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The impact of public health issues on exclusive patent rights

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During 2008 the International Association for the Protection of Intellectual Property will put forward a resolution on the impact of public health issues on exclusive patent rights. The Croatian government has strongly supported the preparatory work for this resolution, carrying out analysis into the current impact of the Patent Law and related legal matters and putting together a report on the situation.

Croatian legislation regarding public health issues and their impact on exclusive patent rights is in line with the EU *acquis communautaire* and other international standards, with the exception of certain provisions that will not come into force until Croatia becomes a full member of the European Union.

This article looks at the following issues:

- the experimental use exception and its commercial purpose;
- the Bolar-type exception;
- parallel imports of patented drugs and medical and similar devices;
- compulsory licensing; and
- the new Article 31*bis* of the World Trade Organisation Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs).

Experimental use

The research or experimental use exception is recognised under Article 63 of the Patent Law. Accordingly, acts carried out for the purposes of research and development or for experiments relating to the subject matter of a protected invention are exempt from the patent owner's exclusive right to exploit that invention. The law gives no further detail as to the scope of and conditions for the application of the experimental use exception. In addition, to date there is no Croatian case law regarding the experimental use exception.

Bolar-type exception

The Bolar-type exception is also recognised under the Patent Law. According to that law, acts carried out for the purposes of research and development or for experiments relating to the subject matter of a protected invention, including those that are necessary to obtain registration or market authorisation for a product that is either a human or veterinary drug or a medical device, are permitted. It is not limited to drugs, but may relate to other protected subject matter and medical devices. Therefore, the Bolar exception can apply to other products that are biological products and research tools.

Parallel imports

At present, neither the Patent Law nor the Medicinal Act provides for parallel imports of patented medicines, medical devices or similar.

Generally, the Competition Law provides an exemption for agreements that contribute to improving the production or distribution of goods and/or services or contribute to consumer welfare and economic progress, provided that the agreements impose no limitations that are unnecessary to achieve their goals (ie, the contractor must not be allowed to exclude significant competitors from the market). Furthermore, the provisions applicable to block exemptions and granted to certain categories of vertical agreement regulate any type of agreement entered into by companies that do not operate

at the same level of the production or distribution chain. Provided that such provisions are not the primary goal of such agreements, this particularly includes:

- traditional distribution (ie, re-sale) agreements;
- franchising, selective distribution and agency agreements; and
- agreements containing provisions giving rights to use IP rights.

This regime is based on a case-by-case analysis of the economic impact of distribution agreements. The primary criterion is to measure the economic impact of the market share of the parties involved.

The block exemption applies to agreements provided that the market share held by a supplier does not exceed 30 per cent of the relevant market on which it sells the contract products. The market share is calculated on the basis of the market sales value of the contract products and other products sold by a supplier that are regarded as interchangeable by the buyer, and is increased by the market sales value realised by the connected undertakings on the contract product market and their substitutes.

If the products originate in markets where they were made available under compulsory licence, parallel import is prohibited.

Compulsory licensing

Compulsory licences are available under the Patent Law and the Commercial Court is competent to grant compulsory licences. The procedure for granting a compulsory licence shall be instituted by a legal action against the owner of a patent or a holder of a supplementary protection certificate. A compulsory licence can be granted on grounds of a lack of use, or insufficient use, of a patent and may be granted to any person filing a request for the grant of a compulsory licence with the government if the patent owner has not exploited the invention protected by the patent in Croatia within a reasonable timeframe or has not made effective and serious preparations for its exploitation. A request for the grant of a compulsory licence can be filed once four years have passed from the filing date of a patent application, or once three years have passed from the date on which the patent was granted. A compulsory licence cannot be granted if the patent owner provides legitimate reasons to justify the non-exploitation or insufficient exploitation of the protected invention.

The court may grant a compulsory licence in respect of the first patent to the owner of a patent or to the owner of a plant variety right who cannot use the patent or his or her plant variety right without infringing the first patent, provided that the invention claimed in the second patent or a protected plant variety involves an important technical advance of considerable economic significance in relation to the invention claimed in the first patent. The competent court may take any measure that it regards as useful to verify the existence of such a situation. In this case, the owner of the first patent shall be entitled to a cross-licence on reasonable terms to use the invention protected by the second patent or protected plant variety.

A compulsory licence can be granted if the exploitation of the patented invention is necessary in situations of extreme urgency (eg, national security, protection of public interest in the field of health, food supplies, environmental protection and improvement or specific commercial interests) or when it is necessary to remedy a practice which has been deemed anti-competitive by a judicial or administrative process.

A compulsory licence may be granted only if the person filing the request has made efforts to obtain authorisation from the patent owner under the reasonable commercial terms and conditions and if such efforts have not been successful within a reasonable period of time.

A compulsory licence is non-exclusive and its scope and duration shall be exclusively limited to the purpose for which it was authorised. A compulsory licence shall be granted predominantly for the purposes of supplying the domestic market, unless it is necessary to correct a practice determined to be anti-competitive after a judicial or administrative process.

To date, no compulsory licences have been granted in Croatia for the domestic manufacture and supply of pharmaceutical products. Furthermore, the government may not use a patented invention without previous licence, and may not expropriate a patent.

The Patent Law does not recognise any other means of facilitating access to medicines, medical devices or diagnostics, even in the context of public health crises. Information tools such as the Orange Book do not exist in Croatia. However,

more recently the Croatian State Intellectual Property Office and the Drug Approval Agency have signed a protocol on cooperation, according to which they will cooperate regarding the future exchange of information related to availability of generic medicines.

TRIPs Article 31*bis*

Provisions of the TRIPs Agreement are in force in Croatia, and therefore the new Article 31*bis* is also in force. Thus, the new Patent Law, which came into force on 31st July 2007, provides for compulsory licences for patents relating to the manufacture of pharmaceutical products intended for export to countries with public health problems.

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