

Uses of Intellectual Assets in Commercializing Applications of Mass Spectrometry

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Bringing improvements in assessing conditions using Mass Spectrometry (MS) requires substantial investment in research, development of devices and methods for diagnostic and therapeutic interventions. Investments are unlikely to be made unless returns on those investments can be realized. Returns are made possible through licensing of patented inventions, trade secrets, and other intellectual assets (IP).

Trade secrets protect technical know-how and other commercially sensitive information. Trade secrets can be protected through a “hub and spokes” strategy, where only one or a few individuals know the entire process, with different components being developed by associates within the organization. Trade secrets are also protected through use of “Non-Disclosure” and “Technology Transfer” agreements, where two entities agree to share information for purposes of collaboration, and create legally enforceable restrictions on disclosure to or use by others.

Successfully bringing innovations to market requires coordinating business opportunities, scientific developments, and creating legally enforceable rights. A world-wide strategy for protecting intellectual assets in diagnosis and treatment using MS requires knowledge of different countries’ policies, laws, and procedures.

Patents provide exclusive rights to their owners though disclosure to the public in exchange for exclusive legal rights to exclude others from practicing the invention. Patent laws continually evolve; recent enactment of new laws, and new court decisions relating to diagnosis and treatment create ongoing challenges to understanding how intellectual property laws are interpreted and enforced, both now and into the future. In 2014, the U.S. Supreme Court rendered an important decision relating to patents relating to “Abstract Ideas.” This case followed a 2012 case (Mayo), and another 2014 case (Myriad), both of which have been relied upon by the USPTO in examining claims, and by lower courts for invalidating significant numbers of claims involving computerized methods. The patent community and the USPTO are working hard to understand the new groundrules.

All countries now use a form of a “first to file” regime that severely penalizes inventors for disclosing inventions before filing a patent application. Inventions can be patented if they are: (1) new, (2) not obvious, (3) adequately described, (5) are for devices, methods of manufacture, methods of use, or compositions of matter. However, under current law, a patent may not be obtained if directed broadly to laws of nature, natural phenomena, or abstract ideas. However, practical applications of laws of nature, natural phenomena, or abstract ideas may be patentable if they do not cover the entire law, phenomenon, or idea.

Implementation of early and ongoing procedures by creators to protect trade secrets and patentable inventions are crucial to successful development of innovations in health care. Examples will be drawn from Asian, European, and American jurisdictions to illustrate some of

the challenges and opportunities available. Once legal rights are obtained, they can be exchanged in a business context to acquire investment, attract key employees, and develop collaborations. With proper strategies combining business, technology, and the law, commercializing important innovations will result in improved patient care, recognition of innovators' contributions, and business success, all of which can lead to further innovation and improvements in health care.