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# INDIRECT INFRINGEMENT OF SECOND MEDICAL USE PATENTS(*)

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**Abstract:** A second medical use patent protects an already known and unpatented (or patent-expired) product for a new indication. Since the product is already known, it cannot be patented as such, but it can be patented for an indication which is unknown until the patent application. In case of marketing a known product for a non-patented indication, there is infringement of the patent if third parties still use the product for the patented indication. That direct infringement is carried out by the person using the known product for the patented indication. Indirect infringement occurs where the supplier of the known substance knows that the product is being used with the intention of infringement. However, if the product is a staple commercial product, indirect infringement occurs only where the supplier promotes unauthorized persons to use the product within the scope of the patent. Indirect infringement will be examined in terms of Turkish Patent Law, taking into consideration the las and practice of the EU Member States.

**Keywords**: Second Medical Use, Staple Commercial Product, Non-Patented Product, New Indication, Indirect Infringement.

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# İKİNCİ TIBBİ KULLANIM PATENTLERİNİN DOLAYLI İHLALİ

**Öz:** İkinci tıbbi kullanım patenti, bilinen ve patentli olmayan (veya patent süresi dolan) bir ürünün, farklı bir endikasyon için korunmasını sağlamaktadır. Ürün zaten bilinen bir ürün olduğu için, tek başına patent konu olamaz, ancak o tarihe kadar bilinmeyen bir endikasyonda kullanılması patente konu olabilir. Bilinen bir ürünün patent koruması bulunmayan endikasyon için piyasaya sürülmesi halinde, üçüncü kişilerin bu ürünü yine de patentli endikasyon için kullanmaları patent hakkı sahibinin haklarını ihlal etmektedir. Buradaki doğrudan ihlali, bilinen ürünü patent altına alınan endikasyon için kullan kişi gerçekleştirmektedir. Dolaylı ihlal, bilinen ürünü tedarik eden kişinin, ürünün ihlal amacıyla kullanıldığını bilmesi durumlarda söz konusu olur. Ancak eğer ürün piyasada her zaman bulunabilen bir ürünse, dolaylı ihlalin söz konusu olması için, tedarik eden kişinin, ürünün patent kapsamında kullanılması için yetkisiz kişileri teşvik etmesi gerekir. Bu konuda AB Üye Ülkelerde verilen kararlar da göz önünde bulundurularak, Türk Hukuku açısından dolaylı ihlal değerlendirilecektir.

**Anahtar Kelimeler:** İkinci Tıbbi Kullanım, Piyasada Her Zaman Bulunan Ürün, Patent Konusu Olmayan Ürün, Yeni Endikasyon, Dolaylı İhlal.

## I. INTRODUCTION

Both in Turkish and foreign law, there are cases related to infringement of second medical use patents and complicated situations arise in consequence. One of these cases is the indirect use of the invention, which constitutes an indirect infringement of the second medical use patent. Indirect use of the invention occurs only when one of the essential elements of the invention is used without directly using the patented invention.

The patent right may be infringed directly and indirectly. Direct infringement is regulated under Article 140 of the IPL which states that the person who produces, sells, distributes, otherwise commercializes, imports, possesses, transfers into practice, or concludes a contract regarding these products without authorization infringes the patent right. The person who uses the patent directly without authorisation infringes the patent. However, if the person who does not directly use the patent, but still deliberately contributes to the infringement of the patent, infringes the patent in indirect manner. Indirect infringement is not the unauthorised use of the patent, but the contribution to the unauthorized use. The person who provides the necessary instruments for the infringement and promotes the occurrence of the infringement is held responsible as indirect infringer. In this context, despite

the fact that Article 86 of the IPL does not literally regulate indirect liability, it regulates the rights of the patent holder against the supplier of the essential element of the patent in case of indirect infringement.

There are many reasons why the patent holder may bring claims against suppliers to prevent them from selling the essential element of the patent. Especially in case of pharmaceuticals, one of the reasons is the fact that doctors can't be accused of patent infringement. The general reason is that it is possible to prevent patent infringement at the source by prohibiting the act of supplying the product. If the patent holder can prevent the activity of the supplier, it will also prevent all infringement connected with the use of that product. To adapt a well-known metaphor, the most effective way to stop the message is to stop the messenger.

In practice, the interpretation of art. 86 and some of its concepts presents difficulties. Many concepts in the provision need to be explained. In this context, it is important to interpret the concepts of essential element in regards to the patent and staple commercial product in general.

This study, however, is dedicated to the concept of indirect infringement of the second medical use patent[1]. For this reason, we will begin with the explanation of the general structure of Art. 86 of the IPL and the conditions of indirect infringement will be discussed. Subsequently, the second medical use will be briefly explained. Notwithstanding the importance of the problems related to second medical use patents, there is no established case law on this issue in Turkish Law yet[2]. Therefore, the practices of EU countries will be examined and we will try to interpret and adapt this concept to Turkish Law.

## 1. Conditions for Preventing Indirect Use of Patent

Article 86 of the IPL regulates the prevention of indirect use of the invention and the circumstances under which the patent is indirectly infringed

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1 For an examination that excludes secondary medical use, but analyzes the *staple commercial product* concept in terms of EU law and practice, see. YUSUFOĞLU BİLGİN Fülürya, "Staple commercial product", **Journal of Intellectual Property Law & Practice**, Vol. 17, No. 10, 2022, p. 871-877, p. 872 ff.

2 As explained below, the Turkish Supreme Court of Justice, ruled on the validity of second medical use patents, which is very important, since there were debates regarding the patentability of second medical use patents in Turkey. See decision of Yarg. HGK E. 2017/11-145, K. 2021/1278, T. 21.10.2021, kazanci.com.tr, accessed 08.09.2022.

by the supplier of the product. The provision primarily introduces the main rule, stating that the patent holder has the right to prevent third parties from supplying essential elements or instruments that enables unauthorised application of the patented invention. As a matter of fact, the basic patent right is the right to prevent the unauthorised application of the patent.

Patent holder cannot prohibit uses, wich fall outside the use of the patent. The important point is that the essential element of the patent is not protected as such. It's use can be prevented only if it's used as instructed in the patent document. Therefore, if there are independent uses of an essential element of the patent, the right holder cannot prevent the non-infringing uses. The patent holder's right to prevent is against those who supply the essential element to third parties who infringe the patent by using the product (the essential element) as indicated in the patent document.

Pursuant the provision, the patent holder's right to prevent arises if the supplier of the essential element is aware that (1) these essential elements or instruments are sufficient to implement the invention and that (2) they will be used for this purpose. Even if the supplier is not aware of the unauthorised use, but it is sufficiently apparent from the situation, the right holder has the right to prohibit the supply. If the supplier does not initially know that the supplied product is acquired for the purpose of performing the patent, it is not possible to bring a claim against the supplier. Whereas after the supplier acquires knowledge (or is informed by the right holder) related to the unauthorised use, the right holder may prevent the supply of the product (the essential element of the patent). Article 86/1 of the IPL will apply on the condition that the third parties (the supplier) know that the essential elements or instruments will be used in a way which falls within the scope of the patent protection.

According to the second paragraph of the provision, if the elements or instruments mentioned in the first paragraph are staple commercial products, the provision of the first paragraph shall not apply, unless the supplier induces the person to whom the product is supplied to perform any act that falls within in the scope of the patent protection. According to Article 86/2 of the IPL, notwithstanding that the supplied product is one of the essential elements of the patent, if the product is generally available and easily obtainable in trade, the patent holder may prevent the supply of the product only if the supplier promotes unauthorized persons to apply the patent.

An examination of Article 86 of the IPL indicates that certain conditions must be satisfied in order for the patent to be deemed indirectly infringed. In order to prohibit the indirect use of the patented product, the following conditions must be fulfilled cumulatively:

(1) The elements used must be essential elements of the invention.

(2) The supplier must know thebelow mentioned facts:

a that these elements or instruments are sufficient to enable the patented use **AND**

b that the invention will be used for this purpose, or this must be sufficiently clear from the facts surrounging the situation.

(3) If the product (element) is a staple commercial product, "unauthorized use" of the patented invention cannot be claimed, unless third parties encourage the unauthorized persons in question to act in a way that falls within in the scope of the patent protection.

In fact, these conditions have been accepted in national and international doctrine[3]. If the staple commercial product is sold freely on the market for different purposes, then there is "unauthorized use" only if there is "inducement." If there is a sale of a staple commercial product and the seller (the supplier) does not induce the patented use of the product indirect infringement cannot be claimed and accordingly the patent holder has no right to prohibit the supply.

In Turkish Law, it is widely accepted that in order act in unauthorized manner, the product shall be supplied exclusively for the purpose of infringement and there must be an "incentive" towards the recipient of the product to use it in a way protected by the patent. In order for the supplier to be considered as indirect infringer, the supplier must encourage unauthorized persons. If the supplier does not personally commit the infringement but induces, promotes, assists third parties to commit the infringement, the supplier is deemed as infringer[4]. Similarly, advising or suggesting the in-

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[3] For international doctrine and practice, see. YUSUFOĞLU BİLGİN, pp. 873-877; BENTLY Lionel / SHERMAN Brad, **Intellectual Property Law**, Oxford University Press, Oxford, 2018, pp. 653-654. For Turkish Law, see, KÖKER Ali Rıza / YALÇINER Uğur, **Uzman Gözüyle Patent ve Faydalı Modelden Kaynaklanan Uyuşmazlıklar**, Adalet Yayınevi, Ankara, 2020, p. 296.

[4] KÖKER/YALÇINER, p. 295; ŞEHİRALİ Feyzan Hayal, **Patent Hakkının Korunması**, Turhan Kitabevi, Ankara, 1998, p. 111.

fringer to carry out the invention is also sufficient for the supplier to infringe the patent (indirect infringement)[5].

If *the elements or instruments in question are staple commercial products*, the patent holder cannot hold the supplier liable, unless the supplier induces the persons to whom the product is offered to perform an act that falls within in the scope of the patent protection[6].

Not all of these elements will be analyzed below. Staple commercial product will be examined related to second medical use patents. The delicacy in the second medical use patent is that the already known substance is protected only if used within the new medical indication. It is refered as *purpose-limited product claim.* In this case, the use of a known product for a new indication constitutes an infringement, but its non-protected use cannot be prohibited. As stated, the protection is only purpose-limited.

In practice there are some problems related to the second medical use of known pharmaceutical substances (products). Is an infringement prevented just by not writing the patented use on the leaflet? Or should it be clearly stated on the leaflet and on the label that the product should not be used for the new medical indication?

## 2. Infringement of Second Medical Use Patents in EU Countries

Infringement of second medical use claims is crucial for the determination of the importance of the number of non-patented uses in indirect infringement. It is important to establish whether the only one non-patented use is sufficient to maintain that the product is a staple commercial product and that its use does not infringe the patentee's rights.

Originally, second medical use claims were not clearly protected under the European Patent Convention 1973. To be protected, a second medical use claim had to be formulated in a special wording. This formulation is called a Swiss-type claim. The Swiss-type claims were developed by the EPO Enlarged Board of Appeal in its decision EISAI/Second medical indication G 05/83. According to this decision, the so-called Swiss-type claims

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5 GÜNEŞ İlhami, **Sınai Mülkiyet Kanunu Işığında Uygulamalı Patent ve Faydalı Model Hukuku**, Seçkin, Ankara, 2019, p. 269; SARAÇ Tahir, **Patentten Doğan Hakka Tecavüz ve Hakkın Korunması**, Seçkin, Ankara, 2003, p. 165; SULUK Cahit / KARASU Rauf / NAL Temel, **Fikri Mülkiyet Hukuku**, Seçkin, Ankara, 2017, p. 294.

6 TEKİNALP Ünal, **Fikri Mülkiyet Hukuku**, Vedat, İstanbul 2012, p. 605.

grant protection for the second medical use inventions as a purpose-bound method claim. The Swiss-type claim is construed as "use of substance X for manufacturing a drug for the therapeutic application Y". As seen, this is not a product claim but a process/method claim. The introduction of EPC 2000 solved the second medical use problem. The EPC amended Article 54(5) so that it allows the patentability of the second medical use. Article 54(5) of EPC 2000 expressly provides use - limited product protection for the second or further medical use of a known substance. EPC 2000 second medical claims are product claims, whereas Swiss-type claims are process claims[7].

Turkey is an EPC contracting state. Therefore, European patents granted by the EPO are also protected within Turkish territory. Nevertheless, provisions on first and second medical use patents were not included in the Industrial Property Law, which is largely in line with the EPC. The Industrial Property Law neither explicitly accepts nor explicitly rejects the application of the second medical use. The issue here lies in determining the novelty and inventive step of the second medical use. In our opinion, since there is no reason to deviate from the basic rules of patent law, the patentability conditions should be interpreted as accepted in the EPC and EU Law and practice[8].

The General Assembly of the Court of Cassation ruled that all kinds of patents, including second medical use claims, can only be deemed invalid if they do not meet the novelty, inventive step or industrial applicability conditions. The General Assembly of the Court of Cassation also expressly rejected the first-instance court's argument that the second medical use claims granted during the EPC 1973 period were legally unfounded. Therefore, in our opinion, the debate on second medical use patents in Turkey has been

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[7] BERRİSCH Clara, "Second medical use claims and scope of protection", **Stockholm Intellectual Property Law Review**, V 2, I1, June 2019, pp. 38-47, 38-40; BHAGWAT Mitali / KAUSHİK Geetesh / SHİVPUJE Vijaykumar, "Second Medical Use Patenting: A Review of Practices Across Different Jurisdictions", **JIPR**, V.21, July 2016, p. 260, 262; FİSHER Matthew, "Second medical indications and the Swiss-form claim: taming Frankenstein's monster: Part 1 - solving one problem creates another", **EIPR**, Vol. 39, 2017, pp. 574-575.

[8] For detailed information on this subject, see; YUSUFOĞLU Fülürya, **Patent Verilebilirlik Şartları**, Vedat, İstanbul, 2014, p. 431,432; AY KAPLAN Ülkü, "İlaç Patentlerinde İkinci Tıbbi Kullanım", **Çankaya Üniversitesi Hukuk Fakültesi Dergisi**, C. 5, S.1-2, 2022, pp.1849-1883, p. 1854 ff; MUTLU Aydın, "İkinci Tıbbi Kullanım İstemlerinin Yeni Sınai Mülkiyet Kanunu Işığında Patentlenebilirliği", **Ankara Barosu FMR**, 26 Nisan Dünya Fikri Mülkiyet Günü Özel Sayısı, 2017, pp. 91-112, p. 104 ff.

conclusively solved with the decision of the General Assembly of the Court of Cassation[9].

In the second medical use patent, the question that arises is whether one can obtain a patent for an invention which consists of the application of a known therapeutic substance to a new therapeutic application, unknown until this time. An already known drug can be patented for new medical use (new medical indication). Where a substance or composition is already known, it may still be patentable under Article 54(4) of the EPC, provided that the known substance or composition was not previously disclosed for use in a method referred to in Article 53(c) of the EPC[10]. As in EPC and EPO member states, the second medical use patent protects the use of a known substance in a new treatment. In this case, the already known substance is patent protected only if it is used for a new therapeutical application that is not disclosed before. In the circumstances of a second medical use, the substance is protected only for the second medical use and can be freely used for the first medical use if the patent for the previous medical use has expired. As the patented indication is protected and the patent holder has the exclusive right to make use of it, the unpatented indication remains in the public domain and can be exploited freely, as long as the patent rights of the same substance are complied with.

In this scenario, the patent holder of the second medical use patent can't prohibit the use of the substance for the already known medical use. So even if there is only one non patented use, the patent holder can't prevent the use of the substance for the non-patented use. In case of direct infringement of the second medical use, the manufacturer of the product is producing it for the patented use without authorisation. In case of indirect infringement, the manufacturer, in appearance, is using the product for the unpatented therapeutical indication but, in fact, is promoting the patented use for the patented therapeutical use.

The classical distinction between patented and non-patented use is made through the labels put on the products. A drug with more than one indication may be marketed by the patent holder bearing a full label, which means that the label of the drug is bearing the patented indications, as well as the non-patented ones. The full label shows that the product is meant for all the indications. On

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9 Yarg. HGK E. 2017/11-145, K. 2021/1278, T. 21.10.2021, kazanci.com.tr, accessed 08.09.2022.

10 EPO Guidelines for Examination, Part G, Ch VI, 7.1, https://www.epo.org/law-practice/legal-exts/html/guidelines/e/g_vi_7_1.htm, accessed 25 May 2022.

the contrary, the generic manufacturer has no right to market the product for the patented indications. In other words, the generic drug manufacturer has to carve out the patented indications and put only the indications which are in the public domain[11]. The products for the non-patented use are marketed under a skinny label, which bears only the non-protected indications.

The skinny labels are important to interpret the purpose of the manufacturer since the manufacturer has to market only the non-patented products in order not to infringe the patent. The skinny labels are just one of the signs showing the intent of the manufacturer.

The problem with the skinny labels is that, despite the label indicating only the non-patented indications, the medical practitioners, such as physicians, can still prescribe, and pharmacists can still dispense the non-patented products for the patented use. In some countries, such as the UK, the drugs are prescribed by the generic name of the chemical substance (its pharmaceutical international non-proprietary name - INN)[12]. In this case, no difference is made between the prescription for the use in the patented therapeutical condition, and the prescription for the use in the non-patented therapeutical condition since both conditions are treated with the same drug and the physician prescribes only the INN. Under those circumstances, the indication on the skinny label has a little effect on the use of the drug for the non-patented area. Despite the skinny label, the physician will prescribe the INN for the patented condition, and the pharmacist will dispense the less expensive product, which is usually the generic drug.

As seen above, despite the skinny labels, the drug intended to be used within the non-patented scope could still be used within the patented scope of the product (cross-label use). In this case, will the manufacturer be held liable for indirect infringement despite the fact that the skinny label is put on the product?

In case the generic manufacturer of the drug has put a skinny label on the product and carved out the patented use, the manufacturer can't be held

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[11] Warner-Lambert Company LLC v Generics (UK) Ltd (t/a Mylan) & Others, UKSC 56, 2018, para 65, https://www.supremecourt.uk/cases/docs/uksc-2016-0197-judgment.pdf, accessed 07.09.2022; BUTRİY Olena, "The interpretation of second medical use claims and the indirect nature of their infringement", **Journal of Intellectual Property Law & Practice**,, Vol. 13, No. 1, 2018, pp. 61-67, p. 62.

[12] The same rule applies in Germany; BERRİSCH, pp. 38-47, p. 41. In some countries like Turkey, the drugs are prescribed not by their names, but by the tradename of the drug.

responsible for indirect infringement unless he has induced third parties to use the drug for the patented indication. In second medical claims, the use of the drug in the non-patented use is not considered infringement unless the manufacturer has acted in a way to promote the patented use.

### A. UK Practice

In the leading case Warner-Lambert v. Actavis, the non-infringing use of the Swiss-form claims was at issue. There were different approaches regarding the protection of second medical claims. According to Arnold J's approach, second medical claims in Swiss-form claims can't be indirectly infringed since the drug was manufactured by Actavis and the drug was supplied with a skinny label, where only the non-protected uses of the drug were listed. Arnold J stated that since no wholesaler or pharmacist will use the manufactured drug to prepare a pharmaceutical composition, there was no possibility of indirect infringement[13].

This decision was overturned on appeal, where Floyd LJ pointed out the danger in translating section 60(2) into a requirement for a "downstream act of manufacture". He stated that what is required is that means for putting the invention into effect are provided[14].

In the Warner-Lambert judgment (2018), the Supreme Court stated that claim 3 relates to the manufacture of pregabalin for use as a neuropathic pain killer and that claim is a process claim. Lord Sumption and Lord Reed pointed out that the Swiss-form claims for purpose limited medical use aim to assess the novelty of the product in relation to its second medical use, that the product in itself is not novel and that the treatment method itself is unpatentable. In their reasoning, the Lords stated that the Swiss-form claim protection is more limited in view of the product claim and that this claim can't extend to the steps taken by the pharmacists[15]. In the decision, Lord Briggs stated that in Swiss-type claims, the claim protects the manufacture

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[13] Generics (UK) Ltd (t/a Mylan) & Others v.Warner-Lambert, Septenber 2015, [2015] EWHC 2548 (Pat)10, para 648, https://www.casemine.com/judgement/uk/5a8ff7c660d03e7f57eb1fa2, accessed 07.09.2022.

[14] Warner-Lambert Company LLC v Generics (UK) Ltd (t/a Mylan) & Others, 13.10.2016, [2016] EWCA Civ 1006, para 223,224, https://www.bailii.org/ew/cases/EWCA/Civ/2016/1006.html, accessed 07.09.2022.

[15] Warner-Lambert Company LLC v Generics (UK) Ltd (t/a Mylan) & Others, [2018] UKSC 56, para 88.

of the product for a new use and that the acts of the pharmacists are not influenced by the claim. Lord Briggs stated that according to his view, the process claims are limited to the manufacture[16]. To sum up, according to the Supreme Court decision, the "use of [pregabalin] for the preparation of a pharmaceutical composition for treating neuropathic pain" relates to the manufacture only and the downstream conduct of the pharmacists is not prohibited by the patent. The only decisive factor for liability is how the product is presented after its manufacture.

In his judgement, the Supreme Court gave some guidance regarding the acts taking place downstream and upstream in the generic market. The actors in the downstream market are the importers, distributors, wholesalers and dispensing pharmacists[17]. Section 60(1)(c) is concerned with conduct downstream of manufacture, such as "supplying the means" and "dealing in the product"[18]. The actor in the upstream generic market is the manufacturer, and the process claims are limited to the manufacture[19]. The steps related to the upstream activity are steps related to the manufacture, wording, drug packaging, and labelling of the product[20].

Warner-Lambert decision illustrates the balance of interest between the owner of the patent to protect his patent and the generic company to manufacture and promote the generic version of previously patented drugs. The manufacture and marketing of a product for a non-patented use doesn't infringe the rights of the patent holder[21].

As a result, in UK jurisdiction, if a claim is formulated in a Swiss-form claim, no indirect infringement could take effect. But in reality, Warner-Lambert suffers damages. To prevent those damages, it was proposed to prescribe and dispense pregabalin for neuropathic pain, by the brand name Lyrica, instead of the generic name *pregabalin*.

By order of 2 March 2015, the High Court of Justice (Mr Justice Arnold) ordered the National Health Service (NHS) to issue guidance to ensure

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16 ibid, para 135.

17 ibid, para 64.

18 ibid, para 135.

19 ibid, para 135.

20 Butriy, 64.

21 PİLA Justin /TOREMANS Paul, **European Intellectual Property Law**, 2. edition, Oxford University Press, Oxford, 2019, p. 189.

that doctors prescribe pregabalin for the treatment of neuropathic pain using the Lyrica® brand name and pharmacists dispensing pregabalin for the treatment of neuropathic pain using the Lyrica brand name. However, when prescribing and dispensing pregabalin for the treatment of anything other than pain, continue to use the generic name pregabalin[22].

As seen, even if no patent infringement occurs, the patent holder can suffer damages, which can be only avoided by prescribing the brand name of the product for the use in the indication taking place in the patent.

Even if, according to UK law and practice, there is no indirect infringement carried out by the physicians and pharmacists, it is still obvious that when there is one non-patented use, there is no infringement unless other circumstances influence the situation.

**B. German Practice**

In Germany, as in the UK, physicians are encouraged to prescribe the drugs generically by the name of the active ingredient. The standard version of the prescription is designed to allow substitution of the branded products according to the active ingredient. Besides, there is a substitution obligation for pharmacists, who are required to dispense the least expensive product having the same active ingredient[23].

Second medical use claims drawn up as Swiss-form claims are method claims, as in the UK and in France. But in case of infringement, courts in Germany leave this strict classification and interpret those claims as product claims for the use in the indication specified in the claim[24]. In Germany, no distinction is made between the enforcement of second medical use claims in the Swiss-type format and those in the EPC 2000 format. They are all universally regarded as giving purpose-limited product protection[25].

If the patented indication of a product is carved out, no infringement occurs. And if no additional advertising for the use of the product for the indi-

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22 [2015] EWHC 485 (Pat), Judgement of 2 March 2015, https://www.bailii.org/ew/cases/EWHC/Patents/2015/485.html accessed, accessed 25.May 2022.

23 BERRİSCH, p. 41.

24 RÜTİNG Dr. Kai, "A New Scenario for Infringement of Second Medical Use Patents: Are Generics Liable when They Participate in Discount Contract Tenders?", https://information.patentepi.org/1-16/infringement-second-medical-use-patents.html, accessed 25 august 2022.

25 FSC, GRUR, 2014, 461 - Kollagenase I; GRUR 2016, 921 - Pemetrexed.

cation stated in the patent takes place, no indirect infringement occurs either. There is indirect infringement only where there is a clear inducement for the use of the product in the indication stated in the patent. As in the UK, in German case law, direct infringement of the Swiss form claim depends on the way the drug is presented. This concerns the packaging, the labelling, the dosage, and the wording of the manufactured drug.

In the Ribavirin case, the Court stated that only the upstream activities could be considered as indirect infringement[26]. Products which are the subject matter of the patent and constitute infringement are those which are sensibly prepared for the patented use. In the case where the products are adapted for the patented use, and it is apparent from their technical design, indirect infringement occurs[27].

One issue considered by the courts was the regulatory reimbursement practice of public health insurance companies. The discount contracts between the public health funds and the generic companies influence the turnover of the company. In order to increase their turnover, generic companies tend to participate in the tenders without excluding the patented indication, despite the fact that the patented indication does not take place on the label. According to the German Courts, generic companies are liable for indirect infringement if they had participated in public tenders of health insurance without excluding the patented indication from the tender[28]. In Lyrica case, the generic manufacturer participated in public tenders for discount contracts conducted by public health insurance without notifying the health insurance that the use of the generic drug for the indication taking place in the patent would constitute indirect infringement. The claimant Warner-Lambert argued that besides participating in tender offer for rebate agreement without notifying the health insurance about the abovementioned situation, taking place in the database of the pharmacies and the wholesalers without notifying them that the drug can't be marketed for the indication in the patent would constitute indirect infringement. The Hambourg court granted a pre-

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[26] District Court of Düsseldorf, 24 February 2004, Case No. 4a O 12/03, GRUR-RR 2004, 193 (196) - Ribavarin. In it's judgement in Warner-Lambert Company LLC v Generics (UK) Ltd (t/a Mylan) & Others [2016] EWCA Civ 1006, para, 224.

[27] Case 2 O 35/16, BeckRS, 2019, 27104.

[28] Warner Lambert LLC v. Hexal AG et al., District Court of Hamburg, 2 April 2015, Case Nos. 327 O 67/15 (Hexal), 327 O 143/15 (1A Pharma), 315 O 24/15 (Ratiopharm), 327 O 132/15 (Glenmark) and 327 O 140/15 (Aliud Pharma). See, RÜTİNG.

liminary injunction with regard to the participation in public tenders for rebate agreements[29]. It was stated that even when the indication taking place in the patent is not indicated in the leaflet and is carved out, there will still be indirect infringement.

Starting with Östrogenblocker case, the German Courts adopted a different approach regarding second medical use infringement. If the generic drug manufacturer is (or at least should have been) familiar with the prescription practice, which is favourable for generic manufacturer's trade and if the manufacturer nonetheless exploits this proactively by supplying its wholesalers, it is adequate to hold the generic drug maker liable under patent law[30].

In the Dexmedetomidin case, OLG Düsseldrof stated that the manufacturer of a product which is produced and labelled out of the patented use can still infringe the patent, even if it has not itself undertaken any infringing acts, adding that this would be in exceptional cases[31].

In a recent decision concerning the active substance Fulvestrant, the Court of Appeal of Düsseldorf formulated a two-step examination: the first thing to define is whether the patent- compliant use is of sufficient scope of use, and then the second thing to define is whether the generic manufacturer is (or at least should have been) aware of the use[32].

In the abovementioned cases, the active substances were old and unpatented. The use of a known substance for known use would not infringe the patent. In the aforementioned cases, the products sold by the generic companies were marketed under "skinny labels", and the label did not contain any information regarding the specific patented use. In those cases, the products were manufactured for non-patented use but ended up being used for the patented one, usually because of the physician's prescription. OLG Düsseldorf stated that even if the producer did not intend the patented use, there still could be patent infringement. But it should be noted that in the aforementioned cases, the Düsseldorf Court rejected the injunction submission

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29 RÜTİNG, https://information.patentepi.org/1-16/infringement-second-medical-use-patents.html, accessed 25 May 2022.

30 OLG Düsseldorf, Beschl. v. 5.5.2017 - I-2 W 6/17; Appeals Court Duesseldorf, GRUR, 2017, 1107 - Oestrogenblocker.

31 Case I-2 U 30/17, GRUR-RS 2018, 2410.

32 OLG Düsseldorf, I-2 U 29/18, 09 January 2019.

based on the fact that sufficient cross-label use had not been established to the court's satisfaction. This means that if the plaintiff can establish "the sufficient extend of use" and the fact that "despite being aware of the patented use, the manufacturer willingly supplied the drug", an interim injunction would be granted[33].

The case-law beginning with Östrogenblocker is rather new, and there are various issues to be addressed. The threshold for "sufficient extend of use" is not clear. It is not clear how "knowledge" and "negligent ignorance" will be assessed. Although the ruling seems to be favourable to the patentee, all three decisions (Östrogenblocker, Dexmedetomidine and Fulvestrant) have been ruled in favour of the defendants. But the fact that in all those cases, the injunctions were not granted shows that the task of proving sufficient evidence seems to be rather difficult.

The German court recognised indirect infringement if the non-patented use was too low compared to the patented use and if the manufacturer (supplier) did not take adequate measures to prevent the patented use. The Court preferred the criterion of not taking the necessary steps to prevent the patented use instead of the inducement criterion. However, in our opinion, such a preference does not comply with the clear text of the law. The law aims to prevent the use of the persons who directly carry out the patented invention. And only if the supplier has an active action for the realisation of this patented use, such as inducement, the result of this action is targeted to be prevented. The decisions of the German Courts paved the way for the patent owner to apply directly to the supplier instead of the direct infringers, which according to our understanding, aggravates the burden of the supplier beyond the letter and spirit of the law.

### C. French Practice

In France, two decisions related to the infringement of a second medical use claim have been handed down in a preliminary injunction (PI) application. The claimant in both decisions was Warner-Lambert and its licensee Pfizer. As in the UK judgement, in France, the Swiss-form claims are considered process claims and not product claims.

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[33] https://www.simmons-simmons.com/en/publications/ck0am31acner80b858w0vy9is/280119-infringement-of- swiss-type-second-medical-use-claims, accessed 07.09.2022.

In the first decision dated 26.11.2018, the Paris District Court rejected the PI claim on the ground that Sandoz has carved out the patent-protected indication from its SmPC and its label and additionally informed more than 30.000 physicians and more than 19.000 pharmacists not to use the generic drug for the patented indication. In its decision, the Court stated that Sandoz could not reasonably be held liable for direct or indirect infringement. The Court stated that direct infringement (art. L 613-3c of the Intellectual property code) is not established in a plausible way and above all during the entire period: the placing on the market and after the hearing, the defender (Sandoz) agreed to send a message to healthcare professionals and to send one even more explicit written message as agreed with the Pfizer companies to the same professionals and to others in the city and in hospitals[34]. The Court denied the indirect infringement on the ground of art. L 613-4/2 on the Intellectual Property Code. The Court stated that it could not be maintained that the French regulatory system relating to the prescription and substitution of medicines will automatically lead to infringement in the event that a second therapeutic use of a given molecule is protected, whereas the previous indications of the same molecule are in the public domain.

The Court stated that it is not in the responsibility of Sandoz to address the health authorities directly and to alert them of the rights of Pfizer related to pregabalin in the treatment of neuropathic pain. The Court noted that this step could only be undertaken by the company holding the patent rights and that this is moreover the reason why the holders of the patent rights are notified of the delivery of an MA (marketing authorisation) to a generic company. Finally, it was indicated that the request towards Sandoz to send an information letter to the College of Physicians and the College of Pharmacists is irrelevant[35]. In its reasoning, the Court held that there has never been evidence that Sandoz induces doctors or pharmacists to sell pregabalin for the treatment of neuropathic pain[36].

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[34] Tribunal de Grande Instance de Paris, Warner-Lambert Company Llc / Pfizer ltd / Pfizer PFE France c. Sandoz, N° RG: 15/58725, 26 Octobre 2015, pp.15-22, https://eplaw.org/wp-content/uploads/2016/03/FR-Warner- Lambert-Pfizer-v-Sandoz.pdf. accessed, 25 May 2022.

[35] Tribunal de Grande Instance de Paris, Warner-Lambert Company Llc / Pfizer ltd / Pfizer PFE France c. Sandoz, N° RG: 15/58725, 26 Octobre 2015, p.23-24.

[36] Tribunal de Grande Instance de Paris, Warner-Lambert Company Llc / Pfizer ltd / Pfizer PFE France c. Sandoz, N° RG: 15/58725, 26 Octobre 2015, p.24.

The second decision is the decision handed down by the Tribunal de Grande Instance de Paris dated 02 December 2016[37]. Warner-Lambert alleged that the defendants (Sandoz, Generics UK, Mylan, Teva, Zentiva, Sanofi, Biogaran, Ranbaxy and others) would commit infringement knowingly and in bad faith by supplying means essentials to the patent. Warner asserted that pregabalin is a patent-protected medicine for neuropathic pain, and even if prescribed for epilepsy or anxiety (the first medical use), given their obligation of substitution, pharmacists will supply generic Pregabalin even for the patented use.

In its judgement relative to indirect infringement, the Court stated that all the defendants have limited their MA to the non-patented indications and have clearly indicated on the instructions included in the packaging and, above all, have carried out extensive information for pharmacists and doctors prescribers who have been notified each time a product is marketed[38].

The Court stated that even if the distribution and prescription of medicine are regulated because of its dangerous nature, it may be considered a staple commercial product[39]. This is an important notice which approves the view that even if only one non patented use exists, the product supplied for a non-patented use is a staple commercial product. In line with the above mentioned French decision, the Court stated that the defendants are not inducing pharmacists or physicians to substitute generic Pregabalin for the patented use.

## 3. Indirect Infringement of Second Medical Use Claims Under Turkish Law

Both in Turkey and EU countries, we see that products with a non-patented use do not constitute a direct infringement of the patent and can be characterized as staple commercial products. When we look at the practice of EU member states, we see that drugs are generally prescribed according to their INN names. In fact, as we have seen in the decisions of the English Court, in order to prevent infringement, in the case of a second medical use patent, doctors should prescribe according to the trademark. In this respect,

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[37] With a docket number 16/57469, https://eplaw.org/wp-content/uploads/2017/01/FR-pr%C3%A9gabaline.pdf, accessed 25 May 2022.

[38] Warner Lambert c. Sandoz and al, pp. 38-39.

[39] Warner Lambert c. Sandoz and al, p. 39.

we can say that the possibility of infringement (at least from this point of view) is weakened considering that healthcare providers in Turkey already prescribe according to the trademark. When we look at the practice in the UK, we realise that it is lawful to supply a known and staple commercial product, for non- patented use. However, it is still possible for the originator pharmaceutical companies to suffer damages. In order to prevent this damage, it was ruled that the National Health Service should publish guidance for doctors and pharmacists. As can be seen, the obligation here is lies on the health authorities, not the supplier.

Similarly, in a decision rendered by the French Court of Justice, it was stated that the company supplying the drug does not need to warn doctors and pharmacists, and that this obligation is on the patent holder.

In our opinion, in terms of Turkish Law, if the person supplying a drug for non-patented use does not promote the patented use of the medicine and does not encourage such use, the supplier should not be held liable for indirect infringement. When we look at the German practice, it is seen that it deviates from the wording of the Law and it is stated by the Court that even in the absence of clear incentive, if the patented use is much higher than the non-patented use, the supplier should be held liable for indirect infringement. According to the decisions, in order to be held liable here, the supplier must clearly know this fact. However, as we mentioned above, there is no reason to deviate from the text of Article 86 of the IPL. In any event, the supplier should only be held liable if it encouraged the patented use.

On the other hand, if the person applying to the Ministry of Health for a drug discount contract also includes the patented use in the indications, the pharmaceutical drug producer might be held liable for indirect infringement. It is understood that the person in question clearly targets the indication protected by the patent. In such cases, it should no longer be possible to claim that there is no infringement.

## CONCLUSION

Where there is only one non-patented use, the stress must be added on the fact that in case of second medical use patents, the first medical use doesn’t infringe the second medical use patent. Even in patentee friendly jurisdictions as Germany, indirect patent infringement will occur only if the generic manufacturer of the substance, despite knowing that the product is

used in the scope of the patent in sufficient extend, didn't take steps necessary which could be reasonably expected from him to minimize the risk of the infringing use. In German practice, if the extent of use is not sufficient or if the manufacturer took the necessary measures to prevent the patented use, no indirect infringement will occur. Necessary steps might be steps where the manufacturer put the necessary warning on the labels and warns the potential users that the use in the patented way is unauthorized use and will be qualified as infringement. But in principle, there is no indirect infringement in case of strictly first medical use.

In our opinion, in Turkish Law, in view of the explicit provision of Article 86 of the Industrial Property Law, indirect infringement of the second medical use patent may be possible if there is an inducement to use the non-patented product within the scope of the patent. The patent owner cannot prohibit the supply of the product if there is no inducement. The fact that the patent holder suffers damages is not enough to prevent the manufacturer of the non-patented product to put it on the market. The key factor is that the product itself is not patented and the patent law targets only the unauthorized use of the patent. There are some remedies that the patent holder should apply. The patent holder can apply to the National Health Service (NHS) and ask to issue guidance to ensure that doctors prescribe the opponent's product only for the non-patented use; the patent holder can send letter to the physicians and pharmacist in order to warn them about his rights on the patented use.

It should be borne in mind that patent law is about prohibiting the unauthorised use of the patent. The purpose of patent law is not to create barriers to entry to the market. Patent law should not obstruct competition or create evergreening patents. Prohibiting the supply of a pharmaceutical product, which is not patent-protected, should be ultima ratio and should be applied if conditions of art. 86 IPL take place.

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