

Dentistry and US/European Patents

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ABSTRACT

Around the world, systems of publication and patenting help ease the tension, but successful navigation of these systems requires a combination of awareness and strategic planning. It is not a simple task for the scientist to strike a balance between publication and protection of discoveries. Patent legislation gives legal protection to new inventions once they have been patented by their owners. A patent is a temporary monopoly granted to the owner in return for disclosure of the invention to the public. This article has provided some insight of US/European patents with regards to dentistry, and will promote a better understanding of the scope and impact of a patent disclosure, and the issued claims in the field of dentistry and medicine as far as US/European patent systems are concerned.

Keywords: Dentistry, Patents, US/European patents, Invention.

INTRODUCTION

It is what every inventor dreams of to happen upon a discovery that transforms the human experience for the betterment of human kind. Around the world, systems of publication and patenting help ease the tension, but successful navigation of these systems requires a combination of awareness and strategic planning. It is not a simple task for the scientist to strike a balance between publication and protection of discoveries. But, the scientific recognition that comes through publication is essential to career development and garnering the resources that enable the advancement of fundamental research.

Patent legislation gives legal protection to new inventions once they have been patented by their owners. A patent is a temporary monopoly granted to the owner in return for disclosure of the invention to the public. Both society and the inventor benefit from the patent system. The inventor benefits by being able to exclude others from exploiting the invention for 20 years, and the public benefits because when the patent expires, the invention is freely available for others to use.

Patenting of methods of medical and dental treatment of human beings is, however, a complicated issue as it is not only based on patent law but also on medical and dental law. Law of medicine has its origins in the Hippocratic oath, and the goal is the preservation of human life. Since, the goal of patent law is to encourage innovation by rewarding inventors, it is quite distinct from the goal of medical law.

Thus, there is a public policy concern that in order to ensure the best possible health treatment, physicians must always be free in their choice of treatment. Since a patent may restrict this freedom, it has been argued that methods of medical/dental treatment should be excluded from patent protection.

Approximately 80 countries around the globe prohibit methods of medical treatment from being granted patent

protection. The list includes all European countries and countries in Asia, Africa, North America, South America and Central America. Patent protection is, however, available in other countries. In the United States, for example, methods of medical treatment have been considered patentable since 1954, when the case *Ex parte Scherer*¹ overruled *Ex parte Brinkerhoff* 24.² Similarly, in Australia, patents have been available for this type of subject matter since 1972, following the High Court decision in *Joos V, The Commissioner of Patents*.³

In 2005, there were 740 worldwide dental patents issued with over 13,000 pages of claims, drawings and diagrams. These patents were issued by the United States Patent and Trademark Office, The European Patent Office and The World Intellectual Property Organization.⁴ These patents were mostly related to goods/commodities used in dental fraternity rather than the services provided.

How to make patent drawings is an essential question for inventors who want to complete a crucial step in the patenting process themselves, creating formal patent drawings that comply with the strict rules of the US Patent and Trademark Office.⁵ Patent drafters charge \$75 to \$100 per sheet to prepare drawings and complete the formalities which can be done by the inventors themselves. Thus, they can save hundreds or even thousands of dollars. As one gains experience working with the patent system, he/she can quickly learn to use the system most effectively.

This article will provide an overview of patents related to dentistry and medicine at United States Patent and Trademark Office and The European Patent Office.

BRIEF HISTORY OF PATENTS

The very first monopolies appeared about 500 BC, according to Phylarchus, who was quoted in the third century AD by Athenaeus in the *Banquet of the Learned* and the first letters of

patent were granted in 1440 to John of Shiedame, who introduced a method of manufacturing salt on a scale never before attempted in England. While originally designed to encourage the setting up of new industries, the monopoly system began to be abused by the Crown, in particularly by Elizabeth I. It led to section six of the Statute of Monopolies in 1623, which declared all monopolies void except those that are manners of manufacture, but only so far as they are 'not contrary to the law or mischievous to the state, by raising prices of commodities at home, or hurt of trade, or generally inconvenient'. Section six was destined to become the foundation of the patent law not only in England but also throughout the world. The requirement that there be a 'manner of manufacture' in the Statute of Monopolies has been described as 'the touchstone of patentability' and still is in force today in Australia, New Zealand and Israel.

The American system reflects a beginning in 1614, when a statute was passed in Massachusetts.⁶

GRANTING PATENTS TO MEDICAL/DENTAL INVENTIONS

Medical equipment or a medicine may be granted a patent as an 'invention of a product' in itself, and a process of manufacturing it may be considered as an 'invention of a process'. On the other hand, methods for treatment of the human body by surgery or therapy and diagnostic methods practiced on humans cannot be granted a patent. Specifically, methods for treatment of the human body by surgery or therapy and diagnostic methods practiced on humans are excluded from the scope of granting patent on the understanding that it cannot be an invention that is capable of industrial application. The basis for this judgment includes the fact that there is no strong need to provide incentives under the patent system because such inventions are made at universities and large hospitals. Furthermore, a political reason is that research and development competition is not suitable in medical research, and a humanistic reason is that it would be inappropriate to require approval of the patent holder when urgent treatment is necessary. Another possible reason is that as medical research is conducted on humans, it cannot ultimately be conducted without the cooperation of the patients, and thus requires a high level of ethical awareness on the part of the researchers. For example, during examinations in the late 1960s to early 1970s, the possibility of industrial application was denied for inventions that required humans and human body parts, not only in medical activity but also such in actions as permanent waves in the hair, methods for surgery, therapy and diagnosis, with the argument that inventions that require human bodies as a component do not fall in the category of inventions in Article 29,¹ the main paragraph of the patent law, because those inventions have no possibility of industrial application.⁷ In the late 1970s and early 1980s, this clause was amended as, "among inventions that require human bodies as a component, inventions pertaining to diagnostic and therapeutic methods, etc. have no patentability because they have no capability of

industrial application as provided in Article 29 of the patent law". Thus, the aforesaid permanent wave and similar methods could be granted a patent. When examination standards were amended in 1993, the phrase 'require human bodies as a component' was deleted, and the provision was amended to 'methods for treatment of the human body by surgery or therapy and diagnostic methods practiced on humans' are 'not inventions capable of industrial application'. The current examination standard after amendment in 2000 provides the same definition.

The examination standard stipulates that in addition to the methods for treatment of the human body by surgery or therapy and diagnostic methods practiced on humans, among the methods to process parts extracted from a human body, the "method to process parts extracted from a human body with the assumption that the extracted part is to be returned to the same person for therapy" falls under the 'methods for treatment of the human body by surgery or therapy and diagnostic methods practiced on humans' and so cannot be granted a patent.⁴ In compliance with this provision, artificial dialysis, for example, falls under the category of "methods for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human" and is not eligible for patent rights, and the culture of skin cells and cell processing methods are also not eligible for patents, if the cultured or processed skin or cells are to be returned to the same person (in the case of autograft). As a result, patents may be granted for the same method if it is heterograft but not if it is autograft. Although the phrase "methods for treatment of the human body by surgery or therapy and diagnostic methods practiced on humans" denotes several similar types of action, which includes not only medical activity but also culture of skin cells for autograft transplant, we shall refer to them as "methods related to medical activity" for convenience.

PATENT RIGHTS FOR INVENTIONS RELATED TO DENTAL METHODS

Patentability of dental treatment is one of the questions that are generally asked about. This could be better explained by one of the illustrations given below:

The IP High Court

Case H19 (Gyoke) No. 10369 decided June 24, 2008.

Facts

The plaintiff, Shade Analyzing Technologies Inc. (US) filed a PCT application (PCT/US99/22857) which entered into the Japanese National Phase as Application No. 2000-579144, addressing "Interactive Dental Restorative Network". The application was rejected on January 21, 2005 and the plaintiff (applicant) filed an appeal against the decision of rejection with the Board of Appeals (Appeal No. 2005-7446). In the appeal, the plaintiff tried to amend the claims on May 26, 2005, but the Board of Appeals did not accept the amendments for failing to satisfy the requirements of amendment. Thus, the rejection made

final. The plaintiff appealed the decision to the Tokyo Appellate Court (currently called “the IP High Court”). The issues in the appeal were: (1) Whether the rejection of the claim amendments was appropriate; and (2) whether the claimed invention satisfies the eligibility of an invention prescribed in Art. 29(1), main paragraph. As to issue (1), the IP High Court affirmed the rejection of the claim amendments. However, as to issue (2), the court negated the Board Decision on the ground that the claimed invention satisfies the statutory eligibility of an invention.

Board Decision

The Board of Appeals states as follows: (1) The claim amendment is disapproved because it fails to satisfy any of the statutory requirements which provide that a substantive amendment shall be limited to (1) cancellation of claim(s), (2) restriction of claim(s), (3) correction of error(s) and (4) clarification of descriptive ambiguity; and (2) The claimed invention is not eligible for a patent, because it does not meet the statutory definition of an invention under Art. 2(1) of the Patent Law.

IP High Court Decision

(1) The Court held that the Board of Appeals had wrongly underestimated the meanings of a means for identifying and a means for designing. The present invention is to provide a technical means for a dentist to rely on when he or she identifies and design a dental restoration need and a treatment plan therefore. (2) It is understood that the invention provides a method and system for assisting a dentist and a dental technician to make preliminary and final treatment plans to meet the identified dental restoration need not by a mental act but by aid of a computer which comprises a network server having a database; a communications network; one or more computers located at a dental office; and a device capable of image display and processing.

In conclusion, the claimed invention can be recognized to be eligible for a patent. Thus, the Court dismisses the Board Decision.

The decision by the Tokyo High Court stated that there are no grounds to interpret the terms “medical activity” and “industries” in a narrow sense, and that although the plaintiff’s plea that medical activity may have industrial applicability in the interpretation of the current patent law is worth considering, there is a significant difference that cannot be ignored between medicines/medical equipment and medical activity when deciding whether they have patentability or not. Furthermore, a patent system that might force physicians to fear possible infringement of patents would be inappropriate, considering the fundamental nature of medical activity. Therefore, as long as there are no special provisions in the patent law, there is no choice but to decide that inventions in medical activity do not

fall under the scope of inventions capable of industrial application.

US/EUROPEAN PATENT GRANTING FOR INVENTIONS IN MEDICAL/DENTAL SERVICES

European Patent Convention (EPC)

Europe has clearly stipulated that inventions of methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body shall not be regarded as industrially applicable [Article 52(4)]. This stipulation was amended to be compatible with TRIPS in 2000, and it is now clearly stated that the methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body fall under the category of unpatentable inventions, whether they are industrially applicable or not, and the conclusion has not been changed [Article 53(c)]. However, it has not yet been enforced and the article before the amendment is still applied. However, among the various inventions on methods related to medical activity, culture of skin and cell processing are not interpreted as medical activity and patents are granted.

United Kingdom (UK)

A requirement for a patent is that an invention be industrially applicable [Article 1(1) (c)] in the UK, but it is clearly stated that a method of treatment of the human or animal body by surgery or therapy or of diagnosis practiced on the human or animal body is not industrially applicable [Article 4(2)].⁸

Germany

A requirement for a patent is that an invention be industrially applicable [Article 1(1)] in Germany, and it is clearly stated that methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body are not industrially applicable [Article 5(2)].⁹

France

A requirement for a patent is that the invention is that an invention be industrially applicable (Article 611–10. 1), and it is clearly stated that methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body are not industrially applicable (Article 611–16).⁹

United States of America

There is no provision regarding unpatentable inventions in the Patent Act (35 USC). Therefore, applications for patents for inventions of methods related to medical activity are judged by whether they meet the patent requirements, such as novelty, and patents may be granted unless grounds for objections are

found. However, in 1993, a physician who held the patent right on a surgical method for cataracts filed a law suit against another physician employing a similar method and the hospital in which the surgery was conducted.¹⁰ The Patent Act was therefore amended in 1996 such that in principle patent rights do not apply to medical activity by physicians, etc. [35 USC 287 (c) (1)]. For biotechnology patents, however, an injunction or damage compensation demand rights may be exercised in case of infringement of patent rights, even if they fall under medical activity [35 USC 287 (c) (2) (A)].

CONCLUSION

The patent examination process is designed to apply a body of laws to achieve two primary purposes. One is to ensure that inventors receive the exclusivity rights of patent protection, they are entitled to for the inventions they make or discover. The other is that the public is compensated for the cost of that protection by receiving a full and complete disclosure of the advance made by the inventor.

The patenting of medical/dental treatment advances knowledge by encouraging the development of new medicines and surgical methods, which in turn increases the public good and, in particular, the quality of the community's health care. The arguable negative effects of such patenting do not outweigh the benefits derived from it, as the patenting of such treatment does not decrease the availability of health care and does not

create new obstacles different from those already existing in the medical world.

Furthermore, in some instances, the availability of patent protection may be the only way to attract investment in costly clinical trials. In this situation, the availability of a patent becomes an incentive to invest in public health research, and, therefore a condition for the very existence of the method itself.

I hope that this article has provided some insight of US/European patents with regards to dentistry, and will promote a better understanding of the scope and impact of a patent disclosure and the issued claims in the field of dentistry and medicine as far as US/European patent systems are concerned.

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