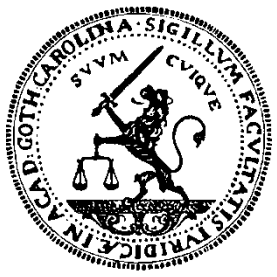

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A legal perspective on biotechnology patents in mergers and acquisitions transactions in the European Union and the United States

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Contents

Abstract

This thesis addresses different aspects of the legal perspective on the patentability, valuation, and scope of biotech patents in the European Union and the United States when mergers & acquisitions transactions are in question. To facilitate mergers & acquisition of a biotechnology company a specific regulatory environment must be established, particularly what effects the most such transactions when the biotech company is in question. This thesis analyses existing peculiarities and similarities of the European Union's and the United States' regulations. Presented findings establish a legal perspective towards the patentability of biotechnology patents and its importance in mergers & acquisitions transactions. Traditionally, courts have used the scope of the application to limit a biotechnology patent that has an overly broad scope for protection. Defining the correct degree of patent scope gives rise to different problems. This in order affects the valuation of intellectual property rights in the biotech industry and might compromise the merger & acquisition transaction because intellectual property assets play the most important role. Unethical practices are also constantly argued. While there are numerous limitations on the value and scope of biotech patents between the European Union and the United States legal approaches, there are various ways in which the two can be harmonized to promote cross-border transactions. Until recently, for various intellectual property assets, numerous standardizations have been fostered with varying methods being implemented based on place and legislative formulation. This study examined potential gaps in patentability procedures, between the European Union and the United States, the assessment, and the determination of biotech patents in cross-border transactions. Based on the established regulatory environment and deeper analysis of that environment, the findings section concludes that legal perspective must be laid down to diagnostic tools, the existing difficulties in the patentability of biotechnology patents and patenting nature as a perspective between the European Union and the United States. A viewpoint to the flexibility of the subject matter, as well as, the importance of the due diligence process in biotechnology plays also an important role, and last but not least a viewpoint towards the distinct features of issuing patents in the European Union and the United States has been discussed.

Keywords: legal perspective, biotechnology, patentability, mergers and acquisitions, regulatory environment.

Abbreviations

CFI	Court of First Instance
CPC	Community Patent Convention
DPMA	Das Deutsche Patent- und Markenamt
DTSA	Defend Trade Secrets Act
EC	European Commission
EPA	European Patent Agency
EPC	European Patent Convention
EPO	European Patent Office
EU	European Union
EUMR	EU Merger Regulation
IAM	Intellectual Asset Management
IP	Intellectual Property
IPR	Intellectual Property Rights
M&A	Mergers and Acquisitions
PCT	Patent Co-operation treaty
PHOSITA	A person having ordinary skill in the art
PRO	Public Research Organisations
R&D	Research and Development
SME	Small and Medium Size Enterprise
TRIPS	The Agreement on Trade-Related Aspects of Intellectual Property Rights
US	United States
USC	United States Code
USPTO	United States Patent and Trademark Office
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

1 Introduction

To start this chapter knowing the degree to which intellectual property rights are involved in mergers and acquisitions (hereinafter M&A) it is important to consider the extent to which mergers and acquisitions activities have become dominant in the field of intellectual property, both in terms of volume and value, and in terms of mergers in general. This condition in the 1990s was real and it is still considerable now. The compelling force behind most of the mergers completed over the past decade has been the buyer's desire to acquire intellectual property (hereinafter IP) assets from the target.[1]

For potential buyers, information on the strength of the IP assets of the target helps to assess any risks associated with the IP portfolio of the seller and can determine whether the transaction is worthwhile. Consequently, when due diligence is not carried out properly, businesses may be vulnerable to unknown risks and liabilities. Due diligence for sellers will boost their company's marketability and allow them to recognize vulnerabilities in their IP portfolio that could compromise a sale.[2]

According to the European Commission (hereinafter EC), effective, well-designed, and well-balanced intellectual property programs are essential to fostering investment, innovation, growth, and the global business activities of its companies. In this sense, the Commission takes an active part in improving the security and regulation of IP rights in third countries, including through its trade agenda.[3]

The same features of technological innovation can be secured as opposed to other IP rights such as designs, trademarks, copyright, utility models and patents. A utility model is in the European Union (hereinafter EU) an exclusive territorial right that forbids third parties from making, selling marketing importing, or using the protected subject-matter in those countries in which it was registered. On the other hand, the patent offers protection for methods and processes, which is not normally the case for utility models and is very much dependent on the law of the national utility

[1] Lanning G. Bryer, Scott Lebson," Intellectual property assets in mergers and acquisitions' (2003) WIPO, 1-7

[2] Yetunde Okojie, 'The Importance of IP Due Diligence In Mergers And Acquisitions' (Mondaq 28 September 2018) <http://www.mondaq.com/Nigeria/x/740668/Patent/The+Importance+Of+IP+Due+Diligence+In+Mergers+And+Acquisitions>accessed 12 January 2020

[3] Colin Mann, 'EC identifies IP problem territories' (Advanced Television, 10 January 2020) <https://advanced-television.com/2020/01/10/ec-identifies-ip-problem-territories/>accessed 13 January 2020

model.[4] In the United States (hereinafter the US) Chapter 35, Part II, Chapter 10, Paragraph 101 of the United States Code covers the essence of a utility patent, which describes it as any invention for which a patent can be issued and thus it states that anyone who: *"invents or discovers any new and useful process, device, manufacture, or composition of a matter, or any new and convenient upgrade, is eligible to get a patent for such purposes, which is subject to the conditions and specifications of this section"*.[5]

The writer sees it important to underline that due to the nonexistence of utility models in the US this work is concentrated on the patents and the importance of other issues such as trade secrets, due diligence, and other relevant topics that will be discussed in further section two when the regulatory environment for this thesis will be established.

It is no doubt that gaining a detailed comprehension of the scope of intellectual property rights, especially concerning mergers and acquisitions is highly crucial. This argument is attributed to the fact that the activities of M&A in this particular field are increasingly expanding and thus dominating the global market today. The primary reason behind the accomplishment of mergers over the past few years is the relentless urge of the buyer to acquire the intellectual property financial resources, among other assets of the target.[6]

In some cases, patents that include a highly specialized update to existing technology or that help improve the product can have relatively limited value in certain instances. On the other hand, in a developed market, patents relating to products with a broad market appeal or representing a substantial advancement over an existing product can produce large economic returns. Therefore, a patent's market value may be partly a function of the size and intricacy of the demand for the product to which the patent relates.[7]

The invention is covered only in countries with a valid member of the patent family (i.e., number of patents which belong together or lead back to the same priority document). A German patent issued by Deutsche Patent- und Markenamt (hereinafter) DPMA, for instance, does not promote defense on the US market. Also, a US patent will shield the United States of America from one's invention. With the scale of the patent family the scope and

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[4] EPO, 'Intellectual Property Teaching Kit. IP Advanced Part I' (EPO, 2016) <http://www.startup-ecosystem.org/wp-content/uploads/2018/02/IPTK_Advanced-I-2-Utility-models.pdf>accessed 28 January 2020

[5] Will Kenton, 'Utility Patent'(Investopedia, Jun 25 2019) <https://www.investopedia.com/terms/u/utility-patent.asp>accessed 19 February 2020

[6] Lanning G. Bryer, Scott Lebson," Intellectual property assets in mergers and acquisitions' (2003) WIPO, 1-10

[7] Krista F. Holt et al." What's It Worth? Principles of Patent Valuation' (2015), Landslide, Vol. 8, No. 1, 33

importance of the protection of intellectual property increase. Particularly, a large patent family plays a significant role when it wants to sell one's property right. A patent family that is valid only in a limited geographical market and thus provides only a specific geographical scope of patent protection for a foreign bidder is worthless. Around the same time, a broad patent family entails high costs-both at the time of filing and by annual maintenance fees.[8]

A common problem that emerges about biotechnological innovations is the question of innovation and the distinction between discovery and invention. It is important to notice that pure, natural products are not patentable. To be patentable in the US in compliance with 35 U.S.C. § 102, a human being must add to the original a new type, a new quality, at least one new property or its combinations to the original product existing in nature. The key problem concerning the patentability of biotechnological innovations is the degree to which they were made available to the public, and the advances alleged vary from what is present in nature. It may be patentable for products with a higher purity or operation, which differentiate physical properties or a particular physical form.[9]

Seeing that national gaps in the legal security of biotechnological innovations could "create barriers to trade and thus hinder the proper functioning of the internal market," the European Community created its legal structure. The laws of national patent law remain, in this context, the fundamental basis for the legal defense of biotechnological innovations. The legal requirements of the European Community are limited to defining certain guidelines for the patentability of biological material as such to be enforced by national legislation.[10]

Not every biotechnology company sees a for example a drug from concept through to development. Small biotechnology companies in many cases license their proprietary inventions to bigger firms with the capital capable of manufacturing them and then selling them. The sustainability of these small businesses depends on how they can persuade investors that their

[8] Patent Pilot, 'Geographical scope and content-related scope determine the range of your patent protection' (Patent-Pilot GmbH, 2020) <https://www.patent-pilot.com/en/obtaining-a-patent/scope-of-patent-protection/>accessed 19 March 2020

[9] Corina Schütt, "Patents for biotechnological inventions
current legal situation and case law in Europe, the US and Japan' (2004) Master Thesis ETH Zürich, 10

[10] Tade Matthias Spranger, "Europe's Biotech P s Biotech Patent Landscape: Conditions and Recent atent Landscape: Conditions and Recent
Developments' (2002) Minnesota Intellectual Property Review
Volume 3 Issue 2 Article 2, 239

companies have a good intellectual property policy. This patent-centric approach helps reduce investor risk.[11]

Unique features of discovery, production, and commercialization of goods and innovations in the life sciences industry give rise to a multitude of issues across a wide range of legal and commercial fields. It is a dynamic and changing legal and regulatory climate that presents unique challenges in the life sciences field for those active in M&A. Especially, it observes the following: a life sciences M&A case study, due diligence, and its impact, intellectual property issues, structuring the deal, competition laws, anti-corruption laws, employment issues, and tax issues.[12]

1.1 The background to the research work

Biotechnology is a technology that evolves or produces new goods using biological processes, living organisms, or parts of that. Work performed in the biotechnology industry and other related areas such as medicine, genetics, etc. has experienced rapid growth with the advent of genetic engineering in the 1970s due to the new possibility of making improvements in the genetic material of the organisms. Biotechnology covers nowadays many disciplines such as genetics, biochemistry, molecular biology, and others and so within the areas listed above each year new technologies and products are innovated.[13]

As in biotechnology innovations, patents also play an important role in other technology industries. Nonetheless, while patents may be vital to the biopharmaceutical and other biotechnology research and development, features prominently in firm strategies of high-tech industries, and play a significant role in enabling start-ups to attract venture capital thus they generally appear to be ancillary to larger opportunities to innovate such as competition, first-mover advantage, and trade secrecy. There is some evidence that patents are seldom the main driver of innovation in some industries. However, this trend does not make patents obsolete in the new economy — far from it. Depending on the condition of their competitors, it can be imperative for technology companies to have patent portfolios that could block their competitors' products. Save in the biotechnology setting,

[11] Online Healthcare MBA, 'Why Patents Matter in Biotech' (George Washington University, School of Business, 2020) <https://healthcaremba.gwu.edu/blog/why-patents-matter-in-biotech/>accessed 27 March 2020

[12] Daniel Pavin and James Halstead 'Key considerations for European M&A in the life sciences sector' (Covington & Burling LLP, 2012) <https://www.cov.com/-/media/files/corporate/publications/2012/01/key_considerations_for_european_ma_life_sciences_sector.pdf> accessed 4 February 2020

[13] NTNU, ' What is Biotechnology?'(NTNU, Department of Biotechnology and Food Science, 2020)< https://www.ntnu.edu/ibt/about-us/what-is-biotechnology>accessed 18 May 2020

where patents are relatively few and are susceptible to deterministic claims, infringement is ubiquitous and unavoidable. Mutually assured destruction, then, allows freedom to act. Relatively symmetrical patent holdings promote shared clearing positions and a measure of balance. Firms that lack patent rights equivalent to those of their competitors may be vulnerable and even completely excluded from the market.[14]

In an industry where intellectual property is a vital part of business interest, companies with poor patent enforceability face serious challenges. Because their portfolios are not as easily covered, their intellectual property can spill over to the commons. Other companies can then "borrow" this technology in their research and development of commercialized products. Firms with high enforceability are at greater risk of excluding other firms from using their intellectual assets. High enforceability can, however, intensify the anti-commons. One logical consequence is that firms with mutually blocking technologies can, in some way, converge and reduce fragmentation.[15]

Extending the use of IP creates new problems for the valuation of patents. Not only do patents need to be valued for use in a wider set of transactions– from decisions on filing or renewing a patent to negotiations on licensing fees to be used as collateral for a bank loan–but valuations are carried out by a wider set of stakeholders. Patent holders, inventors, banks, financial analysts, and venture capitalists are all involved in patent and other IP acquisitions which means that the need for monetary patent valuation is especially important when used by patent holders as funding instruments and by financial firms and venture capitalists as investment properties. Consequently, when valuing a company and assessing its technological ability, financial analysts and investors increasingly find IP as a key factor.[16]

The European Union and the United States vary significantly in their decision on the patentability of biotechnological innovations, apart from some exceptions. The most extreme positions in either direction concerning the individual biotechnological inventions mark the margins of the scope which the World Trade Organization (hereinafter WTO) members may use for ratification of Art. 27 TRIPS. Rulings that do not adhere to Art. 27 TRIPS shall remain unconsidered. All WTO members agree on the most important point: Human beings are not patentable. Other regulations could be considered but it can be assumed that no WTO member intends to use them. Thus, the scope involving this option is only a theoretical one. When

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[14] Lars Kjølbye. *Antitrust and Patent Law* (Oxford Competition Law 2016), 59

[15] Alan C. Marco et. Gordon Rausser. ” The Role of Patent Rights in Mergers: Consolidation in Plant Biotechnology’ (2008) American Journal of Agricultural Economics 90(1), 149

[16] Shigeki Kamiyama, Jerry Sheehan, Catalina Martinez, ’Valuation and Exploitation of Intellectual Property’ (OECD, STI Working Paper 2006/5) <https://www.oecd-ilibrary.org/docserver/307034817055.pdf?expires=1580827259&id=id&accname=guest&checksum=64EC1AA66ED7C83CA71F0DE32F627055>accessed 4 January 2020

it comes to the elements of the human body the situation is different. These may be patented, provided they are chemically created or are isolated from the human body. It extends to all components except totipotent stem cells, in compliance with the regulations. They may be exempted from patenting entirely or their patenting is linked to far-reaching conditions. As an example, it should be named here, the regulation of the European Patent Agency (hereinafter EPA) for patenting gene sequences and so the scope of this area is very great and allows for many options of applying the regulations of Art. 27 TRIPS.[17]

1.2 Importance of the research work

In recent years, numerous assessment standards have been established for different IP assets with different geographical boundaries and different approaches to legislation. For practitioners, organizations, or other purposes, they have specific binding forces. It is important to note that there is no contradictory content to those standards and guidelines. They are also fairly homogeneous from a content perspective. The bottleneck for an IP in business is not in the absence of agreed approaches or guidelines, their substance or accuracy, but in the restricted distribution of the knowledge that they exist and the lack of trust in the results.[18]

New problems in the scope of patentability in biotechnology have arisen:

1. Does the recognition and isolation of genes coding for well-known compounds by conventional methods constitute a breakthrough or innovation? A classic example in this area is insulin, a protein that has been known for some time and is produced by a specific gene in the animal body. The structure of this gene was not known until recently.

2. Are claims directed to genetically engineered known compounds acceptable?
For example, should a claim related to "genetically engineered insulin" be allowed, even though the researcher only invented one of the many methods of gene manipulation, or should the argument be limited to a product by the process?

3. Are practical claims often so broadly worded that, for fear of infringement suits, they may preclude further work in a particular area,

[17] Jürgen Simon," Biotechnology and law: biotechnology patents. Special considerations on the inventions with human material' (2006) Rev. Derecho Genoma Hum, Jul-Dec (25), 13

[18] Peter Kaldos and Dulce Miranda," Final Report from the Expert Group on Intellectual Property Valuation' (2013) European Commission, 5-6

should the appropriate claims be restricted to the actual definition in the specification.[19]

Although it sounds as if both the European and the US eligibility criteria follow the similar principles of excluding "merely" inventions from patentability, the conflicting US and European patent eligibility requirements frameworks reveal significant differences in the US analytical approach. It means that *Sequenom's 35 U.S.C § 101* test runs contrary to the comprehensive, harmonized European approach to subject matter that is excepted or excluded. This atomistic approach to eligibility claims challenges a more than 20-year-old US strategy that promotes global integration of patent standards. It can violate international treaties, to which the United States is the party where applicable. Such regulations include patent co-operation treaty (hereinafter PCT) Rules 39.1 and 67.1 and possibly Article 27 of the TRIPS Agreement.[20]

Furthermore, extensive information on the subject matter is essential for potential buyers as it helps them gain more insight into the target's overall IP asset strength. This helps them be in a favorable position to conduct a strategized analysis of potential risks linked to the entire portfolio of the IP. It is only accurate to say that the failure of a prospective buyer to assess matters to do with due diligence may expose them to possible contingencies, among other liabilities.[21] On the other hand, due diligence is highly essential for buyers, especially since it helps them in terms of marketing their company and pointing out the possible flaws in their IP portfolio.[22]

Despite the existence of some evidence to indicate that patents are not the significant factors for increased innovation, this argument receives a lot of criticism. In the modern world today, patent rights have made it possible for all technology companies to engage in healthy competition. No given corporation is in any position to develop a patent portfolio that can block its rival from competing with its products. In the biotechnological industry, there exist just a few patents. These patents are highly vulnerable when it comes to deterministic regulations and stringent rules which cannot be easily avoided. An industry such as this can only result in mutual destruction in terms of extreme competition, which in turn provides room

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[19] Sahil Gupta, 'The problems raised by biotechnological inventions for patent scope interpretation' (Inter Lawyer 2002) <http://www.inter-lawyer.com/lex-e-scripta/articles/patent-scope.htm>accessed 5 January 2020

[20] Timo Minssen and Robert Shwartz, "Separating sheep from goats: a European view on the patent eligibility of biomedical diagnostic methods' (August 2016) Journal of Law and the Biosciences, Volume 3, Issue 2, Oxford, 365–372

[21] Yetunde Okojie, 'The Importance of IP Due Diligence in Mergers and Acquisitions' (Mondaq 28 September 2018) <http://www.mondaq.com/Nigeria/x/740668/Patent/The+Importance+Of+IP+Due+Diligence+In+Mergers+And+Acquisitions>accessed 12 January 2020

[22] Ibid,

for autonomy. This, therefore, implies that the existence of patent rights, which are relatively proportioned, enhances a free market condition and, ultimately, a state of balance within the market. However, in a real market situation, companies that do not have any patent rights similar to those of their rivals remain to be highly vulnerable and may end up becoming excluded from the global market. Biotechnological companies can acquire intellectual property rights by obtaining a patent directly from the European Patent Office (hereinafter EPO) or the United States Patent and Trademark Office (hereinafter USPTO). However, hardly do academic institutions award a patent to a corporation. Assigning a patent to a company implies a voluntary transfer of the institution's title as well as the future rights to the patent.[23]

It is important to note that IP programs that are highly effective, well-organized, and properly designed are deemed essential for increasing the levels of investment, economic growth, and maximum innovation within the company. The European Commission thereby has its primary role as safeguarding and enforcing intellectual property rights through such means as trade agendas in developing countries. Similar characteristics of ensuring high levels of innovation in the field of biotechnology are evident. These features can be highly secured, unlike other intellectual property rights, including copyrights and patents. Patent rights are known to be rights that provide security towards processes and methods included in the IP portfolio. Contrastingly, firms that have substantial patent rights may push companies with weaker patent rights out of the market. Generally, companies which have mutually blocking technologies may either reduce or increase fragmentation, or act in both ways.[24]

Similar to scientific inventions and innovations, patents are held in high regard in technology industries. It is thereby true to say that patents are very useful when it comes to biotechnological and pharmaceutical corporations. This is because patents allow for the setting up of smaller companies of this kind and contribute to such matters as competition, and trade secrecy.[25]

1.3 Research questions

Throughout this research paper, various aspects surrounding the legal issues of valuation and scope of biotech patents in the European Union and the United States will be discussed. The writer begins by introducing the basics

[23] EPO, 'Intellectual Property Teaching Kit. IP Advanced Part I' (EPO 2016) <http://www.startup-ecosystem.org/wp-content/uploads/2018/02/IPTK_Advanced-I-2-Utility-models.pdf>accessed 28 October 20

[24] Colin Mann, 'EC identifies IP problem territories' (Advanced Television, 10 January 2020) <https://advanced-television.com/2020/01/10/ec-identifies-ip-problem-territories/>accessed 13 January 2020

[25] Ibid,

of patent rights and their usefulness in the operation of all companies across the global business market. The reader will learn that the patents are very important in the sense that they protect companies from the entry of other firms into the market, hence boosting their competitive advantage. There exist numerous rules and regulations that guide companies in their quest to acquire intellectual property rights. Companies should adhere to such regulations as due diligence to avoid the revoking of their patents.

The writer will also conduct a detailed analysis of the major differences between the scope and valuation of the IP rights of biotechnology companies between the US and the EU. The reader will see that these two regions differ in this subject matter on aspects such as the distinct features of issuing biotechnology patents in the US and the EU, as well as the existing difficulties in the patentability of biotechnology patents in the EU and the US, the best mode of conducting practices as well as consequential matters concerning mergers and acquisition transactions in biotechnology. Despite the numerous discussions in various courts of appeal in both the EU and the US, there are still a lot of controversial matters surrounding the application, awarding, and revocation of patent rights of biotechnology companies. Extensive research on this issue is recommended to aid future research and benefits, as well, the growth of the biotech industry.

The criteria in which the law is exercised in many countries are generally different in its definition and scope of work or research delivered. All these depend on the place of inventions and the purpose of the invention to be granted law protection.[26]

In the next chapters, the writer sees it essential to introduce the reader to the regulatory environment in chapter two before the analysis part, and the research findings can be presented. The aim of chapter three is thus to project existing issues in the regulatory environment that exists concerning the patentability of biotechnology and mergers and acquisition of biotechnology companies. Chapter four will present the relevant findings and section five will conclude the research with the suggestions.

It is essential to understand that this thesis concentrates solely on legal perspectives, to compare and accurately and fairly judge biotechnology patents with all the relevant issues if possible (such as scope and valuation of biotechnology patents), and present findings concerning cross-border biotechnology merger and acquisition transactions between the US and the EU.

This thesis sets the following questions that will be answered:

1) What kind of substantial difference and similarity there is in the valuation and scope of biotechnology patents between the US and the EU?

[26] Byrne N. and McBratney A. *Licensing Technology: Negotiating and Drafting Technology Transfer Agreements.* (3rd edition. Bristol, England Jordans, 2005), 20

2) What is the relevant regulatory environment for this research?

3) What kind of existing differences there is between the US and EU's patentability procedures?

4) What is the best mode of conducting practices of mergers and acquisitions concerning biotechnology patents?

5) What should be especially considered in mergers and acquisition of biotechnology company concerning patentability and existing patents?

1.4 Methodology

This thesis was written with a comparative legal approach and the research was conducted by including a theoretical basis, and the literature supporting it. As the topic concerns the legal approach towards biotechnological patents it assumes that the research is based on a legal matter that concerns the patentability, scope, and valuation of biotechnological patents in merger and acquisition transactions in a specified regulatory environment. The work further relates findings in legal matters towards the further acquisition or merger of the companies and highlights the main differences and similarities as well as existing difficulties that may arise when one company from the EU and another from the US acquires other IP rights in the biotechnological field and vice versa.

The data collection and selection were narrowed to specific fields namely patents and regulations in mergers and acquisitions and supporting those findings with the law and cases in the EU and the US. Information was collected from many sources such as journal articles, online journals, cases, legislation, books, command papers, commission reports, and websites, and blogs. Collected information was further analyzed by extracting relevant information regarding the legal perspective on biotechnology patents. The data was further examined in the light of patentability, valuation, and scope of the patents. As this thesis concentrates also on mergers and acquisition part further data supporting the acquisition of IP rights and other relevant issues that come along such as due diligence, patent injunctions, trade secrets, and evolving rights were discussed.

As this thesis has a comparative legal approach, its main aim was to highlight the legal perspective itself as this field of study has not been studied earlier so much and thus the data collection appeared to be challenging as there is not much of a case law or other regulations that might set borders to different patentability issues and possibilities with biotechnology and so the main guidelines that already exist need to be evaluated and compared. Concerning the M&A transactions, the writer noticed in this thesis that as such IP rights are extremely important in biotechnology during the M&A process and thus it needed to be addressed how companies act when biotechnological IP rights are at stake.

The writer evaluates the methodological choice to be a dogmatic method by pursuing to find facts and information that is supporting the topic. This also included a comparative approach as the thesis is discussing legal perspectives in the US and the EU. This thesis has also an economic perspective as a purely legal approach proved to be challenging if the only patentability is concerned as there is not much of studies or case law within constantly evolving biotechnology.

The writer concludes that as such the topic of the thesis is relevant as biotechnology is evolving and becoming a major player in the economy but the patentability in this field is extremely fragile and risky and so there are not many concrete cases or showed practice in this fields. So, the used methods proved to be right and essential to prove findings to be relevant. The writer sees this thesis as a beginning towards further studies as there will be more case law and legal guidelines in the future and thus this thesis could be expanded.

2 Regulatory environment

This chapter concentrates on the regulatory environment and the general rules in mergers and acquisitions and the patentability of biotechnology patents in the EU and the US. It is also important to underline that this chapter has subsequent sections combining essential parts to show a regulatory environment on which this thesis is built upon and the following analysis part can be further discussed. That is why this chapter also includes valuation and scope of biotechnology patents, due diligence, third parties, trade secrets and patent injunctions as all of them are interlinked and must be discussed to grasp the idea of analysis and findings in the following chapters of this thesis. For the beginning:

Corporate assets will be channeled for the ideal future to their best use, and thus mergers and acquisitions help this process through the reallocation of power over companies. Nonetheless, frictions like transaction costs, information asymmetries, and disputes between agencies can impede the successful transfer of control. Recent studies on corporate governance use indicators of the consistency of a country's legal and regulatory environment as proxies for some of these frictions and show that differences in law, regulation, and compliance correlate with capital markets growth, firms' ownership structure, and capital costs.[27]

The rationale of the US antitrust policy, contrary to the European competition model, is that there should be a certain minimum of competition and that this degree of competition could not be sustained

[27] Rossi S. Volpin P. F. "Cross-country determinants of mergers and acquisitions' (May 2004) Journal of Financial Economics 74, 235

without an antitrust policy. Generally, the US antitrust policy is specifically aimed at protecting the rights of competition to guarantee the protection of customers, which is articulated in terms of producing a variety of products at reasonable prices. Unlike the EU, the US law enforcement agencies and courts believe that a vibrantly competitive market would be immediately successful.[28]

Like the US *Hart-Scott-Rodino Act*, the EU's regulation on merger demands both parties to inform the regulator before completing the merger or acquisition of a transaction exceeding above a certain size threshold limit. In the United States, the combining parties must avoid from closing until a 30-day waiting period passes away. In contrast, a notifiable "concentration" (i.e., a merger, takeover, or other consolidation) of two or more "undertakings" (i.e., companies or other entities) must not be accomplished in Europe until it is approved. Nevertheless, the Commission must either sanction (or clear) the transaction or appeal it within a month. In the US, the waiting period will be prolonged to a somewhat undefined time if the government releases a "second request" for information while in the EU an additional four months may be prolonged if the Commission initiates a "second-stage inquiry." Both the US and the EU regulatory authorities have authorized the implementation of rules to facilitate the pre-merger notification process.[29]

Over the past two decades, for example the pharmaceutical-biotechnology sector has undergone a high rate of M&A activity, and this has led to increased market consolidation. Some of today's biggest companies, particularly cross-national mergers, are the product of a series of large fusions. At the same time, other industry companies have avoided large M&A activities and preferred to enlarge through internal research and development (hereinafter R&D) and more simple acquisitions, including licensing of products and technology.[30]

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[28] Doris Hildebrand," The European School of Thought in Merger Cases' (2012) More Pros and Cons of Merger Control, Konkurensverket, 17

[29] William M. Hannay," Transnational Competition Law Aspects of Mergers and Acquisitions' (2000) Northwest Journal of International Law and Business, Volume 20, Issue 2, 287

[30] Patricia. M. Danzon, "Mergers and Acquisitions in the Pharmaceutical and Biotech Industries' (2007) Health Care Management Papers, Wharton Faculty Research, University of Pennsylvania, 31

2.1 General rules in the patentability of biotechnology patents in the European Union and the United States

Unlike the US patents statute, the European Patent Convention (hereinafter EPC) does not attempt to define what constitutes patentable subject matter. Instead, it tells us what is not to be regarded as inventions. The invention must lie in a field of technology, it must concern a technical problem, and it must have technical features. Thus, a technical character is essential for there to be the invention, but rather unhelpfully the EPC does not include a definition of the word "technical". Most of the European Patent Office's (hereinafter EPO) case law on the meaning of "technical effect" relates to the fields of computing, software, and business methods, where lack of technical effect is frequently encountered as an objection; it is much less common in the life sciences.[31]

Do discoveries in genomics and proteomics fall within the range of subject matter that the patent system protects? In the US the Patent Act extends protection to *"any new and useful process, machine, manufacture or composition of matter,"* without excluding the certain subject matter. But in the past, the courts and the United States Patent and Trademark Office have thought that sometimes it seemed appropriate to exclude certain types of inventions from patent eligibility, including medical and surgical techniques, plants, agricultural methods, mathematical algorithms, and products and phenomena of nature. These exclusions have been viewed skeptically by the Court of Appeals for the Federal Circuit (hereinafter Federal Circuit) and by its predecessor, the Court of Customs and Patent Appeals, and by now most have been repudiated. [32]

Biotechnology patent applications must meet all the accompanying prerequisites: novelty, innovativeness, and lack of obviousness. It is impractical to get a patent for a topic that was openly known or clear at the time the appeal was submitted to the patent office containing a satisfactory definition and backing for the supposed creation of something innovative. It is important to uncover adequate data to enable people, in general, to get, make, and utilize the full extent of the claimed invention. Patentability isn't

[31] Christina Gates, 'Patenting the Life Sciences at the European Patent Office' (Cold Spring Harbor Perspectives in Medicine, 2014 Dec; 4(12)) <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4292089/>accessed 6 January 2020

[32] Merrill S.A, Mazza A.M,
'Reaping the Benefits of Genomic and Proteomic Research: Intellectual Property Rights, Innovation, and Public Health' (National Academic Press 2006) <https://www.ncbi.nlm.nih.gov/books/NBK19867/>accessed 6 January 2020

just reliant on these conditions, but in addition to the patent document's meaning of the invention. In biological innovations, it is often also based on the amount of experimental data to demonstrate that the development functions as imagined by the innovator.[33]

A biotech company can acquire an IP through the direct issuance of a patent, but most universities and academic institutions seldom award an IP to any company. The assignment is a voluntary transfer of title along with all future rights to the IP. There are several reasons why the institution will be licensed rather than granted 1) Federal restrictions (USA) on assignment for the university, 2) a hedge chance of business failure, and 3) a desire to continue to research in the relevant areas. The conventional method by which a biotech company obtains IP rights is through licensing agreements. Such licensing agreements have the terms and specifications that the company will meet to maintain the license to use the IP. There are also fines or revocations to the license if certain conditions are not met during the duration of the license. The biotech entrepreneur will always want to receive an exclusive IP license from which he plans to build a company.[34]

Nevertheless, due to the high degree of complexity involved in creating an innovation, the industry may often hesitate to exploit the technological opportunities presented by the public research organization (hereinafter PRO). If the process of intellectual asset management (hereinafter IAM) at the PRO is sufficiently attentive to reserving exclusive rights to IP positions which may be valuable in the context of a start-up, it may be possible to achieve the optimal mix between more traditional exploitation activities and start-ups.[35]

Fundamental principles which underpin the patent system are crucial. They help to better understand some of the latest debates about biotechnological innovations patentability. These inventions have been very controversial in some circles, and their patentability even more so. They have also been alleged to harm scientific study.[36] All of the mentioned above shows that in the patentability of biotechnology innovation exists an uncertainty and this uncertainty has a direct effect on mergers and acquisition of such companies and their IP portfolio. The next chapter opens up general rules in mergers and acquisitions.

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[33] Matthew Latimer, 'Patenting inventions arising from biological research' (National Center for Biotechnology Information 20 December 2014) <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC549056/accessed> 21 October 2019

[34] Graig D. Shimasaki, *The Business of Bioscience: What goes into making a Biotechnology Product* (Springer, New York 2009), 40

[35] OECD, *Turning Science into Business: Patenting and Licensing at Public Research Organisations*, (OECD Publishing, Paris 2003), 99

[36] Sven J.R. Bostyn, "Biotech Patents and the Future of Scientific Research' (2004) ALLEA Biennial Yearbook Critical Topics in Science and Scholarship, 30

2.2 General rules in mergers & acquisitions under the European Union Law and United States Law

From a legal point of view, the principle of concentration used in the EU Merger Regulation (hereinafter EUMR) provides the basis for the powers of the Commission under that regulation. According to Article 3 of the EUMR, any transaction or group of transactions that result in a change of control permanently by conferring *"the possibility of exercising decisive influence on the undertaking concerned is a concentration which is considered to have arisen for the purposes of the EUMR legislation"*.[37]

In the case of T-102/96 *Gencor Ltd v. Commission* [1999], ECR II-753 the court concluded that two companies' centralization was inconsistent with the EU's Merger Control Regulations. The EU Court of First Instance acknowledged that there is a merger regulation "*to prevent the creation of market systems capable of creating or strengthening a dominant position and not specifically regulating potential violations of dominant positions*." Based on the findings of the Court of First Instance (hereinafter CFI), held that it was within the jurisdiction of the Commission to prevent or approve mergers that had been created outside Europe. In other words, the Commission was able to carry out the planned merger on an annual basis, as it can still be kept responsible for a merger that transpires abroad.[38]

If the securities of the target company are registered under the Securities Act in the US (regardless of whether the target company is incorporated in the United States), the bidder must comply with the comprehensive disclosure requirements of the US tender offer rules and a variety of contractual conditions (including the right to withdraw from the target company shareholders throughout the offer duration and certain timing). If the securities of the target company are not listed under the Exchange Act but the target company has security holders in the United States, or if the target company is a foreign private issuer (i.e., its securities are registered under the Exchange Act) and US security holders hold 10% or less of the class of securities requested in the offer, the bidder is not required to comply with the specific disclosure provisions of the US tender offer rules (if the target company is a foreign private issuer and US security holders hold between

[37] British Institute of International and Comparative Law, *Competion Law Forum* (BIICL documents/10062_346) 1-2

[38] Case of T-102/96 *Gencor Ltd v. Commission* [1999] ECR II-753

10% and 40% of the class of securities sought in the offer, some of the provisions of the US tender offer rules apply).[39]

All notes, minutes and other documentation of any kind whatsoever created by the parties to a transaction, their affiliates, and consultants in connection with a transaction are likely to be reviewed by those competition authorities whose prior consent is required to implement the transaction. For example, both the US and the EU pre-merger notification forms include all studies, surveys, analyses, and reports prepared by or for an officer or director to check or analyze the transaction, including market shares, pricing, rivals, markets, the potential for revenue growth or enlargement into the product or geographic markets. Accordingly, all documents that have been prepared to date that might fall within the scope of this requirement should be identified for submission and new documents that might fall within the scope of the requirement should be prepared in "draft" so they can be reviewed by counsel before finalization.[40]

A company-owned intellectual property (IP) is also one of the main properties. Again, if a company does not have the freedom to conduct its business owing to third party IP privileges, this can have a major impact on its ability to function efficiently, and thus on its competitiveness overall. IP due diligence means an assessment of the IP that a client owns or uses, or the IP rights of third parties that affect the client's business. Therefore, IP due diligence may be crucial in determining whether to buy or invest in a business, or to enter some other arrangement with the business where IP is a key factor.[41]

This on other hand touches especially the biotechnology field and plays an important role as it was also explained previously that same mergers and acquisition rules affect all technologies and same rules must be followed but as chapter two also stated especially in biotechnology and in its patentability exist uncertainties thus due diligence plays a very important role and is an essential part in the regulatory environment. This will be discussed further.

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[39] Ann Beth Stebbins and Thomas H. Kennedy' United States: Mergers & Acquisitions 2019' (Skadden, Arps, Slate, Meagher & Flom (UK) LLP 2019) <https://www.mondaq.com/unitedstates/CorporateCommercial-Law/791336/Mergers-Acquisitions-2019>accessed 6 January 2020

[40] Baker and McKenzie, 'Global M&A Handbook' (Baker and Mc Kenzie 2015) <https://www.bakermckenzie.com/-/media/files/insight/publications/2015/12/globalma_handbook_20150514.pdf>accessed 4 January 2020

[41] Mewburn Ellis, 'IP Due Diligence' (Mewburn Ellis 2020) <https://www.mewburn.com/law-practice-library/ip-due-diligence>accessed 22 April 2020

2.3 Due diligence process in mergers & acquisitions

Although representations and warranties must be tailored to specific transactions, the purchaser typically seeks representations and warranties concerning:

• The seller or target company's ownership or right to use the relevant IP, and the sufficiency of the IP assets to operate the business.
• The validity and enforceability of intellectual property rights
• Relevant IP licenses and other agreements.
• Non-infringement.
• Efforts by the seller or the selling company to protect the trade secrets and other sensitive information relevant to that.

Due diligence can be a source of significant information for both parties to the mergers & acquisitions deal. The principal determinants of the deal are intellectual property and product evaluation. The due diligence of the IP is inherently difficult due to the problems encountered by the IP valuation. Poorly crafted or misapplied market strategy is one of the key reasons why IP powered M&A eventually fails. A well-structured and comprehensive due diligence process is therefore essential. This offers vital information relating to future benefits, economic life, property rights, and the limits of properties.[42]

It should be noted that promises are not a substitution for rigorous due diligence. Due diligence is intended to ensure that rights are in place before the registration of a license, allowing informed decision-making on the existence of rights and the risks of entering the transaction in the first instance. Nonetheless, because certain intellectual property rights are not registered, guarantees are typically required, because there is no other way to verify the ownership, validity, and status of these unregistered intellectual property rights.[43]

Due diligence should include a review of the claims of the patents (and patent applications) to ensure that they are broad enough to cover any commercial products or processes of interest. Patent claims scope is a feature of the disclosure information and width of the patent specification. Even if the claims are broadly drawn, if the disclosure is minimal, the

[42] Priyanshi Pandei, 'Intellectual Property Issues in Mergers and Acquisitions' (IP Leaders 21 September 2018) <https://blog.ipleaders.in/ip-issues-in-ma/>accessed 10 January 2020

[43] Christoff Pienaar, 'Back to Basics: Intellectual Property Warranties in Commercial Contracts' (SCL 16 November 2011) <https://www.scl.org/articles/2239-back-to-basics-intellectual-property-warranties-in-commercial-contracts>accessed 13 January 2020

claims may be construed narrowly, and may not survive a validity challenge in court.[44]

Biotechnology companies continue to accelerate progress for example on the pharmaceutical research and development frontlines. The continued growth of this industry is, in part, supported by partnerships, mergers, and acquisitions. To ensure the success of such agreements, organizations and investors will need to understand the value of assets and to determine the optimal development pathway for them.[45]

2.4 Valuation of biotechnology patents

The flourishing research body has concentrated primarily on one evaluating the various factors that can affect the market value of patents, i.e. the financial returns from secured inventions. Those represent the private interest of patents, which are understood to be economic benefits from exclusive rights given for these inventions. Nonetheless, patents also represent claims relating to the public interest in inventions by encouraging the sharing of information, further creativity in research and development, and the practical application of new knowledge. The patent system is an entity with a social structure, where private and public interests converge. Nonetheless, despite the policy significance of understanding the public interest of science, technology, and innovation and the relationship between the social utility of inventions and patenting, less attention has been paid to patent value definitions than to inventors and owners of the financial value of patents.[46]

Essentially, there are four different ways of calculating intangible assets based on an income methodology each of which offers a different way to separate the real cash flow for the specific intangible asset. In general, such methods are equivalent. For individual cases, one or the other approach may be better suited than another due to the importance of a company's unique intangible asset or the fact that it may be difficult to get through the information required for implementing one particular method. Within the income approach, the following methods are applicable:

[44] Adda Gogoris, Clarke, P. "Patent due diligence in biotechnology transactions' (2001) Nature Biotechnology 19, 279–281

[45] ICON, 'Demonstrating potential of drug and device candidates' (ICON 2020) <https://www.iconplc.com/sectors/biotech/due-diligence-asset-valua/>accessed 18 April 2020

[46] Barbara Ribeiro and Philip Shapira," Private and public values of innovation: A patent analysis of synthetic biology' (2020) Research Policy 49, 2

• Direct Cash Flow Prognosis Method,
• Relief-from-Royalty Method,
• Incremental Cash Flow Method and
• Multi-Period Excess Earnings Method.[47]

Differences in patenting practices across industries and technology fields are important sources of unobserved heterogeneity. Researchers typically control with fixed field effects for these, but it is important to understand the underlying reasons that matter to those effects. A broad divide between the "high-tech" industry and for example the pharmaceutical industry has emerged in recent policy debates in patent reform. For complex, component-based technology, such as computers, semiconductors, and telecommunications equipment, intellectual property is often distributed across many parts, innovations are accumulated, and product life cycles are usually fast-paced. In such industries, companies may need hundreds of patents to acquire intellectual property rights for a single product and may rely heavily on cross-licensing to access intellectual property fragments needed.[48]

Inventions are more discrete in pharmaceuticals and chemicals, and a much smaller number of patents may cover the products. Individual patents may yield significant market and/or licensing rentals. Development lead times are long (with some medicines extending into decades), providing short patent life once a product enters the market. Because of that, firms in such fields are likely to spend more effort writing strong patents. This is likely to be reflected in the data, with patents likely to contain a higher number of claims, prior art renewals, and continuations in those fields.[49]

The value of a patent is due to the advantages expected by the winner of a patent battle. When a company acquires a patent, it acquires all associated rights including the right to exclude competitors from using the underlying invention and the right to block other transferred patent rights. Firms that unsuccessfully compete for the patent right suffer the consequences of a competitor becoming the leader. The difference in profits between the two options constitutes the asset value of the patent right. Early estimates of patent value showed a highly skewed distribution. This considerable

[47] Martin A. Bader and Frauke Rüether, 'Still A Long Way to Value-Based Patent Valuation. The Patent Valuation Practices of Europe's Top 500' (Wipo June 2009) <https://www.wipo.int/edocs/mdocs/sme/en/wipo_insme_smes_ge_10/wipo_insme_smes_ge_10_ref_theme06_01.pdf>accessed 7 January 2020.

[48] Michelle Gittelman, "A Note on the Value of Patents as Indicators of Innovation: Implications for Management Research' (August 2008) Academy of Management Perspectives, 24-26

[49] Ibid, 24-26

variation in the value of patents spurred the research for patent value indicators.[50]

Patents constitute a vital corporate asset and business resource for most technology companies, with a few exceptions. By considering patents and IP approaches at the outset, decision-making focus shifts from cost pressures to value opportunities within the overall business strategy context. A patent activity plan helps concentrate on protecting core technologies, managing long-term patenting costs efficiently, protecting proprietary information, and ownership and assignment matters. A well-timed strategy allows for the identification of opportunities producing interest or income at the correct time.[51]

After presenting the chapter on the valuation of biotechnology patents it is essential to establish the scope of protection of bioscience patents. As it was stated before patents are a key corporate asset and commercial tool and because differences in patenting practices across industries and technology fields are important sources of unobserved heterogeneity.

The scope of protection in the study of patent law is an important aspect. In biotechnology, the topic gets even more focus, considering the possible implications for scientific research and technological advancement from a wide perspective. [52] The scope of protection will be discussed in the next chapter.

2.5 Scope of protection of biotechnology patents

Although biotech is a highly unique sector, and is especially dependent on IP, it must comply with the same patent specifications for its innovations as those of all other sectors and it faces the same challenges faced by program management. Regardless of industry, the winning of a patent for a "discovery" or "invention" requires a four-part test by the claimant. There must be innovation in discovery or invention, and it must be convenient. It must be unequivocal. And that must be described appropriately. It is extremely troublesome to formulate and apply reasonable, logical, and up-to-date standards for each standard as simple as these needs can sound,

[50] Timo Fischer and Jan Leidinger, "Testing patent value indicators on directly observed patent value—An empirical analysis of Ocean Tomo patent auctions' (2014) Research Policy April 2014 43(3), 520

[51] Angela de Wilton, "Patent Value: A Business Perspective for Technology Startups' (December 2011) Technology Innovation Management Review, 11

[52] Sven J.R. Bostyn, "Biotech Patents and the Future of Scientific Research' (2004) ALLEA Biennial Yearbook Critical Topics in Science and Scholarschip, 31

particularly when the system is dealing with complicated, high-stakes technical content. Like other sectors, biotechnology lies at the hands of the USPTO and suffers greatly when the intellectual property right (hereinafter IPR) mechanism is ineffective, as does the economy from employment and missed opportunity. Overall, the US patent system continues to face three major challenges — a wide and ongoing backlog of patent applications, low patent quality, and a growing degree of IPR-related litigation and violations. Within a global economy, especially in the biotechnology sector, a poorly behaved patent system is a major burden when market speed, first-move positioning, and cost control are needed.[53]

The EU's Directive on the patentability of biotechnological inventions generally specifies that patent protection for most biotechnological innovations, including human and non-human gene sequences and cell lines and transgenic plants and animals, should, in theory, be available in all European Union (EU) countries. The guideline would extend the scope of protection available for biotechnology patents so that the patent proprietor will prevent unauthorized reproduction of proprietary biological material, while farmers will in some cases be entitled to propagate transgenic crops and breed transgenic animals. Ultimately, the Biotechnology Directive also addresses issues arising from the relationship between patent and plant variety rights, the depositing of biological material in recognized institutions in connection with patent filing, and the provision by the European Commission to the European Parliament of additional information on the effect of the Biotechnology Directive and developments in biotechnology and patent law.[54]

While the patentability criteria prescribed in patent law by World Intellectual Property Organization (hereinafter WIPO) apply in the same way to inventions in all fields of technology, applying patent law to biotechnological inventions must deal with several peculiarities that may not exist in the same way in other technological areas.
One collection of concerns relates to the nature of patent rights and legal requirements. Although patents are in theory available for any innovation in any field of technology under the Trade-Related Aspects of Intellectual Property Rights Agreement (hereinafter TRIPS Agreement), the question of the patentability of biological products, extracted or obtained from naturally occurring living organisms, has prompted wide-ranging debates. Many claim that these biological materials are simply "discoveries" and are therefore not patentable, while others claim that they are "inventions" created by man. Regarding industrial applicability (usefulness) and sufficiency of disclosure, exclusive patent rights can only be issued if the

[53] John Raidt, 'Patents and Biotechnology' (U.S Chamber of Commerce Foundation 2020) <https://www.uschamberfoundation.org/sites/default/files/article/foundation/RaidtPaper.pdf >accessed 7 January 2020

[54] Richard Binns &Bryan Driscoll" The European Directive on the legal protection of biotechnological inventions' (1998) Expert Opinion on Therapeutic Patents Volume 8, Issue 12, 1729-1735

patent application shows an acceptable degree of practical and substantive use of the biotechnological invention.[55]

With the emergence of biosimilar biologics, the option of trade secrets versus patent rights has assumed renewed significance in the biotechnology field. From the originator's viewpoint, the additional emphasis is put on the security of secondary patents, i.e. patents covering production methods, formulations, etc. The object of such litigation is to extend the protection of the original composition and method and use of the patent by protecting manufacturing processes or commercial formulations. However, if they want to keep some of their critical processes as secret, many originator companies may avoid filing patent protection, as well as revealing the bioprocess that comes with them. Factors that weigh in favour of patent or trade secret protection are summarized in the context of products versus processes.[56] The next subsection concentrates on trade secrets in order to establish the relevancy to biotechnology patents.

2.6 Trade secrets

Trade secrets and proprietary knowledge form a pillar of the most popular strategies for intellectual property. Trade secrets provide significant competitive advantages which increase a company's productivity and value. Substantial harm awards strong regulation, and the implementation of clear statutory safeguards. United States has recently confirmed the importance and value of trade secrets. In the M&A context, the disclosure of trade secrets and confidential information that expose the disclosing party to various risks, especially during the negotiation and due diligence phases of an M&A transaction. As such it must be a priority to take measures to protect confidential information.[57]

Recent U.S. Patent and Trademark Office (USPTO) and Supreme Court rulings and amendments, combined with an anti-patent sentiment in the World Health Organization (hereinafter WHO) and the World Trade Organization (hereinafter WTO), undermine the value of patenting by tipping the scales to keep scientific inventions secret. Inside biotechnology

[55] World Intellectual Property Organization,' Patent Expert Issues: Biotechnology' (WIPO 2020) < https://www.wipo.int/patents/en/topics/biotechnology.html>accessed 7 January 2020

[56] Paul A Calvo, 'Choosing between patents and trade secrets for protecting biotech products or bio-production processes' (Journal of Biotechnology and Biomaterials, March 2017) <https://www.omicsonline.org/conference-proceedings/2155-952X.C1.069-004.pdf>accessed 22 April 2020

[57] Mark Davis, 'Protecting trade secrets' (Intellectual property, M&A, Deal Law Wire, September 2017) <https://www.deallawwire.com/2017/09/13/protecting-trade-secrets-in-ma/>accessed 9 January 2020

firms, this poses tremendous management concerns as employees move from one employee to another, taking their trade secrets with them.[58]

A trade secret, then, is usually any proprietary commercial knowledge that provides a corporation with a competitive advantage. It is information that (1) is not commonly known to the public; (2) offers the competitive advantage or economic benefit because it is not known to the public (i.e. not only because of the value of the information); and (3) is subject to reasonable efforts to maintain it as a secret. [59]

Moreover, the restatement includes six criteria to be considered when deciding whether certain information actually counts as a trade secret for protection: (1) the degree to which the information is known outside the company of the claimant; (2) the extent to which it is known to employees and others involved in the business; (3) the extent of measures taken by the claimant to guard the secrecy of the information; (4) the importance of the information to the enterprise and its competitors; (5) the amount of effort or money spent by the enterprise in the first instance on creating the information; and (6) the ease or difficulty with which the information could be properly acquired or duplicated by others, taking into account what the business has publicly disclosed, for example, in a patent application or marketing materials.[60]

No harmonized laws on the protection of trade secrets were in place at the level of the European Union (EU) until 2016. Directive (EU) 2016/943 of the European Parliament and of the Council of 8 June 2016 on the protection of unreported know-how and market information (trade secrets) against their unauthorized acquisition, use, and disclosure of the aforementioned directive was introduced as a response to the unequal protections of trade confidentiality within the EU. Unlike patents, a trade secret does not need to be novel. Its defense does not require registration, as opposed to trademarks or patents. As a result, trade secrets can be secured legally and free of charge for an indefinite period. The protection of sensitive business information by trade secrets may seem especially appealing to small and medium enterprises (hereinafter SMEs) for these purposes. However, to classify this information as a trade secret, it must fulfil the necessity to have a "secret" status.

For information to be protected as a trade secret, it must meet the following requirements:
• It must be a secret

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[58] Nuala Moran, 'The rise of trade secrets in biotechnology' (Science Business, 25 Jun 2008) <https://sciencebusiness.net/news/70454/The-rise-of-trade-secrets-in-biotechnology>accessed 9 January 2020

[59] Tara Nealey, Ronald M. Daignault, and Yu Cai, "Trade Secrets in Life Science and Pharmaceutical Companies" (April 2015) Cold Spring Harbor Perspectives in Medicine, 3

[60] Ibid, 3-4

• It must have commercial value
• It must have been subject to measures aimed at keeping it secret[61]

Trade secrets are secrets that add value to an enterprise. Trade secrets have been in the shadows for many years, a much less well-known form of intellectual property right, but today they gain popularity as an important way of defending other intellectual properties. Any awareness of market interest and relevance— a marketing plan, a new product roadmap, or supplier and customer lists — can qualify as a market secret. And unlike other IP rights, trade secrets can cover a much broader variety of topics and are not restricted to a defined duration of the protection. Trade secrets are not exclusive rights like trademarks or patents and cannot be sanctioned against those who discover the secret independently. Nonetheless, the unauthorized possession or misuse of a trade secret, either in breach of trust or fraud, is actionable and the trade secret proprietor can get compensation and an injunction for such unlawful acts.[62]

Trade secrets are a very important and essential part of the IP portfolios of most companies, and that is why they should be included in any due diligence IP process and should be considered as alternative.[63] It is necessary to discuss in the next chapter the legal aspect of third party rights and patent injunctions as these two correlate with every merger and acquisition transaction as stated before and they also concern the field of biotechnology.

2.7 The right of the third parties

Although representations and warranties must be tailored to specific transactions, the purchaser typically seeks representations and warranties concerning:

•The seller or target company's ownership or right to use the relevant IP, and the sufficiency of the IP assets to operate the business.
•The validity and enforceability of intellectual property
•Relevant IP licenses and other agreements.
•Non-infringement.

[61] European IPR Helpdesk, ‘Fact Sheet Trade secrets: An efficient tool for competitiveness’ (European IPR Helpdesk, 2020) <https://www.iprhelpdesk.eu/sites/default/files/newsdocuments/Fact-Sheet-Trade-Secrets.pdf>accessed 9 January 2020

[62] Prajwal Nirwan, ’Trade secrets: the hidden IP right’ (WIPO Magazine, December 2017) <https://www.wipo.int/wipo_magazine/en/2017/06/article_0006.html>accessed 9 January 2020

[63] Hazel, ‘Trade Secrets in IP Due Diligence During a Merger & Acquisition, Case Study’ (Hazel, 3 November 2016) <http://www.hazeltradesecrets.com/trade-secrets-due-diligence/>accessed 23 April 2020

• Efforts by the seller or the selling company to protect the trade secrets and other sensitive information relevant to that.

Under EU law, third parties can appeal to decisions on the merger, particularly competitors have been successful in this regard. In certain cases, third parties have the right to challenge not only bans but also clearance decisions. The degree to which third parties would be able to contest antitrust decisions and mergers decisions were the topics of debate at the EU level. Some critics have proposed the extension of third-party rights to appeal. Unlike EU law, third parties, for example, have extremely limited rights to challenge decisions on a merger for example under the Swedish legislation.[64]

IP assets are often referred to as the major M&A deal-breaker, the product of potential information imbalances that may occur if the target company's IP assets finish up to be undervalued, incomplete, useless, inconsistent with the acquirer's IP portfolio or other internal tools. Intangible asset evaluation is the main obstacle and pitfall in due diligence. Assessment problems contribute to the anticipated disparity between tangible and intangible properties. It has been shown that tangible asset valuation methods that rely on the analysis of historical data are fairly accurate. Mergers and acquisitions of existing firms, which have operated for a substantial period in a specific division, provide ample evidence for valuations based on past results.[65]

Look at associates, manufacturers, retailers, and more from third parties is important since businesses are just as safe as their respective weakest links, M&A teams need to expand their vigilance to networks of third parties. Many partnerships may be carried forward in acquisition and teams need to make sure this aspect is not ignored. It may necessitate extra time and resources, but it is worth the extra attempt to make sure one isn't buying into the next breached company.[66]

Under accepted contract law principles, parties to an arrangement only establish compliance rights in third parties when such parties are considered intended beneficiaries of the contractual relationship. Third parties who benefit from the contractual relationship only by accident cannot lay claim to enforcement. On the other hand, the standard merger agreement includes an implicit waiver of third-party beneficiary rights, which would tend to bar

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[64] Liana Aleshkina, "Third Party Rights to Appeal Merger Decisions according to EC and Swedish Rules' (2007) Thesis, Uppsala University, 6-7

[65] Ivona Skultetyova, "Intellectual Property in Mergers and Acquisitions: Deal Maker or Deal Breaker? A Substantive Analyses of Due Diligence in IP Driven Mergers and Acquisitions' (2012) Thesis, Tillburg University, 4-6

[66] Nick Gagalis, 'Managing Security Risk in Mergers & Acquisitions' (Bitsight January 2015) <https://www.bitsight.com/blog/managing-security-risk-in-mergers-and-acquisitions>accessed 22 March 2020

compliance rights from the target shareholders, essentially relegating them to an incidental beneficiary status.[67]

2.8 Patent injunctions

While the main players for technology market creation and valuation strategies will come from the private sector, initiatives by governments are also expected to some degree. Such activities differ from one nation to another and from one entity to another. There is general agreement that governments need to ensure that patent systems operate effectively, as well as provide information on patent applications and grants, and develop regulatory mechanisms that promote patent management in public research organizations (hereinafter PROs). Many governments have also taken measures to encourage educational and training programs for groups of specific patent holders e.g. PROs, and small and medium-sized enterprises hereinafter SMEs), and others have started to supplement or support industry efforts to create standards for tracking and valuing IPs.[68]

Unlike copyright, US patent law is not characterized by a series of statutory compulsory licenses. But there is another way to achieve the same effect-decline in granting permanent patent infringement injunctions. In case a permanent injunction is rejected, the court hearing the infringement suit could grant the patent proprietor a fair royalty for the continued use of the patented technology by the infringer. By essence, the combination of failure to issue a permanent injunction and the granting of a fair royalty to the patentee is a mandatory license subject to enforcement by a rate-setting court of the license terms and conditions. Property-rights patent protection was the standard until recently and rate-setting treatment was an aberration. The Federal Circuit, which typically regulates patent law, has followed a common rule that court in the absence of extraordinary circumstances will issue permanent injunctions against patent infringement. However, in its 2006 *eBay v. MercExchange* decision, a fractured Supreme Court rejected this presumptive treatment of patents as property and instead held them as the ordinary permanent injunction.[69]

For example, pharmaceutical patents are especially important and although securing an injunction in Europe in one legal action would be a major advantage, the drawback is that if one loses, the patent is lost in Europe. For

[67] Abbe Dienstag et al., "Target Shareholders Try to Establish Rights After Mergers Fail. Damages for Breach of Agreement Can Be Substantial for Plaintiffs' (March 2003) The New York Law Journal, Mergers and Acquisitions, 1-3

[68] Shigeki Kamiyama, Jerry Sheehan, Catalina Martinez," Valuation and Exploitation of Intellectual Property' (2006) STI Working Paper 2006/5, Statistical Analysis of Science, Technology, and Industry, 40

[69] Daniel A. Crane," Intellectual Liability' (2009) Texas Law Review Volume 88, Number 2, 263

this reason, pharmaceutical companies will probably stick to enforcing their patents in a multiplicity of national court proceedings, at least until some information has been obtained on how the new Pan-European patent court will work in practice.[70]

The differences in the legal structures and the legal problems may have a major effect on the outcome of the case when a patent is litigated in various Member States and their respective judicial bodies. Regarding their approach to procedural aspects, preliminary injunctions, and, most notably, substantive issues such as the existence of the patented invention as set out above; the national courts vary. Therefore, if courts decide if based on their interpretation of the patent, the infringement has taken place, they may make opposing decisions in favor of either the patent proprietor or the alleged infringer, even if the parties to the case are the same as the patented invention. The same covers to other cases where the courts must decide whether or not the patent is legitimate.[71]

A preliminary injunction or permanent injunction shall be issued only when the court decides that the patent holder can suffer irreparable harm. Unless the infringer willingly terminates its infringing conduct, it is arguable that there is then no need for an injunction, due to the compliance of the infringer with the court's rights. However, if the infringer makes statements or shows acts suggesting that he or she is not respecting those rights that the court granted it may thus issue an injunction requiring the infringer to comply with the order of the court to stop the infringement of the patent holder's rights. Injunctions are "equitable" remedies and if the judge determines that irreparable harm is done and the alleged infringer is found to be irresponsible, then an injunction is likely to be issued.[72]

2.9 Summary of the chapter

The next chapter three is the analysis part which will broaden all those relevant issues and problems that exist in a regulatory environment that was discussed in chapter two. The next chapter's goal is to analyze those problematic issues that affect mergers and acquisitions of biotechnological companies and consequently their patents. This in order will give a legal perspective to cross-border transactions between the US and the EU. The

[70] Rowan Freeland, 'Patent injunctions in Europe: the return of the pan-European injunction – or how can you get a decision from one court effective in more than one country?'(Future Science Group, Pharmaceutical Patent Analyst, 2015)<https://www.future-science.com/doi/pdf/10.4155/ppa.15.30>accessed 13 February 2020

[71] Tamar Khuchua,' Different 'Rules of the Game' – Impact of National Court Systems on Patent Litigation in the EU and the Need for New Perspectives' (JIPITEC 10 (2) 2019) <https://www.jipitec.eu/issues/jipitec-10-2-2019/4918>accessed 13 February 2020

[72] James Yang,'Overview of patent-based injunction' (OCPatent Lawyer, 10 March 2017) <https://ocpatentlawyer.com/overview-of-patent-based-injunction/>accessed 13 February 2020

aim of chapter two was to establish all those regulatory principles this thesis is based upon. The writer concluded that relevant regulatory environment is established on general rules of patentability of biotechnology patents and general rules of mergers and acquisitions and it was essential to point out due diligence process in mergers & acquisitions thus before the transaction is completed the valuation of biotechnology patents and the scope of protection of biotechnology patents needed to be investigated. Trade secrets as a part of IP plays an important role nowadays and should be included as biotechnology is an evolving field and the patentability of the inventions is not that clear as in other fields of technology, this in order brings us to the rights of third parties and possible patent injunctions. There are sometimes third parties who seek patent injunctions, so the writer sees it important to include these into the regulatory environment on which this thesis is constructed. The writer sees established regulatory environment most relevant concerning biotechnology and mergers and acquisition transactions. This in order will be backed up by analysing that environment in chapter three.

3 Analysis

In the area of biotechnology, several parties have expressed the view that work would be supported by restricting the security spectrum for genomic DNA molecules. Furthermore, restricting the security of a genomic DNA molecule to a given function will simplify the determination of whether a third party might infringe a patent claim against a genomic DNA molecule with a specific function since each patent would be limited to that function alone. However, most experts believe that these arguments are not convincing. Work would not be encouraged to limit the scope of defense of a genomic DNA molecule to one particular function; it would discourage research because the patentee might feel that the limited scope of protection that might be awarded is not proportionate to the risk and the amount of time and cost associated with beginning the research.[73]

In this relation, reference should also be addressed to a European Parliament resolution of 2001 which reaffirmed an earlier resolution of the year 2000, demanding: “to adopt the measures required to ensure that the human genetic code is freely available for research throughout the world and that medical applications of certain human genes are not impeded through monopolies based on patents.” This position of the European Parliament again was reaffirmed in a resolution in the year 2005 which reads: “Calls on the European Patent Office and the Member States to grant patents on human DNA only in connection with a concrete application and for the scope of the patent to be limited to this concrete application so that other

[73] European Commission,” Final Report of the Expert Group on the development and implications of patent law in the field of biotechnology and genetic engineering’ (May 2016) Final Report, 252

users can use and patent the same DNA sequence for other applications (purpose-bound protection)."[74]

Natural substances are patentable under US patent law if they are isolated in a technical process. Therefore, in terms of patent law, the result is not a mere discovery but a process invention that can grant specific patent rights on the isolated natural substance. Instead of the often-fuzzy boundary between research and invention, case law has generally tended to apply the "technical character" test when answering patentability questions.[75]

Paradoxically, however, ending genetic knowledge privatization could have created more issues than it has solved. A *Myriad* case in the US has been read as banning all-natural goods being patented. It may also be prohibited to patent all products which imitate (or approach duplicate) the materials contained in nature. Complicating the picture, the US Supreme Court also barred patents on diagnostic tests in the case of *Mayo Collaborative Services v Prometheus Laboratories,* depending on similarities between natural phenomena on the field, the relationships constitute principles of nature. As a result, there is growing concern that using the patent method would be difficult to promote the production of a whole range of drugs and intermediate tests which are useful in the creation of new therapeutic approaches. These include proteins, kinases, colony-stimulating factors (for example, growth factors), peptides, antibodies, viruses, and venom.[76]

In the US, The Patent and Trademark Office (the 'Patent Office') reviews patent applications to assess if they meet the conditions of legitimate patenting and must reject patents on inventions that are not valid for the purposes of the subject matter. However, also approved patent applications remain subject to scrutiny, as they can eventually be invalidated by courts for failure to comply with Section 101 of the US Patent Act. The lower courts have since adopted the current eligibility rule, extending the claim of *Myriad* case to invalidate patents on techniques traditionally deemed patentable, including gene-based diagnostic methods. There is growing concern that this shift in jurisprudence has undermined patent protection and that innovators are responding by increasingly preferring to shield their inventions as trade secrets which could have a negative impact on clinical care and on public health.[77]

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[74] Ibid,189

[75] Dr. Peter H. Feindt," Biopatents – A Threat to the Use and Conservation of Agrobiodiversity?' (May 2010) Position Paper of the Advisory Board on Biodiversity and Genetic Resources at the Federal Ministry of Food, Agriculture and Consumer Protection, 12

[76] Rochelle C. Dreyfuss, Jane Nielsen and Dianne Nicol, "Patenting nature—a comparative perspective' (October 2018) Journal of Law and the Biosciences, Volume 5, Issue 3, 552

[77] Christi J. Guerrini et al. "Constraints on gene patent protection fuel secrecy concerns: a qualitative study' (December 2017) Journal of Law and the Biosciences, Volume 4, Issue 3, 553-554

The Defend Trade Secret Act (hereinafter DTSA) was passed by Congress on 11 May 2016 and offers a legal remedy for trade secret misappropriation. To succeed in a DTSA trade secret lawsuit, the claimant must show that (1) they have taken appropriate measures to keep the information secret, (2) the information derives independent economic benefit from not being generally known or readily verifiable, and (3) the information was misappropriated by Defendants.' Misappropriation includes acquisition, disclosure, or the use of a trade secret.[78]

With the introduction of biosimilar biologics, the option of trade secrets versus patent protection has assumed renewed significance in the biotechnology field. From the viewpoint of the originator, secondary patent protection is becoming increasingly important, i.e. patents covering manufacturing processes, formulations, etc. These filings aim to extend the protection of the original composition and process and patent use by covering production methods or commercial formulation. Nevertheless, in favour of keeping some of their critical processes' secrets, many originator firms can circumvent patent protection filing and the disclosure of their corresponding bioprocesses.[79]

Likewise, primary misappropriation conditions under the EU's Trade Secrets Directive are also closely consistent with those laid down in US's legislation expressed above. For example, reverse engineering is specifically allowed by both legislations. These parallels are not shocking because both the EU and the US are parties to TRIPS, which allows countries to safeguard knowledge that fulfils the main features of a trade secret. The continuity in approach provides greater clarity for companies operating in both the US and the EU.[80]

Trade secrets are not as useful in biotechnology as they are not generally applicable to biotechnology companies, because for example most of the drugs produced for clinical use by biotechnology companies need to go through comprehensive disclosure, testing, and validation to be accepted for production and commercial sales. Nevertheless, for trade secret protection, some parts of a complex product or manufacturing process may be suitable.

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[78] Jeff B. Vockrodt et al. "Three ways the DTSA uniquely protects biotech trade secrets in the United States' (September 2019) Healthcare and Life Sciences News Committee Update of the International Bar Association Legal Practice Division, Vol 4 No 1, 12-13

[79] Paul A. Calvo, 'Choosing between patents and trade secrets for protecting biotech products or bio-production processes' (Sterne Kessler Goldstein & Fox, USA 2017) <https://www.omicsonline.org/conference-proceedings/2155-952X.C1.069-004.pdf>accessed 24 February 2020

[80] Osborne Clarke, 'Trade secrets: harmony between the US and Europe?' (Osborne Clarke 15 January 2019) <https://www.osborneclarke.com/insights/trade-secrets-harmony-us-europe/>accessed 24 February 2020

Particularly if subsequent biologics gain regulatory approval, the protection of trade secrets for the initial product's manufacturer will increase.[81]

Patents also improve the businesses they cover in the field of biotechnology. Companies feel motivated to pursue their work, recognizing that they will secure the effects of their efforts. If their proprietary products are a success, these companies are much more likely to have the funds. Biotechnology-patented products have the highest value at the end of their patenting era. By then, these products have gone through clinical trials, obtained regulatory approval, hit the market, and eventually achieved consumer acceptance — all without any rivals. The patented goods produce considerable income, which can then be reinvested into new products for further biotechnological research.[82]

As has been shown in the introduction section of chapter three, there are many difficulties in patenting biotechnology based on legislation and case law, and in this situation it seems that trade secrets would be useful to protect research work, especially with those problematic cases that may arise to gain the patent. It is obvious though that to make a profit even biotechnology companies need patents and, in some cases, as presented in previous chapter patents may be the only asset the company has especially at the stage of growth. That brings us to the next step, which is the compliance process in biotechnology which must be observed because it affects patentability and, in some cases, even the existence of the whole company.

3.1 Compliance procedures when patenting biotechnology patents

EU ABS Regulation means compliance mechanisms for users of the Nagoya Protocol on genetic resources access and equal and equitable income sharing in the Union from their utilization[83] In the form of EU ABS Regulation the level of reasonableness depends to some degree on what constitutes generally agreed procedures under the Nagoya Protocol. It is important to be aware of what other people are doing in similar transactions under this concept. While a user should not rely solely on this principle, doing less than other users as regards similar transactions can be evidence of a lack of reasonable care. If a user is fair in finding, storing, transmitting, and

[81] Eileen Smith et al. "*Biotechnology and Law"* (ABA Publishing, U.S. 2007) 148-149

[82] Online Healthcare MBA, 'Why Patents Matter in Biotech' (School of Business, The George Washington University 2020) <https://healthcaremba.gwu.edu/blog/why-patents-matter-in-biotech/accessed 25 April 2020

[83] European Commission, 'EU ABS Regulation'(European Commission, Environment, 2020)<https://ec.europa.eu/environment/nature/biodiversity/international/abs/legislation_en.htm>accessed 15 May 2020

reviewing information, enough due diligence ensures that it will generally avoid liability. Therefore, the secret to proper due diligence is to get an understanding of the transaction's legal and economic implications and use that information to prepare and carry out a personalized and thorough investigation.[84]

In addition to the regulatory challenges that biotechnology companies face when directing their products through the regulatory approval process and compliance with product-cantered regulations after approval, those participants in the industry are often subject to stringent regulation of their operations. Various compliance mechanisms address a variety of topics that are likely to be applicable to target business, including how its sales force markets its products, production processes, pricing and quality control with respect to specific health care payers, and how it handles patient information. Non-compliance can be expensive not only in terms of penalties but also in terms of limits on the operations of a target company and increased regulatory oversight. Regulatory compliance matters and should be reviewed by a buyer during due diligence. Biotechnology companies and their products face a scope of legal obstacles and regulatory frameworks that are different from those of other sectors. Recognizing the product-specific and enterprise-level criteria mentioned for performing an effective due diligence exercise for a biotechnology acquisition is essential for counsel.[85]

Legal risk management is a mechanism designed to assist companies in defining, quantifying, and managing their legal risk exposures with the overall goal of protecting the company and creating greater value for shareholders and other interested parties. Failure to adequately manage legal risks will place virtually unlimited financial liability on companies and organizations. In other words, risk management can be defined simply as a mechanism that helps protect an organization's bottom line. Because of the large amount of investment and the long turnaround time from innovations to the marketplace, the risk management process in the biotechnology industry is considerably more difficult than in other sectors.[86]

Americans and Europeans disagree on certain topics related to science manipulation, and the European research output framework and other

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[84] European Commission,' What due diligence mean in practice for EU users?' (European Commission, 2020) <https://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetailDoc&id=20819&no=3>accessed 24 February 2020

[85] Reb Wheeler, Mayer Brown LLP, 'Due Diligence in Life Sciences Mergers & Acquisitions' (Lexis Practise Advisor Journal, LexisNexis, November 2015) <https://www.lexisnexis.com/lexis-practice-advisor/the-journal/b/lpa/posts/due-diligence-in-life-scienes-mergers-amp-acquisitions>accessed 24 February 2020

[86] Linda S. Pedding, "*Due Diligence Handbook: Corporate Governance, Risk Management and Business Planning*" (CIMA Publishing, Elsevier, 1st. Edition, Oxford 2009) 221

elements of European regulatory strategies vary substantially from those of the United States. European food control, for example, stretches from farm to table over the entire food production system. The key focus of the US framework is on the final product. The United States perceives it to be primarily a trade issue in international biotech regulation discussions, while the Europeans see trade as just one aspect of a wider set of related issues.[87]

Legal risk management as observed is important to comply with existing rules in the US and the EU when patentability of biotechnological inventions is at stake. This on the other hand brings us to issues in scope and valuation of biotechnology patents, because as it was discussed before in chapter two, even if there is a regulatory environment that regulates patentability in general it still has its problems in two jurisdictions and thus must be observed. Next two subsections will address those issues that are not in a general part of the patent valuation and the scope of biotechnology patents as discussed in chapter two, it will, on the other hand, present those issues that exist and need to be analysed, thus helping the reader to project those problematic parts in the findings section.

3.2 Existing issues in valuation of biotechnology patents

Patent rights valuation is one of the main activities related to the management of intellectual property within an entity or corporation. Indeed, understanding the economic value and significance of intellectual property rights helps in the strategic decisions to be made on the company's assets, but also promotes marketing and intellectual property rights related transactions. There are considerable business situations where valuation is mandatory for example in M&A transactions.[88]

Companies and organizations use various patent valuation methods. These methods are typically divided into two categories: quantitative and qualitative assessment. Whereas the quantitative method relies on empirical and measurable evidence to assess the economic benefit of intellectual property, the qualitative method focuses on the analysis of intellectual property characteristics and possible applications, such as the legal, technological, marketing, or strategic implications of patented technology.

[87] Patrice Lage, Mark Cantley, 'European Responses to Biotechnology: Research, Regulation, and Dialogue' (Issues in Science and Technology, Vol. XVII, No. 4, Summer 2001) <https://issues.org/laget/>accessed 25 April 2020

[88] European IPR Helpdesk, 'Fact Sheet - Intellectual Property Valuation' (European Commission 2013) < http://www.iprhelpdesk.eu/Fact-Sheet-IP-Valuation>accessed 3 March 2020

Qualitative assessment also deals with assessing the risks and opportunities correlated with the company's intellectual property.[89]

Secondly, investors trust both technology assets (whether operationalized by R&D investments or patents) and trademarks. Nevertheless, patents were respected only if their citations weighed them up. Researchers, therefore, have to compensate for their quality to gain useful information from the patents. Likewise, analysts who evaluate businesses should examine the importance of patents instead of merely evaluating them by numbers.[90]

Consideration of the patent's relative value for the whole company is usually a three-step process. Then, the final product will be checked to determine if there may be any separable subcomponents embodying the patented technology. Such a subunit is regarded as the smallest sellable unit. The price of that unit is usually measured or estimated until the smallest sealable unit containing the patented technology is determined. Eventually, due to the proprietary technology, it also measures the portion of the smallest saleable unit value. The exclusion to this is the rule of overall market value. The rule can apply where the patented function for the product as a whole is one of the foundations of customer demand. For such a scenario, the whole company's market value may be the proper value because of the patent, and no further distribution may be needed.[91]

There is no question that additional sources of information outside legal sources will help fill some of these depressions. However, patents provide a unique source of data, particularly given the strong incentives companies to withhold information, and they are one of the most direct ties between legal policies and innovation. It is therefore worth studying carefully how patents can be used more effectively in scientific work and how patent material laws can be updated, even more ambitiously, to encourage research and track patent trends.[92]

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[89] Lagrost, C. Martin D. Dubois C. and Quazzotti S. "Intellectual property valuation: how to approach the selection of an appropriate valuation method' (2010), Journal of Intellectual Capital, Vol. 11 No. 4, 481-503

[90] Philipp Sandner, *The Valuation of Intangible Assets an Exploration of Patent and Trademark Portfolios*, (Dissertation Ludwig-Maximilians-Universität München, Gabler Wiesbaden 2010), 1-3

[91] Krista F. Holt, Brian P. O'Shaughnessy & Thomas B. Herman, "What's It Worth: Principles of Patent Valuation' (2015) ALWD 6th Edition, Landslide, Vol. 8(1), 1-33

[92] Adelman, David, DeAngelis Kathryn L, "Patent metrics:
The mismeasure of innovation in the biotech patent debate' (June 2007), Texas Law Review, Vol. 85, Issue 7, 59-60

3.3 Existing issues in the scope of biotechnology patents

Traditionally, courts have used the extent of the application to restrict a patent that has an overly broad security scope. As part of the declaration, the Federal Circuit is correctly applying the written definition provision to restrict the broad scope of claims in biotechnology patents. The provision for written description is distinct from the enabling requirement, which extends to all statements. Through providing a written description to allow a person having ordinary skill in the art (hereinafter PHOSITA) to evaluate the structural features of the alleged invention, the Federal Circuit (US) is able to limit patents on biotechnology with an overly broad patent scope. Recognizing that specific technologies will become more developed as biotechnology matures in setting the appropriate level of patent scope, giving rise to various problems.[93]

The European Patent Convention allows inventors in more than 25 European countries to receive effective protection for their inventions. It can be concluded that, even though there are still some areas of uncertainty, Europe already has an efficient harmonized tool for granting patents for biotechnological inventions. As for its US counterpart, the delayed launch of the patent system has already put the EU biotechnology industry in a less favourable position and thus the adoption of the Biotech Directive has made the environment in the European Union more biotechnologically friendly and the patent system is no longer an obstacle to the advancement of modern biotechnology but is an aspect of its advancement.[94]

It has been shown a way that patent societies can overcome the core problem of fostering biotechnology innovation without suffocating further work. The arbitration-based plan for compulsory licensing would require patent offices and tribunals to award specific patent protection for inventions. It is a significant inventive move to apply the more lenient enabling disclosure requirement which exists in European patent law on biotechnology. Patents comprising DNA homologs, protein variants, and probable uses of DNA-related subject matter, including patents on research tools, would be the rule, rather than the exception. This would offer initial innovators the requisite incentives to invest in expensive biotechnological work.[95]

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[93] Mull, William C. "Using the written description requirement to limit broad patent scope, allow competition, and encourage innovation in biotechnology' (Summer 2004), Health Matrix: Journal of Law-Medicine, Vol. 14 Issue 2, 434-435

[94] Sasha Bavec and Peter Raspor, "Patenting Biotechnological Inventions' (2002) Food Technology and Biotechnology. 40 (4), 353–359

[95] Schmieder, Sandra, "A Study of Patentability of DNA-Related Inventions with Special Emphasis on the Establishment of an Arbitration Based Compulsory Licensing System '(2004) Santa Clara Computer & High Technology Law Journal, Vol. 21, Issue 1, 163-234

The fact that the court has created technology-specific patent rules for biotechnology is not necessarily a bad thing. As Dan Burk and Mark Lamley suggested elsewhere in their article, different industries experience both innovation and the patent system in very different ways. Biotechnology is no different. Writers don't object, therefore, to the idea that courts treat biotechnology differently. Indeed, writers embrace it. Existing law creates a variety of "policy levers" that permit and may even compel the courts to do so. The concern of the writers is instead that courts do not seem to take the actual characteristics of the industry into account. As a result, the specific biotechnology rules the court has created do not work for the biotechnology industry.[96]

A patent portfolio's monetary advantages include a business monopoly position for the portfolio holder and Intellectual Property Licensing revenues. Non-monetary benefits include competitive benefits, such as first-mover advantages and protection against competing holders of portfolios. The development of a portfolio of patents can also be used to promote investment.[97]

After addressing questions concerning the compliance of the biotech patents and issues in valuation and scope it is essential to raise inquiry of patent portfolios as they concern also biotechnology due to the importance of the patents and difficulties in legal protection against competing holders.

3.4 Patent portfolio in biotechnology

Each asset should be analyzed after gathering knowledge about the intellectual properties, to determine how best to protect it. This determination involves deciding whether the intellectual product is best suited to patent protection or trade secret protection, whether it should be made available to the public domain or whether further development is needed. It also involves deciding whether a patent will be of value when it issues, which is typically approximately 18 to 36 months after it is filed, and if the infringement of that patent would be too difficult to detect.[98]

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[96] Dan L. Burk and Mark A. Lemley, "Biotechnology's Uncertainty Principle', (2003) Advances in Genetics Volume 50, 334

[97] WIPO, 'Entering the national phase early where the international application has not yet been published, Practical Advice' (PCT Newsletter, October 2011, No. 10/2011) <https://www.wipo.int/edocs/pctndocs/en/2011/pct_news_2011_10.pdf>accessed 7 May 2020

[98] Rajiv Patel, 'A Patent Portfolio Development Strategy for Start-Up Companies' (Fenwick West LLP 2020) <https://www.fenwick.com/FenwickDocuments/Patent_Portfolio_Dev.pdf>accessed 10 January 2020

In a patent portfolio acquisition, due diligence generally focuses on:
-The scope and status of the patent portfolio, including:

1) priority and expiration dates,
2) titles and classification codes,
3) prior litigation and other proceedings involving the patent portfolio; and
4) international coverage.

-Property including ownership and maintenance status registered.
-Patentability criteria, such as prior art which may affect validity and enforceability issues.
-Properties and liabilities including security rights, licenses, and responsibilities of standards bodies.

In addition to the patents and patent applications which were inspected and accepted, it is also important to carry out proper due diligence including terminated or abandoned patents and even patent applications, as details of the legal strategy of the seller and therefore the value of his patent portfolio.[99]

Recent court cases may have made it more difficult to obtain patents that provide broad protection in the biotech field. With the exception of innovative inventions, the protection of essential developments by single patents is ineffectual. As a result, patent portfolios provide the only way for biotech companies to secure R&D activities, improve market positions, generate revenue, or create opportunities for cross-licensing or settlement agreements. Ad hoc blocking helps rivals to design at low cost and in a short time around the applicable patents; patent proprietors should avoid this poor form of a portfolio.[100]

The system allows the impact of relative patent portfolio positions on litigation opportunities and terms of settlement to be analyzed. The study shows that "patent peace" is more likely to arise when competition for example on the drug market is low, and the portfolio of each company is either small enough or big enough with a comparable size. If portfolios are small, firms lack offensive litigation capacity whilst when they are sufficiently large, there is a strong potential for counter-litigation.[101]

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[99] Charan Sandhu et al. 'Strategic Patent Acquisitions Evaluating and Acquiring Patent Portfolios' (Practical Law the Journal, Transactions & Business, June 2013) <https://www.weil.com/~/media/files/pdfs/june2013_strategic_patent_acquisitions.pdf>accessed 9 January 2020

[100] Shyh-Jen Wang, "Patent portfolios for biotech inventions' (2013) Nature Biotechnology, Vol. 31 Issue 6, 503

[101] Jay Pil Choi and Heiko Gerlach, "A Theory of Patent Portfolios' (2017) American Economic Journal: Microeconomics 2017, 9(1), 316-31

A portfolio of patents can be said to be important because it spreads the risks over several patents and eliminates reliance on individual patents. When a corporation owns several patents in one technology, it can regulate the markets that depend on that technology and directly influence that. Although getting a broad patent portfolio is often advantageous but there are limits. As the size of the patent portfolio grows, the individual patenting decisions will be less important and will have less effect on the portfolio as a whole, the organization needs to be closely tracking what inventions to file patents on. Therefore, there are many factors that regulate the patent portfolio size e.g. R&D expenditure on patent filings and thus it should be noted that smaller companies should also patent more proportionally because they are investing more in R&D.[102]

As it has been noted that the patent portfolio is important to spread the risks over several patents it is necessary to bear in mind that it concerns also a legal risk management when biotechnology company mergers with another or is acquired by the other. For biotechnology company valuation and scope of patents as well as compliance with patentability rules is essential but due to ethical issues, different approaches to the patentability of biotechnology inventions, and peculiarity of the field itself, and constantly evolving rights in the field, there is no doubt that patents also improve the businesses they cover in the field of biotechnology. There are different economical approaches to the valuation of patents and the scope of them as it was discussed before, but in order to get a legal perspective further analysis is needed. The writer sees it important to discuss evolving rights to valuation and scope of biotech patents, ethical differences, and the impact of the valuation and scope on the cross-border mergers and acquisitions. transactions. But because it is evident that something might go wrong and due to peculiarities of biotechnology liability regimes, differences, and similarities need to be discussed.

3.5 Evolving rights to valuation and the scope of protection of biotechnology patents

High-tech industries provide numerous technological opportunities, but patent uncertainty is very high, and granting patents does not provide absolute protection. Proprietors of intellectual property rights must protect their rights against other competitors' incursions. Intellectual property rights may be questioned in the court of justice or infringed due to financial stakes thus patents become more and more “probabilistic”. Consequently, a patent grants the proprietor permission to seek to exclude third parties. Let us

[102] Surbhi Pandey, ‘Importance of Maintaining A Balanced Patent Portfolio’ (Intepat May 26, 2017) <https://www.intepat.com/blog/patent/importance-patent-portfolio/>accessed 25 April 2020

remember that in the modern sense defined by patent thickets, "probabilistic patents" are recognition of the critical value of patent disputes and patent litigation. In the US, the pattern is greater. MacDonald argues that a strong patenting purpose sometimes is to prevent claims for patent infringement and not to shield inventions.[103]

Numerous studies argue that the patent system is used by companies for various “strategic” motives that aim to protect not particular inventions produced, but the corporation’s technological knowledge base as a whole. Therefore, patenting is seen as a tool to secure the company's future technological space against competitors or to limit its future technological opportunities.[104]

Sivaramjani Thambisetty's article argues that patents are subject to intrinsic and extrinsic uncertainty in newly emerging or nascent technologies which makes them very opaque representations of the underlying inventions. The obscurity is the product of unsettled legal doctrine and scientific jargon, uncertain economic and technical prognosis, and results in significant uncertainty in parameters of ownership. The issue of Mr. Arrow's unrivaled product recognition cannot be addressed by new technology patents, because they do not represent the sharp exclusive right fundamental to Thambesitty's theory. For these cases, patents should be reclassified for terms of their supposed and real intent as credence products. The complexity in assessing the validity of such patents would require credence verifiers, which would further increase the transaction costs of promoting innovation.[105]

From the standpoint of strict intellectual property protection, technology acquisition must be trained to provide, first, the need to protect it and, second, the ability to protect it. As regards the first issue, a patent is not always required, as stated, and there are other mechanisms for enjoying the exclusivity and/or defending technology against competitors. However, the patent is typically important in the sector in question as that is the basis for negotiating product sales or licensing.[106]

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[103] Pascal Corbel, Christian Le Bas, “The evolution of patent functions: New trends, main challenges and implications for firm strategy’ (February 2011) HAL Archive-Ouvertes, 4

[104] Ibid, 5

[105] Sivaramjani Thambisetty,” Patents as Credence Goods’ (2007) Oxford Journal of Legal Studies, Vol. 27, No. 4, 70

[106] Ignasi Costas and Alberto Ouro et al. ‘From research to market: Key issue of technology transfer from public research centres to businesses’ (Biocat and Interbio) <https://4.interreg-sudoe.eu/contenido-dinamico/libreria-ficheros/3D0ED325-A000-2BDC-F737-7534920D685C.pdf>accessed 3 March 2020

3.6 Ethical differences between the European Union and the United States when biotechnology patents are patentable

Ethical relevance of patent rights in patentability practice ensues heated debates between bio-scientific ethical practice activists and critics.[107] Nevertheless, as earlier noted, patents do not offer the right to exploit biotechnology inventions commercially through research or for general purposes.[108]

Although biotechnology advancement advocates argue if it is an unethical practice, the restrictions should be enforced to limit biotechnology research and not the practice itself. The ratification of TRIPS brought about unified characterization of patent laws for WTO member states making these countries adopt varied approaches towards biotechnology patents based on their regional and statutory policies. Notably, being the pioneer in biotechnology research, the US has exerted a greater influence on other countries in their approach towards diversifying in biotechnology research. In the same pursuit, the EU's approach is more reflective of a unified approach influencing its member states through an established and diversified political system.[109]

Within the EU, the EPO provides for patents under strict accordance with its legal framework to ensure ethical practice.[110] As such, the EPC ensures that biotechnology is practiced ethically, and all inventions are exploited within the constraints of Article 53 EPC. Otherwise, any invention contravening the article shall be deemed not patentable. For ethical reasons, Rule 28, Article 53, subsection (a) of the EPC grants that all EU patents be granted for biotechnological inventions except those concerning processes of cloning human DNA, modification of germline genetics related to human DNA, commercialization of human embryos, and all modifications of animal genetic sequences that are likely to result into animal suffering yet

[107] Özdemir Ayşegül, "Patenting Biotechnological Inventions in Europe and the US' (2009) Ankarabar Revıew Vol 1, 43

[108] Ibid, 43

[109] Alice Yuen-Ting Wong and Aurélie Mahalatchimy, "Human stem cells patents- Emerging issues and challenges in Europe, United States, China, and Japan' (2018) The Journal of World Intellectual Property, 12.

[110] Rochelle C. Dreyfuss, Nielsen Jane, and Nicol Dianne, "Patenting nature - a comparative perspective' (October 2018) Journal of Law and the Biosciences, Volume 5, Issue 3 550.

have no medical benefits to other animals or human beings.[111] Furthermore, under the same rule, subsection (b) stipulates clearly that, patents should not be granted for inventions producing plants and animals using exclusive biological processes. [112]

The EPO strictly adheres to the determination made by the ECJ on the correct interpretation of the Biopatent Directive and has since included other such rulings in its working practice to ensure biotechnology inventions follow the required ethical standards.[113] As such, patents in biotechnology in all European states are subject to Biopatent directives which clarify that genes from human bodies, or plants, or animals, remain patentable only if the patent requirements and conditions of practice are justified and fulfilled. Moreover, the EPO involves the members of the public and engages the major stakeholder in biotechnology in open forums to facilitate transparent discussions during decision making on questions relating to patents on living organisms especially plants.[114]

Conversely, to the EU, the most notable feature in US patent laws is that patent laws do not make moral obligations and considerations mandatory while determining whether the invented subject matter should be recommended to patent protection.[115] This, according to Lesser, has allowed for the removal of laws of nature, any phenomenon relative to natural creations, and historical abstracts that the pioneers of biotechnology considered to be cautionary measures for patentability. The US patent law provides that living organisms irrespective of type and gene be patent-eligible. Although, provisions have been made after the court's determinations making patents directed towards or involving human embryos and fetuses not to be considered patentable. [116]

The approach adopted in the US in managing biotechnological innovations is more of a general and liberal approach. On the contrary, the EU sticks to a more moral approach even though critics claim that the EU's approach to

[111] Timo Minssen and Schwartz Robert, "Separating sheep from goats: a European view on the patent eligibility of biomedical diagnostic methods' (2016). Journal of Law and the Biosciences, 367.

[112] Rochelle C. Dreyfuss, Jane Nielsen and Dianne Nicol, "Patenting nature—a comparative perspective' (October 2018) Journal of Law and the Biosciences, Volume 5, Issue 3, 567.

[113] Timo Minssen and Schwartz Robert, "Separating sheep from goats: a European view on the patent eligibility of biomedical diagnostic methods' (2016) Journal of Law and the Biosciences, 368

[114] Alice Yuen-Ting Wong and Aurélie Mahalatchimy, "Human stem cells patents-Emerging issues and challenges in Europe, United States, China, and Japan' (2018) The Journal of World Intellectual Property, 327-348

[115] Ibid, 327-348

[116] Lesser Wilson, "Applying Doctrine of Equivalents Tests to Products of Nature Decisions', (2016) Texas Intellectual Property Law Journal, Vol.24, No, 245-247.

biotechnology is monopolistic and limits its impact on the global economy. According to the USPTO, rendering strict measures to innovators limits investments and jeopardizes the global economy.[117] However, in Lesser's view, it is important to consider issues of establishing the global economy while making life sustainable.[118] Similar observations were made in *Alice* where while examining the *Mayo* and *Myriad cases*, it was ascertained that mere recitations by generic computer software cannot justify the transformation of patent-ineligible abstracts into eligible abstracts of innovation to be included in biotechnology. [119]

3.7 The Impact of valuation and the scope of protection of biotechnology patents on cross-border mergers and acquisition transactions between the European Union and the United States

For over one-half of a century, biotechnology inter-disciplinarians have emerged with multiple solutions promising to address societal challenges while making human health and environmental sustainability in general.[120] Bioscience is thus a dynamic field characterized by transitional and application-oriented research aimed at utilizing inventions to bring about scientific advancement to the market. In the US, for a Bio-scientific invention to be satisfied, it must be specific, credible, useful, and satisfying the utility requirements as established under Rule 35 USC section 101. In the EU, the EPO demands that any Bio-scientific invention whatsoever, shall only be considered susceptible for industrial applications including agriculture is the sequence of the gene alongside its partial sequences are used to invent a protein or sequences of proteins that are specific to that

[117] United States Patent and Trademark Office, *Memorandum - Formulating a Subject Matter Eligibility Rejection and Evaluating the Applicant's Response to a Subject Matter Eligibility Rejection*, (USPTO 2016)

[118] Lesser Wilson, "Applying Doctrine of Equivalents Tests to Products of Nature Decisions' (2016) Texas Intellectual Property Law Journal, Vol.24, Issue 2, 246-279.

[119] Alice Corp. v. CLS Bank Int'l, 573 U.S., 134 S. Ct. 2347 (2014)

[120] Timo Minssen and Schwartz Robert, "Separating sheep from goats: a European view on the patent eligibility of biomedical diagnostic methods' (2016) Journal of Law and the Biosciences, 367

protein, which they are invented from and function to serve the purpose it performs.[121]

Different national laws exempt patenting restrictions for non-commercial activities.[122] However, for cross-border M&As, intellectual property rights and assets are always of value and the desire by an investor to access them is a significant driving force in the market thus influencing any agreements reached in business. There have been some cases aimed at exempting the experimental use of patents from the statutory law for example in the UK under section 60 of the Patent Act.[123] For instance, in Smith, the court determined that private exemptions be applied when the inventive action is for one's personal use however, the court went on to state that no threshold has been reached for commercial purposes.[124]

The USPTO has made several amendments in the follow-up to almost every case against inventions of biotechnology making the trading ground more liberal to operate.[125] To achieve a common goal and attract investors across the borders, it will necessitate the harmonization or combination of functions between key institutions, especially USPTO and EPO to come up with a common regulation. The morality considerations in the EU's approach to patent valuation and protection disadvantages investors. Conversely, the liberal approach by the US leaves the majority of the commentaries in praise of the economic advantages. As a result, many companies criticize the approaches by the EU and find the US as a more attractive market for innovation thereby, impeding potential cross-border M&As.[126]

After deepening the regulatory environment, this thesis is based on, in this analysis section, the writer sees it important to address also liability regimes and existing differences and similarities in the patenting of biotechnology, before the research findings are presented. To begin with, it is stated in Blair Roger's and Cotter Thomas' article the following:

Patent infringement is a strict liability tort in the sense that, prior to the filing of an infringement case, a defendant can be responsible without

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[121] Forsberg Ellen-Merie and Groenendijk Nico, "RRI and Patenting: a Study of European Patent Governance' Nanoethics Vol. 13, 83–101 (2019), 93

[122] Fiona Bor, "Exemptions to Patents Infringement Applied to Biotechnology Research Tools" (2006) E.I.P.R., 6

[123] Ibid, Forsberg Ellen-Merie and Groenendijk Nico, (2019), 91

[124] Smith Kline & French laboratories Ltd. v. Evans Medical ltd. [1989] FSR 561.

[125] Özdemir Ayşegül, "Patenting Biotechnological Inventions in Europe and the US' (2009). Ankarabar Revıew Vol 1, 53.

[126] Parthasarthy Shobita, *Patent Politics: Life Forms, Markets, and the Public Interest in the United States & Europe* (The University of Chicago Press: Chicago 2017), 17.

having had any warning that her conduct was infringing. In other words, innocent infringement is not a defense against a lawsuit for patent infringement and the court will generally order the defendant from infringing even though it was informed only by the filing of the lawsuit.[127] In order not to infringe the patent rights in cross-border transaction differences and similarities in patenting biotechnology should be addressed.

3.8 Liability regimes, differences, and similarities in patenting biotechnology

Patenting guidelines as set out in by the US's, USPTO, and EU's, EPO, regulate and disallow patenting of native genes and protein sequencing.[128] Although in both regimes biotechnological material and sequences are allowed if they are similar or have identical gene and protein sequences to those existing in nature. Additionally, in both regimes' bioscience patenting is allowed and protected based on the circumstances especially for medical propensity. However, the patentability of genes and protein sequences in the US and the EU differ. Therefore, M&A patentees and abstract drafters of patents must consider the liability regimes before considering any cross-border patenting.[129]

In the EU, the 98/44/EC Article 2 of "Biotech Directive" defines a biological material as any form of material that has genetic identity and information enabling its reproduction in biological systems. Once the material composition fulfills the above definition, it is covered under this directive, and as at the end of the year 2019, the "Biotech Directive" covered for nucleotide sequencing, full-length gene reproduction, complementary DNAs and cDNAs, and fragment profiling. Moreover, inventions that are considered new are covered under the "Biotech Directive" as patentable for industrial applications even when they relate to a product containing biological material or a process leading to the production or use of biological material. The directive also provides that a biological material isolated by biotechnological means from its natural habitat be subject to the invention even when the predecessor material still exists in nature. [130]

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[127] Blair Roger D. Cotter Thomas F. "Strict Liability and Its Alternatives in Patent Law' (2002) Berkeley Technology Law Journal, Vol. 17, Issue 2, 800

[128] Minn Mari, "Patenting of genetic research in Europe and the U.S.: A Questionable Future for diagnostic Methods and Personalized Medicines' (2019) Biotechnology law report, Vol. 38, No. 2, 92-155

[129] Keren-Paz Tsachi," Liability regimes, reputation loss and defensive medicine' (2010) Medical Law Review, 1-27

[130] Ibid, 1-27

Until the year 2013, natural biological materials and substances in the US were patented on the condition that they could be isolated sufficiently from their natural state.[131] However, the *Myriad* determination changed the legal inclination about biological material and genetic sequence patenting and since then, the isolation of genes to create cDNAs has been disallowed. [132] However, USPTO has made all possible amendments to its regulations and standards to accommodate as many inventions despite the court's decision in the subsequent cases against the ethical and authenticity of biotechnology use in patenting.[133]

Although it can be argued that *Myriad* determination marked substantial differences between the positions taken by EU and US by law on isolated genetic sequencing of patents, the regimes, and the liabilities are not that dissimilar as the thought of. In both USPTO and EPO rules, artificial DNA constructs and DNA sequences that can be or which are altered by humans remain patentable because they do not exist in the natural environment. These laws protect the patenting of cDNA as they are synthetically manufactured from mRNA molecules and do not occur by natural means or by natural products. Moreover, the methods used in biotechnology were not implicated in the *Myriad* determination implying that in both regimes any innovative methodology of gene manipulation remains patentable similar to new applications concerning the discovery of new gene sequences.[134]

The existing differences and similarities between US and EU regimes regarding liabilities in isolation of genes and protein sequencing using biotechnology must be considered by cross border M&A patentees when formulating patenting strategies or when applying for patenting protection. As observed, there exist scenarios where isolation of biological materials using biotechnology is protected in EU states yet, similar subjects are not patentable and protected in the US. As such, there is a high likelihood of contrasting levels of patenting and patent protection for isolated and synthetically generated sequences obtained from different biological material between the EU and the US, which could substantially affect the

[131] Singh Kshitij, *Patentability of Biotechnology: A Comparative Study with Regard to the USA, European Union, Canada and India* (In: Biotechnology and Intellectual Property Rights. Springer, New Delhi 2015) 33.

[132] USC, *Guidelines for Examination of Patent Applications Under the 35 USC Section 112, "Written Description" Requirement, 66 Fed. Reg. 1099* (USC Jan. 2016) 88

[133] Wong YT Alice and Chan WK Albert, "Myriad and its implications for patent protection of isolated natural products in the United States', Chinese Medicine. 2014. Vol9. No.17. 1-30

[134] Ibid, 1-30

commerciality of new inventions and how their jurisdictions deal with patent portfolios.[135]

3.9 Summary of the chapter

There are many difficulties in patenting biotechnology based on legislation and case law and in this situation, it seems that trade secrets would be useful to protect research work, especially with those problematic cases that may arise to gain the patent. It is obvious though that to make a profit even biotechnology companies need patents and, in some cases, maybe the only asset the company has especially at a stage of growth. The compliance process in biotechnology must be observed because it affects patentability and, in some cases, even the existence of the whole company. Legal risk management is important in order to comply with existing rules in the US and the EU when the patentability of biotechnological inventions is at stake. This on the other hand brings to issues in scope and valuation of biotechnology patents because the regulatory environment regulates patentability in general and thus it still has its problems in two jurisdictions and must be observed.

Patent portfolio is important to spread the risks over several patents it is necessary to bear in mind that it also concerns a legal risk management when biotechnology company mergers with another or is acquired by the other. For biotechnology company valuation and scope of patents as well as compliance with patentability rules is essential but due to ethical issues, different approaches to the patentability of biotechnology inventions, and peculiarity of the field itself, and constantly evolving rights in the field, there is no doubt that patents also improve the businesses they cover in the field of biotechnology. There are different economical approaches to the valuation of patents and the scope of them as it was discussed before, but in order to get a legal perspective further analysis is needed. The writer sees it important to discuss evolving rights to valuation and scope of biotechnology patents, ethical differences, and the impact of the valuation and scope on the cross-border mergers and acquisitions transactions. But because it is evident that something might go wrong and due to peculiarities of biotechnology liability regimes, differences and similarities in patenting biotechnology in cross-border transaction must be discussed.

The approach adopted in the US in managing biotechnological innovations is more of a general and liberal approach. On the contrary, the EU sticks to a more moral approach even though critics claim that the EU's approach to biotechnology is monopolistic and limits its impact on the global economy. The existing differences and similarities between US's and EU's regimes regarding liabilities in isolation of genes and protein sequencing using

[135] Carbonell Pablo, Gök Abbdullah, Shapira Philip, Faulon Jean-Loup, "Mapping the patent landscape of synthetic biology for fine chemical production pathways' (2016) Microbial Biotechnology. Vol. 9, Issue 5, 686

biotechnology must be considered by cross border M&A patentees when formulating patenting strategies or when applying for patenting protection. Conversely, the liberal approach by the US leaves most of the commentaries in praise of the economic advantages. As a result, many companies criticize the approaches by the EU and find the US as a more attractive market for innovation in the field of biotechnology thereby impeding potential cross-border M&A transactions. The aim of the next chapter is to get the reader acquainted with relevant research findings that back up the thesis topic towards a legal perspective on the patentability of the biotechnology patents in M&A transactions, namely to those relevant findings that either facilitate or restrain such transactions and these research findings are tied up to the established regulatory environment and the analysis of that environment.

4 Research findings

Myriad suggestions and recommendations have been made by organizations, councils, and scholars on how granting should be enforced or considered for enforcement of patents in cross-border mergers and acquisition transactions between the EU and the US. For example, the Nuffield council recommends for restrictive granting on DNA sequencing patents but encourages adoption and use of utility guidelines as established by USPTO and as applied in biotechnology inventions by EPO.[136] The council further advises both EPO and USPTO to be keen while observing how the different guidelines that differentiate biotechnology practice in the US from the EU more clearly with the interests of inventors at their full considerations.[137] However, the council cautions that the regulations should not be changed to achieve other goals other than allowing inventors to express their contributions to the scientific business. For example, the Nuffield council recommends the adoption of express sequence tag (hereinafter EST) research tool for DNA sequencing and advice EPO and the WIPO to limit patenting claims for all ESTs as a way of mitigating the use of subsequent patents that contain overlapping DNA and protein sequences.[138]

As observed in sections two and three of this research, there are numerous developments within biotechnological science each day necessitating experimentation to advance on the general understanding of biotechnology. Additionally, national laws exempt bio-scientific experiments for commercialized purposes especially in government facilities and institutions of higher learning which to date are being offered biotechnological

[136] Nuffield Council on Bioethics, *The ethics of patenting DNA*. (Discussion paper 2002), 53

[137] Fiona Bor, "Exemptions to Patents Infringement Applied to Biotechnology Research Tools' (2006) European Intellectual Property Review, E.I.P.R, 7

[138] Nuffield Council on Bioethics, *The ethics of patenting DNA*. (Discussion paper 2002), 59

experimentation licenses with ease. Although there exist various restrictions between the US legal approach and EU legal approaches to the valuation and scope of biotechnological patents, there are various ways through which the two can be harmonized to facilitate transactions of cross border mergers and acquisitions concerning intellectual property rights.

Buyers usually want an assurance that the company of the seller does not infringe, misappropriate or infringe the rights of any other party to the IP and that no other party infringes the rights of the seller. One would also want an assurance that there is no ongoing or potential lawsuits or allegations that may arise post-closure. Buyers typically want to prolong the time over which they may file lawsuits against the vendor for violations of the IP warranties since, in their opinion, the purchase of a technology product is essentially a purchase of the company's IP. Sellers should aim to restrict the extent of these representations and promises by specifying the materiality criteria and content specifications, by restricting representations to infringements of patents issued rather than any other IP rights, and by removing any ambiguous representations, such as the costumer wanting the seller to agree that no other party will dilute the IP of the seller.[139]

4.1 Experimentation

To encourage cross-border M&A transactions between the EU and the US, it is important to designate specific areas of patent constraints, which can be used or expressed via experimental research and exemptions. In the EU for instance, the current law as observed in this research provides for exemptions where bio-scientific practices are aimed for non-commercialized advances. According to Grubb, such an exemption allows an inventor lacking the financial support to claim the right to use a patented tool for research at no charges in cases where there is no acquisition of physical materials from either the licensee or the patentee.[140] It is also important to make amendments to the existing regulation of EPO following the ruling made by the German Supreme Court where the court determined that biotechnological exemptions be accepted in clinical practice trials involving human beings. However, it is important to consider the understatement by the court in the ruling, which specifically restricts such clinical experiments to discoveries of new medical applications and additional information to facilitate the discovery of new treatments.[141]

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[139] Troy Unferman, 'IP representations and warranties in tech M&A, (Del Law Wire, 28 September 2018) <https://www.deallawwire.com/2017/09/28/ip-representations-and-warranties-in-tech-ma/>accessed 10 January 2020

[140] Grubb W. Philip, Patents for Chemicals, Pharmaceuticals and Biotechnology, 4th Edition (2004) Oxford: Oxford Publishers, 58

[141] Sanzo A. Michael, "Patent Eligibility in Biotechnology: A Look under the Hood' (2017) AIPLA Quarterly Journal, Vol.45. No. 1. 1-26

In the US, patent code (35) section 271 restricts commercialization of patents although the courts have to date been applying common law in determining cases involving experimental use of patents.[142] The use of common laws implies that all private purpose exemptions are mainly related to patentees who carry out scientific experiments in private with personally directed intentions and not for commercial objectives. As such, the application of common law does not provide for or cover acts that are carried out by companies. Thereby eliminating direct relevance such codes of regulations for companies dealing with biotechnological experimental research. By allowing private patenting experimentations, it thereby implies that privately undertaken acts of experimentation by companies for the purposes of the invention and not commercial interests would be exempted from patenting. Although, such exemptions for companies' experimentations may support the exemptions adopted by community patent convention under article 31 section b (Art. 31 b of the CPC). As observed through this study, several countries in the EU have transposed the (CPC Art. 31 b) into their patent laws. With both EU and US allowing for the adoption of exemptions based on the (CPC Art. 31 b), although under different stipulations and interpretations, cross-border M&A transactions can be facilitated for companies interested in non-commercialized biotechnological inventions.[143]

From the above suggestions about experimental exemptions, it can be observed that one difficulty emerges if the exemptions cover trials meant to secure protection for patents. The main problem leading to the difficulty is whether to consider the exemptions as realistic researches or not especially when the purpose of experimenting was for biotechnological invention. However, given the ruling made in the *Monsanto* case, an experimental act cannot be justified to be an experiment when the main goal is to verify or justify the already existing findings and knowledge.[144] This implies that according to the law, for every practice to be considered experimental whether done in private or not is directed towards the provision of new information. By merging different amendments of laws and statutes, inventions can be made and experiments without limits by different biotechnological companies on how to improve on the inventions on a broader scope.[145]

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[142] United States Patent and Trademark Office, "Patent Eligible Subject Matter: Report on Views and Recommendations from the Public' (USPTO July 2017), 18.

[143] Forsberg Ellen-Marie, Hanssen A Braarud, Nielsen H Marie, Olesen Ingrid, "Patent ethics: the misalignment of views between the patent system and the wider society' (2017) Sci. Eng. Ethics. Vol. 24, 1559-1561

[144] Ibid, 1559-1561

[145] Ibid, 1559-1562

4.2 Diagnostic Tools

As observed earlier, there are different ways through which patents in biotechnological inventions can be protected. One key area is by use of diagnostic tools especially when there is a need to ascertain the relationship between a given type of gene and its vulnerability to a certain disease. Based on a gene to disease relationship, the emerging concern for companies would be to identify the mutations that the gene undergoes through comparisons between a normal gene and the sick gene from the patient. As such if a company can identify the mutations in the infected or altered gene because of the disease, the company shall have fulfilled the utility requirements and thus subject to receive patent protection. Moreover, since there is a wide scope of diagnostic tools used in patenting, once a given tool has successfully identified the gene mutations associated to a given disease, the cover for the invention protects the tools as well and any other screenings that could identify more mutations in future diagnosis or inventions.[146]

However, since patents provide cover for protein sequencing, it is not possible to screen protein sequencing without an approved license. As such, a company that has legally obtained a screening license for using a given tool can expand the application of the tools to encompass other screening services including the screening of protein sequences because the tool has a patent cover for screening gene mutations. It can, therefore, be suggested that applications of requirements for granting product patents, in this case, for the diagnostic tool, provide the owner company with rights over the gene sequence or the DNA sequence for use in other diagnostic tests. The goal of such a move is to provide biotechnological companies with the product patents of DNA sequencing which can be used in diagnostic tests with exceptional characters.[147]

According to the Nuffield council, it is very much possible for USPTO to revise their patent regulations as well as advise the US government to initiate amendments to the common law to allow for merging of inventions which in turn shall facilitate M&A transactions between the EU and US biotechnological companies. [148]

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[146] Stazi Paolo, “European Union: comment on "International Stem Cell”: the EU Court of Justice revisits the patentability of processes for the production of human stem cells.’ (2015) International Review of Intellectual Property and Competition Law, Vol. 46. No.6, 744.

[147] Nuffield Council on Bioethics, *The ethics of patenting DNA*. (Discussion paper 2002), 3-87

[148] Ibid, 3-87

4.3 Existing difficulties in patentability of biotechnology patents in the European Union and the United States

Contrary to the statute of providing patents in the United States, in Europe, the European Patent Convention does not give detailed information regarding the constituents of things that can be assigned to a patent. This convention helps us understand some of the things that may not be considered as part of an innovative project. In particular, a patentable invention should be structured in such a way that its purpose is to provide a solution to a technical issue. It should also have technical characteristics as well as solve a problem which is specified in a technological field.[149]

In the past years, various debates have been conducted regarding whether it is necessary to provide patents to certain inventions in the fields of proteomics and genomics. In the United States, the Patent Act holds that highly essential projects, regardless of whether they are machines or chemicals, should be patented. In the past years, however, some courts of the law argued that it was sensible to exclude some inventions from being patented. For instance, inventions such as mathematical algorithms, some chemical products as well as various medical techniques could be eliminated from the list of inventions that needed to be protected. These views were, nonetheless, later dismissed by the Court of Appeals across the country.
It is crucial to note that all the applications for biotech patents in the United States must meet certain requirements. They should be highly innovative, not easily predictable, and original. It is only trivial that one cannot be provided a patent for a project that was previously known at the time of submission to the office of patents. Furthermore, acquiring a patent is also dependent on the need for that project or generally its usefulness within modern society.[150]

One example of patentability barriers is the issue of whether patent protection can be secured for new methods of disease treatment – this is important because the production of new disease therapies is a key priority for the biotech and healthcare sector. Another example of these obstacles is whether patent rights for disease diagnosis methods and personalized medicine can be obtained. Again, this is important as other primary biotech and healthcare sector objectives are early-stage disease identification,

[149] Will Kenton, 'Utility Patent' (Investopedia, June 25, 2019) <https://www.investopedia.com/terms/u/utility-patent.asp>accessed 19 February 2020

[150] Alan C. Marco et. Gordon Rausser. " The Role of Patent Rights in Mergers: Consolidation in Plant Biotechnology' (2008) American Journal of Agricultural Economics 90(1), 149

accurate distinction between conditions with similar symptoms but different underlying causes, and personalization of medication to ensure that a patient receives the right treatment.[151]

It is required that biological inventions be supported by a massive amount of experimental data which is highly extensive. This helps prove that innovation is functional as postulated by the innovator. [152]

Bioscience has become a well-established area of research and patents are issued on an ongoing basis, so it is proposed that institutional and legal policy reforms are needed to ensure the judicial demarcation between human genetics, bioscience, and important natural resources. Legal reform was deemed of immediate relevance as the current lack of legal certainty and predictability on where to draw the line between patentable and non-patentable biotechnological innovations raises issues related to access to basic knowledge, DNA and gene-based inventions and individual property rights. Advances of genetic engineering and gene sequencing in the area of biotechnology have resulted in a wider range of potentially patentable subjects, and it can be argued that the dividing line between an innovation and a discovery has also become increasingly difficult to determine.[153]

4.4 Patenting nature, a perspective between the European Union and the United States

However, despite recent judicial rulings, there is still a lack of specific guidance from US legislation and the EU Biotechnology Directive is not doing any better. There are still plenty of doubtful inventions to come through today, and more likely to come in the future, in the US, the EU, and elsewhere. There is still no definitive response on the correct scope of protection for bioproducts, and there is no easy way to address the problem of the need for greater access to the patent system. It is a rapidly evolving area, and the law in question itself continues to change, adapting to technological developments, ethical concerns, and economic pressures. Genetic patents and the scope of protection within and outside the EU and the US will continue to exist as a questionable topic, both from a moral and scientific standpoint and from a forward-looking economic perspective. It is

[151] Isobel Finnie, 'Patenting problems specific to the biotech and healthcare sector' (LSX May 2017) <https://www.lsxleaders.com/blog/patenting-problems-specific-to-the-biotech-and-healthcare-sector>accessed26 April 2020

[152] Ibid,

[153] Aida Zellama, "Owning Life – IPR in Biomaterials. The Legal Challenge to the Patent Eligibility of Human DNA' (2015) Master's Thesis, Jönköping Universtiy, 13-15

evident that many researchers, courts, and companies claim there is an economic justification for granting genetic material patents.[154]

Two patent systems explicitly follow several common rules. In both systems, an invention must be patentable in some form of innovation, a novelty that is "tested" against the prior art. In both systems, an innovation must require an inventive step (for the US this is the legislative non-obviousness test, for the EU the inventive step requirement imposed by Art. 56 EPC). In both cases, innovations must be subject to implementation by industry. In both cases, a 20-year patent is issued. In the US, the effects of patent infringement are delineated in federal patent law and extend to the states, whereas in Europe, the national laws of each Member State tackle these consequences, etc. (EPC Art.64). One of the main discrepancies concerns the definition of prior art (state of the art for Europe). Under US law, prior art means prior art only in the US: international understanding and the use of the alleged invention does not mean that prior art fails the patent application (section 102a of the Patent Act: an invention will be expected if it is recognized in the US). This is sharply in contrast to the European rule, under which foreign prior knowledge counts and defeats an application for a patent (Art. 53 paras 2.)[155]

The only argument that can be finally concluded in a discussion of ethical and moral dilemmas is whether there has been adequate human intervention to establish an entity that is distinct and separate from the one that has existed before. Under almost all patent regimes, directly or indirectly associated with or deriving material from the TRIPS Agreement or their municipal law, bio-patents are permissible. The statement that the subject matter is "product of nature" has been rejected as outdated and obsolete, and therefore indefensible. Nevertheless, when entering this domain of patent laws, circumspection must be practiced. Often an excessive award of "useful patents" to living organisms and associated structures can spark ethical discord.[156]

4.5 Flexibility of subject matter

The consequence of the product of nature doctrine has been successfully used to reject patents on living beings and life. Previous attempts were made to patent living beings, but on the basis of the law, patent offices and courts were reluctant to consider living beings as patentable subject matter. In the

[154] Nicholas C. Whitley," An examination of the United States and European Union patent systems with respect to genetic material' (2015) Arizona Journal of International & Comparative Law Vol. 32, No. 2, 495

[155] Richard Spinello and Maria Bottis, *A defence of Intellectual Property Rights,* (Edward Elgar, Cheltenham, UK, 2009), 67

[156] Ameen Jauhar and Swaiti Narnaulia, "Patenting Life the American, European and Indian Way' (January 2010) Journal of Intellectual Property Rights, Volume 15, 58

case *Ex parte Latimer*, it was viewed that natural products, biological products, and living beings were not patentable. In, *American Fruit Growers* again the fact that classical patent laws do not consider natural, biological products and living beings as the patentable subject matter were reiterated. Further, in *Fun brothers seed co Vs Kalo Inoculant Co*, the claim was a mixed culture of different strains of microorganism, each of which was useful to inoculate the roots of different species of leguminous plants, assisting the plants in nitrogen fixation. Different species of root nodule bacteria have existed in nature. Applicants made efforts to combine the different bacterial species in a mixed culture suitable for inoculating a variety of crops. Both attempts failed because the various species together hindered each other's effectiveness.[157]

Article 27 under section 5 (patents) of Part II of the TRIPS Agreement, entitled "Patentable Subject Matter", provides flexibility concerning the patentable subject matter and patentability requirements, as well as for the possible exclusions from the patentable subject matter. Article 27.1, first sentence, stipulates that "patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application." It, therefore, makes this mandatory for Members to grant patents irrespective of whether the invention is a product or a process, and regardless of the technical field. [158]

Members cannot exclude entire groups of technical innovations from patent protection. Article 27.2 further states that “patents shall be eligible and patent rights shall be enjoyed without discrimination as to the place of invention, the technology sector and whether goods are manufactured or produced locally.” Thus, Members are not allowed to impose conditions of grant and enjoyment of patent rights which amount to discriminating one field of technology against others. [159]

Aside from statutory tailoring measures — flexibility by design — there are nuances in how patent law is applied to different inventions and organizations that cannot be excluded. For common law countries, where the law is theoretically painted with broad brush strokes and the details are filled in by the courts, these differences are easiest to explain. This helps legal evolution (often slow) to cope with unpredictable circumstances by derivations from old concepts to new laws. In fact, courts exercise the same role to varying degrees in countries with civil law. However, where a common statute is supposed to work identically in various contexts, the

[157] Srenivasulu N.S, *Law Relating to Intellectual Property*, (Partridge India), 335-336

[158] Hiroko Yamane, *Interpreting TRIPS: Globalisation of Intellectual Property Rights and Access to Medicines*, (Hart Publishing, Oxford 2010), 419-420

[159] Ibid, 419-421

courts will often come to different conclusions on factual or mixed facts and law issues.[160]

4.6 Importance of due diligence process in biotechnology

While some elements of legal due diligence would be more or less the same in such deals as with any M&A contract, some areas of due diligence tend to take on greater significance in a biotechnology acquisition and thus these problems would include product-specific issues such as intellectual property, marketing authorisations, post-marketing obligations, and licensing and contractual relationships; and secondly, they will also include business-level issues such as enforcement and supply chain aspects.[161]

Regulation 511/2014 implements in the EU those international rules (contained in the Nagoya Protocol) which govern user compliance – i.e., what users of genetic resources have to do in order to comply with the rules on access and benefit-sharing (ABS) established by the countries providing genetic resources.The Nagoya Protocol also includes provisions on access mechanisms – but they do not come under the framework of the EU ABS Regulation and are thus not discussed in this guideline paper. [162]

The standard of reasonableness in the context of ABS depends to some extent on what constitutes commonly accepted ABS practices under the Nagoya Protocol. Under this interpretation, it is important to be aware of what other people are doing in similar transactions. While a user should not rely on this standard exclusively, doing less than other users with respect to similar transactions may be evidence of lack of a reasonable care.[163]

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[160] Sarah R. Wasserman Rajec, "Evaluating Flexibility in International Patent Law' (2013) Hastings Law journal, Vol. 65:153, 174

[161] Reb Wheeler, 'Due Diligence in Life Sciences Mergers & Acquisitions' (Lexis Practice Advisor Journal, November 2015) < https://www.lexisnexis.com/lexis-practice-advisor/the-journal/b/lpa/posts/due-diligence-in-life-scienes-mergers-amp-acquisitions>accessed 26 April 2020

[162] European Parliament, 'Guidance on the EU ABS Regulation implementing the Nagoya Protocol' (European Parliament 2016) <https://www.naturvardsverket.se/upload/stod-i-miljoarbetet/vagledning/genetiskaresurser/scope-guidance-march2016.pdf>accessed 26 April 2020

[163] European Commission,' What due diligence mean in practice for EU users?' (EC, ec.europa.eu, 2020) <https://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetailDoc&id=20819&no=3>accessed 24 February 2020

Despite the fact a user should not be entirely dependent on this particular principle, it is key to note that engaging in activities that are considerably less than those of other people, in this case, may be regarded as a failure to act reasonably. A user who is keen on matters to do with searching for, analysing, transferring, and making appropriate reviews of information implies that the user will highly likely evade any potential liabilities as provided by due diligence. In this case, therefore, proper due diligence can only be achieved by gaining a thorough comprehension of both the legal and economic consequences of the transaction. The user is then supposed to apply that information to conduct a thorough investigation.[164]

The regulatory challenges experienced by biotech companies during the regulatory process of steering their projects for approval are not the only problems they face. These companies are also subjected to a rigorous regulation of their business operations. Many enforcement systems do reflect upon various issues that are highly likely relevant to a target corporation. These issues include the ways in which the company sells its products, its methods of production, overall prices of goods and services as well as product and service quality. Failure to comply with these rules can be very costly to the company in question due to penalization as well as being limited to business operations. [165] This is why a potential buyer needs to review regulatory compliance issues during the process of due diligence.

It is only accurate to say that due diligence is a useful concept as it provides crucial information for both seller and buyer in the Mergers and Acquisitions deal. The primary determining factors of the contract include appraisal and intellectual property. The difficulty ensuring the IP's due diligence comes about as a result of the complications which are experienced by the valuation process of the IP.[166]

4.7 The distinct features of issuing patents in the European Union and the United States

Even though several court sessions in the United States and Europe have been undertaken regarding the subject matter stated above, it remains unclear what guidelines ought to be followed. There are numerous

[164] Ibid,

[165] Reb Wheeler, Mayer Brown LLP, 'Due Diligence in Life Sciences Mergers & Acquisitions' (Lexis Practise Advisor Journal, LexisNexis, November 2015) <https://www.lexisnexis.com/lexis-practice-advisor/the-journal/b/lpa/posts/due-diligence-in-life-scienes-mergers-amp-acquisitions>accessed 24 February 2020

[166] Osborne Clarke, 'Trade secrets: harmony between the US and Europe?' (Osborne Clarke 15 January 2019) <https://www.osborneclarke.com/insights/trade-secrets-harmony-us-europe/>accessed 24 February 2020

inventions which are suspicious in the EU and the US. Furthermore, there is a lack of clarity on matters regarding the safeguarding of biotech products. In addition to that, it is not clear whether the issue of allowing increased access within a system providing patents can be fully resolved. These issues are undergoing a great evolution as do laws associated with IP rights. The constant evolution is due to the increase in technological advancement, ethical issues, and economic burdens. The provision of biotech patents in the United States as well as extending the protection of biotech companies is bound to remain a massive controversy. This argument is especially true from an ethical, economic, and scientific point of view. However, many law scholars, as well as courts and business entities, are in favor of the provision of patents to biotech companies.[167]

The patent systems of the two parties, the EU and the US follow a variety of common regulations. For instance, they both follow that an invention can only be patented if it is considered original. Additionally, both systems acknowledge that innovations are supposed to have an inventive step and be subjected to being executed by their respective industries. Both the EU and the US also allow for the issuing of a 20-year patent.[168]

Contrastingly, the United States and the European Union have distinct features when it comes to the issuing of patents to biotechnological companies. For instance, the United States patent system holds that the implications of patent restrictions should be outlined in the federal patent law and it applies to other states within the country. The European Union, on the other hand, holds that the national laws of individual nation-states should confront these implications themselves.[169]

This argument is true even if the other company was, in fact, the first to get their hands on the invention. This implies that the most vital thing that is highly significant is the date of filing the application.[170] In the United States, a distinct technique was used for a long time. In a situation where two applicants have come up with a similar invention, the patent system was accountable in establishing the company that first invented the project. This

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[167] John Raidt, 'Patents and Biotechnology' (U.S Chamber of Commerce Foundation 2020) <https://www.uschamberfoundation.org/sites/default/files/article/foundation/RaidtPaper.pdf >accessed>7 January 2020

[168] Richard Binns &Bryan Driscoll," The European Directive on the legal protection of biotechnological inventions' (1998) Expert Opinion on Therapeutic Patents Volume 8, 1998 – Issue 12, 1723-1725

[169] European Commission," Final Report of the Expert Group on the development and implications of patent law in the field of biotechnology and genetic engineering' (May 2016) Final Report, 252

[170] Dr. Peter H. Feindt," Biopatents – A Threat to the Use and Conservation of Agrobiodiversity?' (May 2010) Position Paper of the Advisory Board on Biodiversity and Genetic Resources at the Federal Ministry of Food, Agriculture and Consumer Protection, 12

particular process was made possible by evaluating the company laboratory logbooks and determining the exact dates for which the companies came up with their prototypes. If later on, the company which invented the project first is found, the patent received by the other party is revoked and awarded to the later.[171]

When it comes to the grace period, the conditions are different for both the EU and the US. In Europe, for instance, a patent is rejected if the invention was known previously before filing the application of a patent. A patent that is publicly available is one whereby the invention has been sold in the market or has been communicated about by various individuals or even published. The United States, on the other hand, has a grace period of one year. This implies that the inventor has the freedom of publishing his invention without the risk of his patent being revoked. The grace period is nonetheless limited to publications and these publications should have been made by the inventor himself or another individual with whom the inventor shared the information regarding the invention. The involvement of a third party, in this case, will imply a lack of originality of the invention. Additionally, the patent system of the United States requires that the inventor takes into consideration appropriate ethical practices in the application of the patent. Through this, the company is in no position to keep paramount information as to its secrets. Failure to engage in transparent practices thereby imply that the patent could be revoked. On the contrary, the European Union patent system lacks this provision. It holds that the company which has been awarded the patent should only include at least one way with which the invention can be practiced.[172]

Another significant aspect is whereby the rights are conferred by a granted patent. For instance, in the US, a patent is known as a property right whose enforceability applies across the whole country. The patent safeguards the company holding the patent against manufacturing, selling, or using the same invention as the patent holder. Contrastingly, the European Patent Convention is a treaty that considers a patent to be functional in 27 counties only.[173]

Furthermore, the opposition of an awarded patent by another company is different in both the US and the EU. In Europe, for instance, any individual corporation can file an opposition against the patent holder. This opposition should state the reasons as to why the patent should be revoked by providing sufficient evidence. The opponent and the patent holder can then discuss this situation after which the EPO arrives at a conclusion based on the

[171] Ibid, 12

[172] Rochelle C. Dreyfuss, Jane Nielsen and Dianne Nicol, "Patenting nature—a comparative perspective' (October 2018) Journal of Law and the Biosciences, Volume 5, Issue 3, 552

[173] Christi J. Guerrini et al. "Constraints on gene patent protection fuel secrecy concerns: a qualitative study' (December 2017) Journal of Law and the Biosciences, Volume 4, Issue 3, 553-554

effects brought forth by both parties. The United States, on the other hand, has a process for conducting post evaluation of the awarded patent. This process is entirely different from the opposition. Re-examination involves a process whereby any company can present the reasons against the awarding of the patent to the patent holder. The USPTO is in charge of settling this particular dispute. The difference with the EU comes in whereby the patent holder alone discusses the underlying issues with the USPTO intending to analyse reasons behind the validity of the patent. In this case, the opponent is not involved in the entire proceedings.[174]

The inventive step is also a crucial factor that differs in both the EU and the United States. In the European Union, the patent law states that an invention should be characterized by a great deal of novelty and should entail an inventive step. This requirement is indeed similar to that of the United States. The difference, however, is that the inventive step can be deemed sufficient where the invention is considered as non-obvious. This statement implies that the invention should be able to provide a solution to a technical problem but should not be predictable. The United States, on the other hand, is very stringent on the fact that the invention should be entirely original in order to validate the inventive step and thus patent application.[175]

The European Patent System holds that all patents alongside their applications are supposed to have what is known as the "two-part claims". This implies that the invention should have a claim which lists patent characteristics with the clause "characterized in that". In the case where a single-part claim application has been made, the most important thing that should be addressed first is that the examiner recognizes the nearest prior art. This is the document that has similar characteristics to those of the invention. It then has the requirement that the claim should be delineated. Contrastingly, the patent applications of the United States are mostly characterized by one-part claims.[176]

4.8 Summary of the chapter

Although there exist various restrictions between the US and the EU legal approaches to the valuation and scope of biotechnological patents, there are various ways through which the two can be harmonized to facilitate

[174] Rajiv Patel, 'A Patent Portfolio Development Strategy for Start-Up Companies' (Fenwick West LLP 2020) <https://www.fenwick.com/FenwickDocuments/Patent_Portfolio_Dev.pdf>accessed 10 January 2020

[175] Nuala Moran, 'The rise of trade secrets in biotechnology' (Science Business 25 Jun 2008) <https://sciencebusiness.net/news/70454/The-rise-of-trade-secrets-in-biotechnology>accessed 9 January 2020

[176] Tara Nealey, Ronald M. Daignault, and Yu Cai, "Trade Secrets in Life Science and Pharmaceutical Companies" (April 2015) Cold Spring Harbor Perspectives in Medicine, 3

transactions of cross border mergers and acquisitions concerning intellectual property rights. By merging different amendments of laws and statutes, inventions and experiments can be made without limits by different biotechnological companies on how to improve on the inventions on a broader scope. It is only accurate to say that due diligence is a useful concept as it provides crucial information for both seller and buyer in the mergers and acquisitions deal. The primary determining factors of the contract include appraisal and intellectual property. The difficulty ensuring the IP's due diligence comes about as a result of the complications which are experienced by the valuation process and scope of the IP. Although some elements of the legal due diligence process in biotechnology would be more or less the same as with any other M&A contract, it is important to underline that there are certain areas of due diligence in a biotechnology merger and acquisition that takes greater importance.

The regulatory challenges experienced by biotech companies during the regulatory process of guiding their projects for approval are not the only problems they face. These companies are also subjected to a rigorous regulation of their business operations. Contrastingly, the United States and the European Union have distinct features when it comes to the issuing of patents to biotechnological companies.

In the case of for example a genomic DNA molecule with a restricted scope of protection for a specific purpose, research might be discouraged because the patentee may consider that the amount of protection given is not commensurate with the risk and the amount of time and expense associated with starting research. The only argument that can be finally concluded in a discussion of ethical and moral dilemmas is whether there has been adequate human intervention to establish an entity that is distinct and separate from the one that has existed before.

Recent EU and US court decisions may have made it harder to secure patents that provide specific protection in the biotech sector. The defence of important innovations by single patents is unsuccessful, with the exception of revolutionary inventions. Although portfolios are small, companies lack aggressive litigation ability whilst there is a strong potential for counter-litigation when they are large enough.

Furthermore, there is no definitive response as to the appropriate scope of protection for bioproducts, and there is no easy way of approaching the question of the need for greater access within the patent system. Two patent systems explicitly follow several common rules. In both systems, an invention must be patentable in some form of innovation, a novelty that is "tested", an innovation must require an inventive step. In both cases, innovations must be subject to implementation by industry. It is required that biological inventions be supported by a massive amount of experimental data which is highly extensive. This helps to prove that innovation is functional as postulated by the innovator. Moreover, when a single law is meant to function in different forums identically, courts can

always come to different conclusions on factual or mixed fact and law issues.

There exist numerous rules and regulations that guide companies in their quest to acquire intellectual property rights in biotechnology. Companies should adhere to such regulations as due diligence to avoid the revoking of their patents. For instance, the United States patent system holds that the implications of patent restrictions should be outlined in the federal patent law and it applies to other states within the country. The European Union, on the other hand, holds that the national laws of individual nation-states should confront these implications themselves.

5 Conclusion

Historically, patents have played a major role in life science innovations and other biotechnological industrial practices especially gene regenerations and protein sequencing. Research indicates that, for some countries including the US, patents are the major components controlling innovations in the big pharma industry, which is one of the major dependants for biotechnology inventions. However, one of the major impediments in biotechnology inventions is the lack of intellectual property rights that are given with ease to federal institutions in charge of research, and institutions of higher learning. For other companies, patents are not granted but issued by means of licensing agreements that have terms of specifications that a company has to fulfill to maintain the license of using the intellectual property. In an industrial environment where IPs are vital in fulfilling business interests, companies possessing poor patent enforceability are exposed to myriad challenges. This is so because the portfolios in their possession are not covered, then their IP can easily be spilled over to other companies, which may borrow their ideologies and technology for their research and even develop commercialized products. Companies, especially in biotechnology that possess high enforceability, are at a greater danger of alienating other firms and impeding them from using their intellectual assets because high enforceability can easily intensify uneven trading ground for common mergers and uncommon mergers. It is possible that companies having mutually similar blocking technologies can converge and reduce fragmentation in the market necessitating the need for regulations in the highly innovative sectors that are perceived to be open for inventions without limits as a way of providing solutions to existing problems.

Widening the spectrum of use of IP presents new problems in patent valuation, which are more important when used by patent holders as funding instruments and as investment assets by financial companies and venture capitalists. For financial analysts, intellectual properties are fundamental during the valuation of a company and act as an indicator of the company’s technological abilities. Until recently, numerous standardizations have been fostered for various intellectual property assets with varied approaches being adopted based on location and formulation of legislation. For

inventors, practitioners, inventing companies, and potential investors, the regulations have binding forces that are contradictory to content thus infringing on innovation advancements. Regional regulations are homogeneous in nature depending on the content and interests of the market to keep to itself the acquired knowledge and content. However, as noted above, the main challenge in intellectual property business changes do not reside in the lack of accepted approaches, content, or accuracy, but lies in the restricted distribution of the knowledge that they exist and the lack of trust in the results. As such, the biotechnological companies and inventions are majorly restricted limiting conventional methods from providing solutions to existing problems on either ethical grounds or fear of lack of specifications.

As such, this study investigated existing differences between the US and EU's patentability procedures and of valuing and determining biotechnology patents in cross-border M&A transactions. As observed in the study, the US antitrust policy, contrary to the European competition model, demands that for sustainable business, there ought to be a certain minimum level of competition although the degree of the competition must be protected by an antitrust policy. As such, US policy formulation and regulation organs believe that a vibrantly competitive market has immediate success compared to a restricted market. Conversely, the EU believes in a monopolistic approach to business as a way of conservation and refrain from the unnecessary competition that devalues the existing technologies and products. As such, the EPC does not describe what is comprised of patents but only highlights what inventors should not consider for invention. This raises the question of whether the emerging discoveries in the fields of genomics and proteomics can be categorized within the range that is protected by patent systems. The USPTO after several amendments to its Patent Act have included within range of patent protection the processes leading to inventions, machines involved, and the manufacturing and processing compositions of the invention. As a result, biotechnology patents must contain properties of novelty, innovativeness, and eliminate obviousness to meet the experimental prerequisites aimed at developing an actual new idea.

There is a need for heterogeneity in the innovation and inventive fields especially with the advent of technology, which has provided numerous opportunities for both innovators and investors in life science. However, from a legal perspective especially in the EU, allowing heterogeneity in mergers and acquisition practices will make it impossible to control or prevent market systems that have the ability to strengthen their positions into dominant monopolies that imped other potential innovators. As such, both the buyer and the seller are protected by principle determinants that are vested in intellectual property rights for product evaluation. Nevertheless, some of the available IP rights are not registered yet due diligence necessitates that the rights are provided before registration of licenses to enable informed decision-making. Consequently, warranties are used

because there are no other means of validating the patents, authenticity, and status of unregistered intellectual property rights.

Patents represent a claim that relates to interests of the public in inventions through advocacies that encourage information sharing, increased creativity in R&D, and a more practical approach in the application of new discoveries of knowledge. Through methodologies like direct cash flow prognosis, relief-from-royalty, incremental cash flow, and multi-period excess earnings intangible assets can be evaluated on approach to income criteria all of which present a different yet accurate way of isolating actual cash flows for an intangible asset. Innovations and inventions are discrete in nature and as a result, patent values are based on the advantages and benefits that the winner of a patent battle is expected of. This implies that when companies acquire patents, they acquire all of the associated rights including competitor exclusion rights, which limit competitors from exploiting or putting into practice the underlying inventions. It also implies that the companies acquire rights to block other transferred patent rights hence companies that fail to compete for patent rights successfully are disadvantaged by the eventualities of a competitor becoming the market leader.

Initial estimates of patent values have a highly skewed distribution that led to numerous research to create patent value indicators to clear the emerging backlogs in the applications of patents, mitigate the increasing levels of intellectual property rights acquisition, and alienate poor patent qualities. Subsequently, the European Union's Biotechnology Directive with regard to patenting biotechnological innovations and inventions specifies that protection for patenting in a majority of the biotechnological research and innovations, for living organisms including those involving human gene sequencing, cell lines profiling, and transgenic plants and animals, must theoretically be made available in all EU member countries. These guidelines were formulated to widen the scope of protecting available biotechnology patents enabling patent proprietors to control and mitigate unauthorized reproduction of proprietary biological materials for the benefit of goodwill practice.

However, emerging court decisions in recent years across the board in the EU and US have made it harder for the biotechnology sector to secure the available patents. There are increasing concerns that the changes instigated through the emerging jurisprudence have weakened initiatives to protect patents. To counter the courts, innovators, and innovation companies are increasingly protecting new inventions in the form of trade secrets that would enable that have an influence on clinical care. Furthermore, when a specific legal approach is meant to function and influence processes in a unitary manner, mixed facts always emerge from court rulings infringing on the granting of patents. Technological companies have made myriad approaches towards consolidating different technologies, skills, and inventions. As has been observed in this study the liberal approach to biotechnology in the US enables the patent system as used by companies in

the US to foster strategies that protect the inventions unlike in the EU where the moral monolithic approach limits the patenting rights. Nevertheless, irrespective of the multiple differences in patentability and in valuations and scope of biotechnology patents in both the US and the EU, which seem not being resolved in the near future, cross-border M&A transactions can be pursued through experimentations while utilizing commonalities in the interpretation of the law. Additionally, M&A transactions can be pursued through the innovation of diagnostic tools, which upon obtaining a license of ownership the tool can be used for further inventions. Furthermore, it is very much possible for EPC and USPTO to revise their patent regulations as well as advise the US government to initiate amendments to the common law to allow for merging of inventions, which in turn shall facilitate M&A transactions between the EU and US biotechnological companies.

5.1 Answers concerning the set research questions

This subsection answers the questions that were set at the beginning of this thesis. It was first necessary to conclude chapter four regarding research findings in the summary section before the answers to the research questions can be given. The necessary references regarding the answers based on the research has been made earlier in the previous chapters. Answers to set questions in subsection 1.3 in this thesis are based on the analysis of the regulatory environment and research findings as well as conclusion part, and are the following:

1) What kind of substantial difference and similarity there is in the valuation and scope of biotechnology patents between the US and the EU?

As has been observed in this study the liberal approach to biotechnology in the US enables the patent system as used by companies in the US to foster strategies that protect the inventions unlike in the EU where the moral monolithic approach limits the patenting rights. As such, the biotechnological companies and inventions are majorly restricted limiting conventional methods from providing solutions to existing problems on either ethical grounds or fear of lack of specifications. Nevertheless, irrespective of the multiple differences in patentability and in valuations and scope of biotechnology patents in both the US and the EU, which seem not being resolved shortly, cross-border M&A transactions can be pursued through experimentations while utilizing commonalities in the interpretation of the law.

2) What is the relevant regulatory environment for this research and why?

The writer concluded that relevant regulatory environment is based on general rules of patentability of biotechnology patents and general rules of mergers and acquisitions and it was essential to point out due diligence process in mergers & acquisitions thus before the transaction is completed

the valuation of biotechnology patents and the scope of protection of biotechnology patents needs to be investigated. Trade secrets as a part of IP plays an important role nowadays and should be included as biotechnology is an evolving field and the patentability of the inventions are not that clear as in other fields of technology, this in order brings us to the rights of third parties and possible patent injunctions as well as ethical issues.

3) What kind of existing differences there is between the US and EU's patentability procedures?

Conversely, the EU believes in a monopolistic approach to business as a way of conservation and refrain from the unnecessary competition that devalues the existing technologies and products. As such, the EPC does not describe what is comprised of patents but only highlights what inventors should not consider for invention. This raises the question of whether the emerging discoveries in the fields of genomics and proteomics can be categorized within the range that is protected by patent systems. The USPTO after several amendments to its Patent Act and has included within range of patent protection the processes leading to inventions, machines involved, and the manufacturing and processing compositions of the invention. As a result, biotechnology patents have to contain properties of novelty, innovativeness, and eliminate obviousness to meet the experimental prerequisites aimed at developing an actual new idea.

4) What is the best mode of conducting practices of mergers and acquisitions concerning biotechnology patents?

It is only accurate to say that due diligence is a useful concept as it provides crucial information for both seller and buyer in the Mergers and Acquisitions deal. The primary determining factors of the contract include appraisal and intellectual property. The difficulty ensuring the IP’s due diligence comes about as a result of the complications which are experienced by the valuation process of the IP. While certain aspects of due diligence will be more or less the same in biotechnological deals as with any M&A deal, certain areas of due diligence tend to take on greater significance in the acquisition of life sciences. The compliance process in biotechnology must be observed because it affects patentability and, in some cases, even the existence of the whole company. Legal risk management is important to comply with existing rules in the US and the EU when the patentability of biotechnological inventions is at stake.

5) What should be especially considered in mergers and acquisition of biotechnology company concerning patentability and existing patents?

If the portfolios in the possession of biotech companies are not covered, then their IP can easily be spilled over to other companies, which may borrow their ideologies and technology for their research and even develop commercialized products. Companies, especially in biotechnology that possess high enforceability, are at a greater danger of alienating other firms

and impeding them from using their intellectual assets because high enforceability can easily intensify uneven trading ground for common mergers and uncommon mergers. It is possible that companies having mutually similar blocking technologies can converge and reduce fragmentation in the market necessitating the need for regulations in the highly innovative sectors that are perceived to be open for inventions without limits as a way of providing solutions to existing problems.

5.2 Concluding points based on research findings

This thesis concludes following based on the research findings in chapter four and which were earlier referenced in the same chapter:

a) The Nuffield council recommends for restrictive granting on DNA sequencing patents but encourages adoption and use of utility guidelines as established by USPTO and as applied in biotechnology inventions by EPO.

b) In the EU for instance, the current law as observed in this research provides for exemptions where bio-scientific practices are aimed for non-commercialized advances. In the US, patent code (35) section 271 restricts commercialization of patents although the courts have to date been applying common law in determining cases involving experimental use of patents.

c) As such if a company can identify the mutations in the infected or altered gene because of the disease, the company shall have fulfilled the utility requirements and thus subject to receive patent protection.

d) Contrary to the statute of providing patents in the United States, in Europe, the EPC does not give detailed information regarding the constituents of things that can be assigned to a patent. It is crucial to note that all the applications for biotech patents in the United States must meet certain requirements. Such as they should be highly innovative, not easily predictable, and original.

e) For common law countries, where the law is theoretically painted with broad brush strokes and the details are filled in by the courts, these differences are easiest to explain. This helps legal evolution (often slow) to cope with unpredictable circumstances by derivations from old concepts to new laws. In fact, courts exercise the same role to varying degrees in countries with civil law.

f) Potential buyer needs to review regulatory compliance issues during the process of due diligence. The difficulty ensuring the IP’s due diligence comes about as a result of the complications which are experienced by the valuation process of the IP.

g) When it comes to the grace period, the conditions are different for both the EU and the US. In Europe, for instance, a patent is rejected if the invention was known previously before filing the application of a patent. The United States, on the other hand, has a grace period of one year.

h) In Europe, for instance, any individual corporation can file an opposition against the patent holder. The difference with the EU comes in whereby the patent holder alone discusses the underlying issues with the USPTO intending to analyse reasons behind the validity of the patent. In this case, the opponent is not involved in the entire proceedings. The difference, however, is that the inventive step can be deemed sufficient where the invention is considered as non-obvious. In the European Union, the patent law states that an invention should be characterized by a great deal of novelty and should entail an inventive step. The United States, on the other hand, is very stringent on the fact that the invention should be entirely original to validate the inventive step and thus patent application.

Despite the numerous discussions in various courts of appeal in both the United States and the EU, there are still a lot of controversial matters surrounding the application, awarding, and revocation of patent rights of biotech companies. Extensive research on this issue is recommended to aid future research and benefits as well as the growth of the biotech industry.

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