PATENT OFFICE OF THE REPUBLIC OF BULGARIA

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Implementation of Exceptions and Limitations to Patent Rights

i. Acts for obtaining regulatory approval from authorities

Certain acts for obtaining regulatory approval from authorities are deemed to not infringe patent rights.

Such exception is set out in Article 33 of the Act on the Medicinal Products in the Human Medicine, which states as follows:

Art. 33. Conducting the necessary studies and trials with a view to prepare the documentation for obtaining marketing authorisation and the consequential practical requirements related to the marketing authorisation of medicinal products as referred to in Art. 28 and 29 shall not be regarded as infringing the patent rights or the supplementary protection certificates for medicinal products.

The provision thus implements Article 10.6 of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use.

Article 280, Paragraph 14 of the Act on the Veterinary-Medical Activities also provides a similar exception with regard to veterinary medicinal products:

Art. 280(4). Conducting the necessary trials and tests, related to the product, with a view to comply with the requirements of Paragraphs 1-10 shall not be regarded as infringement of patent rights or supplementary protection certificates.

The provision thus implements Article 13.6 of Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products.

It follows that the exceptions cover regulatory approval of medicinal products for human and veterinary use. They apply only to marketing authorisations for generic products that do not require submission of safety and efficacy tests.

ii. Exhaustion of patent rights

The law provides for regional exhaustion of patent rights. Any act of placing a product on the market within the European Economic Area is deemed to exhaust the patents rights in the product itself. Thus the patent protection does not prejudice the rights of the lawful proprietor of a product. As set out in Article 20a of the Act on Patents and Registration of Utility Models:

Art. 20a. (1) (in force as from the date of accession of the Republic of Bulgaria to the European Union) The exclusive patent right in an invention shall not extend to acts relating to the product enjoying patent protection, where that product has been put on the market in the territory of the European Economic Area by the patent owner or with his consent.
(2) The protection under Article 19, paragraphs (6), (7) and (8) shall not extend to biological material obtained through propagation or multiplication of biological material placed on the

market by the patent owner or with his consent, where the multiplication or propagation is an indispensable result of the application for which the biological material is placed on the market, provided that the obtained material is not used later for further propagation or multiplication.
(3) The protection under Article 19, paragraphs (6), (7) and (8) shall not extend to the sale or any other form of trading in plant propagation material performed by the patent owner or with his consent to an agricultural producer for agricultural purposes. The selling or any other form of trading comprises an
authorization for the agricultural producer to use the product of his harvest for propagation or multiplication purposes in his farm.
(4) The procedure of applying paragraph (3) shall be specified in an ordinance of the Minister for Agriculture and Forestry.
(5) The protection under Article 19, paragraphs (6), (7) and (8) shall not extend to the sale or any other form of trading in breeding stock or other animal reproduction material performed by the patent owner or with his consent to an agricultural producer, such sale comprising an authorization for the agricultural producer to use such stock or other animal reproduction material for the purposes of conducting his agricultural activity, but not to sell it within or for the purposes of commercial reproduction activity.
(6) The procedure of applying paragraph (5) shall be specified in an ordinance of the Minister for Agriculture and Forestry.

iii. Compulsory licensing and/or government use

The law prescribes compulsory licensing in four cases:
- non-working working of the patented invention;
- insufficient working of the patented invention, unless the patent holder justifies his inaction by legitimate reasons;
- public necessity;
- dependent patents.

In the first two cases, the interested persons must have unsuccessfully attempted to obtain contractual licensing under fair conditions. In case of public necessity, no such attempt is required to obtain a compulsory license.

Compulsory licensing is also available in case of dependent patents. It is prescribed to the benefit of a patent holder, whose invention falls within the scope of an earlier patent. The patent holder must have failed to obtain a contractual license under fair conditions and must prove that his invention significantly contributes to the technical progress and has high economic significance.

The provisions on compulsory licensing are contained in Article 32 of Act on Patents and Registration of Utility Models:

Art. 32. (1) Any person concerned, who has unsuccessfully tried to get a contractual license from the holder under fair conditions, may request the Patent Office to grant him a compulsory license to use the invention, , provided that at least one of the following conditions is met:
1. failure to use the invention for a period of four years from filing of the patent application or three years from the grant of a patent, the time limit which expires later being applicable;
2. insufficient working of the invention to satisfy the needs of the national market, within the time limits set out in item 1 above, unless the patent owner gives valid reasons therefor.

(2) The person requesting a license under the preceding paragraph shall be required to prove that he is in a position to work the invention within the limits of the compulsory license requested.
(3) Beyond the cases referred to in paragraph (1), a compulsory license may be granted, where demanded by the public interest, without negotiating with the holder of the right in the invention enjoying patent protection.
(4) A compulsory license may be granted to a holder, whose invention is the subject matter of a later patent and is included in the scope of another, earlier patent, if the owner of the earlier patent refuses to grant a license under fair conditions, where the subject matter of the later patent represents significant technical progress of great economic importance compared to the subject matter of the earlier patent. The owner of the earlier patent shall be entitled to a cross license under reasonable conditions for working the invention claimed in the later patent.
(5) A compulsory license may only be non-exclusive. It may only be assigned together with the enterprise in which the licensed invention is being worked.
(6) A compulsory license may be terminated if within one year of its grant the licensee has made no preparation for working the invention. A compulsory license shall be terminated in all cases if the licensee fails to start working the invention within two years of grant.
(7) The scope of a compulsory license shall be determined by the purpose it was granted for.
(8) A compulsory license shall not be granted to an infringer of the patent.13
(9) Bilateral and multilateral treaties to which the Republic of Bulgaria is a party may lay down further conditions for the grant of a compulsory license to patent owners from States party to such treaties.
(10) The compulsory licensee shall owe the patent owner remuneration.
(11) A compulsory license shall be terminated as soon as the ground therefore no longer exists.
(12) The procedure of granting and terminating compulsory licenses shall be specified in the Regulation referred to in Article 55(3).

iv. Farmers' and breeders' use of patented inventions

The rights of farmers and breeders to use an invention are provided in the form of compulsory and cross licenses. It is set out in the Act on Patents and Registration of Utility Models:

Art. 32a. (1) Where a breeder cannot obtain or use the right in a plant variety without infringing an earlier patent, he may apply for a compulsory license for non-exclusive use of the invention enjoying patent protection, in so far as the license is required for using the plant variety for the purposes of its legal protection, subject to the payment of a respective remuneration. Where such a license is granted, the patent owner shall be entitled to a cross-license for using the protected plant variety under fair conditions.
(2) Where the owner of a patent for a biotechnological invention cannot use it without infringing an earlier plant variety right, he may apply for a compulsory license for non-exclusive use of the protected plant variety, subject to the payment of a respective remuneration. Where such a license is granted, the protected variety owner shall be entitled to get a cross-license for using the invention under fair conditions.
(3) The person applying for the grant of a compulsory license according to paragraphs (1) and (2) shall prove that:
1. he has tried unsuccessfully to get a contractual license from the patent or plant variety owner;
2. the plant variety or the invention represents significant technical progress of great economic importance compared to the patented invention or the protected plant variety.