while originator companies are mainly in competition with generic companies when it comes to second medical use patents, they also compete with other originator companies.²⁸ As such, they are always at risk of being potential infringers and thus strengthening the rights of patent holders may not necessarily be as beneficial for patent holders as it seems at first sight.

3. INFRINGEMENT OF SECOND MEDICAL USE CLAIMS

The relation between Swiss-type and EPC 2000 claims manifests itself in infringement cases all over Europe, as a European patent granted for all EPC member states has to be enforced at national level.²⁹ The following section will provide an analysis of the consequences of these decisions for the relation of Swiss-type and EPC 2000 claims with regard to their respective scopes of protection on the basis of German case law.

3.1. Infringement of Swiss-type claims³⁰

The underlying issue with all second medical use cases is that they require two rights to be balanced. On the one side, there is the right of the patent holder to a fair protection of the second medical use patent, and on the other side, the right of third companies to make use of the pa-

¹⁸ See for example the following articles whose titles translate to “The Scope of Protection of Second Medical Use Patents”: Hufnagel (n 7); Nina Schäffner, ‘Der Schutzbereich von Second Medical Use Patent II: Entwicklung im Lichte von “Lyrica”, “Pemetrexed”, “Östrogenblocker” und “Verwendungspatent”/“Glasfaser II”’ [2018] 5 GRUR 449.

¹⁹ Lionel Bently and Brad Sherman, *Intellectual Property Law* (4th edn, OUP 2014), 627.

²⁰ For the purpose of this study, the term “categories of claims” differentiate between process and product claims and is not to be confused with the term “types of claims”, which differentiates between, inter alia, independent and dependent claims, cf Guidelines

for Examination before the EPO, section F-IV, 3.1.

²¹ Frantzeska Papadopoulou, ‘Construction and enforceability of Swiss-type claims: The myth lives on?’ [2015] 5 NIR 479, 480.

²² Case G 2/08 *Dosage Regime/ABBOT RESPIRATORY* [2010], ECLI:EP:BA:2010:G000208.20100219.

²³ Case G 2/08, Reasons 7.1.4.

²⁴ Case G 2/08, Reasons 7.1.2.

²⁵ The EPO touched on this subject in decisions concerning double patenting or post-grand amendments of the patent pursuant to Art. 123 EPC. A detailed study of these decisions is included in the original version of this thesis.

²⁶ Armin Kühne, ‘Verletzungshandlungen bei

zweckgebundenem Stoffschutz’ [2018] 5 GRUR 456, 456.

²⁷ Matthias Zigann, ‘Infringement of Swiss-Type Second Medical Use Patent Claims in Germany - Recent Developments in Case Law’ [2017] 12 Wash. J.L. Tech. & Arts 245, 245.

²⁸ Bühling (n 16) 38.

²⁹ Sir Richard Arnold, ‘An Overview of European Harmonization Measures in Intellectual Property Law’ in Ansgar Ohly and Justine Pila (eds), *The Europeanization of Intellectual Property Law* [OUP 2013], 25, 27.

³⁰ The vast majority of the relevant case law concerns second medical use patents with Swiss-type claims, which is simply due to the time it takes for a patent to be processed.

tent-free first indications, which goes hand in hand with the right of the general public to access cheaper, generic pharmaceuticals after the patent has expired.³¹ After all, the concept of patent law is that an originator is granted exclusive rights for a specific period of time, but in return has to share the knowledge with society, which can then make use of it after that period has lapsed.³² The problem here is that a use for the separate indications cannot be strictly separated. This is due to two regulatory law factors whose explanation requires a small excursus:

The first factor to take into account is the way medications are prescribed by physicians. Most prescriptions are written generically, meaning by reference to an active substance instead of a branded product.³³ In fact, the regulatory system for prescriptions in Germany encourages physicians to prescribe generically. Every prescription contains a box with the phrase *aut idem*, which translates to 'or the same'.³⁴ If the physician does not cross it, the pharmacist is obliged to substitute this product with any other version of the medicament with the same active ingredient that is identical to the prescribed product.³⁵ This means that the standard version of a prescription is designed to allow for substitution.³⁶ Additionally, physicians face a lot of pressure from health insurance companies to not cross out the *aut idem*-box to save costs,³⁷ and even risk to be investigated if they tend to prescribe branded products.³⁸

The second factor is the substitution obligation to which pharmacists are subjected.³⁹ According to § 129(1) of the German Social Insurance Code, fifth Book (SGB V), when they are handed an *aut idem* or generic prescription, they are required to provide the least expensive product (with the mentioned active ingredient in the mentioned composition) available.⁴⁰ In most cases, this will be a generic product.

3.1.1. Purpose-bound protection and manifest arrangement

The common basis of all decisions analysed for the purpose of this section is that they all emphasise the fact that the protection conferred by a second medical use claim is purpose-bound. This special phenomenon is called *Zweckbindung* in German, which would translate to 'purpose-boundness'. This is what makes the nature of a second medical use claim. This type of patent is not awarded for the use of a substance for the manufacture of a medica-

ment but for the fact that this is done to either treat a specific illness or an illness in a specific way.⁴¹ The purposeful use of the substance is what is inventive in these cases. This was also addressed in *Antivirumittel*,⁴² a decision by the BGH from 1987. In the judgement, the Federal Court of Justice held that the use of the patented subject-matter is excluded when the purpose is neither aimed at nor achieved in a targeted way.⁴³

To sufficiently take this into account, the German courts have developed the concept of manifest arrangement as described earlier in this article. The idea behind this is that by manifestly arranging a product, it is given its purpose.⁴⁴ The need for this requisite lies in the nature of the second medical use – as the product can also be used in a non-infringing manner (for the patent-free first medical indication), the use of the product itself does not amount to an infringing behaviour. Infringement only occurs when the product is intended for use for the second medical indication. Thus, a purpose relation is necessary. Requiring the manifest arrangement of a product is a way for the courts to determine whether the potential infringer intends to use the product in the protected manner. Manifest arrangement can be seen in processes such as making into a confection ready-to-use preparation, but also in dosage or label instructions or other ways of arranging the product, when this is done with the purpose to use the product for the protected indication.⁴⁵ The following section will demonstrate how this requisite was adapted over time.

3.1.2. Skinny labelling as a 'Safe Harbour' – Ribavirin, Chronische Hepatitis C-Behandlung and Cistus incanus

The downside to having manifest arrangement as the main point of reference when finding infringement is that the latter can be avoided quite easily by the generic companies, who are the (potential) infringers in these cases. To put a generic drug on the market, they can apply for a marketing authorisation (MA) in a simplified application process, which allows references to the authorisation documents of the original pharmaceutical ('reference pharmaceutical').⁴⁶ This process allows the exclusion of certain patented indications from the summary of product characteristics (SmPC) and the package leaflet (PL).⁴⁷ This method is referred to as 'carve out' and the MA resulting from this process is then called a 'skinny label'.

However, this does not mean that they do not mention the relation between Swiss-type and EPC 2000 claims or that they are not of importance for this relation.

³¹ Stephan Neuhaus, 'OLG Düsseldorf: Zweckgebundene Stoffschutzansprüche – Östrogenblocker, m. Anm. Neuhaus' [2017] 11 GRUR 1107, 1112.

³² Bently and Sherman (n 19) 375.

³³ In the UK, 83 percent of all prescriptions are written generically, cf Papadopoulou (n 21) 481.

³⁴ Bühling (n 16) 63.

³⁵ Schöffner (n 18) 450.

³⁶ U Reese and C Stallberg, *Handbuch des Pharmarechts* (Peter Dieners and Ulrich Reese eds, 1st edn, C.H. Beck 2010), § 17

margin no 272; This is amplified by the fact that prescriptions are now created with a software, that automatically informs the physician of the substitution possibility, cf Kühne (n 26) 453.

³⁷ Hufnagel (n 7) 124; Zigann (n 27) 249; this is also the case in other countries, such as the UK, cf Matthew Fisher, 'Second medical indications and the Swiss-from claim: taming Frankenstein's monster: Part 2 – putting the problem in context' [2017] 39 EIPR 639, 640.

³⁸ Schöffner (n 18) 450.

³⁹ Zigann (n 27) 249.

⁴⁰ *Ibid.*

⁴¹ Hufnagel (n 7) 123.

⁴² BGH Antivirumittel MDR 1987, 932.

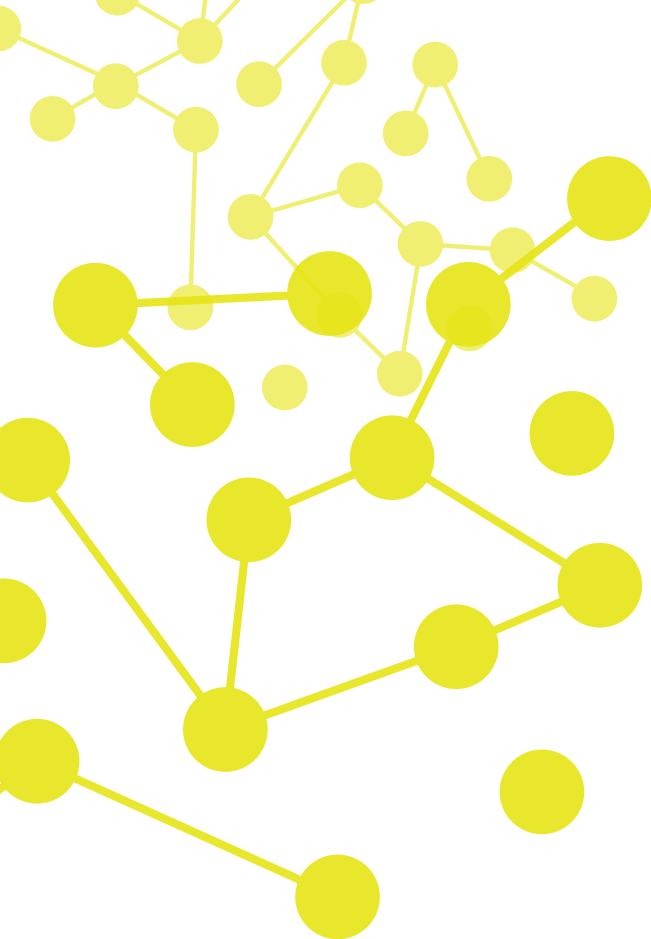
⁴³ BGH Antivirumittel, Leitsatz a).

⁴⁴ K Bacher, *Patentgesetz* (Georg Benkard ed, vol 4, 11th edn, C.H. Beck 2015), § 1 margin no 38b-38c.

⁴⁵ Zigann (n 27) 247.

⁴⁶ Art. 10 and 11 of Directive 2001/83 of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (as amended).

⁴⁷ Fisher, 'Second medical indications: Part 2' (n 71) 639 ff; this is implemented into German law by § 11a(1)(1e) of the German Medicines Act (*Arzneimittelgesetz*).



Following the rules on manifest arrangement set out above, this is not infringing behaviour, even though the drug can be used for the patented indication due to ‘cross-label’ or ‘off label’ use.⁴⁸ Off-label use describes any case where a physician prescribes a drug for an indication that is not mentioned on the label.⁴⁹ The term cross-label use is more specific; it means the case where a drug is prescribed or handed out for an indication for which the active ingredient is generally approved, but which is not mentioned on the label.⁵⁰ The problem described above that occurs due to the social law requirement to substitute medicaments according to § 129(1) SGB V falls under cross-label use.⁵¹ This occurrence is amplified by the fact that most prescriptions do not mention the indication for data protection reasons since the indication allows a conclusion to be drawn regarding the condition of the patient, which falls under medicinal confidentiality.⁵² This means that it is impossible for the pharmacist to avoid cross-label use as they are only provided with the active ingredient and have no information as to the purpose of the intended use.

Thus, by applying a skinny label, a generic pharmaceutical company could ostensibly avoid infringing a second medical use patent as the product would not be deemed as being manifestly arranged for the patented use. Effectively though, this can be used as a method of circumventing the patent since the product will still be used for the patented indication due to the substitution obligation.⁵³ Therefore, the position developed by the courts on how to assess skinny labels in finding infringement plays an important role in shaping the scope of protection.

i. Ribavirin

One of the important decisions to deal with the effects of a skinny label was the 2004 *Ribavirin* decision⁵⁴ of the

Regional Court of Düsseldorf (LG Düsseldorf). In the case, the patent holder brought a legal action claiming infringement of the patent for the use of ribavirin in the manufacture of a medicament for use in a combination therapy to remove HCV-RNA in patients suffering of a chronic hepatitis-C infection.⁵⁵ According to the court, the reason for which the patent was granted and the invention seen as inventive was that it claimed the efficacy of this treatment for a specific patient group that was described by three specific features.⁵⁶ The contested product that was marketed by the defendant did not mention this specific patient group on its label.⁵⁷ However, the claimant was of the opinion that the patent was infringed since the general patient group of patients infected with HCV (as mentioned on the label) comprised this specific patient group.⁵⁸ Additionally, they pointed out that of the patients infected with HCV, more than half pertained to the specific patient group mentioned in the patent claims.⁵⁹

As mentioned above, the point of reference for all courts dealing with second medical use cases is the *Zweckbindung* of these types of claims. In this case, the LG Düsseldorf argued that the purpose laid in the treatment of the specific patient group.⁶⁰ Therefore, it did not matter that the specific patient group was included in a more general patient group. According to the court, it could also not matter that the specific group made up more than 50 % of the more general patient group, since such a protection would not be purpose-bound and thus exceed the scope of protection conferred by the patent.⁶¹ To support their stance, they referred to the above mentioned *Antivirumittel* decision,⁶² in which the BGH stated that it could not be considered that a purpose-bound patent was carried out simply because the effects described in the patent occurred as what can be described as a side-effect.⁶³ Consequently, the outcome of this decision is that the content of a label, in this case a skinny label, is the main point of reference when it comes to determining if a patent was infringed. This leads to the conclusion that a skinny label is a safe harbour for patent infringement. In other words, if the patented indication is carved out on the label, there can be no infringement even if the product is actually (also) used for that indication.

ii. Chronische Hepatitis C-Behandlung

The LG Düsseldorf confirmed its decision in a 2013 ruling named *Chronische Hepatitis C-Behandlung*.⁶⁴ The case was fairly similar to the Ribavirin case in that the patent in suit in both cases related to the treatment of patients with chronic hepatitis-C and that both patents described a treatment that was particularly effective for a specific patient group defined by a number of specific features. The court reiterated its opinion that there was no manifest arrangement for the patented use even if the claimed patient group was included in the patient group mentioned on the label in suit and that this finding was not altered by the fact that the claimed patient group make up an important part of the patient group mentioned on the label.⁶⁵ As far as the significance of this confirmation goes, it should be noted that both decisions were not only made by the same court but also by the same chamber. However, the decisions are nine years apart and so the fact that the

court decided in the same way and specifically confirmed its earlier decision should give the reasoning some weight.

iii. *Cistus incanus I and II*

The impacts of a skinny label were also addressed in *Cistus incanus I*⁶⁶ and *Cistus incanus II*,⁶⁷ two parallel decisions from 2013 by the Higher Regional Court of Düsseldorf (OLG Düsseldorf). The relevant question in both cases was whether general advertisement announcements (*allgemeine Werbeankündigungen* in the original German version) such as flyers, brochures or statements by the sales representatives that contained the patented indication could lead to a manifest arrangement of the product, even though the product itself was marketed and distributed with a skinny label carving out the patented indication. The claimant⁶⁸ argued that this was sufficient to demonstrate that the generic company, which distributed the product, aimed to do so also for the purpose of treating the patented indication.⁶⁹

When it comes to striking a balance between the two positions mentioned at the beginning of this section, this reasoning is understandable. Even though the generic company does not include the patented indication on their label, they want to spread awareness about the fact that the product is objectively suited not only for the patent-free indication(s) mentioned on the label, but also for the one still protected by a second medical use patent. The motive for this might be that doctors or pharmacists will keep this specific generic in mind when they prescribe a product for the patented indication and not dismiss it because of the carve out. Considering the above mentioned factors regarding the social and regulatory law system in Germany, the positive effect of such actions is questionable. Nevertheless, the question remains whether these actions are to be considered as manifest arrangement or as contributing to manifestly arranging the product.

The opinion of the court was that such general advertisement announcements address the patented use in a manner, which is detached from the actual offer and sale of the product.⁷⁰ Therefore, it could not lead to the conclusion that the concerned product was manifestly arranged for the patented use. The reasoning behind this is

that because these announcements are detached from the offer and sale of the product, it is uncertain if the recipient of the product even notices them.⁷¹ Consequently, according to the court, it cannot be determined whether the announcements have led to the patented use.⁷² This reasoning was confirmed and supported in *Chronische Hepatitis-C Behandlung* later in the same year.⁷³ While the court in *Chronische Hepatitis-C Behandlung* is lower in hierarchy to the Higher Regional Court, it is still an affirming sign that the reasoning was mentioned and fully adopted by the Regional Court.

Similar to *Ribavirin*, the court followed a strict principle when deciding on manifest arrangement and thus on patent infringement. This principle can be summarised as follows: infringement can only occur if the product has been manifestly arranged for the patented use and this is the case only where there is an extremely close relationship between the arrangement and the product. Therefore, the content of a Package Leaflet (PL) is decisive for determining if the product in question has been manifestly arranged. While this principle has the advantage of providing a simple test for infringement and promoting legal certainty, it is questionable whether it takes all elements of the claim into consideration and adequately balances the positions at stake. It could be argued that the position taken by the courts favours generic companies by making it easier for them to enter the market without a significant risk of infringing a second medical use patent.

With regard to the scope of protection of Swiss-type claims, the position adopted by the courts in the reviewed decisions is that the scope is strictly limited by requiring any infringing use to be purpose bound. Throughout all decisions, the courts do not cease to repeat the importance of this limitation. The courts try to adhere to this purpose requirement by demanding an especially narrow relationship between the (contested) manifest arrangement and the offer/sale of the product. Hence, it can be concluded that (until 2013), the German courts took the position of a narrow scope of protection for second medical use claims in their infringement decisions.

⁴⁸ Hufnagel (n 7) 124.

⁴⁹ More specifically, it describes any prescription of the drug that is contrary to its approved MA, purpose, patient group, or indication; Isabelle Vrancken, 'Off-label Prescription of Medication' (2015) 22 EJHL 165.

⁵⁰ Hufnagel (n 7) 123.

⁵¹ Jürgen Dressel in 'Roundtable: The Second Medical Use Challenge' (2017) 265 Managing IP 26, 27.

⁵² von Falck and Gundt (n 6) 117; Schäffner (n 18) 450.

⁵³ Schäffner (n 18) 451.

⁵⁴ LG Düsseldorf Ribavirin GRUR-RR 2004, 193.

⁵⁵ Ibid [2].

⁵⁶ Ibid [52].

⁵⁷ Ibid [10].

⁵⁸ Ibid.

⁵⁹ Ibid.

⁶⁰ Ibid [52].

⁶¹ Ibid [56].

⁶² Ibid [77] ff.

⁶³ In the specific case, a pharmaceutical medicament "X" was administered for the treatment of Parkinson's disease. Occasionally, this also had the effect of a prevention against viral diseases, ie the patented indication.

⁶⁴ LG Düsseldorf Chronische Hepatitis-C Behandlung D-Prax Nr. 2011.

⁶⁵ Ibid Reasons II. 3. b).

⁶⁶ OLG Düsseldorf Cistus incanus I BeckRS 2013, 03824.

⁶⁷ OLG Düsseldorf Cistus incanus II BeckRS 2013, 11782.

⁶⁸ For the purpose of facilitating the account of the cases and focusing on the relevant issues, the patent holder is referred to as claimant, which corresponds to the situation in *Cistus incanus I*. In *Cistus incanus II*, the generic company sued the patent holder for refund of, inter alia, legal fees, so that in this particular case the patent holder is in fact not the claimant but the defendant.

⁶⁹ OLG Düsseldorf Cistus incanus I [21]; OLG Düsseldorf Cistus incanus II [33].

⁷⁰ Ibid I [87]; II [139].

⁷¹ Ibid.

⁷² Ibid.

⁷³ LG Düsseldorf Chronische Hepatitis-C Behandlung, Reasons II. 2.

3.1.3. Introducing limitations to the 'Safe Harbour' – The Pregabalin cases

In 2015, this position was questioned by five parallel decisions in preliminary injunction proceedings⁷⁴ from the Regional Court of Hamburg (LG Hamburg) called *Pregabalin*. They all concerned the infringement of Warner-Lambert's aforementioned patent whose corresponding product is marketed under the brand name of Lyrica[®] by various generic pharmaceutical companies.⁷⁵ The substance pregabalin has a number of different indications out of which one – namely the treatment of neuropathic pain – was still protected by a patent.⁷⁶ The others, *inter alia* epilepsy and generalised anxiety disorder, are patent free.

The facts of the case can be summarised as follows: the defendant, a generic company, markets and distributes a generic product with the substance pregabalin. To do so, they use a so-called skinny label, which only contains the patent free indications.⁷⁷ To distribute their product, the defendant has entered a rebate agreement with a health insurance company, whereby the rebate agreement concerns the substance pregabalin without any restrictions with regard to the patented indication.⁷⁸

The court granted a preliminary injunction against the defendant, prohibiting them to enter into such an unrestricted rebate agreement. When it came to their reasoning, the court laid the foundation for the decision by clarifying that skinny labelling did not impede the possibility of indirect patent infringement because in this case the infringement was a foreseeable consequence of entering into an unrestricted rebate agreement.⁷⁹ After that, the court elaborated on the topic of manifest arrangement. In this regard they started by mentioning that it was questionable whether manifest arrangement was necessary for indirect infringement.⁸⁰ Leaving this question unanswered they stated that, in this case, the product was manifestly arranged through its production, as its mere existence was sufficient for a manifest arrangement in this case.⁸¹ This is because the preparation is an essential means of the invention and the only missing factor for a direct patent infringement is the use for the indication 'neuropathic pain', which is added by the pharmacist handing out the product.⁸² This, in turn, is certainly foreseeable because of the social obligations that follow from §§ 129, 130 SGB V.⁸³

By assuming that the production of the product was sufficient for its manifest arrangement, the court explicitly contradicted the LG Düsseldorf in *Ribavirin*, which had then stated that a patent could only be indirectly infringed by offering and/or selling the product, if this occurred to allow a manifest arrangement of the product (in a second step) and not for its direct administration.⁸⁴ Hence, the offer and/or sale of the product itself could not constitute a relevant act for indirect infringement. However, it has to be kept in mind that the reasoning in *Pregabalin* is mainly based on the fact that a patent infringement was fairly obvious due to the implicated social law regulations. Insofar, the two cases are different and cannot be compared directly.

The OLG Düsseldorf had to decide on a different aspect of the same issue.⁸⁵ They faced the question of whether

the health insurance company could rightfully start tender proceedings for an unrestricted rebate agreement for the substance pregabalin in the sense that it did not take out the patented indication for neuropathic pain. They concluded that because of how the tender was formulated it was likely that the product would be used in the patented way, that is for the treatment of neuropathic pain.⁸⁶ Therefore, the court suggested that the most secure solution in these types of cases would be to have separate tenders for the patented indication of pregabalin on the one side and for the other patent-free indications on the other side.⁸⁷ This decision shows that when it comes to unrestricted rebate agreements, the position of the courts is quite clear: an unrestricted rebate agreement will undoubtedly lead to patent infringement, which cannot be tolerated since it is evitable. It is not only unlawful to enter such a rebate agreement, but also to start tender proceedings for this type of agreement. While social law and patent law will continue to collide on this issue, where patent law can easily be enforced without disregarding the legal consequences that social law regulations bring with them, this should be done.⁸⁸

By re-evaluating the relevant issues and introducing limits to this 'safe harbour' that had been the skinny label, the decision in *Pregabalin* is highly relevant not only for the industry, but also in its significance for the scope of protection conferred by Swiss-type claims. It opens up the possibility to include more actual circumstances when finding infringement or manifest arrangement and in doing so tries to strike a better balance between the concerned rights.⁸⁹ This patent owner friendly attitude is in line with further current European decisions on the topic that seem to be in favour of a wider scope of protection for Swiss-type claims.⁹⁰ While it would be interesting to see whether the courts of higher instance confirm this decision, such a decision is precluded as the patent in suit was annulled in 2017 and thus, the motion in the second instance was withdrawn.⁹¹

3.1.4. Putting an end to the 'manifest arrangement' requirement – Östrogenblocker

Most recent developments in case law seem to confirm this attitude. A landmark decision in this regard is the *Östrogenblocker* ruling of 2017 by the OLG Düsseldorf,⁹² which suggests that the German jurisprudence is moving away from the strict requirement of manifest arrangement that it has applied for years.

In the specific case, the court dismissed the case on the grounds of non-urgency.⁹³ However, what is relevant about this decision is that it provides clear guidance on both the relationship between Swiss-type and EPC 2000 claims and the consequences for infringement cases.

The court does this by elaborating on purpose-bound product protection. It reasons that the latter is always conferred when the patented use of the protected product is actually guaranteed, irrespective of whether the person liable for this (through manifest arrangement) is the one offering the product.⁹⁴ In other words, it comes down to a *de facto* patented use of the product and not to the behaviour of a supplier. This goes back to the particularities of purpose-bound protection. These entail that the acts

mentioned in § 9 Patentgesetz, the section governing direct patent infringement, must occur with the goal to lead to a specific objective (the purpose).⁹⁵ This is in line with what was mentioned at the very beginning of this section and is another example of how *Zweckbindung* is the leading principle when it comes to assessing infringement of purpose-bound claims. According to the court, in order to find direct patent infringement, the patented purpose has to be immanent in the product offered or distributed.⁹⁶ This can be done either by manifest arrangement or otherwise, since the relevant factor is that the pharmaceutical is objectively suited for the patented use.⁹⁷ The court argues that – provided that the product is objectively suited for the patented use – it would not be appropriate to refuse patent protection in cases where the patented use occurs due to other circumstances than the manifest arrangement, for instance in cases of cross-label use.⁹⁸ To avoid any confusion, the court then provides a set of prerequisites to ensure the existence of *Zweckbindung*,⁹⁹ meaning that the product in suit is in fact intended for a specific purpose (otherwise put purpose-bound), which can be structured as follows:

- 1) The product has to be suited for the patented use.
- 2) The distributor has to take advantage of circumstances that ensure that the pharmaceutical is used for the purpose-bound therapeutic use, similarly to a manifest arrangement. This requires the following:
 - a) The patented use needs to occur on a sufficient scale; isolated or occasional occurrence is not sufficient.
 - b) The distributor needs to have knowledge thereof.¹⁰⁰

To come back to consequences for infringement cases, the most important ramification is surely that by considering other factors aside from manifest arrangement, infringement is conceivable despite the use of a skinny label.¹⁰¹ This is because the court has distanced itself from the

requirement of manifest arrangement that had been applied strictly for years and had greatly influenced the jurisprudence in Germany in the field of infringement of second medical use claims. In doing so, the court is in line with demands in the relevant literature, which spoke out in favour of focusing on whether the product was objectively being used in the patented way instead of insisting on manifest arrangement.¹⁰² The system set up by the OLG Düsseldorf in *Östrogenblocker* provides a new way of finding infringement in second medical use cases, which is still clear and can be applied objectively. Its clarity is what makes the manifest arrangement-requirement especially appealing and successful, hence it seems important that the new requirement be similarly unambiguous. Another advantage of this approach is that it provides a solution in which an appropriate balance can be achieved between the interests of originator companies in their role as patent holders on the one hand and generic companies as well as the general public, which benefit from the use of non-patented and thus cheaper pharmaceuticals, on the other hand.¹⁰³ Ultimately however, this development strengthens the protection of second medical use patents,¹⁰⁴ which are highly important for innovator pharmaceutical companies.¹⁰⁵ At the time of submission of this article, the LG Düsseldorf has published three parallel decisions that apply the requisites set out in *Östrogenblocker*.¹⁰⁶ It will be interesting to see whether other courts, especially courts of the Highest Instance, will follow suit.

Another highly significant finding of this decision is that it confirms the position taken by the BGH in *Pemetrexed*,¹⁰⁷ according to which Swiss-type and EPC 2000 claims do not differ from one another with regards to their scope of protection but rather both provide purpose-bound product protection.¹⁰⁸ This is in contrast to earlier opinions, which assumed that the Swiss-type claims confer purpose-bound use protection. As the Pemetrexed decision came from the court of highest instance, the BGH, it was given weight. This is intensified by the fact that the OLG Düsseldorf so unambiguously adopted it.

⁷⁴ LG Hamburg Pregabalin, docket numbers 315 O 24/15; 327 O 67/15; 327 O 143/15; 327 O 132/15; 327 O 140/15, published as GRUR-RR 2015, 330.

⁷⁵ The defendant generic companies distributing pregabalin were Ratiopharm, Hexal, 1A Pharma, Glenmark, and Aliud Pharma.

⁷⁶ Filing date: 16 July 1997, LG Hamburg Pregabalin [5], [10].

⁷⁷ LG Hamburg Pregabalin [17].

⁷⁸ Ibid [18].

⁷⁹ Ibid [88].

⁸⁰ Ibid [90].

⁸¹ Ibid [92].

⁸² Ibid.

⁸³ Ibid.

⁸⁴ LG Düsseldorf Ribavirin, Leitsatz 2.

⁸⁵ OLG Düsseldorf BeckRS 2016, 02948.

⁸⁶ Ibid [23].

⁸⁷ Ibid [28].

⁸⁸ Having separate tenders according to the indication is described as a possible practice in competition law, but it is noted that it entails a greater challenge for the contractor and thus this practice would require special justification, cf M Gabriel, Münchener Kommentar Europäisches und Deutsches Wettbewerbsrecht [Franz Jürgen Säcker ed, vol 3, 2nd edn, C.H. Beck 2018], 4. Teil, margin no 78.

⁸⁹ The same conclusion was reached in Schäffner (n 18) 450; 455.

⁹⁰ Zigann (n 27) 245 with references to the specific decisions.

⁹¹ Schäffner (n 18) 450.

⁹² OLG Düsseldorf Östrogenblocker GRUR 2017, 1107.

⁹³ Ibid [56].

⁹⁴ Ibid [70].

⁹⁵ Ibid [72].

⁹⁶ Ibid.

⁹⁷ Ibid [73].

⁹⁸ Ibid.

⁹⁹ Ibid.

¹⁰⁰ Ibid [73].

¹⁰¹ Stephan Neuhaus, 'Patentverletzung von "Second Medical Use"-Ansprüchen durch Produkte mit sog. "Skinny Label" – OLG Düsseldorf, Beschl. v. 5.5.2017, I-2 W 6/17 – Östrogenblocker' IPunkt January 2018, 8, <https://f.datasrvr.com/fr1/018/67701/Patentrecht_Neuhaus_Second_Medical_Use.pdf> accessed 23 April 2018; Schäffner (n 18) 452.

¹⁰² von Falck and Gundt (n 6) 124.

¹⁰³ Neuhaus (n 31) 1112.

¹⁰⁴ Schäffner (n 18) 452.

¹⁰⁵ Neuhaus in IPunkt January 2018 (n 101).

¹⁰⁶ LG Düsseldorf, docket numbers 4c O 46/17; 4c O 47/17; 4c O 10/18, all dated 5 July 2018.

¹⁰⁷ BGH Pemetrexed GRUR 2016, 921.

¹⁰⁸ Ibid [83] ff.

3.2. Infringement of EPC 2000 claims

It can be expected that infringement cases in which EPC 2000 claims are concerned will surface in the next years and it remains to be seen how the jurisprudence will react to these. However, the decision in *Pemetrexed*, as confirmed by the decision in *Östrogenblocker*, can be interpreted as a sign that the courts are preparing themselves for these cases. By clarifying that both claim types shall be treated equally with regard to their scope of protection, meaning that the protection conferred by Swiss-type claims shall be the same as the one conferred by EPC 2000 claims, the courts have laid the foundation for future cases. They can now continue to develop their jurisprudence, irrespective of the claim formulation with which they are faced. This way, they do not need to develop different jurisprudence and argumentation lines for both claim types respectively, but can simply treat them as second medical use claims providing purpose-bound product protection. While neither *Pemetrexed* nor *Östrogenblocker* mention that this reasoning has anything to do with the fact that the courts will shortly be finding infringement of EPC 2000 claims, it is a valid assumption. Of course, the rise of infringement cases concerning EPC 2000 claims would only be one of many reasons for this consequential decision, which is much in line with the general development of the jurisprudence in the field of second medical use claims.

3.3. Significance for the scope of protection of second medical use claims

After considering all the different factors that come into play when finding infringement of second medical use cases, it can be concluded that the national case law plays a great part in defining the scope of protection of second medical use claims. Since national courts are faced with the actual effects of a scope of protection that is either narrower or wider, this allows them to have a more practical view on what type of scope actually makes sense for the enforcement of a claim type. An important consequence of the (current) European patent law system in which only the pre-grant phase is harmonised is that the EPO will never be confronted with patent enforcement cases, which seemingly makes it harder for them to consider the downstream effects of their decisions. While this is comprehensible, it is also the root of many problems.

In the EPO case law regarding the possible differences between Swiss-type and EPC 2000 claims with regard to their scope of protection, the main and recurring argument was the difference in claim category. When solely considering the claim category, the only logical solution seemed to be that EPC 2000 claims confer a broader scope of protection, since they are purpose-bound product claims, whereas Swiss-type claims are purpose-bound process claims.

The national courts, such as the BGH in *Pemetrexed*, have the advantage of years of experience in dealing with the enforcement of second medical use patents and developing a jurisprudence that would allow a reasonable balance between the above mentioned rights. This explains why their focus is more on the actual effect of a claim rather than on a claim category. In *Pemetrexed*, the BGH

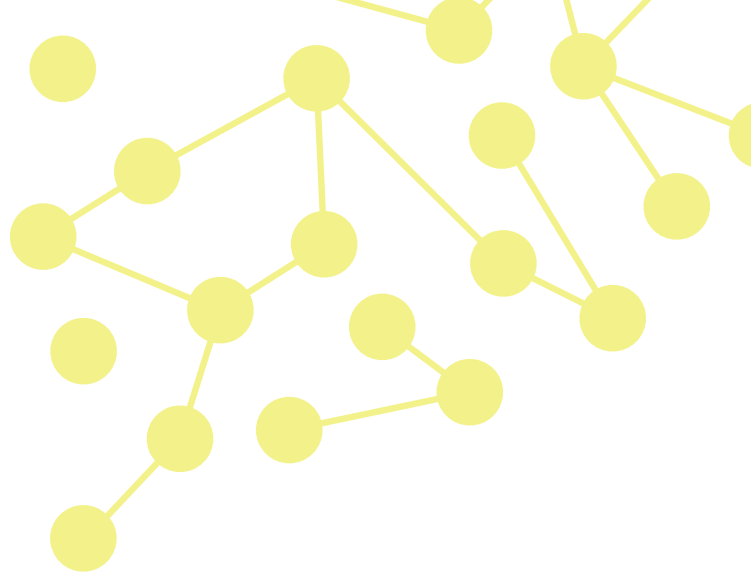
tried to identify the actual subject-matter protected by a Swiss-type claim and came to the conclusion that in fact, this corresponds to a purpose-bound product protection, hence, the protection conferred by EPC 2000 claims. Therefore, the scope of protection conferred by both claim types is equal, irrespective of their formulation. This finding is very much in line with the outcome of the conducted study of the preparatory works, which demonstrates that the main aim behind the EPC 2000 claims was to codify the (then) current jurisprudence regarding Swiss-type claims. Swiss-type claims had only taken the form of process claims because they required a formulation that can only be described as a work-around. Thus, it can only be seen as positive that the BGH focused on the actual subject-matter of both claim types instead of being blinded by their different formulations and the claim categories these entail.

The complexity of the factors to be considered also explains why the jurisprudence has developed as much as it did: the courts are constantly trying to adjust the balance in order to do justice to all relevant rights. The recent developments in the German case law provide a welcome solution to the longstanding debate on the scope of protection of Swiss-type and EPC 2000 claims. It seems that the courts have strengthened the legal status of second medical use patents and achieved a reasonable balance between the rights involved. Additionally, they show a welcome movement away from the dogmatic requirements of manifest arrangement towards a new approach, which includes more relevant factors and so allows for more adequate solutions when finding infringement. This perception is shared by the most recent specialised literature.¹⁰⁹ Finally, the courts lay the ideal foundation for future cases in which the national courts will be faced with finding infringement of EPC 2000 claims.

4. FINDINGS AND CONCLUDING THOUGHTS

As demonstrated by this article, second medical use claims - irrespective of their formulation - are highly complex and require the consideration of many aspects which go back to the core of patent law. Trying to enforce second medical use claims demands a careful balancing of the rights at stake such as the right of the patent holder to a fair protection of the second medical use patent on the one hand, and the right of third companies to make use of the patent-free first indications on the other, which in turn goes hand in hand with the right of the general public to access cheaper, generic pharmaceuticals after the patent has run out. Additionally, the situation is made even more complicated by the interference of social and regulatory law, since a balance between these two regulations needs to be achieved as well.

In the EPC 1973, second medical indication inventions - unlike inventions for the first medical indication - were not considered to be patentable. After the general need for patenting these kinds of inventions was recognised, the latter could first be patented in the form of Swiss-type claims in the EPO's landmark decision in 1984. Later, second medical use claims were introduced into the EPC as part of the reforms that resulted in the EPC 2000.



The EPC 2000 claims were supposed to codify the common jurisprudence regarding Swiss-type claims especially with regard to their scope of protection. However, the new formulation resulted in a different claim category. Thus, the scope of protection conferred by EPC 2000 claims as purpose-bound product claims was de facto broader than the one conferred by Swiss-type claims, which are purpose-bound process claims. This was confirmed by a number of EPO judgements, both from the EBA and the Boards of Appeal. This was in contrast to the intention of the drafters of the EPC, as shown in the travaux préparatoires for the revision of the EPC. In Germany, the BGH in *Pemetrexed* remedied this divergence between the intention of the drafters of the EPC and the actual legal situation by focusing on the actual subject-matter of the two claim types. Consequently, the BGH came to the conclusion both claim types confer purpose-bound product protection.

After having established the scope of protection of both Swiss-type and EPC 2000 claims from the position of the EPO, it is also important to consider the significance of national patent enforcement jurisprudence. On the one hand, the scope of protection conferred by a claim is highly relevant for finding infringement, since infringement can logically only occur where there is patent protection. This means that the courts are somewhat bound by the scope of protection of a claim. On the other hand, where the scope of protection is not inherently clear, it is in the hands of the court to carefully assess which acts constitute infringement. In doing so, the national courts contribute to shaping the scope of protection.

Especially in the last decade, the German national courts have dealt with numerous infringement cases involving second medical use claims and have faced the challenge of striking a balance between the aforementioned rights. The case law assessed in Section 3 shows the complexity of this task. This is amplified by the fact that the enforcement of patent law collides with regulatory guidelines from social law that need to be respected. Namely, the substitutive obligation for pharmacists pursuant to § 129(1) SGB V, rebate agreements pursuant to entered between generic companies and health insurance companies pursuant to § 130a(8) SGB V. Added to this, it is the pressure that physicians face to prescribe generically rather than by reference to the patented products. Collectively, these factors promote cross-label use of pharmaceuticals, which makes it difficult to identify infringement. As demonstrated by this study, until 2013 it seemed that the German courts considered a skinny label to provide a 'safe harbour' from infringing second medical use patents. By focusing solely on the German requirement of manifest arrangement, they concluded that a generic product with a skinny label, meaning that the patented indication had been carved out from both the SmPC and the PL, had not been manifestly arranged for the patented

use. Thus, any actual use of the product for the patented use related to cross-label use could not be attributed to the generic company.

In recent court decisions, the courts have instead moved away from the strict dogma of manifest arrangement and involved additional aspects in finding infringement of second medical use claims. The focus now lies on determining if the patented use actually occurs on a greater scale and whether the generic company somehow intended this. As seen in this article, this is a welcome change of direction, which also finds support in the relevant specialised literature. It seems that the criteria established by the newest developments in jurisprudence allow a balance between the above mentioned rights. Additionally, by implementing the jurisprudence of the BGH in *Pemetrexed* concerning the scope of protection of both types of second medical use claims, which were deemed to confer purpose-bound product protection, the courts have laid the basis for future cases involving EPC 2000 claims.

In the future, it will be interesting to observe how the courts further develop their jurisprudence and, in doing so, shape the scope of protection of second medical use claims. It will be of particular interest to see, firstly, how the national courts address cases involving EPC 2000 claims and, secondly, what stance the Unified Patent Court will take on this matter.



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⁷⁴ cf Neuhaus [n 31], but also more recently Schäffner [n 18] and Kühne [n 26] in the May 2018 issue of GRUR.