IP Management Policy: A Donor's Perspective

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ABSTRACT

This chapter describes how the Wellcome Trust, a major charitable funder of biomedical research, manages intellectual property arising from Wellcome-sponsored research. The trust recognizes that the development of new health technologies requires the enlightened management of intellectual property through partnerships involving funders, scientists, institutions, and companies. This chapter explains how the charitable mission of the trust influences its decision-making process. The chapter includes case studies to illustrate the concerns of the trust and to identify key procedures.

1. THE WELLCOME TRUST

The Wellcome Trust is an independent, U.K.-based biomedical research charity. In the year 2006–2007, the trust will invest nearly US$1 billion in biomedical research, both in the United Kingdom and internationally. The Wellcome Trust was established in 1936 after the death of Sir Henry Wellcome. In his will, Sir Henry vested the entire share capital of a drug company he founded, The Wellcome Foundation, into the Wellcome Trust. The Wellcome drug company was absorbed, by a series of mergers, into GlaxoSmithKline, and, in the process, the trust diversified its investment portfolio. The trust no longer has a significant shareholding in GlaxoSmithKline but operates entirely independently of the drug company.

The mission of the trust is to foster and promote research to improve human and animal health (see Box 1 for a statement of the organization's mission and general policy). Funding by the trust supports a wide range of work in the biomedical arena, including basic science, technology transfer, medical humanities, and public engagement with science. In order to support scientific research of the highest caliber, grant schemes include not only career-based schemes for scientists, from Ph.D. studentships to fellowships, but project and program grants, equipment grants, and infrastructure initiatives.

The majority of trust funding goes to researchers in U.K. academic institutions, but the trust has also always supported research for tropical diseases, particularly in developing countries. Support schemes are available for U.K. researchers who wish to carry out tropical medicine research in the developing world, as well as for researchers, based in developing world institutions, who are conducting research in public health or infectious diseases.

2. IP MANAGEMENT

When considering IP (intellectual property) management, the trust's key aims are (1) to ensure that intellectual property arising from the research that it funds is prudently used to

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Box 1: Wellcome Trust Policy on Intellectual Property and Patenting

Note that the policy is currently under revision and is expected to be approved in spring 2007.[1]

Preamble

The mission of the Wellcome Trust is to foster and promote research with the aim of improving human and animal health. This is the driving force behind all of the Trust's activities, and the basis for its policy on the protection and use of intellectual property rights. The aim of this policy is to provide a clear statement for Trust-funded scientists on the Trust's position on the protection and provide a clear statement for Trust-funded scientists on the Trust's position on the protection and use of intellectual property through patents; and to inform other Trust activities, particularly those relating to genomics.

In developing this policy, the Trust has considered a wide range of issues, in particular the role of intellectual property rights in creating the best conditions for research and in translating that research into tangible healthcare benefits. The Trust supports the appropriate protection and use of intellectual property where this will maximise healthcare benefits and enable biomedical research to flourish.

In order for research advances to qualify for intellectual property protection, the legal criteria for patent protection must be fulfilled. This means that, to be patentable, the results of research must describe an invention that is:

- novel, i.e., not described elsewhere before
- non-obvious, i.e., involving a step sufficiently inventive that most people working in that field could not have predicted it
- capable of industrial application, i.e., described in such a way that it can be made or used.

Patents, including those covering genes and their products, are no exception, and the Trust is supportive of these if there is sufficient information to indicate that the DNA sequences in question can be used to develop healthcare benefits. The Trust does not support the patenting of raw DNA sequences in the absence of such information. This is in line with EU law, which states that a gene sequence, whether partial or complete, is only patentable when it has been isolated and its function described.

The Trust is particularly concerned about patents and patent applications which are unreasonably broad and opportunistic, e.g., when there is limited functional data available to support those patent claims. The Trust may challenge such speculative patents if it believes that they are being applied for or used in ways that could be detrimental to research or limiting to the development of healthcare benefits.

As a charity the Trust is under an obligation to ensure that useful results from the research that it funds are applied for the public good. Technology Transfer at the Wellcome Trust aims to bring together researchers, universities, industry and investors to help ensure that promising lines of research yield practical healthcare benefits. Given the importance of these issues and the potential health gains which should flow from genomics research, the Trust will continue to keep this policy under review.

achieve health care benefits and (2) to maintain and promote a supportive environment for future biomedical research. The trust has historically taken an open and innovative approach to IP management, some examples of this are discussed below.

Other donors, of course, will have different perspectives, mechanisms, and processes for achieving their respective missions. The trust's approach to managing intellectual property has developed in a way that the trust considers appropriate for achieving its own objectives. This chapter is not intended to set out any form of best practice. The authors' aim is simply to present experiences, from their work in technology transfer at the trust, that might be instructive to other practitioners.

3. MANAGING INTELLECTUAL PROPERTY FROM TRUST GRANTS

The trust awards the majority of its grants based on its standard grant conditions.[2] The trust does not normally seek to own intellectual property arising from the research it funds, but the trust does require a sponsored academic and research host-institution to establish agreements with personnel involved in the research that vest in the institution any intellectual property generated. Under the trust grant conditions, the institution must also have established systems for identifying and managing intellectual property generated under a trust grant (for example, a system for invention disclosures and evaluation by the institution's technology transfer office or the equivalent function).

If trust-funded intellectual property is generated, the grant conditions require the host-institution to consider whether protecting the intellectual property is an appropriate way for that research to benefit the public.[3] The usual rationale for doing so is that attracting further research and development funding—which may likely be from a third-party commercial organization such as a venture capital company or a pharmaceutical or biotechnology company—requires protecting the intellectual property, often through a patent filing. Such patent filings offer a potential limited monopoly to any party who might wish to develop the intellectual property.

In some cases, of course, IP protection may not be the best way to obtain a public benefit. Instead, allowing immediate and unprotected access to the research results may directly improve public health or enable other researchers to build upon the results with the aim, for example, of aiding related health research through the creation of large data sets (see also section 7.1.3 below). Alternatively, the research results may be of insufficient value on their own, making patenting worthless.

3.1 *Exploiting Intellectual Property*

Since part of the mission of the trust is to improve human and animal health, translating research successes into health care applications is essential. In the vast majority of cases, further development and investment in the results of trust-funded research are necessary for it to have a health impact. Under the trust's grant conditions, the host-institution has the responsibility to decide whether the exploitation of trust-funded intellectual property is an appropriate way to achieve public benefit. If the institution decides that exploiting the intellectual property is appropriate, then before it grants any rights to the intellectual property, it must first seek the agreement of the trust on this matter. The trust's consent would normally be contingent upon the institution accepting the trust's standard revenue and equity-sharing terms.

Under the trust grant conditions, if the trust reasonably considers that the institution is not adequately protecting, managing, or exploiting trust-funded intellectual property, the trust has the right to take over such activities instead. In addition, to ensure that potential grant recipients can adhere to the trust's policies, the applicant(s) and institution are required to disclose at the grant application stage whether the research will use any technology or materials that are subject to agreements with third parties (such as companies or other research institutions) that might affect the research institution's ability to develop the potential trust-funded intellectual property as envisaged.

3.2 *The consent process*

During the consent process, the institution provides as much detail as possible about the proposed method of exploitation (such as draft license terms, material transfer agreements, and collaboration agreements). In the case of a proposed transfer of intellectual property into a spinout company, the institution should provide the draft shareholders' agreement and the company's articles of association. The trust will assess on a case-by-case basis whether the terms set out an appropriate means by which the intellectual property can achieve a public benefit. If the proposed development route and associated agreement terms are determined to be consistent with the trust's public benefit objectives, the trust will normally enter into a benefit-sharing arrangement with the institution and with any other involved parties. This can include a percentage share of milestone and/or royalty payments. In the case of spinout companies, it will usually involve a share of the equity of that company.

Because of its charitable status, the trust is required to assess any benefit-sharing terms and their public benefit impact. It is a fundamental principle of English charity law that any "private benefit" coming to an individual or company from a charity must be necessarily incidental to the public benefit resulting from the implementation of the charity's objectives. Accordingly, where the trust's charitable funding gives rise to valuable intellectual property and that value is to be shared with other parties, such as the researcher, the host-institution, and a licensee, it is important that those parties receive only a portion of the total value of that intellectual property. The amount should be appropriately related to the amount that the party has contributed to the creation and further development of the intellectual property. The trust must also receive an appropriate share of the value of the intellectual property that its funding helped create.

Because most of the host-institutions that receive funding from the Wellcome Trust are themselves U.K. charities (for example, universities) and are governed by equivalent charity law, the research institutions themselves will consider the public and private benefit balance when establishing any IP exploitation agreement. The consent process, therefore, is usually straightforward, since the proposed exploitation terms will likely be consistent with the trust's objectives.

4. EXAMPLES OF TRUST IP MANAGEMENT

4.1 *Material transfer agreements*

When a trust researcher requires biological materials from a third party, the consent of the trust is required if the relevant material transfer agreement (MTA) grants any rights over trust-funded intellectual property. The trust has often encountered what it considers to be *reach-through* clauses in such agreements that give the provider of the material a payment-free license, for commercial purposes, to any invention made through the recipient's use of the materials. The trust considers this unacceptable in a situation in which the provider of the materials makes no inventive contribution to new intellectual property created by the recipient other than providing materials. In such situations, although a case-by-case approach is taken, the trust will often recommend that either (1) the license for such intellectual property, to the provider, be limited to a nonexclusive, noncommercial research license, or, (2) if the provider has significantly contributed to the new intellectual property and is considered to be a suitable partner for developing it further, the provider should be granted a time-limited option to negotiate a commercial, royalty-bearing license (with the ability for the institution to license the invention to other partners, if license terms cannot be agreed to within the time period). However, where the recipient files patents on inventions that are directly and principally related to the materials, it is usually appropriate for the provider to be granted a nonexclusive license to use the patents solely in connection with the materials, so the provider can continue to use its own materials. Offering the provider a time-limited option to negotiate an exclusive license of such patents can be appropriate in many cases.

4.2 *Pipeline agreements*

Pipeline agreements usually give a company an exclusive license to all future intellectual property arising from, for example, an institution's departments. This type of arrangement is problematic for the trust because should any trust funds be going into such a department, the automatic license prevents the trust from assessing, on a case-by-case basis, whether the proposed exploitation plan of the new intellectual property is a suitable way of achieving a health-care benefit. The breadth of the pipeline arrangement often makes it unlikely that an automatic license to a company would be the most appropriate route of exploitation, particularly if the company's resources are limited and the license field is much wider than that of the company's focus. In such cases, the trust will normally agree with the relevant institution that, prior to granting any license of trust-funded intellectual property to the company under the pipeline agreement, the institution will request the trust's approval of an exploitation plan and the license terms. However, such an arrangement may be considered acceptable if the pipeline arrangement is appropriately narrow, the anticipated intellectual property can be well defined, the company in question is suitably qualified and resourced to exploit the relevant intellectual property, and revenue sharing terms with the host-institution can be agreed on in advance.

4.3 *Licensing arrangements*

The trust commonly consents to the grant of exclusive license, or even the assignment of a patent, to a university spinout company. The trust recognizes that exclusive licensing or assignment will often encourage further investment in and development of trust-funded intellectual property because it gives the investor or developer a competitive advantage. Where appropriate, the trust also uses co-exclusive licensing (the grant of licenses to a small number of partners—typically less than five) to balance incentives for commercial investment in product development, manufacturing, and distribution with wider public access to the new product.

Sometimes, the patent in question is relatively broad. It may address a number of diseases, or it could be widely used by third parties to develop health-care applications without an unnecessarily negative impact on their respective markets or applications. In such cases, the trust may conclude that there is a risk that a single licensee (especially in the case of a resource-limited, early-stage spinout) would be unable to fully exploit the patent across all applicable fields. In addition, if licensing is not carefully handled in such cases, there is a further danger that the research fields would be unnecessarily inhibited. Thus, the trust would normally propose a program of nonexclusive licensing, or careful, selective field-of-use licensing as a more appropriate means of achieving a public benefit.

5. PUBLICATIONS

The trust grant conditions require that the results of research funded by the trust be published in an appropriate form, although it is accepted that publication may be reasonably delayed to allow IP protection. The trust sees publication as a key process in maintaining an active, healthy research base and allows scientists to keep up-to-date with the latest discoveries, makes it possible for their research findings to be challenged and tested by their peers, and lets other scientists build upon and benefit from the new knowledge. Indeed, in the right circumstances, publication alone can therefore be a means of achieving a public benefit.

In 2003–2004, the trust commissioned two reports on the scientific research publishing market.[4] They concluded that although many scientific articles were available electronically, publishers' access policies posed potential barriers to dissemination, and journal subscriptions were a heavy cost burden on institutional libraries and researchers. After these reports were issued, the trust added a new condition to its grants that requires all trust-funded researchers to deposit a copy of their scientific publications relating to trust-funded research into PubMed Central (a free-access, digital repository of full-text, peer-reviewed biomedical journals that was developed by and is maintained by the U.S. National Library of

Medicine). The trust is also part of a consortium composed of medical-research charities and government-funding bodies that is funding and developing a U.K. counterpart of PubMed Central. This initiative aims to ensure that research is disseminated as widely as possible and that both access to articles and long-term preservation of the archive is ensured.

6. IP AND TECHNOLOGY TRANSFER AWARDS

Technology Transfer at the trust makes translation awards to facilitate the development of early-stage health-care inventions to the point at which they can be further developed, usually by a commercial company. Funding through these awards aims to fill what the trust considers to be the funding gap between basic research outcomes in academic research and the point at which the research is sufficiently developed to attract investment by venture capital firms or potential commercial licensees. Trust translation awards may be made to companies, usually early-stage spinouts, or to academic host-institutions. Funding for spinout companies is normally in the form of a program-related investment. With this type of funding—permissible for charities—a "charitable investment" is made into a specific research project with the primary aim of achieving the mission of that charity. Such funding provisions enable the trust to offer charitable funds to commercial vehicles where there is an ongoing research and development project for particular health care applications. While receiving a potential return on such a program-related investment is not the primary objective of making such an award, it is nonetheless important (for balancing public and private benefits arising from charitable assets) for the trust to receive an appropriate share of any benefits that might result from the program-related investment. Accordingly, Technology Transfer normally structures its translation awards into companies as convertible loans rather than as grants.[5]

Because of the critical nature of this stage of the development of a technology, appropriate IP generation, identification, filing, ongoing monitoring, and prosecution are vital. As part of the application process for a translation award, Technology Transfer requires information about whether patents have already been filed, on the technology in question, or will be filed in the course of the funding. The application also typically requires disclosure of information about freedom-to-operate issues related to the relevant technology.

For translation awards in areas of particular high-strategic interest or relevance to the trust, Technology Transfer may make strategic translation awards available. Through such awards, Technology Transfer will often actively participate in project management, including the management of intellectual property that might arise. This involvement may even include assistance with finding commercial partners or further funding. Funding agreements tend to be much more customized for strategic translation awards, but a number of commonly used provisions have been developed to address IP issues that may arise. Two broad categories are addressed in these provisions: 1) keeping the research field open and 2) ensuring the appropriate management and exploitation of intellectual property for a health-care benefit:

1) Keeping the research field open:
   (a) a prohibition on enforcing trust-funded intellectual property against universities/research institutions carrying out non-commercial research
   (b) the grant or reservation of a license for research purposes (which may be sub-licensable) to the trust or relevant institution(s)

2) Ensuring appropriate management and exploitation of intellectual property for a health-care benefit:
   (a) formation of an IP management group, comprising the researchers, independent experts, and representatives from the trust, to provide opinion and guidance on IP strategy
   (b) terms to ensure that the results of research that have a potential developing country application are developed for

such purpose and made available in the developing world

6.1 *Case studies*

6.1.1 *Typhoid vaccine*

With Trust funding, the company Emergent (Europe) Limited is testing its one-dose oral typhoid vaccine in healthy Vietnamese adults and children in preparation for proof-of-concept and phase III studies in the southeast Asia region. Emergent owns the underpinning intellectual property in the vaccine. Typhoid has both a developed-world travellers' market and a less-profitable developing-world endemic market, so the Trust wanted to ensure that the developing world market would benefit from the development of the vaccine. Terms were therefore negotiated, giving timescales within which the vaccine has to be launched in developing world markets. If launch does not take place within the relevant timescale, and there are no concrete plans to do so within a reasonable time, the Trust can acquire the rights to manufacture and sell the vaccine in those countries.

6.1.2 *Drugs for malaria*

The Trust, the Medicines for Malaria Venture, and the Singapore Economic Development Board agreed to fund the Novartis Institute for Tropical Diseases (NITD) to carry out a program of drug discovery in the field of malaria, the main aims being to find a one-dose cure for Plasmodium falciparum and a curative modality for Plasmodium vivax. Novartis agreed to make contributions in kind to the cost of the program.

NITD owns, (or in the case of intellectual property generated by collaborators, has rights to acquire rights to), all intellectual property generated during the funded program, but the Trust and MMV have a noncommercial research license to enable basic research on any findings of the program. If NITD decides not to file or prosecute such IP, the Trust and MMV may, so that valuable IP protection is not lost. In addition, NITD has agreed to covenants not to sue for infringement of the program patents any not-for-profit institutions that may carry out noncommercial research. NITD cannot develop and commercialize products comprising Trust-funded IP without the consent of the Trust and MMV. Consent, not to be unreasonably withheld, is subject to a benefit-sharing arrangement. In the event that NITD puts development on hold for certain periods, or fails to make any sales into developing countries within a certain period following launch, the Trust and MMV have the option to take over the necessary IP rights, to ensure that developing countries benefit from the outcomes of the research.

7. IP MANAGEMENT FOR SPECIAL INITIATIVES

The trust has been involved in a number of large initiatives to create data resources (principally DNA sequence information) for the scientific community. In each case, IP management has been considered from the outset as a key aspect of the resource. In the case of DNA sequencing, the trust's position is that basic DNA sequence information should be placed in the public domain as soon as it is practical to do so without limitations on use.

7.1 *Case Studies*

7.1.1 *The human genome project*

The Wellcome Trust Sanger Institute, which is largely funded by the Trust, took a major role in the Human Genome Project for its part in sequencing almost one-third of the human genome. The participants in the Human Genome Project decided that all the information produced by public human-sequencing centers should be made immediately and freely available to the biomedical-research community, via the Internet, without seeking any IP rights and without restrictions on how the information could be used. These principles were enshrined in an agreement on human sequencing brokered at a strategy meeting sponsored by the Trust in Bermuda in February 1996 and extended to data on other organisms at a later meeting.

7.1.2 *The SNP Consortium*

In partnership with several large pharmaceutical and technology companies, the Trust is a major funder of the SNP Consortium, which aims to

produce a high-quality map of human genetic markers, known as single nucleotide polymorphisms (SNPs). An SNP is a site in DNA where there is a change in a single "letter" of the DNA code. Sometimes this change in a single letter can cause a visible effect or cause a disease, but even if there is no obvious effect, knowing the location of the change can still be useful. The SNP map may be used to identify specific genes involved in disease processes, to develop novel diagnostic tests, and to predict individuals' responses to medical therapy.

As SNPs by themselves are only a small factor in the development of new drugs, the map was considered to be a precompetitive resource that would be of huge benefit to the biomedical research community. The consortium therefore agreed to put the SNP map into the public domain. Consortium members have access to the data on the same terms as other users: there is no preferential access. To keep the SNP map freely available to the public, the consortium filed patent applications on SNPs as evidence of dates of discovery (so that these would act as prior art to any subsequently filed patent). The patent applications would be abandoned prior to grant.

7.1.3 *The international HapMap project*

The Trust, through the Sanger Institute, is a major participant in the HapMap consortium, which is made up of members from the United Kingdom, Japan, United States, Canada, Nigeria, and China. The HapMap consortium aims to build a map of haplotypes, or "blocks" of SNPs that are inherited together in humans, to aid in pinpointing genetic variations associated with disease. These data represent a valuable precompetitive resource for the biomedical research community, and it was decided to make SNPs and haplotypes available to the public as they were identified. There was a concern that in the early stages of the project, when data were not sufficiently dense to derive haplotypes, third parties could combine HapMap data with their own data and file patents on haplotypes. These filings could prevent the HapMap Project from continuing. Accordingly, data were initially released under a "click-wrap" nonexclusive license,[6] which required researchers accessing the database to agree (by clicking a box on the HapMap Web page) to the following standard terms of access:

1. not to restrict access to or the use of HapMap data by others
2. not to file composition-of-matter patents on SNPs, genotypes, or haplotypes based on HapMap data
3. not to file patents containing claims to particular uses of any SNP, genotype, or haplotype data based on HapMap data unless such claims do not restrict, or are licensed on such terms that do not restrict, the ability of others to use at no cost the HapMap data for other purposes
4. to share data with other licensees only under the same license

The main disadvantage of this approach was that HapMap data could not be shared with other large-scale genomic databases. In December 2004, following release of over 1 million SNPs by the HapMap project, a further release into the public domain of 1.6 million SNPs by Perlegen Sciences Inc. and the development of new haplotype analysis tools, the consortium decided that sufficient data were in the public domain to constitute prior art and that derivation of haplotypes and haplotype tag SNPs from HapMap data would be considered to be obvious and not patentable. The click-wrap license was therefore abandoned.

8. CONCLUSIONS

The trust's primary aim when considering IP management is whether it is an appropriate mechanism for achieving part of the trust's mission, namely improving human and animal health. Practically, this translates into a focus on promoting a healthy research community and exploitation of research for health care outcomes. By encouraging exchange of research results, making large-scale databases freely available for researchers, and discouraging restrictions on the research use of inventions, the trust aims to keep the research-base broad and to benefit from the exchange of ideas. The role for commercial (or noncommercial) exploitation is recognized

and encouraged, provided that there is a clear health care benefit as the ultimate outcome. The trust sees intellectual property as a useful tool for achieving these aims and encourages the intelligent management of intellectual property by its grantees to ensure that trust-funded research achieves its full potential.

The trust also recognizes that, on the whole, given the inherently varied nature of research and the diversity of health care applications that may arise, potential intellectual property emerging from trust funding should be considered on a case-by-case basis to determine how to best disseminate, protect, and develop the results. For this reason, the trust has a devoted group, Technology Transfer, to manage these processes and considerations. The trust is also in the advantageous position of being a significant funder in the area of biomedical research. This position offers the opportunity to contribute its perspective as a charitable funder to both governmental policies and institutional mechanisms for managing intellectual property. The trust's collaborators, partners, and IP developers recognize the trust's charitable motives and are usually accommodating to the trust's IP policies and related goals with respect to health impacts. This accommodation is critical because the trust recognizes that the development of new health technologies requires the enlightened management of intellectual property through partnerships of funders, scientists, institutions, and companies. ■

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1. Please visit www.wellcome.ac.uk for the latest policy version.
2. www.wellcome.ac.uk/doc_WTD004055.html.
3. Trust-funded IP includes all IP created, exemplified, or developed in whole or in part from the research that the Trust funds. Trust-funded IP does not normally include copyright in artistic works, books, articles, scientific papers, lectures, or audio or visual aids to the giving of lectures or teaching.
4. The Wellcome Trust. 2003. Economic Analysis of Scientific Research Publishing. *SQW Limited*, A Report Commissioned by the Wellcome Trust: London. www.wellcome.ac.uk/assets/wtd003184.pdf.

   The Wellcome Trust. 2004. Costs and Business Models in Scientific Research Publishing. *SQW Limited*, A Report Commissioned by the Wellcome Trust: London. www.wellcome.ac.uk/assets/wtd003182.pdf.
5. www.wellcome.ac.uk/assets/wtx024257.doc.
6. Click-wrap licenses are similar to the shrink-wrap licenses common with software. If one wants to access data online, one has to click a box that typically states something like "I agree to these terms" before one is let through to the online database.