# Patenting the results of university research with special reference to biotechnology research

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Abstract—Biotechnology and intellectual property are two areas that have played a significant role in the transformation of research. Intellectual property is generally regarded as an important driver of innovation in science and technology, as it allows researchers, institutions, and inventors to recover their investments during the period of monopoly rights. The patent system encourages innovation by providing patent protection to inventions as well as distributing useful information. Researchers at universities increased their use of patents as sources of information and as a significant tool contributing to the economic progress of society. Patents have become as important as scientific papers, especially when assessing the impact of research on society and the economy. Since today it is expected from the Universities not only to engage in research and teaching but also to make money from the knowledge produced. From the collaboration of research institutions and interested companies, Spinoff companies have been formed, as a form of connecting academic researchers and the private sector. New ways of promoting inventions are fully in line with the patent protection system. Therefore, patent law is a key factor in the development of innovative technology and provides investment in further research that is imperative of modern societies.

Keywords – Patent; Researchers; Biotechnology; Spinoff companies; Patent pools

### I. INTRODUCTION

The patent system protects the inventor from economic failure by granting intellectual property rights to the inventor. This is achieved by allowing the inventor to prohibit the manufacture, use or sale of the protected invention for other persons over a period of time. These exclusive rights are granted only for a limited period of time. In Europe, this period is 20 years from the date of application. Furthermore, rights could be granted only for a geographically restricted territory or some specific country. European patents can be granted for up to 38 countries (signatories to the European Patent Convention), but it should be subsequently validated in each country in which the patent owner seeks protection [1].

Patents are the most appropriate form of protection that is primarily encouraging for investors and biotechnologists. They can publicly present the results of the research, both through the possibility of publicly presenting the subject of biotechnological inventions and through the possibility of being rewarded. There is no other area with such a good relationship between patent protection and innovation incentives. The patent system plays an important role in fostering innovation, by providing legal protection to inventions and distributing useful information about them. Throughout its history, the patent system has had to adapt to new conditions. A series of judicial, legislative, administrative and diplomatic actions have influenced the extension of patent protection to new technologies (such as biotechnology) but also the emergence of new actors (such as universities and public research institutions)<sup>1</sup>.

New technologies have weakened the traditional line between basic and applied research, enabling universities and other publicly funded research institutions to generate research results that qualify for patent protection. The results of such research may be further licensed. This is why patents are treated as "vehicles for transporting publicly funded research into innovative products and processes."<sup>2</sup>

## II. ACADEMIC RESEARCH

There is a clear increase in the number of academic patents protected primarily by biotechnological inventions, hence the Academic institutions have become "major players" in the patent arena. In the USA, for example, the number of patents granted to academic institutions has been steadily increasing. In the last decade, 50% of all patents in the field of natural sciences have been allocated to research centers at Universities. Europe is not far behind in terms of academic patents.

For example, 75% of biotechnological patents were granted by the EPO (1985 to 1999) to Belgian universities. The number of Italian university patents has also increased. Patent activities at universities have tripled since the adoption of The Bayh Dole Act in the United States in 1980. It aimed to encourage the patenting of academic inventions.

On the other hand, the university's cooperation with the private sector has increased through research funding, transferring intellectual property rights to license agreements and the creation of spinoff companies.

<sup>&</sup>lt;sup>1</sup>Merril, Levin and Myers M., A patent System for the 21 st Century, Retrieved from: <u>https://www.nap.edu/catalog/10976.html</u>, date: 10. 11. 2016.

<sup>&</sup>lt;sup>2</sup> Straus J. (2017): Intellectual property right and bioeconomy, Journal of Intellectual Property Law and Practice.

Some experts have predicted that there will be challenges in the "interface" of biotechnology and innovation technologies and that these technologies will require the use of not only patent law, but also the copyright and rights of database manufacturers.<sup>3</sup>

Many of the research in this area is still "basic" and is undertaken at universities financed partly by public funds. The cooperation with the private sector and the formation of publicprivate partnerships are needed in order to utilize private funding for the aforementioned research [2]. It should also be emphasized that there is concern about the patenting effects of early-stage research results, its effects on further research and on the price of end products. This is important since the data indicate that a small number of universities with protected inventions also have high revenues, while the quality of patents at US universities is declining.<sup>4</sup>

The Bayh Dole Act stipulates that institutions enter into contracts with inventors on the basis of which the inventors transfer the right to file a patent application to the institution concerned. The institution, on the other hand, grants a free license to the US Government to use the invention for its own purposes. The use of such inventions is especially intended for researchers whose research is funded by the US Government.<sup>5</sup>

The development of biotechnology in the US has certainly been influenced by the increase in patenting and licensing of inventions by the University. In addition to the primary interest of the University, which is the scientific interest, there is increasing financial interest. One of the goals of the University, in addition to advancing scientific knowledge, is to make money. As a result, more and more Universities are seen as "services" rather than organizations, trying to make money on what they explored.<sup>6</sup>

Since the first patent application for stem cells was filed in 1989, in the UK, the number of patent applications has been steadily increasing. Universities are especially active, so almost half of the stem cell patents belong to Universities (42%), while the corporate sector holds 48%. Therefore, the University is now expected not only to engage in research and teaching. Knowledge sharing traditionally takes place through the publication of scientific papers in journals, conference presentations and the like [3]. But today, the Universities are also expected to make money from the knowledge produced, in order to primarily justify the investments made.<sup>7</sup>

The Bayh Dole Act is often seen as a success of US official policy to facilitate the transfer of university research to industry, including universities to patent their inventions.

As in the US, many countries, including European countries, have created their own way of financing university

research. The Lisbon Treaty stipulates that the EU aims to strengthen the scientific and technological basis for the achievement of a European Research Area, in which researchers disseminate scientific knowledge and technology freely, fostering industry competitiveness.

In the biotechnology industry, for example, discoveries such as genetic cloning or mapping of the human genome, otherwise patented, have emerged as a result of research at universities. In the process, the knowledge that emerges from research at universities is "captured" and distributed through the patent system.

Until a few years ago, there were many truths that were stable that patents could represent limited transferable knowledge. European universities and small research organizations are known for encouraging research so that they can focus on objective scientific work and on obtaining patents for their lives. This being the case, I will keep promoting government through patent rules as an important pre-emptive for knowledge transfer. Patents have been given equally important papers and scientific papers, especially when evaluated utilizing investigation and companionship and economics.

The practice of combining patenting and publication is increasingly being used to allow researchers to benefit from both activities. In fact, they can harness the potential gains from patents and be recognized academically for the quality of their work.<sup>8</sup>

One way of collaboration between academic researchers and the private sector is forming the spinoff companies. A subsidiary or spinoff company is a special form of an entrepreneurial company that was previously started and affiliated with another company. It was once a core company, which split off and became an independent company in the market. A special form of spinoff company is an academic spinoff company. It is defined as a company founded by a group of scientists. The main assets of these companies are patentprotected inventions. Interest in the commercial application of knowledge created by universities is particularly pronounced in the field of biotechnology.<sup>9</sup>

Thanks to these companies, university employees can be not only innovators or founders but also managers or directors of spinoff companies. It should be emphasized that even potentially market-successful innovations and well-developed regulations (regarding the establishment and operation of spinoff companies) do not guarantee the successful commercialization of research results. Particularly significant is the issue of financing these ventures. Large sums of money are often needed to ensure that innovation is brought to the market.

<sup>&</sup>lt;sup>3</sup> Genetics Inventions, Intellectual Property Right and Licensing Practices evidence and Policies OECD, 79, Retreived from: https://www.oecd.org/sti/sci-tech/2491084.pdf, date: 10. 05. 2015.

<sup>&</sup>lt;sup>4</sup> Hescot L. A. (2014): Standing on the shoulders of giants? A study of scientists engagement with patent information, University of Shesfeld, School of Law, 29.

<sup>&</sup>lt;sup>5</sup> Rohrbaugh M. L. Stem cell Patents. What every Researcher Should now, 588, Retreived from: <u>www.sciencedirect.com/science/article/pdf/</u> 9780123854735000370, date: 26.5.2019.

<sup>&</sup>lt;sup>6</sup> Nelson R. (2001): Observations on the Post-Bayh Dole Rise of Patenting at American Universities, *Journal of Technology Transfer*, Kluver Academic Publisher, Netherland, no. 26, pp. 17.

<sup>&</sup>lt;sup>7</sup>Hescot L. A,13.

<sup>&</sup>lt;sup>8</sup>Do you do research? Think about patents, EPO,Retreived from: <u>www.zis.gov.rs/upload/Publikacije/Lifleti/Bavite%20se%20istraživanjem.pdf</u>, date: 9.10.2016.

<sup>&</sup>lt;sup>9</sup> Nielsen-Eric J., Aleksic-Stojanovic V., Nikolic J., "The role of entrepreneurial spin-offs in the economic development of Kragujevac, 193, Retreived from: <u>https://ekjav.kg.ac.rs/sities/default/files/Zbornik</u>, date: 12. 06.2017.

Those sums are far greater than the financial capabilities of the company founders, and even of the university. It is, therefore, necessary to raise capital to finance innovative, highrisk ventures.<sup>10</sup> In the field of biotechnology, the use of patent pools is very important, both for the private and public sectors. A patent pool is an agreement between two or more holders of a patent right, on the basis of which they assign the right to the mutual use of the protected rights, or the right to use, jointly, to a third party. They are certainly useful because the companies can obtain licenses to use patent-protected technology from only one entity, thanks to a patent fund. Patent pools also eliminate patent blocking issues while reducing licensing costs.

The patent pools eliminate the need for litigation because disputes can be solved or resolved through the creation of patent pools [4]. Small businesses that would not be able to withstand the costs of litigation, will more often "survive" and prosper if they are exempt from legal action in the future.

The existence of patent pools allows interested parties to license all patents in the fund, which are necessary for the use of a particular technology, rather than requiring a license from each holder individually. Reducing transaction costs, as well as the ability to share R&D risks, are also important. We know that the university's primary mission is to deliver teaching and research. But today, universities are increasingly expected to make money from 'produced' knowledge, in order to justify investing in their research. Patenting research results enables the realization of research in the form of products. The patent system encourages research and development as well as technology transfer, all of which lead to economic development [5].

#### III. PROJECT "HORIZON 2020"

Within the EU, the project "Horizon 2020" has been launched. It is the financial framework that implements" the Innovation Union", one of the key initiatives of the Europe 2020 Strategy. The aim of the project is to ensure the development of science and technology, especially biotechnology at the world level. It is funded with  $\in$  80 billion (2014-2020). The aim of the project is removing all the obstacles to innovation and collaboration between the public and private sectors.<sup>11</sup> The Agreement, provisionally applied from 1 January 2014, between the Government of the Republic of Serbia and the European Union on the participation of the Republic of Serbia in the EU Horizon 2020 - Framework Program for Research and Innovation (2014-2020), the Republic of Serbia was granted the status of an associated country.

The Agreement entered into force in accordance with the Act Confirming that Agreement.<sup>12</sup> Affiliate status means that all legal entities from that country have the same rights and obligations as legal entities from the EU Member States.<sup>13</sup>

The research commercialization enables the return of investment, which can be further invested in the new research. In this direction, a Project in Western Balkans was implemented. Five universities in the Western Balkans (from Kragujevac, Niš, Banja Luka, Podgorica, and Zenica), along with five European partners and five business incubators, in collaboration with the Intellectual Property Office, have developed an "Innovation Management Methodology". The purpose of the project is to help researchers and students, as a first step in the process of intellectual property commercialization. Thanks to partners with five incubators in the region, as well as developing collaboration with businesses, the best ideas will be supported in further market entry.<sup>14</sup>

In Serbia, an agreement was signed between the Intellectual Property Office and the University of Belgrade (in June 2013).On the basis of this agreement, the cooperation between the Intellectual Property Office and the Technology Transfer Center is being developed<sup>15</sup>, in the context of promoting the commercialization of intellectual property rights. Cooperation includes support in the enforcement of intellectual property rights as well as the promotion of cooperation between universities and the economy. Furthermore, this cooperation contributes to raising awareness of the importance of patents and other intellectual property rights in the technology transfer process.

The modern technological revolution and its role as a key driver of social development have influenced not only the increasing importance of the protection of intellectual property rights but also the commercialization of them.

#### IV. CONCLUSION

The modern technological revolution and its role as a key driver of social development has influenced not only the increasing importance of the protection of intellectual property rights but also the commercialization of them. The financial aspect of biotechnology research and the lack of alternative investment protection imposes the need for their patent protection. In the past few years, biotechnological inventions have been constantly quoted in the 10 largest technical areas based on the number of patent applications filed with the European Patent Office (EPO).

About half of these applications come from scientific institutes and universities. Therefore, it is necessary to establish a policy on teaching about intellectual property, then, it is necessary to establish cooperation between universities in the region in order to achieve common goals. More efforts are also needed to develop awareness of the importance of intellectual property teaching in higher education institutions, as university researchers, as noted, are increasingly using patents both as a measure of their own success and as a means of contributing to economic development.

<sup>&</sup>lt;sup>10</sup> National Recommendations for Universities in Serbia for Managing Intellectual Property in Knowledge Transfer Activities, Belgrade, Retreived from: <u>https://erasmusplus.rs/wp-content/uploads/2016/06/</u>

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<sup>&</sup>lt;sup>11</sup><u>www.ec.europa.eu/horizont 2020</u>, date: 15.09.2015.

<sup>&</sup>lt;sup>12</sup>Official Gazette of the RS-International Treaties ", No 9/14

<sup>&</sup>lt;sup>13</sup> "Horizon 2020 Program ", EIC Bulletin No.19, October 2014,1,

<sup>&</sup>lt;sup>14</sup> "Innovation and cooperation with industry in the focus of the Western Balkan University", EIC Bulletin, no.19, 2014, 2.

<sup>&</sup>lt;sup>15</sup> With the joint cooperation of ZIS and the University of Belgrade, the Center for Transfer Technologies was established in Belgrade, by decision of the University Council on 26.10.2010. years.

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