Issues and Perspectives

Intellectual Property: Exploitation of Intellectual Property, Technology Transfer Through the MRC

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The MRC is the primary U.K. government agency for the support of biomedical research. Its annual budget (~£320 million) supports research in its own laboratories and in universities, with approximately equal spending in each mode. The Technology Transfer Group in the MRC Head Office is directly responsible for the management of exploitation of results from the council's laboratories and works in partnership with scientists to identify opportunities and develop and execute exploitation strategies.

Frequently, MRC seeks to protect novel ideas through the patent process, to secure a proprietary position and thereby enhance the value of the opportunity for a prospective industrial partner. It is important to remember that in addition to fulfilling the criteria for patentability (that the results be novel, nonobvious, and of commercial utility), for an opportunity to be taken forward there must be the prospect of commercial return. The patent process can be long, expensive, and often arduous and is not a path to be embarked upon lightly.

In addition to patents, industry is interested in gaining access to practical and theoretical know-how where there is no established patent position. This may be by way of an industrially funded collaboration. There may also be a great deal of commercial value in certain materials, often not apparent at the time they are developed, and it is the duty of the investigator to ensure that these are distributed to fellow academics under an appropriate Materials Transfer Agreement providing that the recipient does not commercially exploit without reference to the originator.

The exploitation route chosen for a particular technology will vary depending on the nature of the opportunity. For example, MRC filed a patent application based on results, from Jo Colston and his team at the MRC National Institute of Medical Research, which demonstrated that certain tuberculosis antigens could influence tumor cell killing. An exclusive license under the patent application was issued to a commercial partner, who in turn invested in a multicenter collaboration including the MRC team. This allowed the originating scientists to investigate the subject further, in both basic and more applied areas, leading to preclinical development of a potential new therapy.

Increasingly, where the novel findings have breadth and can form the basis for multiple developments, an attractive route for exploitation is via the creation of a new company. These start-ups allow for dedicated development of the basic ideas and hence increase the likelihood of the technology being developed into commercial products while providing significant returns. Importantly, the establishment of new companies also benefits national wealth creation, helping to consolidate the maturing U.K. biotechnology marketplace and in the process creating new employment opportunities, primarily in R&D.

An interesting case study is the antibody engineering technology, pioneered at the MRC Laboratory of Molecular Biology (LMB), which provided the basis for a number of exploitation opportunities. In the 1970s, the development of monoclonal antibodies from mouse cells, by Kohler and Milstein, created great excitement over the possibility of producing "magic bullets" to cure a range of hitherto intractable diseases. However, despite their huge potential, the

was mounted against the antibodies. It was clear that a way needed to be found to mask their immunogenicity. In 1986, Greg Winter, also at the MRC LMB, developed the method of "humanization" of monoclonal antibodies through engineering the proteins. MRC filed a patent application to cover this technology and has subsequently issued over 40 nonexclusive licenses worldwide.

It takes approximately 10 years to bring a clinical product to market. The first therapeutic humanized antibodies have recently been launched on the American market (Xenapax, transplant rejection; Synagis, respiratory syncytial virus; Herceptin, breast cancer). MRC now benefits from the licensing royalty stream. In addition, the humanization work has sustained a significant research group at the MRC Collaborative Center Mill Hill, which offers a service to those companies wishing to contract out antibody humanization.

Engineered antibodies provided a springboard for the development of further technologies to create human antibodies. Winter has established a phage antibody screening technology that allows in vitro selection of novel antibodies from human repertoires. Patent applications were filed covering this technology, and a new company, Cambridge Antibody Technology Ltd. (CAT), was founded in 1989 to exploit the opportunity. CAT has since raised approximately £60 million and is listed on the London Stock Exchange. It employs about 150 staff members in the United Kingdom, predominantly scientists. MRC shares financially in CAT's success through a shareholding in the company and royalty income.

Exploitation of scientific results can be financially and intellectually rewarding, for both the owners of the intellectual property and for the scientific contributors. Under U.K. law, the employer of the inventors holds legal title to the invention; MRC therefore "owns" the IPR generated by its staff. However, it is important to recognize and reward the contribution made by the originators of the IP, and MRC operates an Awards to Inventors scheme in which income received by MRC through exploitation of its inventions is shared with the contributing scientists and the MRC laboratory in which the work was undertaken.

Exploitation of IP has many benefits. Financial gains can be seen in both the short and longer term. It can be used to bolster research in a particular area. It can act as a lever to access complementary know-how from a third party. It can provide a significant economic stimulus via the creation of new companies. Most importantly, in the medical sciences, it can enable and hasten the use of fundamental research results in the development of therapeutic and diagnostic products by the commercial sector for the benefit of health care.