PATENTLY OBVIOUS

As contemporary technologies – including biotechnologies – develop, boundaries are blurring between what is patentable and what is not. Aisling McMahon explores the impact that patents are having on access to healthcare

A patent is a type of intellectual property right (IPR) that gives the rightsholder the ability to exclude or stop others from using an 'invention' (that is, a technology) under patent for commercial purposes for generally 20 years (referred to as the patent term). A patent is not, however, an automatic entitlement. Instead, applicants must apply for patent protection for the jurisdictions they are seeking this protection in.

The patent examination process considers whether the claimed invention meets three key patentability criteria: is the invention 'new' (novelty requirement); does it show an 'inventive step'; and does it have a 'technical' function (industrial application).

Alongside this, certain types of subject matter are not patentable – including, for example, discoveries of new naturally occurring materials (see article 52 of the 1973 *European Patent Convention* [EPC]).

Furthermore, there are provisions within 'European' patent law that exclude patents in certain contexts: for example, inventions whose commercial exploitation is against *ordre public* or morality are not patentable in Europe (article 53(a) EPC; article 6, *Biotechnology Directive*), nor are diagnostic, therapeutic and surgical methods (article 53(c), EPC).

The patent system varies, depending on the jurisdiction. By 'European', I mean the system within which the *European Patent Convention*, as amended, applies. This is an intergovernmental treaty signed by all EU

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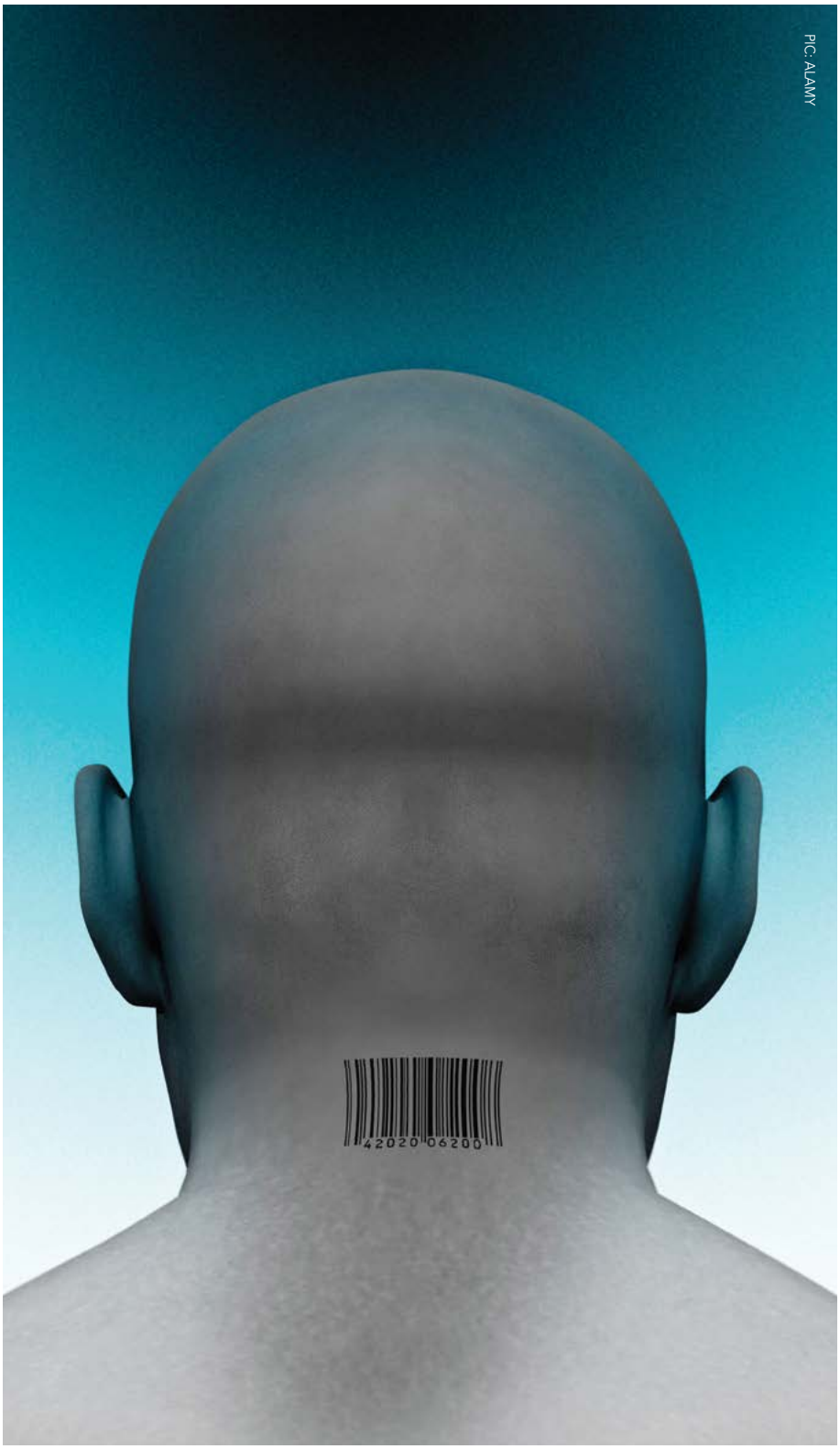
states and several non-EU states. This article focuses on EU states within that context, which are also bound by the *Biotechnology Directive* for patentability of biotechnological inventions.

Blurring of boundaries

The human body itself is not patentable (article 5, *Biotechnology Directive*). However, in practice, these provisions are often applied in a narrow technical manner in Europe. Furthermore, as contemporary technologies, including biotechnologies, have developed, there can be a blurring of boundaries between what is the human body and not patentable, and what is a 'technical invention' and therefore a patentable 'technology'.

Accordingly, a range of 'technologies' that relate to the human body, including elements isolated from our bodies (such as isolated human genes), technologies related to the treatment of the body (such as medicines and elements of vaccines), and technologies that can be used to enable better functioning of our bodies, including surgical tools and medical devices, are patentable in Europe. Importantly, how such patents are used by the rightsholders can have significant implications for access and delivery of healthcare.



PIC: ALAMY

To understand these implications, it is useful to consider the control that patents give rightsholders over certain aspects of patented technologies. Patents are often considered primarily as *economic* tools, because they enable rightsholders to develop an income stream from a patented technology. Once

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a technology is patented, third parties wishing to use that technology for commercial purposes must seek permission from the rightsholders.

Such permission can be granted, in the form of a licence, in return for an exchange, such as a payment or cross-license. Patents enable rightsholders to decide who they will license a technology to, and on what terms.

Monopoly rights

Rightsholders can also decide to refuse to license the technologies to third-parties. This can enable them to become the sole provider of a technology, potentially enabling them to exercise a monopoly right for the duration of the patent and therefore to set high prices for access to that technology. Accordingly, patents, together with other IPRs, are often a key consideration of entities' commercialisation strategy for developing health technologies, and patents are often seen as a mechanism to incentivise the development of technologies.

Having said that, the extent to which patents are the best or most suitable incentivisation tool for health technologies is highly contested, although such issues are beyond the scope of this article.

Alongside their economic role, patents also give rightsholders an important governance role over 'technologies', as they enable rightsholders to control key aspects of how patented technologies can be provided and licensed, to whom, and on what terms (such the price) for the duration of the patent term. When the patented technology is a health-related technology, such as a medicine, vaccine or medical device, how such patents are used can affect access, use, and delivery of such technologies. This, in turn, can have a range of bioethical implications, including impacts on how we can treat, use, or modify our bodies. Developing a deeper understanding and engagement with such issues is the key focus of the PatentsInHumans project.

Access and delivery

The 'PatentsInHumans' project is a large, five-year interdisciplinary project funded by a European Research Council Starting Grant. The project aims to:

- Develop a deeper understanding of the potential bioethical implications posed by the grant and use of patents over a range of technologies related to the human body, including medicines, elements of vaccines, medical devices, isolated elements from the body (such as isolated human genes), etc,
- To understand to what extent existing patent-grant, licensing, and other relevant legal decision-making systems currently engage with these issues, and
- To analyse to what extent current gaps between health law, bioethics, and patent law (and practice) can – or should – be bridged so that the current framework better engages with the bioethical implications that can be posed by patents over technologies related to the human body.

Ultimately, the project aims to reimagine European patent decision-making to develop a more person-centred approach to how we consider the bioethical implications posed by patents over technologies related to the human body.

An example of how patents could affect access to healthcare was in relation to the HIV/AIDS crisis in the 1990s. At that time, even though antiretroviral medications (ARVs) had been developed to treat HIV/AIDs, such ARVs were largely inaccessible to people in low- and middle-income countries (LMICs) due to their high prices. Millions were suffering from HIV/AIDS at that time, which could prove fatal without treatment.

Public backlash

In 1997, at the height of the crisis, the South African government introduced a law that sought to introduce provisions to ensure a greater supply of affordable medicines.

This law was subsequently challenged by over 30 pharmaceutical companies, whose claims included that it was contrary to IPRs under the international TRIPS agreement. Amid significant international public backlash, the challenge was dropped. Eventually, through international negotiations and civil society activism, greater availability of low-cost ARVs was made possible.

This crisis led to the *Declaration on the TRIPS Agreement* and *Public Health* in 2001 (the so-called *Doha Agreement*). This international legal text confirms that the international IP system should be interpreted in a manner that supports states in taking measures to protect public health within their states. This includes using TRIPS 'flexibilities', such as issuing a compulsory licence allowing countries, in certain circumstances, to issue a licence for a patented technology without rightsholder(s) permission.

Compulsory licences can be a useful avenue in some cases, such as to enable the generic production of medicines. However, compulsory licences have limitations and do not resolve all tensions that can arise between patents and access to health. For instance, LMICs may be reluctant to use compulsory licences due to fear of being issued with a trade sanction by higher-income countries (HICs). Compulsory licences must be applied for on a country-by-country basis. Systems for such licences can be bureaucratic and cumbersome to use in some states.

Furthermore, some states may not have the ability to develop generic versions of a medicine in that state, and while there is a mechanism for a state to import a patented product made under compulsory licences outside of that state, there are significant limitations with using this provision in practice.

International tension

This tension between international IPRs and health is not confined to the past, as recently illustrated by the COVID-19 pandemic. COVID vaccines were developed in the early stages of the pandemic. However, at that time, the demand for such vaccines globally outstripped the supplies available. How vaccines were provided, and to which states first, was controlled primarily by the relevant vaccine rightsholders/manufacturers based on contractual agreements between such rightsholders/manufacturers and states.

X spots the mark

A significant inequity arose between LMICs and HICs – with many HICs able to access vaccines for their populations in advance of LMICs and, in some cases, second doses of COVID-19 vaccines were made available to HIC populations before first doses were available in LMICs.

The significant disparity in access to vaccines in LMICs and HICs in the early stages of the pandemic was contrary to principles of health equity, raised significant moral issues and, from a scientific perspective, posed risks, as it left many LMICs with limited vaccine supplies, thereby potentially increasing risks of new strains of the virus emerging. Intellectual property rights were not the only issue affecting supplies and the provision of vaccines, but they were a key factor.

To reduce such tensions, India and South Africa, subsequently joined by other countries, proposed an international waiver or suspension on IPRs for COVID-19 health technologies during the pandemic. However, this received limited support from HICs, and ultimately the text adopted was a much watered-down version of the original proposal that only applied to patents (not to other IPRs) and only to vaccines, not to medicines or diagnostics, unlike the original proposal.

During the pandemic, there were also several voluntary licensing initiatives set up, where rightsholders could voluntarily share/license IP-protected technologies, such as the COVID-19 Technology Access Pool (C-TAP), but this received limited commitments from key rightsholders, including vaccine manufacturers, during the pandemic.

Patents and access to health

Moreover, although patents and access to health are often discussed in health-emergency contexts, the tensions that can arise between how patents are used and how we can access healthcare are also evident in everyday health contexts in both LMICs and in HICs.

For LMICs, there is a range of examples of how patents have been used by rightsholders in a manner that can hinder access to healthcare, including whereby patents have enabled rightsholders to charge prices that are inaccessible for LMICs.

For example, patents related to Bedaquiline, which is used in the treatment of TB, were recently in the spotlight in terms of the potential impacts of such patents on access to TB treatments in many LMICs. Following recent discussions and civil-society action, a deal was reached to enable greater generic provision of this medicine in certain LMICs to expand access.

Patents can also affect LMIC access to vaccines. For example, *Medicins Sans Frontières* has highlighted the impact of IPRs on access to the HPV vaccine (against cervical cancers) and the pneumococcal vaccine against pneumonia in LMICs. In

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the HPV-vaccine context, for instance, in 2018, Tanzania established a HPV vaccination programme, but could only procure limited vaccine supplies, initially due to high demand globally for such vaccines. In such cases, where there are limited global supplies of vaccines available, vaccines will often go first to HICs, as such states have significantly higher purchasing power than can be offered by LMICs. Lack of vaccine supply in LMICs has significant public-health implications.

Such issues are not confined to LMICs: there are many examples of how patents can have an impact on access, affordability, and delivery of health-technologies in HICs. For instance, we increasingly see a range of emerging medicines and therapies, including cancer treatments, that can have life-saving effects for patients, but associated high prices can mean that such therapies/medicines are unaffordable in HICs.

Where HICs provide these medicines at high costs, this also poses bioethical issues. It may lead to 'opportunity costs' – where, due to finite national healthcare budgets, providing high-cost medicines can mean that other medicines cannot be provided. This can affect the overall affordability and provision of healthcare in public-health systems, with knock-on effects for patients.

Rightsholders' discretion

Patents have an economic function and can enable rightsholders to develop an income stream from the development of a technology. However, patents also give rightsholders significant discretion over how patented technologies are used by third parties, the terms of their access (including price), and who can produce such technologies.

Where the patented 'technology' is a health-related technology, such as a medicine, element of a vaccine, or a medical device, how patents are used can affect the access to and the delivery of healthcare. Notably, in terms of the bioethical implications posed by patents in the health context, the key issue is often not the patent right as such, but how such rights are used. Rightsholders can – and, in some cases, do – adopt socially responsible licensing practices, including licensing strategies to facilitate more equitable access to such technologies, especially in LMICs. Nonetheless, greater consideration is needed around how IPRs can be used in a manner that recoups investments, while also limiting the potential negative repercussions that patents can have on access to healthcare.

Moreover, governments, funders, universities, and intermediary bodies – such as biobanks that work with researchers – have a key role in ensuring that their IP licensing policies and agreements enable parties to step in when IPRs are used in a manner that unreasonably affects access to, and delivery of, healthcare. g

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LOOK IT UP

LEGISLATION:

- *Biotechnology Directive* (Directive 98/44/EC of the European Parliament and of the Council, 6 July 1998), articles 5 and 6
- *European Patent Convention 1973*, articles 52 and 53
- *Declaration on the TRIPS Agreement and Public Health* (14 November 2001)