Revista peruana de biología 27(1): 103 - 106 (2020)
doi: http://dx.doi.org/10.15381/rpb.v27i1.17587
ISSN-L 1561-0837; eISSN: 1727-9933
Universidad Nacional Mayor de San Marcos

Trabajos presentados al ***I Congreso Internacional de Biotecnología e innovación (ICBi)***, 9 - 12 de julio de 2018, Universidad Nacional Agraria La Molina, Lima, Perú.
Editoras:
Ilanit Samolski Klein
Maria Lucila Hernández-Macedo
Gretty Katherina Villena Chávez

Autores

Stephany Soto
stephany@mertzperu.com
https://orcid.org/0000-0002-0499-188X

Correspondencia

Consultancy Manager, MERTZ PERU. Calle Los Laureles 670, piso 8, Lima 27.

Citación

Soto S. 2020. Intellectual property in the bio-sector research: Applying Patenting rules in a field with no definition of life. I Congreso Internacional de Biotecnología e innovación (ICBi), Revista peruana de biología número especial 27(1): 103- 106 (Marzo 2020). doi: http://dx.doi.org/10.15381/rpb.v27i1.17587

Section IV:
Innovation in Biotechnology
Mini Review

La propiedad intelectual en investigaciones del sector Bio: aplicación de normas de patentes en un campo sin definición de vida

Intellectual property in the bio-sector research: Applying patenting rules in a field with no definition of life

Abstract

Intellectual Property is a powerful legal and economic instrument. In our "knowledge economy", patents are the preferred IP tool with special emphasis in the pharma – agro biotech industry. However, the growth of patents in the bio sector such as the pharma and agro fields, encounters many challenges. Life itself has not been defined yet. So, how can it be determined exactly when a living being, or a biological entity has been modified by itself or by human intervention, and thus address issues of patentability? Therefore, a researcher in the bio field cannot be alien to Intellectual Property, being the main actor in the revolution of the bio-pharma-agro sectors.

Resumen

La propiedad intelectual es un poderoso instrumento legal y económico. En nuestra "economía del conocimiento", las patentes son la herramienta de propiedad intelectual preferida, con mayor énfasis en la industria farmacéutica – agrícola - biotecnológica. Sin embargo, el crecimiento de patentes en el sector biológico, tales como el campo farmacéutico y el agro, encuentra muchos desafíos. La vida misma aún no ha sido definida. Entonces, ¿cómo podría determinarse exactamente cuándo un ser vivo o una entidad biológica ha sido modificado por sí mismo o por la intervención humana? Por lo tanto, un investigador del sector bio, no puede ser ajeno a la Propiedad Intelectual, siendo el actor principal en la revolución del sector biofarmacéutico y agrario.

Palabras clave:

Propiedad Intelectual; Industria Biotecnológica; Industria Farmacéutica; patentes; economía del conocimiento.

Keywords:

Intellectual Property; Biotech industry; pharma industry; patents; knowledge economy.

The knowledge economy: innovation

Intellectual Property has been conceived as a tool to assist in rewarding research efforts, such as monetary investment or the time invested in research. But, to achieve Intellectual Property protection, a researcher must also be an inventor, having to complete the Raffler circle, which holds that "Research is transforming money into knowledge but, Innovation is transforming knowledge into money". Therefore, when we think of research, we should think of innovation as well and how our research may effectively reach the market.

In today's economy, companies must find their new place in the knowledge economy, where innovation consists in obtaining benefits using the resources of knowledge and creativity (Fernandini & Soto 2018).

Intellectual Property (IP) Management as a powerful economic instrument

Intellectual Property has become the main asset of the 21st century. Mark Getty refers to the enormous importance of oil in the industrialization of the 20th century, and adds: "Intellectual Property is the oil of the 21st century" (WIPO 2017).

The greatest economic and legal battles of our times, such as Apple versus Samsung or farmers and NGOs versus Monsanto, have versed almost entirely about intellectual property. Regardless of the companies behind the IP, we ought to understand that at the base of such IP is the research conducted by researchers (BBC 2018).

The main point of IP Management is to understand the difference with simply applying IP Law or owning IP rights. Whereas IP "Management" consists on actively reconciling the opportunity with the context of the market and allocating resources to achieve a lucrative goal (WIPO 2016), IP law is a matter of knowing and applying regulations, including IP rules, to obtain and protect the rights in this sector at a particular period of time, knowing when or where the rights can be applied, who owns the rights, etc.

In this way, research is attractive to the business world and a basic tool for economic development is promoted: the transfer of technology. In Peru, authorities actively promote technology transfer, attempting to break the traditional market scheme where the university and the company follow different roads. Thus, technology transfer contributes to promote open innovation and in this way link the university with the companies; since, universities have the best researchers in their areas of expertise, and the companies will have excellent staff to sell and/or market. (Soto 2016).

Peru is working to improve its Innovation Culture and ecosystem through policy, funding and strong institutional leadership. For the country's bicentennial (2021), Peru aims to promote technological development in the country by bringing university research closer to industry. That is why, the Special Plan for Technology Transfer (PNCTI 2006-2021) was designed with the recognition of two main actors: the private sector and the academic sector. (CONCYTEC 2016).

Intellectual Property in the bio Sector

The European Community, in its Strategy for Europe in the Life sciences and biotechnology sector mentions: "Life sciences and biotechnology are widely regarded as one of the most promising frontier technologies for the coming decades." (European Commission 2002). What is meant is that the bio sector is a living, growing field, as much as life science, crop science and the pharmaceutical field are ever growing and changing.

As a result, a demand is generated by companies whose researches are in these fields in order to protect them through the use of the IP System as patents for their respective exploitation. In this sense, Rivette et al. (2000) emphasize that intellectual property is an important pillar in the business strategy. What is more, according to the OECD report in 2002, from 1990 to 2000, the number of biotechnology patents granted were around at 15% annually in the United States Patent and Trademark Office (USPTO) and 10.5% in the Office European Patent (EPO), compared to the annual 5% increase in the rest of the patents. (OECD 2002, cited by Burrone 2006).

In line with this, more regulations have been issued, attempting to regulate research relations within the bio sector, such as for example The Nagoya Protocol on Access and Benefit-sharing. In applying this protocol, the national authority (the Peruvian Patent Office-INDECOPI) can question if an invention is about the biological resource or if it accesses the genetic resource and therefore requires permission from the government, also if a license of use for a particular traditional knowledge of indigenous peoples is required for the prosecution of the patent for which protection is to be obtained. For the researcher it is important to understand as soon as possible, if it is likely that the research may result in a patentable subject matter, if access to genetic resources is required, and if a license for associated traditional knowledge is pertinent. Failing to identify these requirements from the outset, may result in substantial delay, ad frequently the abandonment of patent applications. (Soto & Ortega 2016).

However, in practice it is not simple to define when a research will use biological resources and when it will also use genetic resources or traditional knowledge.

Biotechnical patents and undefined life

One of the key issues for any biotech company which is seeking to patent its inventions, is to determinate what bio research results can be patented. The answer to this question is extremely complex as well as specific to each jurisdiction. As is the case with any new technological field, biotechnology has brought challenges for the patent system partially due to the lack of a commonly accepted definition of life. If life cannot be defined, the bio matters related to it could be clearly defined or determined, either. For this reason, in many countries (or regions), guidelines, directives or legislation have sought to clarify what can or cannot be patented in the life sciences (Burrone 2006; Thumm 2003).

The main reason is because "life" per se cannot be parametrized. To this date, we cannot define what life is, in

fact, we can only define if something is alive based on the characteristics of living things, therefore the common requirements that a patent must meet in order to be granted become more complex. It becomes a challenge to determine patentable subject matter, or if the invention meets novelty or inventive step requirement (Audesirk et al. 2004).

For example, if we discuss about the inventive step of changing an amino acid in a protein chain, it may sound very simple and common practice to do so, however we cannot be certain a priori, because one small mutation can trigger diverse metabolic reactions which we could not all predict. (Klein 2019). How can we define when a biological entity has been modified by itself or by human intervention? For example, if a bacterium was moving from a natural medium to another, which would not have been possible without human intervention, it will produce new compounds. Are these new compounds "natural" or can they be taken as a mutation, a mutation induced by human activity? If this were the case, does it fall within the definition of invention? (Thumm 2003).

Therefore, a patent examiner could reject a biotechnology application arguing that this invention which is requesting an IPR, it is merely a creation of nature or what is worse, they may argue that the scientist made an obvious variant of what organically occurs in nature. This is particularly a problem when it comes to genetically modified organisms, tissues and cells (Klein 2019).

Without going very far, it could be argued whether by applying the CRISPR technology, the result will be a GMO or not. If it is a GMO, then the Moratorium law of Peru is applicable, which does not allow for the commercialization of GMO products in the country (MINAM 2016). In order to determine whether gene edited plants and animals are "GMOs", reviewing what a "GMO" is, and is not, is essential. The understanding of a "genetically modified organism" according to the World Health Organization, "as organisms (i.e. plants, animals or microorganisms) in which the genetic material (DNA) has been altered in a way that does not occur naturally by mating and/or natural recombination" (Giddings 2018).

But this definition is problematic on multiple levels, as mentioned by Gidding in 2018, every living thing on earth is "genetically modified" in the time-honored meaning of the words as they have been in common usage since Bateson coined the term "genetics" in 1905. Indeed, life is all about "descent with modification," the modifications are genetic, and they are the reason we are all something other than primordial slime (Giddings 2018).

Conclusion

It is of utmost important that researchers in the bio sector be aware of the importance of intellectual property in their R & D projects. First at all, because everything related to the eventual patent part of his /her research, therefore the researcher is the main actor in this R & D Ecosystem.

So that, knowing about the general legal issues related to the accesses to the genetic resources or biological resources is demanding for the good development of the research, as well as, analyzing the viability of the patentability of the research in order to defend and/or exploit of it.

Finally, as we mentioned in this document, examining whether something in the biological field is patentable or not, it is not going to be as simple as in other fields of research, due to the complexity of life itself. Therefore, scientists must be attentive to the evolution of the patent system in this sector.

Literature cited

Audesirk T, Audesirk GG, Byers B. 2004. Biología: ciencia y naturaleza. Segunda edicion: 5-20

BBC 2018. Apple vs. Samsung: la disputa de años entre los gigantes tecnológicos que resultó en una multa de más de US$500 millones. 25 mayo 2018. < https://www.bbc.com/mundo/noticias-44259879> (acceso 08/03/2018)

Burrone E. 2006. Las patentes, pilar esencial del sector de la biotecnología. Organismo Mundial de la Propiedad Intelectual – OMPI. <https://www.wipo.int/sme/es/documents/patents_biotech.htm> (acceso: 03/03/2019)

European Commission. 2002. Life sciences and biotechnology sector Strategy for Europe. <http://ec.europa.eu/biotechnology/pdf/com2002-27_en.pdf> (acceso 04/03/2019)

CONCYTEC 2016. Plan nacional estratégico de ciencia, tecnología e innovación para la competitividad y el desarrollo humano. <http://portal.concytec.gob.pe/images/stories/images2012/portal/areas- institucion/pyp/plan_nac_ctei/plan_nac_ctei_2006_2021.pdf> (acceso 03/03/2019)

Fernandini C, Soto S. 2018. IP Thinking -Design innovation with IP Thinking. <http://www.mondaq.com/Peru/x/684186/Trademark/IP+THINKINGTM+ Designing+Innovation+With+IP+THINKINGTM?type=related>(acceso: 08/03/2019)

Giddings V. 2018. Gene Editing, GMOs, and Fear-Based Marketing.ITIF.<https://itif.org/publications/2018/06/18/gene-editing-gmos- and-fear-based-marketing> (acceso 03/03/2018)

Kalanje C. 2016. El papel de la propiedad intelectual en la innovación y el desarrollo de nuevos productos. Ompi publishing. http://www.wipo.int/sme/es/documents/ip_innovation_developmen t.htm (acceso 07/03/2019)

Klein C. 2019. The Complications around Patenting Biotechnology. <https://labiotech.eu/features/biotechnology-patents-intellectual-property/> (acceso 04/03/2019)

Rivette K, Northhaft H, Kline D. 2000. Discovering New Value in Intellectual Property. Harvard Business Review. Recuperado de <https://hbr.org/2000/01/discovering-new-value-in-intellectual-property > (acceso 10/02/2020).

Ministerio del Ambiente -MINAM. 2016. Moratoria al ingreso de transgénicos -ovmen el perú. Reporte del estado de la implementación de la Ley n.° 29811. Primera edición <http://www.minam.gob.pe/informessectoriales/wp-content/uploads/sites/112/2016/07/OVM.pdf> (acceso 10/03/2019)

Mohnen P, Hall B. 2013. Innovation and Productivity: an update. Eurasian Business Review, 3(1): 47-65.

Soto S. 2016. Special Plan for Technology Transfer in Peru 2016-2021: Transferring Technology from the Academy to the Market. <https://vlex.com.pe/vid/special-plan-for-technology- 655983905> (acceso 07/03/2019)

Soto S, Ortega A. 2016. Peru and Access to Genetic Resources and Implications of The Nagoya Protocol. <http://www.mondaq.com/Peru/x/491768/Patent/Peru+And+Access+T o+Genetic+Resources+ Implications+Of+The+Nagoya+Protocol> (acceso 05/03/2019)

Thumm N. 2003. Research and Patenting in Biotechnology - A Survey in Switzerland. Swiss Federal Institute of Intellectual Property. Publication No 1.

WIPO. 2017. World Intellectual Property Organization Report 2017: Intangible Capital in Global Value Chains. <https://www.wipo.int/publications/en/details.jsp?id=4225> (acceso 08/03/2019)

WIPO. 2016. World Intellectual Property Organization Academic: IP Panorama Course. Module 1. <https://www.wipo.int/export/sites/www/sme/en/documents/pdf/i p_panorama_1_learning_points.pdf> (acceso 05/03/2019)