

LEGISLATIVE INITIATIVES ON COMPULSORY LICENSING IN LIGHT OF COVID-19

With more than 50 clinical trials underway for covid-19 related therapies, the question as to how and at what price such therapies will ultimately be made available becomes more pressing. Today, it can only be commended that industry, academia and government are working together to combat covid-19, gearing up to provide the world with effective vaccines and treatments as soon as possible. Several countries are nonetheless already considering how to respond should intellectual property rights get in the way of the availability of these therapies, and the anti-IP lobbies are having a field day. Every so often, the conversation tilts towards imposing limitations on patents, granting compulsory licenses, a liberal interpretation of existing exemptions and so on. In the same vein, discussions are ongoing within the World Health Organisation (WHO) to set up '*a pool of rights to tests, medicines and vaccines, with free access or licensing on reasonable and affordable terms for all countries*'¹.

In the vast majority of countries, patent legislation already provides for the possibility of compulsory licensing in line with the conditions put forward by Art. 31 of the TRIPS Agreement, Belgium being no exception. In an attempt to sufficiently balance all rights involved however, the mechanisms provided are cumbersome and thus rarely used. In addition, most countries do not foresee a right of initiative for the government. Instead, it is left to interested parties to formally apply for a compulsory license. Some governments are therefore re-evaluating their options in light of the covid-19 crisis, adopting legislative amendments that provide for a more flexible and less regulated system.

As such, France and Germany already made sure to have the necessary measures in place, should it be imperative for the government to keep the patent exploitation strategies of pharmaceutical companies in line. The same goes for some countries outside the European Union, such as Canada and Chile.

The current contribution briefly discusses the amendments adopted in France and Germany, and then looks at the situation in Belgium.

1. France

In France, Emergency Law No 2020-290 of 23 March 2020 to combat the covid-19 epidemic introduced a new article into the public health code. As a result, Article L.3131-15 of the Public Health Code reads:

¹ See <https://www.who.int/dg/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---6-april-2020%E2%BB%BF>.

“In territorial areas where a state of health emergency is declared, the Prime Minister may, by regulatory decree issued upon advice of the Minister responsible for health, for the sole purpose of guaranteeing public health: (...)

7° Order the requisition of all goods and services necessary for the fight against the sanitary disaster as well as any person necessary for the operation of these services or the use of these goods. Compensation for such requisitions is governed by the Code of Defence;

8° To take temporary measures to control the prices of certain products necessary to prevent or correct the tensions observed on the market for certain products; (...)

9° In so far as necessary, take all measures to provide patients with appropriate medicines for the eradication of the health disaster; (...)”²

The measures must be “*strictly proportionate to the health risks involved and appropriate to the circumstances of time and place. They shall be terminated without delay when they are no longer necessary*”.

These provisions give extraordinary powers to the French Prime Minister, enabling him to (*i.a.*) impose compulsory licences where necessary, thereby bypassing the cumbersome procedure currently provided for in French law.³ Its use in this regard was expressly confirmed during the heated parliamentary debate that preceded the adoption of the law.⁴

It is furthermore interesting to note that this new regime may also affect other industrial property rights, such as designs, for instance to ensure the availability of protective gear such as masks.

2. Germany

As for Germany, legislative amendments were made to the Act on the Prevention and Control of Infectious Diseases in Humans⁵, entering into force on 28 March 2020. Accordingly, in case an epidemic situation of national significance is declared by the lower chamber of parliament, the amendments confer upon the Ministry of Health extraordinary powers, which include the possibility to impose limitations on patents under s. 13 (1) of the Patent Act. Since the occurrence of such an epidemic situation has been announced, decisions in this regard are now possible. If deemed necessary, the Ministry of Health can thus limit patent rights in accordance with s. 13 (1) of the German Patent Act:

² Article L3131-15 of the Public Health Code, available at <https://www.legifrance.gouv.fr/affichCodeArticle.do?cidTexte=LEGITEXT000006072665&idArticle=LEGIARTI000041747466&dateTexte=&categorieLien=cid> (liberal translation, own emphasis).

³ See *e.g.* for public health reasons, Art. L613-16 and R613-10 ff. of the Intellectual Property Code

⁴ Senate, 66th sitting of the ordinary session 2019-2020, 19 March 2020, available at <http://www.senat.fr/cra/s20200319/s20200319.pdf> (p. 19).

⁵ Gesetz zur Verhütung und Bekämpfung von Infektionskrankheiten beim Menschen, 20 July 2000, available in amended form at: <http://www.gesetze-im-internet.de/ifsg/index.html>.

“(1) The patent shall have no effect in a case where the Federal Government orders that the invention is to be used in the interest of public welfare.

(...)

(3) In the cases referred to in subsection (1), the proprietor of the patent shall be entitled to equitable remuneration from the Federal Republic of Germany”⁶

Note that the principle of proportionality still plays a tempering role, requiring a fair balance of all rights involved. It furthermore remains to be seen whether the government will in fact resort to such measures in the course of the covid-19 pandemic, while not having done so in decades.

The French and German measures referred to above are to be distinguished from individual compulsory licenses that are granted in favour of particular licensees. The current legislative amendments have a broader scope, potentially limiting patent rights in a more general manner.

3. Belgium

Currently, Belgian legislation provides for the possibility of compulsory licenses for reasons of public health in Art. XI.38 of the Code of Economic Law (“**CEL**”). However, the procedure is fairly complex and time-consuming, and tailored to the grant of individual licenses rather than the adoption of general measures.

The process starts with a request from an interested party to the Minister of Economy and ends (if successful) with a Royal Decree granting the compulsory license (and determining the conditions thereof). In between, the Advisory Committee for Bioethics is asked to deliver a non-binding advice on the matter, and the patent holder gets the opportunity to present its point of view. The Minister takes all these elements into account and subsequently presents a motivated proposal to the ministerial council. After deliberation in council, the King ultimately takes the decision. This process can – in principle – take several months.

The law nonetheless provides for the possibility to expedite the abovementioned process in case of an actual public health crisis (for which the global covid-19 pandemic of course qualifies). The initiative for acceleration lies with the Minister of Health, though in practice it is still expected of the interested party (looking for a swift compulsory license in times of crisis) to induce the Minister of Health to start the decision-making process. Once the acceleration initiative is taken and after deliberation in the ministerial council, certain measures can be ordered by Royal Decree to expedite the process (e.g. to skip the advice of the Advisory Committee for Bioethics). The question has been raised in the past whether this may even entail the possibility of granting the Minister (of

⁶ Own emphasis, liberal translation.

Economy and/or Health) a right of initiative for compulsory licenses.⁷ This is nonetheless doubtful in light of the wording of the law.

The current system embedded in Art. XI.38 CEL is therefore ill-suited for the adoption of general measures within the framework of the covid-19 situation. Aside from its rather lengthy and cumbersome procedure (even if one succeeds in obtaining acceleration), the procedure targets individually granted compulsory licenses upon initiative of the interested party, and thus with an *intuitu personae* character.⁸ It does not provide for the possibility of the government taking the initiative to set up a compulsory licensing program. During the parliamentary debate, this choice was briefly explained as “to avoid that a first selection would already take place on a ministerial level”⁹. Furthermore, the wording of Art. XI.38 CEL refers to patented inventions only, leaving one to wonder how breaking inventions for which a patent application is still pending are to be dealt with.

Nonetheless, the Belgian Labour Party PVDA submitted a proposal of resolution to the Chamber of Representatives in this regard with reference to Art. XI.38 CEL. The resolution requests the federal government to, amongst others:

*“undertake to resort to the remedy of the compulsory licences provided for in Article XI.38 of the Code of Economic Law, in order to ensure that the medicines and vaccines for COVID-19 can be made available to everyone free of charge. Compulsory licenses must be applied when producers charge excessive prices that are not be proportional to the actual cost of research and development, on the one hand, and when the producer cannot meet demand quickly enough, on the other hand.”*¹⁰

On 5 May 2020, the Commission of Health and Equal Chances voted to dismiss the proposal.¹¹ As it essentially would have forced the government to undertake to resort to compulsory licensing, without touching upon any of the issues with Art. XI.38 CEL as outlined above, this may not come as a surprise.

⁷ G. VAN OVERWALLE, “Zonder trommels en trompetten: EU-Biotechnologierichtlijn in het Belgische octrooirecht”, *IRDI* 2005, p. 372.

⁸ See also *Parl. Doc.* Chamber, 2004-2005, DOC 52 1348/006, p. 66 (regarding Art. 13 of the legislative proposal, today Art. XI.38 of the Code of Economic Law)

⁹ Liberal translation of a statement made regarding Art. 13 of the legislative proposal, *Parl. Doc.* Chamber, 2004-2005, DOC 52 1348/006, p. 64 (today Art. XI.38 of the Code of Economic Law).

¹⁰ Proposal of Resolution to accelerate the discovery and development of vaccines and medicines against COVID-19 and to ensure accessibility and availability, 15 April 2020, *Parl. Doc.* Chamber, DOC 55 1166/001, p. 15.

¹¹ *Parl. Doc.* 55K1166, see for a status update:

<https://www.dekamer.be/kvcr/showpage.cfm?section=flwb&language=nl&cfm=/site/wwwcfm/flwb/flwbn.cfm?dossierID=1166&legislat=55&inst=K>.

It thus remains to be seen how Belgium (and, for that matter, other countries) will respond should patent strategies indeed be deemed an obstacle to the availability of efficient covid-19 related therapies. The question can however be raised whether it is appropriate to be discussing and adopting measures on compulsory licencing, patent limitations, wide exemptions and other (punitive) measures, at a moment in time where effective therapies are yet to be developed, with industry, academia and government intensely working together to get there. There is no question that the solutions coming out of this research should be accessible to all, but it is at least equally important to provide sufficient incentives for private companies searching for a cure to make that investment in the first place – which is precisely the aim of the patent system.

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