The COVID-19 Pandemic: Stress Test for Intellectual Property and Pharmaceutical Laws

I. Introduction

Legal precedents recently emerged in national legislations for providing a legal framework that can better address the challenging situation of the COVID-19 pandemic. For instance, in Germany, the ‘Act on the Protection of the Population in the Event of an Epidemic Situation of National Importance’ (hereinafter ‘Epidemic Protection Act’) of 27 March 2020 opened the possibility of limiting the owner’s exclusive use of a patent due to the COVID-19 pandemic. The Epidemic Protection Act supplements and concretizes the already existing ‘Act on the Prevention and Control of Infectious Diseases in Humans’ (hereinafter ‘Infection Protection Act’), under which the Ministry of Health is authorized to issue use orders for certain patents under Sec. 13 of the German Patent Act (‘government use’). The Federal Ministry of Health itself or a subordinate authority commissioned by the Ministry may take measures or commission third parties to do so in order to ensure the supply of medicinal products as well as active ingredients, starting materials and excipients therefor, medical devices, laboratory diagnostics and auxiliary agents (Sec. 5(2) No. 4 Infection Protection Act). In Sec. 5(2) No. 5, the government use is referred to these products mentioned in No. 4.

In addition to and separate from such government use, which cannot be triggered by third parties, there is the possibility for persons and companies to apply for a compulsory license (Sec. 24 Patent Act).

Against the background of considerable social, economic and public health distortions and a substantial period after the amendment of the ‘emergency law’ of the Infection Protection Act in Germany, the question is now legitimate as to why, according to current knowledge, neither a government use order has been issued nor an action for a compulsory license initiated. There is no doubt that an enormous demand exists for medicines against COVID-19 – above all for vaccines that have already been approved or will be approved in the foreseeable future. Especially during the Corona pandemic, patent law has been in the focus of research-based biotech and pharmaceutical companies as an incentive and as a way of protecting investments through exclusive rights, on the one hand, and as a possible hindrance to access to affordable medicine due to existing patents on the other hand. Tensions and international pressure for the ‘abolition of certain IP rights’ have increased.

In view of the ongoing discussion across a wide area of tension, i.e. between general, vague criticism of vaccine manufacturers, political constraints and the legal framework, this article will shed light on the background, identify weaknesses in the current legal system with an international dimension and discuss possible solutions to the currently existing fragmentation and lack of coherence by applying objective criteria for international harmonization.

II. Legal framework in an international context

The Federal Republic of Germany is only one of numerous countries worldwide which can make use of...
respective lex specialis and national measures to be able to restrict patent rights by emergency laws. Under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), WTO member countries are authorized to adopt regulations on compulsory licensing on the basis of Art. 31. Even before the start of the present pandemic, corresponding standards had existed in numerous countries, including the United Kingdom, the United States, Israel, Brazil, Australia, China, Japan, Korea and others; new legislation specifically geared to the current pandemic situation has been introduced in Germany, Canada and France. According to current knowledge, the only country that seems to have issued a specific compulsory license during the Corona pandemic so far is Israel, but this only applies to one specific situation; by decree of 18 March 2020, the import of a generic version of Kaletra (AbbVie), a drug known per se as an HIV-active drug, was permitted for the treatment of Coronavirus patients. Generally, in Europe the use of patented drugs for testing purposes ('experimental privilege') and for drug approval procedures ('marketing authorization privilege') is legitimate; however, these regulations on exemption from patent protection do not provide any scope for commercial use.

In some countries, attempts are being made to establish opportunities or even facts through measures other than compulsory licensing. In China, for example, the Wuhan Virological Institute filed its own patent application on 21 January 2020 for the use of Remdesivir in the therapy of COVID-19. This example illustrates the emergence of possible conflict situations between patents of different timelines: Gilead actually developed Remdesivir for the treatment of the Ebola virus; however, Gilead is also the owner of the substance patent on Remdesivir as a general antiviral drug. A substance patent claims the product as such, i.e. providing absolute protection independent of the use of the substance. This means that Gilead can in principle make exclusive use of any application of the substance, for example for the purpose of COVID-19 treatment. If the Chinese patent specifically targeting COVID-19 treatment is granted, however, a situation of mutual blocking may arise due to the dependency: Gilead, as the owner of the substance patent, could exclude the exploitation of the Chinese indication patent; whereas the Chinese owner, if and insofar as its use patent was granted in the given country, could prevent Gilead from using Remdesivir for COVID-19 treatment in that country. A way out could be found with the help of cross-licensing; this, however, remains subject to successful negotiations and agreements between the concerned parties. But even in such situations, legislative possibilities can be used if necessary, such as para. 2 of Sec. 24 Patent Act in Germany: the granting of a compulsory license to a license seeker is facilitated if the patent holder cannot use its younger invention without infringing the older patent; whereas a compulsory license normally requires the license seeker to prove a public interest, which is difficult to establish, it is then sufficient for the owner of the younger dependent patent to demonstrate an 'important technical progress of considerable economic significance'.

Another exceptional situation is the production and distribution of Remdesivir in Bangladesh, but this is solely due to the fact that Bangladesh is still allowed to suspend patent protection for pharmaceutical and agricultural inventions until 1 July 2021 by circumventing relevant TRIPS provisions.

In other jurisdictions – typically from the category of developing and middle-income countries – prior existing suspensions from granting patents on medicines have been removed much earlier than required by the TRIPS Agreement. Still, compulsory licensing and public non-commercial use (government use) are instruments for not losing control over situations of unfair imbalance in the

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3 For an overview, see eg Adam Houldsworth, ‘The key covid-19 compulsory licensing developments so far’ (iam, 7 April 2020) <https://www.iam-media.com/coronavirus/the-key-covid-19-compulsory-licensing-developments-so-far> accessed 7 February 2021.

4 In the UK, the statutory ‘Crown use’ provisions, concretized by s 56 of the Patents Act, allow drugs and medicines to be manufactured and supplied in relevant circumstances without requiring permission from the right holder; s 59 of the Patents Act authorizes even more general measures to maintain public health.

5 Under U.S. law, the U.S. government can intervene in patent law and exercise or cause to be exercised licenses to the patent; the right to interfere is available to agencies that provide public funding for research, eg NIH or NSF. Further, specific to the U.S., U.S. Code § 1498, which dates back to wartime emergency laws, permits exemption from patent infringement when required by the state. Historically, § 1498 has only been used to force price reductions for drugs to which there is no alternative in emergency situations, as once in 2001 at the time of the anthrax attacks. There are currently no plans for compulsory licensing legislation specifically related to the COVID-19 pandemic in the U.S.; however, refer to note 51 citing the U.S. Defense Production Act.

6 Under s 104 of the Israeli Patent Law, the patentee is even barred from appealing this order.

7 art 21 Brazil Patent Act.

8 Crown use authorizes the Commonwealth, state or territorial governments to permit the use of patented inventions without the patentee’s permission in ‘emergency situations’. For third parties, ss 133 to 136A of the Patent Law further open up the possibility of applying for a compulsory license.

9 arts 48-50 Chinese Patent Law and Executive Order No 64.

10 art 93 Japanese Patent Law.

11 art 107 Korean Patent Law.

12 A recent overview is provided by the WIPO Standing Committee on the Law of Patents SCP/303 dated 21 May 2019 <https://www.wipo.int/del/docs/scp/en/scp_30/scp_30_3-main1.pdf> accessed 4 April 2021.

13 Law C-13 (COVID-19 Emergency Response Act) of 25 March 2020 allows the Minister of Health, under easier conditions, to have a patented invention produced, sold and used by third parties without negotiation with the right holder.

14 Under the new art L.3131-15 of the Public Health Act, the Prime Minister is empowered to seize appropriate funds, control prices and make essential medical devices available to patients.

15 Unlike the actual and specific compulsory license specifically targeting the COVID-19 pandemic, legislative bodies in Chile and Ecuador respectively decided in March 2020 for a general power to justify compulsory licenses for vaccines, drugs, diagnostics, devices, supplies and other technologies against the Coronavirus in these countries, see ‘KEI Blogs and Research notes on COVID-19/Coronavirus’ (KEI online) <https://www.keionline.org/coronavirus> accessed 4 April 2021.

16 For market authorization procedures in the EU, see art 10(6) of EU Directive 2001/83, which entered into force in national legislations for the experimental privilege/research exemption, national laws exist: for Germany in s 11 Nos 2 Patent Act, for the UK s 60(5)(b) UKPA, for France L.613-5 French Code of Intellectual Property, for Spain art 52(b) of the 11/1986 Spanish Patent Act, for Italy art 68 of the Italian Code of Intellectual Property, for The Netherlands art 53(3) Dutch Patent Act.

17 See Xiaoping Wu and Bassam Peter Khazin, ‘Patent-related actions taken in WTO members in response to the COVID-19 pandemic’ (2020) WTO Staff Working Paper ERSD 2020-12 <https://www.econstor.eu/handle/10419/226168> accessed 10 April 2021.

18 See further details in Enrico Bonadio and Andrea Baldini, ‘Covid-19, Patents and the Never Ending Tension between Proprietary Rights and the Protection of Public Health’ (2020) 11 European Journal of Risk Regulation 390-395.

19 This scenario only applies to countries where second medical use patents – or as in the case of EP patents ‘medical use-limited product claims’ – are allowed.
public health system.\textsuperscript{20} In the past, particularly situations in Latin America have been the subject of strong debate, leading to compulsory license orders rendered by national governments in Brazil and Ecuador to get access to antiviral medicines at reduced prices.\textsuperscript{21} The Efavirenz case in Brazil back in 2007 shows that, after a long negotiation process, the Minister of Health declared the drug to be of public interest, and shortly thereafter a presidential decree granted the compulsory license for non-commercial use at an appropriate remuneration for the patentee.\textsuperscript{22} Here, the distribution of the AIDS drug as such was not the problem at issue, but rather finding an agreement on an appropriate price level for making the medicine affordable and thus accessible to the patients. Ultimately, by way of the compulsory license, the price was lowered from an originally approximately four-fold amount to the same level as internationally available – against the patentee – who strongly criticized the compulsory license order. The U.S. government also invoked warning statements.\textsuperscript{23} The case also illustrates potential problems if an appropriate negotiation solution cannot be reached: without full information about the product, the local producer was forced to redevelop it by reverse engineering and to acquire part of the active ingredient from a foreign generic company. Likewise, two compulsory license orders from the government in Ecuador were issued for antiretroviral drugs with the aim of substantially lowering local prices, which eventually led to 30 and 75% price reductions, respectively. Similarly, these compulsory license orders led to political issues between Ecuador and the U.S.

\textbf{III. Critical factors in the conflict between the legal framework and actual circumstances}

As demonstrated, the respective national legislatures around the world do not lack legislative options to take measures to restrict a patent holder’s rights in emergency situations such as the currently prevailing COVID-19 pandemic, whether it is through compulsory licenses or through governmental use orders. This makes it all the more surprising that, as of April 2021, no country worldwide has taken appropriate action to provide comprehensive welfare to the population by using relevant patents to treat the COVID-19 pandemic. This is especially true for the ‘game changer’ COVID-19 vaccines, which have been developed at a rapid pace since early 2020 and some of which were already approved one year later. The following points will discuss relevant legal and other aspects of why this is the case, despite numerous and highly debated claims.

\textbf{1. The time factor}

From a temporal point of view, it is initially important to note that – at least according to the wording of the corresponding German standard – both the government use and the claim for a compulsory license require the \textit{grant} of a patent.\textsuperscript{24} This requirement makes sense insofar as there is basically no need for compulsory means in the period before the patent is granted. This is because the full effect of the patent, and thus the right to exclude, only comes into effect once a patent is granted. Before that, the applicant is entitled to appropriate compensation but cannot prohibit use by means of a court order. However, patent grants of relevant and very specific inventions targeting COVID-19 therapy are likely to take time, even in the case of accelerated grant procedures established in certain patent offices specifically for inventions that may be significant in combating the COVID-19 pandemic.

This legal situation may lead to real, but ultimately unpredictable, adverse effects in the current acute pandemic: while a steep increase in patent applications specifically directed to COVID-19 therapies is expected,\textsuperscript{25} patent applications on highly effective therapies may remain undisclosed due to the usual 18-month delay until the patent application in question is published. Thus, if the invention is not published by other means, neither the public and thus potential investors or pharmaceutical companies interested in compulsory licenses nor governmental authorities dealing with possible government uses will learn about it.

However, even after learning about the publications, typically during the regular legal 18 month publication period after the application was filed – and this is expected in increasing numbers in the foreseeable future – unauthorized

\textsuperscript{20} Here, reference can be made in particular to the DOHA declaration of the WTO Member States, ‘Declaration on the TRIPS agreement and public health’ (WTO, 14 November 2001) <https://www.wto.org/english/tratop_e/trip_e/ministr_e/min01_e/mindcl_trips_e.htm> accessed 10 April 2021.

\textsuperscript{21} See ‘Latin America, compulsory licensing’ (KEI online) <https://www.keionline.org/latin-america-compulsory-licensing> accessed 10 April 2021; and Carlos M Correa, ‘Reflections on the IP System: A Development Perspective’ (South Centre, 28 February 2013) <https://www.southcentre.int/topics/eb17/> accessed 12 April 2021, reporting about further details of the practice of compulsory licensing in South America.

\textsuperscript{22} See eg ‘Regional Seminar for Certain Latin American and Caribbean Countries on the Implementation and Use of Several Patent-Related Flexibilities’ (WIPO, 6 to 8 February 2012) <https://www.wipo.int/edocs/mdocs/mdocs/en/wipo_ip_bog_12/wipo_ip_bog_12_ref_u10c_bins.pdf> accessed 12 April 2021.

\textsuperscript{23} See the sources of n 21.
use of a promising invention for COVID-19 therapy *prior to grant*\(^\text{26}\) (which normally is substantially later than the publication date) would be associated with risks and imponderables. The user operating without an agreement with the inventor/applicant would risk having his compulsory license application ultimately rejected by the court and having to stop further development. This situation does not create incentives for third parties. It is rather demotivating in view of the fact that the development of an active drug, even more so in the case of a vaccine, is time and resource consuming. It is therefore unlikely that a third-party developer, without having reached an agreement with the applicant, would take the risk of a claim for injunctive relief if the third parties’ claim for a compulsory license eventually fails. On the other hand there is possibly only a vague hope or prospect that the critical requirement of proving ‘public interest’ might eventually be acknowledged in (possibly time-consuming) court proceedings. The motivation is further diminished by the fact that the user could at best acquire a non-exclusive license. Both in the case of a governmental use order and in the case of a compulsory license, the patent owner and other entitled parties, like already affiliated licensees, retain their rights of use. Further, in the case of a government order, the use must be solely for the intended purpose, i.e. for the purpose of public welfare. Profit maximization or broader commercial uses of the invention outside the set scope, for the third party’s own benefit, are negated.\(^\text{27}\)

### 2. Territorial restrictions

The legislation on compulsory licensing is internationally fragmented. Although relevant countries have corresponding national legal norms, there is a lack of international harmonization. On an international scale, a compulsory license obtained in one country is of limited use. Reasonable exploitation is therefore hampered by the need to obtain compulsory licenses separately in each individual country where parallel patents of interest exist. For instance, while a European patent of interest will be granted centrally by the European Patent Office, compulsory licensing needs to be pursued in each EP member state where the patent is valid, based on respective national laws and procedures. However, successful COVID-19 therapy needs unrestricted international application. Without internationally harmonized efforts, it would make little sense for the use of patented inventions to be mandated or approved for use in some countries but not in others. Such an uncoordinated fragmentation of compulsory rights allocation is detrimental to the meaningful development of a COVID-19 medicament. The development of a medicament is expensive, and probably no company or investor will afford risking an expensive development if in the end the marketed territory could be limited to a single or a few countries only and be denied in other countries.

*\(^\text{26}\) Without permission or licensing by the applicant, the user would ‘only’ be obliged to pay compensation before the patent is granted, the basis and scope of the compensation claim being awarded only after the patent has been granted, when the patentability and scope of protection have been decided (cf e.g s 33(1) German Patent Act).*

*\(^\text{27}\) of the only case so far decided in German post-war history on s 13 Patent Act OLG Frankfurt, [1949] PMZ 330, cited in Uwe Scharen, ‘s 13 Nos 7-8’ in Georg Benkard, *Patentgesetz* (11th edn, CH Beck 2015).*

### 3. Factual requirement criteria: Public interest, alternatives, know-how and manufacturing capacity

Compulsory patent licenses, regardless of whether granted by government order or by private claim, represent a significant encroachment on the property right protected by the respective national constitutions. For this reason, the use of such licenses has been extremely rare in the past.\(^\text{28}\) In the draft law on the Epidemic Protection Act recently introducing Sec. 5(2) No. 5 in Germany, it was clarified that the effect of the patent can be restricted pursuant to Sec. 13 Patent Act in order to ensure the supply of products in the event of a crisis and, for example, to be able to manufacture vital actives or medicines.\(^\text{29}\)

The requirement of a public interest in the case of a private law claim for a compulsory license must be assessed by weighing all circumstances relevant in the individual case and the mutual interests. The license seeker must personally be in a position to want to use the invention commercially, but also to be *capable* of using it.\(^\text{30}\) And it is precisely this ‘ability’ that can pose a problem in the case of complex vaccine developments. The license seeker – and in this respect also the person entitled under government use – must want to and be able to use the invention from a technical point of view; the fact that he merely wants to distribute (not manufacture or import) objects made according to the invention is not sufficient. This problem will likely not arise in the future in the case of classical active substances, but it will arise in the case of vaccines with their complex technical manufacturing steps.

In the case of vaccines, which are so important, the focus would probably be on another possible obstacle: alternative therapies. A number of vaccines have already been approved for COVID-19, and more will follow.\(^\text{31}\) So there is no lack of existing or potential new candidates, and certainly no lack of ‘will’ on the part of the original manufacturers. Issues beyond considerations of compulsory patent licensing are more critical: regulatory approval, manufacturing and supply capacity, as well as commercialization. In principle, it is conceivable that compulsory licenses could also be granted if the original

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28 So far, there has only been one positively decided case of legitimate use under s 13 in Germany (see n 25) and one case of a compulsory license under s 24 PatG being confirmed by the Supreme Court, see German Federal Supreme Court, [2017] GRUR 1017 – Kaltegravis; in a single other case, a compulsory license initially positively decided by the Federal Patent Court was reversed by the Federal Supreme Court, see [1996] GRUR 190 – Polyform; cf also the last Supreme Court decision rejecting a compulsory license BGH, [2019] GRUR 1038 – Alirocumab, as well as Klaus-Jürgen Melullis, ‘Zur Ermächtigung von Zwangslizenzen im Patentrecht’ [2021] GRUR 294.

29 Possible negative consequences of a government use for competition are discussed by Carsten Richter, ‘Die Staatliche Benutzungsanordnung in Zeiten der Corona-Pandemie’ [2021] Mitt. 1.

30 For the jurisdiction in Germany, see RGZ 130, 360; see also Benkard (n 27) § 24 margin No 10-11.

31 As of April 2021, these include the mRNA-based vaccines of BioNTech/Pfizer and Moderna, and possibly soon that of Curevac/Bayer, as well as the adenovirus vector-based vaccines of AstraZeneca/University of Oxford, of Gam-COVID-Vac/Sputnik V and of Johnson&Johnson/Janssen; cf the continuously updated overview at INFOMAC <https://www.infomac.de/infomac/aktuell/969-impfstoffe-gegen-covid-19-late-de-klinschen-versuche> accessed 7 April 2021, and from the WHoI source at <https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines> accessed 10 February 2021; a search on 10 February 2021 revealed 63 vaccines in development and 179 in pre-clinical use.
manufacturer cannot provide an effective drug in sufficient quantities. However, government support to increase the supply capacities of the original developers and their partners will be of greater help in the case of vaccines than compulsory licenses to third parties, especially if the third party lacks appropriate know-how.

For the area of substance therapeutics, i.e. small molecular actives, the situation would probably be different. Here, production and supply are much less critical. Unlike vaccines that are associated with challenging and complex development and production processes, classical small molecular substances follow well-established development and production schemes. And in the case of classical active ingredients, the originator and patent holder will likely want to retain the sole right of use. If it and, if applicable, its cooperation partners or licensees can meet the demand, a compulsory license obligation will probably be denied.

4. The issue of patent stacking

A further problem in the field of vaccines against COVID-19 is that the entire vaccine technology is likely based on a large number of earlier filed and granted patents. While patent applications specifically targeting SARS-CoV-2 sequences and vaccines based on them will still be in the granting phase simply due to the timing of development, the vaccines will use a variety of platform technologies that may already be patented by different owners. Such a problem, not new in itself, is generally referred to as difficult-to-license patent stacking or royalty stacking.

Because of the expected interdependence of COVID-19 vaccine patent rights, even in the context of government use or private compulsory licensing, it will be difficult to discern the one or few patents sufficient to develop, manufacture and practice COVID-19 therapy.

Further, more important than the mere existence of patents is the question of whether sufficient know-how is available to develop and manufacture a vaccine against COVID-19. It is undisputed that the manufacturing process and the quality assurance of the already developed COVID-19 vaccines are very complex. The supply chain, from numerous starting products to the final filling of the vaccine, requires a logically fine-tuned set of rules for supply and transfer with many, locally separated stages. That is, technical and logistical challenges that go far beyond what patents can accomplish with their technical information, i.e. beyond what is required to provide sufficient enabling disclosure. It can be assumed that in the case of involuntary threats of compulsory use, the patent holder would have neither the obligation nor the interest to disclose its know-how. Valuable time would be lost. This scenario shows that these challenges cannot be overcome against the will of the patent holder but only with his cooperation. The current situation, however, makes it clear that the originators do indeed want to enter into corresponding cooperations.

The hypothetical case that the specific and effective SARS-CoV-2 medicament is found in the sense of an active small molecule, however, would be different from the case of vaccine technology. This classic area is home to domestic and foreign generic manufacturers who would be effective in meeting a large demand for sufficient active ingredients, if the will and the ability of the patent holder were lacking.

But here, as in the case of vaccine developments, another problematic collision might come up, which is explained in the following section.

5. Lack of coherence with data protection or other special laws

The practicing party, even if entitled to act under government use or compulsory licensing, needs a marketing authorization for a COVID-19 medicament of concern. In Europe, marketing authorization procedures are not governed by the Patent Act, but by a lex specialis specifically provided for this purpose – in Germany, the Arzneimittelgesetz (hereinafter ‘Medicines Act’). If a COVID-19 medicament has already been approved, it would be in the public interest to use the clinical data already available by means of a more rapid generative approval. However, in Europe the first owner of the market approval is entitled to 10 years of data protection according to the ‘8 + 2’ rule. That the prior data protection holder may be judicially obligated (‘sentenced’) to agree to the use of the data can be denied. Neither the Medicines Act nor the Patent Act are, in their current form, likely to provide a legal basis for this.

32 cf Rudiger Rogge and Helga Kober-Dheim, ‘s 24 No 16 PatG’ in Benkard (n 27); Rudiger Wilhelmi, BeckOK PatR (15th edn, 15 January, CH Beck2020) s 24 No 33.
33 See the corresponding answer of the German Federal Government to a parliamentary question concerning a possible compulsory license on the active substance Remdesivir, printed matter 19/21826 of 25 August 2020 (see in particular question 27 therein).
34 The dilemma of multiple royalty obligations to many licensors in the field of vaccines is illustrated by Keith J Jones, Michael E Whitman and Phaluna S Handler, ‘Problems with Royalty Rates, Royalty Stacking, and Royalty Packing Issues’ in Anatole Krattiger, Richard T Mahoney and Lita Nelsen (eds), Intellectual Property Management in Health and Agricultural Innovation – A Handbook of Best Practices online available at <http://www.uphandbook.org/handbook/ch11/p09/> accessed 12 April 2021.
35 Christopher Garrison, ‘What is the ‘know-how gap’ problem and how might it impact scaling up production of Covid-19 related diagnostics, therapies and vaccines?‘ (Medicines Law & Policy, 16 December 2020) <https://medicineslawandpolicy.org/2020/12/what-is-the-know-how-gap-problem-and-how-might-it-impact-scaling-up-production-of-covid-19-related-diagnostics-therapies-and-vaccines/> accessed 12 April 2021.
36 An illustrative presentation of the complex supply chain in vaccine manufacturing using the example of mRNA-based Corona vaccines is provided by Jonas Neubert, ‘Exploring the Supply Chain of the Pfizer BioNTech and Moderna COVID-19 vaccines’ (Jonas Neubert Blog, 7 February 2021) <https://blog.jonasneubert.com/2021/02/10/exploring-the-supply-chain-of-the-pfizer-biontech-and-moderna-covid-19-vaccines/> accessed 7 February 2021.
37 cf art 10 (1) of Directive 2001/83/EC, and s 24b (1) Medicines Act. The prerequisite is that the generic medicinal product has the same composition in terms of type and quantity and the same pharmaceutical form as the reference medicinal product. The applicant only has to prove the bioequivalence of the generic drug by appropriate bioavailability studies.
38 cf the German provision in s 24b (1) Medicines Act: 8 years of data exclusivity, 2 years of market exclusivity since initial approval; market exclusivity may be extended for an additional year if approval of a new therapeutic indication with significant clinical benefit is granted within the initial 8-year period.
39 The lack of coherence of compulsory licensing on the one hand and data exclusivity on the other hand in Europe has already been discussed elsewhere, mainly motivating the use of compulsory licensing for price regulation, see Ellen t’Hooren, Pascale Bootle and Brook K Baker, ‘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 19; Pascale Bootle, Christopher Garrison and Ellen t’Hooren, ‘Data Exclusivity in the European Union: Briefing Document’ (Medicines Law & Policy, June 2019) <https://medicineslawandpolicy.org/wp-content/uploads/2019/06/European-Union-Review-of-Pharma-Incentives-Data-Exclusivity.pdf> accessed 7 February 2021.
legal link between the data protection and a compulsory license under patent law. Also, the owner of the initial market approval and the patent owner of the corresponding patent-protected invention may personally be different parties. From these considerations it becomes apparent that data protection under pharmaceutical law represents a further barrier to a possible compulsory use by third parties. Indeed, in 2016 the issuance of a compulsory license was considered by the government of Romania for the hepatitis C medicine sofosbuvir, but could not be pursued because EU data exclusivity would expire only in 2024. This is in agreement with the position of the European Commission, which, in a response to an inquiry seeking clarification on whether data exclusivity would apply in case of an emergency compulsory license for the flu medicine Tamiflu within the European Union, acknowledged that ‘the Community pharmaceutical acc quis does not currently contain any provision allowing a waiver of the rules on data exclusivity and marketing protection periods’. This problem should therefore not be overlooked when calling for compulsory licenses for pandemic control.

Further, it is questionable whether facilitated emergency drug approval provisions with their exceptions for times of crisis, such as Sec. 79 of the German Medicines Act, can provide sufficient relief in the fight against the pandemic. However, in the view of the author, these or other provisions of the medicine approval laws such as the Medicines Act do not provide a basis for compulsory use independent of the compulsory license under patent law, nor are they suitable for undermining the legitimately acquired privilege of data and market exclusivity. As noted, data protection is not restricted, at least not without the consent of the licensee.

IV. Discussion

1. For the reasons mentioned above, in the current legal situation, compulsory patent licenses – whether based on a government order or a private law claim – do not presently seem to offer an effective means of dealing with the emergency situation in the COVID-19 pandemic. Already the temporal tension between the patented invention prior to grant – to that extent obviously inaccessible for compulsory licensing measures according to the plain text of the law – and the unpredictable and uncertain outcome of compulsory licensing proceedings hardly offer legal certainty for an interested third party. Substantial uncertainties are likely to arise on the issue of the justification for a compulsory license, particularly in the area of COVID-19 vaccines. At present, it is unlikely that there is a shortage of alternatives, and meeting demand is more likely to be a problem of manufacturing, supply capacity and complex supply chains. Without agreement with and expertise from the originator, compulsory measures are unlikely to help. Patent stacking, which can be found in the field of vaccines, and above all the collision with data protection under pharmaceutical law represent further obstacles. Against this background and without further safeguards – such as prior agreement with the originator or the marketing authorization holder – a third party interested in compulsory use is unlikely to expose itself to the risk of having invested, in the end to no avail, the considerable costs and resources required.

2. The situation may change significantly with the discovery and regulatory approval of a molecular therapeutic agent as an alternative to vaccines. But currently it does not seem like this will happen, nor is it expected from the political side under the given circumstances – vaccines alone are currently seen as the so-called ‘game changer’ in pandemic control. In the hypothetical case of classical, active ingredients, compulsory licenses are not expected if and to the extent that the patent owner conducting the original research is willing and able to cover the demand either itself or through sufficient free licensing. Furthermore, the exceptional authorizations in times of crisis according to pharmaceutical laws (such as Sec. 79 Medicines Act in Germany), which allow a COVID-19 therapy under certain circumstances even without a marketing authorization, could help here.

3. Rather apart from such legal conflicts, it is positive to note in the current situation that there is no lack of creative ideas for the use of existing IP in times of the COVID-19 pandemic. The establishment of a ‘medical patent pool’ (MPP) organized by the WHO is an attempt at a contribution in this direction. Patents can be contributed to this MPP, which allows third parties – optionally under agreement of license payments – to test and develop already patented active substances for efficacy against COVID-19. Another movement is for right holders to voluntarily surrender or offer to license IP rights, so-called ‘Voluntary Pledges’. However, despite all the good will and reputation enhancement of the donating companies and academic institutions, it is obvious that these IP rights are at best tools and approaches with uncertain expectations of efficacy. Whether these patents will enable effective COVID-19 therapies and be sufficient to contain the global pandemic is questionable.

Another issue, independent of legal considerations, is illustrated by the COVAX initiative. Although this initiative is intended to make anti-COVID-19 innovations available to Third World countries at the instigation of the WHO, the initiators and sponsors report financial and economic difficulties, for which compulsory licenses could not provide a remedy.

4. Despite the heated debate and ill-considered calls for general compulsory intervention in the patentee’s right to exclude, however, it is important not to lose sight of the fact that the current crisis exposes gaps in the existing legal framework on an international level, including the EU, as a whole and in its individual Member States.

42 See Medicines Patent Pool (MPP) <https://medicinespatentpool.org/> accessed 10 February 2021.
43 See Jorge L. Contreras and others, ‘Pledging intellectual property for COVID-19’ (2020) 38 Nature Biotechnology 1146-1150.
44 See Karlin Mara, ‘Decision on Intellectual Property Waiver of a Covid-Technology on Hold till 2021; what are the next steps?’ (Medicines Law and Policy, 18 December 2020) <https://medicineslawandpolicy.org/2020/12/decision-on-intellectual-property-waiver-over-covid-technology-on-hold-till-2021-what-are-the-next-steps/> accessed 10 April 2021; Francesco Guarascia, ‘Exclusive-WHO Vaccine Scheme Risks Failure, Leaving Poor Countries with no COVID-Shots until 2024’ (Reuters, 16 December 2020) <https://www.reuters.com/business/healthcare-pharmaceuticals/exclusive-who-vaccine-scheme-risks-failure-leaving-poor-countries-no-covid-shots-2020-12-16/> accessed 8 February 2021.
On the one hand, there is the lack of international harmonization in Europe and elsewhere to determine compulsory uses or licenses uniformly in a single procedure. As a result of territorial fragmentation, compulsory licensing would have to be initiated in each country individually, with all the consequences of additional costs and uncertainties due to inconsistent legal practice and poorly coordinated process times.

The lack of coherence in the EU in relevant legal norms for crisis situations is illustrated by another conflict that is difficult to reconcile. This is because all the individual provisions in the respective national legislations on compulsory use/licensing ignore a corresponding loophole in the regulations on data protection (data and market exclusivity) within market authorization procedures. A company, even if it has obtained a compulsory license, would – without permission from the holder of the initial market authorization – be unable to enter the market with the data already available under the 8 + 2 rule until 10 years later.

The EU legislative institutions have not yet addressed this lack of coherence between national compulsory use/licensing provisions in patent law and a lack of exemption in drug approval law. This is despite the fact that as early as 2006, Regulation (EC) No. 816/2006 provided for compulsory licensing of patents for the manufacture of pharmaceutical products for export to least developed or low-income countries and, in this context, exceptionally allowed recourse to data from market authorization procedures for generic medicines under Art. 18 of Regulation 816/2006.

5. In the present acute crisis situation, relevant bodies in the EU have evidently become aware that there are indeed gaps in effective compulsory measures under current EU law. An indication of this is provided by the statement made by Council President Charles Michel in February 2021, who in this context cited Art. 122 of the Treaty on the Functioning of the European Union (TFEU) as a possible legal basis for compulsory measures. According to the Legal Department of the Council of the EU, this Art. 122 TFEU, if broadly interpreted, would provide a basis or justification to take compulsory measures against right holders. While it is true that Art. 122 TFEU in its 2nd paragraph refers to an emergency such as a natural disaster, according to the plain wording such a requirement would merely set in motion a mechanism whereby ‘Union financial assistance shall be granted to the Member State concerned under certain conditions’. Whether and how such an exceptional provision can be reinterpreted as a substantial limitation on property rights, as in the case of a new regulation on government use, a compromise should envisage criteria that might play a role in determining exceptions to data and market exclusivity.

In this regard, the process of vaccine approval in the EU by the European Medicines Agency (EMA) provides a good example: normally, vaccine candidates are successively evaluated for safety and efficacy in five clinical phases. In the case of the Coronavirus, some study phases were carried out simultaneously and the EMA was able to review them in parallel, so that the approval process could be shortened considerably to just a few months. Furthermore, the build-up of vaccine production capacity was associated with a high economic risk for the manufacturers – in case the vaccine eventually proved to be unsafe or ineffective in the course of the trials. In the case of the Coronavirus, governments have contributed to the new harmonized EU law. Legislative procedures take time; before enactment, interested parties should be consulted in order to strike a balance between the public interest and holders of exclusive rights in the form of patents and data protection. Most important in this context will be the necessary definitions of the conditions under which compulsory patent licenses and non-application of data exclusivity, i.e. waivers, should interfere with existing exclusive rights throughout the EU.

On a more widespread international level, an update of the 2001 DOHA declaration with regard to the relation between TRIPS and public health would appear expedient, based on a new Ministerial initiative of WTO member states.

7. The conflict between compulsory use/licensing and data exclusivity could be addressed by law. Indeed, some countries – Malaysia, Chile and Colombia – do provide for explicit data exclusivity waivers for facilitating the registration of generic medicines in case of compulsory licensing or government use. However, how difficult the procedure and how heated the debates are in such legislation to restrict existing proprietary rights at research-based pharmaceutical companies can be seen in the example of a recently introduced EU-wide export waiver for existing pharmaceutical certificates (SPCs). Accordingly, a rapid agreement to balance the interests of the concerned parties does not appear to be easy, even in the case of a new regulation on a waiver in emergency situations.

Anticipating such difficulties in enacting general waivers to data exclusivity in cases of compulsory licensing or government use, a compromise should envisage criteria that might play a role in determining exceptions to data and market exclusivity.

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45 See ‘Charles Michel says EU could invoke “urgent measures” in response to vaccine shortfall’ (Politico, 28 January 2021) <https://www.politico.eu/article/charles-michel-says-eu-could-invoke-urgent-measures-response-coronavirus-vaccine-shortfall/> accessed 8 February 2021.

46 s 5 of Malaysia 2011 Directive of Data Exclusivity, art 91 of Law 19.996 of Chile, art 4 of Decree 2085 of 2002 of Colombia; for example, the Chilean patent law clarifies that data protection ‘shall not apply, when: . . . (b) for reasons of public health, national security, non-commercial public use, national emergency or other circumstances of extreme urgency declared by the competent authority, ending of the protection referred to in Art. 89 [author’s note: the data exclusivity provision] shall be justified, (c) the pharmaceutical or chemical-agricultural product is the subject of a compulsory license, according to what is established in this Law’.

47 of Regulation (EC) No 469/2009 of 20 May 2019, which provides for an exemption from the protective effect of supplementary protection certificates (SPCs) for medicinal products and allows manufacturers located in the EU, under certain conditions, to export a product protected by an SPC or medicinal products for the purpose of export to third countries and to manufacture them at least six months before the expiry of the certificate in order to store them in the Member State of manufacture and to place them on the market in the Member States after the expiry of the certificate (see in particular art 5(2)(a) of Regulation (EC) No 469/2009).
cost of vaccine development, thereby reducing the risk to manufacturers.

Typically, data and market exclusivity are justified by the notion of allowing the research-based pharmaceutical company to recoup the significant investment associated with conducting clinical trials. Thus, the purpose of the 8+2 rule may be inapplicable under certain exceptional circumstances when public funding and regulatory efforts significantly shorten approval procedures and substantially reduce risks.

Indeed, COVID-19 vaccine developers exceptionally benefited from fast-track market approval procedures. Further, early contracting for vaccine purchase reduced the economic risk for the developers for the event that the candidate might eventually fail. Thus, if in the public interest or in crisis situations such as the current pandemic, countries or relevant EU organizations make every effort to accelerate the approval process or take other special measures such as urgency market approvals, and support it with public funding, it could be justified in return to significantly shorten the period of data exclusivity or, in special exceptional cases, eliminate it altogether. Appropriate compensation regulations or payments would be further instruments for creating a balance between the effort and investment of the original researching company on the one hand and the public interest on the other.

8. Further considerations are expedient to overcome the current limitations. These should include a fair financial reward for the originator when its patented invention under compulsory use contributes to people's health and society’s benefit. As noted, the originator’s costs for conducting pre-clinical and clinical trials and for obtaining market approval could be reimbursed: in case of a waiver or inapplicability of the 8 + 2 rule, cost sharing and/or adequate remuneration could be based on audit calculations of the real expenditure.48 On the other hand, for the government use or compulsory licensing as such, it is questionable whether the risk of non-profit rulings can provide an acceptable motivation for substantial investments into anti-pandemic research from the outset, especially if a classical, easier-to-use active drug compound is at stake. A careful (re)consideration of proposals for remuneration in case of non-voluntary use of patents in the medical field, which have been provided by the WHO/UNDP,49 is warranted. This should not exclude a consideration of profitable rewards for the originator in compensation of a government use or compulsory licensing of its patented invention. Justification of profit-based remuneration in case of non-voluntary use of patents is reasoned by mitigating public health risks and avoiding (further) economic damages by the provision of groundbreaking innovations against a fundamental crisis. As can be seen in the current COVID-19 pandemic, even if only the cost aspect is to be considered, the economic damage to be recovered is immense, and therefore the public could afford financial support for the recovery of a functioning economy with the help of a patented innovation concerned. This does not exclude some differentiated rules depending on the territory and the respective countries’ economic power.

Finally, however, political will is needed to overcome these obstacles. As becomes apparent from the cases of compulsory licenses/government use orders in the past,50 the conflicts between innovators and governments or authorities invoking government use are often flanked by pressures raised from the originator’s home country. Fair, balanced and harmonized international rules on compulsory uses/licenses based on objective guidelines as an exemption in cases of emergency like the current pandemic, for example through TRIPS/WTO-based initiatives, may help to fend off doubts regarding the general function of exclusive patents in safeguarding future research and development of innovative medicines and their placement on the market.

V. Conclusion and outlook

As demonstrated in this article, national legislation on government or private compulsory licensing does exist in individual EU and WTO member states. The prerequisite of an emergency situation of national importance is undoubtedly given in the case of the current Corona pandemic, as stated in Germany’s Epidemic Protection Act of 27 March 2020. However, after the analysis and discussion in this paper, the author concludes that numerous legal and factual obstacles exist in the current situation. For example, it is doubtful whether compulsory patent-related measures can contribute to solving the need for comprehensive COVID-19 control.

To this end, there is a lack of appropriate, harmonized rules on compulsory measures based on existing EU law as well as in other territories. In addition, there is a lack of necessary coherence between national compulsory licensing provisions on the one hand, and regulations on data and market exclusivity on the other. Thus, the ongoing pandemic exposes a regulatory gap that should be an incentive to create a sustainable and uniform international regulatory framework. This should strike a balance between, on the one hand, the public interest in being able to react to emergency situations such as the Corona pandemic and, on the other hand, the interest of research companies in allowing exceptions and waivers from the protective effect of IP rights within certain limits only when an acceptable reward is provided to the originator.

Considering that, for the reasons discussed here, compulsory patent licenses cannot be expected to provide a legal solution to the pandemic situation – especially in the case of vaccines against COVID-19 – and that, in the case of classical antiviral agents, there is no prospect of an adequate grant of a therapeutic invention that would at the same time require a compulsory license, one should look to practical factors rather than legal provisions to provide a way out of the crisis, such as production capacities, complexity of supply chains and economic conditions.

A cooperative action plan coordinated with the vaccine developers that goes beyond compulsory measures would

48 As discussed partly by Judit Rius Sanjuan, James Love and Robert Weissman, ‘The Protection of Pharmaceutical Test Data: A Policy Proposal’ KEI Research Paper 2006:1 (KEI online, 21 November 2006) <https://www.keionline.org/book/test-data-protection-for-medical-inventions/the-protection-of-pharmaceutical-test-data-a-policy-proposal-KEI-research-paper-2006-1> accessed 12 April 2021.

49 See James Love, ‘Remuneration guidelines for non-voluntary use of a patent on medical technologies’ (World Health Organization, 2005) <https://apps.who.int/iris/bitstream/handle/10665/69199/WHO_TCM_2005.1_eng.pdf?sequence=1&isAllowed=y> accessed 18 April 2021.

50 See the case review from South America as referenced in n 21.
appear to be much more effective in the present situation.\textsuperscript{51}

In the medium and long term, as discussed in this article, EU-wide and possibly even worldwide harmonization could be found. Factors defining limited data exclusivity waivers should be subject to further discussion; these may include, for example, governmental, administrative or public measures and financial support for obtaining accelerated market approval and mitigating financial risks in favor of the right holders. Furthermore, as a compensation for the non-voluntary uses of their patented inventions in defined emergency situations, fair and balanced remuneration rules could be objectively established for innovators, without excluding profit-based considerations.

As very recent developments from the US administration as well as the Parliament and the Commission of the EU indicate activities to actually address the issue through WTO rulings, it is to be hoped that balanced solutions can be found.\textsuperscript{52} Extreme positions such as waivers of patent rights without consent of the originator and without acceptable reward\textsuperscript{53} – even if only temporarily during the pandemic – should be avoided in order to maintain what patents stand for from the outset: the very motivation for substantial investment in research and development. This should also be kept in mind under the tension of the current situation.

An example is provided by ‘Operation Warp Speed’ in the USA, which was implemented from the ‘Defense Production Act’; there, binding timelines are set by the government, relevant pharmaceutical companies and research institutions as well as logistics service providers are involved, and finally, vaccine testing and licensing as well as ultimately manufacturing are monitored and coordinated by controlling ministries or competent authorities in order to support supply capacities and prioritize them for COVID-19 control; cf ‘This Week in Operation Warp Speed’ (US Department of Defense, 31 December 2020) \texttt{<https://www.defense.gov/Newsroom/Releases/Release/Article/2460517/this-week-in-operation-warp-speed-dec-31-2020/>} accessed 18 February 2021.

The EU has also recently initiated a similar action plan, called ‘Hera Incubator’, which provides for a dedicated HERA authority to identify Covid-19 variants, to enable quicker vaccine approval and manufacturing and to develop voluntary licensing and technology transfer, see European Commission, ‘Preparing Europe for COVID-19 variants: HERA Incubator’ (European Commission, 17 February 2021) \texttt{<https://ec.europa.eu/commission/presscorner/detail/en/fs_21_650> } accessed 18 February 2021.

\textsuperscript{51} An example is provided by ‘Operation Warp Speed’ in the USA, which was implemented from the ‘Defense Production Act’; there, binding timelines are set by the government, relevant pharmaceutical companies and research institutions as well as logistics service providers are involved, and finally, vaccine testing and licensing as well as ultimately manufacturing are monitored and coordinated by controlling ministries or competent authorities in order to support supply capacities and prioritize them for COVID-19 control; cf ‘This Week in Operation Warp Speed’ (US Department of Defense, 31 December 2020) \texttt{<https://www.defense.gov/Newsroom/Releases/Release/Article/2460517/this-week-in-operation-warp-speed-dec-31-2020/>} accessed 18 February 2021.

\textsuperscript{52} On the one extreme side of patent waivers, see news from the U.S., ‘Covid: US backs waiver on vaccine patents to boost supply’ (BBC, 6 May 2021) \texttt{<https://www.bbc.com/news/world-us-canada-57004302> } accessed 20 May 2021; and European Parliament, ‘Parliament to discuss call for waiver of COVID-19 vaccine patents’ (European Parliament newsletter, 19 May 2021) \texttt{<https://www.europarl.europa.eu/news/en/agenda/briefing/2021-05-17/opparliament-to-discuss-call-for-waiver-of-covid-19-vaccine-patents/> } accessed 20 May 2021. As to the opposing side of the pharmaceutical industry, see the recent statement of the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), ‘IFPMA Statement on WTO TRIPS Intellectual Property Waiver’ (IFPMA, 5 May 2021) \texttt{<https://www.ifpma.org/Resource-Centre/ifpma-statement-on-wto-trips-intellectual-property-waiver/> } accessed 20 May 2021.

\textsuperscript{53} See eg recent opinions advanced by some EU Parliament members, ‘EU under pressure to support Covid-19 vaccine patent waiver’ (Research Professional News, 7 May 2021) \texttt{<https://www.researchprofessionalnews.com/rr-news-europe-politics-2021-3-eu-under-pressure-to-support-covid-19-vaccine-patent-waiver/> } accessed 20 May 2021.