醫事綜探

Intellectual Property and Policy Study on Black Box Medicine*

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摘 要

Precision medicine and personalized medicine has been a scientific and policy goal for years, and are a promising new concept for dealing with challenges of health and health systems. “Black box medicine” is a “NEW” type of personalized medicine, which contains the use of big data and sophisticated machine-learning techniques for health-care applications. In order to develop the black box medicine technology and algorithms it needs new approach of patent law intellectual property regulations, or the new technology seems hard to fit the old cogitations. Also how can the black box medicine approach the FDA medicine regulation system is as much important as the intellectual property challenges. This article will like to define the

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black box medicine technology, how can it approach under nowadays regulations. And finally give out some new insights of incentive policies, and intellectual property studies are crucial issues to technology innovations and patient care.

Introduction and Background

In President Obama's 2015 State of the Union Address, he announced the Precision Medicine Initiative, aimed at driving research and development of personalized medicine[1]. Precision medicine and personalized medicine has been a scientific and policy goal for years, and are a promising new concept for dealing with challenges of health and health systems. "Black box medicine" is a "NEW" type of personalized medicine, different from normal precision medicine and personalized medicine, which well-understood scientific links between patient characteristics and interventions are validated through clinical trials and then adopted into medical practice, black box medicine seeks to expand the reach of personalized medicine, and medical science in general, by leveraging implicit, complex relationships beyond the reach of current analytical science[2]. But unfortunately, current intellectual property law fails to provide adequate incentives for black box

1 The White House Office of the Press Secretary, Remarks by the President in State of the Union Address, Jan. 20, 2015, https://www.whitehouse.gov/the-press-office/2015/01/20/remarks-president-state-union-address-january-20-2015 (last visited May 20, 2018).

2 W. Nicholson Price II, *Black-Box Medicine*, 28 HARVARD JOURNAL OF LAW & TECHNOLOGY 419 (2015).

medicine innovations. As the US Supreme Court has restricted the patentable subject matter in the recent cases, including Prometheus, Myriad, and Alice cases, and what might still be patentable is limited by the statutory requirements of written description and enablement.

Black box medicine contains the use of big data and sophisticated machine-learning techniques for health-care applications, which promises to radically expand the reach of personalized medicine, with tremendous potential gains[3]. It lets scientists tap a wider range of biological relationships, and carries correspondingly broad benefits for health care. Matching patients to diseases and treatments more precisely could improve the quality of treatment, reduce the incidence of unnecessary side effects, and potentially save billions in wasted or inappropriate medical care[4]. And also suggests the possibility of new treatments, whether by suggesting new possibilities for drug exploration or by repurposing already-approved drugs for new or more targeted uses[5].

The big data needed to support transformative medical innovation should be considered as infrastructure for innovation and should be the focus of substantial public effort, black box medicine approach and its' regulation system, incentive policies, and intellectual property studies are crucial issues to technology innovations and patient care.

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3 *Id.*

4 PRESIDENT'S COUNCIL OF ADVISORS ON SCI. & TECH., PRIORITIES FOR PERSONALIZED MEDICINE 1 (2008).

5 Benjamin N. Roin, *Solving the Problem of New Uses*, 11 WASHINGTON JOURNAL OF LAW, TECHNOLOGY & ARTS 8-14 (2013).

Definition of the Black Box Medicine

Personalized medicine is treatments that are chosen and tailored based on the characteristics of the individual patient[6]. And "black box medicine" is a "NEW" type of personalized medicine, which seeks to expand the reach of personalized medicine, and medical science in general, by leveraging implicit, complex relationships beyond the reach of current analytical science[7].

Black box medicine uses the nontransparent algorithms to find patterns hidden in the wealth of individual healthcare data (that people or the scientists don't have to know about the hidden pattern that causes the diseases) being generated and collected. As the result, this kind of approach can lead to a faster, less expensive path to leverage many novel biological relationships, increasing possibilities for treatment decisions and developing new therapeutics.

Can Black Box Medicine Be Patented?

Is the first generation personalized medicine (like the gene detection, such as BRCA1 and BRCA2 generic testing) a patentable subject matter under the 35 U.S.C. § 101, "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."?

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6 *Supra* note 4.
7 *Supra* note 2.

US supreme court Association for *Molecular Pathology v. Myriad Genetics, Inc.* case[8] have given a decision in 2013. The primary issue is "Are DNA segments patent eligible under Section 101 of Title 35 United States Code?" And the court reasoning is patent protection strikes a delicate balance between creating incentives that lead to creation, invention, discovery and impeding the flow of information that might permit. The *Mayo* standard is used to determine whether Myriad's patents claim a new and useful composition of matter under § 101, or claim naturally occurring phenomena. The Court took into account the decision of *Diamond v. Chakrabarty,* is central to the patent eligibility inquiry whether such action was "new with markedly different characteristics" from any found in nature. Myriad did not create or alter either the genetic information en-coded in the BRCA1 and BRCA2 genes or the genetic structure of the DNA. It found an important and useful gene, but groundbreaking, innovative, or even brilliant discovery does not by itself satisfy the § 101 inquiry. But when it comes to the second issue "Is cDNA patent eligible under Section 101 of Title 35 United States Code?" The court found out that the cDNA does not present the same obstacles to patentability as naturally occurring, isolated DNA segments. Its creation results in an exonsonly molecule, which is not naturally occurring. Its order of the exons may be dictated by nature, but the lab technician unquestionably creates something new when introns are removed from a DNA sequence to make cDNA. So under the Myriad case the first generation personalized medicine cDNA development is a

8 Association for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576 (2013).