

COMPULSORY LICENSE REGIMES FOR PUBLIC HEALTH IN EUROPE

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Summary

Lately, specially tailored compulsory license mechanisms aimed at serving public health have been established in France, Belgium and Switzerland, following the controversy surrounding diagnostic gene patents. The present chapter describes this controversy and the conventional compulsory licenses, critically examines the newly introduced compulsory license mechanisms and compares them with the conventional compulsory license regimes.

1. Introduction

In recent years, many human genome related patents have been granted. Patents on and in diagnostics are not novel, patents on genes for diagnostics, however, were for long an unseen combination. The grant of patents covering the breast cancer genes, BRCA1 and BRCA2, its mutations, as well as diagnostic and therapeutic applications based on the gene's sequence led to worldwide debates on the nature, legitimacy and scope of gene patents and diagnostic methods instrumental to public health. The restrictive licensing

attitude of the patent holder, Myriad Genetics, led to even stronger reactions on the limits to the freedom to exercise patent rights and triggered serious reflection on tools to remedy restrictive licensing behavior in the area of public health.

The present chapter starts off by looking into the controversy regarding diagnostic gene patents and related licensing practices in some more depth (see Section 2). The chapter then explores a tool which has been suggested to temper the consequences of restrictive licensing behavior, the compulsory license, and describes the international legal framework and the different justification grounds (see Section 3). A *first* category of compulsory licenses, *conventional* compulsory licenses, is then analyzed (see Section 4). This analysis teaches that conventional license regimes are not always adequate in dealing with blocking patents in the field of health care. The chapter therefore turns to a *second*, newly designed, category of compulsory licenses, the compulsory license for *public health* (see Section 5). The chapter describes the legal framework, the scope (material scope, personal scope and geographical scope) and the application procedure for compulsory license schemes for public health in France, (See also: VAN ZIMMEREN and REQUENA, 2007) Belgium (See also: DEBRULLE, DE CORT, and PETIT, 2007) and Switzerland, (See also: GERMANN, 2007) where new compulsory license regimes for public health have been introduced in response to the BRCA-controversy. The chapter concludes with a critical investigation on the effect and potential of these new compulsory license mechanisms.

2. The Context: The BRCA-Controversy

All over the world, patent offices granted patents to US company Myriad Genetics and the University of Utah Research Foundation covering the breast and ovarian cancer genes, BRCA1 and BRCA2, its mutations, as well as diagnostic and therapeutic applications based on the gene's sequence. This triggered fierce reactions.

In Europe, the discussion started in 2001 after the grant of three patents based on the genes BRCA1 and BRCA2 and a fourth patent relating to a method for diagnosing breast and ovarian cancer, when a series of opposition and appeal procedures was launched at the European Patent Office (EPO).

The first European patent (EP0705902) related to 'Nucleic acid probes comprising a fragment of the 17q-linked breast and ovarian cancer susceptibility gene' and was granted on 28/11/2001. Opposition was filed on 28/08/2002 and a first appeal against the opposition decision was lodged on 15/11/2005 (T1213/05) but was rejected. A second appeal was lodged on 16/03/2005 (T1213/05). The second patent, EP0705903, related to 'Mutations in the 17q-linked breast and ovarian cancer susceptibility gene' and was granted on 23/05/2001. Also in this case opposition was filed (25/02/2002). Appeal against the opposition decision was lodged on 01/08/2005 (T0666/05). The oral proceedings took place on 12/11/2008 and led to a considerable limitation of the scope of the patent. EP0785216, the third patent, related to 'Chromosome 13-linked breast cancer susceptibility gene BRCA2' and was granted on 08/01/2003. Opposition was filed on 08/10/2003. The oral proceedings took place on 29/06/2005 and led to the decision that the patent would be maintained in amended form (B2 New Specification of the European patent on 07/06/2006) The fourth European patent EP0699754 related

to a ‘Method for diagnosing a predisposition for breast and ovarian cancer’ and was granted on 10/01/2001. Opposition was filed on 10/10/2001 and the result of the opposition was that the patent was revoked (T0080/05). However, in the appeal procedure initiated by the applicant, the Board of Appeal of the EPO allowed the applicant to reformulate the invention resulting in an amendment of the original patent which now only covers a diagnostic method for a specific type of mutation, namely frame shift mutations. (*Information collected from the European Patent Office (EPO) Register Plus Database, <http://www.epoline.org>*).

Even though all these procedures in the end have resulted in a significant reduction of the patent scope, no legal certainty has been achieved, since the opportunity to challenge the patents in national procedures remains open. There is reason to believe that some of the groups which were active in the European opposition procedure will launch invalidity proceedings on the national level. The latest developments in the US (see below) make it even more likely that also in Europe the debate about the eligibility of gene patents will revive and that some group will start a national invalidity procedure. On top of the issuance of the BRCA patents, the restrictive licensing strategy of the patent proprietor Myriad in the BRCA-controversy intensified the debates. For instance, the European Society of Human Genetics (ESHG), prompted by this controversy, expressed its views on the problems and their potential impact in its “Recommendations on patenting and licensing in genetic testing” (ESHG, 2008). In these recommendations, the ESHG also alludes to the role of compulsory licensing tailored for health care.

In Canada, a public battle emerged in 2001 in which Myriad Genetics and several Canadian provinces were involved and where all kinds of political and legal threats were used which ultimately threatened the availability of tests (See also: GOLD & CARBONE, 2008). Even though never a real solution was found the debate in Canada died out when Myriad decided not to pursue the case further.

In Australia and New Zealand, the debate revived in 2008. Genetic Technologies Ltd. (GTG), Myriad Genetics’ exclusive licensee for Australia and New Zealand, announced that it would start enforcing its exclusive license granted in October 2002 to perform diagnostic testing on BRCA1 and BRCA2 genes variations. In May 2003 GTG still communicated publicly that it would not enforce its rights to prevent public service providers from performing BRCA testing. Hence, GTG’s change in enforcement policy caused a lot of resistance. This is reflected in the media coverage and the introduction of an official Senate inquiry regarding “[t]he impact of the granting of patents in Australia over human and microbial genes and non-coding sequences, proteins, and their derivatives” (Community Affairs Committee Reference, Senator Parry, Tuesday 11 November 2008). In the end, the company decided to moderate its demands and allow public hospitals to continue their testing activities. However, this did not happen without striking a blow: during GTG’s annual general meeting (November 2008) shareholders voted out most of the board of directors and left the board with a team of three led by the company's founder, Mervyn Jacobson (*Company Announcement, ‘Further Information re BRCA testing’, November 24, 2008, <http://www.gtg.com.au/index.asp?menuid = 060.070.130&artid = 10747&function = NewsArticle>*). Dr. Jacobson told the meeting that he would try to reverse the

controversial decision to enforce the BRCA test rights and honor the initial commitment. This promise was realized beginning of December (*Company Announcement, 'New Position re BRCA testing', December 2, 2008, <http://www.gtg.com.au/index.asp?menuid=060.070.130&artid=10748&function=News Article>*).

In May 2009, the American Civil Liberties Union and the Public Patent Foundation at the Benjamin N. Cardozo School of Law, along with a number of other plaintiffs (individual patients, patient groups, physicians, academic researchers and medical societies), filed a lawsuit – in short – alleging that the BRCA gene patents stifle research that could lead to cures and limit women's options regarding their medical care. The suit was filed in the US District Court for the Southern District of New York against Myriad Genetics, the US Patent and Trademark Office, and the University of Utah Research Foundation. The research foundation holds the US patents to the BRCA1 and BRCA2 genes and exclusively licensed the rights to perform diagnostic tests on the genes to Myriad, which provides genetic testing for ovarian and breast cancer. Myriad is also co-owner of several of the patents challenged in the suit. The plaintiffs are challenging the legality and constitutionality of several claims in seven US patents related to the human BRCA1 and BRCA2 genes, a number of mutations and methods for detecting mutations in these genes to diagnose a predisposition to breast and ovarian cancer. The major complaint based on patent law is that isolated nucleic acids are not patentable subject matter as being products of nature (contrary to 35 United States Code (U.S.C.) § 101). On March 29, 2010, Judge Robert W. Sweet rendered a 156-page opinion declaring that the claims related to isolated DNA sequences are invalid as they fail to satisfy the requirements for patentable subject matter because isolated DNA is not “markedly different” from native DNA in a person's body (*Ass'n for Molecular Pathology v. United States Patent and Trademark Office*, No. 09-4515, slip op. (S.D.N.Y. March 29, 2010), at 125. The court held that the method claims are also invalid as they claim an abstract idea, and thus fail to meet the so-called “machine or transformation test” under the Federal Circuit's decision in *In re Bilski* (545 F.3d 943 (Fed. Cir. 2008)). The latter case has been appealed to the US Supreme Court and an opinion is expected soon. The broad range of plaintiffs shows the importance of this topic for patients and the scientific and health community. This is also reflected by the broad coverage of the case in the media and the release of the “Revised Draft Report on Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests of the US Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS) (SACGHS, Revised Draft Report, 2010). The actual impact of Judge Sweet's decision likely will not be known for some time: an appeal to the Federal Circuit is expected which typically requires about one year from filing before a decision is rendered. It is also likely that, whichever party loses in the Federal Circuit, will ask the Supreme Court to review the decision.

This case clearly shows the important role of the media, the scientific community, public pressure, and the role a government or parliament can play in guiding patent and licensing policies when public health may seriously be affected.

The BRCA-controversy received a lot of attention and the patenting and licensing strategies in this case have been described and criticized in detail in various

publications. However, at present relatively few objective empirical data are available on the overall licensing practices in the field of genetic inventions and diagnostic testing in general due to the (presumed) confidential nature of such contracts. Roughly speaking, there are three types (MATTHIJS, 2007 and VAN OVERWALLE et al., 2006) of exploitation and licensing practices described in the literature. One could imagine many different approaches depending on the type of technology, the licensing partners, etc. Moreover, some inventions will not be patented, but are protected as a trade secret or are published and end up in the public domain.

The first approach has been followed by the major public research institutes which have granted free access to gene sequences for diagnostic testing (using ‘home-brew’ methods) but have collected royalties on gene-based commercial test kits. The best-known example is the Cystic Fibrosis gene that was cloned in 1989 and patented by the Hospital for Sick Children of Toronto and the University of Michigan. This approach has been accepted by all parties without criticism.

The second approach has been presented by Bio-Rad, the company that acquired the patent on the Hereditary Hemochromatosis gene after Mercator Genetics went out of business (MERZ et al, 2002). The company offers to license laboratories to perform testing, but at a cost that makes Bio-Rad's own, commercial test kit more economically attractive due to up-front payments and a per test fee of \$20 (for 2 mutations).

The third approach is the one as it is put into practice by Myriad Genetics for the screening of the BRCA1 and BRCA2 genes. The company licensed the test exclusively to a limited number of commercial genetic laboratories for particular territories (cf. GTG for Australia and New Zealand). However, many of these laboratories are apparently only allowed to carry out testing of a limited set of BRCA1 and BRCA2 mutations, while the complete sequence analysis is still carried out only by Myriad Genetic Laboratories in Salt Lake City. It was this third and last approach which has given rise to a strong and worldwide legal and political reaction (MATTHIJS & HALLEY, 2002 and HERRLINGER, 2005).

3. Compulsory Licenses

In an attempt to deal with the wide discontent it has been suggested that compulsory licenses could be useful as a tool to temper the consequences of restrictive licensing behavior in genetic diagnostics in the future.

3.1. Concept

Under a compulsory license mechanism a government or a court can allow a third party to use the subject matter of a patent without authorization of the patent owner.

It is important to clearly distinguish compulsory licenses from so-called “licenses of right” as some people confuse these two legal mechanisms. Licenses of right are *voluntary* in nature, whereas compulsory license schemes are *non-voluntary*. We note, however, that in the UK, when the license of right was introduced into the domestic law by the Patents and Designs Act of 1919, not only could the patent owner register the

patent as being available as of right, but also any interested party could request the comptroller to issue a license of right on the ground that there had been an abuse of monopoly rights under the patent. Hence, by then the distinction on the basis of the voluntary or non-voluntary nature did not apply.

The ‘license of right’ is a legal mechanism by which a patent holder voluntarily chooses to give general access to the patented invention by the payment of a license fee. The patent owner agrees to receive a pre-determined remuneration for the use of his invention and if the user pays the required amount, the patent owner has no right to prevent him from using the invention anymore, hence the term ‘remuneration right’, which is sometimes used in this context instead of exclusive right.

Licenses of right are not new. They exist in several countries, like for instance the United Kingdom. Also in France, there was a special provision on the license of right, but recently this provision was removed from the French Intellectual Property Code (hereinafter FIPC) because the mechanism had never been used. Licenses of right were also already envisaged in the framework of the Community Patent Convention of 1975 (Article 43) (hereinafter the CPC), (76/76/EEC: *Convention for the European patent for the common market (Community Patent Convention)*, 26 January 1976, [1967] OJ L 17/1) the Community Patent Agreement of 1989 (Article 43), (89/695/EEC: *Agreement relating to Community patents - Done at Luxembourg, 15 December 1989*, [1989] OJ L 401/1) as well as in the proposed Community Patent Regulation (Article 20) (For more information, see:

http://ec.europa.eu/internal_market/indprop/patent/index_en.htm#system). The CPC provides that “the proprietor of a Community patent may file a written statement with the Office that he is prepared to allow any person to use the invention as a licensee in return for appropriate compensation. In that case, the renewal fees for the Community patent which fall due after receipt of the statement shall be reduced”. Lately, the license of right has regained a lot of attention as a follow-up to IBM’s proposal for a “soft” Community patent endorsing a license of right (IBM, 2002).

In Switzerland, the license of right has been given a lot of attention too, be it from a somewhat different angle. The specific position of research tools, which according to Swiss law fall outside the scope of the research exemption, was a reason to introduce a new “license of right” regarding research tools (Article 40b of the Swiss Patent Act, hereinafter “SPA”). This provision should safeguard access to essential research tools, such as gene sequences and methods such as polymerase chain reaction (PCR) (PCR is a common technique to amplify a single or few copies of a piece of Deoxyribonucleic acid (DNA) generating thousands or millions of copies of a particular DNA sequence). In case an owner of a patent related to a research tool would refuse to grant a license, the judge will grant a non-exclusive license. This instrument has been called a “license of right for research tools”. However, it is not a voluntary scheme in accordance with the definition of the license of right, as provided above. The scope and duration of the Swiss license of right will be set by the judge depending on the research plan. The royalty rate will be based on the circumstances of the case and the commercial value of the license in line with existing licensing practices (Article 40e §5 SPA).

If one would follow this Swiss line of thinking, the concepts of ‘compulsory license’

and ‘license of right’ would become interchangeable. However, given the above-mentioned national and international examples, we will maintain the distinction on the basis of their voluntary/non-voluntary nature. In the remainder of this chapter we will only focus on compulsory licenses.

3.2. Legal Framework

Both in the Paris Convention for the protection of Industrial Property of 1883 (hereinafter Paris Convention or PC) (*World Intellectual Property Organization (WIPO), Paris Convention for the protection of Industrial Property of March 20, 1883, as revised at Brussels on December 14, 1900, at Washington on June 2, 1911, at The Hague on November 6, 1925, at London on June 2, 1934, at Lisbon on October 31, 1958, and at Stockholm on July 14, 1967, and as amended on September 28, 1979*), http://www.wipo.int/treaties/en/ip/paris/trtdocs_wo020.html) and in the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights of 1994 (hereinafter TRIPs Agreement or TRIPs) (*Annex 1C to the Agreement establishing the WTO, Marrakesh Declaration of April 14, 1994, TRIPs Agreement*, http://www.wto.org/english/docs_e/legal_e/27-trips.pdf), one finds provisions dealing with compulsory license regimes for patents.

Initially, compulsory licenses were not included in the Paris Convention as it entered into force on July 7, 1884. It was not until the 1925 Revision Conference in The Hague that some reference to compulsory licenses was inserted in the Paris Convention. Article 5.A.2 PC now stipulates that “[each] country of the Union shall have the right to take legislative measures providing for the grant of compulsory licences [...]”. The Paris Convention thus affirms the right of Member States to grant compulsory licenses and implicitly confirms the Member States’ autonomy to determine the grounds on which such licenses can be granted.

Article 31 TRIPs deals with “Other Use without Authorization of the Right Holder”. The term ‘other use’ distinguishes the scope of application of Article 31 TRIPs from the use allowed under Article 30 TRIPs. Article 30 allows that Member States provide “limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties”. According to Article 30 TRIPs, these three conditions have to be met in order to allow any exception to the exclusive patent right. Exceptions that have been stated by a WTO panel as falling within the scope of Article 30 TRIPs are for instance use of the patented invention for research; for teaching purposes; in experiments on the invention to test or to improve it; in experiments for the purposes of seeking regulatory approval for marketing of the patented product after expiration of the patent, etc. Articles 30 and 31 are mutually exclusive (*WTO Report of the Panel, Canada-Patent Protection of Pharmaceutical Products, March 17, 2000, WT/DS114/R, at para. 7.20*, http://www.wto.org/english/tratop_e/dispu_e/7428d.pdf) (See: CORREA & YUSUF, 1998).

Article 31 relates in particular to non-voluntary licenses granted to *third parties*. Although the term ‘compulsory license’ does not appear, TRIPs affirms the right of

Member States to grant compulsory licenses and confirms their autonomy to determine the grounds upon which such licenses can be granted. Besides non-voluntary licenses to third parties, Article 31 also addresses *government* use. In many countries the government is allowed to make use of a patented invention without previous license for reasons related to the public interest. In some countries, such use will not even be regarded as an act of infringement. For example in France the government may rely on the Public Health Act to use a patented invention without the need for a license in case of an emergency. In Switzerland and Belgium, however, the government is in principle not authorized to use patented inventions without previous license (AIPPI Question 202).

Given the international legal framework of the Paris Convention and the TRIPs Agreement, virtually all countries around the world allow compulsory licenses in their national legislation. Compulsory licenses are granted either by a judge or the government. The US is often thought of as one of the few countries without compulsory license mechanisms. But in fact in a limited number of cases, US courts or government officials may grant compulsory licenses on the basis of specific legal provisions (For example: *government use*, 28 U.S.C. § 1498; *Atomic Energy Act*, 42 U.S.C. § 2183, *Clean Air Act*, 42 U.S.C. § 7608; *Plant Variety Protection Act*, 7 U.S.C. § 2404 and the “*march in right*” in the so-called *Bayh-Dole Act*, 35 U.S.C. § 203). Furthermore, in US patent and antitrust cases the actual effect of a refusal of a judge to grant an injunction to the patent owner, or an order to license out will be that the alleged infringer can continue using the patented subject matter under the conditions set by the court without the authorization of the patent owner. Hence, the ultimate effects are similar to the grant of a compulsory license.

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Biographical Sketches

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For a list of publications, see <http://www.law.kuleuven.be/cir/cv/Van%20Overwalle/Publications.htm>

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