Copyright to protect intellectual property rights in cDNA, a better legal regime than patent law?

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Abstract:

cDNA (or complementary/engineered DNA) applications are a growing trend in the Biotechnology sphere. cDNA strands are DNA strands that are artificially created. These engineered DNA strands can be used to change the properties of vegetables, livestock, or to find and scope out cancerous mutations in human beings. The possibilities seem endless. Because this industry is a rapidly growing one, the current legal regime might not be suited for cDNA anymore. But is this really the case? The current legal regime is patent law. In literature, it has been proposed to have copyright law be applicable to cDNA. The reasoning behind this is that copyright would be perfect, since it shares many similarities with computer code which can already fall under the copyright regime. It is also much cheaper, and there are no formal requirements. In this thesis, I will evaluate the arguments in favor of making such a change. I will also discuss the counterarguments. My conclusion will be that a hybrid system or a change from one system to another might not be the best solution. I propose a semi-hybrid system. The idea is that copyright law would protect cDNA applications from the moment they are created, up until they receive patent protection. This way cDNA is protected by copyright law but will in the end transition to patent law, which is arguably more robust. After patent protection is given the copyright law drops to prevent the two legal regimes from conflicting with each other.

Contents

1 Introduction

In this thesis, I will answer the following question: "Copyright to protect intellectual property rights in cDNA, a better legal regime than patent law?" The aim of this thesis is to be brief and concise in order to provide the reader with a quick bird's eye view of what is proposed, what the benefits of this proposal would be and whether this is indeed a good proposal.

cDNA is currently protected and governed by patent law and specific biotechnology legislation like the Biotechnology Directive in the European Union.[1] Currently it has nothing to do with copyright. Copyright is another legal regime entirely. However, the interesting idea of using copyright law for cDNA or using it complementary to patent law has been coming up with some regularity. One of its biggest proponents is Professor Chris Holman, who has written extensively on the topic and also addresses this in lectures.[2] But the first paper I could find dates all the way back to 1982, before I was born. It is a paper about copyright and genetic information in an agricultural context by Professor Irving Kayton.[3]

In the literature that is written on using copyright with regard to cDNA, we can see many benefits that the copyright regime has that could possibly offer solutions to problems

[1] Convention on the Grant of European Patents (European Patent Convention) 16th edition 2016;
Directive 98/44/EC of the European Parliament and of the Council of July 1998 on the legal protection of biological inventions

[2] Professor Christopher Holman Addresses Copyrighting Engineered DNA In Lecture, University of Missouri-Kansas City, 4th of November 2015, as mentioned in http://law.umkc.edu/news/professor-christopher-holman-addresses-copyrighting-engineered-dna-in-lecture/, accessed 02-07-2017;
Holman's IP Blog, Professor Chris Holman, holmansbiotechipblog.blogspot.nl;
C.M. Holman, 'Copyright for Engineered DNA: An Idea Whose Time Has Come?', *West Virginia Law Review* (113) 2011;
C.M. Holman, C. Gustafsson and A.W. Torrance, 'Are Engineered Genetic Sequences Copyrightable?: The U.S. Copyright Office Addresses a Matter of First Impression', *Biotechnology Law Report* (103) 2016, issue 3;
C.M. Holman, 'Charting the Contours of a Copyright Regime Optimized for Engineered Genetic Code', *Oklahoma Law Review* (69) 2017, issue 3

[3] I. Kayton, 'Copyright in Living Genetically Engineered Works', *George Washington Law Review* (50) 1982, issue 2, p. 192-194

that the patent system now has. For example, one can think of fair-use. This is a copyright principle allowing people and organizations who want to learn how something works to come up with their own ideas. In order to facilitate this, these people and organizations would need access to a product without having to fear litigation against them. It can also be argued that the patent system is slow and sluggish and costs a lot of money. cDNA is a rapidly growing industry where often small changes in genetic code can create a new and entirely different result from what the genetic code was originally created for. It seems that for these applications, something that offers faster intellectual protection would be more in order. Another argument that is being used across the board, is that cDNA (and DNA in general) can look a lot like computer code. Since computer code was first not copyrightable and now does fall under copyright law, it is argued that cDNA can follow the same path. [4]

This thesis will gather the arguments mentioned above and it will see whether they are convincing or not. Arguments against using copyright for cDNA applications will also be positioned. By weighing these arguments and looking into what a switch in regimes would really bring us, I aim to provide the reader with an answer to the research question. In order to do this, I will first talk about what cDNA is and what it is used for. It is important to know what cDNA is in order to be able to understand the arguments used in favor and against using copyright law for cDNA applications. Subsequently, I will give an overview of patent law and copyright law. By illustrating how both regimes work, I aim to give the reader a more learned opinion as compared to just stating the arguments. After that, I will move on to the arguments that are being positioned in favor of using copyright law for cDNA applications and I will furnish these arguments with my reaction to their merit. In the chapter after that, I will state the counterarguments for using copyright for cDNA applications and I will also furnish them with my reaction. I will then provide the reader with my own idea about what would be the best solution, taking all convincing arguments from both sides in consideration. In the conclusion, I will bundle my assessment of this interesting approach to cDNA copyrightability. Together with my explanation of the nature of patent and copyright law, I will give the reader my thoughts about this idea.

[4] M. A. Lemley, P. S. Menell, R.P. Merges, P. Samuelson and B.W. Carver, *Software & Internet Law*, Wolters Kluwer & Aspen Publishers 2011, p. 34

The reader should know that this thesis does not start out as being predisposed to either position, and only with the arguments positioned and with my own reflections on them shall I reach a conclusion whether or not this idea in the landscape of intellectual property law is indeed a good one.

2 What is cDNA?

We are all familiar with the term "DNA". DNA stands for deoxyribonucleic acid. [5] DNA contains the hereditary information which is vital to make us who we are today. Changes in DNA change us and who we are. The characteristics of us as persons are the result of the DNA that was passed on to us from our parents, generation after generation. After long periods of time and with the help of natural selection and mutation, DNA changes and evolves. This will result in different characteristics in how we look, think and act. Without DNA, we would not exist.

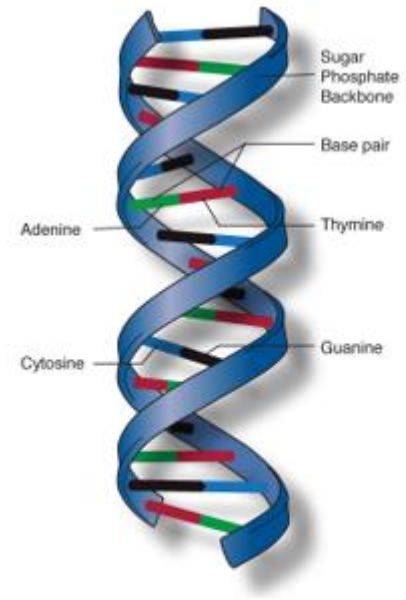
cDNA stands for complementary DNA. Complementary DNA is DNA that is not natural, meaning it cannot be found naturally occurring. However, this does not mean that it is chemical. [6] cDNA is the result of very clever engineering by scientists. To understand what this thesis is about, we need to know a little bit more about what cDNA is and what it is used for. However, given the fact that this is a law thesis, we will try to keep this explanation as brief and concise as possible, because it is very easy to create an information overload when it comes to DNA and biology.

Scientists use DNA because they can use it (among other uses) to create protein building or identifying "machines" which can help with for example locating or destroying certain cells in the body that are not desired. It can also be used to create genetic products like tomatoes or livestock. It is possible to have chickens produce genes and enzymes which they normally do not produce. This can help fight cancer in humans or make sure we get enough

[5] Definition of DNA, Merriam-Webster Dictionary 'DNA', accessible at https://www.merriam-webster.com/dictionary/DNA, accessed 15-08-2017

[6] Definition of cDNA, Merriam-Webster Dictionary 'cDNA', accessible at https://www.merriam-webster.com/dictionary/cDNA, accessed 15-08-2017

vitamins through the enriched eggs or meat.[7] For example, cancerous mutations can be identified with specific man-made DNA strands. To create cDNA, a scientist first takes a piece of normal DNA. This can be any DNA depending on the use case, it does not matter if it is plant, animal or human DNA. DNA is shaped like a double helix, as we can see on the picture.[8]



Structure of the Double Helix [10]

This piece of DNA is then pulled apart to create two halves of a DNA strand. [9] From one of these pulled apart strands a copy is made. This copy is called pre-RNA. We now have our original DNA strand and a copy of one of its halves. This copy is then edited in a machine in order to remove unnecessary parts, so that only the exons remain.

The exons encode proteins and can be used in medical testing. When we are left with this part, we have a strand of RNA. This RNA can

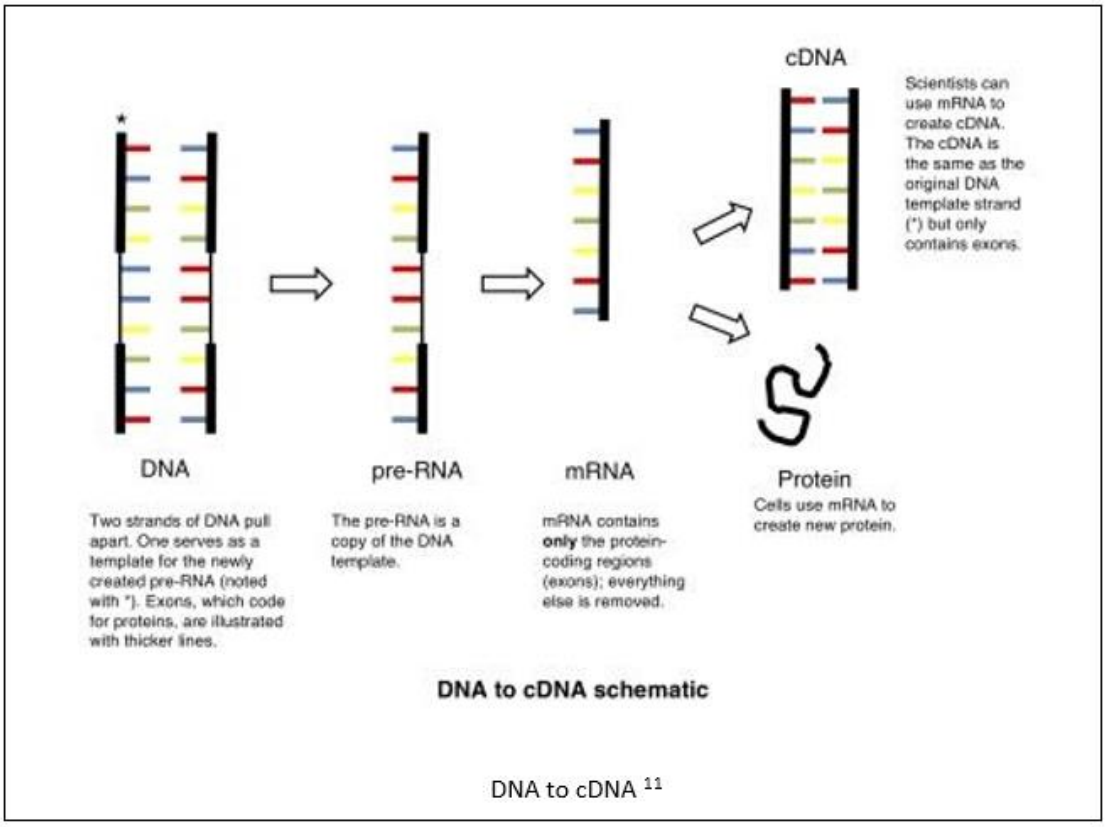
be implemented in a cell that scientists will then use to create the specific proteins we are looking for.

[7] J. Meek, 'Genetic Chickens get DNA copyright tag', *The Guardian* 2000

[8] Structure of the double Helix, GeneED, accessible at https://geneed.nlm.nih.gov/index.php, accessed 01-08-2017

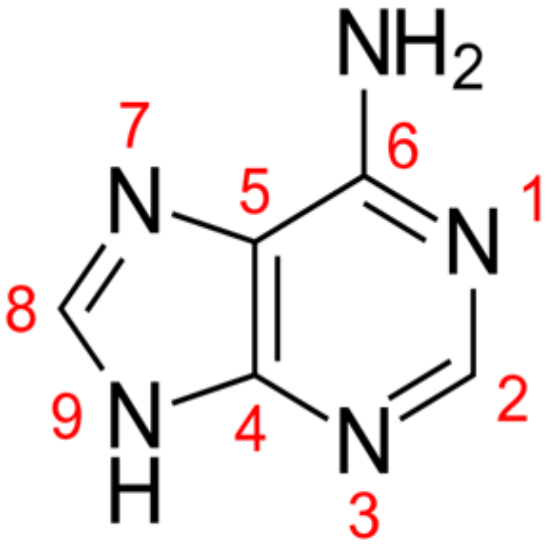
[9] M. Krench, 'New Supreme Court Decision Rules That cDNA Is Patentable What It Means for Research and Genetic Testing', *Scientific American*, 09 July 2013, accessible at https://blogs.scientificamerican.com/guest-blog/new-supreme-court-decision-rules-that-cdna-is-patentablewhat-it-means-for-research-and-genetic-testing/

However, RNA is very unstable and can be lost if it degrades or mutates. What scientists then do, is that they convert it back to DNA. In this state, the RNA is in a stable form and will not degrade. This specific DNA does not occur in the world naturally. We now made RNA that only does what we want it to do: create or help identify certain proteins. Because this DNA is not naturally occurring, we call it complementary DNA. The process can be simplified in a schematic:



DNA to cDNA [11]

For this topic, it is also important to know that DNA and its cDNA counterpart consists of nucleobases. Nucleobases are the basic building blocks that form nucleotides. These can form monomers, that in turn form nucleic acids. Nucleic acids form long chains which form our DNA and cDNA.[10] Nucleobases can be identified as Adenine(A), Cytosine (C), Guanine (G), Thymine (T), and Uracil (U).[11]This is important, because with these identification points we can map out and write down in a molecular formula what a piece of DNA would look like in letters. For example, the nucleobase Adenine looks like this:



Schematic structure of adenine (C5H5N5). [12]

Its molecular formula is "C5H5N5".[12] It is then possible to store this sequence in binary code. The result would be:

"00001001 01000011 00110101 01001000 00110101 01001110 00110101"[13]

These lines of binary code can then be stored on a medium for later synthetization and creation. This will also be important with regards to copyright, but more on this later.

[10] H. Lodish, A, Berk, S. L. Zipursky, P Matsudaira, D. Baltimore, and J. Darnell, *Molecular Cell Biology*, W.H. Freeman & Co Ltd 2000, section 4.1

[11] H. Lodish, A, Berk, S. L. Zipursky, P Matsudaira, D. Baltimore, and J. Darnell, *Molecular Cell Biology*, W.H. Freeman & Co Ltd 2000, section 4.1

[12] Schematic Structure of Adenine (C5H5N5), Research Gate 'Adenine', accessible at https://www.researchgate.net/figure/283577525_fig7_Schematic-structure-of-adenine-C5H5N5, accessed 01-08-2017

[13] Covert Text to Binary, Unit Conversion, accessible at http://www.unit-conversion.info/texttools/convert-text-to-binary/, accessed 03-07-2017

In Europe and in America it is possible to patent cDNA.[14] A company could create or "discover" a certain protein creating or identifying strand of RNA/cDNA and use it to see whether a patient has a decease or runs a high risk of contracting a certain disease. Discover is between quotation marks, because it is not possible to take a sample of human DNA, discovering all of the genes and pieces of DNA, and then simply applying for a patent on them. You cannot "own" a piece of another human. However, this is what Myriad Genetics did in a nutshell in the 90's.[15] The company identified human genes that have a high risk to mutate into breast or ovarian cancer. Subsequently, it tried to apply for a patent to patent their discovery from which they created a test to help identify the risk of developing breast cancer or ovarian cancer. In the Supreme Court's decision in Myriad Genetics, it was affirmed that patenting human genes is not possible or allowed. According to the court, these genes cannot be patented because they occur in nature and "natural phenomena" are not patentable.[16] While Myriad was denied the patent, and lost a major lawsuit, in the verdict it was made clear that cDNA can indeed be patented. The reasoning behind this is that cDNA is in fact not a natural phenomenon and if indeed manmade, with a purpose, it could be seen as an invention. And inventions are patentable.
In the European Union the Biotech directive states that in some circumstances naturally occurring isolated elements are in facet patentable. This is only the case if there is a specific use case for the isolated gene and it sufficiently isolated to do a certain task. This however does not mean that a company now 'owns' a part of your body.[17]

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[14] P. Lee, 'The Supreme Court's Myrias Effects on Scientific Research: Definitional Fluidity and the Legal Construction of Nature', *Irvine Law Review* (5) 2015, issue 5, p. 1099;
Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998, on the legal protection of biological inventions, article 5

[15] M.A. Bedau and E.C. Park, *The Ethics of Protocells – Moral and Social Implications of Creating Life in the Laboratory*, the MIT Press 2009

[16] Association for Molecular Pathology vs. Myriad Genetics Inc. 569 US 201, Supreme Court of the United States 2013

[17] Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998, on the legal protection of biological inventions, article 5;
Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998, on the legal protection of biological inventions, recital 17

The Myriad genetics case was a very important ruling by the Supreme Court, because if a company could patent a naturally occurring gene collection (more importantly a naturally occurring gene collection that *helps identify the risk of a disease*) then it could have tremendous adverse effects on mankind. For example, other companies cannot start using this important gene to start research into other maybe cheaper means to identify this gene. In the end, a company could have a monopoly on the treatment of a certain decease. This could artificially inflate the price of treatment. Not a crazy idea, because the test that Myriad developed already costs more than $3000.[18]

Now that we have a basic understanding of cDNA and the applications it can be used in, we go further and explore how patent law works.

Take away messages:

1. DNA is vital to all life that we currently know.
2. Scientist can create edited DNA or complementary DNA called cDNA.
3. This cDNA can be used to identify diseases in people, or to create organisms with special abilities.
4. cDNA can be patented just like other inventions. This was confirmed in the Myriad case in the American Supreme Court.
5. Patenting naturally occurring DNA is not possible, except in Europe if the natural element of the human gene is sufficiently isolated and has a specific application.

[18] K.E. Noonan, 'A perspective on the cost of the Myriad BRCA Gene Test', Biotech & Pharma Patent Law & News Blog, 02 May 2013, accessible at http://www.patentdocs.org/2013/05/a-perspective-on-the-cost-of-the-myriad-brca-gene-test.html, accessed 08-07-2017

3 Patent law

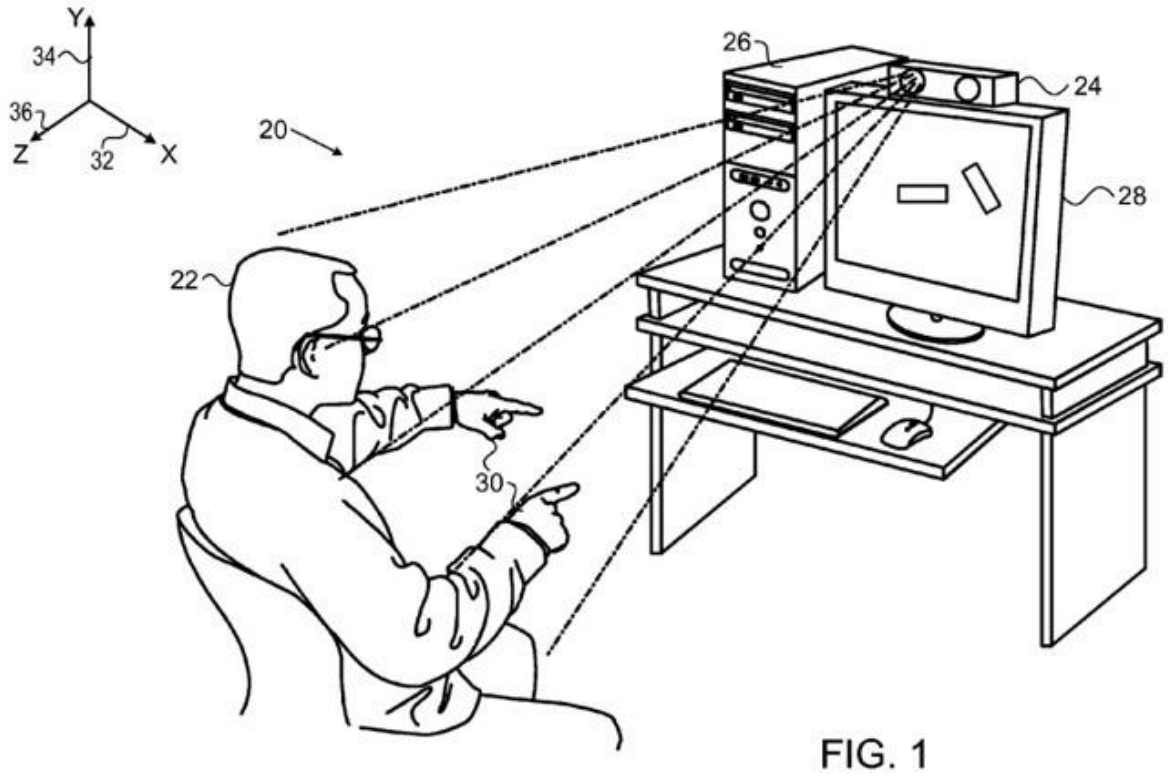
3.1 Introduction

Patents are a concept that most people have heard of one time or another. In this day and age, it will usually have been in a headline like *"Samsung sues Apple over X-patent" "Google to acquire Motorola for patent portfolio"* or *"Kodak only still worth something because of its large patent portfolio".*[19] This has everything to do with the way patents have been developing throughout its existence and the way our market is becoming more and more global. Patents are granted to reward inventions that we as a society can use. The inventor or the company for which the inventor works, produces a product or feature that can be used on a product, that we (the consumers or buyers) find desirable or need: A mobile phone with an extra small bezel or an effective medicine against an illness. With a granted patent, the patentee then enjoys a limited time (in most regimes 20 years) of exclusive protection. Patents can be seen as a form of property rights, and give the owner of the patent the subsequent protection and means to defend these rights in court. This means that only the patentee can create and sell the product. People are allowed to use it and to sell it after they are done, but they cannot create it themselves and subsequently sell it at a 20% discount. Now why would society grand such an exclusive right? The idea is twofold. On the one hand, we want to incentivize inventors for creating products and solutions that we as a society want. By grating an exclusive period of protection, the inventor can earn his investment back and make a profit. The benefit to people is that more inventions will be made to benefit mankind as a whole. On the other hand, after we have granted the exclusive period and it's over, the product enters the public domain and everyone can make the product. This will lead to possible cheaper prices and greater availability. A good example of this is paracetamol. The patent for paracetamol expired in 2007 and since that time various generic drugs are made, lowering the cost of a tablet of paracetamol as far down as $0.004.[20]

[19] Headlines are fictive

[20] K.B.Thakker & G.Billa, 'The concept of: Generic drugs and patented drugs vs brand name drugs and non-proprietary (generic) name drugs', *Frontiers in Pharmacology* (4) 2013, issue 113

But patent law has also changed since the idea of patents was conceived. For one, it used to be the case that a single product would get a single patent as a whole. Now a product can have hundreds or even thousands of patents protecting its intellectual property. This is especially true for the ICT industry. Apple for example registered 1937 US patents in 2015 as per the US Patent and Trademark office.[21]



A 3D interface patent grated to Apple [22]

One could ask whether patent law has not become too sluggish and large to fulfill its original goal, but there seems to be no indication that patent law is no longer promoting but

[21] US Patent and Trade Mark Office, Apple patent registrations 2015, accessible at https://www.uspto.gov/web/offices/ac/ido/oeip/taf/topo_15.htm accesed 10-07-2017

[22] M.Wuerthele, 'Apple awarded pair of 3D user interface patents related to comuter vision', Apple Insider, 16 August 2016, accessible at http://appleinsider.com/articles/16/08/16/apple-awarded-pair-of-3d-user-interface-patents-related-to-computer-vision, accessed 10-07-2017

obstructing innovation. Another change considers the areas of patents that can be covered by a patent. Now patents are available not only for machines and technical inventions, but also for inventions in Biotechnology like cDNA, medicine and inventions to help with surgery and medical procedures.

With patents becoming so widespread in use and large in numbers, other problems do come around the corner. With the global market that we now have, products could be sold across the globe, creating the biggest possible market yet. A patent could be so important that without it a product could not exist. There are now companies that exist solely on paper, which have come into possession of certain patents and which pursue the only goal of suing other companies to receive large sums of money as compensation. They do not innovate and they do not produce anything. The sole purpose is a steady stream of income from IP. This is giving rise to voices that say that patent law should change to prevent these practices from happening. While interesting and an important aspect of patent law, this will be too extensive to go into now.

3.2 Patent law in the European Union

3.2.1 Unitary Patent Package

Patents in the European Union are not yet as harmonized as they could and maybe should be. The idea of a unitary patent system with one easy system for the entire European Union from application to appeal, which is valid in all member states (the Unitary Patent Package), still has its wheels stuck in the proverbial mud.[23]

The treaty is now being propelled by the European Unions enhanced cooperation procedure.[24] This allows member states to cooperate on a certain topic (for example patent law) without all the member states joining in on the procedure. Mainly Spain and Italy did not want to participate because of the languages that were chosen as official languages for the

[23] Regulation 1257/2012 of the European Parliament and of the Council of 17 December 2012, implementing enhanced cooperation in the area of the creation of unitary patent protection

[24] The Treaty on the Functioning of the European Union, C326/47, 2012, Article 326-334

unitary patent system (English, French and German). The Court of Justice of the European Union also voiced concerns about the draft agreement, stating that it would not be in compliance with European Union law at this time.[25] Although the enhanced cooperation treaty continued, the latest news is that the German Constitutional Court has halted ratification into German law. [26]

3.2.2 The current European Patent law system

The European Patent Organization (EPO.org) is administrating the European patent system.[27] The European Patent system is covered by the national law of all respective European Member states and the European Patent Convention.[28] All member states of the European Union are a party to the EPC and also other non-member states can ascend to the EPC, currently 11 parties are not a member of the European Union.[29]

The EPO consists of two bodies. The first one is the administrative council which is filled with representatives from all member states which are a party to the European Patent Convention. The second one is the European Patent Organization (EPO). The EPO receives and carries out patent applications and examines them for their validity, it also grant the patent or rejects it.

The European Patent Convention did not create the one size fits all, unitary patent system that the Unitary Patent Package tries to achieve, but it does have its effect. Member states will in general try to be in compliance with the EPC when making changes and amendments to their own national patent law.

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[25] Court of Justice of the European Union, 'The draft agreement on the creation of a European and Community Patent Court is not compatible with European Union Law', 2011

[26] 'Karlsruhe stops EU Patent Court, Federal President is not to draft a bill', *Frankfurt Allgemeine*, June 12th 2017

[27] European Patent Office, 'About us', accessible at http://www.epo.org/about-us.html, accessed 08-07-2017

[28] Convention on the Grant of European Patents (European Patent Convention) 16th edition, 2016

[29] Convention on the Grant of European Patents (European Patent Convention) 16th edition, 2016

3.2.3 Substantive requirements

All patents must fulfill the substantive requirements laid down in the EPC. The requirements here are roughly the same across member states as well as in the United States, and can be seen as the universal requirements to attain a patent.

Patentable invention, article 52 EPC:

The patent has to fall under the scope of the patentable invention article of the EPC. Discoveries, scientific theories, mathematical methods, aesthetic creations, schemes, rules, methods for performing mental acts, playing games or doing business, and programs for computers are excluded.

Excluded from patentability all together, article 53 EPC:

Inventions which commercial exploitation go against the *odre public* or morality. Plant or animal varieties or essentially biological processes for the production of plants or animals, with the exception of microbiological processes and the production thereof. Also excluded are methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body, with the exception of products, in particular substances or compositions, for use in any of these methods.

Novelty, article 54:

An invention has to be new, meaning it does not form part of the state of the art at the time of application. The state of the art is everything made available to the public by means of a written or oral description, by use or in any other way, before the date of filing of the European patent application.

Inventive step, Article 56:

An invention has to include an inventive step. This means that an invention cannot be obvious to another person that is skilled in the art (a professional). It has to be a true invention that does not just stem from the logical application of an object.

Industrial application, article 57:

The invention has to be susceptible of industrial application, meaning there should be a use for it. This can be in any kind of industry, including agriculture. If there is no practical use for the invention, protection cannot be given. This is logical because the invention does then not add anything to the the public body of human knowledge.

We can state that the requirements for a patent are (in a nutshell) as follows:

1: It has to be patentable subject matter and not be excluded
2: It has to be new (an invention)
3: It has to include an inventive step (something someone else did not think of yet)
4: It has to have a use case (no protection for useless products)

European Patent applications that follow these requirements must then go to the EPO. It must then follow the specific guidelines that are laid down in the convention. Article 78 states the requirements of an application to the EPO: [30]

1. A request for the grand of a European Patent.
2. A description of the invention
3. One or more claims
4. Any drawings referred to in the description or the claims
5. An abstract

The application can be filed in three languages: German, English and French. If the invention is written in another language, it has to be translated to one of the aforementioned languages.
The claims of the application are the most important part of the application. They specify where the protection of the invention is wanted and what must be protected specifically. The protection of the patent application can only extend so far as the claim that is being made. This

[30] Convention on the Grant of European Patents (European Patent Convention) 16th edition, 2016, article 78

is important because if something is not claimed, it is not protected. If something is claimed in way too broad a statement, it can also not be protected.

Filing for an application means that the invention is disclosed. Whatever is claimed (solving a problem that is found for example) must then be able to be reproduced by a skilled person (a professional that knows what he is doing and is an expert in his field). This is a fictive concept, but it illustrates that the invention must be made available to the public in a way that the public can eventually understand and use it.

When the application is filed and all the formal requirements are met, the filing date is established. The filing of the patent is one of the most important aspects of a patent claim. It is up to this date, that the EPO will ascertain the state of the art (meaning the public knowledge that is available about the invention and the particular way this invention solves a problem). With this assessment, it is determined whether the invention is indeed a new invention, and whether or not protection can be given. The EPO will conduct a search for prior art that may invalidate the patent claim. The EPO will then also inform the applicant with a preliminary ruling stating whether all requirements were met and what the search results were. It is possible to withdraw the application or amend the application so that it meets the requirements.

When the application is finally filed, it is no longer possible to make amendments, this makes the correct filing really important, because an application cannot be withdrawn without the already written knowledge becoming state of the art (becoming public knowledge).

After this period, the application is filed on the website of the EPO. It will not be published if the application was refused or withdrawn before this filing. This way the inventor can still keep his invention a secret and file again. After the application is filed and published on the website, the inventor has to make a request for the substantive review of his invention. If he does not do this within six months, the application is rejected. In the substantive review the technical requirements of the invention are examined (novel, inventive step enz.) If these and all the other formal requirements are in order (language, fees). then the patent is issued for the member states where protection was sought and the full patent is published in the European Patent Bulletin.

When the patent is published, other companies and individuals can take notice of the invention and can apply for an appeal procedure. This can happen within nine months of the granting of the patent.[31] The grounds for an appeal can be one of the following claims:[32]

1. The subject-matter is not patentable
2. The patent does not adequately disclose the invention
3. The patent subject matter extends beyond the content of the application as filed

It is also possible for the inventor to limit its own claim of what is to be protected. A reduction of the protection sought in the claim could be beneficial if the protection that is granted does in the end not match up with the prior art. If a part of the granted claim is already in the prior art, the invention is not patentable and can be challenged. By reducing the claim, the invention could possibly remain protected.[33]

If the patent is not successfully challenged, the patent or bundle national patents has to be validated and registered in the different member states that are a party to the EPC. In some cases, this means that it is required that the patent is translated to the member states official language.

The protection that the patent grants is 20 years from the date of filing of the application.[34] The European patent then gives the same level of protection that an applicant would get if he would have filed for a patent only in a specific member state.

[31] Convention on the Grant of European Patents (European Patent Convention) 16th edition, 2016, Article 99 and 115

[32] Convention on the Grant of European Patents (European Patent Convention) 16th edition, 2016, Article 100 sub A, B and C

[33] Convention on the Grant of European Patents (European Patent Convention) 16th edition, 2016, Article 105a (1)

[34] Convention on the Grant of European Patents (European Patent Convention) 16th edition, 2016, Article 63

3.2.4 Biotechnology in specific, the Biotechnology Directive

Biotechnology and its patents are protected under a special regime, the Biotechnology Directive (98/44/EC).[35] The Biotechnology Directive adds to the EPC by illustrating what can be patented and what cannot be patented in the area of biotechnology. The directive serves a clarification purpose and is a *lex specialis* add-on to the EPC. This means that the same basic rules as with regular non-biotechnology patents apply.

The reason that the European Commission chose to address biological patents in a special directive is stated in recital 2 and 3. Recital 2 states that the investment and risk in the field of biotechnology are very high and therefore an adequate legal regime should be put in place. Recital 3 states specifically that harmonized protection is essential to maintain and encourage investments in this field. It is easy to understand that Europe wants to be competitive and leading in the field of Biotechnology, and this directive is here to facilitate this.

Article 3 (1) of the directive describes what is patentable in the biotechnology field. This matches the EPC articles: inventions should be new, they should involve an inventive step and they should be susceptible to industrial application. Article 3 (2) adds that even biological material that is already found in nature can be patentable, but this applies only if the other requirements are met. This most importantly concerns the requirement of industrial application. So, an isolated gene has to be able to solve an existing problem and have industrial application. It is not possible to identify and isolate a gene and just patent it because you are the first to isolate it.

Article 4(1)A excludes plant and animal varieties as a whole, and sub b excludes essentially biological processes for the production of plants and animals. However, if the invention is not confined to just *one* animal of plant variety, it may constitute a patentable invention. This is stated in article 4 (2).

[35] Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions

Article 5 (1) states that the human body at various stages of its formation and development cannot constitute a patentable invention. But an isolated element from the human body including gene sequences can be patented. But here the industrial application has to apply as well. The mere patenting of parts of life itself is not possible, it states in article 5(2) and (3). The reason that patenting isolated elements is allowed is stated in recital 17 of the directive: the current level of disease treatment that is possible is possible in part to medicines that are actually developed from elements isolated from the human body. These elements are already being used by the public and are shown to be beneficial, and this is something that should be encouraged by the patent system.[36]

Ethical considerations and questions that might arise are addressed in article 6. Article 6 states that patents shall be considered unpatentable (in line with article 53(a) EPC) if they go against the *odre public*. It forbids processes for cloning human beings (a), processes for modifying the germ line genetic identity of human beings (b), industrial and commercial use of human embryos (c) and modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal or animals that will result from this process (d).

The scope of protection of a biological patent is illustrated in article 8 (sub 1). It states that the scope of protection that results from the patent extends to any biological material derived from the biological material through propagation or multiplication which is in identical form and has the same characteristics.

For biotechnological processes that produce biological material, the protection shall extend to the material that is being produced by the process, (sub 2). Article 9 continues and states that products or materials in which the biological material that is protected is in cooperated will also enjoy patent protection.

Article 10 limits the protection for biological materials where the subsequent multiplication or propagation is the result of the intended application of the product, and where the material is not being used to propagate or multiply itself for that purpose alone. An example could be that you receive a treatment and the biological material that is being used to treat you will continue to be present in your body, propagating itself. That on its own would

[36] Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biological inventions, recital 17

not be an infringement. Even though the material is still there, your body is using it and it is multiplying itself. An infringement would only exist if you would then take the materials that are being produced and would use them for another purpose, like making a treatment for someone else.

Take away messages:

1. Patents give limited exclusivity to the inventor to earn back the investment that he has made to discover the invention and to solve an existing problem.
2. Without this reward, inventors might not solve existing problems. The investment and the un sure return on investment would be to risky.
3. This system is a tradeoff between the inventor and society. We as mankind give the patent right in exchange for knowledge of the invention. After 20 years the invention enters the public domain and everyone can make it and use it. This way the body of freely existing knowledge grows with the years. The goal is to further mankind as a whole.
4. There are substantive requirements for a patent. Namely it has to be patentable subject matter, it has to be new (novel), it has to involve an inventive step (solve a real problem), and be susceptible to industrial application (have a real use case).
5. cDNA applications are patentable in Europe and have a *lex specialis* directive, namely the Biotech Directive.
6. The European Union is working hard to harmonize patent law across the member states. When the Unitary Patent treaty is in full force it will be easier to apply for a European Union Wide patent in one go and have one centralized patent court. This will spur innovation because when someone can obtain a standardized European Patent in one go, the potential profit will presumably also be higher.

4 Copyright law

4.1 Introduction

Just like patent law, copyright law is not completely harmonized in the European Union. Copyright law is harmonized even to a lesser degree than patent law. The legislation that is adopted by the European Union mainly consists of a number of directives aimed at harmonization of the current national copyright laws that are also in effect. These directives are further explained by court decisions before the Court of Justice. It is therefore still based upon the principle of territoriality.[37] It is not the case that the European Union could not create a community wide copyright, because it has these powers under article 118 of the Treaty on the Functioning of the European Union.[38] In this case it is choosing not to pursue this aim right now. It is said that *'Community legislation should be restricted to what is needed to carry out the tasks of the community. Many issues of copyright law do not need to be subject of action at Community level'.*[39] Copyright also needs less formalities, and for that reason less mechanisms are needed. That being said, directives do provide for a minimum and maximum level of protection. A member state cannot go outside these boundaries.[40]

Copyright protects original works in literature, art and for example computer code.[41] These can be written documents, music, or visual works, but as a rule can protect all creations of the mind. Copyright is a right that is given to the creator from the moment that his creation has left his mind and has materialized outside the mind, like a story written on a piece of paper. This happens instantly and for the creator to have copyright over his work, no registration or approval is required. This is very different from patent law, where the invention has to be

[37] A. Kur and T. Dreier, *European Intellectual Property Law, Text, Cases and Materials*, Edward Elgar Publishing 2013, p. 243

[38] The Treaty on the Functioning of the European Union, C326/47, 2012, article 118

[39] European Commission, 'Greenpaper on Copyright and the Challenge of Technology', Copyright issues requiring immediate action, June 7th 1988, paragraph 1.4.9

[40] A. Kur and T. Dreier, *European Intellectual Property Law, Text, Cases and Materials*, Edward Elgar Publishing 2013, p. 245

[41] A. Kur and T. Dreier, *European Intellectual Property Law, Text, Cases and Materials*, Edward Elgar Publishing 2013, p. 241

registered and approved, else there is no protection. However, just like patent law, the term of protection is not forever.

Copyright protection protects the artistic work for 70 years after the death of the original author.[42] This is still much longer than patent law. The reason for copyright work can be explained as a moral and economic right that the author of the work has. It is the fruit of the labor that was performed and therefore the author has this property right over his work and should be allowed to exploit it.

For the purpose of this thesis, it is not important to discuss all the directives that govern copyright. Neighboring and preforming rights for example are also a part of copyright, but have no importance for this thesis. I will therefore make a short summary of the important directives and what is protected in the European Union and how. With this, we will have a broad understanding of what the playing field of copyright looks like, which we can later use and apply to the research question.

4.2 Most important directives relating to copyright law in the European Union

1. Directive 2009/24/EC (originally 91/250/EC) on the legal protection of computer programs: Computer Programs Directive.[43]

Computer programs are protected under copyright. It was found that the expression that the developer of the program made, was an artistic expression. This means that the computer program itself is protected but not the idea of the program. Protection for computer programs was deemed necessary because computer code can easily be copied and recreated. At first a sui generis system of protection was proposed but this idea was abounded by WIPO in 1985.[44]

[42] Directive 2006/116/EC, of the European Parliament and of the Council of 12 December 2006, on the term of protection of copyright and certain related rights, article 1

[43] Directive 2009/24/EC of the European Parliament and of the Council of 23 of April 2009 on the legal protection of computer programs

[44] A. Kur and T. Dreier, *European Intellectual Property Law, Text, Cases and Materials*, Edward Elgar Publishing 2013, p. 250

2. Directive 2006/115/EC (originally 92/100/EEC) on rental right and lending right and on certain rights related to copyright in the field of intellectual property: Rental and Lending Right Directive.[45]

This directive gives authors of copyrighted work and also people that hold neighboring rights, the exclusive right to control whether or not their work can be loaned out to other people. It was found that renting could give the person that is renting the work an economic benefit.[46] This implies that the author in this case should be enumerated. Lending, meaning giving on loan for a limited amount of time but not for economic benefit, is also a right that the author has and can control.[47]

3. Directive 2006/116/EC (originally 93/98/EEC) on the term protection of copyright and certain related rights: Term Directive.[48]

   and

   Directive 2011/77/EU amending the above directive. On the term of protection of copyright and certain related rights.[49]

The term directive harmonizes the term that copyright protection can be claimed in the European Union. This is important because before the creation of this directive, problems were stating to arise due to the European Union's free internal market. An example was the EMI

[45] Directive 2006/115/EC, of the European Parliament and of the Council of 12 December 2006, on rental right and lending right and on certain rights related to copyright in the field of intellectual property

[46] Directive 2006/115/EC, of the European Parliament and of the Council of 12 December 2006, on rental right and lending right and on certain rights related to copyright in the field of intellectual property, Article 2 (1) (a)

[47] A. Kur and T. Dreier, *European Intellectual Property Law, Text, Cases and Materials*, Edward Elgar Publishing 2013, p. 255

[48] Directive 2006/116/EC of the European Parliament and of the Council of 12 December 2006 on the term of protection of copyright and certain related rights

[49] Directive 2011/77/EU, of the European Parliament and of the Council of 27 September 2011, amending 2006/116/EC on the term of protection of copyright and certain related rights

Electrola v Patricia case[50]. Here music that had lost its copyright protection in Denmark, was imported to Germany were there was still copyright. In this case Germany had a longer copyright term than Denmark. This situation was unwanted so a new term of 70 years instead of the more standard 50 years was established. This term was found to be sufficient, because the protection was to last two generations, and people were generally getting older. It was also easier to implement because this would mean that works that were residing in a territory that had 50+ years of protection would not have to be transitioned to suddenly becoming loyalty free.[51]

4. Directive 96/6/EC on the legal protection of databases: Database Directive

The database directive protects databases which contain collections of literary works. The reason they receive this right is because the selection and/or arrangement of their contents constitute an intellectual creation on its own.[52] The database directive is a *sui generis* right, aimed to protect the economic and intellectual investment that was made compiling the database in the state it is now.[53] An example would be an encyclopedia or an anthology. To have the database, it is not required to be the copyright holder of the works inside the database, we are talking solely about the arrangement. Nevertheless, if you have the copyright, the work inside as well as the database itself are protected by copyright law.

5. Directive 2001/29/EC on the harmonization of certain aspects of copyright and related rights in the information society: Information Society Directive also know as InfoSoc.[54]

[50] ECJ 341/87 EMI Electrola v Patrica 1989

[51] T. Dreier, B Hugenholtz and D. Visser, *Concise European Copyright Law*, Kluwer Law International 2014, p. 287-288

[52] Directive 96/9/EC of the European Parliament and of the Council of 11 March 1996, on the legal protection of Databases, Article 3 (1)

[53] A. Kur and T. Dreier, *European Intellectual Property Law*, Text, Cases and Materials, Edward Elgar Publishing 2013, p. 266

[54] Directive 2001/29/EC, of the European Parliament and of the Council of 22 May 2001, on the harmonization of certain aspects of copyright and related rights in the information society

The InfoSoc directive is an attempt at horizontal harmonization. Whereas previous directives have been very specific in nature, the InfoSoc directive tries to harmonize most general notions of copyright protection (reproduction rights, distribution rights, communication to the public). Although this has proven hard, member states were hard-pressed to conform to a harmonizing effort and because of local exemptions and because of the fact that the InfoSoc directive is filled *with "member states may provide for an exception"* phrases.[55] A special problem is the possibility of making private copies of works, for example a DVD. The InfoSoc directive only states that authors should receive "fair compensation" for copying, but does not go into specifics.[56]

6. Directive 2004/48/EC on the enforcement of intellectual property rights: The enforcement directive

The enforcement directive is a directive that does not deal with IP rights in themselves, but handles the enforcement of them effectively. The directive aims to ensure that IP rights holders can start procedures which are not *"unnecessarily complicated or costly, or entail unreasonable time-limits or unwarranted delays"*[57] The directive asks member states to imply *"effective, proportionate and dissuasive procedures and measures"* to ensure that IP rights holders are protected.[58] One of the ways the enforcement directive protects rights holders is the possibility to apply for injunctions against rights abusers for imminent infringement.

4.3 Most important rights copyright holders have under European Union law

[55] A. Kur and T. Dreier, *European Intellectual Property Law, Text, Cases and Materials*, Edward Elgar Publishing 2013, p. 271

[56] Directive 2001/29/EC, of the European Parliament and of the Council of 22 May 2001, on the harmonization of certain aspects of copyright and related rights in the information society, recital 35

[57] Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004, on the enforcement of intellectual property rights, article 3(1)

[58] Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004, on the enforcement of intellectual property rights, article 3(2)

- Reproductive Rights: Authors have the exclusive right to prohibit direct of indirect, temporary or permanent reproduction by any means and in any form, in whole or in part.[59]

- Communication Rights: Authors have the exclusive right to authorize or prohibit any communication to the public of their works in such a way that members of the public may access them.[60]

- Broadcasting Rights: Authors have the exclusive right to authorize or prohibit the broadcasting by wireless means and the communication to the public of their performances, except where the performance is itself already a broadcast performance or is made from a fixation.[61]

- Distribution Rights: Authors have the exclusive right to make available or prohibit distribution to the public of their works.[62]

- Fixation Rights: Authors have the exclusive right to authorize or prohibit the fixation of their work.[63]

[59] Directive 2001/29/EC, of the European Parliament and of the Council of 22 May 2001, on the harmonization of certain aspects of copyright and related rights in the information society, article 2

[60] Directive 2001/29/EC, of the European Parliament and of the Council of 22 May 2001, on the harmonization of certain aspects of copyright and related rights in the information society, article 3

[61] Directive 2001/29/EC, of the European Parliament and of the Council of 22 May 2001, on the harmonization of certain aspects of copyright and related rights in the information society, article 2(e); article 8

[62] Directive 2006/115/EC, of the European Parliament and of the Council of 12 December 2006, on rental right and lending right and on certain rights related to copyright in the field of intellectual property, article 9; article 4

[63] Directive 2006/115/EC, of the European Parliament and of the Council of 12 December 2006, on rental right and lending right and on certain rights related to copyright in the field of intellectual property, article 7; article 2

- **Rental Rights:** Authors who transfer their work from an original to a copy and rent it out, will receive equitable remuneration for the rental.[64]

- **Enforcements rights:** Authors shall have to their disposal, measures, procedures and remedies necessary to ensure the enforcement of the intellectual property rights under the Enforcement Directive.[65]

Take away messages:

1. Copyright law is harmonized to an even lesser standard than patent law in the European Union, but there is minimum and maximum harmonization.
2. Copyright protects creations of the mind, these can be literary works, art or even computer programs.
3. There are not much formal requirements to copyright, when they work is created and put on a tangible medium the creator can exercise his or her copyright.
4. Computer programs have their own directive in the European Union
5. There is a very strict enforcement directive that can be used by copyright holders in the event of copyright infringement.
6. The most important copyrights for cDNA applications would be reproductive rights, distribution rights and enforcement rights.

[64] Directive 2006/115/EC, of the European Parliament and of the Council of 12 December 2006, on rental right and lending right and on certain rights related to copyright in the field of intellectual property, article 5

[65] Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004, on the enforcement of intellectual property rights, article 3(1)

5 Arguments in favor of using copyright for cDNA Patent applications and a response to them

5.1 Introduction

We will now discuss the biggest arguments in favor of using copyright for cDNA patent applications. After the argument, I will analyze the arguments and provide a short response.

5.2 The biggest arguments in the field of copyrightable engineered DNA

5.2.1 There is a striking similarity between computer code and engineered DNA

Computer code and engineered DNA are similar in resemblance. DNA consists of five base types, like we have read before. Adenine, Guanine, Cytosine, Thymine and Uracil, AGCTU. Computer code consist of one's and zero's. It can be said that they consist of two base types. An interesting fact is that the human body's genome was sequenced by the Human Genome Project in 2003 after years of research.[66] Our complete genome is about 700MB to one gigabyte if we are just talking about the genetic code. [67] If we open this file we would see text that is very familiar to this:

"AGCCCCTCAGGAGTCCGGCCACATGGAAACTCCTCATTCCGGAGGTCAGTCAGATTTACCCTGGCTC
ACCTTGGCGTCGCGTCCGGCGGCAAACTAAGAACACGTCGTCTAAATGACTTCTTAAAGTAGAATAG
CGTGTTCTCTCCTTCCAGCCTCCGAAAAACTCGGACCAAAGATCAGGCTTGTCCGTTCTTCGCTAGTG
ATGAGACTGCGCCTCTGTTCGTACAACCAATTTAGGTGAGTTCAAACTTCAGGGTCCAGAGGCTGATA
ATCTACTTACCCAAACATAG"

[66] All about the Human Genome Project (HGP), National Humane Genome Research Institute, accessible at https://www.genome.gov/10001772/all-about-the--human-genome-project-hgp/, accessed 10-07-2017

[67] R.J. Robison, 'How big is the human genome, in megabytes, not base pairs', accessible at https://medium.com/precision-medicine/how-big-is-the-human-genome-e90caa3409b0, accessed 02-08-2017

If we then take a look at translating that to binary code, which is the code that makes our computers work after being translated from source code, a part of the genetic code above would look like this:

"01000001 01000111 01000011 01000011 01000011 01000011 01010100 01000011 01000001 01000111 01000111 01000001 01000111 01010100 01000011 01000011 01000111 01000111 01000011 01000011 01000001 01000011 01000001 01010100 01000111 01000111 01000001 01000001 01000001 01000011 01010100 01000011 01000011 01010100 01000011 01000001 01010100 01010100 01000011 01000011 01000111 01000111 01000001 01000111 01000111 01010100 01000011 01000001 01000111 01010100 01000011 01000001 01000111 01000001 01010100 01010100 01010100 01000001 01000011 01000011 01000011 01010100 01000111 01000111 01000011 01010100 01000011 01000001 01000011 01000011"

The argument is therefore largely based upon analogy. Now one could say that the genetic code consists of letters and binary consists of numbers but everything can be brought down to numbers. Just like we input the genetic code and converted it to binary. Even this paper can be brought back to binary code when it is stored on a medium, like a flash drive. The main argument being made here, is that the DNA sequence and computer software/binary functions are similar. The idea of the software on your computer is to communicate with the computer, and to create the desired output that was asked for in the code. A line of code will translate into something useful happening on the computer. The same can be said in favor of DNA. DNA consists of instructions for the systems in your body to do something, for example create a protein. A biological machine is instructed by DNA and an engineered machine is instructed by code.

Another similarity is in recreating the work (or in this case cDNA). Just like a literary work, cDNA can be quickly copied and multiplied. The copies of each original are identical to the first work or strand of cDNA and can be used again. The term computer virus illustrates the

quick method to which a malicious computer program can duplicate and multiply itself, another clear analogy to a biological virus.[68]

The fact that computer code can now directly influence DNA in microorganisms is making things even more blurry. With standardized biological bricks (or modules) a computer program can insert these modules in living micro-organisms, changing the microorganism's DNA. In this way, a computer program is directly responsible for DNA code.[69]

Computer code, already being copyrightable and DNA being very similar to computer code, the argument is as follows. cDNA has many similarities with computer code, so it should be treated the same. Chris Holman continues and states that when making the decision whether computer code should indeed be copyrightable, law makers and the judiciary in the United Stated relied heavily on the analogy between traditional literary works and computer code to come to this decision.[70] Ultimately because the courts and legislators have already "grappled with and to a large extend resolved" the issue of copyrightable computer code, this will fundamentally aid in the adoption of copyright for cDNA.[71] With this argument, the writer illustrated that the legal hurdles of implementing copyright in cDNA are basically already tackled. And indeed, since the 1980's computer code is copyrightable and does not have its own sui generis system.[72]

How good is this argument? I believe that this argument is indeed convincing. Computer code and cDNA have large similarities and overlaps. The strongest aspect of this argument is that they both can be put onto a tangible medium as a list of instructions, and this list of instruction can then be used to produce a beforehand intended result. If you change a few lines in the computer code, the computer program will no longer work. To make it work

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[68] C.M. Holman, 'Copyright for Engineered DNA: An Idea Whose Time Has Come?', *West Virginia Law Review* (113) 2011, p. 715

[69] M.A. Bedau and E.C. Park, *The Ethics of Protocells – Moral and Social Implications of Creating Life in the Laboratory*, the MIT Press 2009, p. 169

[70] C.M. Holman, 'Copyright for Engineered DNA: An Idea Whose Time Has Come?', *West Virginia Law Review* (113) 2011, p. 711

[71] C.M. Holman, 'Copyright for Engineered DNA: An Idea Whose Time Has Come?', *West Virginia Law Review* (113) 2011, p. 714

[72] Copyright Protection of Software, World Intellectual Property Organisation, accessible at http://www.wipo.int/copyright/en/activities/software.html, accessed 20-08-2017

you need the exact code. For piracy and copy protection, copyright is a great system. If you have the working code or software, you have to show that you have a license, else there is no legal way you could have obtained the program.

In the European Union, a special computer software directive is in place to protect software creations from (among others) piracy. Piracy with software can be done relatively easily. In its most rudimentary form, software is just copied and subsequently pasted to the computer of someone else who does not hold a license to operate the software. This is one of the reasons why the software directive is in place. The European Union saw the importance of this and reiterates in recital 2 of the directive:

"The development of computer programs requires the investment of considerable human, technical and financial resources while computer programs can be copied at a fraction of the cost needed to develop them independently."[73]

It further states the importance of software to the European Union's industrial development in recital 3:

"Computer programs are playing an increasingly important role in a broad range of industries and computer program technology can accordingly be considered as being of fundamental importance for the Community's industrial development."[74]

The same logic can be applied to engineered DNA. Engineered DNA, when fixated on a digital medium, can be copied and pasted without doing any research. The ease of with which this can be done should not only warrant patent protection, but arguably also copyright protection. This would also make it easier to track down and locate infringers. After all, if the infringer is using the code and does not have a license, he is in violation. This would provide for an effective protection of intellectual property. If you have the working RNA that produces the same amino

[73] Directive 2009/24/EC of the European Parliament and of the Council of 23 of April 2009 on the legal protection of computer programs, recital 2

[74] Directive 2009/24/EC of the European Parliament and of the Council of 23 of April 2009 on the legal protection of computer programs, recital 3

acids and acts the same as the original, you will need to have a license, else you would have copied it without permission. In this way copyright could provide good protection for cDNA.

5.2.2 There is no valid legal basis for excluding engineered DNA from copyright

Looking at copyright law and for this purpose at the Berne Convention which all member states of the European Union but also the United States are a party to, we can say that in order to enjoy copyright protection a copyrightable work has to fulfill the following criteria:

A: It has to be an original work; only the author can claim his copyright.[75]

B: It has to be fixated, meaning it has to be written down or recorded for example. The Berne convention leaves this up to the individual member states to decide upon. In the Netherlands, the work has to be fixated.[76]

C: It has to involve a level of creativity, meaning listing the ingredients of a product does not create a copyright, but a little story you write on the back of a beer coaster does invoke copyright.[77]

It can be argued that a string of engineered DNA fulfills these criteria just as any other work that falls under the scope of copyright law. The engineer makes an original work which has not been done before, because the engineered DNA strand does not yet exist. He makes choices as to include certain aspects of the DNA or not. And only if he copied most of his work, would the work no longer be original.

The engineered DNA can easily be fixed onto a medium (digital) but also in its natural form as DNA. It would then be observable by another scientist who could see the original creation. The engineer will make choices that will be the results of his thinking process. It can

[75] Berne Convention for the Protection of Literary and Artistic Works, 1979, article 1, 2 and 3

[76] Berne Convention for the Protection of Literary and Artistic Works, 1979, article 2 and 9c; Nederlandse Auteurswet, BWBR0001886

[77] Berne Convention for the Protection of Literary and Artistic Works, 1979, article 2 (1)

be argued that he and only he will put certain sequences in a specific order, maybe because he thinks it will look better. Whenever these creative choices are made, it shows that the work is the product of the mind of the author and that it is creative. Originality and creativity are overlapping in this aspect.

It therefore seems that there is indeed no legal basis to excluded cDNA as being copyrightable. This is why Professor Andrew Torrance, Professor Chris Holman and a CCO (chief commercial officer) of a biotechnology company called DNA 2.0 tried to do just that, copyright an engineered DNA sequence with the American Copyright Office.[78]

DNA 2.0 tried to copyright a DNA strand known as the 'Prancer DNA sequence', that encodes a non-naturally occurring fluorescent protein.[79] It was argued that the DNA strand would indeed fall under a literary work, in part because it was created by a human being. And although highly functional in nature, it is not any more than for example copyrightable computer code. The American copyright office responded with the statement that the "material submitted does not contain the minimum amount of authorship required for registration".[80]

DNA 2.0 appealed this judgment, reasoning that their DNA strand indeed was an original work of authorship, fixed into a tangible medium (namely DNA), and that it shows creativity. They received another denial, but this time substantiated with arguments. The first argument was that the DNA sequence does not fall within an enumerated category. This means that it is not a musical work, literary work other dramatic work, which are the classical categories of copyrightable work under the American Copyright act. However, this list is not exhaustive, as illustrated by the legislative history of the Copyright act. The American Standard on Copyright *'Nimmer on Copyright'* explains that 'these categories are illustrative and not limitative, and do not necessarily exhaust the scope of original works of authorship that the bill is intended to

[78] C.M. Holman, C. Gustafsson and A.W. Torrance., 'Are Engineered Genetic Sequences Copyrightable?: The U.S. Copyright Office Addresses a Matter of First Impression', *Biotechnology Law Report* (103) 2016, issue 3

[79] C.M. Holman, C. Gustafsson and A.W. Torrance., 'Are Engineered Genetic Sequences Copyrightable?: The U.S. Copyright Office Addresses a Matter of First Impression', *Biotechnology Law Report* (103) 2016, issue 3, p. 104

[80] C.M. Holman, C. Gustafsson and A.W. Torrance., 'Are Engineered Genetic Sequences Copyrightable?: The U.S. Copyright Office Addresses a Matter of First Impression', *Biotechnology Law Report* (103) 2016, issue 3, p. 104

protect'.[81] It seems that the copyright office requires the US Congress to expand the definition of copyright before it will consider to apply copyright to a new category. But as Professor Holman positions, software also originally wasn't explicatively allowed in the Copyright act. It was through interpretation of what constitutes a work, that the US courts decided that even highly functional software could be patented.[82]

The second argument is that the office is unable to determine whether there are any other similar works (or genetic codes) already made and available. They basically cannot do a search for them. This argument seems to be weird, because software was originally also registered under a rule of doubt when it was not able to do search for similar software. In the paper, Professor Torrance convincingly states that maybe the office would need to develop such capabilities as it did with software, instead of refusing the claim based on policy.[83]

The third argument states that engineered DNA sequences are patentable and that therefore the question arises why they would also be copyrightable. But the office does not explain why the two regimes cannot overlap. And in fact, in the Oracle vs Google case where the Mazer vs Stein Case was mentioned, the Supreme Court stated that "Neither the Copyright Statue nor any other says that because a thing is patentable it may not be Copyrighted".[84] This argument by the copyright office therefore also seems to be based on policy and not on the interpretation of the statute.

The fourth interesting argument is that a genetic code is not copyrightable under the copyright act because an idea, procedure, process, system or method of operation, concept, principle or discovery cannot be copyrighted.[85] They state that the genetic sequence does not describe or explain or illustrate anything. It just states the claim of a formula for a biological

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[81] D. Nimmer, *Nimmer on Copyright*, Lexis Nexis 2017, paragraph 2.03

[82] C.M. Holman, C. Gustafsson and A.W. Torrance., 'Are Engineered Genetic Sequences Copyrightable?: The U.S. Copyright Office Addresses a Matter of First Impression', *Biotechnology Law Report* (103) 2016, issue 3, page 106

[83] C.M. Holman, C. Gustafsson and A.W. Torrance., 'Are Engineered Genetic Sequences Copyrightable?: The U.S. Copyright Office Addresses a Matter of First Impression', *Biotechnology Law Report* (103) 2016, issue 3, page 108

[84] Oracle Am. Inc v Google Inc Decided 2014 NO C10-03561 (citing Mazer vs Stein 347 US 201,217 1954)

[85] C.M. Holman, C. Gustafsson and A.W. Torrance., 'Are Engineered Genetic Sequences Copyrightable?: The U.S. Copyright Office Addresses a Matter of First Impression', *Biotechnology Law Report* (103) 2016, issue 3, p. 108

process or system, and no copyrightable expression. However, this seems to illustrate a lack of understanding, as Professor Holman states, because in Oracle vs Google it was also found that "components of the program that can be characterized as a *method of operation* may nevertheless be copyrighted".[86]

The last argument that is worth mentioning, is that the copyright office states in the denial that the specific sequence of nucleotides is only made by functional considerations. It is not made because the programmer would like it to be a certain way. Therefore, there is no artistic expression, and therefore the cDNA strand known as the Prager sequence cannot be copyrighted. However, this argument also does not convince, as it is well established that software, being highly functional in nature, sometimes can also be copyrighted, as was also found in the Google vs Oracle case. JAVA API packages, being highly functional and abstract, are nevertheless copyrightable.[87]

This try to get a synthetic DNA sequence patented with the copyright office gives us at least a partial look into whether or not such an implementation would be feasible and what exactly the reason would be why such a claim would be denied. Given the fact that here the only example is with American Law and not European Law, we do still get a good view on what the substantial arguments could be. However, the arguments that are made by the copyright office are mostly procedural and policy based. The only legal argument made by the copyright office is that the highly practical nature of the sequence bars it from being copyrighted because it does not show any artistic expression. However, this was already treated in the courts and the court found the opposite to be true in the aforementioned Google vs Oracle case. What is left are arguments that in my view do no substantiate the view that cDNA sequences cannot be patented bases on existing law.

5.2.3 Patent protection is lengthy, costly, complicated and hinders innovation

A patent application can take about three to five years if everything goes the way it is supposed to go. The process is also costly, although not as costly as many people will think. However, it will cost several thousands of euros, and that is without the yearly renewal fee. A company

[86] Oracle Am. Inc v Google Inc Decided 2014 NO C10-03561

[87] Oracle Am. Inc v Google Inc Decided 2014 NO C10-03561, consideration 116

that creates a large body of engineered DNA strands will have to spend a large part of its time and perhaps also its resources on patent applications and litigation. "Synthetic biology is characterized by rapid and profuse incremental innovations."[88] With Europe wanting to stay on the forefront of Biotechnological development a copyright approach might be superior. The protection would be very fast. Even with registration it would take just a fraction of the time of a patent application. This is also stated by Chris Holman in his latest paper, in which a company called ATUM states that the patent process is too lengthy and costly.[89] The company creating build to order genetic sequences for its customers, states that it is almost impossible to apply for a patent because the products or sequences they make are relatively small and subject to change too much to wait for patent approval. Not being able to quickly patent, it leaves the company rather vulnerable to other companies trying to free ride on its creations especially because its creations can often self-replicate. Something like copyright would at least give them partial protection against people with bad intentions, and would spur innovation. ATUM also states that it has no desire to litter the field with as many patents as they can get their hands on, because in their eyes this will hinder innovation.[90]

It could be argued that gene patents hinder innovation and research. When companies hold patents in this rapidly moving field, it is difficult for other companies or people to work in the same area, for example if they want to make use of a patented gene in upcoming research for another application. Sometimes a certain way of using a protein is the only way of doing it right. If you need this as a building block for another application you could be hindered in your research, if the company is not willing to let you have a license, or the license is just too expensive. This also holds true for consumers, if only one company creates and does testing with a certain protein, it might not be possible to look for a similar test from another company to get confirmation. In America, a company by the name of Myriad was initially sued the American Civil Liberties Union (hereinafter ACLU) on behalf of a woman who took a medial test

[88] C.M. Holman, 'Copyright for Engineered DNA: An Idea Whose Time Has Come?', *West Virginia Law Review* (113) 2011, p. 701

[89] C.M. Holman, 'Charting the Contours of a Copyright Regime Optimized for Engineered Genetic Code', *Oklahoma Law Review* (69) 2017, issue 3, p. 406

[90] C.M. Holman, 'Charting the Contours of a Copyright Regime Optimized for Engineered Genetic Code', *Oklahoma Law Review* (69) 2017, issue 3, p. 408

for breast cancer. When she wanted to get a second opinion she found that it was not possible because only Myriad produced and analyzed the administered tests. One of the arguments used by the ACLU was that Myriad was indeed inhibiting research that could benefit people by applying their patent in the way that they did.[91]

5.2.3.1 Idea-Expression Dichotomy

If copyright would have been applied, in this case there might have been an outcome that would be more favorable to the user of the test and to other companies doing research in the same field. In copyright, there is the notion of the 'idea expression dichotomy'. It states that you cannot copyright an idea, you can only copyright what is put down in a work. That means that I can write a story about a young boy who goes to a magical school to become a wizard and get copyright. Of course, I am talking about the Harry Potter novels. It also means that someone else can also write about a wizard and a magical school. Given the fact of course that someone does not copy my story. The 'idea' of the young wizard is therefore not copyrightable, only my exact literal story. For cDNA this would mean that you can create another cDNA strand, that might produce a similar protein that achieves the same function, namely identify a certain protein is someone's body. This would empower companies to create their own versions of cDNA strands and also be good for a consumer, because of the increased competition. In this way, the market would possibly enjoy increased competition, contrary to the maybe restricting application of patents.

5.2.3.2 Merger Doctrine

Another notion in copyright law is the 'Merger Doctrine'. The Merger doctrine could also increase competition and further innovation. The merger states that if an idea "can only be expressed in a limited number of ways, those means of expression cannot be claimed, just like

[91] Gene Patents, American Civil Liberties Union, accessible at https://www.aclu.org/other/gene-patents, accessed 20-07-2017

one author can own the idea itself."[92] This means that for cDNA, if there is only one way to achieve something (for example a certain protein output) it is not possible to copyright that sequence. Just like computer code: if a computer only responds to a certain input to for example turn on a screen, it would not be possible for someone to own that sequence, since everyone making computer code would have to use it. The merger doctrine illustrated that the idea and the expression are merged together.

5.2.3.3 Fair Use

A notion in copyright which might be even more familiar to the average reader is the fair use doctrine. Fair use allows for people, universities / research institutes or companies to study and examine certain copyrighted material for educational purposes that would otherwise be considered infringing. This is allowed to enable people to better understand the idea and functionality of a certain idea, in order to come up with their own interpretation or version which might be better. With cDNA this would allow people to deconstruct a cDNA sequence to understand how it works without incurring liability or informing the copyright owner from the start (something that might be lengthy or cost a lot of money). The notion of Fair Use does not exist in patent law, so this idea would only be viably if cDNA would fall under the copyright regime, and could therefore be seen as a benefit to the public in general. This already applies to software, and was affirmed in the Sega vs Accolade case:

"Where disassembly is the only way to gain access to ideas and functional elements embodied in a copyrighted computer program and where there is a legitimate reason for seeking such access, disassembly is a fair use of the copyrighted work, as a matter of law."[93]
The fact that patents are a lengthier process than copyright is something that we do not have to argue about. Patents also cost a lot more money to obtain, and the process towards a patent can be unsure. It is understandable that companies that produce a lot of small genetic cDNA strands do not fit into the patent system well, especially if they change the cDNA strands whenever there is a need. A patent would then be invalidated. A company could potentially

[92] Zalewski v. Cicero Builder Dev., Inc., 754 F.3d 95, 102-03 (2d Cir. 2014)

[93] Sega Enters. v. Accolade, 977 F.2d 1510, 1520 (9th Cir. 1993) at 1527-28

litter the field with patents, hindering other players from entering and providing competition. This could scare off newcomers and would not progress humanity as is the ultimate goal with patent law (protect and innovate to the betterment of mankind). A copyright system would offer faster and less expensive protection but only against direct copying. There are convincing arguments that copyright with its Idea-Expression Dichotomy, Merger doctrine and Fair Use policy could help boost the industry, but is this really what companies want, or does it sound convenient because patent law does not have these possibilities?

While these aspects of copyright law sound enticing, I am not sure they would fit an invention based system. While a patent application can take a long time, can be complicated and can be costly, it is required to do solid research before we as a society can determine if we can give this invention patent protection. The goal of patent law is to promote and incentivize research. As a reward, we offer an exclusive limited right to exploit the invention. If the state of the art does no longer have to be thoroughly checked, because copyright would apply anyway are we not taking a huge risk as a society? The protection that is offered through copyright is also thinner than patent protection. With copyright, the literal expression of (in this case) cDNA is protected against copying by a competitor, but the solution to the problem (the idea in its full form, the invention) is not protected. It would not be hard for a competitor to reverse engineer a genius idea to work similar *but different enough* in order to also receive copyright protection. I believe that this will in the end potentially hinder innovation instead of boosting it. The protection offered might not be enough for inventors to commit to the process.

For our next chapter, we will be looking more closely at some of the counterarguments of using copyright in the cDNA field.

Take away messages:

1. The main arguments in favor of using copyright for cDNA applications are:

   A. Computer code and cDNA can look the same, and can have the same properties and the for could maybe be treated the same way. In any case they can be seen as a list of instructions for a mechanical or biological machine to follow.

   B. There is no convincing legal basis to exclude copyright with regards to cDNA. It does not state in copyright law in the EU or in the United states that cDNA cannot be copyrightable. It states

that cDNA is patentable, but there is no real reason that the two regimes cannot overlap. C. Patents are costly, have a lengthy application procedure and hinder innovation. While copyright has many benefits like being faster and easier to enforce. Copyright also comes with many interesting aspects like the idea-expression dichotomy, the merger doctrine and fair use.

2. Can we really replace the solid patent law research with the thinner copyright protection? We as a society need to incentive inventors, with copyright being relatively thin, we might not be offering enough even though it might be faster to implement?

6 What are the possible drawbacks or negative aspects of using copyright law for cDNA applications?

6.1 Introduction

Now that we have heard arguments in favor of using a copyright approach we also have to look at counterarguments. What arguments can be found against using the said approach? I will list the arguments and explain what they entail.

6.2 Arguments against using copyright law

6.2.1 Copyright law protection is relatively slim compared to patent law protection

Copyright protects what is written down. It prevents someone from literally copying and pasting a text and using it for themselves, without approval of the original author. It would protect cDNA in the same way. Another company could not copy and paste a line of genetic code and use it in their own DNA creation. However, copyright does not protect the invention that is expressed in the genetic code. If company B discovers that company A uses protein Y to activate receptor X to produce result Z and it understands the workings of this mechanism, it might try to reverse engineer it. Company B, now knowing that receptor X produces result Z, might try to introduce another protein to achieve the same result, for example protein B. If protein B produced the same desired effect, company B now has its own version of what was invented by company A. This is something that copyright law does not offer any protection for, but patent law does. Company A might have invested a lot of resources in discovering that receptor X can produce a desired effect. Company B who saw that this idea works, and produces a similar product, will most probably not have the same resource and development cost that company A did, because they used company a as 'inspiration'. This will then lead to unfair competition and could put company A out of business. Patent law does protect the invention as a whole and its desired effect. The patent protects the solution to a specific

technological problem.[94] Patent law would therefore be able to offer the inventor substantially better protection than copyright law can offer. Considering that inventions in biotechnology can cost millions of euros in research, copyright protection seems too slim to actually protect and therefore incentivize inventors to do what we as a society want, namely produce useful inventions.

6.2.2 Legal certainty: what will happen to the existing patents and their protection?

What would happen to existing patents? Do existing patents get invalidated and transferred to the copyright regime? As patent protection and copyright protection protect different areas of intellectual property (the solution to a problem vs a certain work or text), this would not sound very probable and even destructive to the investment that inventors have made to accomplish the success of their invention.

Or do existing patents get the opportunity to enjoy legal protection in both regimes? This would mean that an existing patent would continue to enjoy the protection in the patent law regime, but that it would then extend to the copyright regime as well. However, this creates additional problems. For example, if a patent would run out in a few years and the inventor would from now on also enjoy copyright protection, how does this relate to the original idea that after the 20 years of exclusive rights the invention should be in the public domain? If the invention is very specific and can only be done in a certain way, for example only a certain type of coded mRNA can produce a very specific protein, it would be impossible for another company to start producing this mRNA, because it is now also protected by copyright for an additional 50 years.

Would a split occur between inventions that are protected by the 'old' patent law regime and inventions that are only protected by the new copyright regime? Patents and patent portfolios can be a large part of the net worth of a company, especially in the field of Biotechnology, they can be worth millions. One of the first biotechnology patents (the Cohen-Boyer patents) changed the industry.[95] If a new biotechnological invention is only protected by

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[94] WIPO, *WIPO Intellectual Property Handbook*, WIPO Publications 2004, p. 3

[95] M. Godar 'History of Biotech: How the First Biotech patent Generated Milions', Labiotech.eu, accessible at http://labiotech.eu/making-dollars-out-of-the-recombinant-dna-biotech-patents/ , accessed 15-08-2017

the relatively slim copyright protection and not by patent law, the net worth of the company could be drastically lower. Especially if the invention and the solution to the technical problem can be reached by coding for a slightly different protein to achieve the same result.

What would happen with precedents in both legal regimes, do they apply vice versa or not? There are certain legal precedents that make sense and apply in one regime, that might not work in the other regime.

Another problem is cross border communication and investment. The world is used to and familiar with the copyright and patent law regime being two different systems. Combining or transferring them in one part of the world for cDNA in for example the European Union while they are separated in the rest of the world, might lead to a great amount of confusion with large companies that have patent portfolios in different parts of the world. Do we want to have that happening? These are questions to which proponents of using copyright for cDNA applications have not given a convincing response to yet.

6.2.3 Copyright protection might be too long

Copyright protection extends for over 70 years, as we have previously seen. There is an argument to be made that this would be too long for inventions. With patent law, we as a society give the inventor an exclusive right over his invention. During this time, no other company can use the invention without the permission given by the inventor. The economic benefits fall solely to the inventor. With inventions in biotechnology potentially having the chance to save human lives, do we really want a company to be the sole and exclusive rights owner for that long of a period? This is a moral argument of course, but not a lesser one to any extent. If a company has such a long period to have exclusivity, is there really a tradeoff between mankind and the inventor? The exclusive right is given to the inventor by ''we the people''. In return for this exclusive period, the invention enters the public domain after 20 years. 20 years is a long period of time, but it can be said that after 20 years, an invention can still be useful. For our benefit, it can then be produced by other companies and possibly cheaper. 70 years on the other hand might be too long a period to give exclusivity to an inventor. We can ask ourselves whether an invention made 70 years ago still has societal relevance at all. If it does not, it would mean that the inventor de facto always has the exclusive rights over his invention. Why would we want to make that trade? If we look at the cost of

medicine and medical treatment, we can see that average prices continue to rise over the years.[96] If we grant a 70-year period of protection, there might not be any benefit to the trade of public knowledge of the invention for a certain predefined period of exclusive rights.

6.2.4 No real call from the industry itself

Does the biotechnological / medical industry want this change itself? There is no conclusive body of evidence that this is the case. Publications about copyright in cDNA have been by academics and scholars or combined and often are about the same companies. [97] And apart from some brief exploratory mentions there is no definitive signal that the industry would welcome a change in legal system. [98] [99]Given this fact, does it make sense to change this? The previously mentioned push from the European Union to become competitive in the Biotechnological industry, and the aforementioned legal certainty principle together would illustrate that it would at least not be a good idea to change directions midflight without a clear indication that the industry wants this change to happen. Patents itself seem to be more interesting. Obtaining a biotechnology patent seems to be *the* strategy of biotechnology companies and ventures.[100] And protecting that intellectual property as it stands today (namely patents) seems to be the core issue in biotechnology.[101]

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[96] T. Barrueta, 'A brief history of drug pricing', May 15 2015, accessible at http://www.achp.org/wp-content/uploads/Tony-Barrueta-Presentation-5_15_15.pdf, accessed 19-08-2017

[97] H. Ledford, 'Bioengineers look beyond patents', *Nature* (499) 2013, p. 16

[98] C.M. Holman, C. Gustafsson and A.W. Torrance., 'Are Engineered Genetic Sequences Copyrightable?: The U.S. Copyright Office Addresses a Matter of First Impression', *Biotechnology Law Report* (103) 2016, issue 3, p. 104

[99] A.W. Torrance, 'DNA Copyright', *Valparaiso University Law Review* (46) 2011, issue 1, p. 4

[100] E. Burrone, 'Patens at the Core: The Biotech Busiuness', World Intellectual Property Organisation, accessible at http://www.wipo.int/sme/en/documents/patents_biotech_fulltext.html#P17_1731, accessed 19-08-2017

[101] N. Thumm, 'Research and Patenting in Biotechnology: A Survey in Switserland, Swiss Federal Insitute of Intellectual Property', *Swiss Federal Institute of Intellectual Property* (1) 2003, p. 6

Take away messages:

1. The main arguments against using copyright for cDNA applications are:
   A. Copyright protection is slim compared to patent protection. It protects against the literal copying and pasting of a work, or in this case cDNA. But it does not protect against the materialization of an idea (the invention). An invention could therefore possibly relatively easily be reversed engineered to work around certain key areas of the invention and achieve the same result. Because the research costs of the second "inventor" would be lower if he would partly copy the invention it could be considered unfair competition.
   B. Legal certainty. What would happen to existing patents. Do they get switched over to the copyright regime or does a hybrid system need to be made? What about different legal precedents in either system, will they suddenly apply in both regimes at the same time?
   C. What about the protection (20 years for a patent and 70 years for copyright)? If an invention is protected for over 70 years are we a society that is even ready to make that trade? One would have to consider the protection for x years versus the knowledge of the invention. Is an invention that is 70 years old even worth giving that much protection and exclusivity for?
   D. No real call from the industry itself. While there are examples of companies like ATUM and intellectuals that position this idea, I did not come across an outcry from industry that clearly positions copyright for cDNA applications as the holy grail to solve all problems. There have been lawyers that are interested in the idea and maybe it will go the same way as computer program copyrightability. This will mean it will have to be brought before the court, but for now it seems that companies are actually happy with more solid patent protection, and would rather not trade that in for slimmer, but faster copyright protection.

7 Using only elements of copyright for cDNA applications to improve the protection of cDNA. A semi- hybrid approach.

Now that we have talked about patent law and copyright law and about the arguments in favor and the arguments against using copyright for cDNA applications, we can look at an alternative solution. The solution would be a semi-hybrid approach. This approach will be different than what is positioned in the literature, as the literature talks about combining the two legal systems in a hybrid system for the duration of the patent or copyright term.

What I position is different, but my idea will use some of the elements that are being proposed because they make good sense. Patent law offers more robust protection than copyright law. Copyright protection in its most rudimentary form prevents plagiarism: the unlawful copying of someone's work. This could work great for literary works, artistic works and computer software, but I doubt that it will be a good supplement for cDNA applications.

While computer software and cDNA share similarities and it is possible to have patent protection and copyright protection apply on computer software, I position that genetically engineered DNA is an invention. I have yet to see a genetic strand of DNA that was created by a biotechnologist without the intend of solving a problem with that strand of DNA. I strongly believe that inventions should be protected by patent law because it is simply more robust and offers a higher level of protection than copyright. It is also a system that is specifically tailored for inventions, unlike copyright law. The European Union is also further ahead with harmonizing patent law than with copyright law throughout the member states. And when the unitary patent treaty and court are implemented it will be relatively easy to gain a European Union wide patent in one application. I believe this will be good for the biotechnology industry as a whole.

Creating a hybrid system, as is being talked about in the literature, will create a few problems. Legal certainty is one of these problems. If two legal systems would be applied simultaneously, it would be harder to see what is protected and what is not. It is also the question whether companies would really want to have it implemented like this. Patent law has very limited fair use and copyright law has a relatively large concept of fair use. If (as an inventor or company) you have committed considerable resources into an invention and

subsequent patent protection, you might not want to have your patent exposed to fair use. While fair use is an arguably admirable thing, we must not forget that patent protection lasts for 20 years. After 20 years, the invention and the knowledge about the invention can be freely used. If we would apply copyright protection to the same invention, it would last for over 70 years at least. During all this time, the public would still be more restricted than it would be after 20 years of patent protection. Patent protection is more robust and strict, but it does not last as long and in my opinion, that is a major benefit to patent protection.

Other concepts, like the idea-expression dichotomy and the merger doctrine, are benefits of the copyright system, but we cannot forget that in patent law you can get a license when a certain aspect of technology is deemed absolutely vital for the general operation in a certain field of technology. It has to consider a piece of technology without which competition would not be possible. It would still be able for competing companies to take a license on that patent on FRAND terms. Using FRAND licensing, it would be impossible to completely corner the market with a patent.

However, seeing that law often ventures into new areas with the start of analogy we have to conclude that the argument that cDNA and computer code being similar is striking in nature. They can both be put on a tangible medium. Both are highly functional in nature and both can be implemented using a computer. Furthermore, looking at the requirements for copyright, we cannot see that cDNA should be excluded because it does fulfill the requirements for copyright. It can be an original work, it can be fixated as shown before, and it certainly involves a level of creativity. According to the Berne convention, there would then not be any hurdles to implement this.

I am not convinced that patents hinder innovation as is often positioned, but I do believe that the patent application process is lengthy and requires more money to follow than is the case with copyright.

Considering the fact that a patent application can take anywhere up to five years and costs a substantial amount of money and because we cannot deny that the eventual protection is superior to copyright protection and that patents subsequently often constitute a large part of what a company is worth, I propose the following. I would call for a semi hybrid system that would make copyright protection available for cDNA applications from the moment that it is

put on a tangible medium. That would in first instance be the cDNA itself, because it is the storage version of RNA. From that moment on, it is observable and what is created is then the original idea of the creator. It would then qualify for copyright, but only if the creator/inventor/company then applies for a patent to protect the invention.

The copyright protection that I position is meant to be a bridge between the creation of the invention, the cDNA and the granting of a patent. When the patent is granted the copyright protection would be removed, in order to make way for the more robust protection of patent law. I believe this would have many benefits, namely the following:

- ✓ It would grant the inventor who has coded his invention in cDNA temporary protection against people who might want to pirate his invention.
- ✓ It would still result in more robust patent protection in the end. That in the end is worth more to an inventor or company.
- ✓ It would continue to incentivize people to apply for patents because if only copyright protection would be available it will be too slim.
- ✓ It would prevent people from having to engage in fair use or other use case mechanisms in copyright law, that could stretch over 70 years after the death of the creator, but instead have the knowledge of the invention be available after 20 years to benefit society and to spur follow up innovation.
- ✓ It will allow people and research institutes to use copyright case mechanism from the start of the patent application and it will incentivize companies to make available their invention for people to research how it works under fair-use. This could lead to even faster follow up innovation. Note: they cannot copy the invention for themselves.
- ✓ It requires minimal adjustment of the copyright regime, and prevents legal uncertainty when combining two whole regimes together.
- ✓ There is no huge call out from the industry yet, but there are small groups talking about this. This will allow for example the European Union to be at the forefront of an industry, and reach ahead with lawmaking, instead of trailing behind like is the traditional role of a legislator.

8 Conclusion

cDNA or complementary DNA is used by scientists in the field of biotechnology to store RNA. This is created to (among other uses) produce certain proteins which can be used in the field of medicine or other fields where engineered DNA traits can be useful. cDNA can be patented because it constitutes an invention. In the European Union isolated naturally occurring DNA can also be patented, but only if it is isolated enough and has a specific use case, for example a gene that detects cancer receptivity for breast cancer in woman.

Patent law is a robust form of protection that protects an invention and gives an exclusive right to its inventor for a period of 20 years. After this period, the knowledge about the invention enters the public domain and we can all benefit from the knowledge and use of the techniques that were patented. This is a healthy trade off that will incentivize inventors to keep solving problems that we as a society experience. Before patent protection is given there are formal requirements that have to be met, like patentability, being novel, having made an inventive step and have the invention be susceptible for industrial application. Patent law is being more and more harmonized by the European Union, with the upcoming Unitary Patent Treaty and Patent Court it will be possible and faster to apply for a one time, whole European Union valid patent.

Copyright law is a form of legal protection that protects original creators of works. These can be (but are not limited to) literary works, artistic works like paintings, but also computer code, which can be thought of as a list of text (instructions) to produce a certain output on a computer. There are no formal requirements for copyright protection to be activated, once the work is made (for example a novel) and it is recorded on a tangible medium (like a piece of paper), the author has copyright protection. Copyright has various interesting mechanisms like fair use, the idea – dichotomy and the merger doctrine that allow people to use or research parts of the copyrighted work without being susceptible to litigation. Copyright is not really harmonized by the European Union, there is only minimum and maximum harmonization.

Professor Holman, among others, has positioned the idea of using copyright protection for cDNA applications because there are many similarities and advantages to be found. The biggest argument is that computer code (which in some cases is patentable and copyrightable)

is similar to cDNA. By analogy he positions that cDNA should also be protected by copyright just like computer code. This argument is convincing as there are similarities to be found and law often enters new territory by use of analogy. The second big argument is that there is not a real legal exclusion that prevents cDNA from being copyrightable. The reason for this being that it fulfills copyright criteria if it is an original work, is stored on a tangible medium and involves some creativity. The third argument is that to obtain patent protection a lot of money has to be spend; the process is lengthy and complicated. This I believe to be partly true, namely the lengthy application procedure of up to five years before the granting of a patent.

Counterarguments can also be made against the use of copyright for cDNA patent applications. First of all, copyright protection is relatively slim as compared to patent protection. Copyright protects against the unlawful blatant copying of someone's work. It also involves other rights like distribution, communication and enforcement rights but the main protection here is that someone cannot use your work without your permission. This would mean that someone could reverse engineer an idea and adjust it just enough so that I can be considered a new work. The solution to a problem could then still roughly be the same, but the second creator would then have accomplished this at a fraction of the cost. Secondly, legal certainty would come into play when combining two legal regimes. It is unsure what would happen with existing patents. Would they enter the copyright domain when their patent is already expired? Would all the copyright notions of the idea-expression dichotomy, the merger doctrine and fair use suddenly apply to patents as well? We found that this might not be ideal. The third notion is that copyright protection is too long for an invention. Patent protection in general is shorter than copyright protection. If a patent expires, the idea is that it enters the public domain. But is this still really possible if the code cannot be copied and used because it is still protected by copyright? A patent could expire in 20 years, and then still have the remainder to 70 years after the death of an author to be protected by copyright. Fourthly, at this moment we cannot state that there is real clear call from industry itself. Yes, there are companies, academics and inventors that talk about this, but this can hardly be called a pressing need at this moment in time. However, this could change within time.

Looking at the argumentation, we can formulate a different approach. Given the fact that there are convincing arguments to use copyright for cDNA applications but also convincing counterarguments and looking at the nature of both regimes, I propose the following. cDNA should indeed be protected by copyright, but not completely and not in a completely hybrid

system. It should be protected in a semi-hybrid system, meaning that copyright would apply for cDNA patent applications during the time of patent application. This will give inventors a limited form of protection during which they can apply for patent protection. It will prevent piracy from happening and will incentivize companies to register their copyright instead of relying on trade secrets. This will have the benefit of allowing people to use copyright mechanisms like fair use during the copyright period. This will result in people being able to research mechanisms in the invention to be able to learn about them. It will of course be prohibited to pirate the code. After the patent is granted, the copyright protection will be removed and the more robust patent protection will be used to protect the invention for 20 years. Lastly, it would require little adjustment to existing copyright law and its subsequent implementation could be done under the Berne convention requiring only the work to be original, creative and be fixed on a tangible medium. Because there is no definitive call from the biotechnology community yet, it would allow the European Union to be at the forefront of industry. Being competitive in the field of biotechnology is one of the aims of the Biotechnology directive. To answer the question that we have started with: should copyright law be used for cDNA patent applications instead of patent law? We can state that this is not the case. Copyright should not be used *instead* of patent law, but it should be used partially in the run up to obtaining a patent.

9 Bibliography

Articles and Journals:

A.W. Torrance, 'DNA Copyright', *Valparaiso University Law Review* (46) 2011, issue 1

C.M. Holman, 'Copyright for Engineered DNA: An Idea Whose Time Has Come?', *West Virginia Law Review* (113) 2011

C.M. Holman, C. Gustafsson and A.W. Torrance., 'Are Engineered Genetic Sequences Copyrightable?: The U.S. Copyright Office Addresses a Matter of First Impression', *Biotechnology Law Report* (103) 2016, issue 3

C.M. Holman, 'Charting the Contours of a Copyright Regime Optimized for Engineered Genetic Code', *Oklahoma Law Review* (69) 2017, issue 3

H. Ledford, 'Bioengineers look beyond patents', *Nature* (499) 2013

I. Kayton, 'Copyright in Living Genetically Engineered Works', *George Washington Law Review* (50) 1982, issue 3

K.B. Thakker & G.Billa, 'The concept of: Generic drugs and patented drugs vs brand name drugs and non-proprietary (generic) name drugs', *Frontiers in Pharmacology* (4) 2013, issue 113

N. Thumm, 'Research and Patenting in Biotechnology: A Survey in Switserland, Swiss Federal Insitute of Intellectual Property', Swiss Federal Institute of Intellectual Property (1) 2003

P. Lee, 'The Supreme Court's Myrias Effects on Scientific Research: Definitional Fluidity and the Legal Construction of Nature', *Irvine Law Review* (5) 2015, issue 5

R. Weinmeyer & T. Klusty, 'Supreme Court to Myriad Genetics: Sythetic DNA is patentable but isolated genes are not', *AMA Medical Journal* (17) 2015, issue 9

Books:

A. Kur and T. Dreier, *European Intellectual Property Law, Text, Cases and Materials*, Edward Elgar Publishing 2013

D. Nimmer, Nimmer on Copyright, Lexis Nexis 2017

H. Lodish, A, Berk, S. L. Zipursky, P Matsudaira, D. Baltimore, and J. Darnell, *Molecular Cell Biology*, W.H. Freeman & Co Ltd 2000

M. A. Lemley, P. S. Menell, R.P. Merges, P. Samuelson and B.W. Carver, *Software & Internet Law*, Wolters Kluwer & Aspen Publishers 2011

M.A. Bedau and E.C. Park, *The Ethics of Protocells – Moral and Social Implications of Creating Life in the Laboratory*, the MIT Press 2009

T. Dreier, B Hugenholtz and D. Visser, *Concise European Copyright Law*, Kluwer Law International 2014

WIPO, *WIPO Intellectual Property Handbook*, WIPO Publications 2004

Caselaw and Court Opinions:

Association for Molecular Pathology vs. Myriad Genetics Inc. 569 US 201, Supreme Court of the United States 2013

Court of Justice of the European Union, 'The draft agreement on the creation of a European and Community Patent Court is not compatible with European Union Law', 2011

ECJ 341/87 EMI Electrola v Patrica 1989

Oracle Am. Inc vs. Google Inc Decided 2014 NO C10-03561
Sega Enters. vs. Accolade, 977 F.2d 1510, 1520 (9th Cir. 1993)

Zalewski vs. Cicero Builder Dev., Inc., F.3d 95, 754 (2d Cir. 2014)

Conventions and Treaties:

Berne Convention for the Protection of Literary and Artistic Works, 1979

Convention on the Grant of European Patents (European Patent Convention) 16th edition, 2016

The Treaty on the Functioning of the European Union, C326/47, 2012

Dutch Law:

Nederlandse Auteurswet, BWBR0001886

Encyclopedia or Dictionary:

Covert Text to Binary, Unit Conversion, accessible at http://www.unit-conversion.info/texttools/convert-text-to-binary/, accessed 03-07-2017

Definition of DNA, Merriam-Webster Dictionary 'DNA', accessible at https://www.merriam-webster.com/dictionary/DNA, accessed 15-08-2017

Definition of cDNA, Merriam-Webster Dictionary 'cDNA', accessible at https://www.merriam-webster.com/dictionary/cDNA, accessed 15-08-2017

Structure of the double Helix, GeneED, accessible at https://geneed.nlm.nih.gov/index.php,

accessed 01-08-2017

Schematic Structure of Adenine (C5H5N5), Research Gate 'Adenine', accessible at https://www.researchgate.net/figure/283577525_fig7_Schematic-structure-of-adenine-C5H5N5, accessed 01-08-2017

Regulations, Directives and Recommendations:

Directive 96/9/EC of the European Parliament and of the Council of 11 March 1996, on the legal protection of Databases

Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998, on the legal protection of biological inventions

Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004, on the enforcement of intellectual property rights

Directive 2006/116/EC, of the European Parliament and of the Council of 12 December 2006, on the term of protection of copyright and certain related rights

Directive 2001/29/EC, of the European Parliament and of the Council of 22 May 2001, on the harmonization of certain aspects of copyright and related rights in the information society

Directive 2006/115/EC, of the European Parliament and of the Council of 12 December 2006, on rental right and lending right and on certain rights related to copyright in the field of intellectual property

Directive 2011/77/EU, of the European Parliament and of the Council of 27 September 2011, amending 2006/116/EC on the term of protection of copyright and certain related rights

Directive 2006/116/EC of the European Parliament and of the Council of 12 December 2006 on the term of protection of copyright and certain related rights

Directive 2009/24/EC of the European Parliament and of the Council of 23 of April 2009 on the legal protection of computer programs

Regulation 1257/2012 of the European Parliament and of the Council of 17 December 2012, implementing enhanced cooperation in the area of the creation of unitary patent protection

Digital magazines:

M. Krench, 'New Supreme Court Decision Rules That cDNA Is Patentable What It Means for Research and Genetic Testing', *Scientific American*, 09 July 2013, accessible at https://blogs.scientificamerican.com/guest-blog/new-supreme-court-decision-rules-that-cdna-is-patentablewhat-it-means-for-research-and-genetic-testing/

Newspapers and Press releases:

European Commission, 'Greenpaper on Copyright and the Challenge of Technology', Copyright issues requiring immediate action, June 7th 1988, paragraph 1.4.9

'Karlsruhe stops EU Patent Court, Federal President is not to draft a bill', *Frankfurt Allgemeine*, June 12th 2017

J. Meek, 'Genetic Chickens get DNA copyright tag', *The Guardian* 2000

Presentations or Lectures:

T. Barrueta, 'A brief history of drug pricing', May 15 2015, accessible at http://www.achp.org/wp-content/uploads/Tony-Barrueta-Presentation-5_15_15.pdf, accessed 19-08-2017

Websites:

All about the Human Genome Project (HGP), National Humane Genome Research Institute, accessible at https://www.genome.gov/10001772/all-about-the--human-genome-project-hgp/, accessed 10-07-2017

E. Burrone, 'Patens at the Core: The Biotech Busiuness', World Intellectual Property Organisation, accessible at http://www.wipo.int/sme/en/documents/patents_biotech_fulltext.html#P17_1731, accessed 19-08-2017

European Patent Office, 'About us', accessible at http://www.epo.org/about-us.html accessed 08-07-2017

Gene Patents, American Civil Liberties Union, accessible at https://www.aclu.org/other/gene-patents, accessed 20-07-2017

Holman's IP Blog, Professor Chris Holman, accessible at holmansbiotechipblog.blogspot.nl, accessed 01-08-2017

K.E. Noonan, 'A perspective on the cost of the Myriad BRCA Gene Test', Biotech & Pharma Patent Law & News Blog, 02 May 2013, accessible at http://www.patentdocs.org/2013/05/a-perspective-on-the-cost-of-the-myriad-brca-gene-test.html, accessed 08-07-2017

M.Wuerthele, Apple awarded pair of 3D user interface patents related to comuter vision, Apple Insider, 16 August 2016, accessible at http://appleinsider.com/articles/16/08/16/apple-awarded-pair-of-3d-user-interface-patents-related-to-computer-vision, accessed 10-07-2017

M. Godar, 'History of Biotech: How the First Biotech patent Generated Milions', Labiotech.eu, accessible at http://labiotech.eu/making-dollars-out-of-the-recombinant-dna-biotech-patents/ , accessed 15-08-2017

Professor Christopher Holman Addresses Copyrighting Engineered DNA In Lecture, University of Missouri-Kansas City, 4th of November 2015, as mentioned in http://law.umkc.edu/news/professor-christopher-holman-addresses-copyrighting-engineered-dna-in-lecture/, accessed 02-07-2017

R.J. Robison, 'How big is the human genome, in megabytes, not base pairs', accessible at https://medium.com/precision-medicine/how-big-is-the-human-genome-e90caa3409b0, accessed 02-08-2017

Copyright Protection of Software, World Intellectual Property Organisation, accessible at http://www.wipo.int/copyright/en/activities/software.html, accessed 20-08-2017

US Patent and Trade Mark Office, Apple patent registrations 2015, accessible at https://www.uspto.gov/web/offices/ac/ido/oeip/taf/topo_15.htm, accessed 10-07-2017