Uh-Oh We are in Trouble! Compulsory Licences v Data Exclusivity in the EU: One More Challenge to Overcome in the Race to Find a COVID-19 Vaccine?

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Abstract

What if a global public health emergency takes place? This question stopped being a hypothetical one or a matter of semantics while interpreting TRIPS or patent law exceptions, to become a reality. As we live in uncertain and trying times, things have become real and it is time to address the elephant in the room: that is, the power of data exclusivity regimes to deter or interfere with the use of TRIPS flexibilities, such as compulsory licenses for public health emergencies. This article's objective is twofold. First, addresses the challenges in making effective use of a compulsory licence according to art.31 of the TRIPS in the EU, given its incompatibility with the EU data exclusivity regime deriving from the rules governing the regulation of pharmaceutical products in Directive 2001/83. And, second, this article makes a lege deferenda suggestion to include public health exceptions to data exclusivity at the EU level regardless of the chosen route to obtain a marketing authorization. To achieve its objective, the article starts by explaining what data exclusivity is, and its relation to marketing authorisations for patented pharmaceuticals. Subsequently, it shows why a patent compulsory licence will not be sufficient to address a global health crisis in the EU unless the data exclusivity issue is solved. Finally, the article concludes that public health exceptions are not only relevant in the context of patent law, and this why any exclusivity regime complementing the patent system cannot be insulated from those exception affecting patent law.

Introduction

While efforts beyond imagination are being made to control the spread of COVID-19, the race to identify either a cure or a way to neutralise the virus began. Scholars have addressed emerging challenges if patents are not forgone or these are enforced. However, patents may not be the only regulatory aspect defying widespread and global access to treatment.[1] Admittedly, the Agreement on Trade Related Aspects of Intellectual Property (TRIPS) foresees the use of certain flexibilities, e.g. compulsory licences, that could mitigate negative effects associated to patent protection should this be the only challenge when addressing a public health emergency. For the EU to enact a compulsory license over determined products, i.e. COVID-19 treatment, is a complicated affair since the pharmaceutical framework is intertwined with the intellectual property one, and this is not necessarily a tale of complementariness. On the one hand, pharmaceutical products—whether patent protection worthy or not—require from a marketing approval (MA) which is generally regulated within the pharmaceutical framework. And on the other, the intellectual property framework has imposed on the pharmaceutical one the protection of information attached to the MA because this is considered to have commercial value.

The challenge emerging from this pharmaceutical/public health and intellectual property duo stems from TRIPS. Within the minimum standards of protection, TRIPS also paved the way for the implementation of sui generis system of protection for those rights not harmonised within the agreement. The international IPR framework in in art.39(3) TRIPS only required from WTO country members to protect the test data submitted when required as a condition to obtain MA against unfair commercial uses.[2] The aforementioned provision did not harmonise the way test data should be

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[1] See Ellen 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 J. Pharm Policy Pract. 19; Christopher Garrison, "Never say Never: Why High Income Countries that opted-out from the art. 31bis WTO TRIPS system must urgently reconsider their decision in the face of the Covid-19 pandemic", *Medicines Law & Policy* (8 April 2020); Adam Houldsworth, "Covid-19 emergency may expose compulsory licensing limits", *IAM Webminars* (24 March 2020), *http://www.iam-media.com/coronavirus/covid-19-emergency-may-expose-compulsory-licensing-limits* [Accessed 27 August 2020]; Enrico Bonadio and Andrea Baldini, "Why Patent Laws Matter, Even in Times of Crisis" in Six Tone (20 February 2020), *Sixth Tone*, *http://www.sixthtone.com/news/1005210/why-patent-laws-matter%2C-even-in-times-of-crisis* [Accessed 27 August 2020]

[2] Marrakesh Agreement Establishing the World Trade Organization, Geneva, 15 April 1994, entered into force 1 January 1995, 1867 United Nations Treaty, Series 3, annex 1C — Agreement on Trade-Related Aspects of Intellectual Property Rights (1994) art.39(3): Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilise new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.

protected. Thereafter, each country moved forward in designing andimplementing its own system of protection under data exclusivity regimes. But how or why is this relevant for a compulsory licence in the EU? Both MA and test data protection—data exclusivity—are found in the EU pharmaceutical legal framework, which is separate from the EU patent framework. Additionally, even when exceptions to patent rights because of public health emergencies, e.g. compulsory licences, are envisaged within the EU, an EU-wide compulsory licence is not possible since this can only be done at the national level.[3] Furthermore, the import of products manufactured under compulsory licences into the single market has also been relinquished by the EU.

In other words, the data exclusivity regime[4] erected in the EU solely allows exception to test data protection in cases where a compulsory licence for exports purposes has been issued, but this is not applicable when the products are manufactured for the supply of the internal market. Even if patent rights are not exercised or a compulsory license is used to grant access to the invention, in this case related to health technology, it is likely that unless adequate voluntary licenses are in place the data contained in the MA cannot be disclosed or used by health authorities in favour of generic manufacturers.

The issue above comes from the fact that patent grant procedures are separate from MA ones. A compulsory licence is an exception to the patent,[5] and not to the MA. Therefore, clinical and pre-clinical trials—test data—as such are not affected by a compulsory licence. The sui generis regime—data exclusivity—protects certain data from disclosure to third parties for a period of time that is automatically granted with the MA itself. The current debate[6] has largely focused on the implications of the patent system and the possibility to make us of compulsory licences at the national level, but, because of how MA and data exclusivity work at European level, this may be more challenging to achieve.

This article follows a holistic approach by addressing the challenges emerging from the analysis of the framework governing the use of a compulsory licence at the EU and international level—TRIPS, together with the EU pharmaceutical framework regulating MA. First, the article focuses in art.31 of TRIPS to highlight its incompatibility with the EU data exclusivity regime found in the regulation of pharmaceutical products in Directive 2001/83 and Directive 87/21. And, second, it makes a *lege deferenda* suggestion to include public health exceptions to data exclusivity at the EU level, regardless of the chosen route to obtain a marketing authorisation.

To achieve its objective, the article will start by explaining what data exclusivity is, and subsequently will show why a compulsory patent licence will not be sufficient to resolve a global health crisis unless the data exclusivity issue is addressed. Finally, the article concludes that public health exceptions are not and cannot be solely considered in the context of patent law, but instead exclusivity regimes developed with the intent to complement the patent system cannot be developed in isolation. In other words, pharma innovation cannot be fostered through a system of incentives that is developed separately from public health legislation; on the contrary, the current situation demands for a closer co-operation and complementariness between patent law, regulatory approvals for medicines, and public health policies ensuring access to medicines.

Marketing approvals and data exclusivity—what a challenge …

Pharmaceutical products require a marketing authorisation (MA) before these can reach the market.[7] In the EU, an MA can be obtained through various routes, depending on the type of medication. In the case of antivirals, the process can be stricter, given that the MA for these can only be applied for through the centralised procedure as established in art.3(1) from EU Regulation 726/2004.[8]

Information related to clinical and pre-clinical trials data—known as undisclosed information—is compiled in a pharmaceutical dossier that later on is examined prior the MA grant. Generating the data to prove efficacy and safety of pharmaceuticals is a lengthy and costly process, and therefore the TRIPS Agreements in art.39(3) recognised the need to protect this data against unfair commercial uses unless when necessary to protect the public. This provision within TRIPS paved the way to establish the sui generis system of protection at the national level known as "data exclusivity". Article 14(11) of Regulation 726/2004 (the Regulation), and art.10(1) of EU Directive 2001/83 (the Medicine Code) are the main provisions within the pharmaceutical regulatory framework governing data exclusivity. In the following section the author uses the case of the hunt for COVID-19 treatment to illustrate the tension between intellectual property exceptions within the IP framework at the

[3] European Commission, "Letter from the European Commission to Mr Greg Perry, EGA-European Generic Medicines Association on the subject of Tamiflu application and data exclusivity in an emergency compulsory license situation" (Brussels, 2006), *http://www.cptech.org/ip/health/dataexcl/ec-de-tamiflu.pdf* [Accessed 27 August 2020].

[4] Directive 2001/83 on the Community code relating to medicinal products for human use [2001] OJ L311/67 (Medicine Code).

[5] Carlos M. Correa, "Intellectual Property: How Much Room Is Left For Industrial Policy?", UNCTAD/OSG/DP/2015/5.

[6] Thus far, very few papers haveaddressed the challenges embodied by the data exclusivity regime in the EU when intending to make use of compulsory licences. This article echoes part of this discussion and provides plausible avenues for solutions toward the conclusions. See Ellen 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 J. Pharm. Policy Pract. 19; Adam Houldsworth, "Covid-19 emergency may expose compulsory licensing limits", *IAM Webminars* (24 March 2020), *http://www.iam-media.com /coronavirus/covid-19-emergency-may-expose-compulsory-licensing-limits* [Accessed 27 August 2020]; and Pascale Boulet, Christopher Garrison and Ellen 't Hoen, "EU Review of Pharmaceutical Incentives: Suggestions for Change' in Medicine Law and Policy" (June 2019).

[7] Directive 2001/83—Medicine Code art.6

[8] Regulation 726/2004 art.3(1): "No medicinal product appearing in the Annex may be placed on the market within the Community unless a marketing authorisation has been granted by the Community in accordance with the provisions of this Regulation."

international level, and the current EU pharmaceutical regulation, since data exclusivity coexists with MA and they are not isolated from each other.

Marketing approvals and COVID-19 in the EU market

Medicinal products in the EU are heavily regulated, rightly so, to protect patients from harmful side-effects or products that simply do not comply with quality, safety and efficacy requirements. Accordingly, Directive 2001/83 on the Community code relating to medicinal products for human use (Medicine Code) establishes the requirements, designates the competent regulatory authority depending on the case, and defines the routes[9] to obtain MA in the EU.

Depending on the MA route, the application should be presented before either a Member State's National Health Authority or the European Medicines Agency (EMA). The type of medicinal product to be commercialised will also determine the procedure to pursue and the type of application. In the case of antivirals, i.e. a COVID-19 treatment, is governed—in principle—by the Medicine Code and also Regulation 726/2004 (the Regulation). In other words, the entry into the market of a COVID-19 treatment would require the MA to be issued through the centralised procedure. Article 3 of the Regulation specifically provides that medicinal products contained within the Annex of the Regulation, e.g. medicinal products containing new active substances for the treatment of viral diseases, should be processed by the Community Agency, the European Medicines Agency. This type of MA allows the product to be placed on the market in all EU Member States without having to pursue a separate application in each of them. Given that COVID-19 treatment is of global interest, generic manufacturers—competitors in normal circumstances—would try to obtain MA through abridged or informed consent applications. The first application type enables the use of already submitted clinical and pre-clinical tests from the originator to be used as reference to obtain MA for the generic product.[10] The latter, although considered a form of abridged application, is somewhat stricter as it can bypass the period of exclusivity if and only if the company that originated the data has granted its consent to the generic manufacturer,[11] however, nothing within the Regulation imposes an obligation on a company to grant such consent.

In 2018 EMA published a plan of action for emerging health threats[12] in which the fast-tracked approval of needed medicines is established, and also four plausible levels of health threats with the steps to take in each case are mapped out. Level 4 in the health threat levels equals a global pandemic, which means that further scientific collaboration is needed to achieve a possible COVID-19 treatment, together with closer co-operation with EMA to develop clinical and pre-clinical trials.[13] The plan for a fast-track approval of a COVID-19 treatment is not enough to bypass the rules on data exclusivity as implemented in the Medicines Code or the Regulation in the EU.

Independently of the route followed to obtain a MA, this application contains a pharmaceutical dossier,[14] where information involving clinical and pre-clinical trials data is compiled. The complexities and formalities pertaining to the MA application fall outside the scope of this article, as its purpose is to illustrate how data exclusivity is attached to the MA. In times such as the one we are living in, it is paramount to circumvent the challenges emerging from the national data exclusivity regime to enable the effective use of patent exceptions needed to address access to medicines in the EU. Admittedly, under exceptional circumstances, a product may be "allowed" under compassionate use programmes[15] to alleviate the suffering of patients, even if the MA has not been granted. For instance, the experimental COVID-19 treatment Remdesvir has been allowed under "compassionate use" programmes within the EU and the United States; however, this does not imply that the product has received a MA to be commercialised. EMA, in a press release[16] earlier in April, provided Member States with recommendations on the compassionate use of Remdesvir for COVID-19, while acknowledging the lack of harmonisation at the EU level in terms of these programmes. EMA also emphasised the need to make the treatment available as fast as possible to all patients suffering from the illness, thus encouraging companies to make the medicine available as transparently and fairly as possible to all Member States wishing to take part in international clinical trials to treat patients.

[9] Marketing approvals can be pursued through the national procedure, mutual recognition procedure, the decentralised procedure, and the centralised procedure. See Maria Isabel Menley and Libby Amos, "Procedures for obtaining a Marketing Authorization and Legal Bases for application" in M.I. Manley and M. Vickers (eds) *Navigating European Pharmaceutical Law* (Oxford: Oxford University Press, 2015).

[10] See Medicine Code art.10(1) and (2).

[11] This type of consent is known as a "piggy-back" licence. See Menley et al., *Navigating European Pharmaceutical Law* (2015), p.106

[12] EMA/863454/2018, Policy and Crisis Management, "EMA plan for emerging health threats",. *http://www.ema.europa.eu/en/documents/other/ema-plan-emerging-health-threats_en.pdf* [Accessed 27 August 2020].

[13] European Medicines Agency, Biological Health Threats and Vaccines Strategy, EMA/166423/2020(31 March 2020),. *http://www.ema.europa.eu/en/documents/other/mandate-objectives-rules-procedure-covid-19-ema-pandemic-task-force-covid-etf_en.pdf*[Accessed 14 April 2020].

[14] A pharmaceutical dossier is a document prepared by the party interested in applying for marketing authorisation to commercialise the product. This compilation of documents is submitted before the regulatory agency, i.e. the European Medicines Agency, and includes information pertaining but not limited to the product name, product information and prescription status, orphan and paediatric requirements, quality, compliance, environmental risk assessment and pharmacovigilance, and a risk management plan (RMP) among others.

[15] Compassionate use is an exceptional circumstance where an unauthorised medicine is "intended to give patients with a life-threatening, long-lasting or seriously disabling disease, and no available treatment options, access to treatments that are still under development and that have not yet received a marketing authorisation". See EMA, Press Release, "EMA provides recommendations on compassionate use of remdesivir for COVID-19" (3 April 2020), *http://www.ema.europa.eu/en/news/ema-provides-recommendations-compassionate-use-remdesivir-covid-19* [Accessed 27 August 2020].

[16] "EMA provides recommendations on compassionate use of remdesivir for COVID-19" (3 April 2020), *http://www.ema.europa.eu/en/news/ema-provides-recommendations-compassionate-use-remdesivir-covid-19* [Accessed 27 August 2020].

Pharmaceutical tests and clinical and pre-clinical trials are imperative to comply with quality, safety and efficacy requirements, and the results of these are to be found within the documents contained in the pharmaceutical dossier submitted before the regulatory agency, i.e. the EMA, when applying for a MA. Generating the scientific data in the dossier represents considerable investment from the pharmaceutical companies developing the pharmaceutical product. Thus, this information is protected from disclosure for a period of time as established in art.10(1) of the Medicine Code, and Art.14(1) of Regulation 726/2004. The EU protection of test data goes beyond the mere requirement in art.39(3) TRIPS. True, the Agreement is about minimum standards of protection that should be implemented in all contracting WTO member countries; however, the public health exception also foreseen in art.39(3) TRIPS—international framework—was not included within the data exclusivity regime implemented in the EU.

Data exclusivity—the pink elephant in the room?

Definitions entail data exclusivity as an IPR of sorts, which

> "provides the holder with specific rights, namely that the data generated by the holder may not be referred to or used by another person or company for a specific period of time."[17]

Similarly, data exclusivity can also be defined as a

> "time bound *form* of intellectual property protection that seeks to allow companies to recoup the costs of investment in producing data required by the regulatory authority. The effect … is to prevent the entry of generic competitors, independent of the patent status of the product in question."[18]

In practice these definitions translate into a regulatory prohibition to third parties or the regulatory agency to use the information in the pharmaceutical dossier—originator's pre-clinical and clinical trials test information—for a determined period of time. This period of non-disclosure is known as data exclusivity.

In a general fashion, data exclusivity refers to the protection of

> "undisclosed *test or other data*, that *involves a considerable effort*, which needs to be submitted by the originator to the regulatory agency to prove safety and efficacy of a new drug and *shall protect such data against unfair commercial use*."[19]

At the international level, the protection of undisclosed information stems from art.39(3) TRIPS, which is divided between trade secret protection, and undisclosed information -test data protection. Additionally, the aforementioned provision also envisages the protection of the public as a causality to limit the protection of undisclosed information. Notwithstanding, given that TRIPS did not seem to intend the establishment of minimum standards in this regard, each WTO member country has either implemented its own sui generis system of protection or pushed for this through free trade agreements.[20]

In the EU, data exclusivity was introduced in 1987,[21] and is also known as the 8+2+1 rule.[22] Accordingly, this means that the originator's pre-clinical and clinical trial data (test data) cannot be used in the processing of a MA for a generic for a period of an 8-year data exclusivity period. Only after these eight years have passed can the health authority can process the said application (8+2), with the caveat that the product cannot be placed on the market before 10 years market exclusivity, have elapsed from the initial MA. In the case where an originator is able to secure a MA for significant clinical benefits in comparison with the existing ones, within the 10 years mentioned above, then an additional year (8+2+1)[23] of exclusivity may be granted. The 8+2+1 rule supports the claim and concern in having data exclusivity challenging the use of flexibilities—i.e. compulsory licences—because of the express prohibition in registering generics while the period of protection is in place. Over all, MAs are valid for five years at the time, and renewable indefinitely[24],[25]; however, this is not applicable to data exclusivity.

Keeping in mind the period of exclusivity in the previous paragraph, is also important to remember that medicines approved or that follow the centralised route

[17] International Federation of Pharmaceutical Manufacturers Associations (IFPMA), "Encouragement of New Clinical Drug Development: The Role of Data Exclusivity" (2000), p.1.
[18] Charles Clift, "Data Protection and Data Exclusivity in Pharmaceuticals and Agrochemicals" in A. Krattiger, R.T. Mahoney, L. Nelsen et al. (eds), *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (MIHR and PIPRA, 2007), p.435
[19] Definition assumed on the basis of art.39(3) TRIPS.
[20] For further reading about patent hedges and lock-in mechanisms through FTAs, see upcoming article, D.M. Cadillo Chandler,"*Supplementary Protection Certificates and Data Exclusivity: the raise of Pharma Patent shields*?" in Tuomas Mylly and Jonathan Griffith (eds),
[21] Data exclusivity was initially available for six years, and later this was extended to eight years generally, and ten years if significant therapeutic improvements were achieved, i.e. paediatric or orphan drug denomination. Directive 2001/83 on the Community code relating to medicinal products for human use [2001] OJ L311/67. This Directive is also referred to as the Medicines Code. The EU Medicines Code art.24(4, 5 and 6) envisages some situations where MA would cease to exist. For instance, not placing the product in the market within a period of three years; or when an authorised product previously in the market is no longer present for a consecutive period of three years. The exception in this case is not about having the authorisation cease to exist, but, on the contrary it would seem that the exception is re-instating or continuing to hold valid the marketing authorisation—on the basis of public health—when otherwise a product could hold it indefinitely.
[22] 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 J. Pharm. Policy Pract. 19.
[23] Id ut Supra art.10 Directive 2001/83 art.10: "The ten-year period referred to in the second subparagraph shall be extended to a maximum of eleven years if, during the first eight years of those ten years, the marketing authorisation holder obtains an authorisation for one or more new therapeutic indications which, during the scientific evaluation prior to their authorisation, are held to bring a significant clinical benefit in comparison with existing therapies."
[24] See Directive 2001/83 art.24(3).
[25] Medicines Code art.10.

through EMA will obtain EU-wide registration[26]; henceforth, the medicinal product will enjoy exclusivity in the EU market without competition during the 8+2+1 period. Additionally, COVID-19 possible treatments fall within the category of medicines approved through the centralised route, since these are antiviral treatments and are also developed on basis of medicines to treat, e.g., HIV, auto-immune and other immune diseases, and viral diseases.[27] Hypothetically, a new treatment on basis of e.g. Remdesvir and Kaletra[28] would constitute a new medical use with a new active substance, and if this were the case, also a new application with new clinical and pre-clinical trials to prove quality, safety and efficacy will be necessary to obtain MA, hence, enjoying exclusivity in the market, since generic manufacturers will not be able to compete before the data exclusivity period expires, unless exceptions are in place to circumvent it.

In theory, test data protection or data exclusivity has no connection with patents, in the sense that one is generated independently from the other. Test data supporting MA follows after the pharmaceutical invention, and not the other way around. [29] Patents and data exclusivity do not overlap in scope of protection: one is awarded to the invention, and the other to the data itself. So, why may data exclusivity be an issue in the current circumstances? First, data exclusivity is granted automatically and at the same time with the MA, hence no separate application to obtain protection is needed. Subsequently, competitors cannot rely on the data already generated by the originator to obtain MA for a generic product, even if the product is off-patent and independent of the legal basis for the MA application; as long as the data exclusivity period is in place the competitor will be prevented from entering the market.

Although patent protection is, in principle, much stronger than data exclusivity in itself, the latter can not only limit the use of compulsory licences but also complicate things for regulatory health authorities to rely on the available test data to grant MA for generics even if for non-commercial purposes.[30] Following on the example a few paragraphs above, let us assume a treatment for COVID-19 is found and the product reaches the market supported by the pharmaceutical dossier in the MA application. If the current EU pharmaceutical framework prevents competitors to enter the market while the data exclusivity period is in place, how can generic manufacturers produce the needed treatment without infringing data exclusivity? This is not about patent infringement, it is about finding an exception to a separate "right" stemming from TRIPS that falls outside the IPRs realm. Meaning is not regulated by the rules or exceptions governed in TRIPS, except where a public health exception is in place.

Considering joint efforts between the private and public sector in sharing data, knowledge, and also allocation of funding destined to R & D for a COVID-19 treatment, data exclusivity governance is not of minor importance.[31] In this regard, the Costa Rican President, Carlos Alvarado Quesada, and his Health Minister, Daniel Salas Peraza, in a letter addressed to the World Health Organization's Director General, Dr.Tredos, Costa Rica, petitioned for world collaboration":

> *"an effort to pool rights to technologies that are useful for the detection, prevention, control and treatment of the COVID-19 pandemic."*[32]
>
> "This pool, although voluntary, seeks to provide either free access or licensing on reasonable basis for every member country to address presently and future patented inventions *as well rights in regulatory test data and know- how among*."[33]

Granting protection to clinical and pre-clinical trial information on basis of the IP system, has not always been easy to understand. Jerome Reichman, long before COVID-19 suggested that this information should be considered public goods and should not be awarded protection unless this is truly worthy of exclusivity.[34] In the current situation, when a breakthrough treatment may be closer than we think, and where this will be the result of global collaboration, Governments' leaders are increasingly emphasising the public good status that such treatment should have.[35]

At the moment, the regulatory layers of protection, that is patents plus data exclusivity, are enabling right holders to maximise their IP rights and similar in a manner that also shields them from State intervention. However, should the data generated for the development of a

[26] Pascale Boulet, Christopher Garrison and Ellen 't Hoen, "EU Review of Pharmaceutical Incentives: Suggestions for Change" in *Medicine Law and Policy* (June 2019).
[27] See Menley et al., *Navigating European Pharmaceutical Law* (2015), pp.85 and 89.
[28] Kaletra is a combination of antiviral drugs lopinavir and ritonavir, approved by the US Food and Drug Administration (FDA) for the treatment of HIV infection in adults and children 14 days of age and older. Kaletra was developed and patented by AbbVie Pharmaceuticals; it has been awarded eight patents in the US and one of them is valid until 2026 (U.S. Patent 5,541,206; 5,648,497; 5,886,036; 5,914,332; 6,037,157; 6,284,767; 6,703,403; 7,148,359; 7,364,752; and 8,025,899). Both Kaletra and Remdesvir are already under patent protection, in the process of obtaining a MA or already with MA, which may complicate things in the future in terms of data exclusivity.
[29] Nuno Pires de Carvalho, *The TRIPS Regime of Patent Rights*, 2nd edn(Kluwer Law International, 2nd ed, 2005), p.388.
[30] Carlos Correa, "Protecting Test Data for Pharmaceutical and Agrochemical Products under Free Trade Agreements" in Pedro Roffe et al.(eds), *Negotiating Health: Intellectual Property and Access to Medicines* (London: Routledge, 2005), pp.81, 91–93; see also Owoeye (2014) 126 (highlights the severity of data exclusivity, since this will not be made available to the public upon the period of exclusivity's expiration date). After all, patents are granted in exchange for the disclosure made over the invention, but in this also is not the case for data exclusivity.
[31] Maria Isabel Menley and Grant Strachan, "Regulatory Data Protection" *Navigating European Pharmaceutical Law* (2015), pp.255–276
[32] Copy of letter from Carlos Alvarado Quesada, Presidente de la República, Costa Rica, and Daniel Salas Peraza, Ministro de Salud, Costa Rica, to Dr Tedros Adhanom Ghebreyesus, Director-General of the World Health Organization,*http://www.keionline.org/wp-content/uploads/President-MoH-Costa-Rica-Dr-Tedros-WHO24March2020.pdf* [Accessed 27 August 2020).
[33] Carlos Alvarado Quesada and Daniel Salas Peraza, to Dr Tedros Adhanom Ghebreyesus, Director-General of the World Health Organization,*http://www.keionline.org/wp-content/uploads/President-MoH-Costa-Rica-Dr-Tedros-WHO24March2020.pdf* [Accessed 27 August 2020].
[34] Jerome H. Reichman, "Rethinking the Role of Clinical Data in International Intellectual Property Law: The case for a Public Goods Approach" (2009) 13 *Marquette Intellectual Property Law Review* 1, 68.
[35] Hugo Miller, Jason Gale and Susan Decker, "No Pandemic Payday as Leaders Demand Cheap, Accessible Vaccines", *IP Law News* (2020).

COVID-19 treatment not now be considered a public good? Although it is tempting to develop that thought, this falls out of the scope of the present article. In light of the effect that MA granted through the centralised procedure and its connection to data exclusivity, is important to examine further the legal tension between these and the plausibility in effectively using compulsory licences in the EU.

Compulsory licences, MA and data exclusivity—not a match made in heaven

Compulsory licences can be understood as

> "the authorization given by the State to a third party to exploit a patented invention, generally in exchange of compensation to the patent holder, and these may be granted according to national laws on several grounds, such as emergency, public interests, non-working of the invention, anticompetitive practices and dependency of patents."[36]

Within the context of TRIPS, compulsory licences are referred to as other uses without authorisation and are required to comply or fulfil with the set of requirements in art. 31 TRIPS, even if in cases of public health emergencies. The DOHA declaration[37] acknowledged public health concerns, thus compulsory licences may be used to supply the national market via local production or through import or export, as long as the mechanism is foreseen within domestic law. TRIPS as the basis for the international IP framework provides compulsory licences as an exception to patent rights and not to data exclusivity. Bear in mind that the latter is a sui generis system of protection designed and implemented at the national level, thus the MA "system" is completely separate from the IP system; however, in terms of pharmaceuticals, these two meet on the point of data exclusivity as attached to the MA affects commercialisation. Additionally, each EU Member State retains autonomy in certain aspects, thus enacting a compulsory licence is an individual or national exercise.[38]

To challenge things further, as addressed earlier in the EU, the route taken to obtain a MA may result in having direct effect on the markets where the product can be commercialised as established within the pharma regulation.[39] Given that compulsory licence is an exception to IPRs at the individual EU Member State level, would this have any effect on the MA for a pharmaceutical product granted through the centralised procedure?

The answer is no: a compulsory licence at the national level may have no effect[40] whatsoever over the data exclusivity protection attached to the MA for those medicines approved through EMA's centralised procedure.[41] In this regard, the European Generic Medicines Association raised the question of whether data exclusivity would also fall within the scope of the compulsory licence in the case that this was required in the EU owing to a public health emergency. The European Commission acknowledged that the "Community pharmaceutical acquis does not currently contain any provision allowing a waiver of the rules on data exclusivity and marketing protection periods".[42] In 2006 a compulsory licence for Tamiflu (oseltamivir) was considered without success.

The only exception found within the EU pharmaceutical framework in terms of data exclusivity is in art.18 Regulation 816/2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems. The Regulation's name itself indicates that this is for the manufacturing of medicines under compulsory licences for export purposes only, and not for the supply of the internal market. Thereafter, the waiver, that is, when the data exclusivity period shall not apply, is only in the context of medicines to be exported. With this Regulation the EU becomes a potential exporting WTO Member Country as envisaged under Doha's Declaration para.6 system or as amended under art.31bis TRIPS.[43] The EU gives up its right to use the system in its favour by expressly prohibiting imports of pharmaceuticals for the purpose of placing them or for free circulation in the internal market.[44]

Given the urgency in having access to a COVOD-19 treatment, a legislative reform may be necessary in the EU to amend the current pharmaceutical framework.[45] Allowing for compulsory licences for EU imports or waiving the data exclusivity regime in the case of a pandemic, notwithstanding the procedure followed to obtain a MA, seem to be steps in the right direction to

[36] P. Roffe, C. Spennemann and J. von Braun, "From Paris to Doha: The WTO Doha Declaration on the TRIPS Agreement and Public Health" in P. Roffe, G. Tansey and D. Vivas-Eugui (eds), *Negotiating Health: Intellectual Property and Access to Medicines* (UK/USA: Earthscan, 2006), p.17, Also see WTO Dispute DS199, *http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds199_e.htm* [Accessed 27 August 2020].
[37] Doha Declaration on the TRIPS Agreement and Public Health as adopted by the WTO Ministerial Conference of 2001 in Doha on 14 November 2001.
[38] Ellen 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 J. Pharm. Policy Pract. 19.
[39] Medicine Code establishes that medicines for the treatment of i.e. HIV, cancer, diabetes, neurodegenerative diseases, auto-immune and other immune diseases, viral diseases, biotechnology products, advanced therapy medicines (e.g. gene therapy), and orphan medicinal products will only obtain a MA through EMA, thereafter the MA is considered to have EU wide effect.
[40] See Parliamentary Questions 24 March 2015 Question for written answer E-004613-15 to the Commission Rule 130 Ernest Urtasun (Verts/ALE) EC answers P-000227/2015, P-000293/2015 and E-000205/2015(1) 'Ernest Urtasun, a member of the European Parliament (MEP) from Spain, sent a formal inquiry to the EC asking about the possibility of using issuing compulsory licenses to get around paying the industry's asking price for the drugs.
[41] See t' Hoen et al. "Data Exclusivity exceptions and compulsory licensing to promote generic medicines in the European Union" (2017) 10 J. Pharm. Policy Pract. 19.
[42] 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 J. Pharm. Policy Pract. 19.
[43] Doha Declaration, para.6.
[44] Regulation 816/2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems art.13.
[45] Christopher Garrison, "Never say Never: Why High Income Countries that opted-out from the Art. 31bis WTO TRIPS system must urgently reconsider their decision in the face of the Covid-19 pandemic", *Medicines Law & Policy* (8 April 2020).

ensure access to the treatment. The fact that data exclusivity behaves as a quasi-IPR, owing to the exclusivities embodied in the form of protection, severely defeats the purpose of patent compulsory licences.

Exceptions to rights conferred by patent rights can be taken, as long as these

> "do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties."[46]

Compulsory licences due to public health concerns shall be granted exclusively for the supply of the national market, limited in time, and be non-exclusive.[47] The public health waiver in art.31 TRIPS is about the requirements in terms of negotiating prior its use, and the compensation, but it does not imply or lead to an expropriation of the rights borne by the right holder. If a compulsory licence is granted for the present case, once COVID-19 is eradicated the status quo of IPRs will be reinstated. Nonetheless, the compulsory licence will not affect data exclusivity if this is not considered an IPR, and if an exception for this is not expressly foreseen at the national level.

The EU Medicine Code prohibits the registration of generics, disclosure of data compiled by an originator and cross-referencing by EMA: in other words, manufacturers cannot rely on the available data. True, a new use is not a generic; however, if a compulsory licence is enacted because this will be non-exclusive, then third parties will be able to manufacture generics for that second medical use as long as there is no centralised MA in place. Otherwise, generic products will may not reach the market if the current exclusivity period and rules cannot be circumvented.

Scientists around the world are also joining the call for further relaxation of IPR norms; countries such as Israel have bypassed IPRs for the sake of finding a treatment for COVID-19.[48] Patents are not only affecting innovation for medicinal products, but also testing processes, and all of these are required from an MA. Should we now recognise that data exclusivity is not solely about a defensive strategy and act accordingly, or is it game over?

Some final remarks

In recent weeks, pharmaceutical companies around the world began choosing not to enforce patent rights over medicines tested to find a possible treatment for COVID-19; such was the case of AbbVie when it announced[49] that the Kaletra patent would not be enforced either in the US or anywhere in the world. Unfortunately, the trend was not harmonious, since both the Wuhan Institute and Gilead did not initially join the efforts and continue to enforce their IPRs. Bonadio et al. have raised the need to evaluate whether the decision to enforce patents or not is beyond companies' will to continue exercising IPRs, and instead time calls for an ethical obligation not to do so.[50]

Having access not only to the treatment, but most importantly to the knowledge or information to continue developing health technologies (i.e. vaccines, test kits, antibodies tests, etc.) is paramount for the survival of humanity in order to fight a virus that may be around for a while. To achieve this, it is perhaps irresponsible to leave it as a company's prerogative to decide whether or not to grant access to information or forgo IPRs in cases of public health emergencies, considering the existence of the current regulatory incentives in place. Admittedly, governments are reportedly increasingly investing and partnering with companies through public private partnerships to find promptly adequate treatment and supply the market.[51] Nonetheless, is worth pondering on whether most of the results or data generated through these public private partnerships should be shared or pooled as a requirement to obtain public funding.

Mitigating the impact of an extremely complicated situation is probably more about trial an error at this point. Nevertheless, this is why the call from the Costa Rican Government to pool test data creates such an important precedent in the need to revisit the current data exclusivity governance in the EU. On a comparative note, is relevant to point out that Costa Rica is one of the few developing countries providing for public health exceptions at the national level to brake or pause the effects of data exclusivity.[52] In this regard the Costa Rican pharmaceutical and undisclosed information protection frameworks are amalgamated by both regulating data exclusivity at the national level but also providing for the exception on basis of public interest to leave data exclusivity without effect.[53]

[46] TRIPs Agreement art.30.
[47] TRIPs Agreement art.31.
[48] James M. Cooper and Bashar Malkawi, "We Need To Relax Intellectual Property Rules To Fight This Virus", Opinion, *The Hill* (4 June2020).
[49] Donato Paolo Mancini in London and Hannah Kuchler in New York, "AbbVie drops patent rights for Kaletra antiviral treatment" *Financial Times* (23 March 2020).
[50] Enrico Bonadio, and Andrea Baldini, "Why Patent Laws Matter, Even in Times of Crisis", in *Six Tone* (20 February 2020), Sixth Tone, *http://www.sixthtone.com/news/1005210/why-patent-laws-matter%2C-even-in-times-of-crisis* (last accessed 10.04.2020); and ENRICO BONADIO And ANDREA BALDINI, 'Drug firms pressed to drop patents to fight Covid-19' in *AsiaTimes* (8th April 2020) Available at *asiatimes.com/2020/04/drug-firms-pressed-to-drop-patents-to-fight-covid-19/* (last accessed 14.4.2020)
[51] See Knvul Sheikh and Katie Thomas, 'Researchers Are Racing to Make a Coronavirus Vaccine. Will It Help?' in *The New York Times* (20 January 2020) Available at *www.nytimes.com/2020/01/28/health/coronavirus-vaccine.html?mod=article_inline* (last accessed 14.04.2020); and Florin Zubaşcu, "EU puts €45M into €90M public-private partnership for coronavirus vaccine research" in *Science and Business* (25 February 2020) Available at *sciencebusiness.net/news/eu-puts-eu45m-eu90m-public-private-partnership-coronavirus-vaccine-research* (last accessed 14.04.2020)
[52] The Dominican Republic-Central America-United States Free Trade Agreement (CAFTA-DR) in 2009. The regulatory framework within this geographical context, specifically regulates data exclusivity through Executive Decree No. 34927-J-COMEX-S-MAG of November 28, 2011, on Approval of the Regulation of the Law on Undisclosed Information, and this together with the Law No. 7975 of January 4, 2000, on Undisclosed Information (as amended by Law No. 8686 of November 21, 2008)
[53] Executive Decree No. 34927-J-COMEX-S-MAG of November 28, 2011, on Approval of the Regulation of the Law on Undisclosed Information, and this together with the Law No. 7975 of January 4, 2000, on Undisclosed Information (as amended by Law No. 8686 of November 21, 2008)

In addition to Costa Rica's effort, EMA's Regulatory Science Strategy to 2025 has a public health angle that seeks among several goals to promote increased information sharing on clinical trial design, together with developing methodologies to incorporate clinical care data in regulatory decision-making. This strategy is to enable further education, training and sharing of best practice in order to accelerate innovative change.[54] Increasing collaboration and sharing data cannot be emphasized enough, since this may be the only way to find an adequate treatment in a timely manner.

As examined above, the EU currently lags behind[55] some developing countries in terms of public health exceptions to counteract the effects of the rigid data exclusivity regime implemented in this context. Costa Rica's move in reformulating national data exclusivity regime to include exception to this on basis of public interest is backed up, or so it would seem, by Art. 39(3) TRIPs. The international legal framework recognizes the need to protect the data, but also the need to waive such protection when required to protect the public or for public health reasons. The Costa Rican provision specifically reads "Protection of data provided with a view to marketing approval for pharmaceutical or agrochemical products. If, as a condition for securing approval to market new pharmaceutical or agrochemical products, applicants are required to produce a marketing license showing undisclosed test data, including data on safety and effectiveness, or other undisclosed information the preparation of which has entailed considerable efforts, the data in question shall be protected against any unfair commercial use and any disclosure, *except where the use of such data is necessary to protect the public*."[56] In 2010 further provisions were introduced as to also allow the use of the data by the health administration and even disclosure as long as measures to prevent unfair commercial uses where in place. In this regard, the legislation is somewhat vaguer, but overall the prevalent mandate seems to heavily weigh in favour of protecting humans, life and health.

Although the EU provides for the manufacture of medicines under compulsory licenses, and also deems possible the suspension or when the data exclusivity period shall not apply, this is only for medicines manufactured under compulsory licenses for export purposes and not for the supply of the internal market as established within Regulation 816/2006. The fact that no exception to data exclusivity, for products to supply the EU market, exist within the EU pharmaceutical framework is indicative of the lack of preparedness prevalent globally to face the current challenges. As it has been recently highlighted, when developed countries or high-income countries (HIC) openly manifested their intention to not become potential exporting Member countries, it is likely they also limited the possibility to fulfil their human rights obligation to provide access to affordable medicines[57] in the unlikely case of a pandemic by relinquishing the use of compulsory licenses for import purposes, or not foreseeing exceptions to data exclusivity. This legal vacuum begs to question how will the EU manage to circumvent the strict data exclusivity regime it has erected around the patent system to supply the internal market in the present time?

Two possibilities come to mind after reviewing the EU pharmaceutical framework. One, may be present through collaboration in the sharing of the data as provided in art.53 from Regulation N° 726/2004. Although, this is a far fetch thought, it may allow for the EU to collaborate for instance with the Costa Rican Government or with other test data pooling initiatives in the sharing of the data to manufacture the products to supply the single market, while appealing to the EU pharmaceutical industry not to enforce either patents nor to oppose to the registration of generics of a referenced pharmaceutical product. Additionally, the EU require from similar provisions in terms of marketing authorizations as those envisaged in art.18 from Regulation N° 727/2004.

The second possibility may be found in Regulation 536/2014 on clinical trials on medicinal products for human use. This Regulation on clinical trials envisages the possibility for EMA to evaluate the existence of an overriding public interest to disclose commercially confidential information. Nonetheless, this is not an indication that a MA can be granted if the period of exclusivity is in place, in only refers to disclosure and management of undisclosed information through the establishment of the EU database[58] seeking collaboration amongst Member States regulatory agencies. In either of the two possibilities above there is a clear path to leave the data exclusivity period without effect for products supplying the internal market under pandemic like conditions. Is equally not enough, to stablish collaboration to address the clinical trial development and disclosure if this will not lead to achieving an exception to obtain an MA when the data exclusivity period is still in place. This particularly important given the effect of an MA

[54] Regulatory Science Strategy to 2025, p 21

[55] The EU data exclusivity regime lacks coherence, not only because the inexistent of a provision suspending the effects of data and market exclusivity due to public health emergencies or interest, but also because the EU medicine code when stablishing the routes to obtain marketing authorizations in itself is an impediment for the use of EU wide compulsory licenses. See Ellen 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 J. Pharm. Policy Pract. 19.

[56] Art.8 Law No. 7975 of January 4, 2000, on Undisclosed Information (as amended by Law No. 8686 of November 21, 2008) Republic of Costa Rica — Ministerio de Salud as amended in the Executive Decree N° 35828-MAG-S-MINAET-MEIC-COMEX as published in Official Gazette N°51 from 15th March, 2010.

[57] Christopher Garrison, 'Never say Never: Why High Income Countries that opted-out from the Art. 31bis WTO TRIPS system must urgently reconsider their decision in the face of the Covid-19 pandemic' *Medicines Law & Policy*, 8 April 2020.

[58] Regulation 536/2014 on clinical trials on medicinal products for human use art.81(4).

obtained through the centralized procedure, since this effect may challenge the distribution[59] and wide access to COVID-19 treatment at the EU level even if a compulsory license is issued.

Circumventing data exclusivity in the EU without the adequate exception, may be more challenging than meets the eye. A global pandemic blurs the fine line dividing the classification of what is to be considered a developing, least-developed and developed country in terms of health needs, but not so in terms of resources available. In the present situation, Pharma innovation is likely to be achieved through collaboration and not necessarily because of the system of regulatory incentives that is in place designed to foster innovation. Thus, highlighting the need to developed incentives with public health policy goals in mind, since closer cooperation and complementariness between e.g. patent law, regulatory approvals for medicines, and public health policies ensuring access to medicines is paramount.

> "Health economic considerations play a major role in determining patient access to medicines. Regulators should continue striving to quantify and communicate systematically benefits and harms, trade-offs, and uncertainties at the time of approval, to inform these downstream decisions. This is expected to bridge the gap between regulatory approval and access."[60]

[59] Distribution and supply chains are also important aspects that will determine the success in reaching a larger portion of the population that will need to be immunize. This topic is not discussed in the paper, but for further insight see Rebecca Weintraub, Prashant Yadav and Seth Berkley, 'A Covid-19 Vaccine Will Need Equitable, Global Distribution' in *Economics & Society — Harvard Business Review* (2nd April 2020) Available at *br.org/2020/04/a-covid-19-vaccine-will-need-equitable-global-distribution* [last accessed 14.04.20].

[60] The Regulatory Science Strategy to 2025 as adopted by EMA's Management Board at its March 2020 meeting, p.26.