Infringement of Second Medical Use Claims

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G. Legal remedies

In principle, in Poland a patent holder may seek legal redress not only when an infringement actually takes place but also when the infringement is merely threatened. **38**

The activities that are covered by a patent monopoly in Poland are as follows: manufacturing, using, offering, marketing, storing or warehousing products which are the subject matter of the invention, exporting or importing them for these purposes, or using the process that is the subject matter of the invention, as well as using, offering, marketing, storing or warehousing products obtained directly from that process, exporting or importing them for these purposes. Claims for patent infringement will only be justified when there is proof that an unauthorised party has undertaken the above activities. **39**

Patent holders may also demand that an unauthorised third party ceases activities that only threaten to infringe the patent. Such a threat should be real and serious. The legal doctrine indicates, that e.g. the purchase of a machine for the production of infringing goods or the conclusion of a contract for the manufacture of a given product, may indicate a risk of infringement. However, all the circumstances surrounding such preparatory activities must be taken into account before reaching conclusion that there is a threat of an infringement under Polish law.[28] **40**

A request to cease patent infringement or activities only threatening to infringe patent is possible only during the term of the patent – after the expiry of the patent, only a claim for compensation for damage or loss and return of unjustly obtained benefits during the time when the patent was in force may be pursued. **41**

Depending on the circumstances of each case, different activities may substantiate a claim of patent infringement or a threat of such. In principle, regulatory actions aimed at obtaining market authorisation (MA) for a medicinal product are not considered a patent infringement in Poland (even if samples of products must be submitted to the authorities). A broad definition of the Bolar exemption allows for any such actions to be undertaken without a risk of patent infringement (also by third parties mandated by the market authorisation holder (MAH) – the clear result of an amendment introduced some time ago after a fierce dispute regarding third party manufacturing mandated by the MAH for the purpose of regulatory proceedings). The conclusion may be different where the obtained MA is granted long before the expiry of patent protection, so that the period of validity of the MA is shorter than the remaining period of patent protection (if the product covered by the MA is not placed on the market within three years of obtaining the MA, then the MA expires[29]). **42**

Despite some court decisions addressing this issues, it is still not unequivocally settled whether an application for reimbursement of medicinal products is sufficient to justify a claim of patent infringement or a threat of a patent infringement; usually all circumstances of the case must be taken into consideration before coming to such a conclusion.[30] However, in more finely differentiated cases (e.g. skinny label) it cannot be ruled out that already at the stage of obtaining regulatory permit there is enough evidence to claim that there is a threat of a patent infringement. Again, this must be evaluated on a case-by-case basis. **43**

[28] See: Stefańczyk-Kaczmarzyk in: Kondrat (ed.), Prawo własności przemysłowej. Komentarz, Warsaw 2021, Art. 285.

[29] Art. 33a Sec. 1(1) of the Pharmaceutical Law of 6 September 2001; → mn. 57.

[30] Court of Appeals in Warsaw, 17 May 2016, docket no. VI ACa 640/15; also Stefańczyk-Kaczmarzyk in: Kondrat (ed.), Prawo własności przemysłowej. Komentarz, Warsaw 2021, Art. 285.

44 Under Polish law, the remedies available to a patent holder, whose rights are infringed by a skinny label medicinal product are similar to those applicable in other patent infringement cases. There is no specific regulation, nor separate established practice.

45 As a first preliminary step to an infringement action, the patent holder may demand a preliminary injunction. This usually consists of a court order prohibiting the alleged infringer from trading in the infringing goods for the duration of legal dispute, sometimes combined with seizure of goods or devices/materials used in the process. The preliminary injunction generally ought to be decided at an open hearing, although it may be granted *ex parte*, in cases of particular urgency or if the injunction is to be executed by a bailiff (i.e. seizure of infringing goods). Instead of an open hearing, the court may request the defendant to respond to a motion for preliminary injunction in writing. The preliminary injunction, if granted, may be enforced e.g. by way of *per diem* penalties levied on the non-compliant defendant.

46 The requirements for a preliminary injunction are that the underlying claim is shown to be plausible and that the preliminary injunction is necessary to achieve the purpose of the legal action (legal interest). Making the claim plausible usually involves providing evidence of trade in infringing goods, coupled with a privately obtained expert opinion confirming that the goods are embodiments of the patented medicinal product, plus proof of circumstances evidencing their use for the patented purpose. The second requirement (legal interest) is usually met in patent infringement cases, as long as the plaintiff acts reasonably urgently (the statutory urgency threshold being rather generous six months from learning about the infringement, however, it cannot be excluded that in particular cases, a shorter delay may be argued to be a sufficient indication of absence of legal interest).

47 If a preliminary injunction is obtained, the patent holder is obliged to file the main action on the merits within a period specified by the court, no longer than two weeks from the grant of injunction. In the main action the patent holder can request the usual range of remedies, including a permanent injunction prohibiting trade in infringing products, publication of the judgment in media at the infringer's cost, destruction of infringing goods/devices used for production of same as well as of ancillary materials, payment of damages (either calculated as loss evidenced by the plaintiff, e.g. lost sales, or as equivalent of reasonable licence fees), transfer of profits derived from the infringing action. The kind of evidence necessary to prove infringement is similar to the proof in preliminary injunction proceedings, except it is more rigorously reviewed by the court and in lieu of a battle of expert opinions provided by parties, a court-appointed expert would opine on technical matters. The parties have a broad range of measures at their disposal, allowing them to obtain evidence in possession of the other party.

48 The duration of proceedings in the first instance is usually not less than one year and may take several years, in particular due to the length of time required for the court expert to prepare the opinion or opinions (in practice usually there are several, as the parties may require supplementary opinions).

H. Statutory provisions

I. Industrial Property Law[31]

Article 25 Sec. 4 49

The provisions of sections 1 to 3 shall not exclude the patentability of any invention concerning substances or compositions comprised in the state of the art, for use or for specific use in treatment or diagnostic methods referred to in Article 29(1)(3), provided that such use is not comprised in the state of the art.

Article 29 Sec. 1(3) 50

Patents shall not be granted for: […]

(3) methods for the treatment of the human or animal body by surgical or therapeutic methods and methods of diagnosis applied to the human or animal body; this provision does not apply to products, in particular substances or mixtures used in diagnosis or treatment.

Article 64 51

1. A patent for an invention concerning a manufacturing process also covers products directly obtained by this process.
2. As regards new products or if the patent holder demonstrates that they were unable to establish, despite having made reasonable efforts, the product manufacturing process actually applied by another person, it is presumed that the product that can be obtained by the patented process was manufactured by this process.
3. In the case referred to in section 2, when admitting evidence to the contrary, the defendant's legitimate interest in protecting their production and trade secrets should be taken into account.

Article 65 52

A patent for an invention concerning the application of a substance that forms part of the state of the art to obtain a product that has a new use also covers products prepared according to the invention specifically for such use.

Article 66 Sec. 1 53

1. The patentee may prohibit a third party, acting without their consent, from exploiting the invention in a commercial or professional manner involving:
   1) manufacturing, using, offering, marketing, storing, or warehousing products which are the subject matter of the invention, or exporting or importing them for such purposes, or
   2) using the process that is the subject matter of the invention and using, offering, marketing, storing or warehousing products obtained directly from that process, and exporting or importing them for these purposes.

Article 285 54

The proprietor of a patent, supplementary protection right (certificate), protection right, right in registration, or a person permitted under the Act may request that the actions posing a threat of infringing his right be ceased.

[31] Act of 30 June 2000, see Journal of Laws 2023 item 1170.

II. Civil Code[32]

55 **Article 422**

Not only a person who has directly inflicted damage but also the person who has induced another person to inflict the damage or who has assisted them, as well as the person who consciously benefited from the damage inflicted to another person shall be liable for the damage.

III. Act on Combating Unfair Competition[33]

56 **Article 3 Sec. 1**

1. An act of unfair competition is any activity in violation of law or good morals if it threatens or infringes the interest of another entrepreneur or customer.

IV. Pharmaceutical Law[34]

57 **Article 33a Sec. 1(1)**

1. An authorisation shall expire if:
   1) the responsible entity does not place the medicinal product on the market within 3 years from the date of receiving an authorisation;

V. Act on Patients' Rights and the Patient Ombudsman[35]

58 **Article 6 Sec. 1**

1. A patient has the right to health services that meet the requirements of current medical knowledge.

VI. Annex to the Regulation of the Minister of Health of 8 September 2015 on the General Terms and Conditions of Contracts for the Provision of Healthcare Services[36]

59 **§ 5**

The healthcare provider is responsible for prescribing medicines, foodstuffs for particular nutritional uses and medical devices to recipients in accordance with the applicable regulations and current medical knowledge.

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[32] Act of 23 April 1964, see Journal of Laws 2023 item 1610.
[33] Act of 16 April 1993, see Journal of Laws 2022 item 1233.
[34] Act of 6 September 2001, see Journal of Laws 2022 item 2301.
[35] Act of 6 November 2008, see Journal of Laws 2023 item 1545.
[36] Journal of Laws 2023 item 1194.

VII. Regulation of the Minister of Health of 6 November 2013 on Guaranteed Services within the Scope of Health Programs[37]

§ 3 Sec. 1 **60**

1. Guaranteed services shall be provided in accordance with the indications of current medical knowledge, using diagnostic and therapeutic methods other than those used in unconventional, folk or oriental medicine.

J. Extracts from court decisions

I. Regional Court in Warsaw (2014)[38] **61**

The obliged party's infringement of the exclusive use of the invention, resulting from the […]

patent granted to the patent holder, is supported by both: the characteristics of the products with the trade names R. (1) transdermal system patch and R. (2) transdermal system patch, and the indication by […].V. of the medicinal product E. transdermal system as the reference medicine for them. Its documentation served to register the obliged party's products, authorised for marketing by the decision of the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, without the obligation to submit clinical and non-clinical studies. The fact that the obliged party's generic medicinal products have fulfilled the patent claim is confirmed by the expert assessment provided in the expert report attached to the application.

II. Regional Court in Warsaw (2015)[39] **62**

In order to make plausible an infringement consisting of an encroachment by the obliged party on the scope of patent exclusivity reserved for the patent holder, the patent holder should have demonstrated that the obliged party was using the invention, in the sense of taking steps to manufacture, import, apply, offer and market medicinal products with the trade names R. T., (…) h, transdermal system patch and R. T., (…) h, transdermal system patch or having any other trade name, containing the active substance (…) for application in a method of preventing, treating or slowing the progression of dementia or disease (…), where (…) is administered in a transdermal therapeutic system (T.) and the approved starting dose is that of a medicinal product called 'E. (…)4 h transdermal system', because this is supposed to be the content of future claims.

The evidence offered shows that the company (…) has obtained a marketing authorisation (MA) in the territory of Poland, where the patent for the invention (…) is protected. Its medicinal products R. T., (…) h, transdermal system, patch, and R. T., (…) h, transdermal system, patch have been entered on the reimbursement list for use in (…) disease. However, this does not mean that it manufactures, imports, applies, markets and offers products specifically formulated for the application and mode of administration protected by the patent. At this stage of the proceedings, it cannot be concluded that the company (…) is actually exploiting

[37] Journal of Laws 2023 item 916.
[38] 7 March 2014, XX GCo 39/14.
[39] 2 February 2015, XX GCo 8/15.

the invention (…) in such a way that belongs exclusively to the patent holder, as provided for in Article 66 in conjunction with Article 287(1) Industrial Property Law.

63 III. Court of Appeals in Warsaw[40]

'Turning to the merits of the statement of claims, one has to agree with the Court of First Instance that, in bringing a claim for patent protection to court, the claimant was required to jointly demonstrate three circumstances:

1) the existence of his right,
2) infringement of the patent by the defendant in any if the forms set out in Article 66(1) Industrial Property Law
3) performance of an obligation exhausting the patent claims.

(…)

Thus, while one may agree that the mere submission of marketing and reimbursement applications does not constitute patent infringement, marketing [of the products] does.'

(Similar holdings in the judgments of the Regional Court in Warsaw of 29 January 2015, XX GC 284/14 and XX GC 311/14)

64 IV. Polish Supreme Court (2019)[41]

It should be noted that when establishing the intention to harm, as a circumstance of a subjective nature, related to a certain state of will (consciousness) of the debtor, the court may resort to inferences based on external, objective and verifiable premises, if they are justified in the light of principles of life experience, general knowledge and logic (Article 231 of the Code of Civil Procedure) (cf. the judgment of the Supreme Court of 9 February 2017, III CSK 60/16, unpublished).

65 V. Polish Supreme Court (2015)[42]

The strict interpretation adopted by the Court of Appeal regarding the scope of rights under the patent (Article 63(2) IPL), the consequence of which is the thesis that infringement of these rights (Article 237(1) IPL) occurs only when the solutions covered by the patent and applied by another person are completely identical, is one of those presented in the literature. However, that Court did not consider the comparison presented in the doctrine and case law referred to as the theory of equivalents or the doctrine of equivalent means. This was developed on the basis of the application of the rules of the Convention on the Grant of European Patents (EPC), drawn up in Munich on 5 October 1973, as amended by the Act amending Article 63 of the Convention of 17 December 1991 and by the decisions of the Administrative Council of the European Patent Organisation of 21 December 1978, 13 December 1994, 20 October 1995, 5 December 1996 and 10 December 1998, together with the Protocols forming an integral part thereof (Journal of Laws 2004 No. 79, item 737). The reason for developing this theory was to prevent the possibility of circumventing the patent by making obvious modifications to the patent not expressly provided for in the patent claims, while modifications that are not obvious and that require independent creative input being outside the extended scope of the patent.

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[40] 17 May 2016, VI ACa 640/15.
[41] 19 April 2019, III CSK 273/18.
[42] 10 December 2015, V CSK 149/15.

This comparison involves determining the scope of patent protection for a given solution in order to check whether the technical solution of another entity, or its particular features, can be considered equivalent to those claimed by the patent. Its essence lies in the possibility of extending the scope of protection granted to an invention by extending this protection also to all those solutions in which certain elements have been replaced by others performing the same functions and leading to the same result as the patented solution. The equivalence of technical means is determined by the function they perform in the solution, the objective they allow to be achieved in that solution and the result they contribute to. The equivalent means will therefore be such that lead to the same solution of the technical issue that underlies the patent.

The comparative examination should consist of the following steps:

- determining the subject matter of the patent on the basis of its claims, description and drawings, taking into account the technical problem underlying the invention in question and the essence of the solution, as well as the type of invention protected;
- determining the technical features of the invention in dispute, including the underlying technical problem and the nature of the invention as a whole;
- determining which technical features of the solution in dispute functionally reflect solutions already existing in the state of the art (determination of the closest state of the art for the solution in dispute);
- comparing the determined subject matter scope of the patent with the technical features of the contested solution in order to verify which features of the protected solution are reflected in the contested solution in the form of their obvious equivalents;
- determining, where the technical features (obvious equivalents) reproduced in the contested solution constitute the essence of the technical solution protected by the patent, whether those features could have been developed by a [so-called] specialist in the field without knowledge of the patent.

The use of this comparison has an advantage over a formalistic approach, which may not reflect the true scope of the solutions under comparison. The differences between the solutions should relate to the essential features of a concept changing the existing state of the art.

VI. Regional Court in Warsaw (2020)[43]

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In the Court's view, both the conclusions presented by the experts' opinions and the above findings confirm that the defendant's medicinal product, in terms of the disputed use in adjuvant treatment, does not infringe the claimant's exclusive rights under the patent. In addition to these arguments, it should be pointed out that, according to the leaflet for (…) and the SmPC of this medicinal product, this drug was not intended for the treatment of inoperable tumors (…), but for application in patients after surgical removal of tumors for preventive purposes, and such use was indicated by the defendant in the above-mentioned documents. As indicated by the experts and confirmed by the positions in the articles on (…), adjuvant treatment means 'complementary', 'preventive', 'prophylactic' therapy after complete removal of the tumor and aims to reduce the likelihood of metastatic recurrence. The defendant could not, for the above reasons alone, infringe the plaintiff's patent, which resulted in the dismissal of the claims covered by the lawsuit.

[43] 16 December 2020, XX GC 1117/16.

§ 10
Portugal

A. Executive summary

1 The case law in Portugal on second medical use patents is scarce, difficult to find and still pretty unclear due to the particularities of the patent landscape in Portugal concerning pharmaceutical patents until 2019, when a mandatory arbitration procedure was introduced to be the sole forum to solve disputes concerning IP rights related to medicines of reference and generic medicines. We are aware of only a few decisions on the subject, issued by arbitral tribunals in 2016 and 2017 (essentially regarding pregabalin and zoledronic acid). After the creation of the IP Court in 2019, the forum handling patent disputes, there are no decisions on the subject.

2 It appears that in order to rule out the risk of infringement, generic companies need to 'carve out' the protected indication from the marketing authorisation and also take additional preventive measures to minimise the risk that the generic product will be used for the patented indication, such as recommendations to health professionals.

3 Court decisions have so far only addressed the issue of generic products, but infringement by a biosimilar product of second medical use patents is likely to be treated in a similar manner.

B. Scope of protection and interpretation of second medical use claims

4 Like Article 54 EPC, Article 53 of the Portuguese Intellectual Property Code (*Código da Propiedade Industrial* – IPC) explicitly provides for the possibility of patenting substances or compositions included in the state of the art for use in a method of treatment provided that its use for any such method is not comprised in the state of the art.[1] The patentability of such substances or compositions for any other specific use in a method of treatment is also allowed, provided that such use is not comprised in the state of the art.

5 Regarding the scope of protection of medical use patents, there is no case law on this matter. However, in line with jurisprudence and EPO guidelines (which are strongly followed by Portuguese courts), the specifically claimed therapeutic use is considered to be an essential element of the invention and an integral part of the scope of protection of this type of patent. Second medical use claims are construed as a 'purpose-limited product claim' and are only infringed when the compound is used for the treatment of the patented indication.

[1] → mn. 30.