Pharmaceutical Patent Law in Times of Crisis: A Comparative Study Part I

David Mulder
Taylor Wessing

Paul England
Taylor Wessing

Christian Dekoninck
Taylor Wessing

Dr Anja Lunze
Taylor Wessing

Patrick Boháček
Taylor Wessing

Dr Agnieszka Sztoldman*
Taylor Wessing; University of Wroclaw

Belgium; Comparative law; Compulsory licensing; Coronavirus; Czech Republic; EU law; Exemptions; Experimental use; Germany; Netherlands; Patents; Pharmaceuticals; Poland

Abstract

The first part of this study discusses the role of and exceptions to patent law in emergency situations in view of the corona pandemic of 2020. The authors elaborate on the application of the experimental use exemption, related exemptions and compulsory licensing, both from a broader EU law perspective as well as from the national perspective of six jurisdictions. Having regard for their practical implications, the similarities and differences in the approaches of these jurisdictions are set off against each other and further discussed in light of the general principles of EU law. Finally, the potential influence of the legislative gap concerning regulatory exclusivity rights and the protection of trade secrets is addressed. Part 2 will be published in a forthcoming issue of E.I.P.R.

Introduction

With the corona pandemic in 2020, states and companies alike are faced with many challenges. Where it concerns patent law in particular, on the one hand there is the search for and development of a vaccine and other medicines. On the other hand, there is the issue of a limited availability of medicines and medical devices. With these challenges, patent law may both be the solution and the problem. If it weren't for the incentive of the exclusive right linked to an intellectual property right, companies might decide not to invest in the development of new medicines, medicinal products and devices. After all, that exclusive right represents the essential means of asserting their intellectual property.[1] At the same time, this exclusive right may also pose as an issue where it concerns access to medicines when a new medicine is developed, for instance if the price is relatively high or if the demand exceeds the production capabilities of the patentee. Patent law may furthermore restrict the use of patented (medicinal) products or devices in the search for a vaccine or cure.

These challenges are acknowledged on an international level. Francis Gurry, Director-General of the World Intellectual Property Organization (WIPO), called demands for access to drugs "a hot and sensitive issue". Tedros Adhanom, Director-General of the World Health Organization (WHO), publicly backed a proposal by which a pool of rights to tests, medicines and vaccines would be created, with free access or licensing on reasonable and affordable terms for all countries.[2] Gurry highlighted the importance of health and safety during an emergency. According to Gurry, the international legal framework does foresee in a certain number of flexibilities for countries to be able to deal with the current situation, and WIPO is involved in discussions with various parties to see what might be done.[3]

With this last remark, Gurry might have referred to the extraordinary instruments included in international treaties such as the Agreement on Trade Related Aspects of Intellectual Property Rights (the TRIPS Agreement). Article 30 of the TRIPS Agreement provides for instruments allowing Member States under extraordinary circumstances to introduce limited exceptions to the

* David Mulder, Christian Dekoninck, Anja Lunze and Patrick Boháček (associate) are attorneys-at-law at Taylor Wessing in Amsterdam (The Netherlands), Brussels (Belgium), Munich (Germany) and Prague (Czech Republic). Paul England is a senior professional support lawyer at Taylor Wessing in London (United Kingdom). Agnieszka Sztoldman is an attorney-at-law at Taylor Wessing in Warsaw (Poland) and assistant professor in intellectual property rights at the University of Wrocław (Poland) (orcid.org/0000-0001-7202-2338; research project: "Freedom of research and patent exclusivity (research exemption)" financed by the National Center for Research on the basis of the agreement with number: 2013/11/N/HS5/03999).

[1] According to settled case law, the essential objective of a patent is to ensure, in order to reward the creative effort of the inventor, that the owner of the patent has the exclusive right to use an invention with a view to manufacturing industrial products and selling them, either directly, or by granting licences to third parties, as well as the right to oppose infringements. cf. *Centrafarm v Sterling* (15/74) EU:C:1974:114 [1972] 2 C.M.L.R. 489 at [9]; and *Football Association Premier League Ltd*) (C-403/08) EU:C:2011:631; [2012] Bus. L.R. 1321 at [107]. Also see the Opinion of AG Wathelet of 20 November 2014 in *Huawei v ZTE* (C-170/13) EU:C:2015:477 ; [2015] 5 C.M.L.R. 14 at [61].

[2] Reuters, Press Release (7 April 2020), "U.N. agency says coronavirus emergency could trump some patent rights" at *https://reut.rs/3aM9Tum* [Accessed 1 September 2020].

[3] Reuters, Press Release (7 April 2020), "U.N. agency says coronavirus emergency could trump some patent rights" at *https://reut.rs/3aM9Tum* [Accessed 1 September 2020]

exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with the normal use of the patent and take the legitimate interests of third parties into account. Consequently, the experimental use exemption, Bolar exemption and breeder's exemption have found their way into (draft) European and national legislation. In addition, legislation has been adopted in (draft) European and national legislation on the issuing of compulsory licences.

With the corona pandemic of 2020, these subjects have never been more relevant on an international scale. Although patent law may provide the necessary incentives for developing a new medicine, patent law might need to be limited under certain circumstances. Compulsory licensing could prove to be a solution in circumstances where patentees are unwilling to grant necessary licences on reasonable terms. These exemptions and the requirements for eligibility for compulsory licences may, however, differ from country to country.

In this article, it will therefore first briefly be discussed on a broader European and country-by-country basis how the experimental use exemption and related exemptions are applied and when compulsory licences may be issued. Second, the various similarities, differences and other practical implications will be discussed from a broader European law perspective. Finally, a short overview will be provided with a view of what the near future may hold for practitioners.

The experimental use exemption and compulsory licensing under national legislation

European legislation

The experimental use exemption, compulsory licensing and the Bolar exemption

Although never fully ratified, art.27(b) of both the 1975 and 1989 draft of the Community Patent Convention first stipulated that acts done for experimental purposes relating to the subject-matter of the patented invention would not fall within the exclusive rights of the patentee. Even though the same provision has eventually found its way to art.27(b) of the UPC Agreement as well,[4] it is highly uncertain if and when the UPC Agreement may enter into force. Consequently, the experimental use exemption has never fully been harmonised on a European level. Until that happens, one has to consult each jurisdiction's national law and interpretation thereof in order to determine the exact scope of that exemption.

The same applies to the instrument of the compulsory licence. Although, other than with the experimental use exemption, it has never been the objective of the European legislator to harmonise compulsory licensing on a European level, the relevant article in the Community Patent Convention and consideration in the Unitary Patent Regulation have yet to enter into effect.[5]

Only the Bolar exemption (named after a similar provision in US law, following the *Roche v Bolar* case),[6] which provides an exemption to conduct the necessary studies for the purpose of obtaining an abridged marketing authorisation, has been harmonised to some extent in the European Union. However, with both the Directives relating to medicinal products for human use[7] and veterinary use[8] providing for *minimum* harmonisation, here too there may be significant differences in how the exemption is interpreted and applied in each jurisdiction.

In this section it will be discussed in detail how each jurisdiction adopted and applies these exemptions and instruments in accordance with their national legislation.

Germany

The experimental use exemption and Bolar exemption

Experimental use exemption German patent law provides that the use of active substances which are patent-protected is exempted from patent infringement if these substances are used for "experimental purposes". This so-called "experimental privilege" is regulated in s.11(2) of the German Patent Act and has led to some particularly practice-relevant decisions of the German courts.

In particular, the two judgments in *Clinical Trials I* and *Clinical Trials II* of the Federal Court of Justice (Bundesgerichtshof) in the late 1990s had a decisive influence on the understanding of the exemption. In the *Clinical Trials I* judgment it was first determined that the German Patent Act exempts all trials which serve to obtain information and thus to carry out a scientific purpose, including those serving to discover the effects of a substance or possible new, previously unknown, uses.[9] According to the Federal Court of Justice, it should be irrelevant whether the experiments serve to verify the statements made in the patent or to obtain further research

[4] Agreement on a Unified Patent Court, 2013/C 175/01 (the "UPC Agreement").
[5] cf. Consideration 10 of Regulation (EU) 1257/2012 (the "Unitary Patent Regulation") and art.45 of the Agreement relating to Community patents (1989), 89/695/EEC, where it is mentioned that the extent and effect of compulsory licences granted in respect of unitary/community patents shall be restricted to the territory of the Member State concerned.
[6] The "Bolar exemption" was adopted in the Hatch-Waxman Act, which was introduced following the decision of the Court of Appeals of the Federal Circuit in *Roche Products v Bolar Pharmaceuticals Co*, 733 F.2d 858 (Fed. Cir.).
[7] Directive 2001/83 on the Community code relating to medicinal products for human use [2001] OJ L311/67.
[8] Directive 2001/82 on the Community code relating to veterinary medicinal products [2001] OJ L311/1.
[9] Federal Court of Justice (Bundesgerichtshof) 11 July 1995 (*Klinische Versuche I*), case no.X ZR 99/92.

results. In particular, the Federal Court of Justice held that it is irrelevant that the tests are carried out for the purpose of obtaining a marketing authorisation.

In the *Clinical Trials II* judgment,[10] the Federal Court of Justice furthermore decided that the experimental privilege in the German Patent Act should also apply if and to the extent that the trials have the objective of researching the subject matter of the invention which is actually protected by a patent. The exemption from otherwise applicable patent law provisions applies irrespective of any additional motives and purposes which the results might serve; they may range from purely scientific experiments to concrete commercially indicated experiments.

Not exempted, on the other hand, is the use of research tools and the performance of bioequivalence tests, as these measures do not provide new insights into the subject-matter of an invention. Purely commercial purposes, such as the use of the invention in market surveys, for example to determine whether there might be a commercial demand, are also not exempted.

Bolar exemption In line with the interpretation of the experimental use exemption, Germany adopted a broad interpretation of the Bolar exemption with its implementation in s.11(2b) of the German Patent Act in 2005. According to this provision, the effect of a patent does not extend to studies and tests which are necessary to obtain a marketing authorisation for medicinal products both in the European Union and in third countries.

This broad wording does not distinguish, for example, whether the exemption only applies to generic medicinal products or also innovative (new) medicines. The provision furthermore covers studies and trials necessary to obtain a marketing authorisation for countries both in the European Union *and* in third countries. According to a judgment of the Higher Regional Court of Düsseldorf (Oberlandesgericht Düsseldorf), even the import of an active ingredient manufactured in a third country without patent protection into the domestic market where protection exists could fall under the German Bolar exemption if such import occurs for the purpose of carrying out trials to obtain a marketing authorisation.[11] Although the Higher Regional Court Düsseldorf eventually referred the case to the European Court of Justice for a preliminary ruling, the court motivated its decision with reference to the objective of the Bolar exemption, which is to enable the immediate market entry of generics and the strengthening of the generics industry in the EU from the time of the expiry of patent protection. However, as the Bolar Directive is based on EU law and the matter with the European Court of Justice has unfortunately been left undecided,[12] there is still a certain degree of uncertainty as to whether the import of patent protected medicines for studies or market approval purposes are indeed permitted.

Governmental use orders and compulsory licences

The German Patent Act provides for two important restrictions on the use of patents. First, the Government could by administrative order restrict the effects of a patent in the way that the invention shall be used in the interest of public welfare only. Second, the Federal Patent Court (Bundespatentgericht) could grant a compulsory licence upon the request of a competitor in the event public interest demands such. These restrictions may come into play in times of a pandemic, for instance if an active ingredient turns out to be effective against COVID-19. This could be both in case of a vaccine and medical treatment for the disease and in particular in the event that the patent proprietor cannot provide it in a sufficient and efficient way to all people who would need it.

Governmental use orders Germany most recently amended s.5 of the German Infection Protection Act (Infektionsschutzgesetz),[13] which serves as a legal basis for the Government to order limitations of patents generally allowed by s.13 of the German Patent Act. With a governmental order of use, the Government itself or any third party may be authorised by the competent authority to use the patented technology lawfully without the authorisation of the patent proprietor. Such use includes the manufacturing, offering for sale and marketing of products normally falling under the scope of protection of the patent. However, third parties may not use the invention for their own commercial purposes and have to limit themselves to the promotion of public welfare.

The indefinite legal term of public welfare in s.13 of the German Patent Act covers all cases in which state care is necessary, in particular cases of emergency such as an epidemic, as specified by s.5(2), under (5) of the German Infection Protection Act. The patent proprietor will, however, remain entitled to appropriate remuneration from the Federal Government. In addition, the measures are only lawful as long as a state of emergency lasts as provided by s.13 of the German Patent Act. In accordance with the German Patent Act, the amended German Infection Protection Act stipulates that the order of use will automatically end upon the repeal of the finding of an epidemic situation of national significance, and otherwise upon expiry on 31 March 2021.[14]

[10] Federal Court of Justice (Bundesgerichtshof) 17 April 1997 (*Klinische Versuche II*), case no.X ZR 68/94.
[11] Higher Regional Court Düsseldorf (Oberlandesgericht Düsseldorf) 5 December 2013 (*Solifenacin*), Case No.I-2 U 68/12.
[12] cf. the Order of the President of the Court of Justice of the European Union of 7 May 2014 in Case (C-661/13).
[13] cf. the Act on the Protection of the Population in Case of an Epidemic Situation of National Significance (Gesetz zum Schutz der Bevölkerung bei einer epidemischen Lage von nationaler Tragweite) of 27 March 2020, which entered into force on 28 March 2020.
[14] German Infection Protection Act s.5(4).

Compulsory licensing Other than the governmental use order, a compulsory licence may be granted in accordance with art.24 of the German Patent Act by the Federal Patent Court (Bundespatentgericht) or on appeal by the Federal Court of Justice (Bundesgerichtshof). If the request for the grant of a compulsory licence is upheld, the licence seeker receives the non-exclusive right to use the patented innovation within the limitations and conditions attached to it. As a compensation, the patentee is entitled to receive an appropriate remuneration from the compulsory licence holder, which is calculated on the basis of the patent's economic value. Thus far, a compulsory licence request was usually raised as a defence in patent infringement litigation in order to avoid the patentee enforcing injunctions.

The grant of a compulsory licence requires first of all that the licence seeker has unsuccessfully tried obtaining a licence under reasonable conditions within a "reasonable" period of time. Second, the use of the patented innovation must be in the public interest. What is considered a sufficient "public interest" in accordance with s.24 of the German Patent Act varies. "Public interest" is not limited to matters of public health. However, in the past, requests for compulsory licences have only been raised in relation to medicinal products. Recently, the Federal Court of Justice (Bundesgerichtshof) found that there was sufficient public interest in the case of an HIV drug,[15] but not in the case of a cholesterol-lowering drug having the same mode of action as the patent proprietor's product but allegedly fewer side-effects.[16] It is therefore likely that the instrument of the compulsory licence may also become relevant in the present COVID-19 crisis, provided that an effective active ingredient will be technically available and not (sufficiently) provided to the German public by the patent owner.

Licence seekers may ask for a preliminary grant of a compulsory licence according to s.85 of the German Patent Act. Such preliminary proceedings took about two to three months in the first instance in the past, but it is likely it could be speeded up by the Federal Patent Court where it would concern an application of COVID-19.

United Kingdom

The experimental use exemption and Bolar exemption

In the United Kingdom, the experimental use exemption was first introduced in s.60(5)(b) of the Patents Act 1977. This (here named) "Original Exemption" applies to all subject-matter, including medicines, medical devices and agrochemicals, with the two leading cases on the interpretation of the Original Exemption being in the latter field.

In its judgment in the case of *Monsanto v Stauffer*,[17] the Court of Appeal permitted limited modifications to the injunction so that it did not prevent the defendants from conducting experiments on a herbicide in laboratories or glasshouses in the UK to find out more about it. The court would not, however, allow field trials for the purpose of full commercial clearance from the competent authorities that existed at the time. The court reasoned that exempted experiments were only those that generate new knowledge, not those that verify existing knowledge, for example to obtain regulatory clearance. The later decision of the Court of Appeal in *Auchincloss*[18] is consistent with this, when it holds that making and experimenting with a patented invention merely for the purposes of gaining official approval would not fall within the Original Exemption.

In a further judgment of the Patents Court in *CoreValve v Edwards Lifesciences*,[19] however, it was held that it does not suffice if the search for innovation is merely of secondary interest. Although this judgment supports the view that, in principle, the experimental use exemption permits trials to be conducted on a patented drug to ascertain its effect in non-patented medical indications, the court also found that the trials at issue did not have the "preponderant" purpose of finding out something new, considering the "very substantial" amount invoiced for the supplied products and the commercial motivation behind it.

Where it concerns the Original Exemption, a distinction is thus drawn between research conducted for the purpose of discovering something new about the subject0-matter of the invention on the one hand, and merely verifying what is already known on the other hand. To the extent that trials and tests on a substance for regulatory approval of that substance are not discovering something new, the exemption will not apply. In particular, it is generally accepted that this is the case as regards bioequivalence studies for an abridged application.

In light of these developments, concerns arose that the UK was losing opportunities to conduct work in support of marketing authorisations. Although in the meantime the Bolar exemption had also been implemented in the UK, the Bolar exemption is to be interpreted rather narrowly.[20] For these reasons, a (here named) "New Exemption" was implemented on 1 October 2014 in ss.60(6D) and 60(6E) of the Patents Act 1977, which specifically only covers medicinal products—it does not have the wider subject-matter scope of the Original Exemption.

[15] Federal Court of Justice (Bundesgerichtshof) 11 July 2017 (*Raltegravir*), case no.X ZB 2/17 - GRUR 2017, 1017.
[16] Federal Court of Justice (Bundesgerichtshof) 4 June 2019 (*Alirocumab*), case no. X ZB 2/19 - GRUR 2019, 1038.
[17] Court of Appeal of England and Wales 12 December 1985 (*Monsanto Co v Stauffer Chemical Co*) [1985] R.P.C. 515.
[18] Court of Appeal of England and Wales 29 October 1998 (*Auchincloss v Agricultural and Veterinary Supplies* [1999] R.P.C. 397.
[19] High Court of Justice of England and Wales 12 June 2009 (*CoreValve v Edwards Lifesciences*) [2009] EWHC 6 (Pat); [2009] F.S.R. 8.
[20] cf. the practice note of the UK Intellectual Property Office (UKIPO) and the Medicines and Healthcare Products Regulatory Agency (MHRA) of 3 June 2014, *https://bit.ly/3dtyk0q* (Accessed 13 May 2020).

The New Exemption applies in addition to the Original Exemption and the Bolar exemption and swept away the restrictions of the exemptions following from the *Monsanto v Stauffer* and *Auchincloss* judgments where it concerns medicinal products. This means that activities of preparing or running clinical trials involving innovative drugs and gaining regulatory approval are now exempted as well. In addition, work undertaken in the UK in support of a regulatory filing in a country outside of the EU is also covered. The UK therewith went from a rather narrow experimental use exemption (for medicinal products), to a very broad exemption in a very short time.

Compulsory licensing

Compulsory licensing Although compulsory licences are rare in the UK, the instrument of the compulsory licence is governed in ss.48–54 of the UK Patents Act 1977. There are basically two regimes for compulsory licences: one for patentees who are WTO proprietors[21] and one for non-WTO proprietors.[22] Most patentees encountered in practice will be WTO proprietors—these are nationals of, or domiciled in, a WTO member country or have a real and effective industrial or commercial establishment in such a country. The discussion below will therefore be limited to compulsory licence for patentees who are WTO proprietors.

There are three grounds for relief by a compulsory licence. An application for a compulsory licence may be upheld: (i) if the demand for a patented product is not being met on reasonable terms; (ii) if an important technical advance of considerable economic significance is being hindered or the development of commercial activities in the UK is unfairly prejudiced; and (iii) if unpatented activities are unfairly prejudiced.[23] The provision covers all patented subject-matter, including matter relevant to public health (but also see Crown use). To obtain a compulsory licence from a WTO proprietor, the applicant must have made efforts to obtain a licence from the patentee on reasonable terms and conditions the patent must not be in the field of semi-conductor technology unless a licence to such technology is required to remedy a practice that has been judicially or administratively determined to be anti-competitive first.

When the grounds for granting a compulsory licence have been satisfied, the UKIPO Comptroller has discretion whether or not to grant a compulsory licence. The Comptroller thereto must take account of the nature of the invention, the time which has elapsed since grant of the patent, and the risks to be undertaken by the applicant in providing capital and working the invention.[24] If all requirements are met, the Comptroller will determine the terms of a compulsory licence on a case-by-case basis.[25]

Crown use Besides the instrument of the compulsory licence, the UK adopts a statutory doctrine of Crown use. The relevant provisions thereto, allowing the use of patented inventions "for services of the Crown", are found in Patents Act 1977 ss.55–59.

Section 55(1)(a) UK Patents Act 1977 provides that

> "any government department and any person authorised in writing by a government department may, for the services of the Crown" do various acts including making, using, importing and keeping, "*without the consent of the proprietor of the patent* …".

The acts also extend to selling or offering to sell for the production or supply of specified drugs and medicines. Products of a patented process and the use of the process itself are also covered.

There is little in s.55 alone to guide anyone on when Crown use may apply, although s.56(1)(b) does provide that "services of the Crown" in this section includes "the production and supply of specified drugs and medicines". But, because Crown use effectively provides the British Government with a discretion to requisition patented technology, it is regarded as a serious step, which should only be considered in rare and narrow circumstances.

During "any period of emergency" within the meaning of section 59, furthermore, the powers exercisable in relation to an invention by a government department or a person authorised by a government department under section 55 above shall include power to use the invention for any purpose which appears to the department necessary or expedient.

The draconian nature of the Crown use provisions (particularly s.59) means that case law is scant and successful use even rarer. However, the recent case of *IPCom v Vodafone*,[26] although it concerns telecommunications patents, provides one example in which the Crown use provisions have been used successfully to defend against a claim of infringement. In this case, IPCom argued that "for services of the Crown" does not necessarily mean that the use has to directly benefit the Crown itself. Furthermore, authorisation must be in writing from a government department[27] and may be implied, according to IPCom.[28] The latter point was the subject of much debate in the

[21] Patents Act 1977 s.48A.
[22] Patents Act 1977 s.48B.
[23] Patents Act 1977 s.48B(1)(d).
[24] Patents Act 1977 s.50(2).
[25] See, for example, High Court of Justice of England and Wales 27 January 1997 *re Therma-Tru Corp's Patent* [1997] R.P.C. 777 Ch D (Patents Court); and Patent Office 14 August 1989 *Re Monsanto's CCP Patent* [1990] F.S.R. 93. Reference should also be made to the decisions made in respect of "licences of right" under s.46 of the Patents Act 1977 (see the House of Lords 12 December 1985 (*Allen & Hanburys Ltd v Generics (UK) Ltd) (No.2)* [1986] R.P.C. 203, which was decided under the Patents Act 1949).
[26] High Court of Justice of England and Wales 28 January 2020 (*IPCom v Vodafone*), [2020] EWHC 132 (Pat).
[27] High Court of Justice of England and Wales 3 July 2009 (*MMI Research v Cellxion*) [2009] EWHC 1533 (Pat).
[28] High Court of Justice of England and Wales 16 May 1923 (*Aktiengelleschaft für Aluminium Schweissung v London Aluminium Co Ltd No.2*) (1923) 40 .R.P.C. 107.

case and is particularly important. Does an authorisation to do a specific act imply an authorisation to infringe a specific patent?

It was eventually held by the court that what mattered is the written authorisation to do the relevant act. In this case the authorisation was requested from a Police Gold Commander who was acting pursuant to Cabinet Office authority. Vodafone therefore did not need to show that it was necessary for them to infringe the particular patent at issue to make use of the defence. According to the court, "authorisation" is defined by the acts authorised rather than the patents that may be infringed. It is an authorisation of the kind "you are hereby authorised to operate process Y/make product Z", which does not expressly identify the specific patent or patents in question. In other words, it does not need to be shown that it is necessary to infringe a certain patent when carrying out that authorised act in order for the defence of Crown use to apply. Nevertheless, similar to the instrument of the compulsory licence, patentees remain entitled to compensation in accordance with Section 57A of the Patent Act.

The Netherlands

The experimental use exemption and Bolar exemption

In the Netherlands, the experimental use exemption is incorporated in art.53 of the Dutch Patent Act. In this article it is stipulated that the patentee's exclusive right (to put the invention into effect) does not extend to acts done *exclusively* for the purpose of research on the patented invention, including the product directly obtained by the use of a patented process.

Although the article has been subject to debate in recent years, it is interpreted rather strictly following the *ICI v Medicopharma* judgment of the Supreme Court of the Netherlands.[29] In this case, the Supreme Court ruled that research is only permitted if and insofar the purpose of that research is justified. This means that the party benefiting from the experimental use exemption will have to demonstrate that the research conducted is (exclusively) scientific in nature *or* (exclusively) performed in accordance with the objective of patent law, such as the further development of existing technologies. This includes experiments whether or not the invention can be put to practical use or may be further developed.

In its later judgment in the case of *ARS v Organon*, the Supreme Court added that performing clinical studies for the purpose of applying a marketing authorisation for a medicinal product, is not exempted by the experimental use exemption. Such research, according to the Supreme Court, concerned studies *with* the patented invention which did not pursue any of the objectives of patent law. Clinical studies directed at the search for a second or further medical indication of existing patented substances or medicinal products, however, would be exempted by the experimental use exemption.[30] Although the performance of clinical studies for the purpose of applying for a marketing authorisation is nowadays exempted in accordance with the Bolar exemption,[31] it follows from this judgment of the Supreme Court that solely research *on* or *of* the patented invention is permitted. Research *with* the patented invention, on the other hand, is not exempted. Consequently, a patented substance, product or process may not be used as a tool in the search for new medicinal products.

Compulsory licensing

In cases where conducting the necessary studies is not exempted and permission (by means of a voluntary licence) is refused by the patentee, a compulsory licence may serve as an *ultimum remedium*. In the Netherlands a compulsory licence for reasons of public interest may be issued to a third party by the Minister of Economic Affairs in accordance with art.57 of the Dutch Patent Act if this is necessary in his opinion. If a compulsory licence is issued, it will have a defined scope in view of the circumstances under which the issuing takes place.

Similar to the experimental use exemption, the instrument of the compulsory licence has been subject to debate in The Netherlands in recent years. However, as far as the authors are aware, a first compulsory license for reasons of public interest has yet to be granted in the Netherlands. It therefore remains unclear how this article should be interpreted exactly and what is to be understood as sufficient reason of public interest. Although the legislative history of 1976 with the introduction of this article in the Dutch Patent Act suggests a broad interpretation by which a compulsory licence may even be granted for the sole reason that a competing product may be brought on the market for a significant lower price,[32] a subsequent decision of the Minister of 9 January 1980 suggests otherwise. In this decision, by which an application for a compulsory licence was dismissed, the Minister mentioned that something should be considered of public interest if it concerns one of the objectives the government pursues.[33] With a sufficient level of protection for patentees being one of these objectives, priority should not be given rashly to the public interest over the interest of the patentee according to the minister.

In a more recent policy document of the Dutch Government, the Minister mentioned that it considered an epidemic, during which a patentee has insufficient production capacities, to be a situation in which a compulsory licence could be granted.[34] Finally, with a

[29] Supreme Court of The Netherlands (Hoge Raad) 18 December 1992 *(ICI v Medicopharma)*, NL:HR:1992:ZC0801.
[30] Supreme Court of The Netherlands (Hoge Raad) 23 June 1995 (*ARS v Organon*), NL:HR:1995:ZC1769.
[31] Following the implementation of Directive 2001/83/EC in art.53(4) of the Dutch Patent Act in 2007.
[32] Legislative History, *Kamerstukken II*, 1975–1976, 13 209, no.8.
[33] Decision of the Dutch Minister of Economic Affairs of 9 January 1980 (*Weidepomp*), BIE 1981, 38.
[34] Policy document Biotechnology (Beleidsnota Biotechnologie) of 18 August 2005, *Kamerstukken II*, 2004–2005, 27 428, no.65.

proposal to amend the Dutch Expropriation Act, the Minister of the Interior and Kingdom Relations proposed to erase art.97 of that Act by which a patent may be expropriated. According to the Minister, the same effect could be achieved by the issuing of a compulsory licence.[35]

At the moment, a special committee has been established by the Dutch Government to further investigate under which circumstances the instrument of a compulsory licence may be applied. Until this committee presents its findings or a compulsory licence is actually applied for and challenged, it remains somewhat uncertain what exactly should be considered sufficient public interest under Dutch law. In light of the above, however, it should be safe to assume that applications in direct connection with the present COVID-19 pandemic definitely qualify as such.

Belgium

The experimental use exemption and Bolar exemption

Under art.XI.34, §1(b) of the Code of Economic Law, the exclusive rights deriving from a patent do not extend to "acts on and/or with the patented invention for scientific purposes". The research exemption under Belgian patent law therewith covers all "acts" (not only experiments) performed for scientific purposes both *on* and *with* the patented invention. It was the clear intention of the Belgian legislator to broaden the scope of this exemption when the patent legislation was amended in 2005 to transpose the EU Biotechnology Directive.[36]

The notion of scientific purposes covers not only activities with a purely scientific or academic purpose, but also activities with a mixed scientific and commercial purpose, as long as the commercial purpose does not prevail.[37] According to the legislative discussions, examples of such exempted activities include

> "the development of new applications, a better therapeutic effect, a more efficient manufacturing method, a new administration form and a new indication".

In view of the wording of the exemption ("on and/or with the patented invention") it is moreover generally accepted that the Belgian experimental use exemption also covers the use of a patented research tool if this tool is used for scientific purposes. Case law has confirmed that the simple fact that the alleged infringer may have a commercial intent does not exclude the application of the research exemption.[38] It is not relevant either where the research takes place (at a university or within a company); only the purpose of the research matters.[39]

Whether clinical trials are covered by this exemption is subject to debate. As these trials are carried out with a view of obtaining a marketing authorisation to commercialise the allegedly infringing product, it is often argued that these trials have a prevailing commercial purpose and are therefore not covered by the research exemption. Others, however, argue that at least phase 1 and phase 2 trials should be exempted as the primary objective of these tests is to obtain scientific information on the efficiency and safety of the tested products.[40] There is, however, no case law yet settling this matter.

Even though the exact scope of the exemption thus remains unclear, the experimental use exemption is without a doubt a broad exemption, which covers various research activities by universities as well as commercial entities relating to the search for new medicines.

It should be noted however that, in ratifying the UPC Agreement, art.XI.34, §1(b) of the Code of Economic Law relating to the experimental use exemption was amended in order to reflect the wording of art.27 of the UPC Agreement.[41] The new wording clearly limits the scope of the exemption. Nevertheless, the amendment will only enter into force as from the moment that the UPC Agreement enters into force. As this will not happen any time soon in view of the recent decision of Germany's Federal Constitutional Court (Bundesverfassungsgericht),[42] the current (broad) version of the exemption will most probably simply remain in place.

The Bolar exemption The Belgian legislator almost literally transposed art.10(6) Directive 2001/83 into Belgian law. The Bolar exemption has been inserted in the Belgian Medicines Act and provides manufacturers of generics and biosimilars with a defence to patent infringement when gaining regulatory approval. Conducting the necessary studies and trials with a view to making an application for a marketing authorisation using the abridged, hybrid or biosimilar application procedure and the consequential practical requirements are thus exempted.

Given the wording of the Bolar exemption, which merely refers to abridged applications and hybrid or biosimilar applications, only activities linked to obtaining data that are required to be supplied to the regulatory authorities in view of such applications are exempted. The Court of Appeal of Brussels (Hof van Beroep Brussel) has confirmed in this regard that the Bolar

[35] Parliamentary History, *Kamerstukken II*, 2018–2019, 35 133, no.3.
[36] Act of 28 April 2005 amending the Belgian Patent Act relating to the patentability of biotechnological inventions implementing Directive 98/44/EC of 6 July 1998 on the legal protection of biotechnological inventions. The Patent Act was incorporated in the Code of Economic Law in 2014.
[37] This is clear from the preparatory works of the Act of 28 April 2005. Also see Buydens, *Droit des brevets d'invention* (Brussels : Larcier, 2020), p.311.
[38] cf. Ph. De Jong et al., "Evoluties in het octrooirecht — overzicht van rechtspraak (2011–2013)" [2014] T.B.H. 439, referring to unpublished case law.
[39] cf. G. van Overwalle, "Zonder trommels en trompetten: EU-Biotechnologierichtlijn in het Belgische octrooirecht" [2005] I.R.D.I. 360.
[40] cf. O. Lemaire, "Essais cliniques et exception d'usage expérimental en droit des brevets" [2000] Ing.-Cons. 436.
[41] Act of 19 December 2017 relating to various amendments of patent law in relation to the implementation of the unitary patent and the unified patent court. Also see subsection "The experimental use exemption, compulsory licensing and the Bolar exemption" above.
[42] German Federal Constitutional Court (Bundesverfassungsgericht) 13 February 2020, DE:BVerfG:2020:rs20200213.2bvr073917.

exemption also covers related pricing and reimbursement applications.[43] It is also clear that the manufacturing, importing and processing of active substances for the necessary studies or tests are exempted. Whether suppliers may invoke this exemption is not clear, as there is no case law yet.

Regulatory approval for originator products, on the other hand, is not covered by this exemption.[44] Moreover, in view of the wording it is accepted that the territorial scope of the Bolar exemption is limited to regulatory data needed to obtain Belgian or EU marketing authorisations only.

Compulsory licences

Article XI.38 of the Code of Economic Law provides for a compulsory licence in the interest of public health.[45] Such licenses may be granted by the Belgian Government for the exploitation and application of an invention protected by a patent in a number of situations and for a number of products. This includes (i) medicines, medical devices, products or medical devices used for performing diagnoses and derived or combinable therapeutic product; (ii) the use of processes or products necessary for the manufacture of one or more products indicated under (i); and (iii) diagnostic methods applied outside a human or animal body.

To obtain such acompulsory licence, an applicant should establish that he has the means (or the bona fide intention to obtain these means) necessary for the effective and continuous manufacturing and/or application of the patented invention in Belgium. The application for such a compulsory licence should be filed with the Minister of Economic Affairs, with a copy to the Consultative Bioethical Committee. This Committee will issue a non-binding advice after having heard the applicant. Following this advice, the Government will take a decision on the licence: if the Government decides to grant a compulsory licence, it will also decide on all aspects of the licence, including the duration of the licence and the licence fee. In case of a public health crisis, the procedure to obtain a compulsory licence may be accelerated (e.g. by not awaiting the advice of the Consultative Bioethical Committee). Contrary to other compulsory licences under Belgian law, it is not necessary to have tried to obtain a licence from the patent owner first.

This compulsory licence furthermore provides a legal basis for a defence against a patent infringement allegation, not only after the licence has been granted, but also to a certain extent pending the application. Any infringement proceedings initiated against the applicant in relation to a patent for which a compulsory licence has been applied is indeed suspended by law until the Government has taken a decision on the application.

As far as the authors are aware, however, such compulsory licences has not been granted yet. It, however, appears an interesting option to consider in the context of the COVID-19 pandemic. This licence indeed cannot only be applied for in relation to actual medicines (such as vaccines), but also for diagnostic methods and for products or devices used for performing diagnoses. As the need for all kinds of tests relating to COVID-19 will probably increase exponentially, any patent rights limiting the manufacturing and/or use of these tests may be subject to a compulsory licence in the interest of public health. It will moreover be possible to apply for an accelerated procedure as the COVID-19 situation certainly can be considered a public health crisis.

Poland

The experimental use exemption and Bolar exemption

The experimental use exemption The experimental use exemption in Polish law covers the use of an invention for research, experimental purposes, assessment, analysis and teaching (art.69(1)(3) of the Polish Industrial Property Law Act (PIPLA)). The exemption is, however, limited to the use of the invention for scientific purposes only and does not include the offering for sale, producing or importing of products which would fall under the scope of protection of a patent. Nevertheless, it is generally accepted that the experimental use exemption also covers preparatory acts for the scientific application of a protected invention, which preparatory acts may consist of making, using, offering or importing products for those purposes or using a protected method which is the subject matter of the invention.[46]

According to the judgment of the Poland Supreme Administrative Court (Naczelny Sad Administracyjny) of 5 July 2007, the research exemption does not cover the use of protected tools in conducting experiments, unless the use of such tools is not aimed at commercially feasible results.[47] Furthermore, the use of a protected invention does not infringe the patent if the activities pursue a specific research or experimental objective or consist of analysis, evaluation or teaching.[48] Use for research or experimental objectives occurs when the action taken is intended to clarify a "state of uncertainty". These are forms of use which contribute to the creation of new knowledge about the subject-matter of the invention or which aim at clarifying doubts related to the invention. The research exemption also covers studies

[43] Court of Appeal of Brussels (Hof van Beroep Brussel) 2 July 2007 (*Merck Sharp & Dohme v Eurogenerics*) [2007] I.R.D.I. 264.
[44] Mignolet et al., *Traité de droit pharmaceutique : La commercialisation des médicaments à usage humain. Droit européen et droit belge* (Waterloo : Wolters Kluwer, 2016), p.759.
[45] The Belgian legislation provides for other types of compulsory licences as well, e.g. in the case of non-exploitation.
[46] cf. T. Targosz in eds. E. Nowicka and K. Szczepanowska-Kozlowska (eds), *System Prawa Handlowego — Part 3* (Warsaw: 2015), p.403.
[47] Poland Supreme Administrative Court (Naczelny Sąd Administracyjny), 5 July 2007, II GSK 92/07, not published.
[48] cf. P. Kostanski, *Die Schutzwirkung des Patents nach polnischem Recht* (Baden-Baden: 2010), p.394.

and (clinical) trials performed for commercial purposes, as long as one of the objectives remains the clarification of a "state of uncertainty". The experimental use exemption only covers the use of the protected invention within Poland itself and is in particular intended for conducting studies and experiments at an early stage of the development of an active substance and/or the development of new medicinal products, including combinations of active substances.

The Bolar exemption/regulatory testing exemption In Polish law, the use of a protected invention for the registration of a medicinal product is allowed based on the equivalent of the Bolar exemption, the so-called regulatory testing exemption. The Regulatory testing exemption applies in addition to the experimental use exemption and may be found in art.69 (1)(4) PIPLA.

Ever since the implementation of the Bolar exemption in the PIPLA in 2004, the exact scope of this regulatory testing exemption has been subject of debate in Poland. According to the original wording of the regulatory testing exemption, acts would not constitute patent infringement if such acts were required by law to obtain registration or a marketing authorisation to put certain products on the market because of their intended use, in particular where it concerned medicinal products. This wording left room for doubt as to whether (i) third-party actions were covered by the regulatory testing exemption; (ii) only trials and studies for abridged applications were exempted or also for hybrid and full procedure applications; (iii) storage of patented active substances were also exempted; and (iv) studies and trials for registrations and marketing authorisations abroad were also exempted.

With its decision of 23 October 2013, the Poland Supreme Court (Sąd Najwyższy) held that the regulatory testing exemption should be interpreted narrowly. [49] According to the Supreme Court, the Bolar exemption only applied to the entity conducting the experiments or trials itself and did not allow infringing acts committed by third-party suppliers or manufacturers.

With the amendment of the regulatory testing exemption in 2019, the scope of the exemption has become much broader. The regulatory testing exemption first of all applies without limitation of the territorial scope, meaning that activities are exempted regardless of where regulatory approval is ultimately sought and that the export of protected substances is allowed. Second, the exemption applies to all qualifying activities, regardless of whether those activities relate to approval of a generic or biosimilar medicine or a new innovative medicine. Furthermore, third parties assisting primary parties in carrying out the preparatory work for regulatory approval (e.g. by contract manufacturing) benefit from the regulatory testing exemption as well, provided that such third-party activities are directed and limited to assisting the primary party in seeking regulatory approval. Finally, also storage of test batches is covered, except for the storage of commercial batches for the launch after expiry of the patent/supplementary protection certificate.

The exemption, however, remains limited to those activities which occur before regulatory approval. Activities which occur after a competing medicine is approved and relevant patents are still in force do not implicate this purpose, but instead interfere with the patentee's exclusive rights, undermine the innovation incentives that patents were designed to provide. Consequently, also clinical trials to investigate market potential are not covered by the exemption.[50]

Compulsory licensing Under Polish law, a compulsory licence may be granted when: (i) it is necessary to prevent or remove a threat to State security, in particular in the field of defence, public order, protection of human life and health and protection of the natural environment; (ii) it is held that the patentee abuses their exclusive rights; and (iii) it is held that the proprietor of an older patent hinders the needs of the domestic market by refusing a licence for a younger dependent patent (PIPLA arts 82–88).

A compulsory licence may be granted by the Polish Patent Office (PPO) by way of an administrative decision, but the PPO is not bound to uphold an application for a compulsory licence, even if all requirements are met. A compulsory licence may be obtained for inventions belonging to any field of technology as long as any of the above-mentioned requirements are met. Where it concerns medicinal products in particular, applications are more common when a patentee abuses its exclusive rights by charging excessive prices and/or provides insufficient quantities or quality of the patented medicines to the domestic market. When a compulsory licence is granted, the licence should be non-exclusive[51] and has to meet the criteria of relevance, necessity and proportionality.

Besides the instrument of the compulsory licence, Polish law also provides for the limitation of a patent in such a way that the patent is not infringed by using the invention for state purposes. Such acts would only permitted to the extent necessary to prevent or remove a threat to important state interests, in particular in the area of public security and public order. To date, however, no compulsory licence has been granted yet in Poland for the use of an invention involving a medicinal product.

[49] Poland Supreme Court (Sąd Najwyższy) 23 October 2013 (*Astellas Pharma v Polpharma*), IV CSK 92/13, OSNC 2014/7-8/80. Also see the judgments of the Court of Appeal of Gdańsk (Sąd Apelacyjny) of 26 June 2012, I ACa 320/12, POSAG 2012/4/3-20 and of the District Court of Gdańsk (Sąd Okręgowy) of 14 February 2012, IX GC 76/11, not published.

[50] cf. A. Sztoldman, "Changing approach to the regulatory testing exemption in patent law (the European Union perspective)" in Ż. Pacud, R. Sikorski (eds), *Rethinking Patent Law as an Incentive to Innovation*, (Kluwer Law International, 2020) (pre-print).

[51] cf. the judgment of the Voivodship Administrative Court in Warsaw (Wojewódzki Sąd Administracyjny w Warszawie) 7 May 2007 VI SA/Wa 117/07, not published.

Czech Republic

The experimental use exemption

The Czech Patent Act[52] stipulates in art.18 which acts are exempted from patent infringement. Such acts in particular include situations where the activities conducted with the patented object are for experimental purposes, including experiments and tests necessary for the eventual marketing of a medicinal product. As art.18 does not specify or limit the experimental uses included in the exemption and there is no case law available, there are ongoing debates among legal experts in the Czech Republic as to the exact extent of the experimental use exemption.

In any case it is clear that the exemption is not unlimited and rights of the patent proprietor have to be protected. It is therefore generally accepted that non-commercial experiments fall under the exemption. However, most experiments have a commercial purpose or potential to some extent as well. In this regard Czech jurisprudence looks across borders (mainly Germany) to assess the issue. In accordance with the decisions of the German Federal Court of Justice in *Clinical Trials I* and *Clinical Trials II*,[53] in Czech jurisprudence the view is adopted that the experimental use exemption is applicable to experiments leading to new findings with possible commercial use, although commercial use cannot be the main purpose of the experiments.

With the implementation of the Bolar exemption, the Czech Act on Pharmaceuticals[54] was amended. In accordance with art.27 of the Act on Pharmaceuticals, the scope of the experimental use exemption was extended. However, it is also clear that the Czech implementation of the Bolar exemption concerns a strict implementation of Directive 2001/83/EC. This means that the Bolar exemption only applies to the abbreviated registration proceedings of generic and biosimilar medicinal products in the Czech Republic. Consequently, the Bolar exemption cannot be benefited from when it comes to conducting the necessary studies for new medicinal products without an existing marketing authorisation.

Compulsory licensing

With art.20, the Czech Patent Act provides a legal basis for a compulsory licence. The Czech Industrial Property Office (Úřad průmyslového vlastnictví – ÚPV) may upon request grant a non-exclusive right of use for a patented invention. This legal instrument is used primarily in situations when the patentee does not exercise their rights to the patent for several years after the patent was granted. In such cases the patentee unnecessarily "blocks" the use of the invention and thus potentially slows progress of innovation and hinders the potential economic benefits of the invention. A compulsory licence may furthermore be granted in case of endangerment of an important public interest.

The term "endangerment of an important public interest" is a most unspecific legal term and is not defined elsewhere in Czech law. Considering the significant adverse effects of the grant of a compulsory licence on the patentee, the term is likely to be interpreted in a strict way, and would only be applicable in extraordinary situations. With statutory laws in other jurisdictions making use of terms such as public health, danger of an epidemic, protection of the environment and/or state defence, it is probable that the COVID-19 pandemic will be a sufficiently extraordinary situation to meet the requirements for the grant of a compulsory licence.

When applying for a compulsory licence, the request must be duly motivated, especially with respect to the fulfilment of the requirements for the grant of the compulsory licence. The applicant should for instance motivate why there is objective endangerment of an important public interest and why it would not suffice if only the patentee would exercise their rights for remedying such endangerment. Furthermore, applicants should duly document the failure to reach a prior agreement with the patent proprietor, except in cases of a state of emergency or in other extraordinary urgent circumstances.[55]

Finally it may be noted that the ÚPV, if an application for a compulsory licence is upheld, will determine the conditions, extent and period of the compulsory license in their decision. Such conditions may include a restriction in time and an obligation to supply the majority of the product to the Czech market. When a compulsory licence is granted, the patentee will be entitled to a reasonable royalty, which will be calculated on the basis of the amount which would be common in comparable cases.

Further considerations from a broader European law perspective

Experimental use exemption and Bolar exemption

It follows from the above that practices differ significantly from country to country. Although harmonisation in the fields of the experimental use exemption and Bolar exemption has been one of the objectives of the European legislator for quite some time, attempts to achieve such harmonisation have yet to lead to the desired results. Both the experimental use exemption (which has not been harmonised at all) and the Bolar exemption (which has a legal basis in EU law) are applied and interpreted very differently. Where for instance Germany, Poland and

[52] Act No527/1990, Coll., on inventions, industrial designs and advancement applications (the Patent Act).
[53] cf. above and the judgments of the German Federal Court of Justice (Bundesgerichtshof) of 11 July 1995 (*Klinische Versuche I*), case no.X ZR 99/92 and 17 April 1997 (*Klinische Versuche II*), case no.X ZR 68/94.
[54] Act No.378/2007 Coll., on pharmaceuticals (Act on Pharmaceuticals).
[55] Which is in line with art.31(b) of the TRIPS Agreement.

Belgium adopt a relatively broad interpretation, and in recent years the United Kingdom and Poland extended the scope of these exemptions,[56] The Netherlands and the Czech Republic adopt a much stricter approach. When conducting the necessary trials and studies in the EU, it thus comes recommended to compare the exempted acts and activities per country beforehand.

Compulsory licensing in times of crisis

Also, insofar as a licence or permission is required, whether because certain acts in conducting the necessary research are not exempted, or in order to manufacture medicines and bring these medicines on the market by absence of the patentee's consent, it seems that almost every country has the necessary legal instruments in place. Be it by means of a compulsory licence and/or otherwise, such as the Crown Use exemption in the United Kingdom or the governmental use order in Germany.

With WIPO identifying 156 countries[57] providing for the instrument of compulsory licensing, it comes as no surprise that these legal frameworks too differ from country to country. This also applies to the EU, where it has not been the legislator's intention to provide for a harmonised legal framework. Some countries, such as Germany[58] and France,[59] in this regard put in place special laws, warranting that the conditions for a compulsory licence or equivalent measure are met more easily. Most countries, however, lack valuable experience when it comes to the instrument of compulsory licensing. WIPO's Standing Committee concludes that the mechanism is rarely used and that Member States indicated that only few or no requests for compulsory licences have been made and granted in most jurisdictions.[60] This finding also applies to Belgium, the Netherlands and Poland, as discussed above.[61]

Germany and the United Kingdom, on the other hand, have more experience with the grant of the necessary compulsory licences and equivalent measures. These regulations could become particularly relevant if—as is currently the case—already known, patent-protected active substances prove to be effective against COVID-19. It can be assumed that with an increasing chance of having found a candidate, legal discussions are likely to result. Even before the product is ready for the market and any orders for use or compulsory licences are issued, the experimental use exemption and Bolar exemption could be "used" here. In the United Kingdom, the conditions that must be satisfied to obtain a compulsory licence remain onerous, and applications are rare, but the *IPCom* decision provides very recent authority in which Crown use is applied. In Germany on the other hand there seems to be more clear guidance by the two leading decisions of the Federal Court of Justice.

Nevertheless, when it comes to compulsory licensing, another angle from which this mechanism may be viewed is the fact that the protection of intellectual property rights is explicitly safeguarded by art.17(2) of the Charter of Fundamental Rights of the European Union (the EU Charter).[62] With intellectual property rights being recognised as a fundamental right, which needs to be protected, priority should not easily be given to the general or public interest over a patentee's fundamental rights. According to art.17(1) of the Charter, no one may be deprived of his or her possessions, except in the public interest and in the cases and under the conditions provided for by law, subject to fair compensation.

The peaceful enjoyment of property is furthermore safeguarded by art.1 of Protocol No.1 to the European Convention on Human Rights (ECHR). Here too it is provided that no one should be deprived of his possessions, except in the public interest and subject to the conditions provided for by law and by the general principles of international law.

Although the issuing of a compulsory licence or equivalent measure might, strictly speaking, not be the depriving of one's intellectual property rights, the issuing of a compulsory licence may as well be compared to such. The Government of the Netherlands, for instance, has proposed erasing art.97 of its Expropriation Act by which a patent may be expropriated. According to the Dutch Government, the same effect could very well be achieved by the issuing of a compulsory licence.[63]

In this respect, the European Court of Human Rights (ECtHR) has recalled in a number of judgments that intellectual property rights enjoy the protection of art.1 of Protocol No.1 to the ECHR.[64] In light of the historical relationship between art.17 of the EU Charter and art.1 of Protocol No.1 to the ECHR, it may be assumed that the extensive jurisprudence of the ECtHR is also relevant to the interpretation of art.17 of the EU Charter.[65] Consequently, intellectual property may be a form of

[56] cf. the recent changes in the laws of the United Kingdom in 2014 and Poland in 2019, as discussed above.
[57] cf. the Draft Reference Document on the exception regarding compulsory licensing of WIPO's Standing Committee on the Law of Patents of 21 May 2019, SCP/30/3, para.72.
[58] In relation to the COVID-19 pandemic, Germany adopted the Act on the Protection of the Population in Case of an Epidemic Situation of National Significance (Gesetz zum Schutz der Bevölkerung bei einer epidemischen Lage von nationaler Tragweite) of 27 March 2020, which entered into force on 28 March 2020. See above.
[59] France adopted emergency law n° 2020-290 on 23 March 2020, amending the Public Health Code (Code de la santé publique) by introducing art.L3131-15 in order to deal with the COVID-19 pandemic.
[60] cf. the Draft Reference Document on the exception regarding compulsory licensing of WIPO's Standing Committee on the Law of Patents of 21 May 2019, SCP/30/3, para.217 and fn.323.
[61] Also compare the TRIPS Flexibilities Database, *http://tripsflexibilities.medicineslawandpolicy.org/* [Accessed 2 September 2020].
[62] Charter of Fundamental Rights of the European Union, 2012/C 326/02.
[63] Legislative History, *Kamerstukken II*, 2018–2019, 35 133, no.3.
[64] cf. ECtHR 11 January 2007 (*Anheuser-Busch Inc v Portugal*), 73049/01, CE:ECHR:2007:0111JUD007304901 par. at [72] and ECtHR 29 January 2008 (*Balan v Moldova*), 19247/03, CE:ECHR:2008:0129JUD001924703 par. at [34].
[65] cf. J. Griffiths et al., *Fundamental Rights and European Intellectual Property Law — The Case of Art 17(2) of the EU Charter*, p.6. Also see the judgment of the Court of Justice of the European Union of 19 July 2019 (*Spiegel Online*) (C-516/17), EU:C:2019:625;[2019] Bus. L.R. 2787 at [57], where the Court recalled that art.52(3) of the EU Charter seeks to ensure consistency between the fundamental rights protected by the EU Charter and ECHR if these rights correspond with each other.

property covered by art.17(1)'s general property guarantee, meaning that case law in the context of this article will be relevant too.[66]

In this regard, the ECtHR adopts the "fair balance" test, holding that an interference with the right of peaceful enjoyment of one's possessions for reasons of public interest should always strike a fair balance between the demands of the general interest of the community and the requirements of the protection of the individual's fundamental rights.[67] This requires that the person concerned should not have to bear a "disproportionate and excessive burden".[68]

In the view of the authors, the scope of the compulsory licences discussed above is in line with art.30 of the TRIPS Agreement and the EU Charter, providing for a fair balance to the benefit of the public interest. It indeed is possible to provide for limited exceptions to the exclusive rights conferred by a patent in times of crisis, such as the COVID-19 pandemic in 2020, to the extent that such exceptions do not unreasonably interfere with the normal use of the patent and take the legitimate interests of third parties into account. After all, the protection of public health too is a fundamental right protected by art.35 of the EU Charter. In the absence of a crisis in "normal" times, however, more weight may be attributed to the protection of one's intellectual property rights. It therefore remains most doubtful whether a compulsory licence or equivalent measure may also serve as a (long-term) solution for ongoing debates on the high prices of medicines.[69]

Market exclusivity, data exclusivity and knowhow

Market exclusivity and data exclusivity

Another matter to consider with applications for compulsory licences is the fact that the issuing of a compulsory licence under a patent does not automatically result in a licence for the necessary knowhow or rights required for the application of a marketing authorisation.

On the contrary. Other than with the issuing of compulsory licences, the issuing of marketing authorisations is fully harmonised in the European Union in accordance with Regulation (EC) 726/2004 for the authorisation and supervision of medicinal products. In accordance with art.3 of this Regulation, generic and biosimilar medicines may obtain a marketing authorisation with reference to the *originator's* registration file. This may be done if, in accordance with art.10(1) of Directive 2001/83/EC, a period of eight years of data exclusivity has elapsed, while the generic medicinal product should not be placed on the market until ten years have elapsed from the initiatial authorisation of the reference product. This period of market exclusivity may even be extended to 11 years, provided that the marketing authorisation holder obtains an authorisation for one or more new therapeutic indications which are held to bring significant clinical benefit (art.14(11) of the Regulation). Parallel to these rules, a marketing authorisation holder may also benefit from the incentives of the Orphan Regulation (Regulation (EC) 141/2000), which provides for a period of ten years market exclusivity if the concerned medicine has a separate orphan designation. This period may be extended with another two years for completion of a paediatric investigation plan.

These so-called rights of regulatory exclusivity are thus governed at the higher level of EU law. However, none of the relevant pharmaceutical legislation on this higher level addresses the issuing of a compulsory licence for a relevant patent as an exception for these regulatory exclusivity rights. Consequently, while the issuing of a compulsory licence is strictly a matter of national law within the EU, EU pharmaceutical legislation may very well prevent the holder of a compulsory licence bringing a competing medicinal product on the market. After all, without the permission of the marketing authorisation holder, the holder of a compulsory licence may not successfully apply for a marketing authorisation of its own and bring its medicine on the market.[70] Only Regulation (EC) 816/2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems contains a relevant provision in art.18(2). In this article it is stipulated that the protection periods of data exclusivity and market exclusivity shall not apply insofar a compulsory licence is issued. However, the article only applies insofar it concerns markets outside of the European Union in conjunction with art.58 of Regulation (EC) 726/2004.

This means that holders of compulsory licences, in the absence of a relevant exception and permission of the marketing authorisation holder—even in times of crisis—would have to conduct their own studies and trials in the case only data exclusivity applies.[71] The

[66] cf. C. Geiger, "Intellectual Property Shall be Protected!? — Article 17(2) of the Charter of Fundamental Rights of the European Union: A Mysterious Provision with an Unclear Scope" (2019) 41 *European Intellectual Property Review* 113, 115.
[67] ECtHR, 5 January 2000 (*Beyeler v Italy*), 332020/96, CE:ECHR:2000:0105JUD003320296 at [107].
[68] ECtHR, 22 June 2004 (*Broniowski v Poland*), 31443/96, CE:ECHR:2004:0622JUD003144396 at [150].
[69] Even though the European Parliament adopted a resolution in procedure 2016/2057(INI) on 2 March 2017 on EU options for improving access to medicines, which includes the use of compulsory licensing by EU Member States and addresses the issue of access to medicines at affordable prices (cf. para.51 of the resolution). A similar resolution was recently proposed in the Belgian Parliament by a left-wing party (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).
[70] Except in cases where a compulsory licence is granted to a pharmacist, to whom the obligation of a marketing authorisation does not apply in accordance with art.3 of Directive 2001/83/EC, or the exotic exception of art.5(3) of Directive 2001/83/EC is applied in accordance with the applicable national law.
[71] cf. the letter of the European Commission of 26 February 2006 to Mr Perry of the European Generic Medicines Association regarding Tamiflu, *http://www.cptech.org/ip/health/dataexcl/ec-de-tamiflu.pdf* [Accessed 2 September 2020].

unnecessary duplication of such studies would not only burden holders of compulsory licences with costs, but also raise ethical questions.[72]

Knowhow

A similar difficulty may arise if the applicant or holder of a compulsory licence lacks the necessary knowhow to manufacture the medicinal products for which the licence is issued. Although art.5(d) of the Trade Secrets Directive (Directive (EU) 2016/943) provides for an exception where a trade secret is disclosed for the purpose of protecting a legitimate interest recognised by Union law or national law, this article does constitute a legal basis to compel the holder of a trade secrets to disclose the contents thereof. In accordance with consideration 11 of the Trade Secrets Directive, however, the Directive explicitly leaves room for national laws and regulations to formulate such obligations. This means that it depends on the existence of such national laws if the holder of the trade secret could indeed be compelled to disclose the contents to the holder of a compulsory licence.

Conclusion

While most jurisdictions have legal instruments in place to deal with patent law in times of crisis, there is but little uniformity in the way these legal instruments are applied. The interpretations of the scope of the necessary experimental use exemption, Bolar exemption and related exemptions differ significantly, even where attempts have been made to harmonise these. Also, when it comes to compulsory licensing, jurisdictions all have their own way of processing applications while case law is very limited. The only subject that has been fully harmonised by European legislation concerns the gap in the pharmaceutical legislation on the regulatory exclusive rights of data protection and market protection. This is a gap that may significantly affect the actual use and efficacy of the issuing of compulsory licences, and which would require an amendment of the legislation on a European level.[73]

The most evident and practical way of overcoming all of these hurdles on both a national and an international level may therefore be the adoption of patent pools. With time not on our side these patent pools, by which researchers and patent proprietors make their research results and patents for the prevention (vaccination) and treatment of COVID-19 available to third parties, might just bypass the issues addressed in this article. In the field of pharmaceutical research, the WHO in fact already investigated the possibility of patent pools in the wake of the SARS epidemic in 2002 and SARS-CoV 1 in 2003.[74] Although the adoption of patent pools raises a number of (solvable) patent, antitrust and administrative issues themselves, patent pools would definitely have the advantage of enabling rights of use in a much more efficient and legally secure manner than it would be the case with compulsory licences or state orders for use as discussed. In any event, with the urgent global need for rapid treatment, the various exemptions being applied differently in each jurisdiction and the doubts regarding the efficacy of the instrument of the compulsory licence, it certainly seems to be in the public interest that the possibility of pharmaceutical patent pools is not buried in the files (again).

[72] cf. 't Hoen et al., "Data exclusivity exceptions and compulsory licensing to promote generic medicines in the European Union: A proposal for greater coherence in European pharmaceutical legislation" (2017) 10 *Journal of Pharmaceutical Policy and Practice* 3.
[73] cf. 't Hoen et al., "Data exclusivity exceptions and compulsory licensing to promote generic medicines in the European Union" (2017) 10 *Journal of Pharmaceutical Policy and Practice* 2017 6.
[74] cf. J.H.M. Simon et al., "Managing severe acute respiratory syndrome (SARS) intellectual property rights: the possible role of patent pooling", *Bulletin of the WHO* (September 2005), p.83.