HSML

Guidance for Issues Involving Relationship with Outside Entities and 35 U.S.C. §101

www.hsml.com
mail@hsml.com

Douglas P. Mueller
Hamre, Schumann, Mueller & Larson, P.C.
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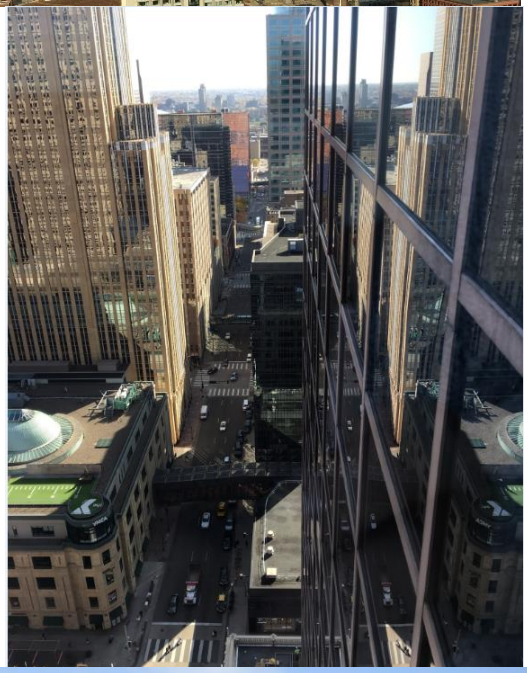

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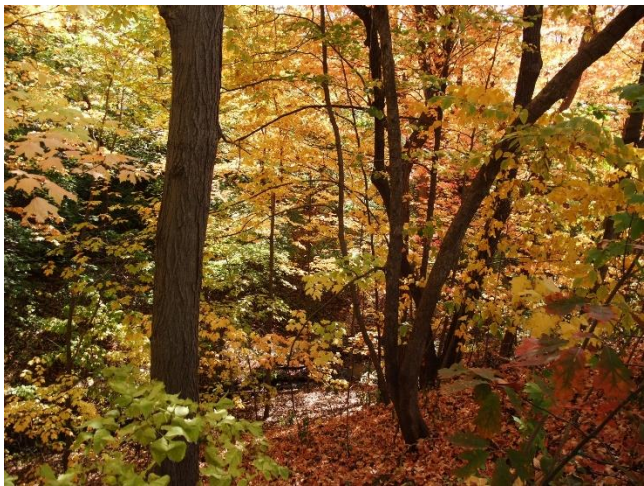

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Full range of IP services: Patents, Trademarks, and Copyrights

Prosecution (711 US & 111 foreign patents obtained in 2019)

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IP Transactions:

- Agreements
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HSML Technical Expertise

- Chemistry including material science
- Biochemistry
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- Electrical
- Computer science

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Issues Involving Relationships With Outside Entities

Introduction

- It is becoming increasingly common for a company to collaborate with outside entities in developing new products, and to acquire technology from other companies to complement the company's product lines. Such collaboration can provide significant benefits but also can affect the intellectual property rights in the U.S. A number of issues should be given careful consideration when entering into such relationships.
- Two that will be considered in this presentation are:

  (i) **inventorship** issues; and

  (ii) **double patenting** issues.

Inventorship

- In ***Dana-Farber Cancer Institute, Inc. v. Ono Pharmaceutical Co., Ltd, et al.,*** **964 F.3d 1365 (Fed. Cir. 2020),** the Federal Circuit affirmed the District Court's decision, finding that Dana-Farber employees were joint inventors on the patent.

Background:

- Dr. Freeman is employed by Dana-Farber, which filed suit for correction of the inventorship of the patents pursuant to 35 U.S.C 256(b). Dr. Wood's employer previously transferred all of its potential rights in the patents to Ono and did not actively participate in the lawsuit.
- 6 patents at issue are directed to methods of treating cancer.
- Claim 1 of U.S 8,728,474 (" '474") requires "A method for treatment of a tumor in a patient, comprising administering to the patient a pharmaceutically effective amount of an anti-PD-1 monoclonal antibody."
- The invention flows from the discovery of an inhibitory receptor on T cells, identified as PD-1, and the binding of one of the ligands of PD-1, identified as PD-L1 and PD-L2, to PD-1 on the T cell suppresses the T cell from attacking the cell expressing the ligand. Expression of the PD-1 ligands by healthy cells thus generally shields the healthy cells from attack by the T cells, but some tumor cells also express the ligands and are shielded from the T cells.
- The claims of the patents require the use of antibodies that target either the PD-1 receptor or the ligand, thereby blocking the receptor-ligand interaction that otherwise would suppress the T cells' immune response against the tumor cells.

Inventorship

Dana-Farber Cancer Institute, Inc. v. Ono Pharmaceutical Co., Ltd, et al – continued

Timeline

- In the early 1990s, Dr. Honjo of Kyoto University discovered the PD-1 receptor and isolated its DNA sequence.
- Dr. Honjo subsequently worked with his colleague Dr. Minato, another named inventor on the patents, in conducting mouse studies showing the PD-1 receptor's involvement in immune-system inhibition. Dr. Honjo believed that PD-1 was in the same family of proteins as the inhibitory receptor CTLA-4. This work was published in August 1999.
- In mid-1998, Dr. Honjo asked Dr. Iwai, another named inventor on the patents, to conduct tests on mice in which PD-1 is not expressed and human tumor cell lines. Dr. Iwai found binding of the PD-1 protein but did not identify the molecule that was binding to the receptor.
- In September 1998, Dr. Honjo met with Ono Pharmaceuticals and Genetics Institute, who connected him to Dr. Wood.
- Dr. Wood believed that the PD-1 receptor could be useful for antibody therapy, and Dr. Honjo provided him with PD-1 reagents and a confidential draft of the article that was being prepared based on the work of Dr. Honjo and Dr. Minato.
- In July 1998, Dr. Freeman was studying B7 ligands and ran a search for sequence of 208 amino acids forming part of the binding portion of the B7-1 molecule. Two human ovarian tumors were included in the results, and Dr. Freeman further investigates the sequence and identified it as 292.
- Dr. Honjo, Dr. Wood, and Dr. Freeman began sharing information directly. Dr. Wood and Dr. Freeman began to work together to determine whether PD-1 binds to 292 (subsequently renamed as PD-L1), which Dr. Wood confirmed to Dr. Honjo.

Inventorship

Dana-Farber Cancer Institute, Inc. v. Ono Pharmaceutical Co., Ltd, et al – continued

Timeline - continued

- Dr. Honjo sent Dr. Wood anti-PD-1 antibodies for further experimentation, and Dr. Freeman contacted Dr. Honjo about research collaboration on the PD-1/PD-L1 pathway.
- In October 1999, Dr. Honjo, Dr. Wood, and Dr. Freeman met in person to discuss their results. Dr. Wood disclosed that PD-1 and CTLA-4 had similar structures, and that PD-L1 antibodies inhibited the PD-1/PD-L1 interaction. Dr. Freeman disclosed that 292 was from a human ovarian tumor, and that PD-L1 shares 20% of its amino acid sequence with B7-1 and B7-2, but does not bind to CD28 or CTLA-4. Dr. Honjo disclosed the unpublished work with mice showing that PD-1 inhibits the immune response. After the meeting, the three exchanged reagents.
- Dr. Honjo conducted in vitro experiments confirming the inhibition of the immune response.
- Dr. Freeman and Dr. Wood filed a provisional patent application disclosing modulation of the immune response based on the PD-1/PD-L1 pathway, but not naming Dr. Honjo as an inventor.
- Dr. Freeman then identified another B7-type molecule that shares 38% of the protein structure of PD-L1, which he identified as PD-L2, and conducted experiments on it. Dr. Freeman also requested that testing be carried out to determine whether PD-1 was expressed by various normal and tumor tissues, which found high PD-L1 expression in a variety of tumors.
- Dr. Freeman advised Dr. Honjo about PD-L1 and its sequence. Dr. Honjo, Dr. Freeman, and Dr. Wood then began working on a journal article based on the PD-L1 discoveries, which ultimately was published in October 2000. In a final revision of the draft, Dr. Freeman added a sentence indicating that PD-L1 was expressed in cancer cells and that some tumors may use PD-L1 to inhibit antitumor immune responses. All three continued their work on antibody candidates, and were discussing development of anti-PD-L1 antibodies and their possible use in treating cancer.

Inventorship

Dana-Farber Cancer Institute, Inc. v. Ono Pharmaceutical Co., Ltd, et al – continued

Timeline - continued

- In June of 2000, Dr. Honjo learned about the provisional application filed by Drs. Freeman and Wood and questioned his omission as an inventor.
- In October 2000, Dr. Iwai generated in vivo data suggesting that mouse melanoma tumors expressing PD-L1 grow faster than tumors not expressing PD-L1. (Ono contended that this established the conception date for the claimed inventions.)
- Dr. Honjo's attorneys requested Genetics Institute, i.e., the assignee of the Freeman-Wood applications, to voluntarily add Dr. Honjo as an inventor to those applications. Genetics Institutes refused and advised that Dr. Honjo should file his own application to pursue the inventorship issue in the USPTO.
- Dr. Honjo filed his first application in Japan in 2002, based on the results of experiments by him., Drs. Minato and Iwai. A PCT application then was filed, and all of the patents at issue in this case claim priority to the original Japanese filing through the PCT application.

ISSUE: Were the contributions to the patent by Drs. Freeman and Wood sufficient for them to qualify as joint inventors?

The District Court held "YES":

- Work by Drs. Freeman and Wood contributes significantly to the **conception of the treatment of tumors with anti-PD-1 antibody**. Therefore, they qualify as inventors for the six patents of the patent family.

Inventorship

Dana-Farber Cancer Institute, Inc. v. Ono Pharmaceutical Co., Ltd, et al – continued

Federal Circuit Decision:

ISSUE: Were the contributions to conception of the patented invention by Drs. Freeman and Wood sufficient for them to be qualified as joint inventors?

The Federal Circuit held "YES":

- The district court conducted a thorough review of the factual issues, and the Federal Circuit found no basis to reject the district court's factual findings about the activities of the various parties.
- 35 U.S.C. §116(a) allows for the possibility of joint inventors of an invention. 35 U.S.C. §116(a) specifically recognizes that joint invention can be present even if:
  - (1) the joint inventors did not physically work together or at the same time,
  - (2) each did not make the same type or amount of contribution, or
  - (3) each did not make a contribution to the subject matter of every claim of the patent.

Inventorship

Dana-Farber Cancer Institute, Inc. v. Ono Pharmaceutical Co., Ltd, et al – continued

The Federal Circuit - continued

- **Ono argued:**

  (i) the work of Drs. Freeman and Wood was too far removed from the claimed subject matter;

  (ii) the possible applicability of PD-1 methods of treating cancer was not conceived until the discussions with Drs. Honjo and Minato following Dr. Iwai's work in October 2000;

  (iii) this work was independent from the work of Drs. Freeman and Wood; and

  (iv) the earlier work was too speculative to qualify as a contribution to conception.

- **The court disagreed:**

Inventorship

Dana-Farber Cancer Institute, Inc. v. Ono Pharmaceutical Co., Ltd, et al – continued

The Federal Circuit - continued

- Joint invention is the product of collaboration between two or more persons working together to solve a particular problem.
- The amount or quality of the contribution is not subject to a specific minimum.
- Conception of an invention is complete when an idea is definite and permanent enough that one of skill in the art can understand the invention.
- It is not necessary for each inventor to know that the invention will in fact work for its intended purposes for conception to be complete, which is part of the reduction to practice, not conception.
  - Dr. Iwai's in vivo work was significant, but the verification provided by the in vivo work is not a requirement for a conception to be sufficiently definite and permanent.
  - Dr. Iwai's in vivo work was conducted after Dr. Freeman showed expression of PD-L1 in tumors and Dr. Honjo showed the PD-L1 expression causes tumor growth.
- **Ono argued:** the grant of its patents over the disclosure of the Freeman-Wood provisional application shows the lack of significance of the work by Dr. Freeman and Dr. Wood to the claimed methods.
- **The court disagreed**:

Inventorship

Dana-Farber Cancer Institute, Inc. v. Ono Pharmaceutical Co., Ltd, et al – continued

The Federal Circuit - continued

- The disclosure of the provisional application may not fully reflect the scope of the relevant contributions made by Dr. Freeman and Dr. Wood to the conception of the invention of the patents in the lawsuit.
- The unobviousness of the claimed invention over the disclosure of the provisional application does not determine whether the collaborative work of Dr. Freeman and Dr. Wood with Dr. Honjo resulted in the conception of the claimed invention.
- Research made public before the date of conception of a total invention can qualify as a significant contribution to the conception of the invention.
- Collaborative joint invention is not disqualified by one of the joint inventor's disclosure of less than the total invention. An early partial publication is potentially harmful to the patentability of the total invention, but does not negate joint inventorship of the total invention.
- Claim 1 of the '474 patent refers to anti-PD-1 antibodies, not PD-L1 antibodies, but PD-1 is a receptor. Without knowledge of a ligand that binds to PD-1 to suppress the immune response, there is no basis to use anti-PD-1 antibodies to treat tumors. Both parties' expert testimony was consistent with this point.

Inventorship

Dana-Farber Cancer Institute, Inc. v. Ono Pharmaceutical Co., Ltd, et al – continued

The Federal Circuit - continued

- Therefore, the court agreed with the district court that

  (i) the work of Dr. Freeman in connecting the 292 sequences to PD-L1 and conducting experiments revealing that several types of tumors express PD-L1; and

  (ii) Dr. Wood's contributions in confirming that the PD-1/PD-L1 interaction was inhibitory, were significant aspects of the conception of the claimed methods of treatment.

- Therefore, **Drs. Freeman and Wood qualified as inventors**.

Inventorship

Dana-Farber Cancer Institute, Inc. v. Ono Pharmaceutical Co., Ltd, et al – continued

- This case shows that the standard for qualifying as a joint inventor in the U.S. is relatively low. All that is necessary is for **the alleged inventor to make some contribution to the conception of at least one feature of the claims**, even if it is only a dependent claim.
- There are no strict requirements about the timing and nature of the collaborative work, or the quantity or quality of the contribution.
- Addition of an inventor originally omitted from a patent can be done **at any time**, even some years after the patent is issued as in this case.
- It is important to keep close track of any **relationships between company researchers and outside sources**. An outside party collaborating with company researchers in some aspect of the development of the invention easily can contribute to the conception of some feature that ultimately is found in one of the claims.
- If there is no agreement in place concerning ownership of any inventive activity arising from the outside party's work, the outside party may be obliged to assign their rights in the invention to their employer, who then would become a co-owner of the application or patent involved.

Inventorship

Dana-Farber Cancer Institute, Inc. v. Ono Pharmaceutical Co., Ltd, et al – continued

- The general rule under U.S. law is that a **co-owner of a patent is free to grant licenses and otherwise exploit the patent right without permission from the other owners or sharing the proceeds with the other owners**. Therefore, the addition of an outside party inventor to a patent could severely damage the ability of the company to enforce or license the patent.
- Similar considerations apply to technology that a company is acquiring from an outside source. Particularly in the case of **an academic outside source**, care should be taken to understand the history of the development technology, including identifying all persons who were involved and funding that was received.
- The U.S. adoption of the first inventor to file system in the America Invents Act largely put an end to new interference proceedings. This may have led some companies to relax the standards for keeping records of the activity by their inventors. However, **the detailed records of the inventors' activities** still can be useful for establishing what information the company researchers possessed at a particular time, and for establishing a timeline of activities, as was done in this case. This information might be used to establish that the company researchers already were in possession of certain information that allegedly was contributed by the outside party.

Inventorship

Dana-Farber Cancer Institute, Inc. v. Ono Pharmaceutical Co., Ltd, et al – continued

- The inventorship for a U.S. patent application is **determined by the content of the claims**.
  - A party who contributed to a feature found in the specification but not the claims does not qualify as an inventor. Therefore, when an outside party has made only a limited contribution to the invention, that party can be omitted as an inventor as long as the limited contribution is not claimed.
  - It of course is important to maintain **good records** so that the exclusion from inventorship can be justified in a later litigation.
  - It is also important to take steps to ensure that **the limited contribution is not added to the claims** during prosecution of the U.S. application.
- The patents at issue in this case were directed to broad and general aspects of a new technology.
  - This contributed to finding the work of Drs. Freeman and Wood on underlying basic principles relevant to the conception of the claimed invention.
  - Had the claims been in the nature of a narrow improvement to an existing technology, work like that of Drs. Freeman and Wood might not have been relevant.

Double Patenting

- In ***Immunex Corporation, et al v. Sandoz Inc., et al.*****, 964 F.3d 1049 (Fed. Cir. 2020),** the Federal Circuit's affirmed the District Court's decision, finding that the '182 and '522 patents did not improperly extend the Immunex patents.

Background:

- Sandoz sought approval for a biosimilar version of the Immunex etanercept product (Enbrel®), which is used for reducing the severity of rheumatoid arthritis. Immunex is the exclusive licensee under two Hoffmann–La Roche (Roche) patents relevant to etanercept, and Roche and Immunex sued Sandoz for patent infringement.

Timeline

- Etanercept is a fusion protein made by combining a portion of a human tumor necrosis factor (TNF) receptor protein with a portion of immunoglobulin G1 (IgG1). In 1990, Roche and Immunex were separately researching TNF for potential therapeutic benefits.
- Roche filed EP Application No. 90116707.2 ("the EP'707 Application") on August 31, 1990 and U.S. Application No. 07/580,013 ("the '013 Application") on September 10, 1990.
- The '013 Application was abandoned in favor of a continuation, U.S. Application No. 08/965,640 ("the '640 Application") that was filed on July 21, 1993. The '640 Application was subjected to a restriction requirement.
- Roche filed two divisional applications on May 19, 1995, prior to the change of the U.S. patent statute to a patent term of twenty years from filing.

Double Patenting

Immunex Corporation, et al v. Sandoz Inc., et al. – continued

Timeline - continued

- The patents in suit were issued from these two divisional applications as U.S. 8,063,182 ("the '182 Patent"; to the etanercept composition of matter) and U.S. 8,163,522 ("the '522 Patent"; to methods for making etanercept), on November 22, 2011 and April 24, 2012, respectively, with a patent term of 17 years from the issue date.
- Immunex worked independently from Roche and obtained approval of its Enbrel® product in 1998.
- About a year later, Immunex and Roche entered into an agreement granting Immunex a license under the EP'707 Application, the '013 Application, and all patents that issued from those applications in exchange for royalty payments based on Enbrel® sales.
- Amgen acquired Immunex in 2002.
- In 2004, Amgen, Wyeth, Immunex, and Roche entered into an agreement directed to the patent family of the EP'707 Application and the '013 Application. The purpose of the agreement was to eliminate the continuing obligations to pay royalties to Roche under the earlier Roche-Immunex agreement. Under the new agreement, Immunex acquired a paid-up and irrevocable exclusive license to the U.S. patent family including the two patents in suit. Wyeth obtained an assignment of the EP patents in the patent family.
- Sandoz sought approval to market Erelzi, a biosimilar version of Immunex's biologic drug, Enbrel®, asserting claims that the '182 Patent and the '522 Patent were invalid.

2004 Agreement

- Under the 2004 agreement, Immunex was given the sole right to grant sublicenses to make, have made, use, sell, offer for sale, and import products covered by the patent family in the United States.

Double Patenting

Immunex Corporation, et al v. Sandoz Inc., et al. – continued

2004 Agreement - continued

- Immunex also was granted the sole authority to prosecute U.S. applications in the patent family, and thus Immunex was responsible for the prosecution of the patents resulting in the '182 Patent and the '522 Patent.
- Immunex also was given the first right to address potential infringement of U.S. patents in the patent family, at its sole expense.
- Immunex further was entitled to retain all damages awarded in an infringement suit. Roche was required to cooperate in any such lawsuit, including participating as a party if required.
- Immunex further had the right to request an assignment from Roche for the patents, upon payment of $50,000.
- It can be seen that Immunex acquired substantial control over the existing and future U.S. patents in the patent family.
- The agreement required Roche to cooperate with Immunex in prosecution and enforcement of the U.S. patent family members.
- Roche retained the right to practice the patented inventions for internal, non-clinical research.
- Roche further retained a secondary right, but not obligation, to address infringement of the U.S. patents that Immunex declined to address. In such a case, Roche would proceed at its own expense and with sole control of any such litigation, and would retain all damages awarded.

Double Patenting

Immunex Corporation, et al v. Sandoz Inc., et al. – continued

ISSUE before District Court:

Does common ownership exist in the patents at issue under the "all substantive rights" test for the doctrine of obviousness-type double patenting?

The District Court held "NO":

- **Sandoz argued:**
  - (i) The '182 Patent and the '522 Patent were invalid for obviousness-type double patenting over several Immunex patents directed to Enbrel®.
  - (ii) Even though Roche is nominally the assignee of the patents, the rights transferred in the 2004 Agreement effectively gave Immunex the ownership rights in the patents.
  - (iii) Thus, the '182 Patent and the '522 Patent, with their patent terms of 17 years from the issue dates in 2011 and 2012, impermissibly extended the effective life of patents that Immunex obtained during the development of Enbrel®, which expired as early as 2014.

The district court rejected the Sandoz double patenting argument.

- The "effective ownership" test argued by Sandoz is not the correct standard.
- Even if the "effective ownership" test were correct, the 2004 Agreement did not result in effective ownership of the patents residing in Immunex.
- Therefore, the '182 Patent and the '522 Patent do not improperly extend the Immunex patents.

Double Patenting

Immunex Corporation, et al v. Sandoz Inc., et al. – continued

ISSUE before Federal Circuit:

Does common ownership exist in Roche's patents at issue under the "all substantive rights" test when determining the presence of obviousness-type double patenting?

The Federal Circuit held "NO":

- **The Federal Circuit affirmed** the district court decision.
- Addressing the issue of whether Roche's status as the current assignee precluded obviousness-type double patenting, the court held:
  - The "**effective ownership**" standard is a suitable one for this issue, and the nominal status of assignee does not fully determine the issue.
  - The court **agreed** with Sandoz, a **party that has acquired all substantial rights in a patent**, including the **right to control prosecution**, can be considered as an **owner**.
  - The court **disagreed** with Immunex that common ownership double patenting arises only when the relevant inventions were owned by the same party at the time of the invention.

Double Patenting

Immunex Corporation, et al v. Sandoz Inc., et al. – continued

The Federal Circuit - continued

- The Federal Circuit previously applied obviousness-type double patenting when a party merged with the original assignee of the double patenting reference (*Geneva Pharmaceutical, Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373 (Fed. Cir. 2003)).
- The court found Sandoz' standard to be more consistent with both of the main principles of obviousness-type double patenting, i.e., **preventing unjustified extension** of patent term and **preventing harassment from multiple suits**.

Double Patenting

Immunex Corporation, et al v. Sandoz Inc., et al. – continued

- The Federal Circuit agreed with the district court that the 2004 Agreement does not transfer all substantial rights in the patents to Immunex and does not effectively assign the patents to Immunex.
- Despite the significant rights granted to Immunex, the 2004 Agreement as a whole does not transfer all the substantial rights to Immunex and leaves some substantial rights with Roche.
  - Particularly, Roche's **secondary right to sue** is established under the 2004 Agreement, i.e., the right to **enforce the patents** in situations where Immunex declined enforcement, and removal of Immunex' ability to remedy infringement, e.g. by granting a license, after Roche's right to sue has been established.
  - Roche's **right to veto any assignment** of Immunex' right to another party is a substantial right retained by Roche.
  - Immunex' option in the 2004 Agreement to formally convert the license into an assignment by paying Roche $50,000 does not transfer all substantial rights in the patents to Immunex when viewed in light of the other provisions of the 2004 Agreement.

Double Patenting

Immunex Corporation, et al v. Sandoz Inc., et al. – continued

- Therefore, the court found that the district court reached the correct result and affirmed the district court decision.

- The dissenting judge argued strenuously that when the 2004 Agreement is considered as a whole, it can be seen that any rights that appear to be retained by Roche in fact are illusory.
- The dissent further pointed out that the prosecution of the patent applications resulting in the ‘182 Patent and the ‘522 Patent while owned by Roche was not focused on etanercept, but that Immunex changed the direction of the applications to focus on etanercept after the 2004 Agreement, and therefore would have found the ‘182 Patent and the ‘522 Patent invalid for obviousness-type double patenting.

Takeaways:

- The case shows the **care that should be taken when acquiring rights from an outside source**, particularly when the objective is to **extend the effective patent protection** for an existing product.
  - The 2004 Agreement in this case clearly seems to have been drafted with the possibility of the common-ownership extension of the length of the patent term in mind.

Double Patenting

Immunex Corporation, et al v. Sandoz Inc., et al. – continued

- There are some situations that can lead to double-patenting issues, for example:
  - when inventors from two companies **jointly develop a product**, but the companies will be applying the product **in different fields of use**, so that each company pursues its own patent application that **names the inventors from both companies**. If the respective applications are owned solely by the different companies, the US Examiner may use the first-issued patent as an obviousness-type double patenting reference against the other company's application due to the overlapping inventorship. A **terminal disclaimer would not be available** to overcome the double patenting issue **due to the different assignees between the two cases**, and the claimed subject matter of the one case must be distinguished from the claimed subject matter of the other on the technical merits; and
  - when **a company is active in a particular field, and requests an outside party to assist in certain research matters**. In some cases, an outside party such as a well-known consultant or professor requires that he/she be given **co-assignee status**. This can create situations where the application assigned jointly to the company and the outside party is cited as an obviousness double patenting reference against an application owned solely by the company. Again, in this situation **the rejection cannot be overcome by a terminal disclaimer due to the difference in ownership** between the two cases, and the claimed subject matter of the one case must be distinguished from the claimed subject matter of the other on the technical merits.

35 U.S.C. § 101

- In ***CardioNet, LLC v. Infobionic, Inc.,*** **955 F.3d 1358 (Fed. Cir. 2020),** the Federal Circuit reversed the district court's granting motion to dismiss the complaint on the grounds that the claims at issue are clearly patent-ineligible under 35 U.S.C. § 101.

FACTS: The patent at issue concerned cardiac monitoring systems and techniques, particularly systems and techniques capable of distinguishing atrial fibrillation and atrial flutter from other types of cardiac arrhythmia. CardioNet sued Infobionic for infringement. The district court granted Infobionic's motion to dismiss the complaint on the grounds that the claims at issue are clearly patent-ineligible under 35 U.S.C. § 101. The Federal Circuit reversed the district court.

Technical Background:

- Various categories of abnormal electrical activity of the heart have been recognized, including atrial fibrillation, atrial flutter, normal rhythm irregularity, irregularity from various heart blocks, premature ventricular contractions, and ventricular tachycardia. Such abnormalities are associated with different physiological conditions that have varying degrees of significance for a patient's health.
- Atrial fibrillation and atrial flutter result from deterioration of the synchronization between the atria and ventricles of the heart. Atrial fibrillation and atrial flutter episodes extending for no more than 20 heartbeats are generally not considered significant. Longer episodes may indicate serious conditions such as stroke, congestive heart failure, and cardiomyopathy.
- Ventricular tachycardia involves a rapid succession of ventricular contractions generally caused by an abnormal focus of electrical activity in a ventricle.

35 U.S.C. § 101

CardioNet, LLC v. Infobionic, Inc. – continued

CardioNet patent at issue:

- The specification explains that atrial fibrillation and atrial flutter typically are not present when irregular ventricular beats are present.
- The CardioNet invention as disclosed thus analyzes time periods between ventricular contractions in detecting atrial fibrillation and atrial flutter.
- The specification explains that the CardioNet invention is able to **more accurately distinguish atrial fibrillation and flutter from other arrhythmias**.
- In testing, the CardioNet invention recognized atrial fibrillation and atrial flutter with small numbers of false positives and false negatives.
- It also is able to carry out **real-time monitoring of atrial fibrillation and atrial flutter**, which is important for quickly identifying the type of medical care that may be necessary.

35 U.S.C. § 101

CardioNet, LLC v. Infobionic, Inc. – continued

CLAIMS:

Claim 1 of the CardioNet patent is directed to a device that comprises:

a beat detector identifying beat-to-beat timing of cardiac activity;
a ventricular beat detector;
variability determination logic determining variability in the beat-to-beat timing;
relevance determination logic identifying a relevance of the variability in beat-to-beat timing to at least one of atrial fibrillation and atrial flutter; and
an event generator generating an event when relevant variability is identified.

The event generation also is required to take into account variability in the beat-to-beat timing caused by ventricular beats identified by the ventricular beat detector. Thus, the device of claim 1 uses the information of the ventricular beats in assessing atrial fibrillation or atrial flutter.

Dependent claim 2 specifies that the relevance determination logic treats beat-to-beat variability caused by ventricular beats as not indicating atrial fibrillation or atrial flutter.

Dependent claim 3 specifies that the variability determination logic compares R-waves in three successive QRS wave complexes in determining the variability in beat-to-beat timing.

Dependent claim 10 specifies that the relevance determination logic uses a non-linear function of a beat-to-beat interval.

Dependent claim 11 specifies that the beat detector comprises a QRS detector.

Claim 12 requires that the device further comprises two or more body surface electrodes for detecting cardiac activity.

35 U.S.C. § 101

CardioNet, LLC v. Infobionic, Inc. – continued

ISSUE: Are the claims patent-eligible subject matter if the claims focus on a specific improvement in the technology and do not merely set forth a desired result or effect and generic recitation of equipment that achieves the desired result or effect, and the specification sets forth specific technical improvements?

The Federal Circuit held "YES".

The Two-Step Alice/Mayo test for evaluating the patent-eligibility of the claims

- **Step 1** of the test evaluates whether the claims are "**directed to**" one of the patent-ineligible categories, i.e. laws of nature, natural phenomena, and abstract ideas.
- If the answer under Step 1 is affirmative, **Step 2** evaluates whether the claims recite features, individually or in combination, establishing that the claims amount to **significantly more** than the patent-ineligible concept itself.

35 U.S.C. § 101

CardioNet, LLC v. Infobionic, Inc. – continued

The district court held:

- In its Step 1 analysis, the claims are directed to the abstract idea that atrial fibrillation and atrial flutter can be identified by focusing on the variability of the irregular heartbeat and taking ventricular beats into account.
- The district court rejected the argument that the invention represents an improvement in the function of cardiac monitoring devices and provides more accurate detection of atrial fibrillation and atrial flutter, and concluded that there was no improvement in a particular computerized technology.
- The district court granted the Infobionic's motion to dismiss CardioNet's complaint.

35 U.S.C. § 101

CardioNet, LLC v. Infobionic, Inc. – continued

The Federal Circuit reversed:

- All inventions at some level embody or use a law of nature, natural phenomenon, or abstract idea, and applications thereof to a new and useful end are patent-eligible.
  - The CardioNet invention is not ineligible simply because it might involve an abstract idea.
- Step 1 of the Alice/Mayo test requires that the claims be considered in their entirety to ascertain whether **their character as a whole** is directed to patent-ineligible subject matter. ***McRO, Inc. v. Bandai Namco, Inc.*, 837 F.3d 1299 (Fed. Cir. 2016)**
  - The court characterized the Step 1 inquiry as looking at the focus of the claims and the character of the claims as a whole, with the written description being relevant in understanding the nature of the invention being claimed.
- In analyzing the CardioNet claims under Step 1 of the Alice/Mayo test, the court considered **whether the claims focus on a specific means or method that improves the relevant technology**.
  - This is contrasted with claims focused on a result or effect, accompanied by generic recitations of equipment or processes.

35 U.S.C. § 101

CardioNet, LLC v. Infobionic, Inc. – continued

The Federal Circuit - continued

- Claim 1, when considered as a whole and in light of the specification, is directed to an **improved cardiac monitoring device** rather than an abstract idea.
  - The claims focus on a **specific improvement in cardiac-monitoring technology** and do not merely set forth a desired result or effect and generic recitation of equipment that achieves the desired result or effect.
- The court cited the CardioNet specification as supporting this conclusion, noting that **the specification set forth several specific technical improvements** achieved by evaluating atrial fibrillation or atrial flutter based on the identification of variability in beat-to-beat timing caused by ventricular beats.
  - These improvements include improved accuracy in identifying atrial fibrillation or atrial flutter, and the ability to identify sustained episodes of atrial fibrillation or atrial flutter that have increased clinical significance.
- Several of the dependent claims recited features that further specified the physical features and operation of the device of claim 1.
- The CardioNet claims are similar to the patent-eligible "technological improvement" inventions in ***Visual Memory LLC v. NVIDIA Corp.*, 867 F.3d 1253 (Fed. Cir. 2017)** and ***McRO, Inc. v. Bandai Namco, Inc.*, 837 F.3d 1299 (Fed. Cir. 2016)**.

35 U.S.C. § 101

CardioNet, LLC v. Infobionic, Inc. – continued

The Federal Circuit - continued

- The district court erroneously assumed that the claims were simply automating known techniques and simply using computers as tools for carrying out basic human steps.
  - The record did not establish that the techniques carried out with the claimed device were well-known and practiced by doctors previously.
- It is erroneous to consider the CardioNet claims as simply collecting, analyzing, and displaying information.
- The claim language and the specification are sufficient to resolve the Step 1 analysis in favor of CardioNet, and therefore remanding the case to the district court for consideration of further extrinsic evidence is not necessary.
- Defendant does not establish something to have been a common practice in the art (which would tend to support patent-ineligibility) simply by finding it in a prior art reference.
- Patent-eligibility under 35 U.S.C. § 101 is only a threshold issue, and analysis of 35 U.S.C. § 102, § 103, and § 112 issues will be considered for patent-eligible inventions under 35 U.S.C. § 101.

The Federal Circuit - continued

- Judge Dyk issued dissenting in part opinion:

  Agreeing with the outcome and main points of the analysis in the majority opinion, but arguing that the majority opinion includes comments about the extent of use of extrinsic evidence for Step 1 of the Alice/Mayo test that go beyond the issues raised by the parties and creates possible confusion with previous cases.

35 U.S.C. § 101

CardioNet, LLC v. Infobionic, Inc. – continued

- The recitation of five different components for the atrial fibrillation or atrial flutter detection in claim 1 of the CardioNet patent may have contributed to the finding of patent-eligibility in this case, but most of the components are defined at a general level referring to the function that each is carrying out.
- However, there were some points with more detail in claim 1, particularly the requirement of attention to the beat-to-beat variability in the ventricular beats.
  - The relevance of this point of detail to the technological advantages provided by the invention was confirmed in the patent specification.
  - This was sufficient for the judges in this case to accept the claimed invention as a patent-eligible improvement to medical devices rather than a patent-ineligible use of computer components to implement an abstract idea.

35 U.S.C. § 101

CardioNet, LLC v. Infobionic, Inc. – continued

- The judges in this case accepted the application of previous cases that established a relatively liberal application of the patent-eligibility issues.
  - This can be seen in the reliance on the teachings of the specification along with the language of all of the claims in determining the **nature of the "invention"**, rather than focusing more heavily on the specific language of the claims.
  - It also can be seen in the discussion of how **potential "patentability" issues** such as sufficiency of the disclosure under 35 U.S.C. § 112 and the relevance of prior art under 35 U.S.C. § 102 and § 103 have at most a **minor role** in the consideration of the 35 U.S.C. § 101 "patent-eligibility" issue.
  - This is somewhat surprising in that two of the judges on this panel who often have tended toward the stricter analysis of the 35 U.S.C. § 101 issues, requiring a relatively high level of detail in the claims to satisfy 35 U.S.C. § 101 patent-eligibility, took such a relatively liberal position.

35 U.S.C. § 101

CardioNet, LLC v. Infobionic, Inc. – continued

- Responding to a complaint of patent infringement with a motion to dismiss for failure to state a claim, due to invalidity under 35 U.S.C. § 101, has been used more frequently by Defendants, because it potentially terminates the litigation at a very early stage.
  - However, in deciding the motion, all of the facts set forth in the complaint must be accepted as true, and Plaintiff is entitled to have all reasonable inferences decided in its favor.
  - This decreases the likelihood of success for Defendant, and the willingness of the court in this case to decide the Alice/Mayo Step 1 issue as a matter of law without remanding the issue to the district court for further fact finding shows potential downsides to the motion to dismiss strategy.

35 U.S.C. § 101

- In ***Electronic Communication Technologies, LLC v. Shopperschoice.com, LLC*, 958 F.3d 1178 (Fed Cir. 2020)**, the Federal Circuit affirmed the district court's decision of patent ineligible subject matter.

FACTS: The patent at issue involved an automated notification system, particularly systems for providing advance notification of the pickup or delivery of a mobile item with increased security through use of authentication information and control of communications. Electronic Communication Technologies (ECT) sued Shopperschoice for infringement. The district court granted the Shopperschoice motion to dismiss the complaint.

ISSUE: Are the claims patent-eligible when the claims reflect a fundamental commercial practice and the mere gathering, storing, and transmitting of information with high level of generality?

The District Court held "NO", and the Federal Circuit affirmed:

35 U.S.C. § 101

Electronic Communication Technologies, LLC v. Shopperschoice.com, LLC – continued

The Claim at Issue:

- Claim 11 of the ECT patent is the sole claim at issue.
- This claim is directed to an automated notification system that comprises one or more transceivers, one or more memories, one or more processors, and a computer code stored in the memory and executed by the processor.
- The claim defines the code as comprising six categories of code, which include:
  - code that enables a first party with a personal communication device to input authentication information for use in subsequent notification communication concerning pickup or delivery of a mobile item;
  - code that causes storage of the authentication information;
  - code that monitors location or travel information in connection with the mobile item;
  - code that initiates the notification communication with the personal communication device in advance of the arrival of the mobile item, based at least in part on the location or travel information;
  - code that, during the notification communication, provides the authentication information to the personal communication device to indicate that the notification communication was initiated by an authorized source; and
  - code that, during the notification communication, enables the first party to select whether or not to engage in a communication session with a second party having access to particulars of the pickup or delivery.

35 U.S.C. § 101

Electronic Communication Technologies, LLC v. Shopperschoice.com, LLC – continued

The District Court held:

- The district court followed the two-step Alice/Mayo test in evaluating the patent-eligibility of the ECT claim in response to the Shopperschoice motion to dismiss the complaint.
- In the step 1 analysis, the claim is directed to the abstract idea of providing an advance notification of the pickup or delivery of a mobile item.
- Business practices of notifying customers of the status of the delivery of goods have been used for at least decades.
- Claim 11 recites generic computer components. Thus, the claim provides nothing significantly more than the abstract idea itself and fails to satisfy the step 2 of the Alice/Mayo test.

35 U.S.C. § 101

Electronic Communication Technologies, LLC v. Shopperschoice.com, LLC – continued

The Federal Circuit held:

- The Federal Circuit agreed with the district court that claim 11 is directed to the abstract idea of advance notification of the pickup or delivery of a mobile item.
- Claim 11 merely refers to conventional computer components in addition to the computer program code.
- Two of the six program functions required by claim 11, i.e., "monitoring the location of the mobile item" and "notifying a party in advance of its arrival", are merely part of the fundamental business practice of providing advance notification of delivery or pick up of an item. The other aspects recited for the computer program code are abstract in nature.
  - The specification explains that authentication information can be essentially any information recognizable by the party being contacted, and lists a wide variety of categories of information that might be useful.
  - Businesses typically provide customers with an identifying order number or the like, and maintain records of customer information, such as name, address, telephone, credit card number and the like, and use such information in communications with their customers.

35 U.S.C. § 101

Electronic Communication Technologies, LLC v. Shopperschoice.com, LLC – continued

The Federal Circuit – continued

Step 1 of the Alice/Mayo test – Satisfied (Abstract idea found)

- Claim 11's use of the authentication information also reflected **fundamental commercial practice** and also reflected the **mere gathering, storing and transmitting of information**.
- The court disregarded with ECT's argument that the invention of claim 11 is unique because it can minimize hacker's impacts when mimicking order confirmations and shipment notification e-mails.
  - The uniqueness of an invention, even if it might be considered groundbreaking, does not in itself provide eligibility under Step 1 of the Alice/Mayo test.
  - The alleged uniqueness of claim 11 in the features that increase security is itself merely an abstract aspect of the claim.
- The weight should not be given to the USPTO's decision to grant the application on the first Office Action, and ECT's subsequent request for the USPTO to reconfirm patent-eligibility of the claim.
  - Such details of prosecution do not shield the granted patent from review of the patent-eligibility issue by the courts.

35 U.S.C. § 101

Electronic Communication Technologies, LLC v. Shopperschoice.com, LLC – continued

The Federal Circuit - continued

Step 2 of the Alice/Mayo test - not satisfied

- Claim 11 is set forth in functional terms at a **high level of generality** that add nothing of significance to the abstract idea itself.
- Claim 11 **merely implements the abstract idea on a computer**.
- The court rejected ECT's arguments about claim 11 being longer and better-enabled relative to other claims that were considered patent-eligible in ***Amdocs (Israel) Ltd. v. Openet Telecom, Inc*, 841 F.3d 1288 (Fed. Cir. 2016)**.
  - ❑ Claim length and enablement by themselves are not relevant to patent-eligibility.

Conclusion:

- Claim 11 did not satisfy the patent-eligibility requirements of 35 U.S.C 101.

35 U.S.C. § 101

Electronic Communication Technologies, LLC v. Shopperschoice.com, LLC – continued

- One judge participated in both this case and CardioNet.
- The level of generality of ECT's claim 11 is similar in many respects to that of CardioNet's claim 1.
- However, the CardioNet claim included a feature that was **relatively specific and tied to the particular advantages and improvements** over the existing technology achieved by the CardioNet invention. This helped the court conclude that the CardioNet invention represented a patent-eligible technological improvement.
- Broad and general characterizations of the ECT invention in the specification supported the abstract nature of the ECT invention.
- Therefore, it is useful, when possible, to draft the specification for inventions that are closely related to laws of nature, natural phenomena, or abstract ideas in a way that **highlights the improvements over conventional technology**, and to identify at least one feature relevant to the improvements that can be **expressed in a relatively specific form**.

35 U.S.C. § 101

Electronic Communication Technologies, LLC v. Shopperschoice.com, LLC – continued

- The ECT patent was examined during the early stages of the USPTO Subject Matter Eligibility Guidance.
- The characterization of ECT's arguments in the decision does not indicate whether the Guidance was argued specifically.
- However, at least this panel of the Federal Circuit seems to consider that the USPTO analysis of the 35 U.S.C. §101 issues should not impact the evaluation of those issues by the courts.
- Thus, while the Guidance is useful for addressing 35 U.S.C. §101 issues during prosecution, the standards applied by the courts also should be kept in mind in preparing and prosecuting applications.

Thank you!

If you have any questions, please contact us at:

dmueller@hsml.com (English) or
myoshida@hsml.com (English and Japanese)