A Comparative Look at Patent Subject Matter Eligibility Standards: China Versus the United States

Liaoteng Wang, Qiang Lin, Shanqiang Xiao, Xiaobin Zong, Xiaodong Li, Lulin Gao

"In a number of fields, such as e-commerce, China has arguably become one of the leading innovators in the world. Although the Chinese Patent Law has yet to be amended for the fourth time since it was first enacted in 1984, recent changes have been made to China's Guidelines for Patent Examination to accommodate the needs of fast-developing new technology."

Over 15 years ago, as a Ph.D./J.D. student, I learned that the U.S. Congress intended patent-eligible subject matter to broadly include "anything under the sun that is made by man" when enacting the 1952 Patent Act, and that two cases, *Diamond v. Chakrabarty*, 447 U.S. 303 (1980) and *Parke-Davis & Co. v. H.K. Mulford Co.*, 189 F. 95 (C.C.S.D.N.Y. 1911), had paved the way for the United States to become the world leader on biotechnology innovation.

Later, as a law firm associate (2005-2010), I happened to work on invalidity contentions based on prior art against U.S. Patent Number 6,355,623, the patent-in-suit in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. 66 (2012) which was held patent-ineligible by the U.S. Supreme Court in 2012, and studied U.S. Patent Number 6,258,540 covering the pioneering discovery made by Dr. Dennis Lo on prenatal diagnostic uses of cell-free fetal DNA at the Chinese University of Hong Kong and licensed to our then-client Sequenom, which was held patent-ineligible by the Federal Circuit in *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371 (Fed. Cir. 2015) based on *Mayo* in 2015.

Obviously, the sun is still the same sun, but much has happened to the patent subject matter eligibility standard in the U.S. since *Mayo*. On April 27, 2020, Judge Paul Michel and John Battaglia published an excellent article on IPWatchdog analyzing the U.S. Section 101 patent subject matter eligibility jurisprudence. In that article, Judge Michel and Battaglia reminded judges and practitioners to reference "the more-favorable foreign patent laws on the patent eligibility for diagnostic testing, business methods and software … in countries such as England, China, or the European Union … to inform such a judicially created ineligibility standard, as opposed to the U.S. Constitution or a federal statute." Here, we take a quick comparative look at the current patent subject matter eligibility standard in China.

Chinese Law on Patentable Subject Matter and Recent Amendments to Patent Examination Guidelines

The following three provisions of Chinese Patent Law, in relevant part, provide the statutory framework for what constitute patentable subject matter in China.

First, Article 2.2 of Chinese Patent Law provides, "Invention in the Patent Law refers to any new technical solution concerning a product, process, or improvement thereof."

Second, Article 5.1 of Chinese Patent Law provides, "No patent shall be granted for an invention that contravenes any law or social morality or that is detrimental to public interests."

This article originally appeared on IPWatchdog on June 12, 2020

Third, Article 25 of Chinese Patent Law provides:

> No patent rights shall be granted for any of the following: (1) Scientific discoveries; (2) Rules and methods for intellectual activities; (3) Methods for the diagnosis or for the treatment of disease; (4) Animal and plant varieties; (5) Substances obtained by means of nuclear transformation; and (6) Designs of two-dimensional printing goods, made of the pattern, the color, or the combination of the two, which serve mainly as indicators.
>
> The patent right may, in accordance with the provisions of this Patent Law, be granted for the production methods of the products specified in (4) above.

In short, similar to the U.S. Patent Law in 35 U.S.C. Section 101, Chinese Patent Law broadly defines patentable subject matter in its Article 2.2 as "any new technical solution … or improvement thereof." Unlike U.S. Patent Law, Chinese Patent Law mirrors TRIPS Article 27 by statutorily providing an *ordre public* or morality exclusion in its Article 5.1, and a number of specific exclusions in its Article 25.1, including not only scientific discoveries and rules and methods for intellectual activities, which are similar to the three judicially created exceptions in the United States (i.e., laws of nature, natural phenomena, and abstract ideas), but also methods for the diagnosis or for the treatment of disease.

Thus, looking at the Chinese patent statute alone, which was last amended in 2008, it's not clear Chinese Patent Law is more favorable than U.S. Patent Law on the patent eligibility for diagnostic, fintech, and software patents. In fact, one could argue it's less favorable given the express exclusions found in its patent statute, as opposed to the implied judicial exceptions under U.S. Patent Law.

This is not entirely unexpected, because, certainly in 2008, China was lagging behind the U.S. on innovation in various technology fields, and its domestic industry did not have as much invention to be protected by a robust patent system. Understandably, because China's patent system was perceived to be weaker than those in the more developed countries, many patent applicants chose not to file patent applications in China. For example, although Dr. Lo was awarded U.S. Patent Number 6,258,540 in 2001 for his pioneering discovery on non-invasive prenatal diagnosis, no counterpart patent application was filed in China for this '540 patent.

However, times have changed; the innovation level in China has been increasing. In a number of fields, such as e-commerce, with exemplary global enterprises like Alibaba and Tencent, China has arguably become one of the leading innovators in the world. Although the Chinese Patent Law has yet to be amended for the fourth time since it was first enacted in 1984, recent changes have been made to China's Guidelines for Patent Examination ("Guidelines") to accommodate the needs of the fast-developing new technology and the requests from domestic innovation entities: On September 23, 2019 and December 31, 2019, the China National Intellectual Property Administration ("CNIPA"), publicly announced certain changes to the Guidelines, which became effective on November 1, 2019 and February 1, 2020 (the "November 1, 2019 Amendment" and "February 1, 2020 Amendment", respectively). Next we look at these two

recent amendments, focusing on where patent subject matter eligibility may be impacted, and briefly discuss the patent eligibility of diagnostic and treatment methods in China.

November 1, 2019 Amendment to China's Guidelines for Patent Examination: Human Embryonic Stem Cells Are Now Patent-Eligible

The CNIPA began its public announcement on the November 1, 2019 Amendment as follows, "To serve the need of fast-developing new technology, respond to new requests from innovation entities on patent examination rules and methods, and improve patent examination quality and efficiency, CNIPA decides to amend the *Guidelines for Patent Examination*."

Regarding patent subject matter eligibility, the November 1, 2019 Amendment includes an important change on the patent-eligibility of certain human embryonic stem cells. Thus, in *Part II, Chapter 1, Section 3.1.2 Inventions-creations Contrary to Social Morality,* the following has been inserted into the Guidelines:

> However, if an invention is to separate or to obtain stem cell from a human embryo which is within 14 days of fertilization and has not gone through *in vivo* development, it should not be rejected on the basis of violation of social morality.

And in *Part II, Chapter 10, Section 9.1.1 Examination of Subject Matter According to Article 5,* the following deletions/insertions have been made to the Guidelines:

> ~~9.1.1.1 Human embryonic stem cells~~
> ~~No patent shall be granted for human embryonic stem cells or a preparation method thereof in accordance with the provision of Article 5.1.~~
>
> 9.1.1.~~2~~1 Human Body at any Stage of Formation or Development
>
> Human body at any stage of formation or development, including human's reproductive cells, fertilized eggs, embryos, and individuals, falls under the patent-ineligible inventions under Article 5.1. Human embryonic stem cells are not human bodies at any stage of formation or development.

Accordingly, stem cells obtained from a human embryo which is within 14 days of fertilization and has not gone through *in vivo* development and methods for preparing the same have become patent-eligible in China since November 1, 2019.

In contrast, the patentable subject matter in the United States has long covered stem cells, including human embryonic stem cells first patented by WARF (Wisconsin Alumni Research Foundation) in 1998. However, because of *Mayo* and *Association for Molecular Pathology v. Myriad Genetics, Inc.*, *569 U.S. 576 (2013),* what constitutes patentable subject matter with respect to stem cells in the United States has become less certain than before.

February 1, 2020 Amendment to China's Guidelines for Patent Examination: Clarifying Examination Rules for Patent Applications in Areas such as Artificial Intelligence, Internet+, Big Data and Block Chain

Similar to the November 1, 2019 Amendment, the February 1, 2020 Amendment was also made by the CNIPA to provide stronger intellectual property rights protection and respond to the needs of innovation entities on clarifying patent examination rules in new fields such as artificial intelligence.

Specifically, the February 1, 2020 Amendment added a new *Section 6* to the end of *Part II, Chapter 9, Some Provisions on Examination of Invention Applications Relating to Computer Programs*. The new *Section 6* is partially translated as follows:

> Section 6. Examination Rules for Invention Patent Applications Containing Algorithms or Business Rules and Methods
>
> Invention patent applications relating to artificial intelligence, "Internet +", big data and block chain usually contain intellectual activities such as algorithms or business rules and methods. This Section intends to address the particularity of examining these kinds of applications based on the Patent Law and its Implementing Regulations.
>
> 6.1 Examination Criteria
> Examination shall focus on the technical solution that is seeking protection, i.e., the technical solution described by the claims. During examination, the technical features, algorithm features, or business rules and methods features shall not be separated; all the contents of a claim shall be treated as a whole, while examining the technical solution, technical problem, and technical effects described by the claim.
>
> 6.1.1 Examination Based on Article 25.1(2)
> If a claim concerns an abstract algorithm or pure business rules and methods, and does not contain any technical feature, then it's a claim falling under Article 25.1(2) rules and methods for intellectual activities, and thus not patent-eligible. For example, a mathematical model building method that is based on an abstract algorithm and does not contain any technical feature will fall under Article 25.1(2) and not be patent-eligible. For another example, a method to provide rebate to user based on the user's spending, all features of which method concern business rules and methods relating to the rebate method, which contains no technical feature, is a method falling under Article 25.1(2) and not patent-eligible.
>
> If a claim contains technical feature, in addition to algorithm or business rules and methods feature, the claim viewed as a whole is not a rule and method for intellectual activities, and will not be excluded from patent eligibility based on Article 25.1(2).

> 6.1.2 Examination Based on Article 2.2
> If a claim as a whole does not fall under Article 25.1(2), then next it shall be examined to see if it is a technical solution under Article 2.2.
>
> While examining whether a claim containing algorithm feature or business rules and methods feature is a technical solution under Article 2.2, all features contained in the claim shall be considered as a whole. If the claim describes a technical means that utilizes laws of nature to address a technical problem, and obtains a technical effect that fits the laws of the nature, then the technical solution described by the claim is a technical solution under Article 2.2. For example, if a claim contains an algorithm comprising steps which are closely related to the technical problem to be solved, such as the data being processed by the algorithm are data that have definite technical meaning, and the execution of the algorithm can directly demonstrate the process of utilizing laws of nature to solve a technical problem and obtain a technical effect, then usually the technical solution described by the claim is a technical solution under Article 2.2.
> …

At present, it would seem a practical application in the fields of fintech and software-related inventions, with properly drafted claims, would be patent-eligible whether examined by the USPTO under its October 2019 Patent Eligibility Guidance Update, or examined by CNIPA under its February 1, 2020 Amendment to the Guidelines. Empirically, that has been our firm's experience as well: Although several years ago there was a period during which we encountered patent eligibility issues at CNIPA for some patent applications of our U.S. clients, it hasn't been an insurmountable issue since then.

Patent Eligibility for Diagnostic and Treatment Methods in China

According to Chinese Patent Law and the corresponding Guidelines for Patent Examination, diagnostic and treatment methods (including surgical methods) *per se*, whether practiced on humans or animals, are not eligible for patent protection in China. However, they can usually be redrafted into product claims and/or Swiss-type claims and enjoy patent protection. For example, the following claim is not patent-eligible in China:

> Method for treating disease X, comprising administering substance Y to a patient in need thereof.

But they are patent-eligible if redrafted in the following forms:

> Compound/composition Y for use in treatment of disease X, …… (Note: This is an acceptable product claim only if Compound Y is novel; otherwise, the next two claim forms should be used)
>
> or

Use of a compound/composition Y in the manufacture of a medicament for the treatment of disease X.

or

Use of a substance/component Y in the manufacture of an apparatus/kit for the diagnosis of disease X.

Evolving Standards

In summary, although China's patent eligibility standard may not have become more favorable than that in the United States yet, it's clear that it has become more favorable in the past decade, while the U.S. trend during the same period has generally been opposite, with the exception of what the USPTO has done under the leadership of Director Andrei Iancu since he took office in 2018. As world citizens, we sincerely hope human ingenuity, wherever it is under the sun, continues to flourish with inventions that improve the living standard of mankind, whether in the United States, China, Europe, or other regions, and that patent systems all over the world continue to be optimized to "promote the Progress of Science and useful Arts," as envisioned by the Founding Fathers in the U.S. Constitution in 1787.

Liaoteng Wang, Ph.D., J.D.

Liaoteng Wang is the Managing Partner in the Silicon Valley office of Beijing East IP, a top Chinese IP firm headquartered in Beijing. Prior to embarking on his legal career, Liaoteng was an accomplished scientist, having received his B.S. degree from Beijing's Tsinghua University and Ph.D. degree from UW-Madison under the guidance of Professors Judith Kimble and Marvin Wickens, and published his scientific discovery in the world-renowned journal Nature. After receiving his J.D. degree from UW-Madison, studying patent law under the guidance of Professor Pilar Ossorio in 2005, Liaoteng interned for Judge Rader at the U.S. Court of Appeals for the Federal Circuit, practiced law at the Silicon Valley offices of top international law firms, and worked as an in-house general counsel for an Intel-backed startup and a top global technology company, before joining forces with his friends and alums at Beijing East IP in 2016 to provide premier IP legal services to clients worldwide.

Qiang Lin, PRC Patent Attorney

Mr. Qiang Lin joined Beijing East IP in 2004 and currently heads the EECS Patent Team at Beijing East IP with over 15 years of experiences practicing intellectual property laws in China. Mr. Lin has represented many multinational companies in patent prosecution before CNIPA (formerly known as SIPO) and has been helping many Fortune 500 multinational corporations managing their patent portfolios in China. As an attorney-at-law, Mr. Lin also has rich experiences in litigation, including before the Patent Reexamination Board and courts at all levels. Mr. Lin's primary technical specialty covers optical engineering, communication, computer software, Internet, control and IC. Mr. Qiang Lin obtained a B.S. degree in Optical Engineering & Photoelectric Instrument from Zhejiang University, and a M.S. Degree in Computer Technology and Application from Institute of Software of Chinese Academy of Science. Mr. Lin also has three years of research experience at Shanghai Institute of Optics and Fine Mechanics, Chinese Academy of Sciences.

Shanqiang Xiao, PRC Patent Attorney

Mr. Shanqiang Xiao joined Beijing East IP in 2002 and currently heads the Chemical/Biotech Patent Team at Beijing East IP. Mr. Xiao has being helping many multinational companies in obtaining and protecting their IP rights in China. As a patent practitioner, Mr. Xiao has extensive experience in patent drafting, filing, prosecution and reexamination at SIPO/CNIPA. Mr. Xiao also has abundant experience in litigation matters, having litigated dozens of cases before the Patent Reexamination Board, Beijing First Intermediate Court/Beijing IP Court and Beijing High Court, for Fortune Global 500 companies. In addition to his practice in chemical/biotech/pharma areas, Mr. Xiao is also experienced in prosecution and protection of industrial designs, representing various clients in many design invalidity lawsuits. Mr. Shanqiang Xiao received his B.S. degree in Polymer Materials and M.S. degree in Organic Chemistry from Tsinghua University and his LLM degree from the John Marshall Law School.

Xiaobin Zong, Ph.D., PRC Patent Attorney

Dr. Xiaobin Zong joined Beijing East IP in 2005 and currently co-heads the EECS Patent Team at Beijing East IP, with 15 years of experience representing many renowned Fortune 500 U.S., European and Japanese corporations in over 1,000 patent applications, as well as patent invalidation, reexamination, and other patent prosecution matters. In addition to his vast experiences in patent prosecution matters, Dr. Zong also represented many multinational clients in asserting claims against Chinese and foreign infringers, as well as defending infringement claims asserted by adverse parties. Dr. Zong graduated from Tsinghua University, where he obtained a B.S. degree in Mechanical Engineering from the department of Precision Instruments and Mechanics, and a Ph.D. in Optical Engineering from the State Key Laboratory of Precision Measuring Technology and Instruments.

Xiaodong Li, Ph.D., PRC Patent Attorney

Dr. Xiaodong Li joined Beijing East IP in 2003 and is the General Manager of Beijing East IP responsible for the entire firm's operation. In addition to his management responsibilities, Dr. Li has also been a senior practicing patent attorney and China Supreme Court appointed attorney for patent litigation with abundant experiences in electrical and electronics engineering related patent matters, including prosecution, invalidation, reexamination, appeal, and litigation before the SIPO/CNIPA, and litigation matters before the People's Courts, and the China Supreme Court. Dr. Li is also experienced on corporate China IP portfolio management and counseling. Dr. Li graduated from Tsinghua University, where he obtained a B.S. degree and a Ph.D. degree, both in Engineering Physics.

Lulin Gao, Ph.D., PRC Patent Attorney

Dr. Lulin Gao is the Founder and Chairman of Beijing East IP, and one of the founders of the modern China intellectual property legal system. He earned his Ph.D. from the Institute of Geological Prospecting in Moscow. He worked the State Planning Commission for years. From 1987 to 1998, Dr. Gao worked as Commissioner of the Chinese Patent Office. In 1998, he was responsible for the establishment of the State Intellectual Property Office (SIPO) and served as its first commissioner. From 1998 to 2000, he was appointed a senior advisor to the World Intellectual Property Organization (WIPO) in Geneva. He currently serves as the Honorary President of the All-China Patent Agents Association, the Advisor of the International Intellectual Property Institute (IIPI), the Vice Chairman of the China Internet Society, the Senior Counsel of the China Internet Network Information Center (CNNIC), an arbitrator with the Asian Domain Name Dispute Resolution Center (ADNDRC) and the Domain Name Dispute of the China International Economic and Trade Arbitration Commission (CIETAC). Dr. Gao has also been an Adjunct Professor at Tsinghua University School of Law and the John Marshall School of Law.