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Biotech Patents in the World We Live In

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INTRODUCTION

With the world entering into the 21st century, the population continuing to increase, and with the resources available quickly depleting, it has become much more important now than ever before for scientists to be able to do more with less. That is when individuals start to look into their environments to find answers to the problems that humanity is facing. This is exactly when biotechnology becomes pertinent. The dictionary definition of biotechnology is “the manipulation (as through genetic engineering) of living organisms or their components to produce useful usually commercial products (as pest resistant crops, new bacterial strains, or novel pharmaceuticals); also : any of various applications of biological science used in such manipulation”.¹

However, the research into the biotechnology field is quite expensive and unprofitable since it undertakes massive investments with uncertain returns.² Much like the bigger pharmaceutical industry they are part of, the biotechnology industry must rely on intellectual property protection, primarily patents, in order to see profits to make up for the costly investments they must make to discover which products can meet US FDA approval requirements.³ When comparing the biotech and pharmaceutical industries to almost all other large industries, upfront costs comprise some 70 percent of drug costs, with manufacturing and other short-run costs account for only about 30 percent. In some cases, the development of a

¹ “biotechnology” Merriam-Webster Online Dictionary 2015 <http://www.merriam-webster.com> (2 Dec 2015)

² Claude Barfield & John E Calfee, *Biotechnology and the Patent System: Balancing Innovation and Property Rights* (1st Edition, 2007)

³ *Id.*

new drug is known to cost approximately \$800 million.⁴ Also, one company spent \$900 million to create a more durable corn hybrid, and \$600 million to create a different hybrid of the soybean.⁵ “The industry will not remain viable unless revenues greatly exceed the costs of drugs actually brought to market and compensate for financial risks associated with the numerous research failures that yield no marketable drugs at all”.⁶ “Protection of biotechnological inventions will certainly be of fundamental importance for the [...] industrial development”.⁷ Under these conditions, without intellectual property protections, it would be all too easy for imitators to easily undercut the prices necessary for research of innovative new drugs by simply copying the research done, and reaping the profits. Additionally, “investors believe that in order for the biotechnology sector to succeed, it is critical that biotechnology firms be able to obtain and enforce strong patents”.⁸ “The field of genetic engineering research and development require a considerable amount of high-risk investment and therefore only adequate legal protection can make them profitable”.⁹

As stated previously, this is a time in which the world as a whole needs innovation and thinking outside of the box in order to run efficiently. As humans use more and more resources than we thought we would originally need, scientists are looking into different ways in which

⁴ Sarah Schieder, Scope of Biotechnology Inventions in the United States and in Europe - Compulsory Licensing, Experimental Use and Arbitration: A Study of Patentability of DNA-Related Inventions with Special Emphasis on the Establishment of an Arbitration Based Compulsory Licensing System, 175, Santa Clara High Technology Law Journal (2004)

⁵ *Id.*

⁶ *Id.*

⁷ Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions, 1998 OJ (L 213)

⁸ Schieder, *supra* note 4, at 170

⁹ Directive 98/44/EC

they can create solutions to problems we thought wouldn't exist for centuries. Additionally, as science advances through research, humans are able to find solutions to problems we never thought we could solve. Treatments to diseases are being developed in the most obscure of places, and world hunger is attempted to be put to rest through the increased production of corn through the world.

Unfortunately, as stated above, nothing in this world is free, not even innovation that could help solve the world's biggest problems. A drug costs almost billions of dollars, and individuals are not keen to invest this much money if there is a high risk of losing it without any return on investment. Therefore, patents for biotechnological inventions become just as important as patents for other types of inventions. Once there is a patent for a new drug, or a new production for a cure for a disease, or even for splitting a piece of DNA to manipulate it to a person's will, the investment and invention become that much more appetizing to consider.

However, there comes a risk with limiting the innovation of a product to the person person or team to be able to patent it. As with any patent, once the patent is awarded, the patent holder is given an absolute right that covers all uses for that invention. Therefore, even if the treatment is essential in healing a disease that the inventor had not originally thought of, that treatment still becomes their "property", since it was originally protected under the patent. One of the only viable solutions in this scenario is that the competitors would have to pay enormous licensing fees in order to be able to even do research using the coveted patented method to see if their solution will be viable. Therefore, some companies choose to not take such a financial risk that could potentially bankrupt them if their idea does not work out, and choose to not develop an idea that might somehow change the world for the better if the license was paid for.

HISTORY OF BIOTECHNOLOGY PATENTS BEFORE LEGISLATION

While the more technical and nuanced aspects of biotechnology are slowly emerging and making their way into the courtrooms, biotech patents are anything but new. The third ever patent to be granted in Finland was to a biotech invention in 1843, for a new method to produce yeast cultures.¹⁰ In France, microbiologist Louis Pasteur obtained a patent for his improved yeast-making method from the French Patent Office.¹¹ In 1969, a German inventor claimed a patent for “creating” doves with red plumage.¹² The request for patent was denied by the German patent office because it was stated that this condition could not be repeatable, a decision which the Supreme Court of Germany agreed. Nevertheless, this was an important step, as it was the first case in which a patent concerning the production of living matter was brought forth before the European Union.¹³ Later in the 1970’s, the German Federal Supreme Court upheld that a patent could be awarded for a biological invention for new micro-organisms if the inventor was able to show it is reproducible.¹⁴ Meanwhile, the European Patent Convention was created in 1973, which ruled that while you may not claim a patent for “products of essentially biological processes,” it did not exclude patenting of products for non-biological purposes.¹⁵

After adoption of the European Patent Convention, the first case in the European Union that truly laid the foundation for patents for living things was *Genentech-I/Polypeptide*

¹⁰ Ayşegül Özdemir, Patenting Biotechnological Inventions in Europe and the US, Ankara Bar Review (2009)

¹¹ *Id.*

¹² Dr. Sreenivasulu & Dr. Raju, Biotechnology and Patent Law: Patenting Living Things, 39 (1st Edition, 2008)

¹³ *Id.*

¹⁴ *Id.*

¹⁵ *Id.*

expression.¹⁶ The patent in this case was regarding a human growth hormone, which included a recombinant plasmid, a “self-reproducing particle of protoplasm,” which can determine hereditary characteristics, into which artificially generated DNA was inserted.¹⁷ The invention in question was claimed to be in the ability of the plasmid, that when inserted into the bacterium host, controls the expression of the polypeptide. The Examining Division stated that there was insufficient disclosure and that all embodiments of the invention “as set out in the claim... were capable of performance by the skilled man in a repeatable manner without practicing inventive skill.¹⁸ Due to the fact that some of the sequences were still unknown by the creators, the results could not fully be replicated without further invention involving identification of the sequences. Also, according to the Division, since the claim described the invention by what it did, and “an invention defined by what it did, rather than what it was, could not ‘define the matter’ for which protection was sought,” the Division refused to grant the patent in this specific case.¹⁹

However, the Technical Board of Appeal disagreed, distinguishing between essential and non-essential claim features of an invention. It went on to iterate that while the essential features of an invention were required to be known to help the skilled man be able to repeat the invention, there are other features that can be unknown for the time being and still be awarded a patent.²⁰ The Board also differentiated between biological processes and non-biological processes, and ruled that the former is not patentable, while the latter would be able to be granted a patent.²¹

¹⁶ *Id.*

¹⁷ Oliver Mills, *Biotechnological Inventions: Moral Restraints and Patent Law*

¹⁸ *Id.*

¹⁹ *Id.*

²⁰ *Id.*

²¹ Sreenivasulu, *supra* note 12, at 40

The Court in this case viewed the present invention as a biotechnological process, which was not necessarily seen as a biological process, and was therefore, able to be patentable. This decision paved the way for biotechnological processes and micro-organisms to be allowed to be patented in the European Union.²²

In 1911, Parke-Davis & Co brought two counts of patent infringement against HK Mulford Co.²³ Both counts for patent infringement were about an extract from the suprarenal glands of living animals. The Circuit Court opined that if a substance is extracted from animal tissue and changed slightly for scientific purposes, then it is patentable. They even went as far as to say, “even if it were merely an extracted product without change, there is no rule that such products are not patentable.” The case was then appealed for reasons not affecting the validity of the patent requested. The Circuit Court of Appeals held that The Court held that a substance derived and purified from nature could be patentable.²⁴

In 1970, *In re Bergstrom*, the inventors brought the case to the United States Court of Customs and Patent Appeals after the patent examiner refused to award them a patent, a decision that was affirmed by the Court of Customs and Patent Appeals.²⁵ In this case, the two previous deciding bodies refused to award a patent due to the lacking of novelty. The Court in this case decided that the two compounds PGE2 and PGE3, that had been extracted and purified from the prostate gland, did not exist, and were, therefore patentable. The Court stated, “Those compounds, as far as the record establishes, do not exist in nature in pure form, and appellants

²² *Id.*

²³ *Parke-Davis & Co v HK Mulford & Co*, 189 F 95 (CCSDNY 1911)

²⁴ *Parke-Davis & Co v H K Mulford & Co*, 196 F 496 (2d Cir 1912)

²⁵ *Application of Bergstrom*, 427 F2d 1394 (CCPA 1970)

have neither merely discovered, nor claimed sufficiently broadly to encompass, what has previously existed in fact in nature's storehouse, albeit unknown, or what has previously been known to exist."²⁶ The board then attempted to bring up the argument that an impure form of PGE2 and PGE3 currently exist from certain procedures. The Court stated that if the impure form of the compounds are the only ones to currently exist as a point of reference, then the pure forms of these compounds that are created are considered "new" and "novel" in comparison to the former.²⁷

In 1977, in another case, *In re Bergy*, the United States Court of Customs and Patent Appeals held that biologically pure cultures of a microorganism did not exist in nature, and could therefore be patentable.²⁸ The Court found:

In short, microorganisms have come to be important tools in the chemical industry, especially the pharmaceutical branch thereof, and when a new and useful tangible industrial tool is invented which is unobvious, so that it complies with the prerequisites to patentability other than the enumerated statutory categories, we do not see any reason to deprive it or its creator or owner of the protection and advantages of the patent system by excluding it from the 101 categories of patentable invention on the sole ground that it is alive.²⁹

²⁶ *Id.* At 1401

²⁷ *Id.*

²⁸ *Application of Bergy*, 563 F2d 1031, 1038 (CCPA 1977)

²⁹ *Id.* At 1038

PIONEER CASE FOR UNITED STATES: *Diamond v Chakrabarty*

In the United States, biotech patents fall under Title 35 USC § 101, which refers to the patentability of inventions and grant of patents § 101 states, “Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.”³⁰ One of the first cases in which the Court relied upon this is *Diamond v Chakrabarty*.³¹ The invention in this case concerned the discovery of a genetically-altered bacterium, which, when modified could break down crude oil, “a property which is possessed by no naturally occurring bacteria.”³² The patent examiner overlooking this patent originally rejected the patent application’s claim, which was then affirmed by the Patent Office Board of Appeals. The Court of Customs and Patent Appeals reversed.³³

The Court opined that when Congress used such broad terms such as “manufacture” and “composition of matter,” it contemplated that patent laws should be given wide scope. They went onto say, “While laws of nature, physical phenomena, and abstract ideas are not patentable, respondent’s claim is not to a hitherto unknown natural phenomenon, but to a non-naturally occurring manufacture or composition of matter—a product of human ingenuity ‘having a distinctive name, character [and] use.’”³⁴ It concludes the opinion by stating that simply because Congress was not able to foresee genetic technology when enacting §101, does not mean that

³⁰ 35 USC § 101

³¹ *Diamond v Chakrabarty*, 447 US 303 (1980)

³² *Id.*

³³ *Id.*

³⁴ *Id.*

microorganisms cannot qualify as patentable subject matter until Congress expressly authorizes so.

In 1973, the European Patent Office established the European Patent Convention, and on July 30, 1998, the European Union passed Directive 98/44, which aims to clarify between what is patentable and what is not patentable in the field of biotechnology.³⁵ “It particularly seeks to confirm that the human body at the various stages of its formation and development, and processes for cloning human beings and for modifying the germ-line genetic identity of human beings, may not be regarded as patentable inventions.”³⁶ However, before the EU took this large initiative to have a united approach towards biotech patents, several countries in Europe were already starting to think progressively.

The German Federal Court, in 1975, held that discovered microorganisms could be patented³⁷, which was soon followed by the decision *Am Cyanamid Co v Berk Pharm Ltd*, in the United Kingdom, which allowed a patent claiming the cultivation of mutant strains of bacteria.³⁸ The Bundesgerichtshof stated that substances that occur naturally are only patentable if they are new and have been isolated by technical means. Another condition is that it has to be made available to the public in that form and that technical intervention must have been required to have found the creation.³⁹

³⁵ Directive 98/44/EC

³⁶ *Id.*

³⁷ Schieder, *supra* at 167

³⁸ *American Cyanamid Co v Berk Pharmaceuticals Ltd*, [1976] RPC 231 (ChD)

³⁹ Schieder, *supra* note 4, at 167

NEED FOR BIOTECHNOLOGY PATENT PROTECTION IN THE EUROPEAN UNION UNION

Directive 98/44/EC truly lays out all the important information concerning biotech patents, from the need for the directive, to what can be patented under the category of biotechnology patents. “Whereas differences exist in the legal protection of biotechnological inventions offered by the law and practices of the different Member States; whereas such differences could create barriers to trade and hence impede the proper functioning of the internal market”.⁴⁰ After reading this paragraph, it can truly be understood why this directive was put into place. Understanding that the European Union is a collection of completely independent Member States with their own sets of laws, the founders of this directive have attempted to create an atmosphere of equality for all inventors to have the same rights when it comes to innovation and discovery.

Paragraph 18 reads, “Whereas, since the patent system provides insufficient incentive for encouraging research into and production of biotechnological medicines which are needed to combat rare or ‘orphan’ diseases, the Community and the Member States have a duty to respond adequately to this problem.”⁴¹ The Directive also realizes the fact that uncoordinated development of patent laws in the Member States could very easily further disincentives between the States, “to the detriment of the industrial development of [...] inventions and of the smooth

⁴⁰ Directive 98/44/EC, *supra* at 1

⁴¹ *Id.* at 2

operation of the internal market”.⁴² Finally, Paragraph 16 truly explains the importance of why patenting biotechnological inventions is necessary:

Whereas patent law must be applied so as to respect the fundamental principles of safeguarding the dignity and integrity of the person; whereas it is important to assert the principle that the human body, at any stage in its formation or development, including germ cells, and the simple discovery of one of its elements or one of its products, including the sequence or partial sequence of a human gene, cannot be patented whereas these principles are in line with the criteria of patentability proper to patent law, whereby a mere discovery cannot be patented.⁴³

As can clearly be seen throughout the selected paragraphs in the directive, the creators have decided that there are several important reasons for why there must be a collection of rules to control patents for biotechnological inventions. They reiterate countless times that, since the European Union is a combination of independent Member States, in order for society in Europe, and in the world as a whole, to be able to collectively move forward upon the finding of such important inventions, we must all have the same standards put into place. Otherwise, a patent for the treatment of an illness found in one sovereign state of the European Union that is perfectly protected in that country, would possibly not have the same amount of protection, if at all, when moved across the border into the surrounding Member States. This, as appears to be the central theme of this paper, would definitely drive down the incentive for innovation, as someone who wants to have the technology that has taken hundreds of millions of dollars to research, would

⁴² *Id.* at 1

⁴³ *Id.* at 2

simply need to wait for it to come across the border into one of the neighboring states to retrieve it freely.

Additionally, the writers also talk about the danger that unregulated protection of patents could potentially bring to the internal market of the European Union. If all of the Member States do not acknowledge to protect the innovations equally, then the states might not be so open-minded in sharing the technology they have discovered.

REQUIREMENTS FOR BIOTECH INVENTIONS TO BE ELIGIBLE FOR PATENTS

Directive 98/44/EC lists the requirements as to what the invention has to include in order to be eligible to receive a patent. Paragraph 8 of the Directive clearly states that “the rules of national patent law remain the essential basis for legal protection of biological inventions”.⁴⁴ The Directive also states in Paragraph 13 that there must be a distinction between what a discovery is and what an invention is. While Paragraph 20 and 21 state that “an invention based on an element isolated from the human body or otherwise produced by means of a technical process”, Paragraph 23 notes that “a mere DNA sequence without indication of a function does not contain any technical information and is therefore not a patentable invention.”⁴⁵

⁴⁴ *Id.*

⁴⁵ *Id.*

DIFFERENT CHAPTERS OF DIRECTIVE 98/44/EC

The Directive is broken down into 5 Chapters: Patentability, Scope of Protection, Compulsory cross-licensing, Deposit, access and re-deposit of a biological matter, and Final provisions. The first chapter, Patentability, in Article 1, ensures that the laws of the Member States are adjusted to suit the necessary legal requirements of the Directive in charge of biotech patents.⁴⁶ Additionally, in Articles 2 through 7 of the same Chapter, it defines the terms “biological material”, “microbiological process”, and “plant variety”, while stating several categories of biotechnological varieties that shall not be patentable.⁴⁷ The uniformity that the Directive tries to enforce is essential when making sure that there is no misunderstanding in even the smallest of details, since this is a piece of legislation that will be followed by an ever expanding union.

The next Chapter of the Directive covers the scope of protection when it comes to biotech patents, where it states that the protection “shall extend to any biological material derived from that biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics.”⁴⁸ While, as stated previously, this broad understanding of the biotech patent regulation might be dangerous to the competition, Articles 10 and 11 illustrate how when the patent holder consensually allows others to use his product for uses, such as agricultural use, as stated in Article, 11, this will imply that the farmer has full authorization “to use the product of his harvest for propagation or multiplication by him on his

⁴⁶ *Id. at 6*

⁴⁷ *Id.*

⁴⁸ *Id.*

own farm...”⁴⁹ This paragraph clearly shows that while the patent holder will be in exclusive control over the creation, upon the revelation of the creation to other users, this will imply authorization of the product to those that have been given permission. This is a solution to one of the ethical challenges that face patents.

Perhaps, if solutions are found to be promising for illnesses that have not been found by the patent holder, but another entity, then the holder of the patent will authorize the use of that innovation.

Another solution for this ethical dilemma can be found in Chapter 3, titled Compulsory cross-licensing. This chapter regards those instances in which a party that does not have the rights to the patent and has unsuccessfully sought permission for the patent use in question. It states that when a breeder isn’t able to produce the product he wants without infringing on the patent in question, “he may apply for a compulsory license for non-exclusive use of the invention protected by the patent inasmuch as the license is necessary for the exploitation of the plant variety to be protected, subject to payment of an appropriate royalty.”⁵⁰ While this Chapter allows for those that do not have the patent, but only the plant variety, to be able to use the technology behind the patent for an agreed upon royalty, it also allows the former party, the holder of the plant variety right to also have bargaining power. It allows in Paragraph 2 of Article 12 that if a patent holder is not able to progress on his research and innovation without infringing on the plant variety right in question, that “he may apply for a compulsory license for non-exclusive use”, again, upon the agreed upon term that there will be a payment of a royalty

⁴⁹ *Id.* at 7

⁵⁰ *Id.*

for the use of the right obtained by the patent holder.⁵¹ As stated above, this works to be able to give not only the patent holders, but also the holder of the rights for the plant variety which the patent holder might need, some advantage when negotiating for royalty fees.

Chapter four of the directive is named, “Deposit, access and re-deposit of a biological material.” This chapter is involved with patents in which the biological material, “is not available to the public and which cannot be described in a patent application” so that the average person skilled in the field will not be able to reproduce it. As with regular patents, one of the requirements for a biotechnological patent is that reading the patent application, a person skilled in the art should be able to replicate the technology presented in the patent. In article 13, it allows exceptions as to when, despite the impossibility of fulfilling this requirement, the patent will still be approved. Essentially, what is stated in this article is that the biological material not accessible by the public must be deposited at the same day as the application, and as much information as possible concerning the material must be provided for in the application.⁵² This provision is enabled to make sure that even in cases where the biological material is not accessible by the public, if the patent holder can show that it meets all of the other requirements for a patent, it will still be approved.

Finally, Chapter 5, titled, “Final Provisions” illustrates when the the deadline by when the Member States will be required to enforce the Directive, as well as what the precise language is that they will be providing to their citizens. Additionally, in order to ascertain that there is uniformity throughout the Union in regards to biotech patents, the Commission will request a

⁵¹ *Id.*

⁵² *Id.* at 8

report on any problems that are seen in either enforcing the Directive, or with any of the international agreements that the Directive may not align with.

CHAPTER 2400 of the United States Patent and Trademark Office: Biotechnology

As the European Union has the Directive concerning biotech patents, the United States designates Chapter 2400 to the explanation of the rules concerning biotechnology and the obtaining of patents for such inventions. Initially, it defines exactly what biological material is in accordance with the chapter, some of the examples being bacteria, fungi, algae, plant tissue cells, and seeds.⁵³ Additionally, it defines what each patent application must consist of, which includes “a written description of the invention sufficient to enable a person skilled in the art to which the invention pertains to make and use the invention.”⁵⁴

Furthermore, similar to Chapter 4 in the EU Directive, the United States provision also states that if the invention has biological material and “words alone cannot sufficiently describe how to and use the invention in a reproducible manner,” then actual samples of the material may be necessary in order to be able to meet the satisfaction of the requirements put in place.⁵⁵ Unfortunately however, this is where the comparison must end between the two guidelines as far as helpfulness goes in terms of what is allowed when it comes to biotechnological patents. Since the United States is based more on case law than Europe is, a majority of the specific standards

⁵³ Chapter 2400 – Biotechnology <http://www.uspto.gov/web/offices/pac/mpep/mpep-2400.html> (2015)

⁵⁴ *Id.*

⁵⁵ *Id.*

for patents comes directly from case law. The rest of Chapter 2400 is based more so on the deposits submitted in for consideration alongside the application for the biotechnology patent.

In the most recent case that has followed the ruling of Chakrabarty, the godfather of biotechnology patent cases, *In re ROSLIN INSTITUTE* found that the cloning of sheep was not patentable, in 2014.⁵⁶ The Court reiterated that “Laws of nature, natural phenomena, and abstract ideas are not eligible for patent protection.”⁵⁷

DIFFERENCE BETWEEN EU AND USA APPROACH TO BIOTECH PATENT LAW

There are several key differences in the approach towards biotech patents that EU takes when compared to the approach taken by the US. One of the major differences between the two unions’ approaches is the EU’s attention to *ordre public*, or morality. In Paragraph 36 of the Directive, it references to how the TRIPs Agreement may choose to exclude inventions from patentability that they believe go against *ordre public*, “including to protect human, animal or plant life or health or to avoid serious prejudice to the environment...”⁵⁸

Paragraph 37 also references that inventions must be excluded from patentability if the commercial exploitation goes against *ordre public*. There is a non-exhaustive list in Article 6 under Chapter 1 of Patentability in the Directive. Exclusions include processes for cloning humans or for modifying the germ line genetic identity, as well as uses of human embryos for industrial or commercial purposes, and processes for modifying the genetic identity of animals

⁵⁶ *In re Roslin Inst. (Edinburgh)*, 750 F.3d 1333 (Fed. Cir. 2014)

⁵⁷ *Id.*

⁵⁸ Directive 98/44/EC, *supra* at 4

that would cause them suffering without causing any substantial scientific benefit.⁵⁹ The importance of morality is very important and has been pointed out in specific ways in the Directive. While, as stated previously, the EU has followed in the steps of TRIPs, it has gone even above and beyond their standards for *ordre public* and morality.⁶⁰ While Article 27(2) says Members, “*may* exclude from patentability inventions commercial exploitation which is necessary to protect *ordre public* or morality, in article 6 of the directive, it states, inventions “*shall* be considered unpatentable where their commercial exploitation would be contrary to *ordre public* or morality.”⁶¹

While overly broad and general inventions that cover a wide range of uses cannot simply be awarded biotechnological patents, since this will limit the prospects of future research, the patent process cannot be narrowed too much, as this will not give innovators enough of an incentive, since research and development costs are high. While not wanting to give credit where it is not due, the Supreme Court of the United States has in the recent past made the process much harder by overly increasing the standard of patentability for biotechnological inventions. Even though Directive 98/44/EC might have several strict standards in place to award biotech inventions, it is still more patent friendly than the United States’ policies.⁶²

It has been argued over the years as to whether the E.U.’s attempt at ruling on biotechnology patents or whether the United States’ is better. While during this research I have read argument concerning both sides, it can be easily seen while reading this paper that the

⁵⁹ Directive 98/44/EC, *supra* at 7

⁶⁰ Astrid Burhöl, *Moral exclusions in European biotechnology patent law*, Lunds universitet (2006), 17

⁶¹ *Id.*

⁶² Schieder, *supra* note 4, at 167

European Union might be taking more into account than just the patent itself. For example, as written above, the European Union is more open to patents that are trying to secure technology that is still in its infancy. On deeper analysis, this makes the most sense. As cited several times, it takes hundreds of millions of dollars in order to be able to invest in a biotechnology project and make it successful. However, there is a plethora of things that can happen throughout this research process that can allow for the technology to get into the competitor's hands. Therefore, seeing this risk, investors might not be as keen to take part in a new technology, when all of their investments might turn out fruitless. This is a huge reason for why the European Union is most likely allowing for the ability to receive a patent on research that has not yet been fulfilled.

Additionally, the European Union has come to understand that only the three factors involved in judging a patent are not the only things that are important for innovation. Nevertheless, while morality does not seem to be as relevant in the United States' eyes as it is in the E.U.'s, this is still understandable. The United States, with biotech patents, as with many other things, chooses to take on quite an aggressive approach. Therefore, it can be seen that they are willing to advance anything and award it a patent as long as it fulfills the requirements for a patent and is able to progress the technology forward that is pertinent for the advancement of human society.

THREE REQUIREMENTS NECESSARY FOR ANY PATENT

Despite the differences that the two large entities might share, there is one thing that both of them agree on, what the basic requirements are for obtaining any type of patent, including biotechnology patents. The three requirements that are demanded from any applicant to apply for a biotechnology patent are novelty, non-obviousness, and utility.

Novelty of a patent means that it must be new, and something that has not been patented previously. Additionally, the patent must not have been known or used by others in the United States before the date of patenting. This is an essential component of the patent system, because if not for this, then individuals would be able to go out and patent anything that has been around for years, or decades, and not only make money off of that “invention” henceforth, but also block the public’s access to that innovation. Previously, it could be objected that a biotech invention was not novel merely based on the fact that the substance existed in nature. However, now it is not that simple. The innovation, in today’s understanding, must have been fully described, and been made available to the public for it to not be considered novel.⁶³ Therefore, it can be seen that the United States has decreased their harsh standards in order to be able to allow the ability to protect their inventions to a larger group of individuals in the U.S.

When compared with the United States standard for novelty, the E.U. standard is quite a bit more cumbersome. It states, “Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature.”⁶⁴ This means that there must have been no previously recognizable use for this and that it must have been completely isolated from its natural environment. Additionally, there is a requirement in the E.U. that the innovation discovered must have been “definable by either its structure or process by which it is obtained.” This is a practice that the United States has also started to accept.⁶⁵ This is something new that the United

⁶³ Minh Chau Dao, NOVELTY AND NON-OBVIOUSNESS OF BIOTECHNOLOGICAL INVENTIONS UNDER EU AND US LAW, 3

⁶⁴ Directive 98/44/EC: Article 3(2)

⁶⁵ Dao, *supra* note 63, at 3

States and the E.U. have begun. In short, this means that governments are not only looking for innovations or biological materials that have never existed on Earth before.

Now, it is becoming acceptable to affirm patent applications that are able to enhance materials or chemicals that are naturally found in nature. In the case regarding Relaxin in 2002, it was found that even though relaxin, a hormone which relaxes the the uterus during childbirth existed in nature, cloning the nucleotide sequence and being able to mass produce synthetic relaxin was still seen as “novel” in the eyes of the European Union.⁶⁶ The Court found that “the skilled person may not have found it obvious to use the same cloning technique as that described in documents” and that “the skilled person would have had reasons to doubt that such an homology would exist between the human and rat or porcine relaxin DNAs”, and thus, the skilled person working in that field might not have known that cloning the sequence and producing synthetic relaxin was possible.⁶⁷ Due to the fact that a skilled person might not have thought of it, the Court found that it was novel.

The second element that must be present for a patent to be eligible in both the E.U and the United States is the “non-obviousness” standard. One of the strongest arguments made against finding of this standard is claiming that an “invention” is indeed a discovery. According to Article 56 of the European Patent Convention, “An invention shall be considered as involving an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art.”⁶⁸ As for the United States, Section 103 of the Patent Act of 1952 reads, “A patent may

⁶⁶ *Id.*

⁶⁷ T 0272/95 (Admissibility of joint opposition or joint appeal) of 15.4.1999

⁶⁸ European Patent Convention, Article 56

not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art.”⁶⁹

There are different ways to test for non-obviousness in the European Union and the United States. The European Union uses a three-part test referred to as the problem-solution approach.⁷⁰ The first step that is taken is by looking at the prior art in this area and the effect it has had. After looking at the most prior art, and what it was, it is then considered whether the invention in question would have been obvious to the skilled person from the prior art. The third and objective step asks whether the prior art that was compared against the present invention would have pushed the skilled person in the art to have discovered the current invention.⁷¹

The approach that the United States takes in attempting to figure out non-obviousness for patent cases is *Graham v. John Deere*.⁷² “Under §103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved.”⁷³ Additionally, in the United States, unlike in the E.U., the courts look at secondary factors, such as “failure of others, long felt but unsolved need, unexpected results or unexpected properties, and commercial success.”⁷⁴ As can

⁶⁹ 35 U.S.C. § 103(a)

⁷⁰ Dao, *supra* note 63, at 6

⁷¹ *Id.*

⁷² *Id.*

⁷³ *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17 (1966)

⁷⁴ Dao, *supra* note 63, at 6

be seen several times throughout this paper, the E.U. and United States have differing standards when it comes to general intellectual property rights, let alone biotechnology patents specifically.

The third requirement that the E.U. and the United States agree must be present for patents is obviously utility. According to the United States, a patent is useful if, “it provides some identifiable benefit and is capable of use.”⁷⁵ Looking at the Utility Examination Guidelines, it is rather difficult to not be able to meet this criteria. “Whenever possible, the examiner should provide documentary evidence regardless of publication date (*e.g.*, scientific or technical journals, excerpts from treatises or books, or U.S. or foreign patents) to support the factual basis for the *prima facie* showing of no specific and substantial credible utility.”⁷⁶ The European Union has quite a low standard of utility as well, which can be seen from Article 57 of the EPO, stating, “An invention shall be considered as susceptible of industrial application if it can be made or used in any kind of industry, including agriculture.”

Despite the European Union and the United States having somewhat different standards when it comes to the elements required to have a patent, they both accomplish the same mission. Both entities have chosen newness, non-obviousness, as utility as the three driving forces for deciding as to whether an invention is advanced enough to earn a patent and reward the innovator. Also, both entities are able to appreciate the importance of what awarding a patent truly means. When a person or company receives a patent, that invention is essentially no longer freely accessible to the public or to the competitors. This means that advancement on it is only

⁷⁵ 35 U.S.C. §101

⁷⁶ Utility Examination Guidelines,
<http://www.uspto.gov/sites/default/files/web/offices/com/sol/notices/utilexmguide.pdf> (2001)

limited to the advances that the patent holder wishes to make, and to whoever is willing to pay the usually exorbitant licensing fees previously addressed in this paper. Therefore, both the E.U. and the United States, when awarding their patents to the inventors are essentially saying the technology portrayed in the applications is the best, and that they are fine with the fact that fewer changes can now be made to that technology considering there is one group or person in charge of it.

As can be seen, both the European Union, as well as the United States, both have different approaches to handling biotechnological patents. The United States is stricter in their implementation of regulation, and does not allow for as much “wobble-room” as far as future innovation regarding the patent in question. It sees the application for patents that will allow for further research in the future as a potential method for “patent trolling” which will block true innovation by cluttering the process with the handling of royalties and other technicalities. The E.U., in stark contrast, is more willing to accept applications for a biotech patent based on potential future innovations. In other words, if there is promise in the advancement of the science behind the patent, the chances for approval are rather promising for it. Additionally, the United States could possibly be seen as less humane when compared to the practices of the European Union. As can be seen in the Directive from 1998, *ordre public* or morality, can be seen being referenced several times. The E.U., while wishing to drive forward innovation through the spreading of ideas, does not wish to tamper with the moral compass of society, simply in the name of innovation. In my personal opinion, the direction in which the E.U. is advancing is much more conscionable as it takes into account the morality of the invention as well as the other guidelines written in the Directive.

In conclusion, biotechnology patents are necessary in today's evolving environment. Intellectual property rights have helped in developing our way of life from the days of the caveman to what we see today. Copyrights, trademarks, and patents have all made their impact in this world. Copyrights have allowed for great innovation in mediums through which individuals are able to express themselves. Artists have been able to use copyrights to make sure that the innovative ideas they have for their literary works can be shared with the public without being stolen and pawned of as someone else's.

Trademarks and trademark secrets have also helped incredibly in the world of innovation. They have allowed entrepreneurs to have the freedom to design their business structures as they see fit and to be able to have uniformity all throughout their locations. Trademarks have made it possible for huge corporations such as Apple, McDonald's, and Target to simply be recognized by simple logos that no one can mistake. Trademark secrets is the one type of intellectual property right that is probably the closest to a patent. It is essentially what allows a business to have a unique product without having to disclose to the world what it consists of. This is essential for businesses like Coca-Cola that wish to not disclose their business secret, even in a patent.

However, I believe that patents have truly been the intellectual property right that has allowed for the most innovation in the world up to date. This is because, due to patents, innovators have had the incentive to create life-changing products. From advances in automobile safety to finding amazing innovations in the technology sector, patents have been the sector that have allowed the world to take a step forward with every creation that is thought of.

Until relatively recently, when somebody spoke of patents, nobody thought of biotechnology patents and the impact they truly have on the world. No one was able to

understand that it is through these patents that some of our greatest problems in the world have been solved or are on the way of being solved, such as world hunger, and the cure for diseases that were at one point in time thought to be incurable. It is through these patents that we are able to change our future and make it a brighter one for the generations ahead, despite all of the mistakes we have made in the past.

As stated previously, these patents are essentially a necessity in our day, as the innovations that are necessary take hundreds of millions of dollars in investments in order to become a reality. If not for the security of knowing that when an innovation is accepted into the field, that it would be protected and the innovator would be able to receive a return on his investment, there would be no incentive for him to do anything.

Nevertheless, this type of “exclusivity” when it comes to patent protection comes at a bit of a steep price. This means that once that patent is protected, any treatment or advancement that could come from that invention will only be able to be used with permission from the person that originally thought of the idea. Therefore, this limits the expansion of ideas down to two possibilities: either the company that holds the patents must think of all of the innovations that could advance the field, which is rather an unlikely scenario, or the competitors that have come up with solutions to some of the world’s greatest problems must spend sometimes exorbitant amounts of money to license the technology from the patent to be able to use it in different methods.

In my opinion, biotech patents are the way of the future. I believe that with these sort of patents, science will be able to pioneer great inventions that will undoubtedly change the way we see the world and the way we live, whether it be through what we eat, how long we live, or any

combination of other benefits that we are not able to foresee right now. The only challenge we have ahead of us is to be able to use the power of patents responsibly.