



## Intellectual Property Review Process

May 31, 2012

Memorial Sloan-Kettering Cancer Center (MSKCC) employees who have made an advance that might constitute an invention or who have developed other types of intellectual property (collectively “Invention”) must disclose such information to the Office of Technology Development (OTD) by submitting an Invention Disclosure Form (available on the OTD website) to a Licensing Manager or to [InventionDisclosure@mskcc.org](mailto:InventionDisclosure@mskcc.org). Each Invention Disclosure is assigned to a Licensing Manager, who will contact the inventor(s) within one week and work with the inventor(s) and with other members of OTD to evaluate the disclosure. There are four main facets to the Invention Evaluation process.

### 1. Invention Description

Initially, the Licensing Manager generates an Invention Description that clearly defines the Invention and its uses and applications, as well the potential benefits of the Invention to patient care, research, and/or education. The Invention Description serves as the starting point for OTD’s formal Invention Evaluation.

### 2. Patentability Analysis

Often, seeking patent protection is the only way the commercial value of an Invention can be realized. However, patent protection is not always necessary to facilitate the commercialization of an Invention. For instance, research materials generally retain their full commercial value even without patent protection. In cases where an Invention does not lend itself to commercial development, e.g., a new mechanism of action, the public interest may be best served simply through dissemination of the Invention via publication.

In order to be patentable, an Invention must satisfy legal requirements for utility, novelty, and non-obviousness. OTD assesses these parameters, in consultation with patent counsel, through comparison of the Invention to related and similar technologies that are available or that have been published in the scientific or patent literature. In addition, OTD assesses a number of other factors that are important in determining the value of a patent application. These factors include determining whether the available data provide proof-of-principle sufficient to obtain a patent, determining whether worldwide or U.S.-only patent rights are available, and assessing which types of patent claims might be obtained for the Invention. (Composition-of-matter claims are generally more valuable commercially than method claims; broader claims are generally more desirable than narrow claims.)

### **3. Market and Business Risk Analysis**

The intention of the market and business risk analysis is to determine the market potential of an Invention and the commercial value of obtaining patent protection for that Invention. OTD's estimates of market potential are based on the size of the market for the potential products and/or services derived from the Invention, the growth rate of that market, and the potential market penetration of the product and/or service. In addition, OTD analyzes market margins, current market segmentation, and to what extent existing commercial infrastructure and current healthcare practice support the development of the products and/or services derived from the Invention. For example, if an Invention addresses only a small market, identifying a company willing to invest in the development of the Invention may be difficult. Similarly, a product that is difficult to manufacture or ship or that requires specialized facilities for administration to patients may fail to find favor with potential licensees.

In addition to market analysis, OTD also examines any pre-existing commitments associated with the Invention. In the case of Inventions generated in the course of sponsored research or with materials obtained under a material transfer agreement, the companies providing the funding or materials almost always retain license rights. Such pre-emptive rights can prevent licensing of the Invention to a third party or decrease the value of such a license to a third party. OTD also analyzes whether existing patents or patent applications related to the Invention might limit the right of potential licensees to make, use or sell the product or service derived from the Invention.

The analysis of commercialization potential is a significant factor in deciding whether or not to move forward with intellectual property protection. In general, OTD pursues patent protection only for those Inventions that seem more likely than not to lead to commercially viable products or services and only if MSKCC retains rights in the Invention and believes that a licensee will have freedom to operate.

### **4. Commercialization Analysis**

OTD's Invention Evaluation also considers various commercialization issues affecting the value of the Invention from the perspective of potential licensees.

Time, effort, and expense are required to transform an Invention into a commercial product or service. Commercialization of MSKCC technologies often requires considerable investment of resources and relatively long timelines. In many cases, the MSKCC technology must be combined with other technologies to produce a viable product or service. For example, development of an Invention might require a delivery system, another proprietary compound, an assay or a new procedure, any of which might need to be licensed from another party. Cost, timeline, and the need to access additional technologies can affect the commercialization pathway and the value of an MSKCC Invention to a potential licensee.

### **OTD's Recommendation**

OTD usually works with the inventor(s) in conducting its Invention Evaluation. Once the evaluation has been completed, the Licensing Manager will discuss the results of OTD's analyses with the inventor(s)

and make a formal recommendation about the Invention and the advisability of seeking patent protection for the Invention. In the event that OTD and the inventor(s) disagree about the commercial value of the Invention and the advisability of seeking patent protection, either may request that the Invention be evaluated by an outside Patent Review Advisory Committee.

### **Patent Review Advisory Committee**

The Patent Review Advisory Committee shall comprise two members who are independent from OTD and shall be appointed by the Vice President, Research and Technology Management. One member shall be an experienced patent attorney who is well versed in patent prosecution. The other member shall be an experienced businessperson who is well versed in biotechnology investments and the evaluation of life science technology.

### **Appeal Process**

If OTD and the inventor(s) cannot reach an agreement regarding the filing of a patent application, either OTD or the Principal Investigator may request a review by the Patent Review Advisory Committee by making such request to the Vice President, Research and Technology Management.

Once an Invention is referred to the Patent Review Advisory Committee, the Committee will schedule a meeting with the inventor(s) and OTD. If such a meeting cannot be scheduled before the deadline to file a patent application, OTD will file a provisional patent application based upon detailed information about the Invention provided by the inventor(s). At the meeting, both the inventor(s) and OTD shall have the opportunity to make a presentation and/or provide comments to the Patent Advisory Committee. If, after such a meeting, there still is no agreement, the Patent Review Advisory Committee shall provide a short evaluation and recommendation to the Vice President, Research and Technology Management as to how to proceed with the Invention.

The Vice President, Research and Technology will review the recommendation of the Patent Review Advisory Committee and decide whether MSKCC will pursue patent protection for the Invention.