

**Reshaping Belgian Patent Law:
The Revision of the Research Exemption and
the Introduction of a Compulsory License for Public Health**

Geertrui Van Overwalle & Esther van Zimmeren
Centre for Intellectual Property Rights, University of Leuven, Belgium

Table of Contents

A. Introduction.....	1
B. The Enlarged Research Exemption.....	2
1. Justification.....	2
2. Scope.....	3
a. Direct Goal of the Experimental Acts: ‘On and/or With’	3
b. Indirect Goal of the Experimental Acts: Scientific and/or Commercial Purpose	3
C. The Compulsory License for Public Health.....	4
1. Justification.....	4
2. Scope.....	4
3. Administrative Procedure	6
a. Regular Procedure.....	6
b. Accelerated Procedure	7
4. Character of the Compulsory License.....	7
5. Exploitation Regime	8
a. From Application until Grant.....	8
b. After Grant	8
6. Review, Withdrawal and Appeal Procedures	8
a. Review.....	8
b. Withdrawal.....	9
c. Appeal	9
D. Concluding Remarks.....	9

A. Introduction

After no less than seven years, the implementation odyssee with regard to the Directive on the legal protection of biotechnological inventions¹ finally came to an end in Belgium. The Belgian Council of Ministers reached a political agreement on 23 April 2004, which largely marked the limits of the implementing bill. The Council opted for a literal transposition of the Directive, with regard to the *existence* of patent rights and more in particular, with regard to patentable biological subject matter, applicable protection requirements and scope of protection.

In addition to the literal implementation, some extra measures with regard to the *exercise* of patent rights in the field of biotechnology were introduced in the current Belgian Patent Act of 1984 (hereinafter BPA)². These measures aim at restricting

¹ Directive 98/44/EC of 6 July 1998 of the European Parliament and of the Council on the legal protection of biotechnological inventions ([1998] *OJEC L* 213/13, available at http://europa.eu.int/eur-lex/pri/en/oj/dat/1998/l_213/l_21319980730en00130021.pdf).

² Belgian Patent Act of 28 March 1984, *Belgisch Staatsblad – Moniteur belge*, 9 March 1985.

potential negative effects of biotechnology patents on health care. The first measure includes the significant widening of the research exemption. The second measure consists of the introduction of a compulsory licensing mechanism for public health reasons. The introduction of the latter was largely inspired by the restrictive licensing policy of the company Myriad Genetics, which refused to grant reasonable licenses to centres for genetic testing and hospitals³. Myriad's restrictive licensing practices led to negative reactions on a worldwide level both in patent and patient's 'circles'⁴.

The Belgian *Conseil d'État*, initially reluctant regarding the two proposed extra measures, finally gave a positive advice on the bill on 3 June 2004. Subsequently, the bill was submitted to Parliament on 21 September 2004. In parliament an extensive hearing with experts took place on 23 November 2004, followed by a series of discussion sessions in working committees. Especially with regard to the new compulsory licence, the Minister of Economic Affairs made a lengthy and significant statement on March 1 2005, aimed at further clarifying the grounds, the scope of application and the administrative procedure for the grant of the license⁵ (hereinafter 'Ministerial Statement'). The bill was finally passed in the House of Representatives on 10 March 2005 and in the Senate on 14 April 2005. It was then promulgated on 28 April 2005 and published in the Belgian official journal, the so-called 'Belgisch Staatsblad' or 'Moniteur belge' on 13 May 2005^{6 7}.

The widening of the research exception, realised through Article 11 of the amending Act of 28 April 2005, significantly changed Article 28 § 1 (b) BPA. The compulsory licensing mechanism for public health reasons, established by Article 13 of the amending Act of 28 April 2005, led to the introduction of Article 31 bis BPA⁸. In the present paper, we will systematically refer to the text of Article 28 § 1 (b) BPA and Article 31 bis BPA, respectively.

B. The Enlarged Research Exemption

The new Article 28 § 1 (b) BPA stipulates that the rights of a patent holder do not extend to acts carried out for scientific purposes *on* or *with* the subject matter of the invention.

1. Justification

³ WALPOLE, I.R., DAWKINS, H.J.S., SINDEN, P.D. & O'LEARY P.C., 'Human gene patents: the possible impacts on genetic services healthcare', 179 *Medical Journal of Australia* 2003, 256-283.

⁴ MATTHIJS, G. & HALLEY, D., 'European-wide opposition against the breast cancer gene patents', 10 *European Journal of Human Genetics* 2002, 783-784

⁵ Statement of Mr. M. Verwilghen, Federal Minister of Economy, Energy, Foreign Trade & Science Policy, *Parl. St.*, Kamer, 2004-2005, DOC 51 1348/006, p. 61-70 (available at <http://www.dekamer.be/FLWB/PDF/51/1348/51K1348006.pdf>).

⁶ *Belgisch Staatsblad* – *Moniteur belge*, 13 May 2005 (available at <http://www.ejustice.just.fgov.be/cgi/welcome.pl>).

⁷ For more information, see VAN OVERWALLE, G., 'De definitieve omzetting van de EU-Biotechnologierichtlijn: van wetsontwerp naar wet', *Intellectuele Rechten – Droits Intellectuels (IRDI)*, 2005 (in press); DE CORT, L., DEBRULLE, J. & PETIT, M., 'La licence obligatoire pour raisons de santé publique dans le droit belge', in *Gene Patents and Public Health*, VAN OVERWALLE, G. (ed.), Brussel, Bruylant (forthcoming).

⁸ Unfortunately, no official English translation of the amending act of April 28 2005 or of the updated Belgian Patent Act of 1984 is available for the moment.

There is a lot of legal uncertainty as to the exact scope of the research exemption in view of the many contradictory court rulings in Europe. In enacting a new wording, the Belgian legislator aims at removing this uncertainty.

2. Scope

Two major questions governed the discussion in the working committees on the enlarged research exemption. The first question was how the twin concept ‘on and/or with’ was to be understood. The second question concerned the notion ‘scientific purposes’.

a. Direct Goal of the Experimental Acts: ‘On and/or With’

The Ministerial Statement clarifies that ‘on’ refers to experiments where it is verified whether the patented invention works the way it is described in the patent or whether the invention is indeed novel and inventive as claimed in the patent. The Statement explains that ‘with’ refers to experiments where the patented invention is used to investigate something else; the patented invention is used as an instrument, as an “Apparativ”. For instance, a patented scale which is used to weigh compounds for manufacturing a vaccin. The Minister underlines that the new Article 28 aims at both exempting research ‘on’ and research ‘with’ the subject matter of the invention to guarantee a maximum freedom to operate for research activities.

b. Indirect Goal of the Experimental Acts: Scientific and/or Commercial Purpose

The Ministerial Statement clarifies that the term ‘scientific purposes’ refers to acts that aim at collecting knowledge. In the debate on whether to opt for a *strict* or a *wide* interpretation of the notion ‘scientific purpose’, Minister Verwilghen supported a wide scope of interpretation. The research exemption encompasses both acts with a strict scientific purpose, and acts with a mixed scientific/commercial aim, in the sense that mixed research should *mainly* be scientific in nature, which excludes companies with *mainly* commercial goals, from the scope of the exemption. It remains to be seen, how this interpretation will be applied in practice. In day-to-day practice borderline cases may regularly arise. For instance with regard to spin-offs originating from university-based research with commercial objectives, or pharmaceutical and/or biotechnology companies having a clear-cut commercial mission, but hosting large research activities as well.

In infringement cases, courts should take up this wide interpretation. Nevertheless, purely commercial acts, such as the preparation of the registration dossier for clinical trials and acts required in order to be eligible for a license to commercialize so-called *me too-medicines*, do not fall under the renewed research exemption. However, the latter will be exempted from patent infringement in the light of an upcoming European directive⁹ and the equivalent Belgian variant of the so-called ‘Bolar exemption’¹⁰.

⁹ See Article 1, sub 8) of Directive 2004/27/EC of the European Parliament and the Council of 31 March 2004 amending Directive 2001/83/EC on the Community Code relating to medicinal products for human use, [2004] OJEC L136/34, replacing Article 10, para. 6: “Conducting the necessary studies and trials with a view to the application of paragraphs 1, 2, 3 and 4 and the

C. The Compulsory License for Public Health

1. Justification

The establishment of a compulsory licensing mechanism for public health reasons can be justified on the basis of Articles 8 and 30 of the TRIPs Agreement. Article 8 stipulates that members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with other TRIPs provisions. Appropriate measures, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology. Article 30 in its turn states that members may 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 parties¹¹.

On top of this, the Doha Ministerial Declaration of 14 November 2001 explicitly stipulates that the TRIPs Agreement can be implemented and interpreted in a manner supportive of public health, by promoting both access to existing medicines and research and development into new medicines¹². In the same line of reasoning, the Declaration on the TRIPs agreement and public health of the same date specifically states that each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted¹³.

2. Scope

The scope of application of the compulsory license for public health is mainly determined by three elements: the ground for which a license may be granted, the inventions susceptible for licensing and the geographical scope of application.

Public Health Interest. The new compulsory licensing mechanism may be invoked in cases where the public health interest is affected. In this regard, Article 31 bis § 1 BPA explicitly stipulates that “*In the interest of public health, the King, by decree established after consultation in the Council of Ministers, can grant a license*

consequential practical requirements shall not be regarded as contrary to patent rights or supplementary protection certificates for medicinal products;”.

¹⁰ Legislative Proposal amending the Act of 25 March 1964 on pharmaceuticals (Belgisch Staatsblad-Moniteur belge 17 April 1964). This proposal aims at implementing the so-called Bolar-exemption in the European Directive and is currently submitted for advice of the *Conseil d’Etat*..

¹¹ See also: GERVAIS, D., *The TRIPs Agreement: Drafting History and Analysis*, London, Sweet & Maxwell (2003), pp. 240-244

¹² *Ministerial declaration, adopted on 14 November 2001* (WT/MIN(01)/DEC/1), Point 17 (available at http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_e.htm).

¹³ *Declaration on the TRIPs agreement and public health, adopted on 14 November 2001* (WT/MIN(01)/DEC/2), Point 5 (b) (available at http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm).

for the exploitation and application of an invention protected by a patent” (italics added).

The Ministerial Statement clarifies that the notion of public interest, like the concept of ‘ordre public and morality’, is susceptible to changes over time. It is therefore not expedient to give a strict definition. Rather, it is recommendable to put forward some examples where the public health interest may be at stake. This is notably the case when products, processes or diagnostic methods are put at the disposal of the public in insufficient quantity or quality, or at abnormally high prices, or when the patent is exploited under conditions which are contrary to the public health interest or which constitute anti-competitive practices. This explanation is by and large a reflection of the criteria established in the French Patent Act by the French government¹⁴. The proposal to include this more detailed wording in the Belgian Patent Act to increase the transparency and compulsory nature of the provision was refused.

Relevant Inventions. This aspect of the Belgian Patent Act has again been modeled after the French system. The inventions which may be susceptible to a compulsory license for public health reasons, are explicitly mentioned in Article 31 bis § 1 BPA: In the interest of public health, the King can grant a license for the exploitation and application of an invention protected by a patent for:

- a) a medicine, a medical appliance, a medical appliance or product for diagnosis, a derived or combinable therapeutic product;
- b) the process or product necessary for the manufacture of one or more products indicated under a);
- c) a diagnostic method applied outside of the human or animal body.

The Ministerial Statement underlines that the medical sector at large is envisioned and not a particular sector within the medical sector, for reasons of non-discrimination. In this regard the Belgian system differs from the mechanism established in Switzerland focusing on diagnostic testing ex Article 40 (c) of the Swiss Patent Act¹⁵.

Geographical Scope - Domestic Market. During the debate in the Belgian parliament several members suggested to widen the geographical scope of application of the compulsory licensing mechanism for public health reasons to the extent that it would be applicable to export to developing countries. The Ministerial Statement highlighted the importance of this suggestion, but referred to the European proposal for a regulation of the European Parliament and of the Council on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries

¹⁴ “Les brevets de ces produits, procédés ou méthodes de diagnostic ne peuvent être soumis au régime de la licence d’office dans l’intérêt de la santé publique que lorsque ces produits, ou des produits issus de ces procédés, ou ces méthodes sont mis à la disposition du public *en quantité et qualité insuffisantes* ou à *des prix anormalement élevés*, ou lorsque le brevet est exploité dans des conditions contraires à l’intérêt de la santé publique ou constitutives de pratiques déclarées *anticoncurrentielles* à la suite d’une décision administrative ou juridictionnelle devenue définitive” (italics added), Article 18 *Loi n° 2004-800 du 6 août 2004 relative à la bioéthique*, amending Articles L. 613-15 and L. 613-16 *Code de la propriété intellectuelle*, *Journal Officiel français*, n° 182, 7 August 2004 (available at <http://www.legifrance.gouv.fr/WAspad/UnTexteDeJorf?numjo=SANX0100053L>).

¹⁵ “Dans le cas d’une invention portant sur un produit ou un procédé de diagnostic dans le domaine humain, une licence non exclusive est octroyée pour remédier à une pratique déclarée anticoncurrentielle à l’issue d’une procédure judiciaire ou administrative”, Article 40 (c) of the Swiss Patent Act, approved 23 November 2005 (available at <http://www.ige.ch/F/jurinfo/documents/j10041f.pdf>).

with public health problems of 29 October 2004¹⁶. This proposal obliges the Member States to grant a compulsory license for the manufacture and sale of patented pharmaceutical products for the export to countries without or with insufficient production facilities in the pharmaceutical sector, in case a number of conditions is fulfilled. As European regulations have direct effect, it was not considered necessary to include a specific provision in the Belgian Patent Act.

3. Administrative Procedure

a. Regular Procedure

The application procedure leading to the grant of a compulsory license for public health is a *sui generis* procedure which differs from the application procedures for the grant of the – already existing – compulsory license for non-working (Article 31 BPA) and dependency (Articles 32-38 BPA): “Articles 31 and 32 through 38 are not applicable to the compulsory license intended in this [article 31 bis] article. The provisions of this article are not applicable to the compulsory licenses intended by Articles 31 and 32 through 38” (Article 31 bis § 12 BPA). The phases of the regular administrative procedure can be described as follows.

Initiative → *Anyone*. Anyone can apply for a compulsory license for reasons of public health, on the condition that he or she demonstrates that he or she has, should the compulsory license be granted, the resources or the *bona fide* intention to obtain resources that are necessary for actual and continuous manufacture and/or application in Belgium of the patented invention (Article 31 bis § 2 BPA). Potential applicants might thus be private enterprises, hospitals, as well as research laboratories. The applicant for a compulsory license submits his/her request to the Minister with a copy to the Advisory Committee for Bioethics (Article 31 bis. § 6 BPA).

The suggestion in the House of Representatives that the right of initiative should only be given to the Minister of Economy and/or the Minister of Social Security and Public Health was rejected. The Ministerial Statement underlines that those Ministers are not entitled to apply for a compulsory license.

Consultation → *Advisory Committee for Bioethics*. The Belgian Advisory Committee for Bioethics¹⁷ shall provide the Minister with a non-binding advice on the merits of the application, explicitly mentioning the reasons (Article 31 bis § 6 paragraph 3 BPA). The Advisory Committee for Bioethics is an intergovernmental council, established by both the national and regional governments to inform the public and the authorities about bio-ethical matters. The Committee is composed of lawyers, geneticists, ethicists, philosophers and physicians from different organizations and

¹⁶ COM(2004)737 def. (available at <http://europa.eu.int/eur-lex/lex/LexUriServ/LexUriServ.do?uri=CELEX:52004PC0737:NL:HTML>). For more information, see: VANDOREN, P., and RAVILLARD, P., ‘A New EC Initiative to Allow Export of Medicines under Compulsory Licences to Poor Countries’, 8 *The Journal of World Intellectual Property*, 2005, 103-121. See also: WTO, *Compulsory licensing of pharmaceuticals and TRIPs. Frequently Asked Questions* (available at http://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm).

¹⁷ *Comité consultatif de Bioéthique de Belgique - Raadgevend Comité voor bio-ethiek van België*, see <http://www.health.fgov.be/bioeth/index.html>.

representing a wide scale of ideological and philosophical beliefs¹⁸. The Committee should produce an advice within 6 months after the request.

Input → Patent Holder. The Minister of Economic Affairs informs the holder of the patent, which is the object of a request for a compulsory license, of the application for the compulsory license. The patent holder is invited to make known his position to the Advisory Committee for Bioethics within a period of one month, regarding the potential granting of a compulsory license as well as his comments on a reasonable level of compensation in case a compulsory license would be granted (Article 31 bis § 6 paragraph 2 BPA).

Draft Opinion → Minister of Economic Affairs. Within a period of three months after receipt of the advice of the Advisory Committee for Bioethics, the Minister shall submit a proposal for a decision on the merits of the application mentioning the reasons to the Council of Ministers for consultation. The Minister shall also submit a proposal for the compensation of the patent holder (Article 31 bis § 6 paragraph 4 BPA).

Decision → King + Council of Ministers. Finally, the King decides to grant the compulsory license after consultation in the Council of Ministers (Article 31 bis § 6 paragraph 4 BPA). This way, the decision will be a ‘team decision’, based on a consensus amongst all Ministers, including the Ministers of Social Security and Public Health.

b. Accelerated Procedure

In the event of a public-health crisis and upon the proposal of the Minister who is responsible for public health, the King can take measures in a decree established after consultation in the Council of Ministers in order to accelerate the procedure explained in the previous section. If necessary, he can decide not to call for the advice of the Advisory Committee for Bioethics, to expedite the decision-making process (Article 31 bis § 6 paragraph 5 BPA)

4. Character of the Compulsory License

The compulsory licenses which are granted shall be non-exclusive (Article 31 bis § 4 BPA). This provision is in line with article 31 d) of the TRIPs Agreement, which stipulates that use of the subject matter of a patent without the authorization of the right holder shall be non-exclusive.

The non-transferable character of the compulsory license, as prescribed by Article 31 e) of the TRIPs Agreement, is not explicitly stipulated under the new Belgian regime. However, the Ministerial Statement underlines that the decision taken in the Council of Ministers to grant a compulsory license has an individual scope. It is a so-called decision ‘*intuitu personae*’: the license only concerns the individual applicant. Other interested applicants can also apply for a compulsory license since

¹⁸ See: <http://www.health.fgov.be/bioeth/nl/voorstelling/ledenlijst.htm>. The Committee generally gives advice on request of public authorities, scientific institutes, healthcare organizations and institutions for higher education. However, the Committee may also give advice on its own initiative.

these licenses are not exclusive (Article 31 bis § 4 BPA). However, later applicants must go through the full administrative procedure from the start.

5. Exploitation Regime

a. From Application until Grant

The implementing act established a special regime for the applicants of a compulsory license who start exploiting the patented invention when the application procedure is still running. The aim of this special regime is to safeguard the rights of the patent holder who can submit his comments in the application procedure but does not have a final say in the granting of the compulsory license. In order to prevent the abuse of the compulsory license detrimental to the interests of the patent holder and the interest in innovation of society at large, a detailed exploitation regime for the period between the application and the grant of the license is included.

This regime includes three main elements:

- Each procedure claiming infringement of an invention covered by a patent for which a compulsory license for public-health reasons has been requested and which claim is directed against the applicant of such a license is suspended with regard to the violation in question until the King decided on the grant of the compulsory license concerned (Article 31 bis § 3 BPA).
- The compulsory license takes effect as of the date of exploitation and at the earliest on the date of the application for the compulsory license (Article 31 bis § 6 paragraph 7 BPA).
- The applicant must pay a reasonable compensation for the use of the patented invention in the period between the application for the compulsory license in the interest of public health and the promulgation of the royal decree granting the compulsory license. The King shall specify the amount of compensation in a decree established after consultation in the Council of Ministers (Article 31 bis § 7 BPA).

b. After Grant

In the event a license is granted, the King shall specify in the decree established after consultation of the Council of Ministers:

- the duration (e.g. *ab initio*, for a fixed or indefinite period),
- the scope of the license (e.g. inventions concerned, authorised exploitation acts, quantities to be produced, aims to be fulfilled);
- the compensation for the use made of the patented invention during the granting procedure, and
- other exploitation conditions (e.g. reasonable remuneration, cf. Article 31, sub (h) of the TRIPs Agreement).¹⁹

6. Review, Withdrawal and Appeal Procedures

a. Review

¹⁹ See Article 31 bis § 6 paragraph 4 BPA, Article 31 bis § 5 BPA and Article 31 bis § 7 BPA.

Insofar as new elements may develop, the King can, by decree established after consultation in the Council of Ministers, at the request of the patent holder or of the holder of the compulsory license review the decision regarding their mutual obligations and, if appropriate, also the exploitation conditions (Article 31 bis § 10 BPA).

The competence to review the license is attributed to the King, after consultation of the Council of Ministers. Thus, the procedure for review basically follows the same path as the procedure for the application of a license, as laid down in Article 31 bis § 6 BPA apart from the role of the advice submitted by the Advisory Committee for Bioethics.

b. Withdrawal

At the request of each party interested and after having taken into consideration the advice of the Advisory Committee for Bioethics, the King can, after consultation in the Council of Ministers, withdraw the compulsory license granted for public-health reasons if, after expiration of the period established by the Council of Ministers for the exploitation, the license holder has not exploited the patented invention in Belgium by actual and continuous manufacture (Article 31 bis § 11 BPA). Only lack of exploitation may justify the withdrawal of the license. A final judgment establishing that the beneficiary of the license is guilty of an illicit act or has not fulfilled his obligations towards the patent holder, cannot as such justify a decision to withdraw.

The King is also competent to withdraw the license after consulting the Advisory Committee for Bioethics and the Council of Ministers. Thus, the procedure for withdrawal, for review and grant all follow more or less the same route.

c. Appeal

The King may decide to grant the compulsory license after consultation in the Council of Ministers. In case he grants the license, the King may modify or withdraw the license in accordance with certain conditions. Alternately, the King may decide not to grant the license. The question can be raised to what extent the license holder may appeal the decision to review or withdraw, and to what extent an applicant for a compulsory license may appeal the decision to refuse the license. In this regard, Article 31, sub (i) and (j) of the TRIPs Agreement obliges Member States that any decision relating to the authorization of the use of the patent without the permission of the patent holder and the remuneration should be subject to judicial review or other independent review by an independent higher authority. The Ministerial Statement clarifies that appeal is possible against all decisions at the Tribunal of first instance (cf. Article 73 § 1, first paragraph BPA). The Minister highlights that the *Conseil d'État* has repeatedly stated its incompetence to deal with matters of patent law.

D. Concluding Remarks

Both the widening of the research exemption and the introduction of a compulsory licensing mechanism for public health reasons were amply discussed during the parliamentary debates. Despite the Ministerial Statement aiming at clarification of the scope of both measures, it remains to be seen to what extent the measures will be able

to fulfil the objectives for which they are designed. First, the interpretation of the research exemption and its application in day-to-day practice is far from crystal-clear. Second, the effectiveness of the compulsory licensing mechanism is uncertain and will depend on the willingness of companies to apply for such a license. One may regret that the Minister of Social Security and Public Health has not been given a right of initiative as well. Moreover, one may have doubts as to whether the long periods for decision-making²⁰ will not turn the compulsory licensing mechanism into another tool of symbolic law-making. However, one should realize that the compulsory licensing regime for public health reasons may indirectly function as a threat to compel a non-cooperative patent holder to enter into fair and reasonable licensing negotiations.

All in all, these ‘revolutionary’ measures might put Belgium on the international map as an actor who is deeply concerned by public health interests and who tries to reconcile both private (patent holder) and public (patient) interests. In other words, a legislator – to paraphrase Abraham Lincoln – who adds the fuel of [financial] interest *and the concern of civil society* to the fire of genius.

²⁰ Ten days for the Minister to submit the application to the Advisory Committee for Bioethics + one month for the patent holder to submit comments to the Advisory Committee for Bioethics + six months for the Advisory Committee for Bioethics to give an opinion + three months for the Minister to prepare a proposal for the Council of Ministers + no decision-making period specified by law for the grant of the compulsory license. Thus, the regular granting procedure might take quite some time.