# Infringements of second medical use patents: An overview of the selected case law

The matter of the protection of new medical uses is one of the most controversial and the most often discussed subjects in patent law. In one of our previous articles in the cycle “Patents Without Secrets” concerning fundamental aspects of the protection of second and further medical uses (“New medical uses: the basic information,” Patents Without Secrets No. 4/2021) we made a promise to return to this question and provide an overview of selected court judgments regarding infringements of patents for second and further medical uses. Naturally, the scope of this text allows us to present only a small piece of the well-developed case law. **The purpose of this Legal Report is it identify certain characteristic trends that reveal themselves in decisions of the European courts, as well as recognize challenges that have arisen along the long and winding paths leading to particular solutions.** When would infringements actually occur, which rules would we apply to assess them? Does the protection of new medical uses exist only “on paper” and we can evaluate it as illusory, or do actually concrete, accessible means of realizing it exist?

We will seek answers to these questions below, let us however begin by recapping several elementary principles underlying the rules that govern the subject of new medical uses.

## The principal foundations of the protection of new medical uses

At the beginning, let us remind you that **in the case of pharmaceutical inventions there is a certain degree of relaxation of rules for the assessment of novelty provided.** If we adhere to the requirement of absolute novelty, only substances and compositions that are entirely novel would be eligible for the patent protection. Meanwhile, pursuant to the provisions of the Convention on the Grant of European Patents signed in Munich in 1973 (EPC), as revised by the amendment of 2000, **it is possible to grant a patent for a substance or composition used in treatment or diagnostics that is already comprised in the state of art but its medical use is not known yet:** either any medical use or the specific one that we are trying to obtain the protection for (Article 54 Sections 4 and 5). In the first scenario we would be dealing with the protection of the first medical use and its scope would be delimitated by the construction of patent claims (it can be broad or narrowed to a particular use); while in the other (second or further medical use), which is the main subject of this Report, the protection would be limited to a concrete application of a given substance or composition. Let us add that before adopting the EPC amendment, a common practice was to rely on the Swiss-type claims which had the format "Use of a substance or composition X for the manufacture of a medicament for disease Y". Such phrasing of claims resulted from the principal controversy surrounding the protection of second and further medical uses which concerns the fact that on the grounds of the EPC patenting of methods for treatment is not allowed (the Enlarged Board of Appeals confirmed in a groundbreaking decision G 5/83 in the EISAI case that a distinction between a method for treatment and a new medical use is permissible). Currently, on the basis of the decision G 2/08, the Swiss-type claims have been expressly rejected (they have been considered redundant in the light of the 2000 amendment) — at the same time, the acceptability of purpose-related claims ("substance X for use in the treatment of disease Y") is undisputed. Nevertheless, the patents that were granted before 29 January 2011, in the case of which applicants included Swiss-type claims, remain in force — therefore, we cannot say that they became irrelevant overnight.

Currently, we can encounter two types of valid claims concerning second medical uses:

**a) Swiss-type claims.**
**b) Purpose-related product claims.**

 

We should also mention that the EPC provisions are mirrored within the Polish legal order in Article 24 Section 4 of the Act of 30 June 2000 - Intellectual Property Law (IPL) which affirms the "permissibility of granting of a patent for an invention related to substances or compositions comprised in the state of the art for a use or for a use in a specific way in methods of therapy or diagnostics, that are referred to in Article 29 Section 1 point 3 [methods for treatment of humans or animals by surgery or therapy and diagnostic methods practised on humans or animals], provided that such a use is not comprised in the state of the art". In the article mentioned in the beginning we referred to the Guidelines of President of the Polish Office which list the properties that can be essential for the purpose of demonstrating that a given solution differs from the state of the art; they included: new medical indications; a new, non-obvious group of patients of a distinguishable physiological and pathological status, and at the same time not having anything in common with the group that the therapy was applied to in the past; a new way of administering a previously known medication; as well as a new dosage regimen.

**Although we can speak of a trend to bolster the position of the holders of the patents for second and further medical uses**, either on the level of applicable European and domestic provisions or the relevant case law, it is worth citing H. Żakowska-Henzler who accurately remarked that **"in last years, it has turned out that obtaining a patent for second medical use is not synonymous with obtaining actual legal means for the protection of such a patent"** ("Patents for second medical use - the never-ending story of doubts and controversies," Studia Prawnicze, Issue 4, Warsaw 2017).

## Difficulties in determining when an infringement of a patent occurs

H. Żakowska-Henzler explains that a key problem with regard to patents for second and further medical uses lies in the fact that when it comes to them, **it is not easy to ascertain what is the scope of the exclusivity that a patent holder is actually entitled to** — and this is the same for Swiss-type patent claims as well as purpose-related claims. **This lack of certainty regarding where are the borders of the sphere of rights of a patent holder translates into a major difficulty in the assessment of when its infringement would take place.** The author indicates at the same time that "a broad formula of the second medical use means (…) that in a considerable number of cases the form of a medical product protected by the second medical use patent is not in any way different from the form of a product falling beyond the scope of such protection," **and, in consequence, what is urgently needed is the identification of some specific criteria that could offer a benchmark for those assessments.** Some experts advocate for examining the subjective element — the intentions of a producer who might be infringing the patent: there is not any consensus, however, whether such a producent would have to act with a

 

direct intent to manufacture a product for the use in a way that is covered by the patent or whether their awareness that the product might be used for such a manner subsequently by someone else (e.g., by a distributor or a pharmacist, etc.) might suffice. Moreover, there are others who claim that the assessment of a potential infringement should be based on the objective properties of a medical product (as in the case Warner-Lambert that will be discussed below).

## The United Kingdom: Warner-Lambert v Generics (Mylan) & Actavis (Pregabalin / Lyrica) (2018)

The state of the facts in the case (cases) was as follows: Warner-Lambert, a company belonging to the Pfizer group, requested a temporary injunction against Actavis. The dispute concerned pregabalin — a prescription drug used chiefly for the treatment of epilepsy (sold by Warner-Lambert under the name Lyrica); the patents owned by Warner-Lambert expired with exception of one that covered the second medical use, namely its use in particular for the treatment of pain, inflammatory pain, and neuropathic pain (the claims in the Swiss-type format). Actavis was aiming at introducing into a market a generic form of pregabalin (Lecaent) for a use in the treatment of epilepsy and anxiety (which were covered by the original, already expired patent). Simultaneously, Generics (Mylan) company has entered a game, filing for a revocation of the patent owned by Warner-Lambert. The case reached the instance of the Supreme Court of the United Kingdom.

The Supreme Court shared the objections raised by Mylan and Actavis against Warner-Lambert and found the patent owned by the latter company for the second medical use to be invalid. This decision was justified on the grounds of **the lack of sufficient disclosure in the patent in question of the possibility of using pregabalin for the treatment of peripheral neuropathic pain.** The Court referred in this context to the plausibility test popularised in the EPO caselaw which does not allow for limiting oneself to speculative claims, unsupported in a sufficient degree by concrete data; the thesis regarding fitness of a medical product for a particular use will not be enough if it is not accompanied by a detailed scientific specification corroborating its effectiveness in a given domain (e.g., submission of test results).

**Furthermore, the Supreme Court held that even if the patent had been valid, the infringement would not have occurred — and in that area a revolution of sorts ensued.** Until that moment, in judicial rulings regarding infringements the intent of the alleged infringer have been considered essential. A judge that adjudicated the case in the first instance tried to determine whether the purpose of Actavis as a producer of a generic medical product was to apply it for the uses protected by the patent owned by Warner-Lam-

 

bert (the subjective intent test). The Appellate Court suggested paying attention foremost to the objective intent of the producer, indicating that a direct infringement would have occurred if Actavis had known or should have reasonably expected that a medical product would be used for the uses covered by the patent (the objective intent test). Finally, the Supreme Court discarded both those tests, underscoring the need of securing the position of distributors and pharmacists; it expressed a conviction that it would be arbitrary to allow for their responsibility for the further circulation of medicines infringing patents just because of a particular intent of another individual. It proposed **an outward presentation test that requires to determine objective properties of a medical product instead of a volitional state of the producer.** What becomes particularly important for that matter is the way in which the product is advertised and, i.a, the very leaflet attached to packaging — it is supposed to guarantee the necessary legal certainty for individuals participating in further sales of the product. Lecaent, manufactured by Actavis, did not indicate, neither on its packaging, nor on a leaflet, any use that would be protected under Warner-Lambert's patent.

## The Netherlands: Novartis v. Sun Pharmaceutical (2015-2017)

Another interesting judicial ruling was delivered in the dispute between Novartis and Sun Pharmaceutical. The Novartis company was granted a patent for zoledronic acid used in the treatment of osteoporosis. Meanwhile, Sun Pharmaceutical which is not a manufacturer of medical products, but deals with their sales and distribution, has acquired a licence for generic zoledronic acid — even though the licence encompassed the use of that composition for the treatment of osteoporosis as well as the treatment of Paget's disease, in order to avoid infringing of Novartis' patent, Sun demanded to carve out the indication for the treatment of osteoporosis from the summary product characteristics and the patients information leaflet. Soon afterwards, the company successfully participated in a tender for the sale of zoledronic acid for an insurance company, the conditions of which explicitly obliged it to provide the chemical composition without restrictions to a single particular use. Subsequently, Novartis sued Sun and the judgments in the case kept changing as it progressed through all the instances.

First, the Appellate Court in January 2015 found that Sun Pharmaceutical in fact had infringed the patent owned by Novartis: Sun provided its contractor with quantities of the medicine that were disproportionate in view of the size of the patient population for Paget's disease, and, in the Court's opinion, Sun must have known that it was used to the treatment for osteoporosis and yet it had failed to undertake sufficient measures to prevent it. In November of the same year, the District Court in the Hague found no infringement — it held that the Novartis' patent, as including the Swiss-type claims, protected the particular

 

process of preparation of the medicine for a specific use, whereas Sun Pharmaceutical used a ready product. Finally, in April 2017 the Supreme Court announced its position on the matter, agreeing with the Appellate Court that delivered the ruling in the first instance: **Sun was found liable for the infringement of the Novartis' patent — Supreme Court stated the company should have undertaken the sufficient steps in order to prevent the application of the generic medical product for patented uses; and the omission of a particular indication from the summary of product characteristics was not considered enough.**

Two specific aspects of this case are worth pointing out. First, it illustrated that in particular situations the assessment of a potential infringement might not be based on a conduct or awareness of solely a producer but also of another individual involved in trade of a product, such as a distributor. Second, the distinction between direct and indirect infringements is clearly drawn here: the first category would encompass the cases in which a product characteristics or a leaflet explicitly list a patented use, while as for the other — an infringement occurs if an application of a product for a protected use can be deduced from other circumstances (in this particular state of facts it was an indirect infringement that Sun was accused of).

## Germany: AstraZeneca v. Hexal - Fulvestrant (2019)

A dispute in another case that we would like to discuss involved AstraZeneca, an owner of a patent for the use of fulvestrant for the hormonal treatment of breast cancer (patent claims in the Swiss-type format), on the hand, and Hexal on the other. The bone of contention was the stage of the treatment during which the medicine was supposed to be administered to patients (the treatment in this case is divided into two stages: the adjuvant phase which takes place immediately after surgical removal of the tumor, and the palliative phase — when the cancer recurs within 12 months after completion of the treatment with aromatase inhibitor). Hexal claimed that the AstraZeneca's patent covered the use of the medicine solely in the palliative stage, while AstraZeneca posited that it should be construed in a broader way as protecting the application of fulvestrant in case of a failure of an earlier treatment, regardless of the stage of the treatment at which it is administered and of the moment when the cancer recurs. The court in Düsseldorf agreed with Hexal, speaking in favor of the restrictive interpretation of patent claims, based above all on their literal meaning.

It must be stressed that the judgment in the fulvestrant case is consistent with the jurisprudence initiated earlier by the Düsseldorf Court of Appeal in its decision in Ostrogenblocker case of 5 May 2017 and its importance stems from the fact that **it confirms**

 

**and develops the criteria that this court employs in the assessment of potential infringements of patents for second medical use.** Taking into consideration the rulings delivered by it so far, we can formulate certain conditions that have to be fulfilled jointly in order for an infringement to occur:

**1.The product in question is suitable for the patented use;**
**2.The supplier or distributor exploits circumstances that consequently lead to the product's utilisation in the patented use;**
**3.Sufficient extent of use is required; and**
**4.The supplier or distributor is, or at least should be, aware of the extent of use required.**

In the case of fulvestrant the third condition turned out to be decisive. The use protected by the patent constituted only about 7% of the total number of patients for the drug, which was not considered by the Düsseldorf Court sufficient. It indicated that if there were more instances of the application of the product for the patented use, it would be more probable to find the infringement. The judges formulated also some relevant guidelines that might be useful in determining the moment for which such an evaluation shall be carried out: namely, to get injunction, a company must demonstrate the sufficient extent of use at the time of the oral hearing in the case (if it reached the necessary threshold in the past but then fell below it, it might still be relevant for a potential compensation). We can also remark that in the test favoured by the German court the subjective element remains important: the test requires us to demonstrate bad faith of the infringer.

**The Appellate Court in Düsseldorf considerably broadened the catalogue of situations in which an infringement of a patent for second medical use can be found.** Until that point, according to the view predominant in the German jurisprudence, an infringement could have taken place only in the context of purposeful arrangements concerning the manufacturing of a medical product to be applied for patented uses. Dosage regimen, packaging and leaflets had to expressly mention such an indication of a product, which drastically limited the protection that a patentee could count on and offered producers of generics a lot of room for circumventing the scope of exclusivity of the former by, i.a., recommending a different dosage regimen in the leaflet or explicitly carving out a patent use from it (so-called *skinny labels*).

## The summary

What picture emerges from the discussed rulings? It is certainly chaotic and hazy.- The dynamics of the processes that shape our understanding of the protection of second

 

medical uses is not unambiguous. **Right now, it would be difficult to conclude that any consensus regarding the best possible method for the assessment of infringements has been achieved. The competition between the alternative criteria: either emphasising subjective or objective elements remains unresolved.** Any distinct tendency to favor one or the other party: either patent holders or producers of generics has not been revealed so far. More often, the cases we discussed were won by the adversaries of huge pharma concerns — the patentees (with the sole exception of Novartis v. Sun Pharmaceutical), however the conclusion that there is a trend to reinforce the position of producers of generics does not seem entirely tenable.

**The decisions of the Appellate Court in Düsseldorf clearly open up a considerable space for those who hold patents for second medical use for pursuing infringements:** by confirming that not only purposeful agreements might be a basis for incurring liability, **they force producers of generics to take into account an increased probability of having their conduct assessed as an infringement. The judicial rulings in the Novartis case**, first of the Appellate Court, then of the Dutch Supreme Court**, likewise lead to strengthening the standing of the owners of patents for second medical uses by showing that not only the conduct of producers might be relevant for finding an infringement, but also that of, i.a., distributors. The British judgment in Werner-Lambert case can also be read as a response to the necessity of greater legal certainty: by objectification of the criteria under which an assessment of a potential infringement is carried out.**

However, the doubts regarding the scope of the protection that holders of patents for second medical use are entitled to remain. The opinions of particular courts differ and it seems that a point where a certain degree of convergence of these views can be achieved lays still far ahead — the doctrine on the second medical uses still needs time to crystallize.

 