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The Shifting Nexus Between Law and Biology: What Does the Future Hold for Gene Patents?

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CHAPTER 1: INTRODUCTORY CHAPTER

1.1 Overview

This paper focuses on the changing nexus between law and biology within the context of gene patents, and examines some of the issues, the legal framework and the socio-economic policies that are involved in this sphere of intellectual property law. The application of patent protection to gene sequences has been riddled with misunderstanding and controversy. Should human genes, and the process of comparing DNA sequences, be patentable? These were some of the questions that were raised in the challenge to Myriad Genetic's patents covering the *BRCA1* and *BRCA2* genes and their use in screening for elevated risks of ovarian and breast cancer. In March 2010, a Federal District Court judge invalidated many of Myriad's claims, re-igniting the academic debate concerning the patentability of genes.¹ Although the decision has no direct application in Europe, it is also appropriate to consider whether European law is compatible with the position of the United States of America in this regard.

Chapter 1 is an introductory chapter that provides a legally and biologically based background to the extension of patent protection to genes, and Chapter 2 canvasses several of the arguments for and against the patenting of genes. The effect of the Agreement on Trade-Related Aspects of Intellectual Property Rights² (TRIPS) on gene patents is discussed in Chapter 3. Chapter 4 looks at the patentability of genes in Europe and Chapter 5 looks at the patentability of genes in the United States. Chapter 6 provides a detailed discussion of the recent decision by the United States District Court for the Southern District of New York in *Association for Molecular Pathology et al v. United States Patent and Trademark Office et al.*³ In this case patents covering isolated DNA

¹ AS Kesselheim and MM Mello 'Gene patenting: Is the pendulum swinging back?' (2010) 362 (20) *The New England Journal of Medicine* 1855 at 1855.

² Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments-Results of the Uruguay Round, 33 *ILM* 1197.

³ No. 09 Civ. 4515 (S.D.N.Y., Mar. 29, 2010) The decision has been appealed.

encoding human breast cancer susceptibility genes (*BRCA1/2*) were held to not be patent-eligible. The potential impact that this ruling has had on academic debate concerning gene patents, and the potential impact that it may have for the biotechnology industry are discussed in Chapter 7. The appeal from this decision to the Federal Circuit is looked at in Chapter 8.

1.2 Background

1.2.1 A legal perspective - what is a patent?

A patent is a legal monopoly that is granted by the state to an inventor, preventing others from using, selling, making or importing an invention for a set time period.⁴ A patent grants the patent holder exclusive economic rights in respect of the use of the patented invention.⁵ Further, patent protection is limited to the jurisdiction in which the patent was granted, and thus patents are considered to be territorial in nature. Where a third party infringes a patent, the patent holder will be entitled to take legal action against the contravening party. There are two main parts to a patent application. The first part is a specification of the invention, which describes the problem the inventor faced and the steps he took to solve it. The second part is a set of claims, which define what the inventor considers the scope of his invention to be.⁶

1.2.2 A biological perspective - what is a gene?

*In Association for Molecular Pathology et al v. United States Patent and Trademark Office et al (AMP v. USPTO)*⁷ Judge Sweet laid out the history and development of

⁴ ER Gold and J Carbone 'Myriad Genetics: In the eye of the policy storm' (2010) 12 (4) *Genet. Med.* S39 at S39.

⁵ M Rimmer *Intellectual property and biotechnology: Biological inventions* (2008) 2.

⁶ RP Merges and RR Nelson 'On the complex economics of patent scope' (1990) 90 *Colum. L. Rev.* 839 at 844.

⁷ No. 09 Civ. 4515 (S.D.N.Y., Mar. 29, 2010) The decision has been appealed.

genetics as a field of knowledge, and provided a concise overview of molecular biology and gene sequencing.

1.2.2.1 The development of genetics as a field of knowledge

The field of genetics concerns the science of heredity and variation in living organisms.⁸ In 1949 researchers discovered the chemical compound known as deoxyribonucleic acid (DNA), and determined that it served as the carrier for genetic information.⁹ Four years later James Watson and Francis Crick published their now famous determination of the double helix structure of DNA. Subsequently, Dr Crick contributed to the decryption of the genetic code, and proposed the ‘central dogma’ of molecular biology. This ‘central dogma’ involves information that is encoded in a segment of DNA (the gene), being transcribed into ribonucleic acid (RNA), which is then translated to direct the formation of a protein. In more recent times, our understanding of DNA has grown exponentially, and has included the completion of the first full-length sequence of the human genome, containing approximately 25 000 genes.¹⁰ The understanding of the information encoded in our DNA has opened up numerous possibilities for biomedical research and the development of novel diagnostic and therapeutic techniques.¹¹

Determining what the best way is to make use of this genomic information for the greater good of humanity is a difficult task that must now be faced. This task touches upon innovation policy, social and economic policy, as well as the ownership of what some view as the common heritage of human kind.¹² In this regard, it can be noted that there is no exact way in which the term ‘innovation’ can be defined. It has been used to describe ‘the introduction of something new,’ as well as ‘a scientific approach for finding newer better solutions to problems,’ to name only a few. However defined, innovation has been said to lie at the core of economic and industrial development.¹³

⁸ *Association for Molecular Pathology et al v United States Patent & Trademark Office et al* (note 3) at 24.

⁹ *Ibid* at 25.

¹⁰ *Ibid* at 26.

¹¹ *Ibid*.

¹² *Ibid* at 27.

¹³ DE Long ‘Crossing the innovation divide’ (2008) 81 *Temp. L. Rev.* 507 at 511.

1.2.2.2 Molecular biology and gene sequencing

1.2.2.2.1 DNA

DNA is a molecule that consists of four repeating chemical units known as ‘nucleotides.’ These are adenine, thymine, cytosine and guanine. These four nucleotides are linked together by chemical bonds to form a strand (or polymer) that is referred to as the DNA molecule. Although DNA can exist in a single stranded form, it typically exists in its double-stranded form referred to as a ‘double helix.’ This structure of DNA is made possible owing to the ‘base pairing’ property that DNA possesses. This property involves an adenine on one strand of DNA always binding to a thymine on the other strand, and a guanine on one strand of DNA always binding to a cytosine on the other strand.¹⁴ This property further provides a mechanism for copying the genetic information in an existing nucleic acid chain to form a new chain.¹⁵

Genes specify the kinds of proteins that are made within cells. The linear order of nucleotides that make up a polynucleotide, such as a gene, is often referred to as the ‘nucleotide sequence,’ ‘DNA sequence’ or ‘gene sequence.’¹⁶ Genes and the information that they contain are considered to be products of nature, universally present in each individual. Moreover, the information content of a human gene sequence is fixed. This is important because although many inventive steps may be necessary to allow researchers to extract and read a gene sequence, it remains an undisputed fact that the ordering of the nucleotides within the sequence is determined by nature.¹⁷ The sequence of a gene without any variations is known as a ‘wild-type’ or a ‘normal’ gene sequence. It is against this sequence that other gene sequences are compared.¹⁸ Variations (also known as mutations) of the human genome are common, and small-variation mutations and large-scale variations are possible. Some of these variations have little or no effect on the body’s processes. However, other variations, including those that appear to

¹⁴ *Association for Molecular Pathology et al v United States Patent & Trademark Office et al* (note 3) at 28.

¹⁵ J Berg et al *Biochemistry* (5ed) (2002) 117.

¹⁶ *Association for Molecular Pathology et al v United States Patent & Trademark Office et al* (note 3) at 30.

¹⁷ *Ibid* at 31.

¹⁸ *Ibid*.

correlate with an increased risk of a particular disease, can indeed interfere with the body's processes.¹⁹ Further, there are variants whose effect on the body's processes, if any, has yet to be determined.²⁰ DNA as it is found in the body is known as 'native' or 'genomic' DNA. It is packaged, along with proteins, into structures known as chromosomes.²¹

1.2.2.2.2 Extracted and purified DNA

In *AMP v. USPTO*²² the Court was of the view that although the parties used the term 'isolated DNA' to describe DNA that is separated from proteins and other DNA sequences, the term 'isolated DNA' possesses a specific legal definition that is related to its use. Judge Sweet provided that the term 'extracted DNA' was to be used to refer to DNA that has been removed from the cell and separated from other non-DNA materials in the cell. Regarding the term 'purified DNA,' the Judge in this case stated that this was to be used to refer to extracted DNA that has been further purified to separate the particular DNA segment of interest from other DNA in the genome.²³ It is possible for native DNA, together with the associated chromosomal proteins, to be extracted from its cellular environment, using well-established laboratory techniques. A specific segment of DNA, such as that encoding a gene, may then be excised and purified.²⁴ Further, DNA molecules can also be chemically synthesised within a laboratory. As mentioned, native DNA, unlike purified DNA or synthesised DNA, is packaged into chromosomes. However, when DNA is copied (replicated), short segments of DNA are dissociated from the chromosomal proteins, although they are still contained within the cell.²⁵ It must also be noted that purified or synthesised DNA may be useful as a tool for biotechnological applications, for which native DNA cannot be used. An example of a biotechnological application for purified or synthesised DNA is their use as a 'probe,' which is a diagnostic tool that is used to target and bind to a particular DNA sequence, thus allowing

¹⁹ *Association for Molecular Pathology et al v United States Patent & Trademark Office et al* (note 3) at 32.

²⁰ *Ibid* at 33.

²¹ *Ibid*.

²² *Association for Molecular Pathology et al v United States Patent & Trademark Office et al* (note 3).

²³ *Ibid* at 35.

²⁴ *Ibid* at 34.

²⁵ *Ibid* at 35.

the sequence to be detected.²⁶ Purified or synthesised DNA can also be used as a ‘primer’ to sequence a target portion of DNA. Sequencing is a process that is used to determine the order of nucleotides in a DNA sequence, or to perform polymerase chain reaction (PCR) amplification. PCR is a process that makes use of target DNA-specific primers to duplicate the quantity of target DNA exponentially.²⁷

1.2.2.2.3 RNA

Ribonucleic acid (RNA) is another nucleic acid that is found in cells. RNA is similar to DNA in that it is composed of a combination of four different nucleotides. Three of these nucleotides are the same as the ones incorporated into DNA, however, unlike DNA, RNA uses uracil instead of thymine. Additionally, the sugar-phosphate backbone in RNA is chemically different from that of DNA. Protein synthesis occurs via a two-step process: transcription and translation.²⁸ During transcription a temporary copy of a specific DNA sequence, in the form of an RNA molecule, is made. During this process, a discrete segment of DNA unwinds itself inside the cell. The bases of the DNA molecule then act as ‘clamps’ that hold the bases of the forming RNA molecule in place while the chemical bonds of its backbone are formed.²⁹ Each nucleotide in the DNA strand corresponds to its opposite nucleotide in the forming RNA molecule. The newly generated RNA is known as pre-messenger RNA (pre-mRNA). This pre-mRNA contains what is referred to as an ‘interrupted character’ owing to the fact that both introns and exons are transcribed from DNA into pre-mRNA.³⁰ Introns do not function in coding for a protein, and are cut out of this pre-mRNA in a process known as ‘splicing.’ What remains after this process are the exons, which are joined in a consecutive order to form the ‘final messenger RNA’ (mRNA).³¹

²⁶ *Association for Molecular Pathology et al v United States Patent & Trademark Office et al* (note 3) at 36.

²⁷ *Ibid.*

²⁸ *Ibid* at 38.

²⁹ *Ibid.*

³⁰ *Berg* (note 15) at 118.

³¹ *Association for Molecular Pathology et al v United States Patent & Trademark Office et al* (note 3) at 39.

During the process of translation, the mRNA molecule serves as the template for the assembly of a protein. In this process the mRNA bases and other proteins in the cell serve as clamps to hold the corresponding amino acids in position whilst the chemical bonds between the amino acids form.³² The codons (three consecutive nucleotide bases) that are originally found in DNA and copied into mRNA determine both which amino acids are incorporated into the protein, and the order in which these amino acids are incorporated.³³ Sixty-four codons are possible owing to the fact that there are four bases and three positions within each codon. In addition, these sixty-four codons code for twenty natural amino acids.³⁴ The genetic code explains the relationship between codons and amino acids, and owing to the fact that more than one codon can code for an amino acid, the genetic code is considered to be redundant. However, the genetic code is not considered to be ambiguous based on the fact that each codon only codes for one amino acid.³⁵ Thus, given a polynucleotide gene sequence with a defined start and stop position, one can predict its corresponding polypeptide sequence by reading the codons, which each map to a specific amino acid. However, owing to the degeneracy of the genetic code the reverse is not true. This means that one cannot determine the precise polynucleotide sequence of a gene from its polypeptide sequence.³⁶

1.2.2.2.4 Complementary DNA

Complementary DNA (cDNA) is a type of DNA molecule, and is produced from mRNA during a process known as 'reverse transcription.' cDNA is 'complementary' to the mRNA from which it is generated, meaning that each base in the cDNA can bind to the corresponding base in the mRNA from which it is produced. A cDNA molecule therefore represents an exact copy of one of the protein coding sequences encoded by the original genomic DNA.³⁷ cDNA is often produced in a laboratory, however, naturally occurring cDNAs, known as 'pseudogenes,' do exist in the human genome and are

³² *Association for Molecular Pathology et al v United States Patent & Trademark Office et al* (note 3) at 40.

³³ *Ibid.*

³⁴ J Kwan 'A nail in the coffin for gene patents' (2010) 25 (9) *Berkeley Technology Law Journal* 9 at 17.

³⁵ *Ibid.*

³⁶ *Ibid.*

³⁷ *Association for Molecular Pathology et al v United States Patent & Trademark Office et al* (note 3) at 40.

structurally, functionally and chemically identical to cDNAs that are produced in a laboratory.³⁸ Owing to the fact that cDNA does not contain introns, the production of proteins from cDNA does not require RNA splicing. In addition, some cDNAs can be used to produce proteins without the addition of regulatory sequences whilst other cDNAs cannot.³⁹

1.2.2.2.5 DNA sequencing

As mentioned previously, DNA sequencing is the process by which the ordering of the nucleotides within a DNA molecule is determined. This process does not change the information that is contained within the native DNA sequence. DNA sequencing plays a role in diagnostic testing to determine whether a gene contains any variations that have been associated with a particular medical condition.⁴⁰ These variations and any association with a propensity to develop a particular disease are caused by nature.⁴¹ Further, the sequencing of native DNA involves having to first extract the DNA from the cells of a tissue sample.⁴²

Many scientific researchers skilled in molecular biology are familiar with the techniques required for gene sequencing. However, owing to the fact that sequencing requires knowledge of the order of nucleotides of a portion of the target DNA sequence, some effort and ingenuity is necessary for the initial sequencing of the target DNA.⁴³

1.2.3 The nexus between law and biology - what is a gene patent?

The debate over the patenting of genes is a long-standing one. Private companies have invested billions of dollars in genetic research with the hope that they will be granted

³⁸ *Association for Molecular Pathology et al v United States Patent & Trademark Office et al* (note 3) at 41.

³⁹ *Ibid* at 42.

⁴⁰ *Ibid* at 43.

⁴¹ *Ibid* at 44.

⁴² *Ibid*.

⁴³ *Ibid* at 46.

intellectual property protection afforded by patents.⁴⁴ Genetic research has had a great impact on the world's economy, as well as on other spheres such as medicine, pharmaceuticals and biotechnology.⁴⁵ However, even though gene patents have been the subject of considerable debate, a precise definition of what constitutes a gene patent is lacking.⁴⁶ The Nuffield Council of Bioethics⁴⁷ sets out what it declares to be an exhaustive definition of the forms in which genes or DNA may be claimed in patents, where the common feature is that the patent claims either a nucleic acid (DNA or RNA) sequence, or a method of identifying the existence of such a sequence in an individual.⁴⁸ Traditionally, patents have been granted for tangible inventions. However, the patent system has grown to keep pace with technological developments, and patents have been granted for less tangible inventions and for biotechnological inventions incorporating genetic material in some manner.⁴⁹ A 2005 study estimated that, at that time, more than 4000 genes had been patented in the United States. Likewise, a large proportion of the genome is the subject of patent claims at the European Patent Office.⁵⁰

Gene patents concerning nucleic acid molecules as products *per se* allow the owner of such a patent to exclude all uses of the molecule. However, a patented process involving a diagnostic method may refer to a nucleic acid molecule, but the use of the molecule for purposes other than the patented process will be permitted.⁵¹ Single nucleotide polymorphisms (SNP) involve a variation in the human genetic code of a single base within a gene. A patent over a SNP within a gene may co-exist with a patent that claims the gene as a whole, and based on this, one gene may be the subject of multiple patents.

⁴⁴ D Resnik *Owning the genome: A moral analysis of DNA patenting* (2004) at 6.

⁴⁵ *Ibid.*

⁴⁶ K Jensen and F Murray 'Intellectual property landscape of the human genome' (2005) 310 *Science* 239 at 239.

⁴⁷ Nuffield Council on Bioethics *The Ethics of Patenting DNA: A Discussion Paper* (2002) Available at: <http://www.nuffieldbioethics.org/sites/default/files/The%20ethics%20of%20patenting%20DNA%20a%20discussion%20paper.pdf> [Accessed 4 February 2011].

⁴⁸ N Hawkins 'Human gene patents and genetic testing in Europe: A reappraisal' (2010) 7 (3) *SCRIPTed* 453 at 454-455. Available at: <http://www.law.ed.ac.uk/ahrc/script-ed/vol7-3/hawkins.pdf> [Accessed 29 December 2010].

⁴⁹ *Ibid* at 454.

⁵⁰ *Ibid.*

⁵¹ *Ibid* at 455.

For example, it is possible for patents to be granted for an entire gene, causative mutations within the gene and diagnostic methods relating to the gene.⁵²

Human gene patents 'test the traditional assumptions and boundaries of the patent system' owing to the fact that they do not at first glance appear to easily fit into the patentability requirements of novelty, non-obviousness and usefulness. For example, they appear to be discoveries rather than inventions in the traditional sense, and are not novel as they have always been present within the human body.⁵³ The problematic nature of human gene patents was recently considered in *AMP v. USPTO*.⁵⁴ In this case, patents for genes as compositions of matter were declared invalid under the United States products of nature doctrine. Furthermore, this case highlights the fact that the United States Supreme Court had not yet considered the question of whether or not genes are patentable subject matter.⁵⁵

⁵² Hawkins (note 48) at 455.

⁵³ *Ibid.*

⁵⁴ *Association for Molecular Pathology et al v United States Patent & Trademark Office et al* (note 3).

⁵⁵ Hawkins (note 48) at 456.

CHAPTER 2: ARGUMENTS FOR AND AGAINST THE PATENTING OF GENES

There are many arguments that have been raised in support of, as well as in opposition to, the practice of gene patenting. Although it is beyond the scope of this dissertation to discuss them all, a few of them will be mentioned in this chapter.

2.1 Arguments for the patenting of genes

2.1.1 Gene patents encourage the full disclosure of scientific research

The written disclosure requirement in a patent application provides that the details of the claimed invention must be fully disclosed. The purpose behind this requirement is to enable a person of ‘ordinary skill in the art’ to make, use or practice the claimed invention. An example of this requirement can be found in section 112 of Title 35 of the United States Code (U.S.C). Proponents of this approach believe that through the written disclosure requirement, other researchers will become aware of the invention, thus avoiding any unnecessary duplication of research effort and assisting research in emerging fields.⁵⁶ It has also been contended that the written disclosure requirement can promote progress by facilitating openness in science and technology and by discouraging secrecy.⁵⁷ Further, supporters of this view have argued that denying patents on genes could potentially lead to the situation where companies wanting to use their knowledge to create products would resort to trade secrecy. Under such circumstances, research development may be slowed owing to the fact that inventors and academics may withhold knowledge and delay the release of products.⁵⁸

⁵⁶ D Keays ‘Patenting DNA and amino acid sequences – an Australian perspective’ (1999) 7 *Health Law Journal* 69 at 71.

⁵⁷ DB Resnik ‘The morality of human gene patents’ (1997) 7 (1) *Kennedy Institute of Ethics Journal* 43 at 49.

⁵⁸ Keays (note 56) at 71.

2.1.2 Gene patents are an incentive for innovation

One of the main arguments for the award of gene patents is that they are beneficial to society owing to the fact that they encourage scientific innovation.⁵⁹ Advances in genetic research have the potential to impact favourably on a broad range of industries, for example, medical research, agriculture and waste processing, to name only a few, and this list is likely to grow as new applications are discovered.⁶⁰ Additionally, many countries view the biotechnology industry as being of great importance to their future economic growth. Governments worldwide are thus making policy decisions aimed at encouraging innovation in their biotechnology spheres.⁶¹ For example, in 1998 the European Union enacted Directive 98/44 on the Legal Protection of Biotechnological Inventions.⁶² This Directive operates on a clear policy goal of encouraging scientific researchers to obtain and isolate elements valuable to medical biotechnology. This approach is in line with the established patent practice of allowing patents on isolated natural substances.⁶³ Furthermore, proponents of this view argue that patent law is an instrument of economic policy, and its function is to provide an incentive to invest and innovate.⁶⁴ This was explained in the preamble to the Venetian Statute of 1474,⁶⁵ the first patent statute in history.⁶⁶ The preamble of this Statute provides as follows:

‘We have among us men of great genius, apt to invent and discover ingenious devices... Now, if such provision were made for the works and devices discovered by such persons, so that others who may see them could not build them and take the inventors’ honour away, more men would then apply their genius, would discover, and would build devices of great utility to our commonwealth.’

⁵⁹ Rimmer (note 5) at 2.

⁶⁰ A Hughes ‘Exploring the parameters of the gene patent debate’ (2004) 8 (2) *Journal of South Pacific Law*.

⁶¹ D Nicol ‘Cooperative intellectual property in biotechnology’ (2007) 4 (1) *SCRIPTed* 136 at 138. Available at http://www.lawgenecentre.org/refereed_pubs/nicolcooperative%202007.pdf [Accessed 5 February 2011].

⁶² Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions [1998] OJ L213/13.

⁶³ Hawkins (note 48) at 459.

⁶⁴ O Mills *Biotechnological inventions: Moral restraints and patent law* (2005) at 13.

⁶⁵ Venetian Statute on Industrial Brevets, Venice (1474).

⁶⁶ RC Kahrl *Patent Claim Construction* (2001) at 2-8.

In the context of biotechnological patents, those in favour of gene patents argue that such patents aid scientific research and development by encouraging investment in what would otherwise be a financially risky and unrewarding industry.⁶⁷ Moreover, it has been argued that it would be fundamentally unfair for researchers to be required to use vast resources, publicise their results and provide benefit to the public with no guarantee of a potential return on their investment in the form of a patent on their invention.⁶⁸ Therefore it has been suggested that without the protection of patents, scientific researchers may be deterred from pursuing high-risk and costly research projects. For instance, numerous companies routinely screen and eliminate potential programs with inadequate patent protection.⁶⁹

2.2 Arguments against the patenting of genes

2.2.1 Moral, ethical and religious objections to gene patenting

Those objecting to gene patents often rely on the argument that the practice of patenting genes is a violation of, or a threat to, human dignity.⁷⁰ Many religious groups have objected to the patenting of genes on moral and ethical grounds as well.⁷¹ For example, in 1995 representatives from more than eighty faiths and denominations held a press conference to declare their opposition to the patenting of genetically engineered animals, human genes, cells and organs.⁷² Additionally it has been argued that gene patents are ethically suspect owing to the fact that they concentrate the benefits of genome research in a few companies that are fortunate enough to have sufficient resources to obtain the gene patents.⁷³

⁶⁷ Keays (note 56) at 71.

⁶⁸ Ibid.

⁶⁹ Kwan (note 34) at 30.

⁷⁰ DB Resnik 'DNA patents and human dignity' (2001) 29 *J.L. Med. & Ethics* 152 at 152.

⁷¹ R Stone 'Religious leaders oppose patenting genes and animals' (1995) 268 *Science* 1126 at 1126.

⁷² Keays (note 56) at 71.

⁷³ Ibid at 72.

2.2.2 Genetic information is the heritage of humanity

The human genome has been described as being a blueprint of humanity's common heritage owing to the fact that the DNA structure that is inherited by each person is the result of millions of years of evolution.⁷⁴ This position is articulated in Article 1 of the United Nations Educational, Scientific and Cultural (UNESCO) Declaration on the Human Genome and Human Rights,⁷⁵ which states as follows:

‘The human genome underlies the fundamental unity of all members of the human family, as well as the recognition of their inherent dignity and diversity. In a symbolic sense, it is the heritage of humanity.’

Further, the World Health Organisation, in its report on ‘Genetics, genomics and the patenting of DNA’⁷⁶ provides that the claim that ‘the human genome is the common heritage of humanity’ implies that DNA has a special character, beyond that of ordinary biological molecules.⁷⁷ Additionally, this report states that human DNA is common to all human beings, past and present, and that it is therefore in some sense foundational. Moreover, based on this line of thinking, DNA is also in some sense instilled with biological, historical and even moral significance.⁷⁸ Article 4 of the UNESCO Declaration on the Human Genome and Human Rights⁷⁹ provides that ‘the human genome in its natural state shall not give rise to financial gains.’ Based on this Article, the decision in *AMP v. USPTO*⁸⁰ by Judge Sweet stating that isolated DNA is not patentable subject matter is arguably not in line with this Declaration. This is owing to the fact that the Declaration provides that the human genome is not patentable in its natural state, and thus

⁷⁴ ML Sturges ‘Who should hold property rights to the human genome? An application of the common heritage of humankind’ (1997) 13 *Am. U. Int'l L. Rev.* 219 at 249.

⁷⁵ AIRE/53/152. Available at: <http://www.unesco.org/new/en/social-and-humansciences/themes/bioethics/human-genome-and-human-rights/> [Accessed 15 January 2011].

⁷⁶ World Health Organisation Report on ‘Genetics, genomics and the patenting of DNA: Review of potential implications for health in developing countries’ (2005) Human Genetics Programme Chronic Diseases and Health Promotion. Available at: <http://www.who.int/genomics/FullReport.pdf> [Accessed 15 January 2011].

⁷⁷ *Ibid* at 31.

⁷⁸ *Ibid*.

⁷⁹ AIRE/53/152 (note 75).

⁸⁰ *Association for Molecular Pathology et al v United States Patent & Trademark Office et al* (note 3).

it can be inferred that parts of the human genome in an isolated state do indeed constitute patentable subject matter.

2.2.3 Gene patents are not in the public interest

Advocates of this view argue that the monopolies provided for by gene patents may come at a cost to the community in general because such patents have the potential to be used to prevent the use of a new invention.⁸¹ It has also been contended that gene patents are not in the public interest because that they can retard, rather than stimulate, scientific and economic progress based on the fact that they can block access to patented subject matter.⁸² Additionally, it has been argued that monopolies arising from patents over genetic tests can reduce incentives to correct flaws in the patented tests or to adopt new technologies,⁸³ and that restricted access to gene patents affects patients seeking to make genetically-informed medical decisions.⁸⁴

2.2.4 Gene patents restrict scientific research

One problem that has arisen is where the identification and patenting of one function of a gene may result in protection in law for all of the possible functions of the gene. Another obvious problem is that the effect that gene patents may have on downstream research at the time that the patents are granted is unknown. For example, patents on human DNA sequences could possibly have a negative effect on the translation of basic biomedical research into clinical applications.⁸⁵ Intellectual property rights can also become fragmented between different owners, and this could lead to a situation where

⁸¹ Keays (note 56) at 74.

⁸² AR Williamson 'Gene patents: Socially acceptable monopolies or an unnecessary hindrance to research?' (2001) 17 (11) *TRENDS in Genetics* 670 at 670.

⁸³ R Cook-Deegan 'Gene Patents' in Mary Crowley (ed) *From Birth to Death and Bench to Clinic: The Hastings Center Bioethics Briefing Book for Journalists, Policymakers, and Campaigns* (2008) 69 at 70. Available at:

http://www.thehastingscenter.org/uploadedFiles/Publications/Briefing_Book/gene%20patents%20chapter.pdf [Accessed 15 January 2011].

⁸⁴ EM Kane 'Patenting genes and genetic methods: What's at stake?' (2011) 6 (1) *Journal of Business and Technology Law* 101 at 101.

⁸⁵ Hawkins (note 48) at 469.

downstream researchers may find it too costly to do research in areas in which access to the patented material is required. Yet another concern is that where there are too many genomic patent rights in one area. This concern is based on the fact that it can become incredibly complicated to negotiate freedom to access the patented material with all of the rights holders.⁸⁶ This in turn can slow innovation, and give rise to what has been dubbed the ‘anti-commons,’ which is a problem that arises where multiple rights to exclude access to patented subject matter exist.⁸⁷ More specifically, the ‘tragedy of the anticommons’ refers to a public resource that is underused or made unavailable for public benefit owing to the fact that it is too encumbered by private interests.⁸⁸ Further, gene patents, unlike patents in other technical areas, are often difficult to invent around.⁸⁹ Even if it is possible to invent around a patent on a gene, it may prove to be very costly and time-consuming to do so. Therefore patent thickets to genetic testing may arise owing to gene patents. A patent thicket occurs where different individuals hold patents over the same DNA sequence.⁹⁰ Further, gene patents have the potential to lead to reduced access to genetic tests where disputes over licenses for particular patents are resolved too slowly.⁹¹

2.2.5 Gene patents encourage biocolonialism

Proponents of this view argue that gene patents can promote or legitimise biocolonialism, also known as biopiracy. Biopiracy can be defined as being the exploitation of the biological resources of other countries.⁹² In most instances biopiracy arises in respect to third world countries, which lack adequate resources to take advantage of their unique natural assets.⁹³ In this respect, developing countries have raised concerns regarding the

⁸⁶ Nicol (note 61) at 139.

⁸⁷ JM Buchanan and YJ Yoon ‘Symmetric tragedies: Commons and anti-commons’ (2000) 43 *The Journal of Law & Economics* 1 at 1.

⁸⁸ TA Hemphill ‘Gene patents, the anticommons, and the biotechnology industry’ (2010) 53 (5) *Research Technology Management* 11 at 12.

⁸⁹ Hawkins (note 48) at 471.

⁹⁰ *Ibid* at 472.

⁹¹ *Ibid* at 473.

⁹² Keays (note 56) at 72.

⁹³ *Ibid* at 73.

need to reconcile TRIPS⁹⁴ with the Convention on Biological Diversity⁹⁵ (CBD), which deals with the sustainable use and conservation of genetic resources. Their concerns stem from the fact that TRIPS⁹⁶ does not require the sharing of benefits of biodiversity-related patents with source countries or communities.⁹⁷ Advocates of this approach thus argue that the patenting of genes that are unique to another country is an unfair and inequitable utilisation of genetic resources.⁹⁸

2.2.6 Gene patents have a negative impact on developing countries

Many developing countries, for example, Kenya, are heavily dependent upon foreign organisations for technology transfer.⁹⁹ The ability of biotechnology firms in developing countries to copy inventions by examining foreign patent specifications may be restricted, but even this possibility is prevented when foreign inventions are patented in those countries themselves.¹⁰⁰ Although many believe that patents promote innovation, it can also be argued that from the perspective of developing countries, the development of an innovative system begins with copying. Proponents of this approach argue that the freedom to copy in a poor environment should ensure the uptake of foreign technology and information.¹⁰¹ For example, it can be seen that intellectual property laws have played a large role in the development of economic growth in the United States. However, upon closer inspection, one will see that until 1982 the United States had one of the developed world's most pro-competitive (least protective) patent laws. This demonstrates the fact that in many developing countries, strong intellectual property laws may not necessarily encourage economic growth, and may in fact have the opposite effect

⁹⁴ Agreement on Trade-Related Aspects of Intellectual Property Rights (note 2).

⁹⁵ (1992) 31 *ILM* 818.

⁹⁶ Agreement on Trade-Related Aspects of Intellectual Property Rights (note 2).

⁹⁷ LR Helfer 'Regime shifting: The TRIPS Agreement and new dynamics of international intellectual property law making' (2004) 29 (1) *The Yale Journal of International Law* 1 at 30.

⁹⁸ Keays (note 56) at 73.

⁹⁹ O Hannington et al 'Innovation and policy process: Case of transgenic sweet potato in Kenya' (2002) 37 (27) *Economic and Political Weekly* 2770 at 2775.

¹⁰⁰ G Dutfield et al 'Exploring the flexibilities of TRIPS to promote biotechnology capacity building and appropriate technology transfer' (2006) Produced for the European Commission's 6th Framework Programme as part of the project "Impacts of the IPR Rules on Sustainable Development (IPDEV)" at 40. Available at <http://ictsd.net/i/ip/3555/> [Accessed 5 October 2010].

¹⁰¹ *Ibid* at 13.

of hindering such growth.¹⁰² Concerns have also been raised, especially by developing countries, regarding the fact that gene patents can have a negative impact on health care costs. These health care costs include the cost of genetic tests and genetic therapies.¹⁰³

2.3 Discussion of the arguments for and against the patenting of genes

In sum, whether or not genes should be patentable presents a difficult question. In assessing whether or not genes should be regarded as being patentable subject matter, it is important to understand that a patent over a DNA sequence does not equate to ownership of that sequence.¹⁰⁴ Rather, a patent is a monopoly that is granted by the state that allows exclusive use of the invention for a set period of time (usually twenty years). Therefore a gene patent is more similar to a state sanctioned license than to an exclusive right of ownership.¹⁰⁵ One of the most convincing arguments against gene patents is that they threaten to inhibit scientific research. This is owing to the fact that, where patents are granted, patent thickets can arise making access to the patented subject matter difficult. Moreover, where biocolonialism is concerned, it would indeed be inequitable for a small number of companies to be vested with the exclusive rights to exploit the human genome, and there is clearly a need for benefit sharing.¹⁰⁶ Thus the argument against gene patents on the basis that they encourage biocolonialism is also one of the more convincing arguments against gene patenting.

Further, the argument that patents provide an incentive to invest and innovate is a compelling one, owing to the fact that the commercial incentive that is provided for by a patent is becoming increasingly significant as research is being funded more and more as a private enterprise.¹⁰⁷ However, no matter how much funding a research project is provided with, where existing patents cover basic research platforms research may still be hindered. On the other hand, even if it is accepted that patents promote innovation in

¹⁰² JH Reichman 'Intellectual property in the twenty-first century: will the developing countries lead or follow' (2009) 46 (4) *Houston Law Review* 1115 at 1117.

¹⁰³ Cook-Deegan (note 83) at 69.

¹⁰⁴ Keays (note 56) at 75.

¹⁰⁵ *Ibid.*

¹⁰⁶ *Ibid* at 77.

¹⁰⁷ Keays (note 56) at 75.

developed countries, where developing countries are concerned, it could also be argued that the development of an innovative system starts with copying.¹⁰⁸ Therefore the patenting of genes may hinder innovation in the biotechnology spheres of developing countries, as these countries will most likely not be able to afford access to patented subject matter. In addition, innovation may be hindered, especially in developing countries owing to the fact that patents are fundamentally anticompetitive because they have the potential to create monopolies. Therefore great care is required for an acceptable balance to be found between the protection of intellectual property rights and the promotion of competition.¹⁰⁹

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¹⁰⁸ Dutfield et al (note 100) at 13.

¹⁰⁹ D Schertenleib 'The patentability and protection of DNA based inventions in the EPO and the European Union' (2003) 25 *European Intellectual Property Review* 125 at 125.

CHAPTER 3: THE EFFECT OF THE TRIPS AGREEMENT ON THE PATENTABILITY OF GENES

Currently, intellectual property law is regulated through a combination of international organisations and treaties, bilateral agreements, regional treaties and instruments, and national laws.

3.1 Introduction to the TRIPS Agreement

The global intellectual property regime has changed radically over the past several decades owing to the emergence of new types of knowledge. These changes have obliged countries to reform their national intellectual property laws so that they are in line with the international standards of intellectual property protection required by international intellectual property treaties.¹¹⁰ The TRIPS Agreement¹¹¹ is an important international treaty because it consolidates pre-existing intellectual property conventions into one agreement. TRIPS extends the ambit of these agreements by establishing sanctions for non-compliance and universal minimum standards of protection.¹¹² Further, TRIPS increased the responsibility of World Trade Organisation member governments to enact enforceable and clear national laws to allow them to comply with the standards of intellectual property protection set out within this Agreement.¹¹³ However, a problem with requiring member states of TRIPS to address intellectual property issues on an individual basis is that it has led to inconsistent intellectual property rights being implemented at national levels.¹¹⁴

¹¹⁰ BP Mey 'Unfettered consumer access to affordable therapies in the post-TRIPS era: A dead-end journey for patients? Kenya and India case studies' (2010) 13 (3) *The Journal of World Intellectual Property* 403 at 403.

¹¹¹ Agreement on Trade-Related Aspects of Intellectual Property Rights (note 2).

¹¹² D Rangnekar 'Geneva rhetoric, national reality: Implementing TRIPS obligations in Kenya' (2008) CSGR working paper 241/08 at 3.

¹¹³ Mey (note 110) at 403.

¹¹⁴ CA Fowler 'Ending genetic monopolies: How the TRIPS Agreement's failure to exclude gene patents thwarts innovation and hurts consumers worldwide' (2010) 25 *Am. U. Int'l L. Rev.* 1073 at 1078-1079.

3.2 Provisions of TRIPS that are relevant to the patentability of genes

According to Article 1 of TRIPS, member states can enforce any level of intellectual property protection as long as the level of protection that they choose meets the minimum standards of protection set out in TRIPS, and does not conflict with TRIPS. Patentable subject matter is set out in Article 27.1 of TRIPS, which provides as follows:

‘Patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application..’

‘Footnote 5 For the purposes of this Article, the terms "inventive step" and “capable of industrial application” may be deemed by a Member to be synonymous with the terms “non-obvious” and “useful” respectively.’

Patentability is therefore subject to qualification under only three independent criteria as set out in Article 27.1 of TRIPS. However, TRIPS does not define these three requirements for patentability, for example, TRIPS provides no uniform standard of what constitutes an ‘invention.’¹¹⁵ Owing to this, member states of TRIPS have the flexibility of adapting these concepts as they see fit.¹¹⁶ Further, TRIPS allows, but does not require, member states to exclude from patentability various subject matter set out in Articles 27.2, 27.3(a) and 27.2(b).¹¹⁷ For example, Article 27.2 provides as follows:

‘Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.’

¹¹⁵ Fowler (note 114) at 1081.

¹¹⁶ CM Corea *Trade related aspects of intellectual property rights: A commentary on the TRIPS Agreement* (2007) 94.

¹¹⁷ Fowler (note 114) at 1080.

Article 33 of TRIPS also states that the duration of a patent is a minimum of 20 years, counted from its filing date, Article 30 provides for exceptions to rights conferred and Article 29 contains the disclosure requirement for patentability. Overall, TRIPS is silent with regard to the patentability of naturally occurring material, and it does not list genetic material as an exception to patentable subject matter.¹¹⁸

3.3 Effect of TRIPS on developing countries

Individual member states of TRIPS are at different levels of social and economic development, and problems therefore arise with addressing complex issues concerning patentable subject matter on an *ad hoc* basis.¹¹⁹ For example, one of the problems faced by developing countries is that if they open their domestic markets to trade, then they are confronted with political and economic pressure to protect foreign intellectual property under TRIPS. However, if they choose to protect foreign intellectual property under TRIPS, they create conditions that force them to abandon their option of obtaining intellectual property at the lowest price possible.¹²⁰ This problem has been referred to as the ‘development dilemma,’¹²¹ and it has been worsened by the implementation of free trade agreements containing ‘TRIPS plus’ provisions. These ‘TRIPS plus’ provisions have the effect of further increasing the level of intellectual property right protection in developing countries.¹²²

¹¹⁸ Fowler (note 114) at 1082.

¹¹⁹ *Ibid.*

¹²⁰ Reichman (note 102) at 1119.

¹²¹ *Ibid.*

¹²² *Resource book on TRIPS and development* (2005) UNCTAD-ICTSD Project on IPRs and sustainable development (2005) at 409. Available at: http://www.iprsonline.org/unctadictsd/docs/RB2.5_Patents_2.5.5_update.pdf [Accessed 24 January 2011].

CHAPTER 4: THE PATENTABILITY OF GENES IN EUROPE

The Convention on the Grant of European Patents 1973 (hereinafter the EPC), national laws, and European Union directives govern intellectual property rights in the European Union.¹²³

4.1 Legislative framework

4.1.1 The European Patent Convention

The EPC is a multilateral treaty, and it harmonises the national laws of member states in the spheres of patentability of inventions and validity up until the point of grant.¹²⁴ The EPC also provides a legal framework for the granting of European patents using a single harmonised procedure before the European Patent Office (EPO). EPC membership goes beyond countries of the European community, and covers an economic area of considerable weight.¹²⁵ After a patent is granted through the EPO it is nationalised in individual countries designated by the applicant. However, national laws govern the enforcement of a patent in each individual country.¹²⁶ Based on the fact that each country has different national laws, there is a lack of uniformity between these countries. Thus, the European Union sets minimum standards for patent protection by issuing directives that member states are required to implement into their national laws.¹²⁷

Article 52 of the EPC is important because it determines which types of inventions constitute patentable subject matter.¹²⁸ Article 52.1 of the EPC states as follows:

‘European patents shall be granted for any inventions which are susceptible of industrial application, which are new and which involve an inventive step.’

¹²³ E Bryan ‘Gene protection: How much is too much? Comparing the scope of patent protection for gene sequences between the United States and Germany’ (2009) 9 *Journal of High Technology Law* 52 at 56.

¹²⁴ C Seville *EU Intellectual Property Law and Policy* (2009) 101.

¹²⁵ R Hacon and J Pagenberg *Concise European patent law* (2007) 1.

¹²⁶ Bryan (note 123) at 57.

¹²⁷ *Ibid.*

¹²⁸ Seville (note 124) at 118.

Article 83 of the EPC provides the disclosure requirement for patentability, and states that the patent application ‘shall disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.’ Grounds for revocation of a patent under Article 138 of the EPC include the ground that the subject of the European patent is not patentable subject matter, as well as the ground that the European patent does not disclose the invention in a manner that is sufficiently clear and complete for it to be carried out by a person skilled in the art.

4.1.2 The Directive on the Legal Protection of Biotechnological Inventions

The Directive on the Legal Protection of Biotechnological Inventions¹²⁹ (hereinafter referred to as the Biotechnology Directive 98/44) was introduced in 1998, and one of its main objectives is to assist in the harmonisation of patent practice in the sphere of biotechnology amongst member states.¹³⁰ This Directive was a highly contested issue in Europe at the time that it was introduced, and therefore it can be used as another example to demonstrate the controversy surrounding the topic of gene patents. Although many individual European countries objected to the Biotechnology Directive 98/44, by 2007 all of these countries had incorporated it into national law.¹³¹ Another goal of the Biotechnology Directive 98/44 was to clarify the protection afforded to biotechnological inventions, and the Directive makes it clear that biotechnological inventions are to be considered for patent protection based on the same standards applied to any other area of technology.¹³² In addition, the Biotechnology Directive 98/44 sets out what is considered patentable. For example, Article 3.2 provides that biological material isolated from its natural environment is considered to be patentable.¹³³ Recital 22 of the Biotechnology Directive 98/44 states as follows:

¹²⁹ Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions [1998] OJ L213/13.

¹³⁰ F Leverve ‘Patents on genes, usefulness, and the requirement of industrial application’ (2009) 4 (4) *Journal of Intellectual Property Law & Practice* 289 at 290.

¹³¹ Gold and Carbone (note 4) at S39.

¹³² Bryan (note 123) at 57.

¹³³ *Ibid* at 57-58.

‘Whereas the discussion on the patentability of sequences or partial sequences of genes is controversial; whereas, according to this Directive, the granting of a patent for inventions which concern such sequences or partial sequences should be subject to the same criteria of patentability as in all other areas of technology: novelty, inventive step and industrial application; whereas the industrial application of a sequence or partial sequence must be disclosed in the patent application as filed’

Article 1.1 of the Biotechnology Directive 98/44 states that ‘Member States shall protect biotechnological inventions under national patent law,’ and thus requires Member States to adjust their national law to take account of the Biotechnology Directive 98/44.

Further, Article 3 of the Biotechnology Directive 98/44 states that:

1. ‘For the purposes of this Directive, inventions which are new, which involve an inventive step and which are susceptible of industrial application shall be patentable even if they concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used.
2. Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature.’

4.2 Isolated DNA – invention or discovery?

*Howard Florey/Relaxin*¹³⁴ involved a patent for a hormone (relaxin) that relaxes the uterus during childbirth. It was hoped that the use of this hormone would reduce the need for caesarean deliveries. Relaxin from pigs had been previously described in 1926, but it was not until 1975 that a human form of relaxin was isolated and its chemical structure

¹³⁴ [1995] EPOR 541 (EPO (Opposition Division)).

determined. However, it would only be possible to use human relaxin for the medical treatment envisaged. Although human relaxin occurs naturally in the human body, a synthetic form of the human hormone was required for medical use. Having isolated the nucleotide sequence coding for the hormone, recombinant DNA techniques were used to produce a synthetic form of human relaxin. A patent was issued, but was later opposed.¹³⁵ This opposition was in part based upon the ground that the subject matter of the patent was a discovery and therefore not patentable. The Opposition Division agreed that the finding of a substance that occurred naturally would indeed not be patentable subject matter.¹³⁶ However, the Opposition Division was of the view that if the substance that occurred naturally was isolated from its surroundings and a process for obtaining it was developed, then that process would itself be patentable. Moreover, if the substance could be properly characterised by its structure and was new in the sense that it did not have any previously recognised existence, then the substance may itself be patentable subject matter.¹³⁷ Article 3.2 of the Biotechnology Directive 98/44 has now confirmed this decision.¹³⁸

Generally, patents are granted for inventions, not discoveries under the EPC and the United Kingdom Patents Act 1977. However, the term ‘invention’ is not defined in either.¹³⁹ Section 1(2)(a) of the Patents Act 1977 and Article 52.2 of the EPC provide that discoveries are not inventions, and are therefore not considered to be patentable.¹⁴⁰ However, the courts have interpreted this to mean that the useful product or process resulting from a discovery may indeed be patentable.¹⁴¹ Further, the discovery together with its technical application can form part of the assessment for inventive step and novelty.¹⁴² This means that the technical application of a previously unknown discovery may be considered to be inventive and new despite the fact that the discovery itself is not

¹³⁵ Seville (note 124) at 121.

¹³⁶ *Howard Florey/Relaxin* [1995] EPOR 541 (EPO (Opposition Division)). Now confirmed by EPC 2000, Rule 27(a). See also Article 3.2 of the Biotechnology Directive 98/44.

¹³⁷ Seville (note 124) at 121.

¹³⁸ [1995] EPOR 541 (EPO (Opposition Division)).

¹³⁹ Hawkins (note 48) at 456.

¹⁴⁰ *Ibid.*

¹⁴¹ *Ibid.*

¹⁴² *Genentech Inc's Patent* (1989) RPC 147 (CA) at 208.

patentable and the technical application on its own would be too obvious for a patent.¹⁴³ The expression of a nucleic acid sequence in a vector, or the application of the sequence in a genetic test would therefore not be excluded from patentability on the basis of the fact that it is a discovery and not an invention as such.¹⁴⁴ The Biotechnology Directive 98/44 prohibits the patenting of discoveries as well. However, Article 5.2 of this Directive states that:

‘An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.’

This exact wording can be found in Rule 23(e)(2) of the EPC as well. The European approach to patentability here is thus different to the approach taken by a United States District Court in the recent decision by Judge Sweet in *AMP v. USPTO*.¹⁴⁵ In this case the breast cancer genetic testing patents held by Myriad Genetics were invalidated. Although there is no specific prohibition of the patenting of discoveries in the United States, the court in this case relied on the ‘product of nature’ doctrine, which denies patentability to substances isolated from their naturally occurring form in the absence of the isolated substance having ‘markedly different characteristics’ to the naturally occurring substance.¹⁴⁶ DNA has a dual nature in that it has a chemical form, but its value is mainly found in the information that it encodes. In this case Judge Sweet held that owing to the fact that the value of DNA was primarily informational, and as the information was the same in both its isolated and natural state, that the substance in question therefore did not have ‘markedly different characteristics.’ Further, based on this reasoning, Judge Sweet held that the substance in question was not patentable.¹⁴⁷

¹⁴³ Hawkins (note 48) at 456.

¹⁴⁴ *Ibid.*

¹⁴⁵ *Association for Molecular Pathology et al v United States Patent & Trademark Office et al* (note 3).

¹⁴⁶ Hawkins (note 48) at 457.

¹⁴⁷ *Ibid.* It must be kept in mind that this decision is the subject of an appeal and even if the non-patentability of DNA is upheld on appeal, the decision may be supported on different reasoning.

Whether or not this holding in *AMP v. USPTO*¹⁴⁸ also accounts for the degenerative nature of codons for DNA is not entirely clear. This is owing to the fact that more than one codon can code for the same amino acid and thus contain the same information. However, it is likely that, based on the reasoning of Judge Sweet that DNA is primarily informational, the holding will indeed account for the degenerative nature of codons for DNA. Thus, an isolated DNA sequence in which the codons have been altered so that they differ from the native sequence, but which still produces the same protein as the native sequence, will likely be regarded as being unpatentable under this reasoning as well.

Article 5.2 of the Biotechnology Directive 98/44 largely prevents such an approach to the nature of DNA in Europe, where DNA has consistently been regarded as being a chemical substance without reference being made to the information that it encodes.¹⁴⁹ However, many legal commentators do not agree with this current approach in Europe. Doubts have been raised regarding whether the isolation and characterisation of a naturally occurring substance (for example, a DNA sequence) is adequately different from the discovery of the substance.¹⁵⁰

Generally, patent offices grant patents for DNA sequences by treating them in the same way that they treat other chemical entities. Therefore, a problem arises owing to the fact that the dual nature of DNA makes patents on genes different from patents on other chemical compounds. It can thus be argued that it is the information encoded in the DNA sequence that is the most important element of a product patent, and in this sense, the isolated DNA would serve the same purpose as the native DNA sequence in that they both encode the same information.¹⁵¹ Further, owing to the fact that the information encoded in the DNA sequence is not itself invented by the researcher or patent holder, but is rather inherent in the nature of the DNA itself, it could also be argued that a DNA

¹⁴⁸ *Association for Molecular Pathology et al v United States Patent & Trademark Office et al* (note 3).

¹⁴⁹ Hawkins (note 48) at 457.

¹⁵⁰ *Ibid* at 458.

¹⁵¹ *Ibid*.

sequence is a discovery and not an invention.¹⁵² However, on the other side of the argument it may be scientifically incorrect to characterise a DNA sequence according to only its informational value without reference to its chemical structure. This is owing to the fact that DNA does act via its chemical structure within the body, and many diagnostic tests are also based on the chemical structure of the DNA.¹⁵³ Overall, it may be difficult to come to an intellectually defensible distinction between invention and discovery, especially with regard to the patenting of genes.¹⁵⁴ Although this debate concerning the appropriateness of isolated natural products continues, in practice it remains the case that product patents on DNA sequences *per se* have been granted by European patent offices.¹⁵⁵

4.3 Novelty

Section 1(1)(a) of the United Kingdom Patents Act 1977 (hereinafter the Patents Act 1977) and Article 52.1 of the EPC provide that a patent may be granted only for an invention that is new. Further, section 2(1) of the Patents Act 1977 and Article 54.1 of the EPC state that an invention shall be taken to be new if it does not form part of the state of the art. Based on section 2(2) of the Patents Act 1977 and Article 54.2 of the EPC, the question that must be asked in assessing what forms part of the state of the art is whether or not the invention has already been made public, and this is essentially a factual enquiry.¹⁵⁶ Where gene patents are concerned, it is often argued that the invention does not meet the novelty requirement owing to the fact that the substance in question exists in nature, and is therefore not novel. Nevertheless, it is established patent practice to recognise novelty for a natural substance that has been isolated for the first time, and that has not been previously recognised.¹⁵⁷

¹⁵² Hawkins (note 48) at 458.

¹⁵³ *Ibid.*

¹⁵⁴ Seville (note 124) at 121.

¹⁵⁵ Hawkins (note 48) at 459.

¹⁵⁶ Seville (note 124) at 105.

¹⁵⁷ Hawkins (note 48) at 459-460.

4.3.1 Enabling disclosure

In *Asahi Kasei Kogyo KK's Application*¹⁵⁸ the British House of Lords stated that an invention is not made available to the public merely by a published statement of its existence, unless the method of working is so self-evident as to require no explanation. In this case the House of Lords concluded that for anticipation, published information is required to contain an enabling disclosure.¹⁵⁹ Here it can be noted that anticipation is the word commonly used to assess the impact of the prior state of the art on the later invention.¹⁶⁰ Based on this principle, disclosure only destroys the novelty of a later invention if 'the information it contains, when understood by a person skilled in the art, is sufficient to allow reproduction of the later invention.'¹⁶¹

4.3.2 Product by process claims

The definition of infringement in section 60 suggests that the Patents Act 1977 assumes that any invention will involve either a product or a process.¹⁶² In addition, Article 64.2 of the EPC provides as follows:

'If the subject-matter of the European patent is a process, the protection conferred by the patent shall extend to the products directly obtained by such process.'

In the recent decision of *Kirin-Amgen Inc. and others v Hoechst Marion Roussel Ltd and others*¹⁶³ the House of Lords held that Article 64.2 of the EPC largely takes away the practical argument for allowing product-by-process claims. As a result, the EPO has been able to accept the argument that a new process is not enough to make the product

¹⁵⁸ [1991] RPC 485 (House of Lords).

¹⁵⁹ MI Schuster 'Sufficient disclosure in Europe: Is there a separate written description doctrine under the European Patent Convention?' (2007) 76 (2) *UMKC Law Review* 491 at 497.

¹⁶⁰ Paul Torremans *Intellectual property law* 5ed (2008) 56.

¹⁶¹ The United Kingdom Intellectual Property Office Examination Guidelines for Patent Applications relating to Biotechnological Inventions (2009) para 11.

¹⁶² *Kirin-Amgen Inc v Hoechst Marion Roussel Limited* (2005) 1 All ER 667 at 694.

¹⁶³ *Ibid.*

new.¹⁶⁴ Generally, the EPO will not accept ‘product by process’ claims, owing to the fact that a patentee who wishes to complain about dealings in a product made by his patented process can rely on Article 64.2 of the EPC and on his process claim. The House of Lords further held that the only time the EPO will accept a claim to a product that has been defined in terms of the process by which it is made, is when the product is new in the sense that it is different from any product that exists in the state of the art, but where this difference cannot be described using chemical or physical terminology.¹⁶⁵ Lord Hoffmann acknowledged that this would mean a change in practice in the United Kingdom, however, he added that this change was unlikely to be of great practical importance.¹⁶⁶ Thus, the Intellectual Property Office will now take the approach that a claim to a product obtained or produced by means of a process is anticipated by any prior disclosure of that particular product *per se*, regardless of its method of production.¹⁶⁷

4.3.3 Sequence claims

The circumstances in which a polynucleotide sequence is published can have a bearing on whether such an earlier publication will destroy the novelty of a later claim for that sequence.¹⁶⁸ However, the prior publication of a polynucleotide sequence as it is embedded in the human genome will not impugn the novelty of a polynucleotide sequence when it is claimed in its isolated state.¹⁶⁹

4.4 Inventive step (non-obvious)

4.4.1 Meaning of ‘person skilled in the art’/ ‘common general knowledge’

¹⁶⁴ *Kirin-Amgen Inc v Hoechst Marion Roussel Limited* (2005) 1 All ER 667 at 694.

¹⁶⁵ *Ibid.*

¹⁶⁶ *Ibid* at 696.

¹⁶⁷ The United Kingdom Intellectual Property Office Examination Guidelines (note 161) para 14.

¹⁶⁸ *Ibid* para 17.

¹⁶⁹ *Ibid.*

According to Article 52.1 of the EPC, for an invention to be patentable, it must have an ‘inventive step.’ Further, Article 56 of the EPC states that:

‘An invention shall be considered as involving an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art.’

The aim of Article 56 is to ensure that there is a quantitative advance on what constitutes the state of the art. The person ‘skilled in the art’ is presumed to be an ordinary practitioner aware of what was common general knowledge in the art at the relevant date.¹⁷⁰ The nature of the qualifications of the person ‘skilled in the art’ will also be dependent on the technical field in which the invention falls.¹⁷¹

4.4.2 Assessing inventive step: The goal is known

There is a general consensus that a patent should not be granted merely because the applicant has been involved in a laborious or costly effort. This is of particular relevance in the sphere of biotechnology. If the goal is known and enough of the practice and theory is known for an applicant to predict where he is going, then an obviousness objection will be well founded.¹⁷² Decisions of the EPO Boards of Appeal have confirmed that a specific recombinant DNA will be considered to be obvious if there is evidence to support the fact that all of the techniques required to produce the sequence were well known.¹⁷³ Thus, as more becomes known about various genomes and the genes that they contain, the more difficult it will become to establish an inventive step for any isolated gene.¹⁷⁴ The rate of innovation in the field of biotechnology is very rapid, which makes it difficult to answer the question of whether or not an invention is obvious. What constitutes the state of the art at the priority date of the application will therefore be of great importance to the outcome of the case at hand.¹⁷⁵ For example, data mining to

¹⁷⁰ Seville (note 124) at 112.

¹⁷¹ Ibid at 113.

¹⁷² The United Kingdom Intellectual Property Office Examination Guidelines (note 161) para 29. See for example *Genentech Inc's Patent* [1989] RPC 147 (Court of Appeal).

¹⁷³ Ibid para 31.

¹⁷⁴ Ibid para 32.

¹⁷⁵ Hawkins (note 48) at 460.

identify a new polynucleotide that is homologous to a polynucleotide with an already known function will not normally involve an inventive step.¹⁷⁶ Moreover, while a specified degree of homology may aid in distinguishing the newly identified sequence from one or more known homologous sequences, it will not usually be able to aid in the establishment of an inventive step.¹⁷⁷ Based on this, the identification of a human homologue of a gene that has previously been characterised from another species will not be considered to be inventive, regardless of the methods used in the identification of the homologue.¹⁷⁸

However, there are still areas of gene patents for which it is possible for the requirement of inventive step to be met. For example, the identification of the function of a novel gene that has not previously been identified may be inventive. This will in turn be dependent on the methods used to determine the function of the gene, and what is known in the prior art at the time.¹⁷⁹ Similarly, the identification of a novel single nucleotide polymorphism(s) within a known gene may be considered to be inventive provided that a novel and a non-obvious function can be assigned to it. An example here would be a relationship between a particular polymorphism(s) and the predisposition towards a certain disease.¹⁸⁰ It must also be kept in mind here that any prior art disclosure of any polymorphisms within the same gene, and their link with the same diseases, will generally render as obvious the discovery of further polymorphisms.¹⁸¹

4.5 Industrial application (useful)

It has been contended that the requirement of usefulness (also referred to as utility) should be applied stringently in order to ensure that inventions rather than discoveries are

¹⁷⁶ Hawkins (note 48) at 460.

¹⁷⁷ The United Kingdom Intellectual Property Office Examination Guidelines (note 161) para 34.

¹⁷⁸ Ibid.

¹⁷⁹ Hawkins (note 48) at 460-461. See also The United Kingdom Intellectual Property Office Examination Guidelines (note 161) para 35.

¹⁸⁰ The United Kingdom Intellectual Property Office Examination Guidelines (note 161) para 36.

¹⁸¹ Ibid.

patentable.¹⁸² Only inventions that are capable of industrial application are considered to be patentable subject matter under Article 52.1 of the EPC. Article 57 of the EPC provides that an invention shall be considered to be susceptible of industrial application if it can be made or used in any kind of industry. Further, Rule 27(1)(f) of the EPC stipulates that the description should indicate explicitly, when it is not obvious from the description or nature of the invention, the way in which the invention is capable of being exploited in industry. The requirement of industrial application for an invention to be regarded as being patentable subject matter raises a hurdle for the patenting of biological research, in particular for the patenting of gene sequences.¹⁸³ This is owing to the fact that it is not enough to merely identify a gene, one also needs to provide a use for it, which amounts to industrial application.¹⁸⁴

In addition, the Biotechnology Directive 98/44 addresses this subject, and states in Recital 23 that a DNA sequence without indication of a function does not contain any technical information and thus is not a patentable invention. Article 5.3 of the Biotechnology Directive 98/44 provides that the industrial application of a sequence (or partial sequence) of a gene must be disclosed in the patent application, and Recital 24 further provides useful hints as to how the requirement of industrial application should be applied. Recital 24 states as follows:

‘Whereas, in order to comply with the industrial application criterion it is necessary in cases where a sequence or partial sequence of a gene is used to produce a protein or part of a protein, to specify which protein or part of a protein is produced or what function it performs.’

The Biotechnology Directive 98/44 has been incorporated into the Implementing Regulations of the EPC, so as to avoid conflict between the EPC and this Directive. The Biotechnology Directive 98/44 can also be used as a supplementary means of interpretation according to Rule 23(b)(1) of the EPC.

¹⁸² Leverve (note 130) at 289.

¹⁸³ Seville (note 124) at 117.

¹⁸⁴ Ibid.

In *Eli Lilly and Company v. Human Genome Sciences, Inc.*,¹⁸⁵ Judge Kitchin carried out a review of the case law of the EPO in the sphere of biotechnological patents. The result of this review led to Judge Kitchin formulating a list of nine principles that should be considered when assessing the industrial application of biotechnological inventions.¹⁸⁶ In response to the patenting of genes, the requirement that an invention be susceptible to industrial application has proven to be a significant constraint to patentability.¹⁸⁷ A review of recent EPO jurisprudence shows that the requirement of industrial application has evolved towards an actual test of usefulness.¹⁸⁸ The usefulness of an invention is usually obvious from the nature of the invention where more conventional technologies are concerned.¹⁸⁹ However, the usefulness of a DNA sequence coding for a gene is not always apparent because it is possible to identify the chemical structure of the sequence without understanding its function, and mere speculation on possible functions will be insufficient to fulfill the industrial application requirement for patentability.¹⁹⁰

4.5.1 Meaning of ‘industry’

In *BDP1 Phosphatase/Max Planck*,¹⁹¹ it was stated that the notion of ‘industry’ must be interpreted broadly to include all manufacturing, extracting, and processing activities of enterprises that are carried out continuously, independently and for financial or commercial gain.

4.5.2 Meaning of ‘made or used’

As mentioned, Article 57 of the EPC provides that ‘an invention shall be considered as susceptible of industrial application if it can be made or used in any kind of industry.’ This implies that an invention must be capable of being literally made, and that a

¹⁸⁵ [2008] EWHC 1903 (Pat).

¹⁸⁶ R Fitt and E Nodder ‘The industrial applicability of biotechnology patents – a new test for Europe’ (2009) 28 *Biotechnology Law Report* 151 at 151.

¹⁸⁷ Leverage (note 130) at 289.

¹⁸⁸ *Ibid.*

¹⁸⁹ Hawkins (note 48) at 461.

¹⁹⁰ *Ibid.* See for example *Eli Lilly and Co v Human Genome Sciences Inc* [2008] EWHC 1903 (Pat).

¹⁹¹ *BDP1 Phosphatase/Max-Planck* (T 0870/04) (EPO (Technical Board of Appeal)) cf. point 3 of the reasons.

practical application be identified.¹⁹² In *BDP1 Phosphatase/Max Planck*,¹⁹³ the Board held as follows:

‘Merely because a substance (here: a polypeptide) could be produced in some ways does not necessarily mean that the requirements of Article 57 EPC are fulfilled, unless there is also some profitable use for which the substance can be employed.’¹⁹⁴

Based on this reasoning, the meaning of the term ‘made or use’ is to be interpreted to mean that some ‘profitable use’ must be derived from the invention. This in turn means that an industry may benefit from the invention, rather than the invention only being theoretically capable of being manufactured.¹⁹⁵

4.5.3 Meaning of ‘profitable use’

The term ‘profitable use’ was explained in *Hematopoietic Receptor/Zymogenetics*.¹⁹⁶ In this case the Board stated that ‘profitable use’ is not to be understood in the narrow sense of an actual or potential economic profit or of a commercial interest. Instead, it must be understood in the wider sense that the invention claimed must have such a sound and concrete technical basis that the skilled person can recognise that its contribution to the art could lead to practical exploitation in industry.¹⁹⁷ Accordingly the Board held that the expression ‘profitable use’ is to be interpreted more in the sense that ‘immediate concrete benefits’ should be able to be derived from the description.¹⁹⁸

¹⁹² Lerverve (note 130) at 291.

¹⁹³ *BDP1 Phosphatase/Max-Planck* (note 191) cf. point 3 of the reasons.

¹⁹⁴ Ibid cf. point 4 of the reasons.

¹⁹⁵ Lerverve (note 130) at 291.

¹⁹⁶ (T 0898/05) (EPO (Technical Board of Appeal)).

¹⁹⁷ Ibid cf. point 5 of the reasons.

¹⁹⁸ Lerverve (note 130) at 291.

4.5.4 Meaning of ‘immediate concrete benefit’

The Board in *BDP1 Phosphatase/Max Planck*¹⁹⁹ held that for the purposes of Article 57 of the EPC, a vague and speculative indication of possible objectives that might or might not be achievable by carrying out further research with the tool as described is not enough to fulfill the requirement of industrial applicability. The Board further stated that the purpose of granting a patent is not to reserve an unexplored field of research for an applicant.²⁰⁰ In addition, in *Hematopoietic Receptor/Zymogenetics*²⁰¹ the Board held that the words ‘concrete benefit’ could be understood to mean the need to disclose, in definite technical terms, the purpose of the invention and how it can be used to solve a given technical problem.²⁰²

To sum up, it can be seen that in general, the requirement that an invention be susceptible to industrial application has been said to involve three levels of consideration. The first is that the invention must belong to an industrial field and the second is that the invention should be capable of actually being made. The third is that the disclosure should be such that some immediate concrete benefit can be derived from the subject matter claimed.²⁰³

4.5.5 *BDP1 Phosphatase/Max-Planck* test

In assessing whether a claimed invention involving a gene fulfills the industrial application requirement set out in Article 57, what is important is the protein product that is coded for by the gene.²⁰⁴ In *BDP1 Phosphatase/Max-Planck*,²⁰⁵ the Board held that:

¹⁹⁹ *BDP1 Phosphatase/Max-Planck* (note 191) cf. point 21 of the reasons.

²⁰⁰ *Leverve* (note 130) at 291.

²⁰¹ (T 0898/05) (EPO (Technical Board of Appeal)).

²⁰² The United Kingdom Intellectual Property Office Examination Guidelines (note 161) para 58.

²⁰³ *Leverve* (note 130) at 292.

²⁰⁴ *Ibid.*

²⁰⁵ *BDP1 Phosphatase/Max-Planck* (note 191).

‘In the case where a substance, naturally occurring in the human body, is identified, and possibly also structurally characterised and made available through some method, but either its function is not known or it is complex and incompletely understood, and no disease or condition has yet been identified as being attributable to an excess or deficiency of the substances, and no other practical use is suggested for the substance, then industrial applicability cannot be acknowledged...’²⁰⁶

Thus, the disclosure surrounding the protein product that a gene encodes should be such that it can be identified and its function clearly understood. Additionally, a condition or disease should be identified, as well as its correlation with the disease or condition.²⁰⁷ However, this is not an absolute test, and other practical uses may be suggested.²⁰⁸ With regard to the first feature that the protein is required to be identified, it is not requisite for the protein to be structurally characterised. Nevertheless, under many circumstances the structural characteristics of a protein would indeed provide the basis from which its actual function would be deduced. This in turn could enable an inference to be made involving its correlation with certain conditions or diseases.²⁰⁹

4.5.6 Meaning of ‘function’

In general, as per the Board in *BDP1 Phosphatase/Max-Planck*,²¹⁰ it is required that the function of the protein claimed be identified.²¹¹ This approach was reaffirmed in *Hematopoietic Receptor/Zymogenetics*²¹² where the Board held as follows:

‘The disclosure of the function of a newly discovered protein is of utmost importance when examining the issue of ‘industrial applicability’ as the function

²⁰⁶ *BDP1 Phosphatase/Max-Planck* (note 191) cf. point 6 of the reasons.

²⁰⁷ *Leverve* (note 130) at 292.

²⁰⁸ *Ibid.*

²⁰⁹ *Ibid* at 291.

²¹⁰ *BDP1 Phosphatase/Max-Planck* (note 191) cf. point 6 of the reasons.

²¹¹ *Leverve* (note 130) at 292.

²¹² *Hematopoietic Receptor/Zymogenetics* (note 201).

is the gateway to understanding the concrete benefits which may derive from exploiting the invention industrially.²¹³

The Board went on to reason that the function of a protein, and therefore the nucleic acid sequence encoding it, can be seen at three different levels. The first of these levels is the biochemical activity or molecular function of the protein. The second is the cellular function of the protein, and the third is its biological function.²¹⁴ Further, the Board stated that in order for the subject matter claimed to derive a profitable use, it is only necessary for one of these three levels of function to be fully disclosed, and each level may prove to be sufficient as long as a practical application is obtainable.²¹⁵

4.6 Exceptions to patentability

Although genes may be regarded as being patentable subject matter if the requirements of patentability are met, concerns have been raised regarding the use of the human body as a source of patentable material. As a result, a number of specific exclusions to patentability have been included in the EPC.²¹⁶ In general, the human body and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot be considered to be patentable subject matter. Nevertheless, an element that has been isolated from the human body, or produced by means of a technical process, including the sequence or partial sequence of a gene may indeed constitute patentable subject matter. This is regardless of whether or not the structure of the element is identical to that of an element that occurs naturally.²¹⁷

Article 53(a) of the EPC provides that patents shall not be granted in respect of inventions, the commercial exploitation of which would be contrary to *ordre public* or

²¹³ *Hematopoietic Receptor/Zymogenetics* (note 201) cf. point 20 of the reasons.

²¹⁴ *Leverve* (note 130) at 292. See also: *Hematopoietic Receptor/Zymogenetics* (note 201) cf. point 29 of the reasons.

²¹⁵ *Ibid* at 293.

²¹⁶ *Seville* (note 124) at 121.

²¹⁷ *Ibid* at 122.

morality. Furthermore, Article 53(c) of the EPC provides that patents shall not be granted in respect of methods for treatment of the human or animal body by surgery or therapy, and diagnostic methods practised on the human or animal body. The rationale for this exclusion is based on public health considerations.²¹⁸ It should also be noted that genetic diagnostic tests that are carried out on tissue samples away from the human body do not fall within this exception.²¹⁹ For example, in *Method of Diagnosis/University of Utah*²²⁰ the EPO Board of Appeal held that the patent for a method of detecting frameshift mutations giving rise to breast cancer susceptibility is a useful diagnostic test, and was not excluded from patentability by Article 53(c) of the EPC. The reason for this was that all the steps of the diagnosis were carried out on tissue samples of a human subject, and not on a living human or animal body.²²¹

In the recent case *Monsanto Technology LLC v Cefetra BV and others*²²² the Court of Justice of the European Union was asked to clarify, through the interpretation of the Biotechnology Directive 98/44, whether a DNA sequence is entitled to patent protection as a compound as such, or only under circumstances in which the DNA performs its function.²²³ In this case, Monsanto was the holder of a European patent that claims a DNA sequence coding for an enzyme which, when expressed in a plant, renders the plant resistant to the herbicide glyphosate. Further, Monsanto developed a genetically modified soy plant containing this gene.²²⁴ This genetically modified soy plant has no patent protection in Argentina, where it is cultivated on a large scale. However, an analysis of the soy meal imported from Argentina to the European Union revealed that there were intact DNA sequences coding for the enzyme present within it, and therefore Monsanto claimed infringement of its patent by the importer (Cefetra).²²⁵ Article 9 of the Biotechnology Directive 98/44 provides that:

²¹⁸ Hawkins (note 48) at 468.

²¹⁹ Ibid.

²²⁰ (T80/05) (EPO (Technical Board of Appeal)) at [62]-[63].

²²¹ Hawkins (note 48) at 468.

²²² Case C-428/08.

²²³ MA Kock 'Purpose bound protection for DNA sequences: In through the back door?' (2010) 5 (7) *Journal of Intellectual Property Law & Practice* 495 at 495.

²²⁴ MA Kock 'Patent protection for DNA sequences – to be or not to be?' (2010) 5 (11) *Journal of Intellectual Property Law & Practice* 754 at 754.

²²⁵ Ibid at 754.

‘The protection conferred by a patent on a product containing or consisting of genetic information shall extend to all material... in which the product is incorporated and in which the genetic information is contained and performs its function.’

The Court in this case held that Article 9 of the Biotechnology Directive 98/44 does not confer patent protection:

‘In circumstances such as those of the case in the main proceedings, in which the patented product is contained in the soy meal, where it does not perform the function for which it is patented, but did perform that function previously in the soy plant, of which the meal is a processed product, or would possibly again be able to perform that function after it had been extracted from the soy meal and inserted into the cell of a living organism.’²²⁶

The Court based its reasoning on the use of present tense ‘performs’ and the use of the phrase ‘material . . . in which’ in Article 9 of the Biotechnology Directive 98/44, and found that both require that the function is performed at the present time as well as within the actual material in which the DNA is found.²²⁷ The Court held further that, owing to the fact that the soy meal is dead and incapable of expressing its function (conferring resistance to glyphosate) the DNA residing in the soy meal is thus not eligible for patent protection.²²⁸

The consequence of this decision is that a DNA sequence will not be protected where it does not perform the function for which it was patented. On the basis of this, patent claims to DNA sequences seem to be an exception to the general principle that product claims confer absolute protection.²²⁹ Moreover, on this approach it would appear that not only would a residual DNA sequence in dead material be outside the scope of the patent,

²²⁶ *Monsanto Technology LLC v Cefetra BV and others* (note 222) at [50].

²²⁷ Kock (note 224) at 754.

²²⁸ Ibid.

²²⁹ Ibid at 755.

but also an isolated and purified DNA sequence. This may have severe implications for genetic diagnostic testing, which typically involve the isolation and/or amplification of the gene sequence being tested. However, whether or not the Court intended this consequence for purified DNA sequences will only be revealed by subsequent case law.²³⁰

4.7 Defences to gene patent infringement

Section 60(5)(b) of the Patents Act 1977 is commonly known as the ‘research exception.’ It provides a defence to patent infringement of a valid patent for acts done for experimental purposes relating to the subject matter of the invention.²³¹ The first question that must be asked in evaluating whether or not this ‘research exception’ is applicable is to look at whether the conduct in question can be said to be for experimental purposes. This defence will apply where the purpose of an act is to discover something unknown.²³² In the context of gene patents, it is probable that research performed to determine new functions of a patented gene and research directed at improving a known genetic diagnostic, will fall within the scope of this defence.²³³

Researchers carrying out genetic testing should refer to the patent landscape in order to establish their freedom to operate.²³⁴ If a patent exists that appears to cover the area in which those carrying out the genetic testing wish to work, then a decision must be made regarding how to proceed. If the patent seems to be a valid one, and if it is clear that the genetic testing in question would infringe the patent, then it may be possible to obtain a license to use the patented subject matter. On the other hand, if the validity of the patent is not clear it may also be possible to challenge the patent through proceedings seeking revocation of the patent.²³⁵ Another alternative is to proceed with the potentially infringing conduct, and raise a counterclaim for revocation of the patent where the patent

²³⁰ Kock (note 224) at 755.

²³¹ Hawkins (note 48) at 469.

²³² Ibid.

²³³ Ibid at 470-471.

²³⁴ Ibid at 471.

²³⁵ Ibid.

holder issues infringement proceedings. However, this course of conduct may result in damages being awarded to the patent holder against the infringing party in the situation where the patent is held to be valid. Overall, in these respects gene patents operate the same as patents in other spheres of technology.²³⁶

²³⁶ Hawkins (note 48) at 471.

CHAPTER 5: THE PATENTABILITY OF GENES IN THE UNITED STATES OF AMERICA

The patent law of the United States of America provides the broadest protection for biotechnological inventions worldwide. Thus, in the United States a wide range of biotechnological inventions are patentable, including inventions concerning human gene therapy and genetically engineered plants and animals.²³⁷ The foundation of patent law in the United States is embodied in Article 1, Section 8, Clause 8 of the United States Constitution.²³⁸ Further, the present statutory scheme for patent law in the United States can be found in Title 35 of the U.S.C, which embodies the Patent Act of 1952. The statutory requirements for patentability include satisfying patentable subject matter and utility (usefulness) as set out in Section 101 of Title 35 of the U.S.C, which states that:

‘Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.’

Although this section does not exclude specific types of subject matter from patentability, the courts have done so. For example it has been held that the Patent Act of 1952 does not allow ‘ownership of laws of nature, products of nature or physical phenomena.’²³⁹ Further, the ‘discovery of a principle in natural philosophy or a physical science’ is also not patentable.²⁴⁰ This is different to the EPC, which excludes numerous categories of subject matter from patentability. For example, Article 53(a) of the EPC provides that patents shall not be granted in respect of inventions, the commercial exploitation of which would be contrary to *ordre public* or morality.

²³⁷ J Chambers ‘Patent eligibility of biotechnological inventions in the United States, Europe and Japan: How much patent policy is public policy?’ (2002) 34 *Geo.Wash.Int’l L.Rev* 223 at 226.

²³⁸ Bryan (note 123) at 55.

²³⁹ *Diamond v Chakrabarty* 447 U.S. 303 (1980) at 309. See also *Parker v. Flook* 437 U. S. 584 (1978).

²⁴⁰ *O’Reilly v Morse* 56 U.S (15 HOW.) 62, 116 (1853).

Section 102 of Title 35 of the U.S.C defines the requirement of novelty, section 103 sets out what constitutes non-obvious subject matter, and the written description requirement is provided for in section 112.

5.1 Patentable subject matter

In deciding whether or not an invention is patentable, a court must first determine what subject matter is sought to be patented. In *Parker v Flook*²⁴¹ the Supreme Court held as follows:

‘The obligation to determine what type of discovery is sought to be patented must precede the determination of whether the discovery is, in fact, new or obvious.’

Since its inception, the United States Patent Office (USPTO) has granted patents on new pharmaceuticals and medical devices.²⁴² However, during the 1970’s many medical researchers and legal scholars began to view DNA sequences as being unpatentable based on the fact that DNA is a naturally occurring substance rather than a human invention.²⁴³ This viewpoint changed in 1980 with the Supreme Court’s ruling in *Diamond v Chakrabarty*,²⁴⁴ which has been heralded as being a landmark case in biotechnology-related patent law.²⁴⁵ In this case the patentability of a new strain of bacteria produced artificially by bacterial recombination was in dispute. This new strain of bacteria dissolved oil spills, and had been specially constructed to include a DNA plasmid. The United States Supreme Court held, by a majority of five to four, that although the Patent Act did not allow ownership of laws of nature, products of nature or physical phenomena, ‘anything under the sun made by man’ was deemed to be patentable subject matter, including the artificially produced new strain of bacteria.²⁴⁶ Thus, according to the Court,

²⁴¹ 437 U. S. 584, 593 (1978).

²⁴² Kesselheim and Mello (note 1) at 1855.

²⁴³ Ibid.

²⁴⁴ 447 U.S. 303 (1980).

²⁴⁵ Chambers (note 237) at 227.

²⁴⁶ Kesselheim and Mello (note 1) at 1855.

the test for patent-eligible subject matter is not whether an invention embraces living matter, but whether or not the living matter is a result of human intervention.²⁴⁷ The Court supported its conclusion in part by quoting one of its earlier cases, *Hartranft v Wiegmann*²⁴⁸ for the proposition that what was being claimed was a ‘product of human ingenuity having a distinctive name, character and use.’²⁴⁹ Further, regarding the interpretation of section 101 of Title 35 of the U.S.C, the Court noted that:

‘In choosing such expansive terms as “manufacture” and “composition of matter,” modified by the comprehensive “any,” Congress plainly contemplated that the patent laws would be given wide scope.’²⁵⁰

After this decision gene patents, and in particular, patents concerning ‘isolated DNA,’ became commonplace in the United States.²⁵¹ USPTO examiners justified the patenting of genes (and other previously unpatentable subject matter) on the basis that these substances had been purified and thus transformed from their natural form through the use of artificial tools.²⁵² Technological advancements in science and the rise of recombinant DNA techniques soon began to enable researchers to discover and isolate new genes at a rapid rate. Thus far, thousands of patents have been awarded on different parts of the human genome, and it has been reported that approximately 20 per cent of the human genome is currently patented.²⁵³ For example, *Amgen Inc v Chugai Pharmaceutical Co., Ltd., and Genetics Institute, Inc*²⁵⁴ involved a patent on genetically engineered human erythropoietin. Human erythropoietin is a protein which stimulates the production of red blood cells, and thus is a useful therapeutic agent in the treatment of anaemia or blood disorders characterised by low or defective bone marrow production of red blood cells. In this case the Court held that:

²⁴⁷ Chambers (note 237) at 227.

²⁴⁸ 121 U.S. 609, 615 (1887).

²⁴⁹ LC Tyler ‘Genes and 35 U.S.C § 101: Are DNA sequences corresponding to genes patentable subject matter?’ (2007) 19 (6) *Intellectual Property & Technology Law Journal* 16 at 24.

²⁵⁰ *Diamond v Chakrabarty* (note 239) at 309.

²⁵¹ Kesselheim and Mello (note 1) at 1855.

²⁵² *Ibid.*

²⁵³ *Ibid.*

²⁵⁴ 927 F.2d 1200 (Fed. Cir.).

‘A gene is a chemical compound... and it is well established in our law that conception of a chemical compound requires that the inventor be able to define it so as to distinguish it from other materials, and to describe how to obtain it... It is not sufficient to define it solely by its principal biological property, e.g., encoding human erythropoietin... Conception has not been achieved until reduction to practice has occurred, i.e., until after the gene has been isolated.’²⁵⁵

The USPTO and courts have not regularly considered morality and public policy when addressing the issue of patent eligibility. However, the filing of an application claiming a human/non human chimera did prompt the USPTO to put forward an argument for patent ineligibility based on morality and public policy grounds.²⁵⁶ The position of the USPTO here was that:

‘Congress did not intend to allow patents on humans or on creatures that are essentially human when it passed the Patents Act in 1956.’²⁵⁷

5.2 Useful (industrial application)

Under Section 101 of Title 35 of the U.S.C, one of the requirements for patentability is that the invention must be ‘useful.’ The main rationale for this requirement of utility (or usefulness) is to secure a *quid pro quo* for society, which is from the Latin meaning ‘this for that.’ However, no definition for utility is provided for in the U.S.C, thus it has been left to case law to develop the concept. The utility of an invention has been said to lie in its ability to achieve a desired and specific result, and the USPTO has developed guidelines for determining compliance with this requirement. For example, the USPTO

²⁵⁵ 927 F.2d 1206 (Fed. Cir.).

²⁵⁶ Chambers (note 237) at 230.

²⁵⁷ Ibid at 231.

2107 Guidelines for Examination of Applications for Compliance with the Utility Requirement²⁵⁸ provides that:

‘An invention has a well-established utility if (i) a person of ordinary skill in the art would immediately appreciate why the invention is useful based on the characteristics of the invention (e.g., properties or applications of a product or process), and (ii) the utility is specific, substantial, and credible.’

The terms specific, substantial and credible are further defined in the Utility Guidelines Training Materials.²⁵⁹ For example, the term ‘substantial utility’ is described here as being a utility that defines a ‘real world’ use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a ‘real world’ context of use are not considered to be substantial utilities.²⁶⁰ Further, with regards to the term ‘specific utility,’ it is provided that this is ‘a utility that is specific to the subject matter claimed.’ The term ‘specific utility’ can therefore be contrasted with that of ‘general utility,’ which would apply to the broad class of the invention. For example:

‘A claim to a polynucleotide whose use is disclosed simply as a “gene probe” or “chromosome marker” would not be considered to be specific in the absence of a disclosure of a specific DNA target.’²⁶¹

In *Brenner v. Manson*,²⁶² the Supreme Court held that in order to be patented, an item must have ‘substantial utility’ or ‘confer a specific benefit... in its currently available form.’ In addition, the Court stated that the granting of patents for products that have no known utility ‘may confer power to block off whole areas of scientific development’ and

²⁵⁸ USPTO 2107 Guidelines for Examination of Applications for Compliance with the Utility Requirement - 2100 Patentability. Available at: http://www.uspto.gov/web/offices/pac/mpep/documents/2100_2107.htm [Accessed 19 January 2011].

²⁵⁹ Available at <http://www.uspto.gov/web/menu/utility.pdf> [Accessed 19 January 2011] at 5-6.

²⁶⁰ Ibid at 6.

²⁶¹ Utility Guidelines Training Materials. Available at <http://www.uspto.gov/web/menu/utility.pdf> [Accessed 19 January 2011] at 5.

²⁶² 383 U.S. 519, 534-535 (1966).

that discoveries that have no use except for further experimentation cannot be patented.²⁶³ Based on this reasoning, one limitation laid by the utility requirement is that it excludes the patenting of research proposals and objects of pure research. However, the remaining boundaries of the utility requirement have not been so clearly defined.²⁶⁴ Patent applications for methods of treating diseases also generally present test results in order to satisfy the utility requirement for patentability.²⁶⁵

The requirement of utility is closely tied to an analysis of enablement. The enablement requirement in section 112 of Title 35 of the U.S.C provides that the specification must disclose to a person of skill in the art how to ‘make and use’ the invention, without undue experimentation.²⁶⁶ Thus, it is common for the patentability of DNA elements to hinge on whether or not adequate information has been given to enable at least one credible or specific utility.²⁶⁷ Although technically the requirement of utility is a stand-alone requirement, if a patent does not exhibit utility then it is also not enabled. This is logical owing to the fact that that if a patent is not useful, it cannot be enabled, since enablement requires the disclosure of both how to make and how to use the invention.²⁶⁸

5.3 Novelty

The logic behind the novelty requirement for patentability is that it makes no sense to grant someone a patent on something that already exists and that is available to the public.²⁶⁹ The requirement of novelty is set out in Section 102 of Title 35 of the U.S.C. Section 102 (a) provides that a person shall be entitled to a patent unless:

²⁶³ Sturges (note 74) at 233.

²⁶⁴ JD Garretson and LM Pringle ‘Patenting more than an idea: Testing the bounds of enablement’ (2009) 5 (4) *Industrial Biotechnology* 227 at 227.

²⁶⁵ *Ibid* at 228.

²⁶⁶ *Ibid* at 227.

²⁶⁷ JJ Doll ‘The patenting of DNA’ (1998) 280 (5364) *Science* 669 at 669.

²⁶⁸ Garretson and Pringle (note 264) at 227.

²⁶⁹ SW Halpern et al *Fundamentals of United States intellectual property law: copyright, patent and trademark* (2007) 210.

‘The invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent.’

The concept of new under the novelty requirement means novel in a ‘prior art’ sense and does not mean ‘not pre-existing.’²⁷⁰ Thus, in order to meet the novelty requirement, the invention must be new (novel) compared to the prior art. If an invention is not novel, it is said to be anticipated by the prior art. Further, a patent claim is said to be anticipated by the prior art in circumstances in which each claim limitation is disclosed ‘expressly or inherently’²⁷¹ in a single prior art reference that existed prior to the patent applicant’s date of invention. In this context, the date of invention is taken to be the date on which the inventor ‘reduced his invention to practice.’²⁷² Section 102 (b) of Title 35 of the U.S.C serves as a statutory bar, owing to the fact that if the inventor waits too long before seeking patent protection for his invention then the right to the patent may be lost. This section provides that a person shall be entitled to a patent unless:

‘The invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States.’

5.4 Non-obvious (inventive step)

One of the most currently contentious areas of patent law is the requirement of non-obviousness.²⁷³ Obviousness, or lack of inventive step, is one of the grounds for rejecting a claim during patent prosecution, or for invalidating the claim in patent infringement

²⁷⁰ *Resource book on TRIPS and development* (note 122) at 392.

²⁷¹ *Rowe v Dror* 112 F.3d 473, 477 (Fed. Cir. 1997).

²⁷² Halpern (note 269) at 210-211.

²⁷³ KM Lesciotta ‘KSR: Have gene patents been ko’d? The non-obviousness determination of patents claiming nucleotide sequences when the prior art has already disclosed the amino acid sequence’ (2008) 86 *Washington University Law Review* 209 at 210.

litigation.²⁷⁴ Section 103 of Title 35 of the U.S.C provides that non-obviousness requires a hypothetical judgment by a person with ordinary skill in the art to which the subject matter pertains. This hypothetical judgment involves determining if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole should have been obvious at the time the invention was made.²⁷⁵

In 2007 the Supreme Court substantively addressed the obviousness standard in *KSR International Co. v. Teleflex Inc*²⁷⁶ (hereafter referred to as *KSR v Teleflex*). It should be noted that although the patent at issue in *KSR v Teleflex* was unrelated to biotechnology, the law subjects patents from every type of technology to the same obviousness requirement.²⁷⁷ In *KSR v Teleflex* the Supreme Court changed how the tests for obviousness (that applied at the time of the case) interacted. These tests included the *Graham* factors and the teaching, suggestion and motivation test. Instead of strictly requiring some type of teaching, suggestion, or motivation to find an invention obvious, the Court referred to this test as merely being a ‘helpful insight’ into the *Graham* factors.²⁷⁸ Further, the Supreme Court favored a flexible approach to the obviousness standard, and held that the obviousness inquiry should encompass a broad scope of prior art with allowances for common sense and creative inferences. On this point, the Court stated that common sense teaches that familiar items may have obvious uses beyond their primary purposes, and that in many cases a person of ordinary skill would be able to fit the teachings of multiple patents together like pieces of a puzzle.²⁷⁹ Moreover, the Court stated that a person of skill in the art is ‘one of ordinary creativity, not an automaton.’²⁸⁰ The Court also provided that an invention might be obvious if it would have been

²⁷⁴ S Wang ‘The obviousness rejection as a barrier to biotech patent prosecution’ (2009) 27 (12) *Nature Biotechnology* 1125 at 1125.

²⁷⁵ *Ibid.*

²⁷⁶ 550 U.S. 398 (2007).

²⁷⁷ Lesciotto (note 273) at 212.

²⁷⁸ *Ibid.*

²⁷⁹ Wang (note 274) at 1125.

²⁸⁰ KML Hayes ‘Three years post-*KSR*: A practitioner’s guide to “winning” arguments on obviousness and a look at what may lie ahead’ (2010) 9 (3) *Northwestern Journal of Technology and Intellectual Property Law* 243 at 244. See also *KSR International Co. v. Teleflex Inc* 550 U.S. 398, 420 (2007).

‘obvious to try’ to a person with ordinary skill in the art.²⁸¹ The Supreme Court held further that:

‘If a person of ordinary skill in the art can implement a predictable variation, and would see the benefit of doing so, Section 103 likely bars its patentability. For the same reason, if a technique has been used to improve one device, and a person of ordinary skill in the art would recognise that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond that person’s skill... A court must ask whether the improvement is more than the predictable use of prior-art elements according to their established functions.’²⁸²

Previously Federal Circuit precedent in the 1990s had foreclosed the use of the ‘obvious to try test’ to invalidate gene sequence patent claims.²⁸³ In *In re Deuel*²⁸⁴ and *In Re Bell*²⁸⁵ the United States Supreme Court of Appeal placed focus on the obviousness of the sequence rather than on the obviousness of the method used to isolate the sequence.²⁸⁶ In both cases the Court of Appeal found that gene sequences for proteins of known function were patentable, owing to the fact that the gene sequence would not have been known without cloning and sequencing, which is enough for the sequence to be considered to be non-obvious. Further, in both cases the Court of Appeal accepted that the degeneracy of the genetic code meant that a number of different nucleotide sequences may code for a specific protein, and thus held that the nucleotide sequence claimed was not obvious.²⁸⁷

More recently, in *In re Kubin*²⁸⁸ (hereafter referred to as *Kubin*), the Federal Circuit revisited the ‘obvious to try’ test as applied to gene sequences under the post-*KSR*

²⁸¹ Kwan (note 34) at 9.

²⁸² *KSR International Co. v. Teleflex Inc* 550 U.S. 398, 417 (2007).

²⁸³ Kwan (note 34) at 9.

²⁸⁴ 51 F.3d 1552 (Fed. Cir. 1995).

²⁸⁵ 991 F.2d 781 (Fed Cir. 1993).

²⁸⁶ Keays (note 56) at 83.

²⁸⁷ *Ibid.*

²⁸⁸ 561 F.3d 1351 (Fed. Cir. 2009).

obviousness standard.²⁸⁹ This case concerned a patent application claiming the polynucleotide sequence of a human gene encoding the Natural Killer Cell Activation Inducing Ligand (NAIL protein).²⁹⁰ In *Kubin* the Court rejected as obvious claims directed to the isolation and sequencing of this gene. The court found that a prior art reference disclosing the existence of the NAIL protein, a method for isolating the gene encoding the protein, a probe for the performance of the isolation of the gene and a manual disclosing general methods for the isolation of a gene, led to the cloning of the gene to be ‘reasonably expected in light of the prior art’ and ‘obvious to try’.²⁹¹ The court also interpreted *KSR v Teleflex* as overruling *In re Deuel*, and held that the ‘obvious to try’ test could indeed be applied to the ‘unpredictable art of biology.’ This decision has been said to represent a major shift in the law that will lower the bar for finding biotechnological invention patents obvious.²⁹²

In *Kubin*, the court also resurrected its own *In re O’Farrell*²⁹³ decision in which two situations had been identified where what is ‘obvious to try’ is nonetheless not considered to be obvious. The first of these situations occurs when success is dependent on trying numerous possibilities but where the prior art fails to indicate the choices or parameters that would likely lead to success.²⁹⁴ The second situation occurs when the prior art provides only general guidance for a specific approach or technology. However, the court held that neither of the two situations were applicable to the case at hand.²⁹⁵ *Kubin* also set a new standard for patents concerning gene sequences because structural similarity is no longer required to show obviousness of polynucleotide sequences.²⁹⁶

The potential impact of *Kubin* on the patentability of gene sequences raises uncertainty and apprehension in the field of biotechnology. This is owing to the fact that obviousness challenges may invalidate many gene patents if the protein was known and gene cloning

²⁸⁹ Kwan (note 34) at 9.

²⁹⁰ *Ibid* at 20.

²⁹¹ *Ibid* at 9-10.

²⁹² *Ibid*.

²⁹³ 853 F.2d 894 (Fed. Cir. 1988).

²⁹⁴ Kwan (note 34) at 20.

²⁹⁵ *Ibid* at 21.

²⁹⁶ Kwan (note 34) at 26.

depended on routine methods.²⁹⁷ Unless and until the appellants obtain *en banc* or Supreme Court reversal, *Kubin* will govern polynucleotide patent claims. The decision in *Kubin* thus brings into question the patentability of polynucleotide inventions, and the validity of issued patent claims to polynucleotides.²⁹⁸

Post-*Kubin* an important issue in evaluating obviousness is whether variations to established methods involve mere routine changes or require an inventive step.²⁹⁹ In circumstances in which less is known about the encoded protein, where applicants or patentees can offer evidence of failed attempts, or where non-routine methods were used in the cloning process, it may be possible for an invention to survive a non-obvious challenge based on *Kubin*.³⁰⁰ Moreover, for patents that have already been issued, there may still be hope of validity if the inventor's laboratory books demonstrate that a modified or an unusual method was used in the development of the invention. Secondary indicia (circumstances that point to the existence of a given fact as probable) may also be able to be used as evidence of non-obviousness. For example, in biotechnology the failure of others to make the invention may prove to be an important factor when considering the non-obviousness requirement.³⁰¹

²⁹⁷ Kwan (note 34) at 29.

²⁹⁸ MJ Stimson 'Is the gene patenting party over? Biotechnology patents after *In re Kubin*' (2009) 28 (3) *Biotechnology Law Report* 329 at 329.

²⁹⁹ Kwan (note 34) at 16.

³⁰⁰ *Ibid* at 29.

³⁰¹ Stimson (note 298) at 331.

CHAPTER 6: THE JUDGMENT IN ‘*AMP v. USPTO*:’ THE FEDERAL COURT DECISION

The latest battleground in the war over gene patenting is the United States of America.³⁰² In *AMP v. USPTO*³⁰³ opponents of gene patents were victorious when a United States District Court rejected the patentability of genetic material. In this case the American Civil Liberties Union Foundation filed suit on behalf of four scientific associations, two women’s health groups, eight researchers and genetic counselors, and six breast or ovarian cancer patients (the Plaintiffs).³⁰⁴

The Plaintiffs moved for summary judgment to declare invalid fifteen claims (the ‘claims-in-suit’) contained in seven patents (the ‘patents-in-suit’) relating to the human *BRCA1* and *BRCA2* genes (Breast Cancer Susceptibility Genes 1 and 2). This invalidity was sought under section 101 of Title 35 of the U.S.C; Article I, Section 8, Clause 8 of the United States Constitution and the First and Fourteenth Amendments of the Constitution. Further, this invalidity was sought on the basis that the patent claims cover products of nature, laws of nature and/or natural phenomena, and abstract ideas or basic human knowledge or thought. The defendant USPTO had issued the patents-in-suit held by the defendants Myriad Genetics and the University of Utah Research Foundation.³⁰⁵

The challenged patent claims were directed to the isolated DNA containing all or portions of the *BRCA1* and *BRCA2* gene sequences, and to the methods for ‘comparing’ or ‘analysing’ these sequences to identify the presence of mutations associated with a predisposition to breast or ovarian cancer.³⁰⁶

³⁰² Fowler (note 114) at 1075.

³⁰³ *Association for Molecular Pathology et al v United States Patent & Trademark Office et al* (note 3).

³⁰⁴ A McHugh ‘Invalidating gene patents: *Association for Molecular Pathology v. U.S. Patent & Trademark Office*’ (2010) 62 *Hastings Law Journal* 185 at 187.

³⁰⁵ *Association for Molecular Pathology et al v United States Patent & Trademark Office et al* (note 3) at 1.

³⁰⁶ *Ibid* at 2.

Judge Sweet stated that this challenge posed a unique question:

‘Are isolated human genes, and the comparison of their sequences patentable?’³⁰⁷

6.1 The facts

6.1.1 The development of the patents-in-suit

In the 1980’s, researchers from many countries around the globe sought to be the first to identify DNA nucleotide sequences that were associated with breast cancer. In 1990 a landmark paper was published in which it was demonstrated for the first time that a specific gene, whose sequence was not yet known, was linked to breast cancer. Some time later, this gene was designated *BRCA1*. Soon after, research increased as teams around the world focused on this region of the gene in an attempt to be the first to determine its DNA sequence.³⁰⁸ In 1994 a group of Myriad researchers, along with researchers from various other institutions, announced that they had sequenced *BRCA1*.³⁰⁹

Following the isolation of *BRCA1*, researchers continued to search for a second gene also suspected of being linked to ovarian and breast cancer. Myriad collaborated with several research groups in this regard, including a team of researchers led by Dr. Stratton. In November 1995, Dr Stratton’s group identified a mutation in breast cancer patients that seemed to be located in the as-yet-unpublished *BRCA2* gene. However, Dr. Stratton ended the collaboration with Myriad after learning of Myriad’s plans to patent the *BRCA2* gene sequence.³¹⁰ Myriad filed for patents on *BRCA2* in the United States and in Europe in December 1995.

³⁰⁷ *Association for Molecular Pathology et al v United States Patent & Trademark Office et al* (note 3) at 2.

³⁰⁸ *Ibid* at 47-48.

³⁰⁹ *Ibid* at 50.

³¹⁰ *Ibid* at 52.

The District Court in this case was of the view that the isolation of *BRCA1* and *BRCA2* required considerable effort on the part of Myriad and its collaborators. However, the Court stated that the techniques used were well understood, widely used, and fairly uniform insofar as any scientific researcher searching for a gene sequence would have used a similar approach.³¹¹

6.1.2 The application of the patents-in-suit

Variations in the *BRCA1/2* gene sequences correlate with an increased risk of ovarian and breast cancer. The existence of mutations in these genes is thus an important consideration to the provision of clinical care for breast and/or ovarian cancer.³¹² Myriad offered various forms of *BRCA1/2* testing to the general public. Its standard test, known as the Comprehensive BRCAAnalysis, was made up of the full sequencing of the *BRCA1/2* genes. In 2006 Myriad offered another supplemental test known as the BRCAAnalysis Rearrangement Test (BART), which according to Myriad, could detect virtually all large rearrangement mutations in the *BRCA1/2* genes. These tests were available at a cost of over \$3000 per test. In 2008, the total cost to Myriad of providing these tests was \$32 000 000, with resulting revenues of over \$200 000 000.³¹³ The Plaintiff's noted several cases in which women were unable to obtain funding for Myriad's testing services, and contended that a number of researchers and clinicians had the personnel, equipment, and expertise to sequence the *BRCA1/2* genes at a lower cost than Myriad's testing.³¹⁴

In addition, various research institutions conducting *BRCA1/2* analysis received cease-and-desist letters from Myriad. These included Drs. Kazazian and Ganguly of the Genetic Diagnostic Laboratory (GDL) at the University of Pennsylvania, and the director of the Yale DNA Diagnostics Lab.³¹⁵

³¹¹ *Association for Molecular Pathology et al v United States Patent & Trademark Office et al* (note 3) at 53.

³¹² *Ibid* at 54.

³¹³ *Ibid* at 55-56.

³¹⁴ *Ibid* at 58.

³¹⁵ *Ibid* at 59-62.

6.1.3 Disputed issues

6.1.3.1 The impact of Myriad's patents on *BRCA1/2* testing

According to the Plaintiffs, the patents held by Myriad, and the position of Myriad as the sole provider of *BRCA1/2* testing had prevented patients from receiving the highest-quality breast cancer genetic testing. The Plaintiffs also asserted that the position of Myriad had gotten in the way of the development of improvements to these tests, and that other laboratories were in a position to offer more comprehensive testing than Myriad's standard testing services. In response, Myriad contended that its full sequencing test has been recognised as the 'gold standard' for *BRCA1/2* mutation testing, and argued that it constantly worked on improving its testing process.³¹⁶

Another contention made by the Plaintiffs was that, as a result of the patents-in-suit, *BRCA1/2* testing was one of the few tests performed as part of breast cancer care and prevention for which a doctor or patient could not get a second confirmatory result done through another laboratory. Myriad's response to this was that the re-sequencing of a patient's genes by another laboratory would be a waste of time owing to the accuracy of the original test. Myriad also asserted that it has never prohibited a second interpretation of the results of its diagnostic tests, and that there were many laboratories available to conduct confirmatory *BRCA1/2* testing owing to patent licenses granted by Myriad. However, Myriad did concede that the confirmatory testing was limited to the confirmation of specific positive test results only.

The Court was of the view that this issue of whether or not the patents in question impacted favourably on the testing of variations was one of factual dispute. Judge Sweet therefore held that this issue was not one that could be resolved in the case at hand.³¹⁷

³¹⁶ *Association for Molecular Pathology et al v United States Patent & Trademark Office et al* (note 3) at 63-65.

³¹⁷ *Ibid* at 67-68.

6.1.3.2 The impact of gene patents on the advancement of science and medical treatment

A further disagreement between the parties existed regarding the effects that gene patents had on the progression of scientific knowledge. For instance, the Plaintiffs contended that patents over gene sequences impeded upon research aimed at identifying the role of genes in medical conditions.³¹⁸ On the other hand, one of the arguments that Myriad raised was that the *quid pro quo* (Latin term meaning ‘this for that’) of the patent system was that inventors, in exchange for a limited period of patent exclusivity, must provide a sufficient description of the patented invention so that others may improve upon it. Judge Sweet also noted that there was a sharp dispute regarding the impact of patents directed to isolated DNA on genetic research and, as a result, on the health of society. However, the Court held that the resolution of this dispute was also not possible within the context of the case at hand because it was one of fact and policy.³¹⁹

6.2 The patents

6.2.1 Summary of the patents

Fifteen claims contained in seven patents issued by the USPTO were the subjects of this declaratory judgment. Further, these patents were granted based on a formal written policy that permitted the patenting of ‘isolated and purified’ DNA encoding genes, and pursuant to a practice that allowed DNA patents, as well as the patenting of correlations created by nature between natural elements of the body and a predisposition to disease.³²⁰ The claims-in-suit can be divided into composition claims and method (also known as ‘process’) claims.³²¹

³¹⁸ *Association for Molecular Pathology et al v United States Patent & Trademark Office et al* (note 3) at 68.

³¹⁹ *Ibid* at 79.

³²⁰ Utility Examination Guidelines, 66 Fed. Reg. 1,093 (2001).

³²¹ *Association for Molecular Pathology et al v United States Patent & Trademark Office et al* (note 3) at 80.

6.2.1.1 Composition claims

Claim 1 of United States (U.S) patent 5,747,282 represented the group of composition claims. It was directed to an isolated DNA molecule that possessed a nucleotide sequence that translated into the *BRCA1* protein. Owing to the fact that most amino acids can result from the translation of more than one DNA codon, there were many DNA sequences that corresponded to the nucleotide sequence claimed in this claim.³²² Claim 2 of U.S. patent 5,747,282 was dependent on claim 1, and contained an additional limitation that identified the specific *BRCA1* nucleotide sequence of the claimed DNA.³²³ Claims 5 and 6 of the U.S. patent 5,747,282 were directed to fragments as short as 15 nucleotides of the DNA molecules claimed under claims 1 and 2. Further, claim 7 of U.S. patent 5,747,282 and claim 1 of U.S. patent 5,696,473 were directed to isolated DNA containing one of the specified mutant *BRCA1* gene sequences.³²⁴

Claims 1, 6, and 7 of the U.S. patent 5,837,492 covered isolated DNA molecules that contained specified nucleotide sequences relating to the *BRCA2* gene. Claim 1 here was directed to an isolated DNA molecule that encoded the *BRCA2* protein. This claim was similar to claim 1 of U.S. patent 5,837,492 patent owing to the fact that it covered many possible DNA sequences as a result of the redundancy of the DNA codons.³²⁵ However, Claim 6 of U.S. patent 5,837,492 was broader than claim 1 of U.S. patent 5,837,492 because it was directed to any DNA nucleotide sequence coding for any mutant *BRCA2* protein that was associated with a predisposition to breast cancer. Claim 7 of U.S. patent 5,837,492 was dependent on claim 6 of U.S. patent 5,837,492, but was restricted to the mutated forms of the *BRCA2* nucleotide sequence set out in the specification. The result of the breadth of these composition claims was that they aimed to isolate *BRCA1/2* that was obtained from any human being.³²⁶

³²² *Association for Molecular Pathology et al v United States Patent & Trademark Office et al* (note 3) at 80-81.

³²³ *Ibid* at 81.

³²⁴ *Ibid*.

³²⁵ *Ibid* at 82.

³²⁶ *Ibid*.

6.2.1.2 Method claims

Based on claim 1, U.S. patent 5,709,999 covered the process of identifying whether certain specific mutations in the *BRCA1* gene existed by ‘analysing’ the sequences of the *BRCA1* DNA, RNA, or cDNA made from *BRCA1* RNA acquired from a human sample. In addition, claim 1 of U.S. patent 5,710,001 claimed a method for determining whether a sample from a human tumour contained a variation in the *BRCA1* gene by ‘comparing’ the sequence of the *BRCA1* gene from the tumor with the sequence of the *BRCA1* gene from a non-tumor sample from the same person.³²⁷ Claim 1 of U.S. patent 5,753,441 and claim 1 of U.S. patent 6,033,857 were both directed at the same process, which involved establishing whether an individual had inherited an altered *BRCA1/2* gene sequence. However, they differed as to whether the claimed method was directed to *BRCA1* (U.S. patent 5,753,441) or *BRCA2* (U.S. patent 6,033,857). These processes involved comparing the *BRCA1* or *BRCA2* gene sequence of an individual with the wild-type *BRCA1* or *BRCA2* gene sequence.³²⁸ Lastly, claim 20 of U.S. patent 5,747,282 claimed a method used to determine the effectiveness of a potential cancer therapeutic.³²⁹

6.2.2 Construction of the claims

6.2.2.1 Legal standard

The Court held that before the patent-eligibility of a patent claim could be considered, the disputed terms in the claims had to be interpreted in order to ensure that the scope of the claims was accurately assessed. Judge Sweet referred to *Datamize, LLC v. Plumtree Software, Inc*³³⁰ in which it was stated as follows:

³²⁷ *Association for Molecular Pathology et al v United States Patent & Trademark Office et al* (note 3) at 83.

³²⁸ *Ibid* at 84.

³²⁹ *Ibid* at 85.

³³⁰ 417 F.3d 1342, 1354 (Fed. Cir. 2005).

‘A utility patent protects “any new and useful process, machine, manufacture, or composition of matter, or any new or useful improvement thereof,” 35 U.S.C. section 101 (2000), the scope of which is defined by the patent’s written claims.’

The Court in this case also noted that when interpreting the meaning of claim terms, the words of the claim are generally given their ordinary and customary meaning to a person of ordinary skill in the art at the time of the invention. Here the time of the invention is taken to be the effective filing date of the patent application.³³¹ Further, the person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but also within the context of the entire patent.³³² In addition, Judge Sweet provided that the claim language must be read in the context of the patent specification.³³³ On this point, the Court stated that the Federal Circuit has warned against confining the claims to what is described in the specification as well.³³⁴ Judge Sweet referred to *Phillips v. AWH Corp*³³⁵ in which it was held that Courts may rely on extrinsic evidence under certain circumstances. However, in determining the legally operative meaning of the claim language such extrinsic evidence is not as important as the intrinsic record, and it cannot be used to contradict the meaning of the claim terms as evidenced by the intrinsic evidence.³³⁶

6.2.2.2 Resolution of the disputed claim terms

The parties disagreed on the definition of the term ‘DNA.’ On this point, Judge Sweet agreed with Myriad that the term related to a tangible chemical compound. Further, Judge Sweet held that Myriad was correct in noting that the patent specifications made it clear that the term ‘DNA,’ as used in the patent specifications, referred to the physical manifestation of the acid, one that may be ‘substantially separated from other cellular components which naturally accompany a gene.’ Despite the description of the term

³³¹ *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–1313 (Fed. Cir. 2005).

³³² *Ibid* at 1313.

³³³ *Association for Molecular Pathology et al v United States Patent & Trademark Office et al* (note 3) at 87-88.

³³⁴ *Phillips v. AWH Corp.* (note 331) at 1323.

³³⁵ 415 F.3d 1303 (Fed. Cir. 2005).

³³⁶ *Ibid* at 1317-1319.

‘DNA’ set forth in the briefs of both parties, Judge Sweet was of the opinion that this understanding of the meaning of term ‘DNA’ was in fact shared by both parties.³³⁷ The parties also disagreed on the definition of the term ‘isolated DNA.’ In order to resolve this conflict, the Court referred to the definition of ‘isolated DNA’ provided for in the specification of the patents-in-suit. Based on this definition, Judge Sweet provided that ‘isolated DNA’ was to be interpreted to refer to a segment of DNA nucleotides that existed separately from other cellular components that were normally associated with native DNA. Further, it was to be interpreted to include both DNA originating from a cell, as well as DNA synthesised through chemical or heterologous biological means.³³⁸ Moreover, the parties disagreed on the meaning of the terms *BRCA1* and *BRCA2*. However, based on the definitions given in the specifications of the patents-in-suit, the Court provided that ‘*BRCA1*’ was to be construed to refer to a human gene, normally integrated into chromosome 17, some alleles of which cause susceptibility to breast and ovarian cancer. Similarly, ‘*BRCA2*’ was to be construed to refer to a human gene, normally integrated into chromosome 13, some alleles of which cause susceptibility to breast and ovarian cancer.³³⁹

6.3 Conclusions of law

6.3.1 The summary judgment standard

The District Court noted that summary judgment is only granted where there is no genuine issue of material fact, and where the moving party is entitled to judgment as a matter of law.³⁴⁰

³³⁷ *Association for Molecular Pathology et al v United States Patent & Trademark Office et al* (note 3) at 90-91.

³³⁸ *Ibid* at 92.

³³⁹ *Ibid* at 94.

³⁴⁰ *Ibid* at 95.

6.3.2 35 U.S.C section 101 and its scope

Section 101 of Title 35 of the U.S.C states as follows:

‘Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent thereof, subject to the conditions and requirements of this title.’

In interpreting the language in this section, the Court in this case took note of the fact that the Supreme Court has observed that Congress clearly contemplated that patent laws be given a wide scope.³⁴¹ However, Judge Sweet stated that this is not without its limits, and noted that the Supreme Court has identified three categories of subject matter that falls outside the scope of section 101, and which are thus not capable of patent protection. These categories are the ‘laws of nature, physical phenomena and abstract ideas.’³⁴² Additionally, the Court stated that the exclusion of products of nature as patentable subject matter reflects the Supreme Court’s recognition in *Gottschalk v. Benson*³⁴³ that:

‘Phenomena of nature, though just discovered, mental processes, and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work.’

Judge Sweet referred to the holding in *Funk Bros. Seed Co. v. Kalo Inoculant Co.*,³⁴⁴ which stated that ‘manifestations of laws of nature are free to all men and reserved exclusively to none,’ and also noted the following holding in *Parker v Flook*:³⁴⁵

‘The obligation to determine what type of discovery is sought to be patented must precede the determination of whether that discovery is, in fact, new or obvious.’

³⁴¹ *Diamond v Chakrabarty* (note 239) at 308.

³⁴² *Ibid* at 309.

³⁴³ 409 U.S. 63, 67 (1972).

³⁴⁴ 33 U.S. 127, 130 (1948).

³⁴⁵ 437 U. S. 584, 593 (1978).

Further, Judge Sweet referred to the discussion of section 101 of Title 35 of the U.S.C by Judge Rich in *In re Bergy*,³⁴⁶ which provides as follows:

‘Section 101 states three requirements: novelty, utility, and statutory subject matter. The understanding that these three requirements are separate and distinct is long-standing and has been universally accepted. . . . Thus, the questions of whether a particular invention is novel or useful are questions wholly apart from whether the invention falls into a category of statutory subject matter. Of the three requirements stated in §101, only two, utility and statutory subject matter, are applied under §101...³⁴⁷

Judge Sweet provided that the Supreme Court subsequently affirmed this understanding of the §101 analysis in *Diamond v. Diehr*.³⁴⁸ Based on this reasoning, the Court in this case held that, in determining whether the patents-in-suit comply with section 101, the proper analysis requires the determination of whether the claimed invention possesses utility. Further, it also requires the determination of whether the claimed invention constitutes patentable subject matter. Under this determination, it must be decided whether the claimed invention is a ‘process, machine, manufacture, or composition of matter, or any new and useful improvement thereof,’ or whether it falls instead within the judicially created ‘products of nature’ exception to patentable subject matter, being ‘laws of nature, natural phenomenon and abstract ideas.’³⁴⁹ Based on the fact that it was not disputed that the claimed compositions and methods possessed utility, the Judge in this case held that the sole issue that the Court faced was to resolve whether the claimed compositions and methods could be considered to constitute statutory subject matter, or fell within the judicially created products of nature exception to patentable subject matter.³⁵⁰

³⁴⁶ 596 F.2d 952, 960-961 (C.C.P.A. 1979).

³⁴⁷ *Association for Molecular Pathology et al v United States Patent & Trademark Office et al* (note 3) at 100-101.

³⁴⁸ 450 U.S. 175, 189-190 (1981).

³⁴⁹ *Diamond v. Chakrabarty* (note 239) at 309.

³⁵⁰ *Association for Molecular Pathology et al v United States Patent & Trademark Office et al* (note 3) at 102.

6.3.3 The composition claims are invalid under 35 U.S.C. §101

As previously mentioned, the task presented to the Court was to determine whether or not claims directed to isolated DNA containing naturally-occurring sequences fell within the products of nature exception to section 101. Based upon the reasons set out below, Judge Sweet concluded that the composition claims-in-suit were indeed considered to fall within this exception.³⁵¹

6.3.3.1 Consideration of the merits of Plaintiffs' challenge is appropriate

The primary reason given by Myriad as to why the Court should dismiss the claims of the Plaintiff was based on the 'carefully considered policy of the USPTO,' which is 'entitled to great respect from the courts.'³⁵² Further, Myriad noted the presumption of validity that was afforded to patents under section 282 of Title 35 of the U.S.C and the USPTO's prior consideration of the eligibility of gene-related patents.³⁵³ In considering these arguments by Myriad, Judge Sweet stated that in *Arnold P'ship v. Dudas*³⁵⁴ the Federal Circuit held that it owes no deference to USPTO legal determination. Further, the Judge in this case stated that although Congress has created a presumption of validity for issued patents, approximately forty per cent of patents challenged in the courts have been held to be invalid, which shows that this presumption is far from absolute. The Court was of the view that the lack of Congressional action to specifically prohibit the patenting of genes in response to the USPTO's prior grant of such patents also does not preclude their review by the courts.³⁵⁵ As an example, Judge Sweet looked at *In re Bilski*³⁵⁶ where the Federal Circuit set out a test for the patentability of method claims that has the potential to invalidate thousands of patents on business methods, despite Congress' silence regarding the patentability of such methods. Moreover, the Judge held that, in the

³⁵¹ *Association for Molecular Pathology et al v United States Patent & Trademark Office et al* (note 3) at 103.

³⁵² *Ibid.*

³⁵³ Utility Examination Guidelines 66 Fed. Reg. 1092, 1092-99 (Jan 5, 2001).

³⁵⁴ 362 F.3d 1338, 1340 (Fed. Cir. 2004).

³⁵⁵ *Association for Molecular Pathology et al v United States Patent & Trademark Office et al* (note 3) at 103-104.

³⁵⁶ 545 F.3d 943 (Fed. Cir. 2008).

absence of a section 101 challenge to patent validity, the fact that courts have previously upheld the validity of patents directed to biological products in response to section 102 and/or section 103 challenges did not have any bearing on the case at hand.³⁵⁷

Further, the Court in this case found Myriad's suggestion that invalidating the patents-in-suit would be an unconstitutional taking in violation of the Fifth Amendment of the Constitution or a violation of the United States' obligations under TRIPS unpersuasive. Judge Sweet stated that this argument by Myriad ran counter to a long history of invalidation of patents claims to the Court, and was not supported by legal precedent. In addition, the Court noted that Articles 8.1 and 27.3 of TRIPS allow governments to incorporate public health concerns into their national intellectual property laws, and exclude from patentability diagnostic, therapeutic, or surgical methods as well as particular inventions on the grounds of public interest.³⁵⁸ Based on this reasoning, the Judge held that the invalidation of the patents-in-suit would not amount to a constitutional violation or conflict with the United States' treaty obligations.³⁵⁹

6.3.3.2 Patentable subject matter must be 'markedly different' from a product of nature

Judge Sweet noted that Supreme Court precedent had established that products of nature do not constitute patentable subject matter without a change that results in the creation of a fundamentally new product. For example, in *American Fruit Growers, Inc. v. Brogdex Co*³⁶⁰ the Supreme Court stated as follows:

'Manufacture implies a change, but every change is not manufacture, and yet every change in an article is the result of treatment, labor, and manipulation. But something more is necessary . . . There must be transformation; a new and different article must emerge having a distinctive name, character, or use.'

³⁵⁷ *Association for Molecular Pathology et al v United States Patent & Trademark Office et al* (note 3) at 105. See for example *In re Kubin*, 561 F.3d 1351 (Fed. Cir. 2009) (considering obviousness of claims).

³⁵⁸ *Ibid* at 106.

³⁵⁹ *Ibid* at 107.

³⁶⁰ 283 U.S 1, 12-13 (1931).

Judge Sweet also stated that the Supreme Court had considered the application of section 101 to product claims in *Diamond v. Chakrabarty*.³⁶¹ In this case the Supreme Court had held that a live, human-made micro-organism was considered to be patentable subject matter under section 101. In reaching this conclusion, the Supreme Court had observed that the claim was not to a hitherto unknown natural phenomenon, but to a non-naturally occurring manufacture or composition of matter - a product of human ingenuity, 'having a distinctive name, character and use.'³⁶² In addition, Judge Sweet held that Courts have specifically held that purification of a natural compound, without more, is insufficient to render a product of nature patentable.³⁶³

On the other hand, Myriad argued, quoting *In re Bergstrom*³⁶⁴ that the purification of 'naturally occurring' compounds that 'do not exist in nature in pure form' renders such compounds eligible for patentability. The Court in this case was not persuaded by this argument owing to the fact that it found that the cases cited by Myriad did not support Myriad's position.³⁶⁵ Myriad relied heavily on the holding of Judge Hand in *Parke-Davis & Co. v. H.K. Mulford Co.*³⁶⁶ However, Judge Sweet stated that the question before the court in this case had been one of novelty and not one of patentable subject matter (the section 101 question before the Court in the present case). In addition, Judge Sweet observed that, in framing the issue, Judge Hand had stated as follows:

'The validity of the claims is attacked, first, because they are *anticipated* in the art; and second, for a number of technical grounds which I shall take up in turn.'³⁶⁷

³⁶¹ 447 U.S.303.

³⁶² *Diamond v. Chakrabarty* (note 239) at 309–310.

³⁶³ *Association for Molecular Pathology et al v United States Patent & Trademark Office et al* (note 3) at 110. See for example *Cochrane v. Badische Anilin & Soda Fabrik*, 111 U.S. 293 (1884).

³⁶⁴ 427 F.2d 1394, 1401 (C.C.P.A. 1970).

³⁶⁵ *Association for Molecular Pathology et al v United States Patent & Trademark Office et al* (note 3) at 114.

³⁶⁶ 189 F.2d 95 (S.D.N.Y. 1911).

³⁶⁷ *Parke-Davis & Co. v. H.K. Mulford Co* 189 F.2d 95, 101 (S.D.N.Y. 1911).

The Court in this case went on to reason that, only after concluding that the claimed purified product was novel over the prior art, did Judge Hand offer, as dicta, the statement to which Myriad cited: ‘But, even if it were merely an extracted product without change, there is no rule that such products are not patentable.’³⁶⁸ On this point, Judge Sweet was of the view that this statement was no longer good law in light of subsequent Supreme Court cases which required that a claimed invention possess ‘markedly different characteristics’ over products existing in nature in order for it to constitute patentable subject matter.³⁶⁹ Additionally, the Court stated that Judge Hand’s suggestion that a claimed invention was patentable, based on the fact that it was ‘a new thing commercially and therapeutically’³⁷⁰ had also been firmly contradicted by subsequent case law that establishes that ‘it is improper to consider whether a claimed element or step in a process is novel or nonobvious, since such considerations are separate requirements’ when evaluating whether a claim is patent-eligible subject matter.³⁷¹

Overall, the District Court held that there was a clear line of Supreme Court precedent and accompanying lower court authorities that established that the purification of a product of nature, without more, cannot transform it into patentable subject matter. Rather, the purified product must possess ‘markedly different characteristics’ in order to satisfy the requirements of section 101.³⁷²

6.3.3.3 The claimed isolated DNA is not ‘markedly different’ from native DNA

The question that was presented by the Plaintiff’s challenge to the composition claims was whether the isolated DNA claimed by Myriad possessed ‘markedly different

³⁶⁸ *Parke-Davis & Co. v. H.K. Mulford Co* 189 F.2d 95, 101 (S.D.N.Y. 1911).

³⁶⁹ *Association for Molecular Pathology et al v United States Patent & Trademark Office et al* (note 3) at 116. See for example *Diamond v. Chakrabarty* (note 239) at 310.

³⁷⁰ *Parke-Davis & Co. v. H.K. Mulford Co.* (note 367) at 103.

³⁷¹ *Prometheus Labs, Inc. v. Mayo Collaborative Services.* 581 F.3d 1336, 1343 (Fed. Cir. 2009).

³⁷² *Association for Molecular Pathology et al v United States Patent & Trademark Office et al* (note 3) at 121.

characteristics' from a product of nature.³⁷³ To support its position, Myriad cited several differences between the isolated DNA claimed in the patents and the native DNA found within human cells. However, Judge Sweet held that none of these differences established the subject matter patentability of isolated *BRCA1/2* DNA. Further, Judge Sweet stated that the central premise of Myriad's argument that the claimed DNA is 'markedly different' from DNA found in nature was the assertion that 'isolated DNA molecules should be treated no differently than other chemical compounds for patent eligibility,' and that the alleged 'difference in the structural and functional properties of isolated DNA' rendered the claimed DNA patentable-eligible.³⁷⁴ However, the Judge in this case found that Myriad's focus on the chemical nature of DNA failed to acknowledge the unique characteristics of DNA that differentiate it from other chemical compounds.³⁷⁵

The Court was of the view that the informational quality of DNA was unique among the chemical compounds found in the human body, and held that it would be erroneous to view DNA as 'no different' than other chemicals previously the subject of patents.³⁷⁶ In addition, the Court held that Myriad's argument that all chemical compounds necessarily convey some information ignores the biological realities of DNA. On this point, Judge Sweet stated that the information encoded in DNA is not information about its own molecular structure incidental to its biological function, as is the case with other chemicals found in the body. Rather, the information encoded by DNA reflects its primary biological function: directing the synthesis of other molecules in the body, namely, proteins. The Court stated that DNA, and in particular, the ordering of its nucleotides, thus serves as the physical embodiment of laws of nature - those that define the construction of the human body.³⁷⁷ The Judge in this case concluded that, based on the unique quality of DNA as a physical embodiment of information, none of the structural and functional differences cited by Myriad between native *BRCA1/2* DNA and the isolated *BRCA1/2* DNA claimed in the patents-in-suit rendered the claimed DNA

³⁷³ *Association for Molecular Pathology et al v United States Patent & Trademark Office et al* (note 3) at 121-122.

³⁷⁴ *Ibid* at 122.

³⁷⁵ *Ibid*.

³⁷⁶ *Ibid* at 123.

³⁷⁷ *Ibid* at 124.

‘markedly different.’ Further, the Court held that the preservation of this defining characteristic of DNA in its native and isolated forms justified the conclusion that the challenged composition claims are directed to unpatentable products of nature.³⁷⁸

Myriad also argued that the section 101 inquiry into the subject matter patentability of isolated DNA should focus only on the differences alleged to exist between native and isolated DNA, rather than considering the similarities that exist between the two forms of DNA.³⁷⁹ On this point, Judge Sweet believed that Myriad offered no authorities in support of such an approach. On the contrary, the Judge stated that the Supreme Court in *Diamond v. Diehr*³⁸⁰ held that:

‘In determining the eligibility of a claimed process for patent protection under section 101, the claims must be considered as a whole.’³⁸¹

The Judge also stated here that were Myriad’s approach the law, it would be hard to discern how any invention could fail the test.³⁸² The Court in this case provided that the correct section 101 inquiry was whether, considering the claimed invention as a whole, it was sufficiently distinct in its fundamental characteristics from natural phenomena to possess the required ‘distinctive name, character, and use.’³⁸³ Further, the Court was of the view that none of Myriad’s arguments established the distinctive nature of the claimed DNA. Myriad had attempted to rely on its assertion that native DNA contains intron sequences that are absent in the claimed *BRCA1/2* DNA. However, the Court found that some of the claims, such as claim 1 of U.S. patent 5,747,282 were directed broadly to DNA ‘coding for a *BRCA1* polypeptide.’ By definition, native *BRCA1* DNA encodes the *BRCA1* protein, and therefore Judge Sweet found that claim 1 of U.S. patent 5,747,282 would cover purified *BRCA1* DNA possessing the exact same structure found

³⁷⁸ *Association for Molecular Pathology et al v United States Patent & Trademark Office et al* (note 3) at 125.

³⁷⁹ *Ibid.*

³⁸⁰ 450 U.S. 175, 188 (1981).

³⁸¹ *Association for Molecular Pathology et al v United States Patent & Trademark Office et al* (note 3) at 126. See also *In re Grams*, 888 F.2d 835, 839 (Fed. Cir. 1989).

³⁸² *Ibid.*

³⁸³ *Ibid* at 127. See also *Diamond v Chakrabarty* (note 239) at 310.

in the human cell, including both introns and exons. This same reasoning was applied to claim 1 of U.S. patent 5,837,492, which similarly claimed isolated DNA ‘coding for a *BRCA2* polypeptide.’³⁸⁴ Additionally, the Court noted that several of the composition claims were directed to isolated DNA sequences containing as few as fifteen nucleotides of the *BRCA1* coding sequence, and stated that at least some of these short DNA sequences would be found within a single exon of the native *BRCA1* gene sequence. Based upon this reasoning, the Court held that for these short DNA sequences, the existence of introns in native *BRCA1* DNA was thus irrelevant to the question of structural differences when comparing these short DNA sequences with native *BRCA1* DNA.³⁸⁵

On a more general note, the Judge in this case held that the fact that the *BRCA1/2* cDNA molecules covered by the composition claims-in-suit contained only the protein coding exons, and not the introns found in native DNA, did not render these cDNAs and their native counterparts ‘markedly different.’ Moreover, the Judge noted that, at least in the case of *BRCA1*, the claimed cDNA sequences are actually found in the human genome in the form of a naturally occurring pseudogene.³⁸⁶ Further, the Court held that Myriad’s argument that the functional differences between native and isolated DNA demonstrates that they are ‘markedly different’ relied on the fact that isolated DNA may be used in applications for which native DNA was unsuitable. For example, Myriad argued that the utility of isolated DNA as a primer or a molecular probe arose from its ability to target and interact with other DNA molecules, such as a specific DNA target sequence. However, Judge Sweet stated that the basis of this utility was the fact that the isolated DNA possessed the identical nucleotide sequence as the target DNA sequence, thereby allowing target-specific hybridisation.³⁸⁷ The Judge also held that the utility of isolated DNA as a sequencing target was reliant on the preservation of native DNA’s nucleotide sequence. Moreover, the Judge noted that the entire premise on which Myriad’s genetic testing was based involved the claimed isolated DNA retaining, in all relevant respects,

³⁸⁴ *Association for Molecular Pathology et al v United States Patent & Trademark Office et al* (note 3) at 128-129.

³⁸⁵ *Ibid.*

³⁸⁶ *Ibid* at 129.

³⁸⁷ *Ibid* at 130-131.

the identical nucleotide sequence found in native DNA. The Court noted that although the absence of proteins and other nucleotide sequences was required for DNA to be useful for the stated purposes, the purification of native DNA did not alter its essential characteristic, being its nucleotide sequence.³⁸⁸ On this reasoning, Judge Sweet held that that the use of isolated DNA for the purposes cited by Myriad did not establish the existence of differences ‘in kind’ between native and isolated DNA that would establish the subject matter patentability of what is otherwise a product of nature.³⁸⁹ Further, Judge Sweet stated as follows:

‘The identification of the *BRCA1* and *BRCA2* gene sequences is unquestionably a valuable scientific achievement for which Myriad deserves recognition, but that is not the same as concluding that it is something for which they are entitled to a patent... Because the claimed isolated DNA is not markedly different from native DNA as it exists in nature, it constitutes unpatentable subject matter under 35 U.S.C §101.³⁹⁰

6.3.3.4 The method claims are invalid under 35 U.S.C §101

Judge Sweet referred to *Gottschalk v. Benson*,³⁹¹ in which it was held that phenomena of nature, mental processes, and abstract intellectual concepts are not patentable, owing to the fact that they are the basic tools of scientific and technological work. However, the Judge also referred to in *In re Bilski*,³⁹² which stated that ‘an application of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection.’ Further, the Court noted that in *In re Bilski*³⁹³ the Court set forth:

³⁸⁸ *Association for Molecular Pathology et al v United States Patent & Trademark Office et al* (note 3) at 132.

³⁸⁹ *Ibid* at 133.

³⁹⁰ *Ibid* at 135. See also *Funk Bros. Seed Co. v. Kalo Inoculant Co.* 33 U.S. 127, 132 (1948).

³⁹¹ 409 U.S. 63, 67 (1972).

³⁹² 545 F.3d 943, 953 (Fed. Cir. 2008) quoting *Diamond v. Diehr* 450 U.S. 175, 187 (1981).

³⁹³ 545 F.3d 943, 954 (Fed. Cir. 2008).

‘The definitive test to determine whether a process claim is tailored narrowly enough to encompass only a particular application of a fundamental principle rather than pre-empt the principle itself.’³⁹⁴

Under this test, known as the ‘machine or transformation’ test, a claimed process is considered to be eligible for patentability under section 101 if one of two conditions is met. The first condition is that it must be tied to a particular machine or apparatus, and the second condition is that it must transform a particular article into a different state or thing. Further, ‘the involvement of the machine or transformation in the claimed process must not merely be insignificant extra-solution activity.’³⁹⁵ In other words, the ‘transformation must be central to the purpose of the claimed process.’³⁹⁶ In *In re Bilski*³⁹⁷ the Court held that the addition of a data-gathering step to an algorithm was insufficient to convert that algorithm into a process that was eligible for patentability. Judge Sweet provided here that, although the Supreme Court had yet to issue its own opinion on *In re Bilski*, until such time this test was the law.³⁹⁸ In addition, the Court stated as follows:

‘The language of the method claims-in-suit and the plain and ordinary meanings of the terms “analysing” or “comparing” establish that the method claims-in-suit are directed only to the abstract mental processes of “comparing” or “analysing” gene sequences.’³⁹⁹

Judge Sweet found that none of the methods in the case at hand were tied to any particular machine, nor did they bring about a tangible transformation of anything.⁴⁰⁰ Thus, the Judge concluded that all of Myriad’s process claims failed on this ‘machine or

³⁹⁴ Ibid.

³⁹⁵ Ibid at 961-962.

³⁹⁶ Ibid at 962.

³⁹⁷ Ibid at 963.

³⁹⁸ J Conley and D Vorhaus ‘Pigs Fly: Federal Court invalidates Myriad’s patent claims’ (2010) *Genomics Law Report*. at 2. Available at <http://www.genomicslawreport.com/index.php/2010/03/30/pigs-fly-federal-court-invalidates-myrriads-patent-claims/> [Accessed 9 January 2011].

³⁹⁹ *Association for Molecular Pathology et al v United States Patent & Trademark Office et al* (note 3) at 141.

⁴⁰⁰ Conley and Vorhaus (note 398) at 2.

transformation' test. Instead, the Court held that, the claimed comparisons of DNA sequences were abstract mental processes and thus constituted unpatentable subject matter under section 101.⁴⁰¹ Moreover, based on the reasoning in *In re Bilski*,⁴⁰² the Court stated that even if the challenged method claims were read to include the transformations associated with isolating and sequencing human DNA, these transformations would constitute no more than 'data-gathering step(s)' that were not 'central to the purpose of the claimed process.'⁴⁰³ Thus, they would still fail the 'machine or transformation' test under section 101 for subject matter patentability.⁴⁰⁴

6.4 Conclusion

In conclusion, for the reasons set out above, Judge Sweet declared that the claims-in-suit were invalid pursuant to section 101 of Title 35 of the U.S.C.⁴⁰⁵

⁴⁰¹ *Association for Molecular Pathology et al v United States Patent & Trademark Office et al* (note 3) at 4.

⁴⁰² 545 F.3d 943, 962-63 (Fed. Cir. 2008).

⁴⁰³ *Association for Molecular Pathology et al v United States Patent & Trademark Office et al* (note 3) at 145.

⁴⁰⁴ *Ibid* at 147.

⁴⁰⁵ *Ibid* at 152.

CHAPTER 7: THE IMPACT OF THE JUDGMENT IN ‘*AMP v. USPTO*’

The sheer complexity of the intellectual property law system is highlighted in *AMP v. USPTO*.⁴⁰⁶ This is owing to the fact that even though a patent right may provide an inventor with the legal right to exclude others from using an invention, a range of laws, business practices and institutions affect whether, as well as how, a patent holder can exercise that legal right.⁴⁰⁷ In addition, although the decision in this case was well grounded in legislative history and the precedent of the Supreme Court, it does conflict with years of decision making by the USPTO.⁴⁰⁸

The most important feature of this case is the question that it answers: is an isolated gene patentable subject matter?⁴⁰⁹ The approach taken by the Court in answering this question has been stated as being radical owing to the fact that it departs from the approach that has traditionally been taken since the inception of gene patenting. More specifically, in this case the Court placed focus on the informational quality of a gene, whether in the body or in isolation. However, on the traditional approach, patent lawyers have always presumed that genes are just chemicals, and that their information carrying function is of no relevance to their patentability.⁴¹⁰ In addition, patent lawyers have presumed that isolated genes are patentable based on the fact that, in their isolated state, they cannot be considered to be products of nature.⁴¹¹ This presumption has been based on statute, case law, written Patent Office policies and the issuance of numerous gene patents. Similarly, the USPTO and the courts have also favoured such an approach.⁴¹² Thus, the decision in *AMP v. USPTO*⁴¹³ came as a surprise to many. However, it may be some time before the impact that this decision may have can be fully understood.⁴¹⁴

⁴⁰⁶ *Association for Molecular Pathology et al v United States Patent & Trademark Office et al* (note 3).

⁴⁰⁷ Gold and Carbone (note 4) at S64.

⁴⁰⁸ Kesselheim and Mello (note 1) at 1857.

⁴⁰⁹ AJ Morrison ‘Rethinking the gene patent’ (2010) 29 *Biotechnology Law Report* 609 at 609.

⁴¹⁰ Conley and Vorhaus (note 398) at 2.

⁴¹¹ *Ibid* at 2.

⁴¹² Morrison (note 409) at 609.

⁴¹³ *Association for Molecular Pathology et al v United States Patent & Trademark Office et al* (note 3).

⁴¹⁴ Conley and Vorhaus (note 398) at 2.

7.1 Impact on the biotechnology industry

One of the questions that must be asked is how this decision will, if upheld, affect the biotechnology industry? In view of this, the Court in *AMP v. USPTO*⁴¹⁵ was careful to limit its holding to the patentability of isolated DNA sequences, as distinct from other compounds. The Judge in this case held that isolated DNA sequences are unique owing to the fact that they are ‘a physical embodiment of information.’ Thus, based on this reasoning, it is possible that the decision will only affect a narrow segment of the biotechnology industry. However, it has been proposed that the impact that the decision may have on this narrow segment could potentially be great.⁴¹⁶ It has also been suggested that beyond the power of this decision to make headlines, some industry observers and legal experts see little chance that it will pose a real threat to gene patents. One of the reasons for this is the fact that United States Courts outside the boundaries of New York's Southern District are not compelled to follow the precedent of this case, and another reason is the fact that Myriad has appealed against the decision.⁴¹⁷

7.2 Impact on the academic debate concerning gene patents

The decision by Judge Sweet in *AMP v. USPTO*⁴¹⁸ has re-ignited the academic debate in legal and scientific communities over several issues.⁴¹⁹ These include the ideal scope of patentable subject matter in general, whether or not isolated genes should be excluded from patentable subject matter, and the potential effect of such patents on scientific research and health care accessibility, to name only a few.⁴²⁰ For example, Fowler strongly supports the position that genes should not constitute patentable subject matter, and has recommended that section 5 of TRIPS be amended to specifically exclude

⁴¹⁵ *Association for Molecular Pathology et al v United States Patent & Trademark Office et al* (note 3).

⁴¹⁶ Kesselheim and Mello (note 1) at 1857.

⁴¹⁷ ‘Testing time for gene patents’ (2010) 464 (7291) *Nature* 957 at 957. Available at: <http://www.nature.com/nature/journal/v464/n7291/full/464957a.html> [Accessed 23 January 2011].

⁴¹⁸ No. 09 Civ. 4515 (S.D.N.Y., Mar. 29, 2010) The decision has been appealed.

⁴¹⁹ Morrison (note 409) at 609.

⁴²⁰ *Ibid.*

genetic material from patentability.⁴²¹ Fowler believes that the broad language of section 5 allows for inconsistencies in the national laws of individual member states, and that this ambiguity in turn creates serious legal conflicts between member states, as well as between patent holders and the governments themselves.⁴²²

Various possible alternatives to excluding isolated DNA from patentability have been suggested as well. For instance an advisory committee to the United States Department of Health and Human Services has recently provided an analysis of the impact of gene patents on genetic testing.⁴²³ In its report, this advisory committee recommended that gene patent rights should not be enforced in circumstances in which they are violated in the course of research or genetic testing.⁴²⁴ Hoffenberg has suggested that a possible solution may be found in the compulsory licensing of some patents.⁴²⁵ Here it can be noted that a compulsory license has the effect of authorising a third party to make, use or sell a patented invention without the consent of the rights holder.⁴²⁶ On this point, Article 30(h) of TRIPS provides that the rights holder is to be paid adequate remuneration in the circumstances of each case. Following this approach, innovative companies will be able to receive a return on their investment in research, and consumers will be able to have access to the technology at a fair and reasonable price.⁴²⁷ This is important because the public's access to gene patents needs to be balanced with the biotechnology industry's incentives to invest capital to develop commercial products that ultimately benefit the public.⁴²⁸ Van Overwalle has also proposed the use of a compulsory license for public health, and a narrow diagnostic-use exemption in order to discourage exclusive or overly restrictive licensing.⁴²⁹ In addition, Kubick has suggested that the tightening of patent-

⁴²¹ Fowler (note 114) at 1078.

⁴²² *Ibid* at 1093-1094.

⁴²³ Report of the Secretary's Advisory Committee on Genetics, Health, and Society 'Gene patents and licensing practices and their impact on patient access to genetic tests' (2010). Available at: http://oba.od.nih.gov/oba/sacghs/reports/SACGHS_patents_report_2010.pdf [Accessed 23 January 2011].

⁴²⁴ 'Testing time for gene patents' (2010) 464 (7291) *Nature* 957 at 957. Available at:

<http://www.nature.com/nature/journal/v464/n7291/full/464957a.html> [Accessed 23 January 2011].

⁴²⁵ HL Hoffenberg 'Will the patentability of genes survive?' (2010) 28 *Nature Biotechnology* 925 at 927.

⁴²⁶ C Chien 'Cheap drugs at what price to innovation' (2003) *Berkeley Tech. L.J.* 853 at 855.

⁴²⁷ Hoffenberg (note 425) at 927.

⁴²⁸ M Yoon 'Gene patenting debate: Meaning of Myriad' (2010) 9 *J. Marshall Rev. Intell. Prop. L.* 953 at 953.

⁴²⁹ G Van Overwalle 'Turning patent swords into shares' (2010) 330 (6011) *Science* 1630 at 1631.

eligibility standards for medical diagnostic and therapeutic methods would be effective in cutting healthcare costs.⁴³⁰

Yoon has proposed the use of narrowly tailored legislation where gene patents are concerned. Under the proposed legislation a court may grant compulsory licensing under certain circumstances in order to encourage the commercialisation of human gene-related inventions, for example, diagnostics and therapeutics that benefit the public. Further, under this proposed legislation a court would prohibit the enforcement of human gene patents related to diagnostic genetic testing against medical practitioners. Therefore, the proposed legislation would preserve patients' access to human gene patents related to genetic diagnostic testing, while at the same time encourage reasonable licensing policies that maximise the commercial development of diagnostics and therapeutics to benefit the public.⁴³¹ McHugh has also proposed that Congress could enact legislation similar to that of other countries by excluding diagnostic, therapeutic, or surgical methods from patentability, or by denying patentability to an invention on moral grounds. Both of these exceptions are listed as possible options for countries to adopt under TRIPS.⁴³² However, McHugh believes that it is unlikely that Congress would implement legislation excluding DNA or diagnostic methods from patentability on moral grounds. This is owing to the fact that in the United States there is generally no accepted exclusion from patentability based on morality. On the other hand, McHugh believes that it may indeed be possible for Congress to implement legislation that allows for the exclusion of diagnostic methods from patentability.⁴³³

Various academic commentators are in disagreement with the decision in *AMP v. USPTO*,⁴³⁴ and believe it should be overturned on appeal. For example, Morrison has stated that Judge Sweet cited no statute or case law for relying on DNA's unique features in concluding that the composition patents were invalid. On this point, Morrison argues

⁴³⁰ M Kubick 'An uncertain future: The impact of medical process and diagnostic method patents on healthcare in the United States' (2010) 9 (3) *Northwestern Journal of Technology and Intellectual Property* 280 at 280.

⁴³¹ Yoon (note 428) at 974.

⁴³² McHugh (note 304) at 218.

⁴³³ *Ibid.*

⁴³⁴ *Association for Molecular Pathology et al v United States Patent & Trademark Office et al* (note 3).

that the unique role of DNA as a carrier of information is in ‘addition to’ and not ‘instead of’ its status as a molecule, and believes that the Judge relied upon what appears to be a ‘new and problematic doctrine’ excluding isolated DNA from the sphere of patent-eligible subject matter.⁴³⁵

⁴³⁵ Morrison (note 409) at 614.

CHAPTER 8: THE ‘AMP v. USPTO’ APPEAL

Myriad Genetics, Inc. (Myriad) has appealed the decision in *AMP v. USPTO*.⁴³⁶ The case is now pending before the United States Court of Appeals for the Federal Circuit.⁴³⁷ In addition, it is possible that the decision may ultimately reach the United States Supreme Court.⁴³⁸

8.1 Myriad’s appeal to the Federal Circuit

Myriad filed its appellant’s brief in October 2010, joined by the Directors of the University of Utah Research Foundation. The appellants make three main arguments in this brief. Their first argument is that the District Court lacked declaratory-judgment jurisdiction, and the second argument is that the composition claims are drawn to patent-eligible subject matter. The third argument is that Myriad’s method claims cover patent-eligible subject matter under section 101 of Title 35 of the U.S.C.⁴³⁹

8.1.1 The District Court lacked declaratory-judgment jurisdiction

Myriad’s first argument attacks the jurisdiction of the District Court, rather than the merits of the Court’s decision.⁴⁴⁰ This argument is based on the assertion that none of the plaintiffs in the original case had any controversy of ‘sufficient immediacy and reality to warrant the issuance of a declaratory judgment.’⁴⁴¹ Should Myriad prevail on this

⁴³⁶ *Association for Molecular Pathology et al v United States Patent & Trademark Office et al* (note 3).

⁴³⁷ *Association for Molecular Pathology, et al. v. United States Patent and Trademark Office, et al*, No. 2010-1406.

⁴³⁸ Morrison (note 409) at 609.

⁴³⁹ Appellants Brief, *Association for Molecular Pathology et al v. United States Patent and Trademark Office et al*. No. 10-1406 (Fed. Cir.) at ii-iii. Available at: <http://patentdocs.typepad.com/files/myriad-brief-of-appellant.pdf> [Accessed 28 January 2010].

⁴⁴⁰ JJ Mullen et al ‘Surprise reversal of the U.S government position frames the issues in Myriad Genetic’s Federal Circuit appeal’ (November 2010) Morrison Foerster client alert at 2. Available at: <http://www.lexology.com/library/detail.aspx?g=36af60c0-578b-4a66-9b70-58e9be00d5f4> [Accessed 28 January 2010].

⁴⁴¹ Appellants Brief, *Association for Molecular Pathology et al v. United States Patent and Trademark Office et al* (note 439) at 16.

procedural ground, the Federal Circuit could dispose of the case without reaching the merits of the underlying decision of the District Court.⁴⁴²

8.1.2 The composition claims are drawn to patent-eligible subject matter

Myriad's next argument hinges on the fact that isolated DNA molecules are 'compositions of matter' under section 101 of Title 35 of the U.S.C, and are therefore entitled to patent protection.⁴⁴³ This argument challenges the decision of Judge Sweet that isolated DNA molecules fall within the scope of exceptions to patentable subject matter under section 101.⁴⁴⁴ Quoting *Diamond v Chakrabarty*,⁴⁴⁵ the appellants state that:

'In choosing such expansive terms . . . modified by the comprehensive "any," Congress plainly contemplated that the patent laws would be given wide scope.'⁴⁴⁶

Further, new to this argument is the citation of *Bilski v Kappos*⁴⁴⁷ for the proposition that the Supreme Court continues to recognise that Congress has 'plainly contemplated that the patent laws would be given wide scope' and that 'this breadth ensures that ingenuity should always receive liberal encouragement.'⁴⁴⁸ In addition, Myriad contends that:

⁴⁴² Mullen (note 440) at 2.

⁴⁴³ Ibid.

⁴⁴⁴ Ibid.

⁴⁴⁵ 447 U.S 303, 308 (1980).

⁴⁴⁶ Appellants Brief, *Association for Molecular Pathology et al v. United States Patent and Trademark Office et al* (note 439) at 30.

⁴⁴⁷ 130 S. Ct 3218 (2010).

⁴⁴⁸ K Noonan 'Myriad files appeal brief in *AMP v USPTO*' (October 2010) Patent docs, biotech and pharma patent law and news blog 1 at 1. Available at: <http://www.patentdocs.org/2010/10/myriad-files-appeal-brief-in-amp-v-uspto.html> [Accessed 28 January 2011]. See also Appellants Brief, *Association for Molecular Pathology et al v. United States Patent and Trademark Office et al* (note 439) at 30.

‘The claimed isolated DNA molecules are unquestionably “compositions of matter,” or at the very least a “new and useful improvement” upon native DNA.’⁴⁴⁹

In support of this argument, Myriad cites the USPTO’s 2001 *Utility Examination Guidelines*⁴⁵⁰ for the proposition that a purified DNA molecule isolated from its natural environment is a chemical compound and is patentable if all of the statutory requirements are met.⁴⁵¹ The appellant’s brief also argues that isolated DNA does not fall within the three recognised exceptions to patent eligibility, being ‘laws of nature, physical phenomena, and abstract ideas.’ Further, an extensive argument that Supreme Court precedent does not contain a ‘categorical’ prohibition of patenting ‘products of nature’ is provided.⁴⁵² The appellants argue here that:

‘These isolated molecules are new chemical compositions, which were unavailable to the public until these inventors discovered and isolated them. They did not cease to be patent-eligible compositions of matter simply because one characteristic of an isolated DNA molecule is (in the words of the District Court) a “physical embodiment of genetic information.”’⁴⁵³

According to Myriad, the District Court’s holding also ignores the fact that the *BRCA1* and *BRCA2* molecules are:

‘Not only purified; they are chemically extracted (breaking their covalent bonds) and isolated from the native DNA as well, resulting in a new composition that is structurally and functionally different from native DNA.’⁴⁵⁴

⁴⁴⁹ Appellants Brief, *Association for Molecular Pathology et al v. United States Patent and Trademark Office et al* (note 439) at 31.

⁴⁵⁰ 66 Fed. Reg. 1092-1094.

⁴⁵¹ Appellants Brief, *Association for Molecular Pathology et al v. United States Patent and Trademark Office et al* (note 439) at 31.

⁴⁵² Noonan (note 448) at 3.

⁴⁵³ Appellants Brief, *Association for Molecular Pathology et al v. United States Patent and Trademark Office et al* (note 439) at 34.

⁴⁵⁴ *Ibid* at 36.

Further, the appellants argue that the categorical exclusion of DNA molecules from patentability under section 101 would disrespect longstanding practice of the USPTO, a long and consistent line of precedent, as well as the proper role of congress in making patent law.⁴⁵⁵ In support of this argument, Myriad provides that over 2645 patents have been issued with claims to ‘isolated DNA’ and over 50 000 containing claims to nucleic acid sequences.⁴⁵⁶ Myriad warns that the District Court’s decision, if upheld, would make patent-ineligible a wide range of new and useful inventions derived from naturally-occurring sources.⁴⁵⁷

The appellants also contend that in applying its ‘markedly different’ standard, the District Court correctly stated that the claims must be ‘considered as a whole.’ However, the appellants further contend that Judge Sweet violated that rule by focusing on only one aspect of isolated DNA (its informational content) while ignoring the manifold differences between isolated and native DNA.⁴⁵⁸ This section of the brief concludes with the contention by the appellants that the District Court improperly granted summary judgment because there remain questions of fact concerning ‘whether the characteristics of isolated DNA are “markedly” different from those of native DNA.’⁴⁵⁹ Here the appellants state that:

‘Because the meaning of “markedly different” has never been developed in case law, the court improperly viewed itself as free to draw the “legal” conclusion that “none of the structural and functional differences . . . between native BRCA DNA and the isolated BRCA DNA claimed in the patents-in-suit render the claimed DNA ‘markedly different.’”⁴⁶⁰

⁴⁵⁵ Appellants Brief, *Association for Molecular Pathology et al v. United States Patent and Trademark Office et al* (note 439) at 37.

⁴⁵⁶ *Ibid* at 39.

⁴⁵⁷ Mullen (note 440) at 2. See also Appellants Brief, *Association for Molecular Pathology et al v. United States Patent and Trademark Office et al* (note 439) at 46.

⁴⁵⁸ Appellants Brief, *Association for Molecular Pathology et al v. United States Patent and Trademark Office et al* (note 439) at 51.

⁴⁵⁹ Noonan (note 448) at 3.

⁴⁶⁰ Appellants Brief, *Association for Molecular Pathology et al v. United States Patent and Trademark Office et al* (note 439) at 52.

8.1.3 The method claims cover patent-eligible subject matter under section 101

The appellants brief addressed the patent eligibility of Myriad's method claims as well, which the District Court had held to be patent-ineligible under the 'machine or transformation' test of the Federal Circuit in *In re Bilski*.⁴⁶¹ Myriad contends that the claims, properly construed, encompass a transformation step that is sufficient to satisfy this test.⁴⁶² Myriad also refers to the recent decision of the Supreme Court in *Bilski v. Kappos*,⁴⁶³ which held that while:

'The machine or transformation test is a useful and important clue . . . for determining whether some claimed inventions are processes under § 101' that test 'is not the sole test for deciding whether an invention is a patent-eligible "process."⁴⁶⁴

It can also be noted here that *Bilski v. Kappos*,⁴⁶⁵ was the Supreme Court's first opportunity to shed light on the standards for method patent eligibility since 1981 in *Diamond v. Diehr*,⁴⁶⁶ when the Court opened the door to increasingly broad patents of medical diagnostic and therapeutic methods.⁴⁶⁷ Chihane believes that the Supreme Court in *Bilski v. Kappos*⁴⁶⁸ was reluctant to make a sweeping decision that may cause collateral damage to other industries.⁴⁶⁹

Looking to the guidance provided in the Supreme Court's decision in *Bilski v. Kappos*,⁴⁷⁰ the appellants argue that the method claims include 'transformations' of a human sample

⁴⁶¹ 545 F.3d 943 (Fed. Cir. 2008).

⁴⁶² Noonan (note 448) at 5.

⁴⁶³ 130 S. Ct 3218 (2010).

⁴⁶⁴ For further reading see for example: WJ Simmons 'Bilski v. Kappos: the US Supreme Court broadens patent subject-matter eligibility' (2010) 28 (8) *Nature Biotechnology* 801.

⁴⁶⁵ 130 S. Ct 3218 (2010).

⁴⁶⁶ 450 U.S. 175 (1981).

⁴⁶⁷ Kubick (note 430) at 281.

⁴⁶⁸ 130 S. Ct 3218 (2010).

⁴⁶⁹ KG Chahine 'Anchoring gene patent eligibility to is constitutional mooring' (2010) 28 (12) *Nature Biotechnology* 1251 at 1251.

⁴⁷⁰ 130 S. Ct 3218 (2010).

and thus constitute patent-eligible subject matter.⁴⁷¹ Myriad also refers to *Prometheus Laboratories, Inc. v. Mayo Collaborative Services*,⁴⁷² a recent decision of the Federal Circuit, in which it was held that diagnostic methods involving transformations of human tissue and blood samples were eligible for patentability under section 101.⁴⁷³ In this case, the Court found transformative steps for assaying blood for the presence of thiopurine or its metabolites, since these steps involved physical or chemical transformations of levels that ‘cannot be determined by mere inspection.’⁴⁷⁴ Similarly, Myriad contends that its claimed methods involve ‘extracting, processing and analysing a human tissue or blood sample using “nucleotide sequences,” which are molecules.’⁴⁷⁵

8.2 The brief for the United States as amicus curiae in support of neither party

In its brief, the United States acknowledges that the conclusion that it reaches is contrary to the longstanding practice of the Patent and Trademark Office, as well as to the practice of the National Institutes of Health and other government agencies that have in the past sought and obtained patents for isolated genomic DNA.⁴⁷⁶ The United States took the position that the District Court correctly held that ‘genomic DNA that has merely been isolated from the human body, without further alteration or manipulation, is not patent-eligible.’⁴⁷⁷ Thus, under this reasoning it may not be possible to patent genetic diagnostic tests that require the use of short nucleotide sequences to amplify up gene sequences of interest.

Further, in its brief, the United States provided as follows:

⁴⁷¹ Mullen (note 440) at 2.

⁴⁷² 130 S. Ct. 3543 (2010).

⁴⁷³ Mullen (note 440) at 2.

⁴⁷⁴ Noonan (note 448) at 3.

⁴⁷⁵ Appellants Brief, *Association for Molecular Pathology et al v. United States Patent and Trademark Office et al* (note 439) at 55.

⁴⁷⁶ Brief for the United States as amicus curiae in support of neither party, *Association for Molecular Pathology et al v. United States Patent and Trademark Office et al*. No. 10-1406 (Fed. Cir.) at 18. Available at: <http://graphics8.nytimes.com/packages/pdf/business/genepatents-USamicusbrief.pdf> [Accessed 28 January 2010].

⁴⁷⁷ *Ibid* at 10.

‘The chemical structure of native human genes is a product of nature, and it is no less a product of nature when that structure is “isolated” from its natural environment than are cotton fibers that have been separated from cotton seeds or coal that has been extracted from the earth.’⁴⁷⁸

In addition, the United States provided that DNA of this type should be treated as a ‘product of nature.’⁴⁷⁹ However, the United States believes that the District Court made an error in casting doubt on the patent-eligibility of various man-made compositions of matter whose value derives from the information encoding capacity of DNA. Examples given here include cDNAs, vectors, and recombinant plasmids. On this point, the United States believes that these man-made compositions of matter are the ‘fruits of human ingenuity’ and therefore qualify as ‘human-made inventions,’ eligible for patent protection under section 101.⁴⁸⁰ According to this brief, the fundamental question under section 101 is:

‘Whether the inventor has created something through the application of human ingenuity or merely exposed something previously unappreciated in nature.’

It must also be noted that various other amicus curiae briefs have been filed in this appeal. For example, Alnylam Pharmaceuticals, Inc. filed a brief in support of Defendants-Appellants, supporting reversal,⁴⁸¹ and Genetic Alliance filed a brief supporting reversal, but not in support of either party,⁴⁸² to only mention a few.

⁴⁷⁸ Brief for the United States as amicus curiae in support of neither party (note 476) at 10-11.

⁴⁷⁹ E Marshall ‘Amicus brief unfriendly to gene patents’ (2010) 330 (6005) *Science* 746 at 746.

⁴⁸⁰ Brief for the United States as amicus curiae in support of neither party (note 476) at 9-10.

⁴⁸¹ Brief for Alnylam Pharmaceuticals, Inc as amicus curiae in support of Defendants-Appellants, supporting reversal, *Association for Molecular Pathology et al v. United States Patent and Trademark Office et al.* No. 10-1406 (Fed. Cir.). Available at: <http://patentdocs.typepad.com/files/alnylam-amicus-brief.pdf> [Accessed 28 January 2010].

⁴⁸² Brief for Genetic Alliance as amicus curiae in support of reversal but not in support of either party, *Association for Molecular Pathology et al v. United States Patent and Trademark Office et al.* No. 10-1406 (Fed. Cir.) <http://patentdocs.typepad.com/files/genetic-alliance-amicus-brief.pdf> [Accessed 28 January 2010].

CONCLUSION

Many of the recent cases described have changed the way in which gene patents are viewed and understood. For instance, the recent case of *Monsanto Technology LLC v Cefetra BV and others*⁴⁸³ has raised doubts concerning the validity and infringement of many biotechnology patents currently in force in Europe. This is owing to the fact that the consequence of this decision is that a DNA sequence will not be protected where it does not perform the function for which it was patented.⁴⁸⁴ The potential impact of *In re Kubin*⁴⁸⁵ on the patentability of gene sequences in the United States has also raised uncertainty, since obviousness challenges may invalidate many gene patents if the protein was known and gene cloning depended on routine methods.⁴⁸⁶ Coupled with *AMP v. USPTO*,⁴⁸⁷ it appears that Courts in both Europe and the United States are taking a more restrictive approach to DNA patents than they have over the past two decades. Whether this restrictive approach to DNA patents will continue remains to be seen, and will depend in part upon how these cases are interpreted in future decisions.⁴⁸⁸

For example, it remains to be seen whether the decision in *AMP v. USPTO*⁴⁸⁹ will be upheld on appeal. The decision by the Court of Appeals for the Federal Circuit in this case may indeed answer the question of what the future holds for gene patents in the United States. However, it is possible for the Court to dispose of the case without reaching the merits of the decision if Myriad is successful on its first argument attacking the jurisdiction of the District Court.⁴⁹⁰ Although the outcome of this case will not occur for months, possibly even years, it has the potential to present a 'watershed moment' in biotechnology patent law.⁴⁹¹ This is because it has the potential to change the legal status

⁴⁸³ (C- 428/08) (Court of Justice of the European Union).

⁴⁸⁴ Fitt and Nodder (note 186) at 621.

⁴⁸⁵ 561 F.3d 1351(Fed. Cir. 2009).

⁴⁸⁶ Kwan (note 34) at 29.

⁴⁸⁷ No. 09 Civ. 4515 (S.D.N.Y., Mar. 29, 2010).

⁴⁸⁸ Fitt and Nodder (note 186) at 622.

⁴⁸⁹ No. 09 Civ. 4515 (S.D.N.Y., Mar. 29, 2010).

⁴⁹⁰ Mullen (note 440) at 2.

⁴⁹¹ *Ibid* at 3.

of isolated human DNA. Should the decision in *AMP v. USPTO*⁴⁹² be upheld, isolated DNA will be regarded as being unpatentable subject matter. However, if the Federal Circuit agrees with the amicus curiae brief of the United States, various man-made compositions of matter whose value derives from the information encoding capacity of DNA will still be regarded as being patentable. I am inclined to agree with the test set out by the United States in its amicus brief, stating that the fundamental question that must be asked under section 101 is:

‘Whether the inventor has created something through the application of human ingenuity or merely exposed something previously unappreciated in nature.’

This is based on the fact that I believe that effort and ingenuity should be rewarded by the patenting of true inventions and applied research. Further, I believe that the patentability of such subject matter must at the same time be coupled with the stringent application of the other requirements for patentability in the award of a patent. Another benefit of this approach is that, owing to the full disclosure requirements for patentability, the knowledge of these inventions will enter the public domain, and will not be kept as trade secrets. Additionally, this approach will ensure that those who invest money on research can recoup some of it in a commercial product, and therefore it provides an incentive for innovation. If a prospect of recoupment was not possible, it is unlikely that companies and private investors would spend money on research and the development of novel products and techniques that will ultimately benefit the public.

Further, I believe that patents over ‘various man-made compositions of matter whose value derives from the information encoding capacity of DNA’ must simultaneously not restrict research nor hinder patients access to gene patents related to diagnostic testing. Thus, in my opinion, the use of compulsory licenses for public health reasons, exemptions from patent infringement for education and research purposes, and the non-

⁴⁹² No. 09 Civ. 4515 (S.D.N.Y., Mar. 29, 2010).

exclusive licensing of gene patents for fields of use such as genetic testing, may prove to be effective at mitigating some of the negative consequences that such patents may have.

In addition, a decision that DNA which has merely been isolated from the human body (without further alteration or manipulation) is unpatentable may have the benefit of increasing innovation. This is owing to the fact that such DNA will be available for the biotechnology industry to access and use in the development of novel products. In this way the application of genetics to medicine can also be advanced for the benefit of all.

To conclude, in order to settle the controversy surrounding gene patents, the balancing of both the pros and cons of gene patents, as outlined above, is required. However, there are many ways in which this can be done, and the challenge for the future will be to find the best balance possible. That being said, I hope that the Federal Circuit will take the opportunity presented in *Association for Molecular Pathology, et al v. United States Patent and Trademark Office, et al*⁴⁹³ to clarify the legal status of isolated human DNA in the United States, and that the Court does not dismiss the matter on procedural grounds.

⁴⁹³ No. 2010-1406.

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