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# 4

## Conclusions

Intellectual property has existed, in some countries, for centuries, and biotechnology patents have been granted in several jurisdictions for years, but it is only in the past decade that heated controversy has arisen around the patenting of biological entities (Eisenberg, 2002b). Various theories have been promulgated to explain this fact; what is clear is that the debate has by no means been put to rest.

The patenting of DNA presents an interesting point for consideration, because it is a topic about which there is great polarity in views, not only about its effects on research and access, but also due to more basic misgivings about whether DNA is the right sort of thing to patent. Ethical, legal and scientific concerns intermingle to create a complex milieu for discussions that range from consequentialist arguments about possible practical implications, to renewed and vigorous discussion of the meaning of “innovation”. In this report, we have attempted to consider the various sides of this debate through the lens of public health.

One of the challenges with respect to DNA is that it is an upstream *tool* for basic research (e.g. PCR), a medically valuable *product* (e.g. gene therapy), as well as vital *information* about the molecular basis for disease. Some individual patents are therefore at once the basis for involved studies to develop therapeutics, and for immediate use in laboratories as research tools. That is, in some cases, DNA patents can conceivably do considerable work to encourage the development of therapeutics or diagnostics, and at the same time be needed for researchers, widely and at low cost. The Human Genome Project, which was itself a case study of innovation, employed incentives for

scientific and medical, but not primarily commercial, research. There remains, as we have seen, an unresolved question about whether such an approach can equally succeed in spurring the work needed to move the fruits of this research down the pipeline, to produce benefits for public health. In other areas, evidence suggests that a proliferation of patents has not been accompanied by a proliferation of medical applications—though this tells us only that patents are not solving the problem, not that they do not matter. While much of this perceived lag is no doubt owed to technical issues and the inherent complexity of the science, it is unclear how much is related, if only indirectly, to a failure of incentive mechanisms, including patents, to generate new and useful products and services.

We have seen that one possible exception is the field of diagnostics, where genetic tests are generally considerably easier and cheaper to develop than treatments or cures. Indeed, medicine has long been practised on a diagnostic model that acknowledges the tremendous importance of identifying risks, even in the absence of therapies. Diagnostics, then, for developing countries, appear to be a far more achievable application of genomics in the short term, to fill a very important public health need. Building the skills locally to diagnose these conditions not only addresses a real and present need facing many countries with endemic disease burdens; it can lay the groundwork for developing capacity in genomic applications more generally, and contribute to what is an ongoing effort on the part of researchers worldwide to translate the wealth of genomic knowledge into beneficial applications.

Indeed, given the complexity of the work to translate the wealth of raw genomic data into practical solutions, it would be preferable to permit as many researchers as possible to take up this challenge. Tying patent protection to products further down the development pipeline links innovation with socially valuable inventions that should give evidence of real-world utility. Facilitating widespread access to gene sequences and other upstream discoveries useful as research tools could encourage a large number of researchers and institutions to undertake the much trickier work to develop end-products—particularly if those products are assured of patent protection, or other reward. Patent standards are currently being stretched to accommodate arguably sub-patentable items such as gene sequences. While these useful discoveries may merit some protection of some kind, they in most cases may not deserve the absolute protection provided by patents that exclude access.

In developed countries, where the science is more advanced, there is talk of a transition from traditional *medical genetics*, which focuses narrowly but effectively on heritable conditions, to *genomic medicine*, which integrates genetic information into everyday clinical practice. Indeed, according to proponents of genomic medicine, it is knowledge that will transform medical practice in the long-term—knowledge of how genes interact with each other and with the environment to cause disease. In the foreseeable future, then, genetic tests will play an increasing—not a diminishing—role in the diagnosis and prognosis of a range of conditions of great public health concern in all countries. But even before we have the tools to treat or cure these conditions, we can make important strides in the areas of early detection and prevention.

In this report, the aim has been to evaluate the current landscape of issues and evidence. Here, we present the major conclusions of this report, and in each case offer proposals for avenues of fruitful investigation that could usefully inform policy-making in the future.

## 4.1 Proposals

### — Ongoing ethical, legal and social controversy regarding the patentability of human DNA

The controversy about the patenting of DNA remains unabated. This controversy is at several levels, from moral and legal claims, to consequentialist arguments about social benefit. Questions of benefit sharing also arise in relation to human genetics research, particularly regarding the obligations of inventors or researchers towards those who provide genetic samples. Many of these issues are parallel to those currently being debated within the context of biodiversity, plant genetic resources and traditional knowledge. In both cases, there is arguably a similar claim that the resource in question is both communal and “cultural”, and at the same time commercially valuable, suggesting that it is both “person” and “property” to those who have been its caretakers. One particular area where WHO with other agencies might make a useful contribution is in suggesting how policy-making around ethically thorny subject matter, such as DNA, might take better account of the legitimate concerns of the public. Some possible avenues of inquiry are as follows.

- Explore possible mechanisms for soliciting public input into policy changes relating to IP, including making use of the *ordre public* clause within TRIPS. Examine how such input might contribute constructively to the development of policy, particularly in relation to issues of widespread controversy (e.g. the patenting of biological organisms, like DNA and stem cells, and what kinds of innovation are judged to be of social value).
- Explore policies that encourage entities involved in commercial aspects of research to openly negotiate with community leaders (including disease-associated advocacy groups, in the case of genetic diseases) for

equitable benefit sharing, and create standards to guide such negotiations. Moreover, carefully assess the value of certificates of origin, or similar mechanisms, for negotiating benefits for the results of international genetic research.

- Assess the relevant similarities and differences of benefit-sharing issues relating to genetic resources derived from humans, and those derived from the environment, i.e. biodiversity. Explore what these contrasts suggest for the synergistic development of policy in these areas.
- Consider strategies for increasing the transparency of funding sources that support both public and private R&D initiatives in genomics and related fields in selected developed and developing countries, in order that there might be greater accountability for publicly supported ventures. Likewise examine ways of increasing the transparency of licensing inventions arising from federal and non-profit funding, in order to better track how inventions are being used.

### — **Ambiguity in TRIPS regarding whether DNA may be excluded from patentability**

National legislation is constrained by provisions within international agreements. TRIPS, in particular, requires that WTO Members adopt minimal standards of intellectual property protection, though countries may take advantage of certain flexibilities to protect the health and safety of their populations. In relation to DNA patents specifically, however, there is ambiguity as to whether TRIPS requires countries to grant patents on DNA sequences. DNA patents have been widely permitted in Europe and the United States, but not all countries have responded in like manner. In light of this, it would be useful to undertake the following.

- Conduct comparative studies of selected developing countries to identify ways in which they have employed flexibilities in TRIPS for the protection of health-related interests (e.g. ambiguity about some types of patentable subject matter; compulsory licences; etc.) to advance health priorities, particularly in relation to genomics.
- Compare the status of DNA as reflected in the patent law of different developing countries, and analyse how this has affected (or will in the future affect) the ability of developing countries with relatively strong research and technology bases to harness gene-based approaches to improve the health of their populations. Furthermore, evaluate how these issues intersect with the overall changes to these countries' patent systems as a result of TRIPS coming into force in these countries in 2005, with a view to providing guidance for least developed countries that must make the same transition in 2016.
- Clarify the impact of current research exemption clauses on clinical research in selected countries (both developed and developing), and particularly on genomic research. This work could help to guide developing countries in devising clear and effective methods of fostering research. In particular, issues to consider include whether the exemption should be statutory, and if so, how to define so it does not destroy reagent, instrument and other "research tool" industries aimed towards research laboratories; whether it be made explicit for non-profit and government-funded research, mandating "research use" exemptions in licensing practices; and whether it should

emerge from norms and practices (i.e. self-regulation) in technology licensing, such as through humanitarian-use licensing.

- Assess the role of petty patents/utility models in encouraging domestic innovation and weigh their use against the possible monopolization of particular fields by large companies, using petty patents. The particular value of petty patents in cumulative sectors, such as biotechnology and genomics, should also be evaluated, especially in relation to encouraging domestic innovation.

### — **Developing countries stand to benefit from genomics**

There is a body of epidemiological data that attests to the not inconsiderable burden of debilitating genetic diseases, particularly blood disorders, in developing countries. Moreover, other conditions with a significant genetic component, including heart disease, cancer and diabetes, contribute to a growing burden of common conditions among all countries. DNA-based diagnostics, which can be applied to diagnosis of both infectious and noncommunicable diseases, are generally inexpensive to manufacture. Building on the *Genomics and World Health* report, WHO and its partners can work to build a global strategy on how innovation in genomics can better serve the health needs of the world's poor. This would include considering how developing countries at the leading edge of technological development in genomics and biotechnology, such as Brazil, China, India and South Africa, could provide leadership by sharing experiences and expertise relating to the development of endogenous research capacity, as well as the development of infrastructure and capacity for appropriately evaluating, processing and enforcing patents. Questions whose answers might usefully inform such a process include the following.

- Consider how the development of low-cost, effective gene tests for use in developing countries could form a case study

for the application of a compensatory liability rules system.

- Identify platform genomic technologies, such as microarrays, that could be easily adapted for application in poor settings, as a basis for pinpointing research opportunities. For example, for infectious diseases DNA analysis could mean making links with the biodefence research establishment, particularly academic and company groups developing portable detection methods.
- Undertake studies to systematically identify genetic tests of specific importance to developing countries (particularly genetic disorders and infectious diseases), and to determine which patents exist on these tests, by whom and in which countries. These studies would also assess the current licensing agreements surrounding the use of these tests. This will fill an important lacuna of knowledge, and provide a starting point for determining concrete policy steps, where necessary.
- Study cases such as Mexico, which has adopted a national strategy for the integration of genomics into medicine, to discover the factors underlying this move, including existing capacity in molecular science and biotechnology, and to shed light on the role of patents in the innovation process in these areas.
- Assess the extent to which researchers in developing countries make use of the growing repository of publicly available genomics data, and current strategies to develop indigenous capacity in bioinformatics and data mining in low-resource settings.
- Explore mechanisms for developing countries to share experiences, and work together to strengthen the capacity of patent offices and courts to respond to the challenges of newcomer fields, like genomic

industries. In particular, develop strategies for building capacity among policy-makers in developing countries to permit them to recognize and avail themselves of the flexibilities in TRIPS.

- Explore policies in OECD countries that foster indigenous technical development, particularly in biotechnology and genomics, and assess to what extent these have been effective in generating health applications of local relevance.
- Explore patent pooling, as well as open source approaches to licensing genetic research tools, particularly genomics databases, as an alternative to proprietary approaches. In particular, assess their viability for providing incentives for the development of medical applications, such as diagnostics and therapeutics (being careful to consider relevant differences between these fields) for populations with no ability to pay.

## 4.2 Some final remarks

Research networks, and particularly those in the biotech sector, are increasingly complex; understanding how they affect, and are affected by, the patent system is by no means a straightforward project, particularly when one tries to assess the implications for countries that are behind the wave of technological development. The most productive way to move forward is undoubtedly for countries, to the greatest extent possible, to share their experiences and challenges with each other, and to work together to create best practices that can also usefully guide those likely to face similar challenges in the future. Many industrialized countries have valuable experiences at both the technical and policy levels, and international bodies should double their efforts to encourage supportive networks for information sharing and capacity building in these areas.

WHO can, as an international body principally concerned with public health, play an important

role, as it has in the past, by focusing a health-centred lens on the debate around intellectual property and in fostering dialogue in this area. It can also facilitate the studies that are needed to fill the remaining gaps in our knowledge about the true impact of intellectual property systems on health outcomes, particularly in developing countries. Indeed, in 2003 the World Health Organization, at the request of its membership, established a Commission on Intellectual Property Rights, Innovation and Public Health to consider IP in addition to broader issues impinging on health-related R&D.

It is clear that a discussion of patents does not present a complete picture of all the issues relevant to the discussion of access. The notion of innovation itself is a complex one; to the extent that patents impact on this process, they are certainly one factor among many. Education, scientific capacity, physical infrastructure, and appropriate regulatory and safety standards are among an array of components needed to ensure a functioning innovation system.

Finally, it is important to maintain a realistic and moderate view of the impact of genetics and genomics on health outcomes. The reality is unlikely to involve dramatic shifts in the short term, or even the longer term; rather, what we have seen so far suggests an evolution of practice rather than a revolution. The work of sequencing the human genome was a landmark achievement, but only a first step along a process that will inevitably take many years to achieve its full potential. Nevertheless, it is at the beginning of the process that timely consideration can be given to the possible incentives and barriers that could mould the directions of research, and affect access to its results.

Clarifying the interplay among patents, innovation and genomics could suggest one set of strategies for encouraging the right kinds of research, and a more equitable distribution of benefits.