Bioethical Implications of Intellectual Property Rights on Public Healthcare: The UK as Case Study

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FEW ISSUES today illustrate the gulf between the pharmaceutical and genomics industries and the healthcare sector as starkly as intellectual property rights (IPRs). IPRs are one of the corner-stones of industry, allowing companies to recoup the costs of expensive research and development programmes while ensuring the investment needed to produce the therapeutic and diagnostic products of the future. Much has been written about the problems faced by healthcare providers within developing countries when faced with vigorously protected healthcare-related technologies, but little about the problems faced by healthcare providers within the developed world. For a predominantly publicly funded healthcare sector, such as that in operation in the United Kingdom, there are strong public interest concerns that IPRs may generate disproportionate claims from right-holders, leading to undue restrictions and charges in licences and constraints upon further research. The upshot could be unacceptable barriers against access to medicines and diagnosis, curtailing the healthcare sector's ability to fulfil its primary role and restricting its own ability to generate healthcare products. For those charged with overseeing the delivery of such a healthcare system the intricacies of intellectual property policy and practice are proving challenging to put it mildly. Whilst these issues are rarely couched in terms of their *bioethical* implications, it is clear that there is a strong underlying ethical, in the sense of public interest, issue which has to be addressed, namely how to reconcile the diversity of roles which now have been played by healthcare providers.

The challenge mentioned is exacerbated by government initiatives encouraging internal intellectual property creation and protection and the fostering of public/private partnerships. In the UK these initiatives have resulted in the setting up of a number of Hubs utilising funding from the

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government, academic and private sectors. These Hubs are expected to become fully self-supporting within a few years of coming into being with government support being guaranteed for the first year only. One of the functions of the Hubs will be to identify and protect intellectual property generated by those National Health Service (NHS) Trusts[1] affiliated to it.

This presents the Department of Health with two sets of problems. Firstly, it has to determine what is the best policy to be adopted for buying intellectual property protected technology. Secondly, it has to inculcate within healthcare providers a sense of their own value as innovators and provide a suitable platform for appropriate income generation from those inventions so created. It is easy to envisage a conflict between the two positions arising unless care is taken to ensure that the policies adopted are coherent and cohesive. On the face of it a simple task, but the magnitude of which only really becomes apparent when it is recognised: (a) the sheer vastness of the healthcare sector (it is the UK's largest employer), (b) the fact that there is no single group with overall responsibility for determining and disseminating healthcare policy, and (c) that the Department of Health's influence within the Hubs is likely to be reduced once the Government ceases to provide funding and the Hubs become increasingly free to compete, not only with non-Department heathcare technology innovators, but with each other and possibly with the Department itself. As the actual IPR function of the Hubs has yet to be decided, despite the Hubs already being in operation, this is a matter of immediate current concern.

A key problem facing the Department of Health is the fact that the Hubs will be responsible for the selling out of its own intellectual property (giving rise to issues about coherence in policy, practice and pricing between Hubs) whilst the Department is likely to retain responsibility for licensing in protected technologies. The potential for conflict and confusion as to policy and practice is apparent not least when set against the overarching social objective of the NHS to ensure that any "exploitation....must not significantly interfere with core health service duties."

It is clear, in the context of the UK at least, that IPRs are going to be increasingly relevant in the provision of genomic healthcare, and an understanding of these will determine how the Department of Health is able to maximise its use of both protectable genetic material generated "in-house" and protected genetic material "bought in" from third parties. Underlining the importance of intellectual property rights in the context of both the Hubs and the health service in general, the Government's White

1. In very simple terms, in the UK the Department of Health, under the direction of the Minister for Health, is responsible for determining policy relating to healthcare provision, including such matters as procurement agreements. The National Health Service, under the direction of the Department, is responsible for actual healthcare delivery.

Paper on Genetics, published in June 2003, states very clearly that the Government sees these rights as central to the development of UK healthcare. What is equally clear is that there is a lack of understanding about IPRs and the options available to the Department and this is now something recognised by the Department itself. The catalyst for this recognition was the breakdown in negotiations with Myriad Genetics over the right to use the breast cancer testing kits[2].

In 2002, the Department of Health commissioned a study to look at the implications of IPRs on genomic technology with a view to developing an appropriate management response. The study was undertaken by Professor

2. As is well-known the American company Myriad Genetics holds the patents on the BRCA 1 and 2 genes. In early 2000 Rosgen and Myriad announced that they had agreed a licence agreement for the delivery of BRCA1/2 testing in the UK. As a result of the exclusive nature of this agreement Rosgen might have been placed in the position whereby they could force the NHS to stop all BRCA1/2 testing in the UK unless such testing was undertaken under a licence from Rosgen. Negotiations between the NHS and Rosgen produced an agreement over which tests NHS labs would be able to perform and set the level of royalties for the testing. The main points of this agreement were:

   - No licence fee, royalties or back charges for tests;
   - No cap on the number of patients undergoing BRCA testing in the NHS;
   - The agreement would be for the remaining lifetime of the patents
   - Rosgen would share mutation data with the NHS;
   - The NHS may purchase tests from Rosgen at a discounted rate;

   However, Rosgen went into liquidation and the Department of Health began negotiations with Myriad, to date the content of any final agreement is unknown. Initial indications from Myriad suggest that they would wish to restrict the licence to use the BRCA1 and BRCA2 sequences in order to concentrate, in Salt Lake City, a key part of the testing process - scanning for the causative mutation in a new family. Their rationale for this is that the Myriad system brings together the best of current automated sequencing technology with informatics to allow a highly specific and sensitive test for unknown mutations in BRCA1 and BRCA2. An analysis for unknown mutations can be completed in 10 to 21 days. Their current charge for a complete sequence of both genes is $2,400. The Department of Health is unhappy about not being able to conduct the tests in the UK and about the lack of any guarantee to protect the information provided in a confidential manner and also not to use it for further research purposes.

   In light of this, Myriad may grant licences for laboratories in Europe only to test for characterised mutations for confirmation of diagnosis or predictive testing and for a limited set of population-specific founder mutations. Any other use of the testing kits would have to be undertaken in conjunction with Myriad and would probably involve sending sampled tissue to the US for examination by Myriad. This carries with it concerns over privacy not to mentions worries over Myriad using the sampled tissue in its research programme which would not be controlled by UK regulation. From the information available it would seem that Myriad would allow research protocols to be exempt from licence restrictions but that they would reserve the right to define research from patient testing activities.

W.R. Cornish, Dr Margaret Llewelyn and Dr Mike Adcock. The Report, which was published in July 2003, outlines the current IPR legislation, focusing on issues surrounding patents, but also taking into account the impact of other types of IPRs. The Report also highlights other relevant areas and issues, such as human rights, that may have a role to play on the impact of access to healthcare. In addition, the Report looks at the balance between the industry and the healthcare sector, and identifies the main issues of contention. The central objective of the Report is to help develop a positive, effective and appropriate IPR management strategy and appropriate reward for the perceived benefit to society.

The type of IPR with widest impact in the field of genetics is the patent for invention. Other rights which are also addressed include copyright and its extension, database right; proposals for a right to remuneration for the copying and other exploitation of genetic information; and the protection of confidential information.

I. Patents

The patent system has an innate capacity to adapt itself to novel technologies. Unfortunately, unless legislation intervenes, change can be slow, being dependent upon practice in patent offices and decisions of courts. It is, nonetheless, vital to consider, in relation to biotechnology, what developments are necessary in patent law and practice and how they can be achieved. These are primarily the following:

(a) The definition of what subject-matter is patentable; and in particular, what should be excluded as mere discovery; information without sufficient technical effect; claims to inventiveness which lack sufficient disclosure of how to perform them; and claims which are either not novel or not inventive and so do not satisfy basic criteria of patent validity.

(b) The scope of the right granted, and in particular whether protection should extend to all methods of obtaining a product genetically engineered, and whether it should be for all potential uses of the subject-matter or only for the beneficial effect actually demonstrated - the problem, in current jargon, of the "reach through claim".

(c) The nature and extent of the research exemption for those who make use of patents in order to further clinical knowledge.

(d) The role of public interest exemptions and constraints on abuse of a monopoly position through competition law - as a means of curbing over-protection.

In relation to (a), the study notes with approval, developments which would exclude from the range of what is patentable claims upon genetic

fragments, which are not shown to have practical advantages (being mere discoveries which lack industrial application). It points out the growing significance of adequate disclosure as a legal requirement, which plays an important role in curbing claims to a gene, polypeptide or protein, whatever the means of production, when the invention is only of one method of production; and it notes the critical approach to patent validity and scope which English courts have taken in reaching decisions on biotechnology patents.

In relation to (b), it draws attention to the rising concern that patents are being granted over genes as such without any limit to the particular inventive function or use. It contrasts the need for limitation in the genetic field with the forms of claim allowed in respect of novel pharmaceuticals in general.

In relation to (c), it notes the current doubts about the scope of the research exemption in European patent law and urges clarification of two issues in particular: when can it be said that the research is upon the subject-matter of the patent? And how far can clinical trials be regarded as experimental use when they seek for further information about the patented invention at the same time as providing treatment to patients?

In relation to (d), it outlines the possible impact on patent rights of (i) the compulsory licence and Crown use provisions in the Patents Act 1977; and (ii) Rules of Competition under the EC Treaty, Articles 81 and 82 and the Competition Act 1998 (UK). It suggests that consideration of compulsory licensing could be of use where the demands of one or more patentees are proving importunate; and it addresses the use of competition law even against a person holding IP rights where the situation gives rights to an economic monopoly in healthcare provision.

II. Other IPRs

Of various other forms of IPR which may now or in the future have an impact on the exploitation of genetic knowledge, the Report draws attention particularly to:

Database right: for the right which it confers on the financier of a database over substantial extraction from it – a right with likely impact on SNP libraries and other gene-banks. Database right is distinguished from the protection of personal data and rights of access to it given by the Data Protection Act 1998.

Confidential information: for the right which resides in any information imparted or acquired in confidence against any unauthorised disclosure or use of it – a right which in principle has many applications in healthcare provision, but which in practice may prove of less substance than may at first appear.

The Report draws attention to the possibility of future extensions of rights (i) by way of copyright or unregistered design right in the representation of complex molecules; (ii) by the introduction of a utility model right; (iii) through the guarantees of life and privacy contained in Human Rights Act; and (iv) by virtue of the Data Protection Act 1998.

III. Conclusion

It is clear that the Department of Health will be directly affected by the patenting of genetic material. The impact of these patents will be two-fold. The Department will stand as a receiver of patented products and processes. It could also stand as a provider of patented products and processes developed by NHS trusts. The Department needs to develop a coherent policy for both the receipt and the provision of patented material.

Developing and thinking the Project has been assisted by three key publications: the Nuffield Council on Bioethics' discussion paper on *The Ethics of Patenting DNA*; the European Commission's report on the *Development and Implications of Patent Law in the Field of Biotechnology and Genetic Engineering*; and the UK Patent Office's *Examination Guidelines for Patent Applications Relating to Biotechnological Inventions in the UK Patent Office.*

The following recommendation were made to the Department of Health.

1. It should recognise its unique position with regard to healthcare related intellectual property and take an active role in monitoring developments in relevant areas of intellectual property law (most notably patent law).
2. It should, as provider and recipient of intellectual property, support the appropriate use of intellectual property law, and in particular patent law, in protecting inventions involving genetic material.
3. In light of the ongoing advancements in bioscience, and difficulties in establishing and maintaining concrete distinctions between types of genetic innovation, it should focus its attention not on the *type* of material being patented but on the way in which the UK Patent Office applies the new guidelines on applications involving biological material, and on equivalent decisions in the EPO; and endorse the position taken by the Nuffield Council regarding the application of the granting criteria.
4. It should have in place a mechanism for assessing:
   (i) whether to send information to the EPO or UKPO during the examination of a patent application which would restrict the scope of any patent on the disclosed genetic invention
   (ii) whether to challenge the validity of a genetic patent once granted, either in the UK before the Comptroller of Patents or in court; or

(for a European patent) by opposition proceedings in the EPO (commenced within 9 months of grant)

(iii) whether to challenge any abuse of monopoly in the manner in which a patentee exploits his rights by referring the matter to the *UK Office of Fair Trading* or the EC Competition Directorate.

5. It should seek clarification on the research use exception to patent infringement at the UK, EU, EPO and International levels; particularly with regard to use in clinical trials; and offer advice on good practice concerning the use of patented material and procedures in the course of research conducted by or in relation to its services.

6. It should establish a framework for partnership between the Department of Health and commercial providers of intellectual property (e.g. pharmaceutical companies and universities).

7. It should instigate a robust central policy for "licensing in", designed to moderate excessive demands by licensors by considering, as possible options, the use of compulsory licensing, competition law and Crown use.

8. It should adopt a balanced approach for "licensing out", particularly over the question of exclusivity, and where appropriate the Department should provide model agreements for use by Hubs and Trusts.

9. It should seek greater interaction with the Department of Trade and Industry, with which it should consider the establishment of a single UK policy on IPRs and healthcare provision (encompassing both internally generated and externally sourced innovation).

10. It should make full use of existing monitoring and horizon scanning work being undertaken by groups such as the Human Genetics Commission, the Nuffield Council on Bioethics, and the Intellectual Property Advisory Committee and make representations to these groups where necessary.