

TCM, Personalized Medicine and Intellectual Property Law

How to Overcome Obstacles Towards Protection of Old and New Personalized Medicines?

Danny Friedmann

Living creatures are so diverse, because of their different genetic backgrounds and lifestyles. Their states are also *in flux*; for most diseases it does not make sense to provide the same medical treatment to the whole population. Researchers have determined that fifty percent of a drug's power originates from its placebo effect.¹ The situation is worse when the drug has adverse effects for particular individuals due to their particular nature and nurture. Traditional Chinese Medicine (TCM), the holistic healing and health concept that passed from generation to generation for over thousands of years, recognizes that each patient is fundamentally unique and also changing. TCM, is the first medical system to apply a personalized approach to medicine. One important problem of TCM is that the efficacy of most of its medicines has not been proven. What some researchers are doing is to test TCM compounds' efficacy on populations. From a theoretical perspective, this remains problematic since TCM's claim is that it will have beneficial effects to the right particular person. In contrast, the fast pace of improvements in diagnostic technology in the U.S. that is more narrowly focused on symptoms is very promising for the future of modern personalized medicine.

It is China's government's highest goal to use TCM as complementary medicine to Western medicine for its population and to share TCM to the world. But it is unacceptable for China's government that companies from other countries, such as South Korea and Japan, source TCM ingredients and TCM formulas from China without channeling some of the revenues back to the country of origin. Protection of TCM via patent law is difficult, because it is impossible for TCM to prove novelty of the process or product or compound claims: many of the formulas were held secret for thousands of years, but are now published for a very long time. Another patent requirement is utility. Here, researchers could be further challenged to measure the efficacy, blurred by the concept that TCM is a comprehensive system of balance, harmony, moderation and prevention, one in which lifestyle changes are sometimes considered imperative.

Since it is so difficult to protect TCM with patents, the government is trying creative ways: to protect it via other intellectual property rights, such as trademark law and geographical indication-style registration systems. China is generously funding research on TCM and has promulgated the first Chinese Medicine Law in 2016.

After two Supreme Court cases; *Mayo Collaborative Services v Prometheus Laboratories, Inc.* in 2012 and *Association for Molecular Pathology v Myriad Genetics* in 2013, modern personalized medicine has become much more difficult to protect via patent law in the U.S. After

¹ Ted Kaptchuk and Franklin Miller, 'Placebo Effects in Medicine' NEW ENGLAND JOURNAL OF MEDICINE (Perspectives) 2015 373;1 8-9.

Mayo, Chao found out that 22.5% of actions against patent grants were rejected because of 35 U.S. Code § 101, compared with 5.5% in 2011.²

This paper will research what TCM can learn from this new case law and provides a call to action for further development of TCM in the context of the modern intellectual property law regime.

² Bernard Chao and Amy Mapes, An Early Look at Mayo's Impact on Personalized Medicine (April 4, 2016) U Denver Legal Studies Research Paper No. 16-11, available at: <https://ssrn.com/abstract=2758994>.