Biotechnology, health and patents as private governance tools: the good, the bad and the potential for ugly?

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Abstract

This article argues that patents, although often viewed primarily in terms of their economic or incentivising function, also have an important but often overlooked private governance function. Inherent in the grant of a patent is the right given to the patent holder to exclude others from using that invention, and to set the parameters around the terms of use for the duration of the patent (via licensing). This right can in turn impact the trajectory of the patented invention and also multiple downstream inventions, potentially dictating uses in that field for the duration of the patent. Moreover, existing avenues offering potential oversight around the broader implications of decisions on patent use and grant, such as the morality provisions for patent grant, compulsory licensing provisions or mechanisms to challenge patents post-grant are limited in their effect in practice. Hence, patent holders exercise such governance functions with limited, if any, external oversight. Furthermore, patent holders' decisions on patent use can have significant consequences that are particularly acute for health-related biotechnologies. Accordingly, this article argues that in the context of health-related biotechnologies there is a need for greater consideration and oversight over patent holders' private governance function.

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Introduction

This article argues that patents, although often viewed primarily in terms of their economic function,[1] also play a highly significant but often overlooked role in shaping downstream research. In doing so, it will be argued that patents act as *private governance tools*.[2] Put simply, inherent in the grant of a patent is the right given to patent holders to exclude others from using the patented invention, and to set parameters around what conditions will attach to the use of the invention (via patent licensing). The article argues that this amounts to a governance function because once granted patent holders govern that invention for the duration of patent grant.[3] Moreover, given that many technologies are dependent on the use of patented upstream inventions to operate, therefore a patent holders' governance role has the potential for significant knock-on effects in the surrounding field of technology.

Depending on the nature of the patented invention, patent holder decisions in relation to the licensing of an invention can have significant effects in shaping the trajectory of multiple downstream technologies and even that field of technology. Furthermore, as will be demonstrated, there is always the potential for patents to be licensed in a way which is contrary to broader public interests, for example, limiting downstream access to an invention for use and research, and applying restrictive terms effecting how the invention can be used. This in turn can have significant consequences for the development of technologies downstream and for access to technologies more broadly. Accordingly, the article makes the case that there is a need for greater oversight over how patents once granted are used by patent holders.

Importantly, in making this argument, the article is not seeking to question the economic function which patents offer in incentivising technologies, nor is it suggesting patent rights should not be granted. Instead, its focus is in demonstrating that alongside their economic function patents also have a governance function which is often overlooked and this needs to be probed more deeply. In this vein, the article focuses specifically on the context of health-related biotechnologies because the effects of decisions on patent use in such contexts are particularly acute both in terms of the *potential* impacts of decisions on patent use on health and also on the *potential* implications patents on some inventions can have on technological development downstream more generally. Thus, arguably, there is a heightened justification to consider the need for oversight over patent holders' discretion around patent use in the context of health-related biotechnologies. This does not necessarily mean that the arguments made do not also apply for other technologies, however, the arguments as they pertain to other technologies are beyond the scope of this current article.

In building the analysis, the article argues for two major shifts in how the legal framework is

[1] Patents are often viewed as providing an incentive for research/innovation by providing an avenue of investment return for the patent holder, this point is developed in the first part of the article.

[2] See discussion in L. Bently and B. Sherman, "The Ethics of Patenting: Towards a Transgenic Patent System" (1995) 3(3) Medical Law Review 275.

[3] The term "govern" is used in this context to mean how patent holders dictate uses and the future development of the patented invention and related inventions.

conceptualised in the patent context. First, the article conceptualises patents as private governance tools. Patents have been referred to in terms of exercising a private governance role by Sherkow previously[4]; however, his use of this term refers primarily to the way patents could be used by patent holders to implement conditions on the use of technologies. This article goes beyond such claims, putting forward a broader argument that patents, regardless of how they are used, are private governance tools because they give patent holders the right to dictate the conditions of use for the patented technology for the duration of patent grant. In doing so, patents transfer governing control over the direction and path of an invention to private actors (patent holders) and out of the public sphere. This analysis brings to the fore the largely unfettered space patent holders occupy in exercising control over and shaping the direction of patented technology. It then puts forward an argument for why the extent of this discretion and control given to patent holders needs to be reconsidered for health-related biotechnologies.

Second, the article demonstrates that the lack of focus on the governance role of patents means that existing checks and balances over patent use are limited. In particular, it will be argued that limitations on patent rights such as the morality provisions at patent grant stage in Europe,[5] avenues for challenging patent grant before national courts or patent offices, and potential limitations on patent holders discretion at licensing stage, e.g. via compulsory licensing, have a limited and often exceptionalised role in practice. A reinforcing cycle occurs where there is limited oversight over potential impacts on the public interests of the patent at grant stage, and once granted patents are relatively insulated from external challenge for the duration of patent grant or from limitation via compulsory licensing. In building this argument, the article is not necessarily suggesting that, e.g., morality provisions or compulsory licensing mechanisms should be routine per se. Rather it argues that, given that such avenues do not currently act as a routine filter to discern potential impacts of decisions on patent use on the public interests, this strengthens the significance of the arguments made, and provides greater justification for external oversight, or at least greater justification of the need to question the extent of the discretion given to patent holders in the health-related biotechnological context.

In building these arguments, the article is structured as follows: the first part sets out the core argument that patents are private governance tools. The second part then illustrates the significance and extent of this governance function in the context of health-related biotechnologies by demonstrating the potential impacts that patent holders' decisions on patent use can have in such contexts. It argues that significant unfettered discretion is maintained by patent holders over patent use even where there is a potential for significant adverse health outcomes to arise. Following this, the third part demonstrates that the extent of the discretion given to patent holders is compounded by the fact that existing checks within patent law, such as the morality provisions at patent examination and grant stage, are minimal at best,[6] and that restrictions imposed via compulsory licensing are often narrowly used and

[4] J.S. Sherkow, "Patent protection for CRISPR: an ELSI review" (2017) 4 Journal of Law and the Biosciences 565, who cites: Broad Institute Inc v Regents of the University of Cal., Patent Interference No.106,048, 2017 WL 657415 (P.T.A.B. 15 February 2017), which states: "By prohibiting uses the patent holder deems unethical, a patent license can function as a tool of private governance."

[5] EPC art.53(b) provides that inventions are not patentable where their commercial exploitation is against ordre public or morality.

[6] Such provisions do not exist in all jurisdictions.

interpreted in practice. Moreover, avenues for legally challenging patents to address such potential broader impacts of patent use are institutionally deficient for a number of reasons. Such issues taken together build a strong justification for why greater questioning and oversight of patent holders' *governance role and decisions on patent use* is needed. The fourth part concludes by arguing for a reframing of the role of patents. It argues that, instead of viewing patents in primarily economic terms, we must also consider their governance function. As part of this reframing, there must be an acknowledgement of the significant and relatively unfettered power patent holders have over patent use, and of the need for greater scrutiny around whether the extent of this discretion is appropriate particularly for health-related biotechnologies.

Patents as private governance tools

Patents are granted if an invention meets the criteria of novelty, inventive step and industrial application,[7] and provided the patent is not applied for an excluded category of invention.[8] Once granted, patents allow the patent holder to exclude others from using an invention for the duration of patent grant which is generally 20 years.[9] Third parties require the patent holder's consent to use a patented invention,[10] given by way of a licence from the patent holder. In this way, patents serve an economic function as they allow patent holders to derive an income stream from the invention via licensing, and thereby patents can encourage or incentivise innovation.[11] As noted, this article does not seek to challenge this economic function of

[7] This is the European terminology; it should be noted that different terminology is used in other jurisdictions. The main conditions for patentability imposed under the TRIPS Agreement which applies to all World Trade Organization States are outlined in art.27(1), which states that: "1. Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application…."

[8] There are limited exclusions to patentability which exist within regional patent treaties, and these exclusions can differ across jurisdictions. The TRIPS Agreement provides that states *may* have exceptions to patentability in limited circumstances under art.27(2) and (3). Article 27(2) states: "Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law." In the European context, art.53 of the European Patent Convention states that: "European patents shall not be granted in respect of: (a) inventions the commercial exploitation of which would be contrary to "ordre public" or morality; such exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States; (b) plant or animal varieties or essentially biological processes for the production of plants or animals; this provision shall not apply to microbiological processes or the products thereof; (c) methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body; this provision shall not apply to products, in particular substances or compositions, for use in any of these methods."

[9] The TRIPS Agreement art.33 states that: "The term of protection available shall not end before the expiration of a period of twenty years counted from the filing date." Thus, all TRIPS parties must provide patent protection for a minimum period of 20 years.

[10] The TRIPS Agreement art.28 states: "1. A patent shall confer on its owner the following exclusive rights: (a) where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing for these purposes that product; (b) where the subject matter of a patent is a process, to prevent third parties not having the owner's consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process. 2. Patent owners shall also have the right to assign, or transfer by succession, the patent and to conclude licensing contracts."

[11] *Dominique Guellec, "Patents as an Incentive to Innovate" in Dominique Guellec and Bruno van Pottelsberghe*

patents. However, it argues that alongside this economic function, patents have an important governance function which is often overlooked. The power given to patent holders enables patents to facilitate *private governance* over the use of an invention and this power in turn requires greater consideration.

To demonstrate this point, this section will first build the case that patents act as *private governance* tools, and will then argue that this role is particularly problematic in the health-related biotechnology context, given: (1) the nature of inventions in the biotechnological sphere wherein patent holders' decisions related to an invention may impact multiple downstream inventions; and (2) the potential health implications arising from decisions regarding patent use.

The article argues that patent holders exercise a private governance role in *refusing or granting licences* to third parties for the use of the patented invention. If we consider that one of the main justifications for patents is that the grant of a patent has an incentivising effect (or the potential for this) as they encourage inventors by providing a means to gain an income stream from the invention (the economic function), we must then also consider that once a patent is granted, it cordons off an area for that patent holder as no one can use that patented invention for commercial purposes without the patent holder's permission, including if that technology is needed to operate downstream inventions. This in turn could affect how other inventions are incentivised to develop. Thus, it is not enough to consider the incentivising effect of patents on the patent holder without also considering the effect of the grant of a patent on related technologies and technological development downstream—in other words, the effects of *patent use*. In considering this, we must be aware of the consequences of giving a (relatively) absolute right over the use of the patent to the patent holder for 20 years—and whether in some contexts there is a need for limitations or external oversight over the use of this right.

The effects of patent holder discretion on patent use can be particularly acute in the biotechnological context as, while all inventions have the potential to relate to previous inventions, and hence for patents to have de-incentivising effects on related technologies, arguably for some biotechnologies the effects are particularly significant given their potential to act as *platform technologies* which are required for use by multiple downstream technologies. Thus, in short, a patent holder's discretion over the use of an invention does not merely act in a linear way limiting access to that invention. Instead, patents over inventions should be seen as acting in a manner akin to tentacles which span from that patented invention as the control given by the patent stretches out, not just to impact use of that patented invention, but also to impact other inventions which require use of the patented upstream invention to operate.

To demonstrate this, it is useful to conceive of some inventions as resources akin to water in a

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de la Potterie (eds), The Economics of the European Patent System: IP Policy for Innovation and Competition (Oxford: Oxford University Press, 2007). However, some have questioned whether patents offer the most appropriate mechanism for encouraging innovation; for a discussion, see: *B. Pretnar, "Patents and the Economic Incentive to Invent" in W.P.W. Pyrmont, M.J. Adelman, R. Brauneis, J. Drexl and R Nack (eds), Patents and Technological Progress in a Globalized World (MPI Studies on Intellectual Property, Competition and Tax Law, Vol 6 (Berlin/ Heidelberg: Springer, 2009)*.

river.[12] Denying access to water from a river has a range of impacts on plants, animals and human life surrounding that river. Thus, systems of water rights have developed to deliver access to water and ensure that limitations are placed on property owners who own surrounding lands.[13] Arguably, some patented inventions should also be conceived of as akin to resources analogous to a flowing river because the lack of access to that invention can similarly limit the development of other inventions or areas within the biotechnology field, with knock-on implications for broader aspects of the public interest such as health, these consequences are examined in detail in the second part below.

Given this governance role, patent holders' discretion and how this is exercised over patent use can have non-trivial implications for downstream technologies and the broader public interest, yet there is limited external oversight of this discretion. For instance, if the patent holder refuses to license an invention, then only the patent holder will be able to use the invention, thereby potentially creating a monopoly over the use of an invention for the duration of patent grant. This can have knock-on implications in terms of downstream access for individuals and for researchers who may need to use the patented invention to develop their own inventions. It could also impact on aspects including the price of the patented technology, which may exclude certain actors from using the upstream technology as even if patent holders are willing to license the technology the price may be too high. Moreover, if the patent holder chooses only to license with specific conditions, this will dictate how the technology will be used downstream. The way the patent is used also has the potential to impact the future development of that technology and related technology. For example, a patent holder could refuse to licence for a specific area of use, which could potentially lead to commercial developments in that area being abandoned for the duration of patent grant. This could in turn delay possible developments of a technology until after patents on an upstream technology have expired, or it could force other researchers to seek alternative ways to use their inventions. All of this could have knock-on adverse effects on health depending on the nature of the invention in question.

Indeed, arguably, in the biotechnology context given the nature of such technologies, the consequences of giving full control over patent use to a patent holder has expanded beyond what may have been envisaged when patent systems were developed in the industrial era. This must give us pause to consider the implications of patent holders' private governance role, and whether the extent of the discretion on patent use currently given to patent holders in the biotechnological context is still justified. Put simply, patents act as an incentive for technological developments, but it is questionable whether this justifies such full and unfettered control for patent holders over the invention for the duration of patent grant given the governance functions of patents, and particularly given the implications of this function for health-related biotechnologies which the article now turns to consider further.

Patent use—the good, the bad and the potential for ugly?

Having argued that patents act as private governance tools, this section now expands on the

[12] The author is particularly grateful to T.T. Arvind for his helpful comments on earlier versions of the article in this context.

[13] See *Jill Robbie, Private Water Rights (Edinburgh: Edinburgh Legal Education Trust, 2015)*.

consequences of patent holders having such discretion over use of a patented technology in the context of health-related biotechnologies. It demonstrates that patents can be exercised both in "good" or "bad" ways, by reference to potential effects of patent use on broader public interests in this context. However, there is always a potential for ill-effects depending on the patent holder's decisions, their enforcement strategy concerning patents, and the system within which the patents are applied. Given the significance of these consequences for how patented technologies are used downstream, and the constant residual *potential* for patent holders to use the discretion given to them by virtue of the patent grant in a way which leads to potentially adverse impacts upon human health, this section argues that greater consideration and oversight is needed over the largely unfettered control currently given to patent holders in this context.

The good—the rise of "ethical" licensing?

This section examines examples of where patent holders: (a) attach conditions to patent licences with third parties to curtail or restrict uses of a technology to encourage more "ethical" uses of a technology as defined by the patent holder,[14] and (b) patent licensing conditions which offer preferential access to specific groups, e.g. hospitals, researchers etc. Such endeavours are laudable and should be encouraged; however, two central difficulties arise: (1) it is questionable, given the likely conflicts of interests which will arise (depending on the nature of patent holders) how many patent holders will implement such policies; (2) even where "ethical" licensing conditions are adopted,[15] although such approaches may ostensibly be well-intentioned, it is questionable if patent holders (depending on the nature of the patent holder) are necessarily the appropriate actors to design, put in place or monitor such "ethical" conditions on patent use.

Ethical licensing conditions—the case of CRIPSR-Cas9

A recent example of the use of "ethical" licensing conditions relates to CRISPR-Cas9 gene editing techniques.[16] Licensing restrictions on the use of CRISPR-Cas9 technology by third parties were implemented by the Broad Institute to address ethical issues they thought pertinent around the technology.[17] In 2016, the Chief Business Officer of the Broad Institute, Issi Rozen, outlined key safety and ethical concerns which the Broad Institute had with CRISPR-Cas9 technology, and the Broad Institute committed to the following three conditions

[14] As noted, it is in this narrower sense that Sherkow and others have analysed patents as a form of private governance as "[b]y prohibiting uses the patent holder deems unethical, a patent license can function as a tool of private governance" see J.S. Sherkow, "Patent protection for CRISPR: An ELSI review" (2017) 4(3) Journal of Law and the Biosciences 565, 572.

[15] Christi J. Guerrini, Margaret A. Curnutte, Jacob S. Sherkow and Christopher T. Scott, "The rise of the ethical license" (2017) 35 Nature 22. There is also an increasing discussion of socially responsible licensing, which refers to broader policies to encourage patent holders to offer licensing on a socially responsible basis and thus is relevant to point (b), and licensing for preferential access, see: *Netherlands Federation for University Medical Centers, "Ten principles for Socially Responsible Licensing" (June 2019)*, see also discussion in: Jenilee M. Guebert and Tania Bubela, "Implementing Socially Responsible Licensing for Global Health: Beyond Neglected Diseases" (2014) 6 Science Translational Medicine 260.

[16] Guerrini, Curnutte, Sherkow and Scott, "The rise of the ethical license" (2017) 35(1) Nature 22.

[17] See https://www.broadinstitute.org/news/licensing-crispr-agriculture-policy-considerations [Accessed 25 June 2020].

on the licensing of such patented technologies in the agricultural context:

- *Prohibiting use of their licensed technology for gene drives*: "Gene drives" have been described by Sherkow as a "daisy chain of gene editing that essentially forces future generations to inherit and subsequently pass on only a single variant of a particular gene".[18] Gene drives are contentious because they are difficult to manage once started, and if it is discovered that a particular genetic variant has negative consequences for a population, it subsequently may be difficult to alter.[19]
- *Prohibiting use of their licensed technology to create terminator or sterile seeds:* These are seeds that are modified to terminate after one use and thus are not fertile the following year so farmers and others using them must buy seeds each year to produce crops.[20]
- *Prohibiting use of their licensed technology to modify tobacco for any use other than the following*: "(i) In the context of a model organism for research not directed to the commercialization of tobacco, and (ii) for manufacturing purposes of non-tobacco products."[21]

Examples of Broad's use of licences with such conditions included in them are evident between Monsanto and the Broad Institute,[22] and DuPont Pioneer and the Broad Institute.[23] These licences and conditions therein demonstrate both how patent holders can use patent licences to limit particular uses deemed to be ethically, or from a safety perspective, contentious. The clause imposed to limit the production of sterile terminator seeds also highlights how patent licensing conditions can be used to increase downstream access to by-products of a technology.

These actions of patent holders, such as the Broad Institute, are laudable and have the potential to have considerable positive effects. Having said this, the likelihood and appropriateness of patent holders *generally* developing such ethical licensing policies, however well intentioned, is open to question for two main reasons. First, the Broad Institute is

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[18] J.S. Sherkow, "Patent protection for CRISPR: An ELSI review" (2017) 4(3) Journal of Law and the Biosciences 565, 572

[19] Sherkow, "Patent protection for CRISPR" (2017) 4 Journal of Law and the Biosciences 565, 572.

[20] Terminator seeds have been highly contentious generally. For example, in 2000, the United Nations Convention on Biological Diversity (CBD) adopted Decision V/5 s.III, para.23, which recommended that state parties would not approve terminator seed technology (or genetic use restriction technology GURT) for field testing or commercial use. See https://www.cbd.int/doc/external/cop-08/ma-eco-2006-03-21-newsletter.pdf [Accessed 25 June 2020]. The de facto moratorium on use of GURTS was re-affirmed by the CBD in 2006. See discussion in *Michael Blakeney, Intellectual Property Rights and Food Security (Wallingford: CABI, 2009), p.181*.

[21] See https://www.broadinstitute.org/news/licensing-crispr-agriculture-policy-considerations [Accessed 25 June 2020].

[22] See *Sharon Begley, "Monsanto licenses CRISPR technology to modify crops — with key restrictions" (22 September), Stat News*.

[23] The licence also has restrictions excluding uses of CRISPR technology application for gene drives or tobacco products for human use. See https://www.broadinstitute.org/news/dupont-pioneer-and-broad-institute-join-forces-enable-democratic-crispr-licensing-agriculture [Accessed 25 June 2020]. Furthermore, the Broad Institute incorporates provisions for broader access to technology within its licensing policies: *David Cameron, "DuPont Pioneer and Broad Institute Join Forces to Enable Democratic CRISPR Licensing in Agriculture" (18 October 2017), Broad Institute News*, https://www.broadinstitute.org/news/dupont-pioneer-and-broad-institute-join-forces-enable-democratic-crispr-licensing-agriculture [Accessed 25 June 2020].

a peculiar institution, in that it is an academic non-profit institution,[24] and thus differs from many patent holders in the biotechnological space which tend to be for-profit commercial companies. Instead, the Broad Institute comprises an amalgamation of academic scientists, and collaborations between MIT and Harvard. It has as its core values "propelling the understanding and treatment of disease".[25] Thus, its work is embedded with an aim of addressing public health issues. Hence, the nature of the Broad Institute is, arguably, distinct from e.g., large pharmaceutical/biotechnological companies which tend to be many of the key patent holders in the biotechnological sector. Accordingly, while the Broad Institute, given its public interest motivations, may be willing to adopt ethical conditions on uses of patented technologies, as will be examined below, it is questionable whether other patent holders can or would be likely to do the same.

Second, the extent to which patent holders are the appropriate entities to draft and agree upon "ethical" conditions on patent use is questionable. The Broad Institute stated that it had decided upon the three restrictions listed above following consultations with "external experts and careful internal consideration", and that although many of these issues were:

> "under the oversight of federal agencies in the United States, including the USDA, FDA, and EPA. Still, the Broad feels it is important to include explicit restrictions in the technology licenses as well. We wanted to share our thinking with others who may be considering licensing of related technologies".[26]

This aim as noted is laudable; however, it could be problematic if applied to other technologies by other patent holders. The conditions the Broad Institute adopted were in line with issues being discussed around CRISPR in the scientific community and relatively non-controversial exclusions on use of CRISPR technologies. However, other patent holders are likely not to be mandated by public interests aims, may have strong profit maximisation aims and, in such scenarios, it is questionable whether for-profit patent-holding entities are appropriate entities to devise restrictions on patent use without any public or regulatory oversight, given the conflicts of interest which are likely to arise. Thus, whilst in theory it would be laudable that patent holders would attempt to consider and adopt conditions on licences for ethical purposes, in practice, such moves, depending on the patent holders, and how/if any consultation processes were engaged in, should give rise to caution.

These points are explored further in the subsection below, but suffice it to consider here, that if there appears to be a move towards uses of patent licensing conditions to shape downstream uses of technologies in a particular ethical direction, then there needs to be thorough consideration of what that ethical direction should be, and what entities are best placed to determine this. Arguably, many for-profit patent holders, despite their best intentions, would not be the most appropriate entities to do so alone, and instead such decisions would be better placed within a broader regulatory context.

Licensing to ensure broader access for technology

[24] See *Broad Institute, "Principles for the Dissemination of Scientific Research"*, https://www.broadinstitute.org/principles-disseminating-scientific-innovations [Accessed 25 June 2020].
[25] See https://www.broadinstitute.org/about-us [Accessed 25 June 2020]
[26] See https://www.broadinstitute.org/about-us [Accessed 25 June 2020].

Licensing can also be used to offer differential (often broader) access to specific groups. This is often done to provide free or lower-cost access for academic institutions or research organisations to the technology in question.[27] An example of this type of licensing was the legal settlement agreed by the Children's Hospital of Eastern Ontario (CHEO) in relation to Transgenomic's patents related to Long QT syndrome. The CHEO had instituted a legal challenge against Transgenomic, challenging the patents it held on isolated genes related to Long QT syndrome (a disease which can cause sudden young adult death). In doing so, it also challenged whether isolated genes generally are patentable in Canada.

On condition that the CHEO ceased such legal proceedings, Transgenomic agreed a licensing agreement with the CHEO to allow it to use diagnostic testing involving the patented genes associated with Long QT syndrome, without payment to Transgenomic. Transgenomic also agreed to enter into a similar agreement with other non-for-profit entities in Canada. This approach was considered a potential solution as a model agreement for use for other gene patent contexts in Canada to deliver access within the public health arena.[28]

Such strategies in theory could provide a useful compromise solution to public health concerns related to patents on biotechnology as on the one hand they allow patent holders to reap rewards from innovation and generate an income stream from private-for-profit uses of technologies, while on the other hand they ensure that public hospitals and other institutions can gain access to the technology. Having said this, these solutions are entirely at the behest of the patent holder; they are subject to the patent holder entering into them and are subject to the conditions the patent holder chooses to employ. The public hospital/academic institution/individual seeking to use the technology often has limited power in terms of negotiating with the patent holder, should the patent holder decide not to license or to impose stricter conditions around licensing. Moreover, the control given to patent holders in such contexts, without any overarching regulatory oversight scrutinising the content of such licensing agreements in order to recommend more favourable agreements for public or non-for-profit use, could give rise to significant health implications which will likely go largely unchecked for the duration of patent grant.[29]

The bad—monopoly control and refusal to license?

Alongside the above examples of attempts to offer "ethical" uses or broader access to patented technologies via licensing strategies, there are also examples of patent licensing which has potentially harmful effects on public access/use of technologies. Because patents give the patent holder the right to control others' use of that invention, such patent holders can refuse to license the technology, or only license it with restrictive conditions or at high prices. In

[27] See generally the *Broad Institute, "Principles for the Dissemination of Scientific Research"*, https://www.broadinstitute.org/principles-disseminating-scientific-innovations [Accessed 25 June 2020].

[28] See *Sarah Ali-Khan and Richard E. Gold, "Contracting to counter gene patents — a 21st Century solution to access and innovation" (22 May 2017), Petrie Flom Blog, Harvard Law School*, and *Julius Melnitzer, "Canadian patent dispute sets model for non for profit gene testing" (12 April 2016), Financial Post*.

[29] As noted above, there are moves to consider the voluntary adoption of socially responsible licensing practices which are also relevant in this context: see *Netherlands Federation for University Medical Centers, "Ten principles for Socially Responsible Licensing" (June 2019)*; see also discussion in Guebert and Bubela, "Implementing Socially Responsible Licensing for Global Health" (2014) 6 Science Translational Medicine 260.

some cases, this has the potential for significant effects on human health.

Myriad and gene patents

An example of a patent holder's ability to impose restrictions with significant potential health implications is Myriad's enforcement of its patent on isolated BRCA1 and BRCA2 genes in the United States (US). Individuals sought testing for mutations on BRCA1 and BRCA2 genes as such mutations can indicate a higher risk of developing certain cancers, particularly, breast and ovarian cancers.[30] If such risks were discovered some individuals would undergo preventive surgery to avoid or minimise the risk of developing breast/ovarian cancer. However, to carry out genetic testing one must isolate the BRCA1 and/or BRCA2 genes and Myriad argued that the isolation of the gene(s) and testing would infringe its patents. Accordingly, Myriad issued cease and desist letters to other laboratories who tried to provide genetic testing for mutations on BRCA1 and BRCA2 in the US.[31] As a result of Myriad's enforcement strategy of its patents, nine laboratories which were previously offering BRCA genetic testing in the US stopped doing so, and Myriad became the sole commercial provider of genetic testing for BRCA mutations in the US for a period of time.[32] Myriad did not licence other US laboratories to carry out initial genetic testing on BRCA1 and BRCA2.[33] Myriad's patent enforcement policy had five key impacts from a health perspective on individuals and for research, which include but also go far beyond issues of high costs of testing.[34]

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[30] Recent studies suggest that, in terms of breast cancer, approximately 72% of women who inherit a potentially harmful BRCA1 mutation and about 69% of women who inherit a BRCA2 mutation will develop breast cancer by the age of 80. The average risk in the general population for developing breast cancer is around 12%. For ovarian cancer, approximately 1.3% of women in the general population will develop ovarian cancer some time during their lives. In contrast with this, about 44% of women who inherit a BRCA1 mutation and about 17% of women who inherit a BRCA2 mutation will develop ovarian cancer by the age of 80. See K.B. Kuchenbaecker, J.L. Hopper, D.R. Barnes et al. "Risks of breast, ovarian, and contralateral breast cancer for BRCA1 and BRCA2 mutation carriers" (2017) 317(23) J.A.M.A. 2402; *N. Howlader, A.M. Noone, M. Krapcho et al. (eds), SEER Cancer Statistics Review, 1975–2014, National Cancer Institute, Bethesda MD*, https://seer.cancer.gov/csr/1975_2014/, as cited in https://www.cancer.gov/about-cancer/causes-prevention/genetics/brca-fact-sheet#r1 [Both accessed 25 June 2020].

[31] Richard E Gold and Julia Carbone, "Myriad Genetics: In the eye of the policy storm" (2010) 12 Genetic Medicine 39.

[32] Robert Cook Deegan, and Anne Niehaus, "After Myriad: Genetic Testing in the Wake of Recent Supreme Court Decisions about Gene Patents" (2014) 2(4) Curr. Genet. Med. Rep. 223, citing Gold and Carbone, "Myriad Genetics: In the eye of the policy storm" (2010) 12 Genetic Medicine 39; M.K. Cho et al., "Effects of patents and licenses on the provision of clinical genetic testing services." (2003) 5(1) J Mol. Diagn. 3; *S. Parthasarathy, Building Genetic Medicine: Breast Cancer, Technology, and the Comparative Politics of Health Care Inside Technology (Cambridge, MA: MIT Press, 2007), p.271*.

[33] It did license some laboratories to do more basic follow-up testing (where if one relative was diagnosed with BRCA1 or BRCA2 mutation their family member could ask for their genetic profile to be compared with an affected family members profile for around 1/10th of the cost. Myriad spilt revenues evenly with such laboratories performing this secondary single genetic mutation testing. However, this test was at a more basic level, and individuals may have wanted a broader test. Furthermore, it was of no benefit to anyone who did not have a family member already diagnosed with a BRCA1 or BRCA2 mutation. See Gold and Carbone, "Myriad Genetics: In the eye of the policy storm" (2010) 12 Genetic Medicine 39.

[34] These issues are examined in full in Aisling McMahon, "Gene Patents and the Marginalisation of Ethical Issues" (2019) 41(10) European Intellectual Property Review 608.

First, on the cost implications for diagnostic testing for mutations on BRCA1 or BRCA2, before the 2013 US decision which stated that isolated genes are not patentable in the US, BRCA1 and BRCA2 genetic tests provided by Myriad were costing approximately $2,200[35]—a price arguably influenced at least in part by the fact that Myriad at that time was the only commercial provider of the testing. Following the US decision excluding isolated genes from patentability in the US, competing providers of BRCA tests offered testing for $995.[36] There are arguments around the extent to which a patent influences costs, and this article does not seek to assert that patents are the sole cause of high drug and diagnostic testing costs. Instead, it merely argues that these figures support the argument that the role of Myriad's patent was at the very least *influential* in the price, as it allowed Myriad to control (and potentially limit) supply of the testing.

Second, Myriad's patent enforcement strategy in the US led it to become the sole commercial provider of genetic testing for BRCA1 and BRCA2 mutations; this meant that if individuals had used Myriad's services, obtained testing but were unsatisfied with the result, there was no alternative provider they could turn to. Instead, a patient's only option in such cases was to request a second test from Myriad. It was not possible to obtain another provider's opinion, hence this meant patients did not have access to an alternative avenue for a second opinion.[37]

Third, if only one provider exists, this can potentially cause shortages in the availability of testing, which can result in longer waiting times, or delays if the material must be sent away for screening. Fourth, there were questions in terms of whether other companies could provide better-quality testing, and whether Myriad was providing the best testing available.[38] Fifth, Myriad's patent enforcement strategies were alleged to have impacts on downstream research; for instance, Hawkins highlighted that gene patents have the potential to reduce research if researchers divert attention away from working on patented inventions owing to the fear of patent infringement claims.[39]

These issues remained in the US for the duration of Myriad's US patent on BRCA1 and BRCA2. Myriad filed for patents in relation to BRCA1 in 1994, and was granted key patents by the US Patents and Trademark Office (USPTO) in 1995 and 1998, and patents on BRCA2 were granted to Myriad in 1998 and 2000.[40] Myriad's gene patents were rejected by the US Supreme Court in 2013 which found that isolated genes could not be patented.[41] As a result of

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[35] Deegan, and Niehaus, "After Myriad: Genetic Testing in the Wake of Recent Supreme Court Decisions about Gene Patents" (2014) 2 Curr. Genet. Med. Rep. 223.

[36] *Jeremy Perkel, "Gene Patents Decision: Everybody Wins" (18 June 2013), The Scientist*, https://www.the-scientist.com/daily-news/gene-patents-decision-everybody-wins-39160 [Accessed 25 June 2020].

[37] See also discussion in Naomi Hawkins, "A red herring: invalidity of human gene sequence patents" (2016) 38 European Intellectual Property Law Review 83, which raises some interesting counter-arguments to the above concerns.

[38] These were raised in the plaintiffs claim in the Myriad US case.

[39] See discussion in Hawkins, "A red herring: invalidity of human gene sequence patents" (2016) 38 European Intellectual Property Law Review 83, 91 which raises counter-arguments. For a discussion of gene patents and patentability standards in Europe, see also Naomi Hawkins, "Human Gene Patents and Genetic Testing in Europe: A Reappraisal" (2010) 7(3) SCRIPTed 453.

[40] Gold and Carbone, "Myriad Genetics: In the eye of the policy storm" (2010) 12 Genetic Medicine 39.

[41] Association for Molecular Pathology v Myriad Genetics Inc, 569 U.S. 576 (2013).

the 2013 decision, Myriad could not continue to exert control over such testing for BRCA1 and BRCA2 mutations on the basis of their patents in the US. Nonetheless, the control Myriad exerted before this decision was extensive and ranged from at least 13 years and up to 18 years for Myriad's longest running patent on BRCA1 and BRCA2. Accordingly, Myriad had significant control over BRCA1 and BRCA2 diagnostic testing in the US context for a substantial period of time, with potentially significant health implications.

Moreover, the US case was decided on narrow patentability criteria, which thus only affects the patentability of the specific claims discussed in the case. The case was not considered based on potential human rights implications or the potential healthcare consequences arising from Myriad's patents and no special exemption is set out in this context. Thus, even after the US decision, Myriad initially (albeit unsuccessfully) sought to draw technical distinctions between its overlapping broader claims on BRCA1 and BRCA2 to argue that the case did not affect all of its patents and it would still have control over testing in some contexts.[42]

Furthermore, if similar health-related or broader ethical issues arise in future over a different type of patented technology, such patents would have to be challenged again in the US context, highlighting the narrow effect of this particular case. The limited self-correctional role of judicial/quasi-judicial decisions in the patent context is returned to in the subsection below. Nonetheless, this case study demonstrates, that patent holders' control over patent use and thus their private governance function over an invention, can have significant and multiple direct and indirect downstream effects on the provision of healthcare.

Patents and external influences on licensing

Aside from the above, there can also be broader external influences which affect patent holders' willingness to license a patented technology within a jurisdiction which have knock-on implications for access to that technology. A stark example of this is the way the patent over the drug RU-486 (now more commonly referred to as Mifepristone) was initially used in the US. This drug could be used in the early stages of pregnancy, up to a certain time-limit, to induce abortions, and meant that women seeking abortions in such cases could avoid surgical procedures. The drug was invented by Dr Etienne-Emile Baulieu, and the patent assigned to his employer French company Roussel-Uclaf, [43] whose German parent company was Hoechst.[44] Roussel-Uclaf refused to license the drug initially in the US. It had been targeted by anti-abortion protestors who sought to pressurise the company to discontinue the drug, and as a result the company and its parent company Hoecht were reportedly concerned with the potential backlash it could face if it provided a licence for the drug's use in the US.[45] The effect according to Allen was that:

> "Roussel-Uclaf used its U.S. patent rights to effectively prohibit any use of the pill within the United States, even though it was said that the pill could directly serve "health

[42] See Deegan and Niehaus, "After Myriad: Genetic Testing in the Wake of Recent Supreme Court Decisions about Gene Patents" (2014) 2 Current Genetic Medicine Reports 223.
[43] See John R. Thomas, "Liberty and Property in the Patent Law" (2002) 39 Hous. L. Rev. 569.
[44] See A. Dorozynski, "Boycott threat forces French company to abandon RU486" (1997) 314 B.M.J. 1150.
[45] See discussion in Scott A Allen, "Patents Fettering Reproductive Rights" (2012) 87(1) Indiana Law Journal 445, 457.

benefits … for millions of women worldwide." [46]

The decision not to license took place against a backdrop of other companies affiliated with similar reproductive technologies being boycotted in the US, including Upjohn's company, which was boycotted after it marketed FDA-approved Prostaglandins, a drug used to induce abortions.[47] The anti-abortion movement called for and sustained among supporters a boycott of Upjohn's other products for over two years in the US. Eventually, after sustained boycotts and pressure from shareholders, Upjohn stopped its research and production of such drugs.[48] Thus, Roussel-Uclaf arguably had a well-founded fear of the economic impact that providing the drug in the US context would have had at that time. Nonetheless, in refusing to license the drug in the US, where abortion was legally available at the time, this effectively prohibited all uses of the drug in that jurisdiction with significant implications for many women. [49] Accordingly, women who could have benefited from non-surgical abortions in the US at the time did not have access to this drug as the company refused to license it. Consequently, although the drug was developed in 1982 in the French context, it was not until 1994, after considerable negotiation and an executive order from President Clinton,[50] that the drug was licenced to Population Council a not-for-profit group for use in the US.

Crucially, this case-study demonstrates the broader influences patent holders are susceptible to, highlighting that decisions on whether to licence a patented technology or not may be influenced by a range of broader socio-legal and economic factors which may be antagonistic to other broader interests at stake.[51] This example shows the serious implications of the control that patents give patent holders over an invention: in the above case all downstream access to the drug was effectively delayed and halted for many years. Indeed, it was only the subsequent agreement of the patent holder, and actions of the Government and Population Council in actively seeking to bring access to the drug which made it possible to do so. Moreover, this might not even have happened if "more politically conservative individuals controlled Roussel Uclaf".[52] Patents could also be deliberately used to obstruct access to

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[46] Scott A. Allen, "Patents Fettering Reproductive Rights" (2012)87(1) Indiana Law Journal 445, 457, citing Mindy J. Lees, "I Want a New Drug: RU-486 and the Right to Choose" (1990) 63 S. Cal. L Rev. 1113, 1122, at 1127 (quoting *Rone Tempest, "French Drug Firm Bows to Protest, Halts Abortion Pill" (27 October 1988), LA Times, 1988, Pt. I, at p.12, col.1*).

[47] Allen, "Patents Fettering Reproductive Rights" (2012) 87 Indiana Law Journal 445, 457.

[48] Lees, "I Want a New Drug: RU-486 and the Right to Choose" (1990) 63 S. Cal. L. Rev. 1113, 1122 at 1123 cited by Allen, "Patents Fettering Reproductive Rights" (2012) 87 Indiana Law Journal 445, 452.

[49] See Allen, "Patents Fettering Reproductive Rights" (2012) 87 Indiana Law Journal 445, 457, citing Lees, "I Want a New Drug: RU-486 and the Right to Choose" (1990) 63 S. Cal. L. Rev. 1113, 1127 (quoting *Tempest, "French Drug Firm Bows to Protest, Halts Abortion Pill" (27 October 1988), LA Times, 1988, Pt. I, at p.12, col.1*,).

[50] See Allen, "Patents Fettering Reproductive Rights" (2012) 87 Indiana Law Journal 445, 457, noting that one of President Clinton's first official acts as president was to issue a memorandum directing the FDA to analyse RU-486. See Memorandum on Importation of RU-486, 29 Weekly Comp. Pres. Doc. 57, 89 (22 January 1993).

[51] It is conceded that there is no international consensus in relation to access to abortion generally. However, in the US context, laws provided access to abortion since Roe v Wade 410 U.S. 113 (1973). Thus, the effect of the patent holder's action was that individuals had to have invasive surgical procedures which had potentially greater risks for them, than being able to access abortion pills (where clinical use may have been indicated and where no legal barriers to providing access to abortion generally were evident in the US at that time).

[52] Indeed, Prof Thomas goes further and argued that: "The possibility of an anti-abortion group purchasing such a patent and using it to restrict access to the claimed invention is a real one." John R. Thomas, "Liberty and Property in the Patent Law" (2002) 39 Hous. L. Rev. 569, 582.

contentious technologies, as Thomas argues the possibility, for example, of anti-abortion groups seeking to acquire patents over abortion drugs in order to block access is a real one.[53]

It is acknowledged that this is not a case study involving biotechnological inventions per se; however, the example is used here, as a similar scenario could easily arise related to health-related biotechnologies. It demonstrates the sheer weight of patent holders' private governance role over the patented invention, and the fact that patent holders' discretion in such contexts can be affected by a multitude of factors which can have significant potential effect on delivery of and access to healthcare. This lack of oversight over the governance function of patents—even where it directly blocks technological use—is highly questionable in such contexts.

The potential for ugly?

Based on the foregoing, the article argues that the extent of control patents divest to patent holders which they exercise in a largely unfettered manner (albeit only for the duration of patent grant) creates a residual potential for ugly—that is, the potential for adverse effects on the development or access to patented inventions downstream due to patent holders decisions/discretion on patent use. Furthermore, once the patent is granted, how the patent holder uses the invention through licensing is currently difficult to even trace, given that patent licences are often not published, and when licences contain commercially sensitive data they may be redacted. This lack of transparency in patent licensing means that it is also hard to scrutinise patent use and to investigate the effects of licensing conditions on the development of downstream technologies or the knock-on potential effects of this on broader interests such as public health. As has been argued, the potential for significant adverse effects arising from decisions on patent use in the context of health-related biotechnologies lends greater weight to the argument that it is time to reconsider patent holders' governance role and consider whether oversight is needed over patent holders' discretion on patent use in such contexts.

Patent grant, challenge and compulsory licensing—a self-reinforcing cycle

The significance of the largely unfettered control which patents give to patent holders is compounded by the lack of other checks on patent use in the patent system, specifically: (a) the lack of oversight over potential ethical issues arising from patent use at grant stage; (b) the limitations within the system for patent challenges which means there is limited self-correctional effect within patent litigation; and (c) the (traditionally) limited/exceptionalised role of compulsory licensing within the patent context. This part expands on each of these points below in turn, making the argument that, taken together, they act as a self-reinforcing cycle maintaining patent holders' governance role and limiting the scope for external scrutiny over patent holders' discretion.

In short, the light touch approach to ethical issues at grant stage, together with the difficulties imposed in raising legal challenges to patents post-grant, and finally the exceptionalised nature of compulsory licensing, operate together to mean that patent holders or patent applicants

[53] Thomas, "Liberty and Property in the Patent Law" (2002) 39 Hous. L. Rev. 569, 582

uses of patented technologies downstream are insulated from broader scrutiny. Given the potential adverse effects that can arise from patent use as outlined in the second part and the extent of the power given to patent holders by virtue of the patent right, this control and lack of scrutiny arguably needs to be fundamentally reconsidered.

Patent grant—limited ethical oversight

Most patent systems contain limited avenues to consider human rights or health-related issues posed by patent grant/use at grant stage, and even when such avenues are evident such as in Europe, they have tended to be used in a light-touch manner providing a minimal gate-keeping role to limit patents on technology where patentability is likely to pose ethical issues. Thus, the potential effects of patent grant and use, by virtue of the nature of the technology that patents are granted over, comes under limited/no scrutiny (depending on the jurisdiction) at the grant stage.[54]

This article is not seeking to make an argument for broader ethical scrutiny at grant stage per se. Instead, it is arguing that this lack of scrutiny at grant stage strengthens the justification for greater oversight on how patents are used post-grant, as otherwise the limited scrutiny at both grant stage and post-grant act as a self-reinforcing cycle insulating the potential uses/effects of patents from broader external scrutiny.

To demonstrate this argument, this section takes the European context as a case study because, unlike many jurisdictions, it has express morality provisions built into its patent grant process,[55] which means that patents shall not be granted on inventions if their commercial exploitation is against ordre public or morality. Europe is therefore arguably the most likely of many patent jurisdictions to engage with the ethical considerations around patent grant over health-related biotechnologies. However, as will be seen even within Europe, the European Patent Office (EPO) places limited salience on such morality provisions in practice.[56] Accordingly, if in Europe, where there are express avenues to take into account such considerations in patent law, yet it fails to do so, there is nothing to suggest that other jurisdictions would consider such issues at grant stage.[57]

European patent framework—a space for ethical considerations

[54] See also *T.T. Arvind and Aisling McMahon, "Commodification, control, and the contractualisation of the human body" in Elodie Bertrand, Marie-Xavière Catto and Alicia Mornington (eds), The Limits of the Market: Commodification of Nature and Body (Paris: Mare & Martin, 2020)*, where we argue that inventions regardless of their nature are treated as fungible within the patent system.

[55] In particular, see art.53(a) European Patent Convention, and art.6(1) Biotechnology Directive 98/44, the "general morality provision'" which provides that inventions shall not be patentable where their commercial exploitation is against ordre public or morality.

[56] In the US context, see: MA Bagley, 'Patent first, ask questions later: morality and biotechnology in patent law' (2003) 45(2) William Mary Law Rev. 469. For an interesting broader argument on the scope of patent holders' power, see *Margaret Llewelyn, "Schrodinger's cat: an observation on modern patent law"* in Peter Drahos (ed.) Death of Patents (Oxton: Lawtext Publishing, 2005).

[57] The TRIPS Agreement art.27(2) provides that: "Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law."

Under the TRIPS Agreement,[58] States *may* deny patents if their commercial exploitation is against o*rdre public* or morality,[59] but many jurisdictions do not have express provisions denying patents on the basis of morality/ordre public. In Europe, art.53(a) of the European Patent Convention (EPC) states that inventions *shall not* be patentable if their commercial exploitation is against ordre public or morality (emphasis added),[60] and this provision applies to all categories of inventions. This provision is replicated by the EU's Biotechnology Directive 98/44, and the Directive also introduced four specific categories of inventions which were expressly excluded from patentability on this basis.[61] The Directive makes express reference to the need to take human dignity into account in decisions on patenting,[62] and the importance of abiding by human rights instruments in patenting decisions.[63] Following the adoption of the EU Biotechnology Directive, the European Patent Organisation (EPOrg) voluntarily aligned its provisions with the Directive by incorporating these provisions into the EPOrg's Implementing Regulations,[64] and the EPOrg adopted the Directive as supplementary interpretation for the EPC.[65] Thus, in practice, the European Patent Office (EPO) can refer to the Directive when assessing the patentability of biotechnological inventions and hence can also rely on the four exclusions from patentability and the need to protect human rights and dignity, etc. when making decisions on patent grant.

This overlap between EU and EPC systems is significant, as the EPO acts as the patent-granting body for all patents applied for in EU States when the applicant applies via the EPO route.[66] However, to date, the EPO has adopted a very light touch approach to the

[58] The TRIPS Agreement must be adopted by all WTO Members; currently 164 States are party to it.

[59] TRIPS art.27(2).

[60] The EPC is applicable in 38 states, including all EU Member States. It is administered by the European Patent Organisation (EPOrg), an international body not part of the EU legal framework.

[61] See Biotechnology Directive 98/44 art.6(2).

[62] Recital 16 states that: "Whereas patent law must be applied so as to respect the fundamental principles safeguarding the dignity and integrity of the person; whereas it is important to assert the principle that the human body, at any stage in its formation or development, including germ cells, and the simple discovery of one of its elements or one of its products, including the sequence or partial sequence of a human gene, cannot be patented; whereas these principles are in line with the criteria of patentability proper to patent law, whereby a mere discovery cannot be patented"; Recital 38 states that "Whereas the operative part of this Directive should also include an illustrative list of inventions excluded from patentability so as to provide national courts and patent offices with a general guide to interpreting the reference to ordre public and morality; whereas this list obviously cannot presume to be exhaustive; whereas processes, the use of which offend against human dignity, such as processes to produce chimeras from germ cells or totipotent cells of humans and animals, are obviously also excluded from patentability."

[63] Recital 43 states that: "Whereas pursuant to Article F(2) of the Treaty on European Union, the Union is to respect fundamental rights, as guaranteed by the European Convention for the Protection of Human Rights and Fundamental Freedoms signed in Rome on 4 November 1950 and as they result from the constitutional traditions common to the Member States, as general principles of Community law."

[64] Implementing Regulations to the EPC rr.28 and 29.

[65] See *European Patent Office, Patent Examiner's Guidance, para.5.2*

[66] Under this process, an applicant can apply for a patent to the EPO designating as many of the 38 EPC Contracting States as they wish and if granted the patent is refracted into a bundle of national patents whose post-grant life is dealt with separately under each jurisdiction. This means that the EPO patent examining office has a significant role in applying the patentability criteria and in taking decisions on whether inventions should be excluded based on the morality provisions or other criteria for all states party to the EPC states including all EU Member States. Many applicants choose to use the European route rather than merely applying individually to each national state because it is a quicker and more convenient way to obtain patents in multiple European jurisdictions. For an overview of this process, see Aisling McMahon, "An Institutional Examination of the Implications of the Unitary Patent Package for the Morality Provisions: A Fragmented future too Far?' (2017)

morality provisions. In relation to the general morality provision in art.53(a), the EPO has consistently both before and after the Directive's adoption made express statements which highlight its perception that the EPO should have a limited, if any role in this context. In Howard Florey/Relaxin,[67] decided before the introduction of the Biotechnology Directive, the EPO stated that whether

> "Human genes should be patented is a controversial issue on which many persons have strong opinions … *[T]he EPO is not the right institution to decide on fundamental ethical questions*."

It stated that it was only inventions which would be "universally be regarded as outrageous" that should be denied patentability based on the morality provisions. Its approach did not change even after the Directive was introduced, even though at least on paper the Directive adopts a broader approach to the morality provisions and to incorporating human rights and dignity concerns within patent law. In Leland Stanford,[68] the EPO stated that the "role of the EPO was not to act as a moral censor",[69] and the purpose of art.53(a) was to deny patents on technology relating to extreme subject-matter such as letter bombs and anti-personnel mines, which "would be regarded by the public as so abhorrent that the grant of a patent would be inconceivable".[70] Other decisions of the EPO demonstrate a similar reluctance to apply the morality provisions to deny patent grant: the thresholds applied are exceptionally high, and the EPO decisions suggest a pre-disposition towards granting patents and against EPO involvement in decisions of an ethical/moral nature in terms of patent grant.[71]

Moreover, even in the context of the four express exclusions from patentability within the Directive under art.6(2), to date these have only successfully been used to challenge patents in cases concerning human embryonic stem cells (hESC) technology, where the EPO has denied patents.[72] However, in doing so, the EPO merely applied a definitional test—of whether the technology claimed under the patent fell within the definition of an excluded invention in art.6(2)(c) as this was defined as excluded from patentability by the Directive in 1998. However, such cases do not necessarily suggest that the EPO has changed its practices in the context of the general morality provision to scrutinise technologies not falling within the four defined excluded categories in art.6(2) in greater depth than previous cases suggest.[73]

48(1) IIC International Review of Intellectual Property and Competition Law 42.

[67] Howard Florey/Relaxin [1995] E.P.O.R. 541.

[68] Leland Stanford [2002] E.P.O.R. 2.

[69] Leland Stanford [2002] E.P.O.R. 2 at [23].

[70] Leland Stanford [2002] E.P.O.R. 2 at [23].

[71] EPO decisions on the application of art.53(a) EPC include: Harvard/Onco-Mouse [1989] OJ EPO 451; [1990] OJ EPO 476; [1992] OJ EPO 588; [2003] OJ EPO 473; [2005] OJ EPO 246; Lubrizol/hybrid plants [1990] E.P.O.R. 173; Plant Genetic Systems/Glutamine Synthetase Inhibitors (Opposition by Greenpeace) [1995] E.P.O.R 357; University of Utah Research Foundation T0666/05, Technical Board of Appeal, 13 November 2008.

[72] For decisions of the EPO involving human embryonic stem cells, see: Case T1079/03 Edinburgh University (Unreported) [2003] OD EP 94913174.2; Case T522/04 California Institute of Technology (CIT) (Unreported) [2003] ED EP 93921175.1); Wisconsin Alumni Research Foundation (WARF) (G002/06), Decision of the Enlarged Board of Appeal of 25 November 2008; TECHNION/Culturing stem cells [2014] E.P.O.R. 23; ASTERIAS/Embryonic stem cells [2015] E.P.O.R. 9.

[73] The EPO also demonstrated a dearth of analysis and arguably is simply not institutionally equipped to apply the morality provisions in the way in which encompass a consideration of broader human rights and dignity issues (as appears envisaged by the Directive) without institutional change. See Aisling McMahon, "The Morality Provisions in the European Patent System: An Institutional Examination" (PhD Thesis, University of Edinburgh,

Furthermore, these four specific exclusions from patentability were defined by the Directive in 1998, and science has moved on significantly since then, to the extent that much discretion is now left to the EPO when called upon to interpret these provisions in relation to how they apply to current technological developments/inventions.[74]

Thus, the general morality provision is interpreted in a very light touch manner, rarely used to deny patents in practice, and the specific exclusions, have been used to deny patents but only, for example, in the context of hESC related inventions where a definitional test applies. Therefore, scrutiny at grant level appears to only have effect where technologies fall within definitions of excluded inventions in Art 6(2) and science has also moved on since such inventions were defined giving greater discretion to the EPO in how such provisions are defined. The effect is that the text of such specific provisions in Art 6(2) is failing to keep apace of scientific developments and becoming outdated in terms of ethical concerns around patentability of currently contentious emerging biotechnologies. Hence, the morality provisions (the general and specific exclusions) in the European context are currently of limited practical force in terms of providing scrutiny at grant stage over potential adverse or contentious uses of patents or patented technologies downstream.

Patent challenges—limited self-correctional effects

Alongside the limited checks on the basis of morality/ordre public at patent grant stage, this subsection argues that judicial/quasi-judicial challenges to patents post-grant also often have a limited effect in providing oversight over patent holders' control. Litigation to challenge patents is extremely costly and can take a long time. Moreover, if the patent one is challenging is owned by a large company or multi-national corporation, as noted, they are likely to have deeper pockets and more access to legal expertise and time than most companies/individuals who may be motivated to challenge a patent on the basis of its implications from a public health perspective. Indeed, in recent high-profile cases involving gene patent challenges in the US,[75] Canada[76] and Australia,[77] the lawyers involved in all cases worked on a pro-bono

2016). However, this discussion is beyond the scope of this current article. See also Aurora Plomer, "Human Dignity and Patents" in C. Geiger (ed.), Research Handbook of Human Rights and IP Rights (Cheltenham: Edward Elgar, 2015), p.493.

[74] For example, see art.6(2)(b), which excludes patents on "processes for modifying the germ line genetic identity of human beings". It is questionable to what extent this provision should be implicated in the context of e.g. CRISPR gene-editing technologies, although there is also evidence of careful drafting/approval of patent claims to avoid/restrict claims for methods involving uses of CRISPR-Cas9 in relation to the human germline: For a discussion of CRISPR gene editing, human rights and patenting see: Duncan Matthews, "Access to CRISPR Genome Editing Technologies: Patents, Human Rights and the Public Interest" (May 2020), Queen Mary School of Law Legal Studies Research Paper No.332/2020, SSRN, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3595392 [Accessed 25 June 2020]. For a discussion of patenting of CRISPR Cas-9, including the application of the morality provisions, see: A. Nordberg et al., "Cutting edges and weaving threads in the gene editing (Я)evolution: reconciling scientific progress with legal, ethical, and social concerns" (2018) 5 Journal of Law and Biosciences 35.

[75] Association for Molecular Pathology v Myriad Genetics, Inc., 569 U.S. 576 (2013).

[76] Children's Hospital of Eastern Ontario (CHEO), challenge of Transgenomic patents: see *Julius Melnitzer, "Canadian patent dispute sets model for non for profit gene testing", Financial Post (12 April 2016)*.

[77] D'Arcy v Myriad Genetics Inc [2015] HCA 35.

basis.[78] While such cases show how interested parties opposition to patents can assist in successful challenges, they are nonetheless likely to occur as an exception to the norm rather than the norm, as it is arguably relatively rare for patents to capture the public interest in the way that gene patents and Myriad's actions did. It is also likely to be relatively rare that legal teams can work on such issues on a pro-bono basis.

Furthermore, depending on the rules of legal standing in a given jurisdiction, in order to challenge a patent, the opposing party may need to prove a direct interest or harm arising as a result of a patent, and it may be difficult to find a challenger who fulfils the criteria to establish legal standing in a given case.[79] Moreover, in the health context, public hospitals are likely to be the most affected and aware of the effects patents have on the provision of treatment/care but generally hospitals have limited budgets that already have to be carefully rationed to provide patient care. Such budgets do not extend to challenging patents, and it would be understandably difficult to convince hospital committees or management boards otherwise. The likely outcome of hospital funding being used for patent litigation is an opportunity cost of spending on patient care which, even if the challenge was successful, is likely to be difficult to justify and could mean in the short term that funding for other treatments would need to be reduced if some of the hospital budget goes on litigation. Moreover, hospital legal teams generally are not experts in patent law, and instead would be more likely to be specialised in medical negligence litigation etc; thus the expertise to challenge patents or to know when challenges may be possible is also arguably potentially lacking in many such contexts.

Finally, conflicts may arise in terms of university teaching hospitals challenging patents or uses of patents in a particular way; this is because universities often hold many patents or have spin-off companies that hold patents, which in turn may be affected by patent challenges brought by the university. Accordingly, conflicts of interests may arise which would compromise universities or university teaching hospitals in challenging patents. Moreover, as in the public hospital context, many universities as publicly funded institutions have limited budgets which generally must be exercised primarily towards educational ends. For these reasons, judicial challenges, or challenges via relevant patent offices over patents are likely to be rare and arguably provide limited self-correctional effects on the broader ethical issues posed by patent grant and patent use.[80]

Compulsory licensing—an exceptionalised landscape?

Finally, the main avenue currently which allows checks on patent use post-grant is via compulsory licensing, whereby under certain circumstances governments can impose a compulsory licence on the patent holder, thereby allowing the Government itself, or the Government to give a third party permission to use/produce the patented technology without

[78] In the US ACLU were involved; in Australia, Maurice Blackburn solicitors became involved; and prior to this, the applicant Yvonne D'Arcy had re-mortgaged her house and secured funding from Cancer Voices Australia to pursue the challenge, while in Canada a number of lawyers acted pro-bono to support the Children's Hospital of Eastern Ontario's challenge. See discussion in McMahon, "Gene Patents and the Marginalisation of Ethical Issues" (2019) 41(10) E.I.P.R. 608.

[79] For a discussion of the US context, see: Megan M. La Belle, "Standing to Sue in the Myriad Genetics Case" (2011) 68 The Circuit 46.

[80] This is examined in further detail in McMahon, "Gene Patents and the Marginalisation of Ethical Issues'"(2019) 41(10) E.I.P.R. 608.

the patent holder's consent. However, as will be discussed, the nature of this mechanism, together with the way the criteria for its use has been interpreted and challenged, mean that in practice it is often seen as an exceptional measure.[81]

Compulsory licences are provided for under art.31 of the TRIPS Agreement. This provision allows for the use of the patented invention without the patent holder's consent by the Government or a third party authorised by the Government. The main conditions for compulsory licences as set out in art.31 of TRIPS are that: (1) Each decision on a compulsory licence is considered on its individual merits—thus, a blanket licence for a particular field of technology, e.g. medicines, cannot be granted; (2) Compulsory use is only permitted if the proposed user previously took reasonable steps to obtain a license on reasonable commercial terms/conditions but such steps were unsuccessful within a reasonable period of time. Notably, this requirement can be waived in the context of a national emergency, extreme urgency, or where the invention is intended for public non-commercial use. Thus, compulsory licences are available in any context, including contexts that are not emergency scenarios, provided the Government has taken steps to seek a licence on fair and reasonable terms.[82] However, in an emergency context, the requirement of having to show that the Government sought a licence on fair and reasonable terms is waived. Yet, in practice, compulsory licences are sometimes perceived as only being available in the emergency context, which is a common misunderstanding, as acknowledged by the World Trade Organization (WTO);[83] (3) The scope and duration of use shall be for the limited purposes it was granted for; (4) Such use shall be non-exclusive; (5) Generally, compulsory licences are granted for uses to supply predominantly the domestic market of that state. However, there have been reforms which allow use to supply another state where that second state needs a patented invention produced via a compulsory order but does not have the domestic manufacturing capacity to produce it itself;[84] (6) The patent holder must be given adequate renumeration in each case taking account the economic valuation of the authorisation.

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[81] At the time of writing, compulsory licensing is obtaining greater traction in the Covid-19 pandemic context, with many countries adopting measures to allow for compulsory licensing if needed on future potential treatments/vaccines for Covid-19; see Justin Hill, "The key covid-19 compulsory licensing developments so far" (7 April 2020), IAM, https://www.iam-media.com/coronavirus/the-key-covid-19-compulsory-licensing-developments-so-far [Accessed 25 June 2020]. However, it remains to be seen if this discussion of the use of compulsory licensing in the Covid-19 context will start a broader change around how compulsory licensing is viewed generally within the international patent community, and will lead to change in the post-Covid-19 context, or if such moves will be confined to the Covid-19 emergency context. It also remains to be seen, how (if at all) compulsory licensing will be used in this context once effective potential treatments/vaccines for Covid-19 are (hopefully) developed.

[82] Recently, there have been threats for use of compulsory licences in non (public health) emergency contexts, such as in the context of Orkambi in the UK; see Francesca Burke, "Orkambi drug for cystic fibrosis in UK context: Compulsory License on Table in UK for Orkambi", Pinksheet (13 June 2019). The UK Labour party also pledged that it would use compulsory licensing to access patented drugs at lower prices if successful in the UK election; see Labour Party, Medicines for the Many: Public Health before Private Profit (1 September 2019), p.21; see also Elisabeth Mahase, "Drug pricing: Could Labour's 'radical' plan work?' [2019] B.M.J. 367. However, by and large, compulsory licensing in practice has traditionally often been presented as a relatively exceptionalised tool.

[83] This is acknowledged by the WTO: see https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm. See also the discussion on this in Ellen t'Hoen, "The Most Common Misunderstanding about Compulsory Licensing" (25 May 2017).

[84] Doha Agreement para.6. See also Doha Reforms art.31(f) TRIPS.

Three main issues arise in relation to compulsory licensing in terms of its role in providing oversight on patent use at the post grant stage. First, compulsory licensing is often perceived as a relatively rare measure which is exceptional in its use rather than being perceived as a measure which could be routine in providing a check on patent use.[85] This article is not arguing that compulsory licensing should necessarily be a routine check for all patents;[86] instead, the point here is the fact that it is clearly not considered as routine in practice highlights that at least currently it does not fulfil an oversight role over patent use more generally.

Second, using compulsory licences was traditionally received with considerable push-back from industry and other parties.[87] For example, compulsory licences issued by India, Brazil and Thailand came under considerable backlash from the US and within Europe.[88] The US in particular has listed countries which have granted compulsory licences on a priority list of foreign countries that are judged to have inadequate intellectual property protections by the Office of the United States Trade Representative (USTR) Special 301 Report. This has resulted in some countries being placed on a watch list by the US for failing to provide adequate intellectual property protections, and comes with the threat of possible trade sanctions. Furthermore, traditionally many countries which issued compulsory licences faced legal challenges (or threatened challenges) against the acceptability of compulsory licences.[89] This push-back arguably suggests a traditional normative conception that patent holders by virtue of the grant of a patent should have absolute discretion over use of the patented technology with limited or no interference with this, and a perception that compulsory licences in interfering with this discretion are or should be exceptional or last resort in nature.[90]

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[85] Compulsory licensing is "not frequently" used within the EPO States; see *European Patent Academy, Compulsory Licensing in Europe (December 2018)*.

[86] The author is not opposed to the use of compulsory licences in this way, but it would require extensive institutional change within patent law, which may be difficult to achieve. Moreover, making a broader claim for compulsory licensing to be routine is beyond the scope of this article, and is not necessary for the purposes of the more discrete arguments made here for greater consideration and oversight over patent holder's governance role for health-related biotechnologies.

[87] Hembadoon Iyortyer Oguanobi, "Broadening the conversation on the TRIPS agreement: Access to medicines includes addressing access to medical devices" (2018) 21 Journal of World Intellectual Property 70.

[88] See C.T. Scopel and G.C. Chaves, "Initiatives to challenge patent barriers and their relationship with the price of medicines procured by the Brazilian Unified National Health System" (2016) 32 Cad Saude Publica 121; *S. Tantivess, N. Kessomboon and C Laongbua, "Introducing government use of patents on essential medicines in Thailand, 2006–2007: policy analysis with key lessons learned and recommendations" (Nonthaburi: International Health Policy Program, 2008)*; *Z. Siddiqiu, "India defends right to issue drug 'compulsory licenses'" (23 March 2016), Reuters*, as cited in E. t'Hoen et al, '"Medicine procurement and the use of flexibilities in the Agreement on Trade-Related Aspects of Intellectual Property Rights, 2001–2016" (2018) 95 Bulletin of the World Health Organisation 185, 189.

[89] See also discussion in Duncan Matthews, "WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: A Solution to the Access to Essential Medicines Problem?" (2004) 7(1) Journal of International Economic Law 73.

[90] T'Hoen and others have argued that: "However, their use [TRIPS flexibilities including compulsory licensing] should not be regarded as a measure of last resort because they can be considered for the routine procurement of generic versions of expensive, new, essential medicines, while providing adequate remuneration to the patent holder." in t'Hoen et al., "Medicine procurement and the use of flexibilities in the Agreement on Trade-Related Aspects of Intellectual Property Rights, 2001–2016" (2018) 95 Bulletin of the World Health Organisation 185, 190. Arguably, there is considerable merit in this view; however, as noted, this particular argument is beyond the scope of this current article.

Third, arguably compulsory licensing as traditionally conceived of and used is too blunt a tool in terms of what it can do over patent holder's discretion to be used as a general measure of oversight which is suggested as needed by this article. Using a compulsory licence one can merely grant a licence for use of that patent—which is directed primarily at addressing access issues related to that patented technology. However, compulsory licensing as understood in this traditional sense is not a tool that has been used to vary, recommend or question broader terms of existing licences or patent holders' general practices on licensing. Instead, while compulsory licences could be part of an approach in terms of offering oversight over patent holders' discretion on patent use (and this would require reframing traditional perceptions of how compulsory licences are used, moving away from the perception of such licences being a device of last resort), further measures are needed in the biotechnological sphere to address the arguments made in this article.

Interim reflection: patent grant and oversight—a self-reinforcing cycle?

Based on the foregoing, it has been argued that patent holder's power or discretion is entrenched by how systems of patent grant, patent challenge and compulsory licensing operate. Patent grant offers minimal scope for consideration of the potential effects of patent use including, ethical issues that may arise, or, for example, effects of patent use on health. Moreover, patent challenges are difficult to resource, given the costs and time involved. There are also difficulties in finding suitable litigants who may challenge patents, and even where successful, decisions tend to be narrowly framed, meaning that future challenges are needed if technologies develop and new issues arise.[91] Furthermore, the compulsory licensing system is arguably often exceptionalised in its operation in practice. Thus, considered together, the patent grant, patent challenge and compulsory licensing stages mean that a self-reinforcing cycle is evident whereby ethical issues are given minimal oversight at patent grant stage, patents are also difficult to challenge at post-grant stage in practice, and it is relatively rare that compulsory licences are granted. In effect, this means that patent holders currently have (virtually) absolute control over use of the patented invention and its trajectory for the duration of patent term, with limited oversight with patent holder's discretion.[92]

Conclusion

The article has argued that patents, alongside their economic function, also have a significant private governance function. Patents give patent holders a right to control the use of an invention, and the patent holder can use this right to decide to license or refuse to license that invention in ways which could significantly shape the downstream development of that patented invention, and also related technologies, for the duration of patent grant. Effectively, a patent holder's discretion on patent use, depending on the nature of the patented invention, has the potential to dictate how multiple related downstream technologies are used and developed, and potentially how an entire field of technology operates downstream for the duration of the patent.

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[91] McMahon, "Gene Patents and the Marginalisation of Ethical Issues" (2019) 41(10) E.I.P.R. 608.

[92] It is acknowledged that regulatory systems may prohibit use of a particular technology, which will mean that no one including the patent holder can use that technology, but this is a relatively rare circumstance in practice.

Furthermore, patents holders' decisions can have significant consequences in the health-related biotechnological context, with the potential to cause significant adverse implications for individual access to healthcare and public health more generally. Moreover, as has been demonstrated, even though some patent holders may seek to license technologies in a socially beneficial or responsible manner, they are not mandated to do so, and there is always a residual potential for patents to be used in a way that has harmful effects on the public interest in terms of restricting technology development downstream, or creating issues around access to a patented invention. In making such arguments, the article does not purport to make the broader claim that patent use should exclusively align with the public interest in all contexts. Instead, it argues that, if so much power is being given to patent holders, it behoves us to question what external control/scrutiny is, or should be, exercised over this power particularly where potentially significant implications can arise as a result of patent holders licensing practices (or failure to license) in the biotechnological context.

Despite such potential consequences, currently the grant of a patent comes with limited avenues for external scrutiny over how patented inventions are licensed. In effect, once a patent is granted, the patented invention falls within the remit of the patent holder's discretion, and patent holders effectively become private governors of that invention for the duration of patent grant. There are also limited avenues to interfere with patent holders' decisions on licensing via public regulation. Furthermore, given that patent licences are often not published, it is difficult to question the terms upon which such licences are granted, or conditions within such licences, instead an opaque private governance system operates.

The need for oversight at the post-grant level is further compounded, given that other elements of the patent system operate to create a self-reinforcing cycle maintaining a patent holder's position of power, whereby ethical issues related to patent grant and use are given minimal, if any, scrutiny at grant stage. Furthermore, mechanisms for challenging patents post-grant are restrained by institutional obstacles, such as finding adequate resources or ascertaining suitable individuals who will have standing and interest to challenge patents. Moreover, even where successful, patent challenges are often decided based on narrow technical applications of patent law, which means that legal challenges may have limited broader effects in terms of providing general oversight or guidance for other patent holders on licensing more generally. Finally, compulsory licensing tends to be (at least traditionally) an exceptional measure often perceived as a measure of last resort to obtain access to patented technology. Taken together, these limitations at grant stage, and at post-grant stage, create a self-reinforcing cycle where ethical issues surrounding patent uses are marginalised at grant and post-grant stages, and the patent holder's discretion is rarely questioned.

In short, patents confer a private governance function on patent holders which can have significant implications for downstream technological development and use, particularly in the context of health-related biotechnologies. Yet, this governance role is often overlooked in practice, where the focus has tended to be on the economic/incentivising function of patents. The article does not seek to challenge the economic role of patents; instead, it argues that we also need to take into account the broader governance function of patents, the implications of this function particularly in the context of contemporary biotechnologies, and the lack of current oversight over patent holders' decisions on patent use. In doing so, we must consider that patents were not designed for the modern biotechnology context. In the biotechnological

context, the power given to patent-holders, and how this may impact on related downstream technologies or fields of technologies (depending on the nature of the invention), combined with the ethical issues which can arise from how patents over biotechnologies are used, can be highly contentious. Depending on how patent licences are used, patents can have potentially devastating impacts on individual patient's access to healthcare and on health research. Thus, the time has come for us to re-evaluate the role of patents and patent holders in the modern biotechnological context—and as part of this, a consideration of the appropriateness of the largely unfettered control that patents divest to patent holders is long overdue.