Working Competition and Biotechnology Patent Pools

By Elizaveta Osipchuk

ABSTRACT

Patent pools have always been a subject of heated discussions due to their ambiguous position on the market as they bear both anti-competitive and pro-competitive characteristics. On the one hand, they create a common market for licensors and licensees, guarantee access to the industry standards (if any), as well as induce further innovation. They bear a certain risk of violating anti-trust laws".

Patent pools were introduced into life sciences quite recently. Biotechnology patent pools play an immensely important role in providing access to essential, up-to-date medicines for terminal diseases that affect a great number of population in certain countries. They make medicines affordable to the local generic producers in developing and least developed countries who bring the affordable new drug formulations to the market. Furthermore, since modern medicine is largely based on gene patents, pooling is suggested to resolve the patent thicket issue around genetic diagnostics. At this moment, the most successful and global example is the Medicine Patent Pool founded in 2010 by UNITAID.

Patent pools generally encompass patents that protect developed technology. However, for the pharmaceutical industry, it is of major importance that the patent pools facilitate further development of the drugs. This necessity stems from, among other factors, a) the ability of viruses to develop resistance to the treatment, b) scarcity of paediatric drug formulas, and c) the need in fixed dose drug combinations (FDCs) for the treatments requiring simultaneous consumption of several medicines such as antiretroviral drugs.

As patent pools gained more popularity, concern about their adverse impact on competition practices grew as well. Despite the recognized benefits of patent pooling, such as promotion of technical progress, dissemination of technology rights as a special type of goods allowing for an even further increase in manufacturing capacity, the technology transfer block exemption under Regulation 316/2014 is inapplicable to the pooling agreements.[1]

As a result, an examination of the relationship between current EU competition law policy towards patent pools appears to be a particularly relevant and valuable subject for discussion. By establishing whether legal safeguards of the EU anti-trust framework help to reach a healthy balance between the protection of market competition and industrial development, we could identify the place of patent pooling in the context of legal solutions for distributing the benefits of health care biotechnologies.

1. DEFINING PATENT POOLS AND THEIR RELATION TO BIOTECHNOLOGY

1.1 Development History and Closely Related Concepts

Historically, technology pools were created as a facilitating instrument for the efficient use of supplementary patented technology pertaining to a single innovative product. The first pools were created as early as in the XIX cent.: the 'Sewing Machine Combination' trust by Grover & Baker Co., Wheeler & Wilson Co. and I.M. Singer Co. and attempted to resolve endless litigation disputes and blocking patents. Even though a pooling agreement generally implies that the participation in it is voluntary, proposals of a compulsory mechanism also emerged.[2] In 1917, the Manufacturers Aircraft Association was formed under

1 Guidelines on the application of Article 101 of the Treaty on the Functioning of the European Union to technology transfer agreements 2014/C 89/03 (Guidelines on technology transfer agreements (2014)) provide that Art. 101(1) of the TFEU does not apply to technology transfer agreements as long as they meet a number of enlisted criteria; each case has to be assessed individually.

2 For instance, in 2005 it was suggested to form a patent pool for AIDS (Essential Patent Pool for AIDS). The holders of patents essential to the manufacturing of antiretroviral drugs were urged to place their patent rights in the pool, or become subject to compulsory licensing, if refused to do so. Essential Patent Poll for AIDS (EPPA): Background Information (2005) [Online]. Available from: http://www.essentialinventions.org/docs/eppa/ [Accessed on 7 March 2017]. The Manufacturers Aircraft Association is another example of involuntary licensing; see para. 2.2.1 for more information.

3 Neelie Kroes European Commissioner for Competition Policy, 'Setting the standards high'. Address at Harvard Club of Belgium (15 October 2009, Brussels), SPEECH/09/475. [Online]. Available from: http://europa.eu/rapid/press-release_SPEECH-09-475_en.htm?locale=en [Accessed 3 April 2017]

4 Anderman, S. and Ezrachi, A. (eds.) (2011) Intellectual Property and Competition Law. New York: Oxford University Press, 374.

5 '... abuse of the market power gained by virtue of IPR being included in a standard constitutes an infringement of Article 102 [TFEU]'. Draft Communication from the Commission, Guidelines on the applicability of Article 101 of the Treaty on the Functioning of the European Union to horizontal co-operation agreements' (2010) SEC(2010) 528/2 ('Draft Horizontal Cooperation Guidelines').

6 Bhat, A. & Shaffer, E.R. (2008) Trade Related Aspects of Intellectual Property Rights (TRIPS): Protecting patents or patients? [Online] Available from: https://www.cugh.org/sites/default/files/TRIPS%20-%20Protecting%20Patents%20or%20Patients.pdf

the pressure of the US government to break the market barrier held by two dominant aircraft patent holders.

Due to the fact that the pools were treated with substantial apprehension for anticompetitive risks, very few of them were created between 1920 and 1990s. By the 1990s, the incentives for pooling changed: pools were needed to clear patent thickets on inventions lying at the foundation of a technical standard. Generally, standards aim at achieving the interoperability of companies' products on a global level, thus creating "the level playing field on which all can compete."[3] Standards proved to be successful in minimizing the risks of purchasing a technology that may become outdated in a short time, and in decreasing the consumer's expenses that occur due to the technology switching.[4] To balance licensees and licensors' interests, the FRAND (fair, reasonable and non-discriminatory) commitments were implemented as a responsibility of any company that gained its market power by contributing to a standard.[5]

Modern pool models focus mainly on the standardization of telecommunication technologies and include, for instance, GSM, MPEG-2 standard (a digital technology for video compression), Bluetooth, DVD-1, DVD-2, 3G, 4G and soon-to-be 5G. IT products are a combination of highly complicated essential software and hardware, which is why the customer is more interested in purchasing a complete patent portfolio to start the production, rather than pursuing the licensors separately without any guarantee of obtaining all the necessary rights.

By contrast, the pooling business model has been introduced to the biotechnology industry fairly recently in the face of a global challenge – public health. The international treaties on intellectual property protection, such as the agreement on 'Trade-Related Aspects of Intellectual Property Rights' (TRIPS) resulted in the increased protection of the pharmaceutical firms patents and restraints on smaller drug manufacturers and researchers.[6] Meanwhile, the issue of specificdiseases is far from being solved. Alongside numerous economic factors - including high drug prices, the absence of local production, transportation and storage facilities - the main legal stumbling block here is the patent monopoly: from being the owners of resources necessary for drug research and development, pharmaceutical companies resist sharing their scientific welfare with generic producers. Nevertheless, in recent years pooling has become more accepted by the industry, not least because of public pressure and state endorsement.[7]

A patent pool provides a mutually beneficial solution, where patent holders receive decent compensation and the licensees are receiving access to affordable patented technology for commercialization and further development. One of the most successful examples of manufacturers cooperation is the Medicine Patent Pool (MPP), created under the guidance of UNITAID.

1.2 Natute of Technology Pools

The presence of pro- and anti-competitive characteristics in technology pools depends on a number of factors, such as interdependency of the technology inside and outside of the pool. Relatively to their nature, the technologies can be divided in two groups: complementary and substitutionary, essential and non-essential.[8]

The technologies are complementary if both of them are required to produce the product or to carry out the process to which they relate. On the contrary, if just one of the two technologies is needed to produce or carry out the related product or process, these technologies are substitutable.[9] Patent pools that only include substitutes may decrease competition and demand higher royalty payments from licensees. Hence, they are treated harshly by the legislator and are explicitly declared to be in viola-

[7] See, i.e., Boseley, S. (2011) Big Pharma Shows Willingness To Pool HIV and AIDS Drug Patents. Posting on Sarah Boseley's Global Health Blog, The Guardian. Available from: https://www.theguardian.com/society/sarah-boseley-global-health/2011/feb/10/drugs-pharmaceuticals-industry [Accessed 6 March 2017]; Medicines Patent Pool (2011) G8 Encourages Drug Companies to Work with the Pool. [Online]. Available from: http://www.medicinespatentpool.org/g8-encourages-drug-companies-to-work-with-the-pool/ [Accessed 6 March 2017] (highlighting the importance of governmental endorsement of the Medicine Patent Pool initiative by the countries where most of the patent holding companies are located); GlaksoSmithKline (2013) ViiV Healthcare announces a voluntary licence agreement with the Medicines Patent Pool to increase access to HIV medicines for children [Online]. Available from: https://us.gsk.com/en-us/media/press-releases/2013/viiv-healthcare-announces-a-voluntary-licence-agreement-with-the-medicines-patent-pool-to-increase-access-to-hiv-medicines-for-children/

[8] Guidelines on technology transfer agreements (2014), para. 250, EuC.

[9] Guidelines on technology transfer agreements (2014), para. 251, EuC.

tion of Art. 101(1) of the Treaty on the Functioning of the European Union (TFEU); the requirements for exemption under Article 101(3) TFEU are not likely to be met, even where independent licensing is available to the pool members.[10] Moreover, the technologies will be deemed complementary if: the patent holders have contributed their rights to the pool on a non-exclusive basis; the pool is willing to out-license the technology separately from the package, and the overall amount of royalties for individually licensed technologies does not exceed the royalties charged by the pool for the whole package.[11] However, the distinction between complementary and substitute technologies is not always obvious.

A technology is considered essential in two cases: a) a technology cannot be replaced by another on technical or commercial grounds for producing a product or carrying out a process to which it relates; b) a technology is necessary to the standard supported by the pool and there is no substitute available (in relation to a patent – standard essential patent, SEP).[12] An irreplaceable technology remains essential as long as the technology is covered by at least one valid intellectual property right. Besides, the essential technologies are by necessity also complementary.[13] Therefore, patent pools that comprise only of essential technologies are generally unlikely to infringe Article 101(1) of the TFEU as a single entity. However, the conditions of their licensing agreements may be still at risk.
It must be borne in mind that a technology may cease being essential, if, after the pool was established, alternative technologies were introduced on the market by the third parties. This leads to the risk of anti-competitive conduct unless the technology is removed from the pool.[14] Nevertheless, once a technology is included in a standard, it is more likely that the alternative undemanded technologies will be withdrawn from the market.[15]

Whether a technology is essential or not has to be decided by an independent specialist. The involvement of independent experts in creating a pool guarantees a transparent process of patent selection, and may even improve competition between the available technical solutions.[16] However, as the decision about the pool's establishment is made long before the final product is introduced, it is difficult to conclude with certainty whether a picked piece of technology is essential. This supports the argument that favours passing up the essentiality criteria.[17]

In a market dominated by a few powerful players, the exchange of sensitive information may lead to price-fixing arrangements.[18] It is therefore important to ensure that safeguards are present, such as hiring an independent expert or a licensing body as they would make it possible to calculate and verify royalties without disclosing sensitive information to the competitors.[19]

In sum, other factors decreasing competitive risks include:
- open participation: if the pool membership at the time of its creation and operation is open to all interested parties;[20]
- involvement of independent experts in technology selection and pool's operation;[21]
- autonomous dispute resolution;[22]
- safeguarding the sensitive information exchange between parties.[23]

1.3 The Notion of a Patent Pool

The guidelines define technology pools as, "arrangements whereby two or more parties assemble a package of technology which is licensed not only to contributors but also to third parties". Unlike technology pools, there is no unified opinion on the definition of patent pool. For instance, Shapiro describes patent pools as an organization where a number of complementary patents are licensed as a single package by several patent holders simply "to anyone willing to pay the associated royalties."

The nature of pooled patents is a key factor for assessing the anti-competitive characteristics of a pool. Complementarity gives value to an individual patent that would be heavily discounted unless fitted in the licensee's portfolio. Substitute patents cover alternative technologies needed for producing one product. The two are therefore not usually in conflict with each other. Complementary patents concern different inventions that cannot compete on the same market position as substitute patents.

To reach the right conclusion, one should consider the nature of technologies from a legal standpoint. For example, from a technical perspective, two complementary patents must be used in a production process together, and it is not possible to interchange them. From the legal perspective, these patents are complementary because they are 'blocking' the functions of each other, which also

[10] Guidelines on technology transfer agreements (2014), para. 219, EuC.
[11] Id.
[12] Guidelines on technology transfer agreements (2014), para. 252, EuC. As to the standard essential patent (SEP) term, see Commission decision no. 39985 Motorola - Enforcement of GPRS standard essential patents (Motorola), (2014) slip op. para. 52.
[13] Guidelines on technology transfer agreements (2014), para. 216, EuC.
[14] Guidelines on technology transfer agreements (2014), para. 263, EuC.
[15] Motorola, slip op. para. 53.
[16] Guidelines on technology transfer agreements (2014), paras. 256-257, EuC.
[17] Greene, H. (2010) Patent Pooling Behind the Veil of Uncertainty: Antitrust, Competition Policy and the Vaccine Industry, Boston University Law Review, 90 (4), 1437. Available from: https://ssrn.com/abstract=2157277 [Accessed 6 March 2017].
[18] Guidelines on technology transfer agreements (2014), para. 259.
[19] Id.
[20] Guidelines on technology transfer agreements (2014), paras. 248-249, EuC.
[21] Guidelines on technology transfer agreements (2014), para. 248, EuC.
[22] Id.
[23] Id.
[24] WIPO Secretariat (2014) Patent Pools and Antitrust – A Comparative Analysis. [Online], 4. Available from: http://www.wipo.int/export/sites/www/ip-competition/en/studies/patent_pools_report.pdf [Accessed 20 May 2017].
[25] Charles River Associates Ltd. (2003) Report on Multiparty Licensing. [Online]. Available from: http://ec.europa.eu/competition/antitrust/legislation/multiparty_licensing.pdf [Accessed 23 January 2017].

decreases their individual value. Thus, licensing agreements are necessary to avoid patent infringement and produce the desired product.[24] While one might think that creating a pool consisting solely of complementary technologies would be the best solution against antitrust risks, in some cases substitute (competing) technologies are also needed "to produce the defined product without infringing upon a patent outside the pool."[25]

Patent pools are usually established by the initiative of their members, who, at the same time, serve as contributors of intellectual property and financial investors. As a result, the members retain significant influence on the terms of concluded licensing agreements between the patentees and licensees. The licensing model for the patentees and pool administration can work in two ways. In the first case, an agreement is concluded between the patentees represented by one assigned partner and the third parties. This model works best for pools with a small number of patent holders. In the second case, a special entity is set up to administer the pool and be an independent licensing authority.[26]

Based on their internal structure, patent pools can be differentiated in three ways:

1) **Joint licensing schemes,** which are developed by a group of licensors concerned about a common technology or a standard. One of the patent holders can act as an agent for the joint licensing contract.
2) **Patent pools with a licensing administrator,** which are initiated by an open call for essential patents from an independent body. An independent licensing administrator is responsible for: determining whether the patents are, in fact, essential; setting the royalty rate for the patent packages; collecting royalties and re-distributing them, given a pre-agreed scheme. The licensors are not supposed to know the other licensors that will be joining the pool. For instance, MPEG-2[27] and ViaLicensing[28] are good examples of organisations where an independent body is acting as a licensing administrator for more than one patent pool simultaneously covering many technical standards.
3) **Patent platforms,** which function as IP aggregators, allow dealing with multiple technologies and standards or product groups involving one or more essential patents. They aim to be flexible towards the respective agreements between licensors and licensees. The patent platform structure consists of one umbrella organisation and multiple entities, where each develops specific licensing programmes. In the bilateral world of patent markets, patent platforms also help to connect sellers and buyers. At present, several patent platforms exist, some of them in online form.

Since there are only a few examples of patent pools that have completed their business lifecycle, they are mostly studied as theoretical models. Hence, the lack of empirically collected data and limited possibility to explore the practical effects of legal provisions.

1.4 Biotechnnology Patent Pools

1.4.1 Overview of the Biotechnology Industry

Biotechnology can be defined as "the manipulation (as through genetic engineering) of living organisms or their components to produce useful, usually commercial products (such as pest resistant crops, new bacterial strains, or novel pharmaceuticals)."[29] From this definition, we can see that the industry can be divided into several sectors based on the application of technology: health care, agricultural and industrial biotechnology. Despite this variety, this article focuses on health care biotechnology and its operation within the patent pool model. Health care biotechnology covers medicinal or diagnostic products and vaccines that consist of, or has been produced in, living organisms and can be manufactured via recombinant technology (an artificial assembling of DNA sequences).[30]

Patenting in biotechnology has for a long time been limited by the "product of nature" doctrine that stopped inventors from claiming monopolies on natural substances, such as genes, animal species or microbes, as they are not an outcome of a human effort.[31] Since TRIPS Agreement does not oblige WTO members to make natural substances patentable within their national legal frameworks, states are able to set their own boundaries between inventions and discoveries, and some states define inventions by using even stricter terms.[32] Hence, the European Patent Convention differentiates between a discovery and an invention, where the latter is achieved by modifying or isolating an otherwise not patentable product or process.[33] A judicial interpretation that has broadened the term 'product of nature' was given by German

[26] See Shapiro, 2001; Clark, J. (2000) Patent Pools a Solution to the Problem of Access in Biotechnology Patents? [Online] in a White Paper commissioned by Q. Todd Dickinson, the Under Secretary of Commerce for Intellectual Property and Director of the US Patent and Trademark Office. Available from: https://www.uspto.gov/patents/law/patent_pools.pdf [Accessed on 18 April 2017]; Merges, R. (1998) Institutions for Intellectual Property Transactions: the case of patent pools. [Online], University of California at Berkeley. Available from: https://pdfs.semanticscholar.org/0eff/e6d273264282c6eaaf57185b9cbc71fb0f03.pdf [Accessed on 18 April 2017].

[27] See www.mpegla.com

[28] See www.vialicensing.com

[29] «Biotechnology». Merriam-Webster Dictionary. [Online]. Available from: https://www.merriam-webster.com/dictionary/biotechnology [Accessed 5 May 2017].

[30] Ernst & Young, European Association of BioIndustries (2014) Biotechnology in Europe: The tax, finance and regulatory framework and global policy comparison. [Online], 4-5. Available from: http://www.ey.com/Publication/vwLUAssets/EY-biotechnology-in-europe-cover/%24FILE/EY-biotechnology-in-europe.pdf [Accessed 5 May 2017].

[31] Krishna, R. (2008) Patents and Products of Nature Doctrine. [Online]. In: Correa, C. (ed.) A guide to pharmaceutical patents. Geneva: South Centre, 1-10. Available from: https://www.researchgate.net/publication/228171935 [Accessed 6 May 2017].

[32] Agreement on Trade-Related Aspects of Intellectual Property Rights, 1994, Art. 27.3.b.

[33] Id.

Federal Supreme Court in 1969: a patentable invention would include animal breeding methods if they were proved to use controllable natural forces to achieve a casual, perceivable result.[34] As for modern European legislation, Article 53(b) of the European Patent Convention (EPC) states that plant or animal varieties or essential biological processes are not patentable.[35] Nevertheless, technical inventions include those which use natural processes to achieve a technical result.[36] With regards to the human body and genome, under Art. 51(1) of the EU Biotechnology Directive and Rule 23e of the EPC, patents are granted if they constitute "an element isolated from the human body or otherwise produced by means of a technical process." However, if isolated and/or purified, human DNA – the process of obtaining it as well as the actual sequence - can be a part of many patent claims, for instance, a patent on human relaxin DNA.[37]

The process of patenting chemical compounds present in natural substances may be complicated by the difficulty of identifying the prior art, since the natural material can have various applications, and the derived substance occasionally has a totally new use.[38] Over the years, there has been a noticeable decline in interest from pharmaceutical companies in deriving new chemical compounds from natural materials, which became a secondary source for new drugs in R&D.[39] Therefore, it can be concluded that today, the "product of nature" doctrine's applicability is rather limited in developed countries due to technological progress, changes in law and its interpretation by the courts.[40]

1.4.2 IP-related Issued Faced by the Biotechnology Industry Today

In Europe, biotechnology occupies a large part of the market, creating new job positions and delivering countless medical products for European citizens. As any other industry that holds a great value in its IP assets, biotechnology suffers from an abundance of granted and pending patent applications, which nowadays mainly concern the DNA sequences and human genes.

The problem of blocking patents, as well as patent stacking, is common among biotech companies.[41] Hence, the Heller and Eisenberg's "tragedy of the anti-commons" applies here in addition to the IT industry. The costs and efforts dedicated to combining upstream patents to develop one product are frequently too high to maintain a balance between the public enjoyment of progressive biotechnological innovations, and the monopolistic rights of patent holder. Moreover, patent stacking raises end-product prices. The founders of the tragedy of anti-commons suggest that the upraise of utility requirements for patent grants and patent pools could be a solution to the anti-commons problem in biotech field:

> *... patent law only weakly prevents excessive fragmentation in biomedical research. Old-fashioned boundary doctrines, such as the "utility" requirement in patent law, have not kept pace with technological change. Rebecca Eisenberg and I have argued that creating property rights in isolated gene fragments seems unlikely to track socially useful bundles of property rights – a form of excessive "physical" fragmentation.*[42]

By contrast, recent findings by other researchers claim that there are no indications of a substantial patent thicket problem in the field of human genetics in particular.[43]

Despite this point of view, some characteristics of the biotech industry indicate that the appearance of anti-commons is a possible issue. For instance, the expansion of patents held by numerous parties and the sporadic tendency of companies to compile IP assets signalthe real risk of patent thickets. Contrary to the IT industry, the holder-companies on the biotech market are much more protective over their immaterial capital, which imposes certain difficulties on incentivizing their participation in cooperative organizations like patent pools.[44] Companies tend to adopt the policy of restrictive licensing or refusal to license, which causes wide disapproval due to the possible adverse effects it may have on public health.[45]

1.4.3 Biotechnology Patent Pooling and Public Health

It has been claimed by some authors that biotechnology is unlikely to succeed in pooling since the result of technological development will be aimed at one product with a limited scope of application.[46] However, it appears that these researchers primarily addressed situations where the main conflict of interest lies between biotechnology companies, thus putting the public interest in a secondary position. Indeed, it is impossible to ignore the economic and even political power of modern pharmaceutical

[34] German FSC, GRUR 1969, 677 and IIC 1970, 136 – "Rote Taube" ("Red Dove"). See, for example, Krishna, 2008.

[35] European Patent Convention of 5 October 1973, as revised by the Act revising Article 63 EPC of 17 December 1991 and the Act revising the EPC of 29 November 2000.

[36] See the EC Directive on the legal protection of biotechnological inventions 98/44/EC (EU Biotechnology Directive).

[37] See WIPO (2006) Bioethics and Patent Law: the Relaxin Case. [Online] WIPO Magazine. Available from: http://www.wipo.int/wipo_magazine/en/2006/02/article_0009.html [Accessed 6 May 2017].

[38] Krishna, 2008.

[39] Id.

[40] Conley, J. & Makowski, R. (2003) Rethinking the Product of Nature Doctrine as a Barrier to Biotechnology Patents in the USA and Perhaps Europe as well. [Online] Journal of the Patent and Trademark Office Society, 85, 301 (Part I), 371 (Part II). Available from: http://whoownsyourbody.org/conley_article.pdf [Accessed 7 May 2017].

[41] European Patent Office, Biotechnology patents at the EPO. [Online]. Available from: https://www.epo.org/news-issues/issues/biotechnology-patents.html [Accessed 9 May 2017].

[42] Heller, M. (2009) The Boundaries of Private Property. The Yale Law Journal, 108 (6), 1163-1223. Available from: http://www.jstor.org.ezp.sub.su.se/stable/797326 [Accessed 8 May 2017].

[43] See Hopkins, M.M., Mahdi, S., Thomas, S.M., Patel, P. The patenting of human DNA: global trends in public and private sector activity (The PATGEN project). Report on a European Commission's 6th Framework programme 2006. As referred to in van Overwalle, G. (2009); Huys, I. Berthels, N., Matthijs, G. & van Overwalle (2009) Legal Uncertainty in the Area of Genetic

firms; nevertheless, due to the size of their IP portfolios and production powers, these companies have a tremendous effect on the worldwide problems concerning the population's health. As a result, some international organisations and private enterprises had to take over initiative in finding a balance between public and private interest.

Public health has been one of the leading issues on the world's agenda for many years. With many terminal illnesses such as AIDS/HIV, malaria, and tuberculosis affecting a large percentage of the population in certain countries, the access to highly demanded medicine is hindered by - apart from other social, economic, and political factors - the lack of financing available for purchasing the drugs from foreign countries or the ability to produce the drugs locally. Protecting the health of people worldwide is a global issue that can only be solved by reaching a consensus between the parties with unequal bargaining power. Although it may seem that the initial problem is of economic nature, as it usually happens, business models go hand in hand with the law. In recent years, through incentives from international organizations, patent pooling has been tried as a licensing model for enabling generic producers and patients to benefit from the new health technologies. In 2006, World Health Organization (WHO) published a report by the Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) on the improvement of relationship between IP and R&D, which has been negatively affecting developing countries. In this report, the Commission called for increasing the number of partnerships and boosting funding, as well as considering alternative approaches to the current R&D system. Previous solutions have provided only temporary relief and were costly to maintain, which is why the new approaches should not be simply a new fund, such as the Global Fund to Fight Aids, Tuberculosis and Malaria.[47]

The former chairwoman of the Commission, Ruth Dreifuss, claimed that the patent system is not the main obstacle to innovation, but the lack of incentive mechanisms. However, judging by the number of commission members who joined the reservation on the report, it can be suggested that the opinion on suitability of the patent system for public health protection was doubted.

The report has also promoted the use of TRIPS flexibilities by developing countries, in particular, compulsory licensing.[48] However, these mechanisms were designed to force collaboration between technically developed, and developing countries. Their application of TRIPS flexibilities should arguably be limited to the dead-end circumstances, where all other available instruments of influence are exhausted. In the past years, prosperous pharmaceutical firms such as GSK, Bristol-Myers Squibb, Merck, Hoffman-La Roche and Boehringer Ingelheim became infamous for suing South Africa's government for implementing TRIPS flexibilities to access competing generic drugs for HIV/AIDS.[49] The health policy reform conducted in South Africa in 1977 led to the adoption of a law allowing parallel import of patented drugs – Section 15C of the South African Medicines and related Substances Control Act (MRSCA). The discontent of pharmaceutical companies, fearing the establishment of a precedent, met overwhelming opposition from government supporters and attracted wide media coverage which, at the end, pushed the companies to drop the claims. This instance tells us that, ideally, voluntary participation of the most influential drug developers and producers in collaborative schemes should be considered a primary tool for reaching mutually satisfying arrangements.

Another global health issue is the development of vaccines for epidemic outbreaks. To ensure a fast operational reaction, it is necessary to conduct extensive research on the virus in advance and have the vaccine on hand before an outbreak prevails. Developing countries affected by an epidemic are not willing to cooperate with other affected states, because they risk engaging in a one-way, non-beneficial agreement. For example, H5N1 virus samples were retained by Indonesia based on its right to fully control the management of biomaterial under Convention on Biodiversity, until the WHO intervened in the negotiations. The WHO undertook the responsibility to create "a framework for accessing influenza virus samples... in exchange for sharing the benefits resulting from the use of the samples," also called Pandemic Influenza Preparedness.[50] The investments in Pandemic Influenza Preparedness steadily grow. According to the WHO report from August 2016, Member states of the EU have contributed $56.5 million "to support the running costs of Global Influenza Surveillance and Response System (GISRS)[51]; Coalition for Epidemic Preparedness Innovations (CEPI) secured $500 million for the development of pandemic vaccines.[52] CEPI includes many pharmaceutical firms

Diagnostic Testing, Nature Biotechnology, 27, 903-909.

44 Verbeure, 2009.

45 For more information about the relationship between biotech patenting and public health, please, see para. 2.4.3 of this thesis.

46 Levang, B. (2002) Evaluating the Use of Patent Pools for Biotecnology: A Refutation to the USPTO White Paper Concerning Biotechnology Patent Pools. Santa Clara High Technology Law Journal, 19 (1), 229-251. Available from: http://digitalcommons.law.scu.edu/chtlj/vol19/iss1/6 [Accessed 5 May 2017].

47 See www.theglobalfund.org.

48 Gerhardsen, T. (2006) WHO IP Report Comprehensive, But No Calls For Major Change In IP System, [Online] Intellectual Property Watch. Available from: https://www.ip-watch.org/2006/04/03/who-ip-report-comprehensive-but-no-calls-for-major-change-in-ip-system/ [Accessed 20 April 2017].

49 See, for example Fisher, W. & Rigamonti, C. (2005) The South Africa AIDS Controversy: A Case Study in Patent Law and Policy. [Online] Harvard Law School. Available from: https://cyber.harvard.edu/people/tfisher/South%20Africa.pdf [Accessed 24 February 2017].

50 Beldiman, D. (2012) Patent Choke Points In The Influenza-Related Medicines Industry: Can Patent Pools Provide Balanced Access? Tulane Journal of Technology & intellectual Property, 15 (31). Available from: https://dx.doi.org/ [Accessed 15 May 2017].

51 WHO, PIP Framework Review Group 2016: Preliminary findings. [Online], 2. Available from: http://www.who.int/influenza/pip/2016-review/pip_review_group_prelim_findings.pdf [Accessed 15 May 2017].

52 Rathi, 2017.

such as GSK, Takeda, Pfizer, Johnson & Johnson, Merck and Sanofi.

These statistics show that the market for influenza-related drugs and technologies is growing popular among investors, including governments, national healthcare organizations, and international organizations. Meanwhile, private pharmaceutical companies are often unwilling to take the accompanying risks of R&D if the outbreak does not actually happen.[53] The partnership between private and public corporations only works when a government entices the producers to conduct R&D by providing regular funding.[54]

A pooling project in relation to vaccinations and therapeutic treatments was attempted by patent holders of genetic sequences responsible for causing severe acute respiratory syndrome coronavirus (SARS CoV). Right after 2002, when the first pneumonia outbreak occurred in China, a handful of institutions united under the WHO initiative and carried out research on the cause of the disease. Subsequently, the research organizations filed complementary patent applications for the genetic sequence of SARS CoV. Taking into consideration the traditional benefits associated with patent pooling, it may seem that in this case pooling could provide the interested parties with access to a group of fragmented IP rights on the target vaccines. Making the patents available at a standard rate would incentivize the manufacturers, and shift investors focus from upstream technologies to the development of new downstream products. The primary patent holders were identified, and the WHO affirmed the parties intentions to move forward and form a pool. However, in the midst of the pool's establishment, complications arose. Since there were no further outbreaks after 2003, it was uncertain whether the investments to set up a patent pool would have been recouped. Besides, some of the patent applications were still pending, and including them in a pool might have resulted in shielding invalid patents – one of the obstacles to competition. Nevertheless, this should not be a problem in the presence of a mechanism that would allow the exclusion of invalid technologies post factum.[55]

Unlike R&D for unpredictable virus outbreaks, investments in drug development against persistent widespread diseases such as cancer, HIV/AIDS, or diseases where the predisposition to disease is dependent on several genes and their mutations, will almost certainly be recouped. In the sphere of genetic diagnostics, the patent thicket problem seems to be particularly sharp if several patents are needed to conduct a test. However, where a gene responsible for the diagnosis has just one owner (for example, BRCA-1), a patent pool is not a suitable option. In such as case, some alternative solutions may be of greater assistance.

Alternative forms of innovative partnerships proved to function well in biotechnology. The SNP Consortium, Merck, the Institute for Genomik Research and the Human Genome Project are non-profit organizations that facilitate the pooling of research results and the development of genetic resources. For example, Consortium supplies its database to scientists free-of-charge. The database should help the pharmaceutical companies to find treatments for genetic diseases. Most importantly, members of the Consortium undertake to not to patent any SNPs (single nucleotide polymorphisms), although downstream inventions are free to patent. This form of collaboration differs from a patent pool in the sense that the former aims at putting upstream inventions into the public domain instead of creating a pool which can only be accessed by licensees.[56]

1.4.4 The Medicines Patent Pool

The Medicines Patent Pool (MPP) is an organization that was founded by UNITAID and focuses on providing public access to HIV, hepatitis C and tuberculosis treatments in low- and middle-income countries. Its new business model allows different stakeholders to predict, pri-

[53] Id. In addition, the previous participation of many pharma giants in fighting influenza breakouts, such as SARS (2003), H5N1 (2009-2010), Ebola (2014) and West Nile virus, resulted in an insignificant return. See Branswell, H. (2016) The race for a Zika vaccine is intense. But it may be missing the most important players. [Online]. Available from: https://www.statnews.com/2016/08/08/zika-vaccine-development-drug-makers-pharmaceutical/ [Accessed 15 May 2017]

[54] Branswell, 2016.

[55] See Correa, C. The SARS case: IP fragmentation and patent pools. [Online], 44-48. In: van Overwalle, 2009; Simon, J., Claassen, E., Correa, C., Osterhaus A. (2005) Managing severe acute respiratory syndrome (SARS) intellectual property rights: the possible role of patent pooling. [Online] Bulletin of the World Health Organization 2005, 83, 707-710. Available from: http://www.who.int/bulletin/volumes/83/9/707.pdf [Accessed 15 May 2017]

[56] Organization for Economic Co-operation and Development, Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies. [Online], 68. Available from: https://www.oecd.org/sti/sci-tech/2491084.pdf [Accessed 2 May 2017]

[57] See http://www.medicinespatentpool.org/about/; report by KPMG. [Online]. Available from: http://www.medicinespatentpool.org/wp-content/uploads/MPP-Impact-Q2-2016.pdf [Accessed on 4 May 2017]

[58] MPP, Summaries of licensing agreements. [Online]. Available from: http://www.medicinespatentpool.org/summaries-of-licensing-agreements/ [Accessed 5 May 2017]

[59] Medicines Patent Pool Foundation By-Laws of 8 December 2011. [Online]. Available from: http://www.medicinespatentpool.org/wp-content/uploads/By-Laws-August-20165.pdf [Accessed 15 May 2017]

[60] Turner, J.D.C. (2015) Intellectual Property and EU Competition Law. Oxford: Oxford University Press, 78.

[61] Article 101(3) TFEU.

[62] Regulation 316/2014, rec. 7.

[63] Id.

[64] Guidelines on technology transfer agreements (2014) paras. 56, 247.

[65] Turner, 2015, 197.

[66] Guidelines on technology transfer agreements (2014) para. 261(a).

[67] Guidelines on technology transfer agreements (2014) para. 261(b). Such safeguards may be ensured by acquiring the services of an independent expert. See Guidelines on technology transfer agreements (2014) para. 256, EuC.

[68] To that extent, see section 4.5 of this thesis.

[69] Guidelines on technology transfer agreements (2014) para. 261(c), EuC.

[70] Guidelines on technology transfer agreements (2014) para. 261(d), EuC.

[71] Guidelines on technology transfer agreements (2014) para. 261(e), EuC.

[72] Guidelines on technology transfer agreements (2014) para. 261(f), EuC.

[73] Guidelines on technology transfer agreements (2014) para. 261(g), EuC.

oritize and license needed medicines. The MPP serves as a bridge between 16 generic manufacturers and developers, and 9 patent holders by licensing 15 medicines. By this day, MPP licenses have provided the access to WHO-recommended medicines in 125 countries, 79 of which were previously unable to benefit from generic competition.[57] The sales are geographically concentrated to the areas with the largest numbers of HIV-affected persons in the developing world (87-94%).

Despite certain geographical limitations, terms and conditions present in MPP licenses were recognized as providing wide access, containing great flexibilities and having the broadest geographical scope.[58] It is arguable that today, the MPP is the most successful example of patent pooling in biotechnology and life sciences in general.

The pool is governed by two main bodies: the Governance Board and the Expert Advisory Group. Every member of the Governance Board is selected among the most dedicated and competent experts for a standard term of two years - there is no cap limitation on the number of terms. Transparency and accountability are ensured by the appointed body of External Auditors, which conducts an annual audit of the pool's accounts and reports to the Board for its approval, as well as ensures the compliance with the foundation's by-laws. The Expert Advisory Group provides consultations to the Board and the Executive Director, upon request, with regards to ongoing negotiations and decisions on licencing agreements. Unlike the Board members, experts of the Group do not receive a regular salary.[59]

Any violations of the foundation's policies are investigated by the MPP Compliance Officer. The fulfilment of legal requirements is ensured by *pro bono* legal consultations by several companies.

2. EU COMPETITION LAW

2.1 Legal Framework

From the perspective of EU competition law, agreements between companies that distort or extinguish competition on the internal market as a whole or in its parts undercut the pillars of a single market. Article 101 of the TFEU regulates this issue by allowing the competition authorities (European Commission's Directorate-General for Competition) to outlaw, eliminate and penalize firms which create cartels. Art. 101 of the TFEU concerns intellectual property right when it is the subject, the means, or the result of a restrictive agreement or a concerted practice between undertakings,[60] including licensing and transfer agreements.

Art. 101 of the TFEU applies where:

1) there is an agreement between undertakings, a decision of an association of undertakings, or a concerted practice;
2) which may affect trade between Member States; and
3) which has as its object or effect the prevention, restriction, or distortion of competition within the common market.

Nevertheless, Art. 101 occasionally lifts these restrictions when a contract positively affects the production and distribution of goods and/or supports technical and economic development, and at the same time offers consumers a substantial share of the gained advantage.[61] To escape the aforementioned restrictions and comply with EU competition law, the agreements also have to reach the safe harbour of a block exemption regulation under Art. 101(3).

According to the Guidelines on technology transfer agreements, the agreements establishing technology pools do not fall under the Technology Transfer Block Exemption Regulation (TTBER).[62] The rationale of this exclusion is that the purpose of such set-up agreements is to license the pooled technologies to third parties, while the TTBER is aimed at agreements which allow the licensee and/or its sub-contractors to exploit the licensed technology rights, perform research and develop them for the *purpose of producing* goods or services.[63]

The licences granted by technology pools are also excluded from the block exemption as they generally involve more than two parties.[64] On the other hand, it is not uncommon that the licensor is represented in the agreement by the pool as a single entity rather than a group of autonomous right holders. Thus, leaving just two parties – licensor and licensee - involved in the contract. This raises the question of what should be understood as an 'undertaking' for the purpose of the Regulation. According to Art.1(2) and Art.1(2)(e)(ii), this term includes 'connected undertakings.' There is an opinion that a narrower interpretation would better fit the general concept of an undertaking in competition law, to the extent that the undertakings in question constitute a single economic unit for the purpose of the agreement.[65]

The agreements on establishment, governance, as well as on licensing pooled technology, would not be infringing Art. 101(1) of the TFEU, if the following criteria are met:

a) the pool is open to any interested party wishing to contribute its rights on a particular technology;[66]
b) sufficient safeguards are adopted to ensure that only essential (and, consequently, complementary) technologies are pooled;[67]
c) sufficient safeguards[68] are adopted to ensure that the exchange of sensitive information (such as pricing and output data) is restricted to what is necessary for the creation and operation of the pool;[69]
d) the pooled technologies are licensed into the pool on a non-exclusive basis;[70]
e) the pooled technologies are available to all potential licensees on FRAND terms;[71]
f) the parties contributing technology to the pool and the licensees retain the right to challenge the validity and essentiality of the pooled technologies;[72] and
g) have the right to develop competing products and technology.[73]

2.2 Pro- and Anti-Competitive Effects of Technology Pools

By creating a combined product consisting of complementary technologies, patent pools promote competition by decreasing transaction costs and royalty stacking.[74] This effect is especially valuable in the industry where intellectual property rights are fragmented. Fragmentation, in turn, is intrinsic to (among others) the biotechnology industry.

The biggest beneficial effects to be mentioned are the elimination of patent thickets, royalty stacking, and increased efficiency of R&D.

The formation of a patent pool usually involves an exchange of technical information that does not form part of the patent claims, as well as the know-how data needed for the further facilitation of innovation and efficient use of the resources. Competition regulations also impose a restriction on the information allowed for sharing: it has to be of a technical character only and should not extend to an exchange of business information between competing enterprises, as such behaviour risks resulting in a cartel formation.[75]

Another pro-competitive effect of patent pools is the minimization of litigation and transaction costs. A pooling agreement curtails potential disputes between its members, although decreasing litigation costs is no longer the primary objective of such agreements.[76] Instead of negotiating with multiple patent holders and risking exclusion without one of the essential patents, a licensee only needs to make a single arrangement with the pooling organization. Apart from that, pooling prevents price gouging on the patents whose individual value is much less than in combination with the others. The final amount that would have to be paid for the whole bundle of patent licenses is often unbearable for an average licensee and, consequentially, makes the downstream product less affordable, too.[77]

Despite the many positive ways in which patent pools affect competition, there are several factors that may diminish this influence and expose the pool to prosecution by a competition authority. Among the possible negative factors is the pooling of competing patents. Patent pools involving substitute technologies aim at softening the price competition among its members rather than benefitting social welfare.[78] Such organization may amount to the creation of a price-fixing cartel.[79] In the case of a pooling agreement between competitors, it is suggested that the absence of actual exploitation of the licensed technology indicates an underlying anti-competitive rationale.[80]

Some governing provisions of pools, such as grant-back clauses, are relevant to the assessment of the potentially harmful effects that a pool can have on the market. Grant backs oblige pool members to offer the future patents to the pool royalty-free, if the pool considers them relevant for its purposes.[81] From the pool's perspective, this ensures the common benefit from individual innovation. From the member's point of view, it erases the incentive to invest in further development of the product. Hence, the outcomes of the grant-back provisions are also harmful to the public benefit. In the context of international law, grant-backs are explicitly listed as potentially anti-competitive in Article 40 of the TRIPS Agreement. According to Art. 40, Member States may on a voluntary basis interfere with licensing agreements and address anti-competitive practices by defining them as illegal per se or allowing for a rule of reason review.[82]

If members of the pool are not allowed to independently licence their contributed technology in the absence of alternative products, the pool may charge a price above the competitive rate. It is not in the legislator's interest to allow the pool prices of be higher than the total sum of independently charged royalties. Therefore, the presence of independent licensing in the pool's government policy decreases the possibility of price-fixing. In return, independent licensing does not collide with the pools of complementary patents, because the value of its separate components is much lower or the licensing takes place in a non-competing market.[83] Moreover, independent licensing facilitates searching for alternative uses of patented inventions and prevents pseudo-innovations that are produced for perspective blackmailing of the pool members and prosecution of a buyout strategy.[84]

Furthermore, pooling organizations may facilitate potential collusion amongst the competitors by creating a setting for the exchange of sensitive information on pricing, marketing strategies, or R&D information between the members.[85]

Other competitive risks include situations where a pool creates an industry standard and may preclude other

[74] Guidelines on technology transfer agreements (2014) paras. 247, 253, EuC.

[75] Verbeure, 2009.

[76] See para. 2.2.1 on the history of the patent pools.

[77] Lin, L. (2011) Licensing Strategies in the Presence of Patent Thickets. [Online] Journal of Product Innovation Management, 28 (5), 698-725, Business Source Premier. Available from: https://doi.org/10.1111/j.1540-5885.2011.00835.x [Accessed 1 April 2017].

[78] World Intellectual Property Report (2011) The Changing Face of Innovation, Ch. 3, 123. [Online]. Available from: http://www.wipo.int/edocs/pubdocs/en/intproperty/944/wipo_pub_944_2011.pdf [Accessed 3 April 2017]

[79] Guidelines on technology transfer agreements (2014) para. 246, EuC.

[80] Guidelines on technology transfer agreements (2014) para. 59, EuC.

[81] See Layne-Farrar, A. & Lerner, J. (2011) To Join or Not to Join: Examining Patent Pool Participation and Rent Sharing Rules. [Online] International Journal of Industrial Organization, 29 (2), 294-303. Available from: https://doi.org/10.1016/j.ijindorg.2010.08.006 [Accessed 4 April 2017]..

[82] Pires de Carvalho, N. (2008) The TRIPS Regime of Antitrust and Undisclosed Information. Kluwer Law International, 161 et seq. As referred to in World Trade Organization Secretariat's Report (2014) Patent Pools and Antitrust – a Comparative Analysis. [Online]. Available from: http://www.wipo.int/export/sites/www/ip-competition/en/studies/patent_pools_report.pdf [Accessed 3 April 2017].

[83] See Lerner, J. & Tirole, J. (2004). Effcient Patent Pools. The American Economic Review, 94(3), 691-711; Lerner, J. & Tirole, J. (2008) Public Policy toward Patent Pools. [Online]. In: Jaffe, A., Lerner, J., Stern, S. (eds.) Innovation Policy and the Economy. University of Chicago Press, 8, 157-186. Available from: http://papers.nber.org/books/jaff08-1 [Accessed 4 April 2017].

technologies from successful commercialization and exploitation, notwithstanding their quality.[86]

3. BIOTECHNOLOGY PATENT POOLS

3.1 Pooling Against Patent Thickets in Biotechnology

The presence of dispersed patent rights in certain technology fields requires the licensee to simultaneously bargain for many agreements. It inevitably increases the number of payed royalties (royalty stacking) and prevents easy access to the technology needed for innovative research. Patent thickets lead to a situation which is described in literature as anti-commons effect.[87] A patent pool can be a suitable way to avoid these difficulties and widen access for a bigger audience. The model, which has initially been designed to fit the requirements of machine industry, is nowadays applied in the field of biotechnology, which also bears the characteristic of a field with multiplied patents. Several of its subdivisions, such as gene-based technology and vaccination programs, have tried out or are suggested to try the patent pooling scheme as a possible solution.

Patent pools are deemed by some authors, due to the nature of biotechnology industry, to be unsuitable for resolving its intellectual property problems. Apart from the inherent advantages and disadvantages of the pooling system, the unique characteristics of biotechnology sector contributes with some specific concerns.[88]

3.2 Application of Patent Pools to Biotechnology

The problem of restricted access to genetic resources and data was addressed in a United States Patent and Trademark Office's (USPTO) paper. The USPTO offered patent pools as an answer to challenges associated with the patent system in biotechnology industry.[89] Four advantages of patent pooling were suggested. First, the application of pooling model may decrease the number of blocking and stacking patents in the biotech industry.[90] Since this sector has many patent applications covering genes, ESTs and DNA sequences, combining these patents into a single pool will reduce the blocking and stacking issues faced by the downstream product manufacturers. After being established, these patent pools will also indirectly benefit from encouraging further innovation and easing the burden of collecting patents required for a certain project.[91] Second, patent pools help to reduce the licensing transaction costs.[92] Companies are less likely to initiate legal suits against each other, because it will be in their best interest to protect their patents from invalidation. Third, pooling should be attractive to biotechnology businesses for the purpose of reimbursement of the high R&D costs. The companies can at least recoup expenses, if not profit, from licensing their inventions to a greater number of interested parties. Thus, biotechnology businesses can distribute the risks and provide wider access to related technology.[93] The last benefit is connected to the intensified sharing process of undisclosed technical information between the pool members. The USPTO points out the increased trust amongst the companies will save valuable resources and help avoid the duplication of each other's work.[94]

However, if one looks carefully at the advantages outlined by the USPTO, one will find that precisely the same benefits can be found in any patent pool without relation to a particular industry. Although for other types of businesses patent pooling proved to be advantageous, for the biotechnology sector, the downsides and obstacles associated with pooling outweigh the possible benefits.[95] Therefore, these specific obstacles need to be examined.

The biggest concern is that the biotechnology industry is critically different from the other industries. One of the main benefits of pooling is the dissolution of the blocking patents problem. The number of filed patent applications for the biotechnological inventions is, indeed, tremendous and keeps growing: from 5539 EPO filings in 2012 to 5744 biotech applications in 2016.[96] Patents on pharmaceutical products take 55% of all patent in biotechnology industry in Europe. Nevertheless, not all patent applications receive approval from the patent authorities. In 2016, EPO granted only 3108.[97] As previously mentioned, most innovative and interest-bearing drugs in modern biotech industry are based on genetic discoveries, and sometimes on the experiments involving human embryonic stem cells. Obtaining a patent on human embryonic stem cells is complicated because of its collisions with ethical considerations. Patent offices around the world tend to apply stricter utility requirements to patent filings on genes and inventions involving human embryos, which inevitably decreases the number of granted patents.[98] The

[84] World Intellectual Property Report (2011), The Changing Face of Innovation. Ch. 3, 124. [Online]. Available from: http://www.wipo.int/edocs/pubdocs/en/intproperty/944/wipo_pub_944_2011.pdf [Accessed 3 April 2017].

[85] Pires de Carvalho, 2008, 67.

[86] Guidelines on technology transfer agreements (2014) para. 246, EuC.

[87] The anti-commons effect is further elaborated in section 3.2 of this thesis.

[88] See Levang, 2002.

[89] United States Patent and Trademark Office (2000) Patent Pools: A Solution to the Problem of Access in Biotechnology Patents? [Online], 2. Available from: http://www.uspto.gov/web/offices/pac/dapp/opla/patentpool.pdf [Accessed 8 May 2017]

[90] Id. 8.

[91] Clark, 2000, 8.

[92] Id.

[93] Clark, 2000, 8.

[94] Id. 10.

[95] Levang, 2002, 241.

[96] EPO, European Patent Applications 2007-2016 per field of technology. [Online] Available from: https://www.epo.org/about-us/annual-reports-statistics/statistics.html [Accessed 9 May 2017]

[97] EPO, Granted Patents 2007-2016 per Field of Technology. [Online] Available from: https://www.epo.org/about-us/annual-reports-statistics/statistics.html [Accessed 9 May 2017]

[98] USPTO implemented new guidelines for granting patents on expressed sequence tags (ESTs) in 2001. See Levang, 2002, 241. From the EPO's point of view, ESTs are most likely not to be patentable at all; European law allows protection of gene sequences if the claims a) reveals the technical effect (Guidelines C-IV, 2.3), b) their structure and function are specified (Guidelines C-IV, 4.6), c) their industrial application must be disclosed (EPC, Rule 23(c)(3); Decision of the Board of Appeal T-0870/04 (BDP1)). Also see Correa, C. The SARS case: IP fragmentation and patent pools. [Online]. In: van Overwalle, 2009.

EPO, however, followed the more liberating opinion of the European Court of Justice (ECJ) given in decision C-364/13, where the ECJ held that parthenotes[99] are not classified as embryos.[100] After this case, the EPO allowed the patenting of human embryonic stem cells that were generated by morally acceptable means, starting from 5 June 2003.

Despite a reasonable decrease in granted genetic patents, biotechnology will still face the problem of blocking patents. The industry, though, keeps using 'traditional uses cross-licensing' as a solution instead of patent pooling.[101] Although the costs of obtaining a patent are high, the costs of infringement litigation with another competitor are even higher. This explains the companies' preference to play it by ear and continue producing new formulas, ignoring the actual or potential infringement risks. Taking into consideration the falling numbers of granted genetic patents and the availability of alternative methods, patent pools are not the only, nor a common, solution to the issue of blocking patents.[102]

The second suggested benefit of patent pooling - reduction of litigation costs – should allow businesses to receive an economic gain. However, to present a more accurate and fuller picture, the costs of establishing and maintaining a patent pool should be considered, too. Upon the initiation of a pooling enterprise, the participants stake on the demand in a product produced on the basis of pooled patents, which would generate big profits and therefore substantiate the financial and material expenses needed to form a pool.[103] Unlike IT technologies utilized for the production of consumer devices, biotechnologies may have a limited audience and a restricted field of application. Consequently, it is likely that the high costs of the pool set-up may exceed the possible litigation costs with competitors in the absence of a pool, thus making it unprofitable for biotech businesses to establish patent pools.[104]

Lastly, the biotechnology industry normally derives the last mentioned benefit – risk distribution and information exchange – by applying its traditional methods, including licensing and royalty plans. These methods allow participants to access the most important methods of research and development that are used by any modern biotech business without resorting to patent pooling. Traditional schemes help companies save up on doubling the research efforts put in by the patentees, and the royalty fees for licenses usually incorporate the costs of development, thereby gaining profits.[105]

3.3 Biotechnology Patent and Antitrust Concerns

Similar to patent pools in other industries, biotechnology patent pools are subject to antitrust policies. Biotechnology patent pools have also often been discouraged because of their predisposition towards antitrust violations, ability to raise production prices, and spark collusions.[106] Apart from the traditional antitrust concerns faced by all patent pools, biotechnology pools have to navigate through the distinguishing issues of the industry.

3.3.1 Traditional Antitrust Concens and Biotechnology Pools

When companies decide to combine their anti-competitive technologies, it may result in collusion. A prominent example of this are the Summit/ VISX and MPEG-2 patent pools, which were established within the same time frame. The Summit/ VISX patent pool was a solution to a litigation conflict between two holders of the blocking patents on technology for photorefractive keratectomy (vision-correcting eye surgery). The pool allowed its parties to share the revenue for licensed technology, which came from a set price of $250 for every single use of the patented laser technology in an eye surgery. Elimination of a patent thicket for accessing the market was the main reason for establishing both patent pools. However, only Summit/ VISX was found to be a cartel, since it consisted only of two members and imposed restrictions on third party licensing rights, while, in MPEG-2, there were several licensors independent from the party that set up the pool and it allowed any third-party licensing from the pool. The American Federal trade commission was convinced that both technologies were able to compete within a single market, and any patent blocking occurred because of the collision with an invalid patent held by VISX. Hence, the parties should generally be advised to, firstly, calculate the number of competing technologies, and, secondly, determine the presence of a patent thicket.[107] Additionally, the patent pool had to be dissolved because it facilitated the raise, fixation, and stabilization of the price that physicians must pay to perform laser eye surgery procedures.[108]

[99] An organism produced from an unfertilized ovum, which is incapable of developing beyond the early embryonic stages. Oxford Dictionary. [Online] Available from: https://en.oxforddictionaries.com/definition/parthenote [Accessed 20 February 2018]

[100] CJEU, C-364/13 International Stem Cell Corporation v Comptroller General of Patents, Designs and Trade Marks, [2014] ECLI:EU:C:2014:2451, para. 38.

[101] Shapiro, 2001, 12.

[102] Levang, 2002, 242.

[103] Shapiro, 2001, 17.

[104] Levang, 2002, 242.

[105] Id. 243.

[106] Levang, 2002, 244.

[107] Lundqvist, B. (2014) Standardization under EU competition rules and US Antitrust Laws: The Rise and Limits of Self-Regulation. Cheltenham: Edward Elgar Publishing Ltd, 291.

[108] Levang, 2002, 244.

[109] Id. 246.

[110] For more information on the history of patent pools, please see para. 2.2.1 of this thesis.

[111] For more information on SNP Consortium, see section 2.4.3 of this thesis.

[112] Levang, 2002, 248-249.

[113] Id. 250.

[114] Horn, L. (2009) MPEG LA® Licensing Model: what problem does it solve in biopharma and genetics? [Online]. In: Geertrui van Overwalle (ed.) Gene Patents and Collaborative Licensing Models: Patent Pools, Clearinghouses, Open Source Models and Liability Regimes. Cambridge University Press, 33-41. Available from: https://doi.org/10.1017/CBO9780511581182.004 [Accessed 28 April 2017]

[115] Horn, 2009, 33-41.

[116] Id.

Another issue that commonly accompanies the creation of a patent pool is the preservation of potentially invalid patents. When a company is sued by a competitor and is concerned about its patent's validity, a patent pool may be proposed as a settlement measure to protect patent rights and the income from royalties for the holder of the challenged patent. At present, large numbers of biotechnology companies use litigation as a method for resolving invalidity and other intellectual property issues. There is a risk that patent pools will encourage businesses to settle for royalties from a patent pool instead of wasting money on extensive litigation procedures and ending up with an invalidated patent.[109]

3.3.2 Pooling Concerns Based on the Peculiarities of the Biotechnology Industry

Historically, patent pools have emerged only after long and exhaustive disputes, sometimes with the encouragement from the government.[110] Therefore, pooling was considered to be the last resort for dead-end situations where continuance of litigation was causing more harm than profit to both parties. It follows that the independent manufacturing and/or development of a new product is still preferred by the most companies. This tendency equally applies to biotechnology companies, which stick to obtaining required technologies and placing their products on the market through licensing or extensive litigation, as opposed to collaboration. In regards to government involvement, it has been minimal within the biotechnology industry and has delivered some results only in the placement of several DNA fragments in the public domain,[111] which, strictly speaking, cannot be classified as a patent pool, since these genes are not privately owned nor licensed to the pool by the patent holders.

From an economic perspective, companies that operate within a same or similar field and have a long history of mutual cooperation enjoy a greater chance of successfully forming a patent pool. Biotechnology companies for the most part do not meet the requirements of homogeneity and relationship duration, consequently decreasing the number of chances for forming a profitable pooling organization. In addition to this, participants of the biotechnology industry differ in size and overall perspective on the best ways to utilize their patents. The mismatched concepts of patent value and appropriate licensing fees will hinder parties from reaching a consensus. For instance, a university may be interested in making its invention accessible to as many parties as possible to support new research programs, thus sacrificing the high royalties. In contrast, a pharmaceutical company will usually aim to commercialise the patent and maximize the profits. As a result, the chances of such entities forming a pool on mutually beneficial terms are low.[112]

Furthermore, even if there are enough parties interested in forming a pool, another obstacle appears: the difficulty of patent evaluation at the moment of contribution. Many technologies do not possess an extensive history of research and applications, so their full potential is not revealed yet. The speculations about their usefulness to other member's goals decreases a patent's value. However, after a patent is incorporated and undergoes the testing in combination with other pooled methods and inventions, its valuation would surely increase. In biotechnology, companies quite often apply for the patents on genes and DNA sequences without full knowledge about their utility and function. Two extreme situations are likely to take place: either a company will not be able to receive a fair price for a contributed patent, or it will artificially inflate the price of its patents because the main economic asset of many biotechnological companies is their intellectual property portfolio. If, nevertheless, a gene is known to be responsible for the creation of a highly successful product, it would seem natural for its patentee to resist joining a patent pool where it will become accessible to the company's competitors.[113]

Overall, it could be concluded that the main characteristics of the biotechnology sector that hinder patent pooling are the disparate goals of its members and the difficulty of determining a patent's value at the moment of contribution to the pool. Due to the high costs of establishing a pool, a potential licensee often prefers to work around the issue of patent stacking, look for alternative solutions, such as public databases, or simply wait for the patent to expire.[114]

A juxtaposition of a currently existing pool governance system and a licensing model for a new biotech product may give a good understanding of the industry's ability to fit into the created business-legal environment for cooperation. To exemplify this, the MPEG LA Licensing Model which is worshiped as the most successful solution to patent thicket problem, is used. MPEG LA holds the rights to multiple essential intellectual property objects on a basis of non-exclusive sub-licence. An independent licensing administrator is responsible for: offering the licensees a licensing package on fair, reasonable, non-discriminatory terms; collecting and distributing royalties for the profit of the essential patent owners, and receiving an administrative fee out of collected royalties.[115] The status of an independent licensing administrator implies that MPEG LA is not affiliated with any standard agency or patent owner, and does not own any patent rights under a licensing agreement. It acts as a buffer between multiple IPR holders and customers, thus responding to the needs of the "many-to-many" licensing model: multiple patent rights that are demanded by multiple interested parties.[116] The presence of buyers and sellers for a technology is the ground for its marketability. A few other factors play a role in its success: a) a pool's licence should be favoured over

the bilateral agreements, b) royalty products should be identifiable, and c) the licensing fee should reflect a balance of royalty, revenue, administrative fee and other material stimulants that ensure a reasonable return to patent providers, reasonable access for licensees, reasonable profit for an administrator, and legal compliance.[117]

Moreover, MPEG LA employs all legal safeguards ensuring the pool's credibility, such as providing the license on equal terms to any interested party and hiring independent experts to evaluate the essentiality of technology covered by the patent claims. Both licensors and licensees are free to license their technologies outside the pool.

Having the expertise in biopharma and genetics, MPEG LA conducted research in which it identified the problems that its licensing model can solve and tried to encourage industry representatives to apply it. In accordance with this research, biopharma and genetics differ from telecommunications, consumer electronics, computers and similar industries, in ways that may affect the feasibility of one-stop technology platform licensing and they should be accounted for as such.[118]

First, it is not common to form standards in biotech and genetics industry, as they are not usually the main spurring power for further development. Second, interoperability and non-exclusivity can be expedient in these industries for the early-stage research technology (upstream development) that is currently available, and for certain diagnostic applications. However, the value of upstream development is restricted by the research exemption,[119] troublesome tracking of infringements and the minimal number of reach-through patent claims[120] that limit the patent value.[121] The value of a company is closely connected to its IP portfolio that fosters a "bunker mentality" to protect the exclusivity of the end-product; unlike IT, branding does not play a significant role in promoting the product on the market.

Moreover, vertically integrated pharmaceutical companies may not be interested in joining a pool since they usually possess all the necessary resources to take the product from the research to the market.[122] To ensure its feasibility, a patent pool has to be an economically attractive undertaking. The holders of required technologies must thus be encouraged to commit to sharing their rights for creating wholesome patent packages. The attractiveness is, *inter alia*, related to the schemes of distribution of the pool's revenue. There are several theoretical models used in recent works for the problems of pool participation. Aioki and Nagaoka's theoretical model suggests that the income from licensing a pooled technology should not be distributed evenly among members. Three types of possible participants are identified: manufacturing-only firms, R&D-only firms, and vertically integrated firms that perform both the research and the production of the downstream goods. Accordingly, the motivation to contribute depends on the corporate structure and functional diapason of a member. A company with a primary focus on R&D lives off the licensing fees and mostly benefits from the circumstances where the charged royalties are not too high. Such firm will always be interested in deviating from a patent pool, but independent licensing also can make its financial position worse. A vertically integrated or manufacturing-only company, in contrast, are interested in lowering royalty rates to their minimum so they can minimize their own production costs. Therefore, the authors conclude that the equal treatment of all pool members would be detrimental to the pool.[123]

Thirdly, a voluntary collaboration of the patent holders is always better than a forceful governmental intervention because it drives the market of innovative products. Nevertheless, it also has a drawback in a form of a holdout, when a patent owner purposefully remains outside the pool in hope to yield more from direct licensing with the third parties. Such actions can hinder the pool's formation, and there is little that other parties can do to ensure the pool's creation. The acute interdependency of the patent holders in consumer electronics in creating a market for their products decreases the chances of holdout behaviour. For biotech businesses it is more common to run in parallel rather than a team, since their culture is not, to the same extent as consumer electronics, dependent on forming a common market.[124]

Finally, patent pools should be formed where the presence of a proactive intermediary – the administrator – is necessary to solve the problem in question. Therefore, biotechnology pools around a specific target surrounded by multiple of patent thickets are most likely to succeed.[125] Whether it be a molecule, a specific type of drug or even a disease, a pooling model similar to MPEG-LA may be helpful in resolving the access issue.

3.4 The Medicines Patent Pool and EU Competition Law Requirements

Under a closer look at its structure, governance and licensing model, it can be deciphered that the MPP fulfils all requirements of the EU competition law Guidelines:

a) reduces the licensing transaction costs. Interested companies and institutions can license patents for no charge or as little as 5% of the net sales of the final product;

b) clears patent thickets by creating a one-stop-shop for

licences;

c) Facilitates dissemination of technology and stimulates innovation. Through the MPP, generic manufacturers and research institutes gain access to technology that is necessary to develop acutely needed paediatric formulas of AIDS/HIV drugs. The manufacturers deliver the latest versions of drugs with higher effectiveness to the patients who cannot otherwise receive the treatment. In addition, terms of the licence allow a licensee to export a product manufactured with the aid of the licensed technology to other countries. However, the geographical application is still limited to certain states or only states where a compulsory licence has been issued;
d) Includes only essential and complementary patent technology. The Expert Advisory Group of the MPP consists of independent experts with various specializations. Their work in several focus groups supports a high standard of expertise. As for their autonomy from other governing bodies, it can be argued that the election method and the absence of regular salary apart from the compensation of work expenses such as travelling costs,[126] guarantees the experts' impartiality;
e) Does not shield any invalid patents. The validity of all patents contributed to the pool their validity has not been challenged at the moment of licensing or afterwards.

Despite the overall compliance with the law and the needs of the market, the MPP has been subject to criticism. One of the arguments pointed out the incoherence of the pool's aim to provide equal access to all of the pooled patents with the absence of a standardized licensing agreement. Various proposals for the license were claimed to be available for any interested party to get acquainted with and express its opinion.[127] The second point of criticism was the ambiguous status of the object of the sub-licence provided by the MPP and its first contributor - Gilead Sciences - to an Indian producer in 2011: at the moment of taking on the obligations, the patent on tenofovir disoproxil fumarate (TDF) compound has not been granted by the Indian patent office.[128]

3.5 Reflection of the MPP's Success on the Private Biotechnology Sector

Following the success and public support of the MPP model, several companies are already willing to employ a new system of IP protection for certain biotechnologies, allowing wider access to innovative medicines around the world. In its recent press release, GSK announced its next-level graduated approach to filing and enforcing patents so that IP protection reflects a country's economic maturity. Besides adopting a tiered pricing system and data-sharing practices, the company acknowledged that even reduced costs do not solve the problem for the countries with lowest income rates. Thus, abandoning property rights may be the only acceptable solution.

> *"For the Least Developed Countries (LDCs) and Low Income Countries (LICs), GSK will not file patents for its medicines, so as to give clarity and confidence to generic companies seeking to manufacture and supply generic versions of GSK medicines in those countries."* [129]

[117] Id. 35.
[118] Horn, 2009, 38.
[119] Research exemption allows generic manufacturers to start drug testing before patents expire, which allows to put the product on the market as soon as possible after the expiry date. In the EU law, research exemption is provided by Directive 2001/82/EC (as amended by Directive 2004/28/EC) and Directive 2004/27/EC (Art. 10(6)).
[120] «In certain technical areas (e.g. biotechnology, pharmacy) cases occur where:
(i) one of the following and its use in a screening method have been defined as the only contribution to the art: a polypeptide, a protein, a receptor, an enzyme, etc., or
(ii) a new mechanism of action of such molecule has been defined.
It may happen that such applications contain so-called "reach-through" claims, i.e. claims directed to a chemical compound (or the use of that compound) defined only in functional terms with regard to the technical effect it exerts on one of the above molecules». See EPO Guidelines for Examination, Ch. III, para. 9. [Online]. Available from: https://www.epo.org/law-practice/legal-texts/html/guidelines/e/f_iii_9.htm [Accessed 2 May 2017].
[121] Horn, 2009, 38-39.
[122] Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies. [Online] Organization for Economic Co-operation and Development. Available from: https://www.oecd.org/sti/sci-tech/2491084.pdf [Accessed 2 May 2017]
[123] Aoki R. & Nagaoka S. (2004) The Consortium Standard and Patent Pools. [Online]. Available from: http://hi-stat.ier.hit-u.ac.jp/research/discussion/2004/pdf/D04-32.pdf [Accessed 04 May 2017].
[124] See Goldstein, J. (2009) Critical analysis of patent pools. [Online] In: van Overwalle, G. 2009. Available from: https://doi.org/10.1017/CBO9780511581182.006 [Accessed 28 April 2017].
[125] Horn, 2009, 40.
[126] Medicines Patent Pool Foundation By-Laws of 8 December 2011.
[127] Love, J. (2011) KEI comments on the ITPC Letter to the Medicines Patent Pool Foundation and UNITAID. [Online]. Available from: http://www.keionline.org/node/1294 [Accessed 15 May 2017].
[128] Tripathy, S. Bio-patent Pooling and Policy on Health and health Technologies that Treat HIV/AIDS: A Need for Meeting of [Open] Minds. [Online] In Perry, M. (ed.) Global Governance of Intellectual Property in the 21st Century, Switzerland: Springer International Publishing, 29-50. Available from: https://doi.org/10.1007/978-3-319-31177-7 [Accessed 15 May 2017].
[129] GSK expands graduated approach to patents and intellectual property to widen access to medicines in the world's poorest countries. (2016) [Online]. Available from: http://www.gsk.com/en-gb/media/press-releases/gsk-expands-graduated-approach-to-patents-and-intellectual-property-to-widen-access-to-medicines-in-the-world-s-poorest-countries/ [Accessed 2 May 2017].

GSK has also decided on licensing its patents on oncology drugs to the MPP. Despite being a great forum for innovative partnership, MPP licenses are limited to a number of countries and do not address all of the important access challenges. This is why it is crucial that the MPP licenses allow medicines produced on their terms to be marketed outside of the licensed territory, where the patent is not protected or where compulsory licenses have been issued. GSK's access-to-medicine strategy has set a good example for other pharmaceutical companies to engage in expanding the access to their patented medicines, besides HIV and HCV drugs.[130] Gilead and Bristol-Myers Squibb have answered the roll call by becoming the first companies to deploy non-exclusive voluntary licensing of the new effective products for curing hepatitis C, which were added on the WHO Essential Medicines List.[131]

As a public stimulant for the companies' activity and an informative source on their responsiveness, every two years the Access to Medicine Foundation[132] researches drug companies behaviour when it comes to making certain medicines more accessible to populations in need. The leading companies are appraised for being needs-oriented and ready to invest in urgently needed, although not blockbuster, drugs. The Access to Medicine Index[133] ranks the top 20 largest pharmaceutical companies, based on seven areas of behaviour connected to access: strategy, governance, R&D, pricing, licensing, capacity building and donations. According to the last report in 2016, GSK leads the industry for the fifth year in a row by focusing primarily on R&D, improving the pricing, manufacturing and distribution policy (a quarter of its sales is in emerging markets), and, as verified above, patent and licensing strategy. Despite indisputable leadership on the most grounds, GSK recedes in compliance with some national regulations on corruption and unethical marketing; however, the compliance index appears to be quite low for any company in the ranking.

4. CONCLUSIONS

4.1 What Conditions are to be Satisfied by Patent Pools to Avoid Incompliance with Art. 101 of the TFEU?

According to the current European antitrust regulation, patent pools are completely excluded from the scope of block exemption. To be found pro-competitive, these agreements need to be in conformity with Art. 101(3) of the TFEU. The EU Commission Guidelines on technology transfer agreements provide information on the assessment methods within the legal framework of market competition.

To avoid falling under Art. 101(1), by the rule of Art. 219 of the Guidelines, patent pools should not include substitute patents. This general rule prompts that patent pools should consist solely of essential patents. It further imposes the obligation on parties to seek independent expertise on the matter of essentiality when considering to add a new technology to the pool. Autonomous examination of essentiality prevents the pools from unequal representation of complementary technologies on the market or of retaining a non-essential technology and, consequently, violating the competition regulation. Finally, the Guidelines on technology transfer agreements (2014) suggest a list of criteria, which can help a pool comply with the antitrust regulation.[134]

4.2 What Effect does EU Competition Law on the Innovating Function of a Patent Pool?

The basis of patent pools innovating function is the guaranteed access to knowledge vested in IP. This access requires a consensus between the interested parties. In a case where two or more complementary technologies are needed for production or research, and the lack of access to one of the technologies makes others useless for this purpose, from the licensee's and licensor's point of view, cartel pricing is more beneficial as it removes royalty stacking and increases profits. This seemingly positive interest, indeed, contradicts the EU competition law, which forbids the formation of cartel agreements because of their negative effects on the competition practices.

In case of several competing and non-infringing patents and no patent pool, harsh competition between the technologies will yield little profit. Licensing from a pool for a smaller fee decreases the attractiveness of litigation; a pool becomes a conglomerate of monopolistic power and decreases competition among the patent holders. Such pools should be prohibited.

Moreover, the Guidelines tell us that patent pools should include only complementary patents. However, as it previously demonstrated, the patent's nature is dynamic, and what is deemed to be complementary today may become a substitute tomorrow. A flexible licensing package that allows to choose from a list of non-strictly essential technologies opens up new opportunities to the licensees, giving them a choice between similar tools to achieve the same functionality.

As it can be seen, competition law does not always match the interests of patent pool participants, although

[130] Love, J. (2016) KEI statement on GSK's announcement of policies to expand access to patented medicines. [Online]. Knowledge Ecology International, 31 March. Available from: http://keionline.org/node/2452 [Accessed on 2 May 2017]

[131] Non-exclusive voluntary licensing outside of HIV/AIDS. [Online]. Available from: https://accesstomedicineindex.org/best-and-innovative-practices/non-exclusive-voluntary-licensing-outside-of-hivaids/ [Accessed 2 May 2017]

[132] See www.accesstomedicinefoundation.org

[133] Access to Medicine Index 2016. [Online]. Available from: https://accesstomedicineindex.org [Accessed 2 May 2017]

[134] See para. 2.1.

[135] Id.

the imposed precautions can hardly be called unreasonable. It has been argued that existence of a pool may create a false increase in the number of innovations which bear no social benefits and are solely made to be bought out by the pool to avoid competition.[135] Therefore, a pool where the parties retain the right to license their technologies independently outside the pool provide greater welfare. Supposedly, it is for this purpose that the EU Commission included independent licensing in the current list of safeguards in the Guidelines on technology transfer agreements (2014), while historically this condition did not accompany the pools' formation.

In conclusion, patent pools can stimulate innovation, if they contain the following characteristics:

1) fair, reasonable, and non-discriminatory terms of access for all interested parties;
2) licensing terms that are publicly available for ensuring their transparency;
3) flexible licensing packages including essential and complementary technologies;
4) licensees which have a freedom to use the resulting products;
5) licensees which are be able to conduct further research on the licensed technology.

Thus, as long as the antitrust regulations create a welcoming environment for the prospective participants of a pool, the industrial development and social welfare can be increased by means of this licensing mechanism.

4.3 What Factors Hinder Biotechnology Businesses from Pooling their Technologies in the Context of Modern EU Competition Law?

Patent pooling has for a long time been a popular model of collaboration between the companies in the consumer electronics industry, where a great number of patents are united to create industrial standards and ensure the product compatibility of various producers within a new common market. Due to the rise in demand of biotechnology and pharmaceuticals on a global level and the acute shortage of affordable medicines for lethal diseases in countries of the developing world, patent pooling became a seemingly suitable solution to satisfy the demand. Biotechnology patent pooling is believed to be a new answer to the public health issues, including the access to HIV/AIDS, tuberculosis and hepatitis treatments, and to facilitate the development of urgently needed paediatric formulas and fixed dose combinations.

However, there are some peculiar characteristics that may hinder the success of the pooling model. Some experts in the field mention the following qualities:

a) The tradition of using litigation and licensing to resolve patent thickets. In the presence of a patent pool, the claimant may prefer to settle for the pool royalty fee instead of pursuing a patent's invalidation in a costly procedure. This creates a risk of shielding the invalid patents inside the pool;
b) That, generally, biotechnology corporations do not need to ensure the interoperability of products within a common market;
c) That the exclusivity and protectiveness of the biotech companies' over their IP portfolios are necessary for commercial success but contradict the open licensing goal;
d) If the pool founders comply with the antitrust requirement of an open membership, biotech businesses with different goals may not reach a consensus on the appropriate size of the royalty fees;
e) Insufficient knowledge about a patent's potential value for the pool is another value-decreasing factor leading to disagreements between the patent holders. If, however, the patent is known to yield high profits, the company is likely to retain the technology to itself.

The Medicines Patent Pool is a living example of international success, and is one of the first examples of pooling in life sciences. However, its activity covers a limited number of countries in need and it issues licenses only for a certain scope of diseases. Patent pooling in the biotechnology industry appears to be advantageous where the target is well-defined and has a potential for creating substantial demand on the product. From this observation, it follows that pooling might not be as fruitful when it concerns the development of vaccines for epidemics. Nevertheless, patent pooling appears to be a promising formula for genetic diagnostics – the future technology of the medical industry with the most acute problem of patent thickets.

Elizaveta Osipchuk

Elizaveta Osipchuk is an 2017 LL.M. graduate from Stockholm University with a degree in European IP Law and a background in Russian law. She works with trademark and pharmaceutical patent litigation, advertising regulation and anti-counterfeiting issues in Moscow, and dedicates her professional development to learning about cross-border IP matters.