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Not fully harmonized: Differences in biotechnology patenting between Europe and the United States

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ABSTRACT

There has been a trend of worldwide harmonization of patent laws. Due to the continuing harmonization, examination of patents in Europe and the United States are very similar. However, examination standards between the two patent offices can differ. Thus, applicants should be aware of the differences between examination standards since both standards need to be addressed in the single patent application. This paper will review some of these differences, both major and subtle, that should be considered when drafting a biotech patent for filing in both the U.S. and Europe.

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INTRODUCTION

To streamline the demand for worldwide intellectual property protection, the patent cooperation treaty (PCT) was ratified in 1970 to allow an applicant to file one patent application that can be examined in any country party to the treaty. Further, the European Patent Office (EPO) was established as a regional patent office to have one centralized examination. Then a granted patent can be validated in any European country that participates. Thus, an applicant can file one PCT patent application and have it examined by both the U.S. Patent & Trademark Office (USPTO) and the EPO.

There has been a trend of worldwide harmonization of patent laws. An example is the passage of the America Invents Act of 2011 which converts the U.S. from a first to invent system to a first inventor to file system. Due to the continuing harmonization, examination of patents in Europe and the United States are very similar. Terms may be different (e.g., novelty vs. anticipation), but the basis of evaluation is the same or nearly the same. However, differences do exist between the two patent offices. Thus, applicants should be aware of the differences between examination standards since both standards need to be addressed in the single patent application.

Advances in biotechnology have pushed the limits of patent law. The law evolves to continue to address what is and what is not patentable subject matter. Recent court decisions in both the U.S. and Europe have helped define patentable subject matter. This paper will review issues of patentable subject matter in the U.S. and Europe. There are differences between the U.S. and Europe, both major and subtle. These differences need to be considered when drafting and filing a biotech patent application for examination in both the U.S. and Europe.

METHODS OF MEDICAL TREATMENT

In the U.S., methods of medical treatment and diagnostic assays had been broadly patentable until the recent U.S. Supreme Court decision in *Mayo v. Prometheus*.[1] Up until this recent decision, methods of treatment were considered *per se* patentable since the body is transformed from

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1 *Mayo Collaborative Services v. Prometheus Labs, Inc.*, No. 10-1150 (U.S. March 20, 2012)

one state to a different state.[2] For example, a method of immunizing a subject with a vaccine immunologically transforms the subject. Diagnostic methods would also typically contain a transformative step. Including language such as "determining" denoted an active step that often conferred patentability.[3] However, the *Mayo* decision requires a claim to add a significant step beyond the natural correlation.[4] Most likely, true method of treatment claims will remain patentable.[5] However, diagnostic methods that rely on an administration with a determination of a biological relationship will be much more difficult to patent. These claims cannot simply rely on the newly discovered biological relationship to confer patentability. It will take time to discover and work out the full ramifications of the *Mayo* decision in regards to examination by the patent office and in litigation.

In Europe, methods of treatment and diagnostic methods practiced on the human or animal body are specifically excluded from patentability. In general, excluded treatments are restricted to those suitable for maintaining and/or restoring health or for preventing disease in humans or animals. Cosmetic surgery is not considered curative and is therefore not excluded from patentability in Europe. Methods not practiced on the human or animal body are not excluded from patentability in Europe.

However, this prohibition does not apply to products, such as substances or compositions, used in such methods. A special type of claim known as a "medical use claim" can lead to a granted patent for the use of a product in medicine in Europe. Such claims fall into two types, known as first or second medical use claims.

Usually first medical use claims are written in the form "Substance X for use in therapy" or "Substance X for use as a medicine". Such types of claim can be directed to a novel product, or a known product for which there is no known therapeutic use. If the product was known to have any other therapeutic use then a first medical use claim would not be considered novel.

Second medical use claims are allowed in the case where a therapeutic use of a known substance is disclosed. Previously a claim format called "Swiss-type" second medical use claims, such as "Use of substance X for the manufacture of a medicament for the treatment of Y", was commonly used. However, second medical use claims are now written in the form "Substance X for use in the treatment of disease Y".

If a new and inventive medical use for substance X is found, a further medical use claim in the form of "Substance X for use on the treatment of disease Z" may also be allowable.

In general, U.S. style method claims can be converted to the European style medical use claims, and vice versa, for prosecution. Although explicit support for both forms is not necessary in an application, it is advisable to provide the language for both forms of claims if planning to prosecute in both Europe and the U.S.

EMBRYONIC STEM CELLS

Recent research and development of embryonic stem cells have created bioethical dilemmas. These dilemmas have created consequences in many countries for whether embryonic stem cells are patentable subject matter.

In Europe, the patentability of stem cells has been in question due to a rule stating that European patents shall not be granted in respect of biotechnological inventions which concern "uses of human embryos for industrial or commercial purposes". An initial decision by the EPO Enlarged Board of Appeal (G2/06) held that a patent cannot be granted for an invention which necessarily involves the use and destruction of human embryos. This ruling effectively precluded patent protection for old patent applications where the only technology available for the generation of stem cells involved destruction of an early stage embryo.

It appeared after the Enlarged Board decision that inventions arising from publically available human embryonic stem cell lines might be patentable. However, the Court of Justice of the European Union (CJEU) recently ruled (C-34/10 Brüstle v. Greenpeace) that an invention is excluded from patentability where the subject matter of the patent application requires the prior destruction of human embryos or their use as a base material, whatever stage at which that takes place. This appears to exclude from patentability any inventions which use a stem cell line if at any point in the creation of that cell line involved the destruction of an embryo, even if it occurred in the distant past.

In order to obtain a patent relating to stem cells in Europe, in an ideal world one would include an example showing that the invention may be worked using methods that do not involve the destruction of an embryo, such as induced pluripotent stem (iPS) cell technology. Alternatively, it may be enough to provide argumentation or evidence that, at the time of filing the patent application, such technologies were available and could be used in connection with the invention.

However in the U.S., isolated embryonic stem cells themselves and methods utilizing the stem cells, includ-

2 *Prometheus Labs., Inc. v. Mayo Collaborative Services*, 628 F.3d 1347 (Fed. Cir. 2010).

3 *Id.*; See, also, *Ass'n. Molecular Pathology v. U.S. Patent & Trademark Office*, 653 F.3d 1329 (Fed. Cir. 2011).

4 *Mayo v. Prometheus*, slip op. at 3.

5 *Id.* at 18.

ing treatment methods, are patentable subject matter. Any controversy surrounding embryonic stem cells in the U.S. are in regards to funding research by federal and/or state governments. There has not been any controversy regarding the patentability of such cells.

AGRICULTURAL BIOTECHNOLOGY

The agricultural biotechnology industry derives from the development of newly developed plant breeds, and seeds thereof. The new plant breeds can be transgenic, inbred, or hybrid plants. Again, the issue of patenting a life form presents bioethical issues in some countries.

In 2001, the U.S. Supreme Court in *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc*. held that newly developed plant breeds fall within the scope of 35 U.S.C. § 101.[6] Protection of plants is not limited to plant patents under the Plant Patent Act of 1930 or the Plant Variety Protection Act. Thus, plants and seeds are eligible for a utility patent (and its 20 year term) under U.S. patent law.

In Europe, "plant or animal varieties or essentially biological processes for the production of plants or animals" are excluded from patentability. The EPO Enlarged Board of Appeal decision G1/98 attempted to clarify the distinction between a "plant" and a "plant variety". Plants which are not plant varieties have been patentable before the EPO. However, claims related to a plant variety *per se* are considered excluded from patentability. Whereas, claims to plants *per se* that may cover plant varieties but where the plant varieties are not specifically claimed are patentable in Europe.

Recent Enlarged Board of Appeal decisions (G2/07 and G1/08) have concluded that a non-microbiological process for the production of plants which contains the steps of sexually crossing the whole genomes of plants and subsequently selecting plants is in principle excluded from patentability as being 'essentially biological'. In order for a process of plant production to be patentable an additional step of a technical nature is necessary, which step *"by itself introduces a trait into the genome or modifies a trait in the genome of the plant produced"* so that the introduction or modification of that trait is not the result of mixing of the genes of the plant chosen for sexual crossing. Claims in Europe for inventions directed to methods of producing plants should be formulated to exclude any sexual crossing and selection steps. For example a method claim may be drafted as a method of identifying a plant with elevated levels of a compound of interest which method comprises steps of a technical nature only.

Whether plants obtained solely by an excluded method will be patentable in Europe is still under review. Technical Boards of Appeal (such as in T1854/07) previously confirmed that such "product-by-process" claims remain a product claim (i.e., a claim to the plant *per se*) irrespective of the process it refers to. Therefore a claim to a plant is not excluded from patentability even if the method by which the plant is produced is excluded. However, very recently the Technical Board of Appeal in T1242/06 (the Board that originally referred questions in G1/08 to the Enlarged Board of Appeal) has attempted to refer further questions to the Enlarged Board of Appeal to seek clarification on whether plant claims are patentable when they are solely produced by an excluded method. The questions that have been referred at the time of writing have not been finalized, and the Enlarged Board of Appeal has not yet formally accepted the referral. However, any decision from such a referral may change the landscape for plant patenting in Europe.

For the avoidance of doubt, plants produced by recombinant gene technology are not part of this review and assuming they are novel, inventive, industrially applicable and enabled will continue to be patentable in Europe.

POLYNUCLEOTIDES

Isolated DNA has been patentable subject matter for thirty years. Now isolated DNA is the subject of a high profile lawsuit in the U.S--*The Association for Molecular Pathology v. Myriad Genetics, Inc.* This case is destined to ultimately be decided by the U.S. Supreme Court. Currently, the U.S. Supreme Court remanded the case back to the U.S. Court of Appeals for the Federal Circuit in view of the Supreme Court's *Mayo v. Prometheus* decision.[7] Oral arguments are scheduled for July 20, 2012.

In the U.S., the term "isolated" differentiates claimed polynucleotides from those polynucleotides found in nature (e.g., chromatin). Unless the Supreme Court overturns 30 years of patent policy and implicit approval from Congress, isolated DNA is patentable subject matter. In Europe, the term "isolated" is not necessary, and DNA is patentable subject matter.

Additionally, DNA polynucleotide fragments are also patentable subject matter in both the U.S. and Europe. In the U.S., patentable subject matter has a utility requirement. Any invention must have a "substantial and specific utility."[8] This requirement can be difficult for some polynucleotide fragments. If the fragment has the same function as the complete polynucleotide, then it would meet the utility requirement. Without a known function, a fragment can be difficult to patent. For exam-

6 122 S. Ct. 593 (2001).

7 *Ass'n Molecular Pathology v. Myriad Genetics*, No. 11-725 (U.S. March 26, 2012).

8 *Brenner v. Manson*, 383 U.S. 519 (1966)

ple, expressed tag sequences (ESTs) were found to lack the substantial and specific utility requirement in *In re Fisher*.[9] Although ESTs have a function in genomic mapping, the court found that the five claimed ESTs did not have a utility unique from the >32,000 ESTs disclosed in the application. Thus, polynucleotide fragments are patentable but the utility of such fragments must be described.

CONCLUSION

Although the trend United States and Europe have been harmonizing their patent laws, differences in patentable subject matter exist. When drafting an application for prosecution in both the U.S. and Europe, knowledge of these differences allow one to draft support in a single application that meets the standards for both the USPTO and EPO.

9 421 F.3d 1365 (Fed. Cir. 2005).