Poland

Contributing firm
Patpol

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Selection, clearance and registration

The law

The Industrial Property Law of June 30 2000 (Official Journal of Laws 2001 No 49, pos 508, consolidated text of June 13 2003, Official Journal of Laws No 119, pos 1,117, as amended) defines the requirements for obtaining trademark protection in Poland. The law specifically governing pharmaceuticals includes the Act on Pharmaceutical Law of September 6 2001 (Official Journal of Laws 2004 No 53, pos 533, as amended) and related regulations. The act is almost entirely based on EU principles. Moreover, all EU regulations and the judgments of the European Court of Justice (ECJ) relating to pharmaceutical issues are directly applicable in Poland.

National bodies and procedures

The Polish Patent Office is the main national body responsible for granting trademark protection, while the Polish Ministry of Health controls the registration process and approval procedure for medicinal products. Registration of marks for medicinal products is governed by the procedure and requirements set by the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (ORMP), a government agency competent for the evaluation of the quality, efficacy and safety of medicinal and biocidal products, as well as medical devices.

The Main Pharmaceutical Inspectorate is a centralized organ authorized to ensure compliance with pharmaceutical regulations in the context of advertising. Appeals against its decisions are filed before the District Administrative Court in Warsaw. Further appeal should be brought in the form of a cassation complaint with the Supreme Administrative Court.

An entity seeking to produce or import medicinal products must file an application for approval with the inspectorate. The application must specify the medicinal name of the product and any other commonly used names.

Names of medicinal products and trademarks

Pharmaceutical marks not only need to comply with the trademark provisions of the Industrial Property Law, but also need to meet the requirements regarding names of pharmaceutical products contained in the Act on Pharmaceutical Law and its executive regulations. Pursuant to these regulations, a pharmaceutical name can be:

- an invented name, as long as it does not cause confusion with a common name (ie, an international non-proprietary name (INN) recommended by the World Health Organization or, if such name has not been attributed to a given product, a common chemical name); or
- a common, or scientific name accompanied by a trademark, a company name or the name of the marketing authorization holder.

According to case law, obtaining an authorization for the release of a medicinal product under a given name does not exempt an entity from liability if the name violates third-party trademark rights. Applicants must therefore also keep in mind the provisions of the Industrial Property Law and the Law on Combating Unfair Competition.

Registration at the ORMP

An announcement of the president of the ORMP issued on March 12 2008 gives further guidance on the process of naming medicinal products and the substitution of names that have already been granted. It sets out the following instructions:

- The new name of a medicinal product should differ from an earlier registered product name in at least three letters and the new name cannot include a sequence of more than two of the same letters. An applicant is required to provide a justified written statement when seeking a waiver from these rules.
- The new name cannot result in the likelihood of confusion (in print, spelling and pronunciation) with an earlier registered name.
- Signs such as '®' and '™' cannot form part of the new name.
- The name of a medicinal product cannot contain personal names and surnames, including the name of the inventor. Further, it must not contain:
  - names of abstract persons that are used together with scientific titles, aliases or pseudonyms;
  - expressions which bring to mind religious, geographical or historical associations;
  - names of natural objects; or
  - obscene words or words suggesting obscene content.
- The name of the medicinal product must also be placed on the packaging in the Braille system.

Evidence of registration of a medicinal product name with the ORMP can act as evidence of use of the sign as at that date when attempting to protect the name as an industrial property right.

Parallel imports and repackaging

Regulations regarding the parallel importation of pharmaceutical products were introduced into Polish law under amendments to the Act on Pharmaceutical Law. The relevant amendments became effective on May 1 2004 – the date of Poland's accession to the European Union.

According to these new regulations, parallel importation into Poland of a pharmaceutical product from other EU member states or members of the European Economic Area (EEA) is acceptable provided that it meets all of the following conditions:

- The parallel-imported medicinal product must have the same active ingredient(s) as the product authorized for marketing in the territory of the Republic of Poland (ie, the same indications at least up to the third level of the Anatomical Therapeutic Chemical (ATC) or the ATC veterinary (often referred to as ATCVet) classification).
- The parallel-imported product must have the same strength and administration route as the authorized product, as well as the same or similar form. Slight differences in form cannot lead to any therapeutic differences between the products.
- Where the product authorized for marketing in Poland is a brand name pharmaceutical, the parallel import must also be the brand name product. Similarly, where the authorized product is a generic, the parallel-imported pharmaceutical must also be a generic.

A parallel importation licence is available on application to the health minister. The licence is issued on the basis of an assessment report prepared by the president of the ORMP. The application must include a sample of the packaging and the product information leaflets. A licence is granted for a period of five years.

A parallel importer can place the pharmaceutical product on the market in Poland under:

- the name used in Poland;
- the name used in the EU/EEA member state of origin; or
- the common name or scientific name together with the trademark or name of the parallel importer.

A parallel importer intending to put a medical product on the Polish market must inform the holder of the marketing authorization in Poland as to the expected date of entry onto the market at least 30 days before such date.

In order to place a product on the market, the parallel importer must alter the packaging thereof to adhere to local standards. The packaging must comply with that approved in the import licence. Polish authorities generally require the repackaging of parallel-imported medical products into new boxes that contain informational leaflets for patients in Polish. The informational leaflet must also be consistent with the parallel import licence.

The process of repackaging frequently causes disputes between parallel importers and mark owners. However, there is no case law in Poland with regard to this issue at present. Therefore, the decisions of the ECJ in this area are crucial to resolving such disputes.

One important consideration is the fact that Poland's accession to the European Union allowed for the importation of cheaper medical products from other EU countries into Poland, while the freedom to import medical products from Poland to other EU countries was limited. Under provisions of the accession treaty, a so-called 'special mechanism' was implemented, which provided for an exception to the principle of exhaustion of rights in relation to patents.

In essence, the holder of a patent or supplementary protection certificate for a pharmaceutical product filed in an EU member state at the time when such protection could not be obtained in Poland (ie, before January 15 1993), or the rights holder's beneficiary, may prevent the import and marketing of that product in the member state(s) where the product in question enjoys patent or supplementary protection, even if the product was put on the market in Poland for the first time by the rights holder or with its consent.

The first parallel-imported medical products were placed on the Polish market in November 2005. As of the end of March 2008, over 200 parallel import licences had been granted in Poland.

Anti-counterfeiting and enforcement

The responsibility for combating the trade and distribution of counterfeit medicines in Poland falls on the bodies responsible for the prosecution of crime. Detection and seizure of imported counterfeit medicines are usually conducted by the customs authorities or the police.

Trade in counterfeit medical preparations is flourishing on the Internet and through unauthorized retailers at markets, fitness clubs and sex shops. According to the Main Pharmaceutical Inspectorate, 99% of medicines offered for sale from illegal sources are counterfeit and are hazardous to life or health.

The most popular groups of medicines favoured by counterfeiters include drugs designed to aid sexual potency and steroids, as well as antibiotics, pain killers, hormonal medicines and slimming preparations.

Analysis of counterfeit medicines seized in Poland reveals that they frequently contain the incorrect active ingredient (or no active ingredient at all) and high levels of pollutants.

There has been no evidence of counterfeit medicines entering legal distribution channels (including parallel imports), which are tightly controlled by the inspectorate.

At present, no legal regulations on counterfeit medicines exist. However, a draft of amendments to the Act on Pharmaceutical Law have been proposed based on information provided by the Unit for Combating Counterfeit Medical Products, a body established by the health minister. Among other things, the draft calls for the introduction of a definition for 'counterfeit medical product'. It also extends the authority of the inspectorate and imposes a penalty of up to 10 years' imprisonment for manufacturing and trading in counterfeit medicines. It is hoped that the proposed amendments will allow the authorities to combat the trade in counterfeit medical preparations more effectively. However, it is not yet known when and to what extent the amendments will be implemented.

Advertising

The Act on Pharmaceutical Law sets out the requirements for advertising pharmaceutical products in Poland (Journal of Laws of 2008, No 45, item 271, as amended).

Among others, the following activities are seen as advertising of pharmaceutical products:

- Advertising of pharmaceutical products addressed to the public;
- Advertising of pharmaceutical products addressed to individuals authorized to issue prescriptions or involved in the distribution of pharmaceutical products;
- The visiting by sales or medical representatives of individuals authorized to issue prescriptions or involved in the distribution of pharmaceutical products;
- The provision of pharmaceutical product samples;
- Sponsoring promotional meetings for individuals authorized to issue prescriptions or involved in the distribution of pharmaceutical products; and
- Sponsoring scientific conferences, meetings and congresses for individuals authorized to issue prescriptions or involved in the trade of pharmaceutical products.

The following are no longer regarded as advertising of pharmaceutical products:

- Information placed on packaging and the pharmaceutical products enclosed therein, provided it complies with the relevant permissions for distribution;
- Correspondence with attached informational materials having no promotional character, which are necessary to respond to questions regarding a particular pharmaceutical product;
- Informational announcements, not addressed to the public, regarding in particular a change of packaging and warnings against side effects, on condition that they do not refer to the properties of pharmaceutical products;
- Trading catalogues or price lists, containing exclusively chemical names, common names or information about dosage, form and price of pharmaceutical products, and – in the case of pharmaceutical products covered by the refunding system – the official retail price, on condition that they do not refer to the properties of pharmaceutical products, including therapeutic benefits;
- Information about health or disease of humans or animals, on condition that the information does not refer, even indirectly, to pharmaceutical products; and
- A reference to the official pharmaceutical product description or a veterinary pharmaceutical product description.

Pharmaceutical products may be advertised exclusively by the parties responsible for the products or by persons who have been commissioned by such parties.

An advertisement for a pharmaceutical product cannot be misleading. It should present the product objectively and inform about its rational use. Further, the following types of advertising are prohibited:

- Advertising offering or promising any advantages in a direct or indirect manner in return for purchasing the product, or providing any evidence of having purchased the product.
- Advertising addressed to children or containing any element which might be considered as being addressed to children.
- Advertising of pharmaceutical products that have not been admitted for trade in the territory of Poland or contain information which is inconsistent with the officially approved pharmaceutical product description.

Special restrictions are also imposed on advertising directed to specialists and the public.

The Health Minister Regulation of November 21 2008 on the advertising of pharmaceutical products (Official Journal of Laws No 210, pos 1,327) governs the detailed information that must be included in any advertising of pharmaceutical products.

Generic substitution

Generic substitution is allowed under Polish law. Generic drug names comprise the name of the company producing the medicine together with its INN or invented name.

Online issues

E-pharmacies

The term 'pharmacy' is a reserved name that is legally protected under pharmaceutical and criminal law, as well as unfair competition regulations. Any entity wishing to use the term 'pharmacy' must meet strict regulatory requirements. Online operators that do not meet the conditions set by the regulations on pharmacies can neither use the term 'pharmacy' nor trade in pharmaceutical products.

Domain names

Where a domain name including a pharmaceutical trademark has been registered by an unauthorized third party, the mark owner can use mediation, alternative dispute resolution (ADR) proceedings or civil court action to obtain the cancellation or transfer of such domain. However, following a recent judgment of the Polish Competition and Consumer Protection Court, ADR is unlikely to succeed if the disputed domain name is registered in the name of a natural person. The court held that a contractual clause forcing a natural person to appear before the ADR court is unlawful and reported it to the Register of Prohibited Clauses. WTR

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Malgorzata Zielinska-Lazarowicz has a master's of law degree from Warsaw University, where she also completed postgraduate studies in IP and European law.

Since 2008 she has been a patent and trademark attorney at Patpol focusing on litigation proceedings and enforcement of industrial property rights. Mrs Zielinska-Lazarowicz specializes in patents, designs and trademarks. Being a member of the legal department at Patpol, she also has experience in rendering professional advice on combating unfair competition and copyright issues, as well as EU law.

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Tomasz Rychlicki is a lawyer with Patpol. He is a graduate of the Centre of European Law at the University of Gdańsk. He also studied international IP law as part of a master's of law programme at the Chicago-Kent College of Law.

Mr Rychlicki handles copyright, trademark and domain name cases, as well as customs seizures. He is a member of the editorial board (copyright, related rights and designs, including *sui generis* database rights) of the *Journal of Intellectual Property Law & Practice* and a country correspondent for *Computer and Telecommunications Law Review*.