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July 2016

**69**

# **INTELLECTUAL PROPERTY AND ACCESS TO SCIENCE**

Carlos M. Correa





**RESEARCH PAPERS**

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SCIENCE**

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**JULY 2016**



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This paper was first submitted to CEIPI (University of Strasbourg) for publication in *Global Perspectives and Challenges for the Intellectual Property System*, A CEIPI-ICTSD publication Series.

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## I. INTRODUCTION

Free access and use of scientific knowledge is fundamental for the advancement of the scientific enterprise. Researchers need that access to test and build on prior findings. Any barrier erected in this regard may retard or impede progress to the detriment of the whole mankind. For this reason, transparency and accessibility to scientific data is a key concern for scientists in all disciplines.<sup>1</sup>

Access to science is not only of practical importance. It is one of the universally recognized human rights. As noted by the United Nations Special Rapporteur in the field of cultural rights:

[t]he conjoined human right to science and culture should be understood as including a right to have access to, use and further develop technologies in self-determined and empowering ways. New scientific knowledge and innovations increase available options, thereby strengthening people's capacity to envisage a better future for which access to specific technologies may sometimes be pivotal... Access to the benefits of scientific progress not only allows improving one's socio-economic situation, but also gives the opportunity for meaningful participation in the life of local, national or international communities (para. 55).<sup>2</sup>

In some areas the boundaries between science and technology have become blurred. For instance, a person conducting scientific research in molecular biology at a university laboratory possesses the knowledge indispensable to produce a biological medicine in a company working in biotechnology. The development of new drugs is increasingly dependent on deep scientific knowledge, such as in the case of immunobiologicals. As noted by Dasgupta and David:

What makes a knowledge-worker a 'technologist' rather than a 'scientist', in this usage, is not the particular cognitive skills or the content of his or her expertise. The same individual, we suppose, can be either, or both, within the course of a day. What matters is the socio-economic rule structures under which the research takes place, and, most importantly, what the researchers do with their findings: research undertaken with the intention of selling the fruits into secrecy belongs unambiguously to the realm of Technology.<sup>3</sup>

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<sup>1</sup> See, e.g., the *Declaration of Helsinki on Ethical Principles for Research Involving Human Subjects* the World Medical Association (as revised in 2008) stating that authors, editors, and publishers share ethical obligations related to the disclosure of research results. See also Trudo Lemmens and Candice Telfer, 'Access to Information and the Right to Health: The Human Rights Case for Clinical Trials Transparency', *American Journal of Law & Medicine*, 38 (2012): 63-112, 2012, p. 71.

<sup>2</sup> Report of the Special Rapporteur in the field of cultural rights, A/70/279, 4 August 2015.

<sup>3</sup> See, e.g., Partha Dasgupta and Paul A David 'Toward a new economics of science', *Policy Research*, vol. 23, 1994, available at <http://www.compilerpress.ca/Competitiveness/Anno/Anno%20Dasgupta%20&%20David%20Toward%20a%20new%20economics%20of%20science%20Policy%20Research%201994.htm>, p. 495.

The universities' policies aiming at creating spin-off companies and the possibility for scientists to move from research jobs in universities to undertake profit-oriented research in the private sector also exemplifies the close link between science and technology.<sup>4</sup>

The existence of such a close link in some areas, however, does not mean that science and technology cannot be differentiated. While the former provides evidence and explanations on natural phenomena, the latter creates tools to address technical problems. Keeping this differentiation in view is crucial to define the boundaries of what may be subject to appropriation under intellectual property rights. As noted by Ghidini, 'if basic research were attracted to the appropriability rationale of applied research, not only the potential to innovate but even the room for freedom would be reduced'.<sup>5</sup>

Some developments in intellectual property, notably in the field of patent law, have led to the appropriation of scientific knowledge that by its very nature should remain in the public domain, thereby jeopardizing its dissemination and further use.

This paper briefly discusses the expansion of patents into the scientific realm, taking as an example knowledge relating to biological sciences. There are other examples of such expansion (e.g. in the area of computer science<sup>6</sup> and nanotechnology<sup>7</sup>) whose study would involve considerations similar to those made here. The policies adopted in some countries to encourage patenting by universities are also mentioned in this context, as well as a number of measures that may be adopted to limit the appropriation of scientific knowledge or its restrictive impact.

There are important issues regarding access to scientific knowledge under copyright law, particularly in countries where narrow exceptions are provided for under the applicable law.<sup>8</sup> Text and data mining, in particular, may be regarded as prohibited under many copyright regimes. These issues, however, are not addressed in this paper.

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<sup>4</sup> See, e.g., Shane, S. *Academic Entrepreneurship: University spinoffs and Wealth Creation*, Edward Elgar, Cheltenham, 2004; W. Daring, R. Oakey and S. Kauser (Eds.), *New technology-based firms in the new millennium*, vol. III, Pergamon Press, Oxford.

<sup>5</sup> Ghidini, G.: Aspectos actuales del derecho industrial. Propiedad intelectual y competencia, Edit. Comares, Granada, 2002, p. 23.

<sup>6</sup> See, e.g., John Swinson, 'Copyright or patent or both: an algorithmic approach to computer software protection', *Harvard Journal of Law & Technology*, vol. 5, Fall issue, 1991, available at [jolt.law.harvard.edu/articles/pdf/v05/05HarvJLTech145.pdf](http://jolt.law.harvard.edu/articles/pdf/v05/05HarvJLTech145.pdf).

<sup>7</sup> ETC, *Nanogeopolitics*, available at [http://www.etcgroup.org/sites/www.etcgroup.org/files/publication/pdf\\_file/nano\\_big4web.pdf](http://www.etcgroup.org/sites/www.etcgroup.org/files/publication/pdf_file/nano_big4web.pdf), p. 35.

<sup>8</sup> See, Jerome H. Reichman and Ruth L. Okediji, 'When Copyright Law and Science Collide: Empowering Digitally Integrated Research Methods on a Global Scale', *Minnesota Law Review* 96:1362-1480.

## II. NATURE AS INVENTION

Traditionally, patent laws have distinguished between patentable technical inventions and discoveries or laws of nature. Thus, in the USA courts have denied patent protection to ‘laws of nature’ and ‘natural phenomena’. In 1853, in *O'Reilly v. Morse* (56 U.S. 62. 112-21) the patentability of the principles of electromagnetism, even if confined to telecommunication, was rejected. In *Funk Bros. Seed Co. v. Kalo Inoculant Co.* (333 U.S. 127, 130, 1948) a combination of naturally occurring nitrogen-fixing bacteria was deemed not patentable subject matter, although the particular combination was not found in nature.<sup>9</sup> The US Supreme Court in *re Chakrabarty* (1980) affirmed the patentability of ‘anything under the sun that is made by man’. This decision opened the way for the patentability of genetically modified organisms. The US Patent and Trademark Office (USPTO), however, understood its mandate to grant patents in a broader manner. It did not hesitate to grant patents on cells<sup>10</sup> and genes including of human origin.

In fact, thousands of patents were granted by the USPTO over ‘isolated’ natural genes with an identified ‘utility’. The ban to provide patent protection to natural materials was deemed to be overcome by the fact that genes were claimed as ‘isolated’, a format that a court depicted as a ‘lawyers’ trick’ in *Association for Molecular Pathology v. Myriad Genetics*,<sup>11</sup> a case relating to a set of patents on BCRA genes the presence of which is associated with an increased risk of hereditary breast and ovarian cancer. Interestingly, in an *amicus curiae* submitted to the court by the US Department of Justice in this case it was held that

[t]he chemical structure of native human genes is a product of nature, and it is no less a product of nature when that structure is ‘isolated’ from its natural environment than are cotton fibres that have been separated from cotton seeds or coal that has been extracted from the earth.<sup>12</sup>

In reversing the appellate court decision, the US Supreme Court ruled (569 U.S. 12-398, 2013) that naturally occurring isolated DNA is **not** valid patentable subject matter.<sup>13</sup> However, the court made an improper distinction between DNA and cDNA, that is, a form of synthesized DNA used in genetic engineering to produce gene clones. cDNA contains the same information found in a natural DNA but omits portions within the DNA segment that do not code for proteins (introns): ‘a cDNA molecule housing the DNA of a naturally occurring protein is not "markedly different" from anything found in nature just as "isolated and purified

<sup>9</sup> See also *Diamond v. Diehr*, 450 U.S. 175, 185 (1981); *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (dictum); *Parker v. Flook*, 437 U.S. 584, 598 (1978) (Stewart, J., dissenting) (“It is a commonplace that laws of nature, physical phenomena, and abstract ideas are not patentable subject matter.”); *Flook*, 437 U.S. at 594-95 (mathematical formula is not patentable, even as limited to use in cracking hydrocarbons); *Gottschalk v. Benson*, 409 U.S. 63, 67, 71-72 (1972) (algorithm for converting binary-coded decimal numbers to binary numbers in digital computers is not patentable) (quotes from Jay Dratler, Jr, ‘Fixing our broken patent system’, *Marquette Intellectual Property Law Review* (1 January 2010), available at <http://www.thefreelibrary.com/Fixing+our+broken+patent+system.-a0222408982>).

<sup>10</sup> See, e.g., *Bioethics and Patent Law: The Cases of Moore and the Hagahai People*, WIPO Magazine, 2006, available at [http://www.wipo.int/wipo\\_magazine/en/2006/05/article\\_0008.html](http://www.wipo.int/wipo_magazine/en/2006/05/article_0008.html).

<sup>11</sup> *Ass’n for Molecular Pathology v. U.S. Patent and Trademark Office*, 702 F.Supp.2d 181 (S.D.N.Y. 2010). The court considered that all DNA sequences whether isolated or synthetic were products of nature, indistinguishable from naturally occurring DNA sequences.

<sup>12</sup> US Department of Justice-*Amicus curiae* in *Association for Molecular Pathology v Myriad Genetics* (569 U.S. 12-398, 2013).

<sup>13</sup> See, e.g., L.O. Gostin, «Who Owns Human Genes? Is DNA Patentable?», *JAMA* 310: 791, 2013.

DNA" is not. Both are artificial, but neither are inventions'.<sup>14</sup> As a result of this reasoning, the US Supreme Court decision may not drastically affect the possibility of appropriating basic genetic information.<sup>15</sup>

The Australian High Court similarly ruled, in October 2015, in the case *D'Arcy v Myriad Genetics Inc. & Anor* that an isolated gene sequence cannot be patented. It held that 'an isolated nucleic acid, coding for the BRCA1 protein, with specified variations, is not a manner of manufacture'. It added that '[w]hile the invention claimed might be, in a formal sense, a product of human action, it was the existence of the information stored in the relevant sequences that was an essential element of the invention as claimed'.<sup>16</sup>

In contrast, although the European Patent Convention stipulates that 'discoveries' are not inventions, substances found in nature may be the subject matter of a valid patent.<sup>17</sup> In particular, according to the jurisprudence of the European Patent Office (EPO), patents on genes are admissible.<sup>18</sup> Moreover, according to EPO's practice gene patents may be granted with a broad scope, including aspects that the applicant was unaware of.<sup>19</sup> The patent owner, hence, is presumed to have 'invented' what was actually unknown to him.

In summary, the referred to court decisions in the USA<sup>20</sup> and Australia show some positive steps towards a limitation to the appropriation of purely scientific biological information through patents. In fact, patent laws may contain specific rules on the matter. The 1996 Brazilian Industrial Property Code (No. 9.279, 14 May 1996), which excludes from patentability living beings or "biological materials found in nature", even if isolated, including the "genome or germplasm" of any living being (article 10.IX), provides a useful model in this respect.

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<sup>14</sup> Adam Liptak, 'Supreme Court Rules Human Genes May Not Be Patented', 13 June 2013, available at [http://www.nytimes.com/2013/06/14/us/supreme-court-rules-human-genes-may-not-be-patented.html?\\_r=0](http://www.nytimes.com/2013/06/14/us/supreme-court-rules-human-genes-may-not-be-patented.html?_r=0).

<sup>15</sup> Myriad Genetics, for instance, holds other BRCA-related patents including claims to cDNA that have not been invalidated.

<sup>16</sup> [2015] HCA 35 available at <http://www.hcourt.gov.au/assets/publications/judgment-summaries/2015/hca-35-2015-10-07.pdf>.

<sup>17</sup> In accordance with article 3 of the European Directive on Biotechnological Inventions '1. ...inventions... shall be patentable even if they concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used. 2. Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature'.

<sup>18</sup> See, e.g., Technical Expert Working Group on Genetic Sequence Data, *Final Report to the PIP Advisory Group*, WHO, 2014, available at [http://www.who.int/influenza/pip/advisory\\_group/PIP\\_AG\\_TEWG\\_Final\\_Report\\_15May2014.pdf](http://www.who.int/influenza/pip/advisory_group/PIP_AG_TEWG_Final_Report_15May2014.pdf).

<sup>19</sup> See e.g. decisions T 301/87 and T 923/92.

<sup>20</sup> In the area of plant varieties, however, discovered varieties may be protected under the US Plant Patent Act of 1930. See, e.g., Carlos Correa (with contributions from Sangeeta Shashikant and Francois Meienberg), *Plant Variety Protection in Developing Countries. A Tool for Designing a Sui Generis Plant Variety Protection System: An Alternative to UPOV 1991*, APBEBES, Berne Declaration, TWN, SEARICE, Utviklingfondet, Alfter (Germany), September 2015.

### III. UNIVERSITIES' PATENTING POLICIES

Many developed and developing countries (including China, Brazil, and South Africa) have introduced policies to encourage (or mandate) patenting by universities and other institutions that are beneficiaries of public funding for research. In adopting this policy, many countries have been largely influenced by the Bayh-Dole Act (Patent and Trademark Law Amendments Act, Pub. L. 96-517) enacted in the USA in December 1980, which permitted universities, small business and non-profit institutions to acquire patents on research results obtained with federal funding. The adoption of such policy has been stimulated by the expectation of generating net benefits from the protection and exploitation of research results.<sup>21</sup> However, this objective has not been achieved in most cases, including in the USA where a report found that 84 per cent of universities operating technology transfer offices 'did not generate enough licensing income to cover the wages of their technology transfer staff and the legal costs for the patents they file'.<sup>22</sup> Moreover, concerns have been raised that

the law, intended to spur research, has created a culture whereby the profit motive often trumps more purely scientific based inquiries. Colleagues have become competitors. Critics say that instead of freely trading information for purely scientific goals, the effect of the law has been to distort the motivations of researchers who once only had science on their minds. Even if individual researchers are still keeping their motivations clean, that may not be true with the institutions for whom they work, which are eager to keep control of their research for potential future sale, and so are motivated to fiercely protect their findings.<sup>23</sup>

While the incentive (or requirement) to seek patents over universities' research has not attained the desired economic outcomes, they promote in some instances the appropriation of scientific knowledge. In view of the spread of this type of policies, the United Nations Special Rapporteur in the field of cultural rights has echoed the concerns noted above. She noted in the already quoted report that

[a] worrisome trend is the expanding roles of patent-seeking in scientific research at universities and public research institutions. The result is that the fruits of publicly funded scientific research are often transferred to exclusive private ownership. Of equal concern is the change in the culture surrounding university research, away from an activity conducted for the public good and human advancement towards an activity valued only for its potential commercial application.<sup>24</sup>

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<sup>21</sup> Bhaven N. Sampat, 'The Bayh-Dole Model in Developing Countries: Reflections on the Indian Bill on Publicly Funded Intellectual Property', Policy Brief Number 5, October 2009, UNCTAD – ICTSD Project on IPRs and Sustainable Development, available at [http://unctad.org/en/docs/iprs\\_pb20095\\_en.pdf](http://unctad.org/en/docs/iprs_pb20095_en.pdf); see also S. Basheer and S. Guha (2010), 'Patenting Publicly Funded Research: A Critique of the Indian "Bayh Dole" Bill', available at <http://spicyipindia.blogspot.com/2010/01/indian-bayh-dole-bill-critique-and-some.html>.

<sup>22</sup> Walter D. Valdivia, 'University Start-Ups: Critical for Improving Technology Transfer', 20 November 2013, available at <http://www.brookings.edu/research/papers/2013/11/university-start-ups-technology-transfer-valdivia>.

<sup>23</sup> Samuel Loewenberg, 'The Bayh–Dole Act: A model for promoting research translation?', *Molecular Oncology* 3 (2009) 91-93 available at [http://www.elsevierstechnology.com/pdfs/molonc0910/9\\_TheBayhDoleAct.pdf](http://www.elsevierstechnology.com/pdfs/molonc0910/9_TheBayhDoleAct.pdf).

<sup>24</sup> Report of the Special Rapporteur, op. cit.

In fact, an overstatement of the role of intellectual property in promoting transfer of technology from universities may distort the research agenda and lead universities 'to be so aggressive in their pursuit and defence of patents that these activities hinder the progress of research and serve as obstacles rather than aids to university-industry technology transfer and collaborative research'.<sup>25</sup>

Despite the questionable benefits of a pro-patenting policy by universities, the World Intellectual Property Organization established in 2002 the 'WIPO University Initiative Program', which reportedly encompasses some 250 universities worldwide, to assist universities in the establishment of IP and technology management infrastructure, develop human capital skilled in IP and technology management and promote an 'effective use of IP, in particular, patents...with a view to promoting scientific innovation and IP rights so that universities can enjoy the full benefit of IP systems'.<sup>26</sup> In view of the concerns referred to, it would seem appropriate to review the premises and impact of this program on the dissemination and use of universities' research outcomes in developing countries.

#### IV. KEEPING SCIENCE ACCESSIBLE

A number of policies and legislative measures have been taken in some countries to counter the appropriation of science under intellectual property rights, including limitations to the scope of patent rights and legislation mandating public access to the outcomes of government funded research, as discussed below.

##### IV.1 Research Exception

Most national laws incorporate exceptions allowing third parties to conduct research and/or experimentation on a patented invention, albeit with differences regarding their scope.<sup>27</sup> The adoption of this type of exception, if properly formulated may facilitate follow-on innovation and "inventing around" a patented technology. The exception may also be useful to allow for the evaluation of an invention in order to request a voluntary or compulsory license, or for other legitimate purposes, such as to test whether the invention works, or whether it has been disclosed in a manner that complies with the disclosure requirements of the applicable law. A research exception may also be of particular importance in the area of plant breeding.<sup>28</sup>

In European and other countries, experimentation **on** an invention (as opposed to **with** an invention) is allowed even for commercial purposes<sup>29</sup>. Courts in European countries, for instance, have deemed legitimate research done to find out more information about a

<sup>25</sup> Sampat, op. cit., p. 4-5 (references omitted).

<sup>26</sup> <http://www.wipo.int/uipc/en/>.

<sup>27</sup> See Correa, Carlos (2005), *International Dimension of the Research Exception*, SIPPI Project, AAAS, Washington D. C., available at <http://citeseerx.ist.psu.edu/viewdoc/download;jsessionid=6267EF2C019CBA7513EB651864A6C345?doi=10.1.1.207.4033&rep=rep1&type=pdf>.

<sup>28</sup> See, e.g., Viola Prifti, *The Breeder's Exception to Patent Rights Analysis of Compliance with Article 30 of the TRIPS Agreement*, Springer, 2014.

<sup>29</sup> The Community Patent Convention, for instance, provides that there is no infringement in case of "acts done for experimental purposes relating to the subject-matter of the patented invention" (Article 27.b).

product - provided that it is not made just to convince licensing authorities or customers about the virtues of an alternative product, and to obtain further information about the uses of a product and its possible side-effects and other consequences of its use<sup>30</sup>. In the United States, however, research without the authorization of the patent owner has only been narrowly admitted for scientific purposes.<sup>31</sup>

Although there has been no case in WTO clarifying whether a research exception is compatible with the TRIPS Agreement, it may be deemed to be fully covered by article 30 of this Agreement, interpreted in the light of accepted principles of treaty interpretation as codified in the Vienna Convention on the Law of the Treaties.<sup>32</sup>

## IV.2 Claims' Scope in Gene Patents

When patents covering genes are granted, an important issue is whether the exclusive rights extend to any possible utilization of the gene. If this were the case, nobody could use the patented gene even for functions not discovered or disclosed by the patent owner. An absolute protection of this kind is likely to discourage further research and prevent other possible uses of a patented gene until the patent expires. Even if research is allowed under a 'research exception' a product that contains the patented gene could not be commercialized without the patent owner's authorisation until the expiry of the patent.

This problem may be addressed in different ways. One option would be to grant a compulsory license based on patent dependency, as permitted by article 31(l) of the TRIPS Agreement. However, the conditions set out by this provision are quite burdensome, as it may be necessary to demonstrate that the invention claimed in the second patent involves an important technical advance of considerable economic significance in relation to the invention claimed in the first patent. Another option is to limit the scope of the patent claim to the functions of the gene that were actually discovered by the applicant<sup>33</sup> so as not to interfere with third parties' research and use of the gene for other functions.

This second alternative has been suggested by the European Parliament,<sup>34</sup> and implemented in Germany but with regard to human DNA.<sup>35</sup> French patent law more broadly stipulates that the scope of a claim is limited to that part of the sequence directly linked to the function specifically disclosed in the specifications, and that such a claim cannot be enforced against a subsequent claim on the same sequence that discloses another specific application

<sup>30</sup> W Cornish "Experimental Use of Patented Inventions in European Community States", 29 IIC 7, (1998) 736. See also C Correa, International Dimension of the Research Exception, SIPPI Project, AAAS, Washington D. C., available at <http://citeseerx.ist.psu.edu/viewdoc/download;jsessionid=6267EF2C019CBA7513EB651864A6C345?doi=10.1.1.207.4033&rep=rep1&type=pdf>.

<sup>31</sup> The Federal Circuit Court of Appeals held in *Madey v. Duke* (307 F.3d 1351, Fed. Cir. 2002) that 'regardless of whether a particular institution or entity is engaged in an endeavor for commercial gain, so long as the act is in furtherance of the alleged infringer's legitimate business and is not solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry, the act does not qualify for the very narrow and strictly limited experimental use defense. Moreover, the profit or non-profit status of the user is not determinative'.

<sup>32</sup> See, e.g., Carlos Correa, *Trade Related Aspects of Intellectual Property Rights (Volume VI of Commentaries on the GATT/WTO Agreements)*, Oxford University Press, 2007.

<sup>33</sup> These claims are generally known as 'use-bound' claims.

<sup>34</sup> Available at [www.europarl.europa.eu/sides/getDoc.do?type=TA&reference=P6-TA-2005-0407&language=EN](http://www.europarl.europa.eu/sides/getDoc.do?type=TA&reference=P6-TA-2005-0407&language=EN).

<sup>35</sup> *Patent Act* of 16 December 1980, as last amended by the Law of 28 February 2005.

thereof<sup>36</sup>. In a case relating to a plant gene construct that provides resistance to glyphosate, the European Court of Justice interpreted that the European Directive on Biotechnological Inventions ‘makes the patentability of a DNA sequence subject to indication of the function it performs’ (paragraph 45).<sup>37</sup>

The scope of patents covering genes, where accepted, remains a largely undefined issue in most developing countries. Limitations of the type applicable under European laws should be considered to address this gap.

### IV.3 Open Access to Research Results

Some initiatives have been taken in a number of countries by governments or particular institutions that may partially counter the referred to trends towards the appropriation of scientific results. Thus, an omnibus spending bill passed by the US Congress in 2007 contained a provision requiring the National Institutes of Health (NIH) to mandate open access for NIH-funded research, in a manner consistent with copyright law.<sup>38</sup> In 2013 the US Office of Science and Technology Policy instructed each federal agency with annual R&D expenditures of over US\$100 million ‘to develop a plan to support increased public access to the results of research funded by the Federal Government. This includes any results published in peer-reviewed scholarly publications that are based on research that directly arises from Federal funds’.<sup>39</sup> This policy was codified in 2014 through the FY 2014 Omnibus Appropriations Bill which required federal agencies under the Department of Labour, Department of Education, and Department of Health and Human Services<sup>40</sup> to implement such open access policy.

The European Commission has issued guidelines to ensure open access to scientific information and to boost the benefits of public investment in the research funded under the EU Framework Programme for Research and Innovation Horizon 2020 (2014-2020). The Guidelines note that

the European Commission's vision is that information already paid for by the public purse should not be paid for again each time it is accessed or used, and that it should benefit European companies and citizens to the full. This means making publicly-funded scientific information available online, at no extra cost, to

<sup>36</sup> Article L613-2-1 of the French Industrial Property Code.

<sup>37</sup> Case C-428/08, *Monsanto Technology LLC v Cefetra BV et al.* More specifically, the ECJ General Advocate held that ‘Directive 98/44 permits and, in fact, requires an interpretation to the effect that, in EU territory, the protection conferred on DNA sequences is a ‘purpose-bound’ protection (paragraph 29). See <http://curia.europa.eu/jurisp/cgi-bin/gettext.pl?where=&lang=es&num=79899690C19080428&doc=T&ouvert=T&seance=CONCL#Footnote7>.

<sup>38</sup> In accordance with such provision, the ‘Director of the National Institutes of Health shall require that all investigators funded by the NIH submit or have submitted for them to the National Library of Medicine's PubMed Central an electronic version of their final, peer-reviewed manuscripts upon acceptance for publication to be made publicly available no later than 12 months after the official date of publication: Provided, That the NIH shall implement the public access policy in a manner consistent with copyright law’.

<sup>39</sup> Executive Office of the President, Office of Science and Technology Policy Memorandum for the Heads of Executive Departments and Agencies, 22 February 2013, available at [https://www.whitehouse.gov/sites/default/files/microsites/ostp/ostp\\_public\\_access\\_memo\\_2013.pdf](https://www.whitehouse.gov/sites/default/files/microsites/ostp/ostp_public_access_memo_2013.pdf). A Fair Access to Science and Technology Research Act (FASTR).

<sup>40</sup> It includes research agencies such as the National Institutes of Health, Food and Drug Administration, and the Centers for Disease Control and Prevention.



European researchers, innovative industries and citizens, while ensuring long-term preservation.<sup>41</sup>

Some developing countries have adopted similar initiatives. In Argentina, for instance, law No. 26.899 (2014) mandated the setting up of institutional ‘open access digital repositories’ and required researchers, professors as well as postdoctoral fellows, graduate and PhD students whose research is financed by public funds, to deposit or expressly authorize the uploading of a copy of the final version of their scientific and technological production, published or accepted for publication to the open access institutional digital repository within a period of six months. Primary research data must be deposited in the institutional digital repository within a period of five years from the date of collection. Mexico adopted in 2014 a policy on the subject through an amendment to its laws relating to science, technology and education. Open access is to be given through a digital platform without any subscription requirement, but without prejudice to the protection of the information by patents, copyrights and other modalities of intellectual property, including trade secrets.

These regulations may contribute to ensure free access to scientific research outputs, although with some questionable limitations (such as the US\$ 100 million threshold of the US law and the possibility of preserving research results as trade secrets under the referred to Mexican law). They will not prevent the practice of patenting up-stream research where this is possible under the applicable law. This may only be achieved through the right design of policies of universities and other research institutions and, more importantly, through changes in legislation and in patent offices’ practices regarding what constitutes an ‘invention’.

## V. CONCLUSIONS

The boundaries between scientific and technological knowledge are nebulous in some technical fields, such as the biological sciences and their applications. This has led to the appropriation under patents of knowledge (such as on specific genes) of scientific nature, which may not only have negative effects for the further development of science and new technological contributions, but also encroach on the fundamental right of access to science. The patenting policies adopted by some universities and other research institutions may aggravate this problem.

Court decisions in the USA and Australia and some national laws (e.g. Brazil) have limited the possibility of that appropriation, which is still feasible, however, in many jurisdictions. Other measures – such as a well formulated research exception, the limitation of the patent claims’ scope, and legislation mandating open access to research results achieved with public funding – may mitigate the effects of the exclusivity granted by patent rights, but more fundamental policy changes may be necessary in order to preserve scientific outcomes in the public domain for free use and follow-on research.

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<sup>41</sup> European Commission, Directorate-General for Research & Innovation , Guidelines on Open Access to Scientific Publications and Research Data in Horizon 2020, 30 October 2015, available at [http://ec.europa.eu/research/participants/data/ref/h2020/grants\\_manual/hi/oa\\_pilot/h2020-hi-oa-pilot-guide\\_en.pdf](http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/oa_pilot/h2020-hi-oa-pilot-guide_en.pdf) p. 4.



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**ISSN 1819-6926**