

Chapter

6

Conclusions and
recommendations

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- 6.1 In this paper we have examined issues relating to intellectual property in the context of genetics, particularly those that concern healthcare and research related to healthcare. After considering the ethical and technical issues raised by patenting DNA sequences, we have suggested a number of ways in which the patent system should be modified for the future. We have also made a number of recommendations aimed at ameliorating the deleterious effects of patents that have already been granted.
- 6.2 Despite concerns about the application of the patent system to genetics, we accept the general view that patents have promoted the public interest by encouraging the development of new medicines and vaccines. Both to do justice to the achievements of inventors and because we recognise the importance of stimulating innovation, particularly in the pharmaceutical sector, **we conclude that exclusive rights awarded for a limited period are, in the main, defensible and that the patent system has in general worked to the benefit of people. Nonetheless, we consider that in the particular case of patents that assert property rights over DNA, consideration should be given to whether the balance between public and private interests has been fairly struck (paragraph 2.10).**
- 6.3 We note that in most countries, patent litigation is very expensive and slow. We welcome the efforts of patent offices to improve the efficiency of the various methods for challenging patents (paragraph 2.21).

Are DNA sequences eligible for patenting?

- 6.4 We have considered the question of whether DNA sequences should be eligible for patenting. Even though we think that the judgement that isolated DNA sequences are eligible for patenting is based on a questionable extrapolation to the case of genetic information from the case of the isolation of chemical compounds, we accept that a limited number of the early patents granted on that basis need not now be called into question, in view of the inventiveness required to isolate the DNA sequences. Since the early days of the pioneering experiments using positional cloning techniques, patents have been filed on many DNA sequences which were mass-produced by a mixture of computational and cloning techniques. Even if it can be convincingly argued that these sequences were eligible for patenting, the patents should be examined in the light of the criteria for inventiveness and utility. We note that as techniques have advanced, and in particular as the use of computers to identify genes has become more widespread, the eligibility of DNA sequences for patenting should have diminished (paragraphs 3.22 – 3.25).

Do DNA sequences meet the legal criteria for patenting?

- 6.5 With regard to the legal criteria for assessing patents with claims to DNA sequences, while we accept that the test of novelty can be met, the tests of inventiveness and utility are more problematic. In the case of inventiveness, we hold that as the use of computational databases becomes the standard way of identifying genes, it is difficult to see how this criterion can be fulfilled. Currently, the USPTO and the EPO differ in their application of the criterion. We take the view that the approach of the EPO, which sets a higher threshold for inventiveness, is appropriate (paragraphs 3.30 – 3.34). **We agree that rights asserted over DNA sequences that have been identified and characterised only by *in silico* analysis of**

the DNA sequence and comparisons with other identified sequences should not be allowed, on the grounds of lack of inventiveness (paragraph 5.11). In the case of utility, we argue that the standard of credibility required for a claimed utility needs to be set higher than the mere theoretical possibility of this utility; some positive evidence that the DNA sequence has the claimed utility should be required. Furthermore, the utility in question should be more than a biological function. Even if the biological function ascribed is correct, it is only a description of a fact of nature, and not a practical utility in the usual sense applied to an invented product (paragraphs 3.35 – 3.37).

- 6.6 **In light of these conclusions, we conclude that in the future, the granting of patents that assert rights over DNA sequences should become the exception rather than the norm.** However, since there are various ways in which DNA sequences can be claimed in patent applications, a generalised consideration would generate a superficial and unsatisfactory analysis. Although many patents will assert rights over more than one way of using a DNA sequence, we distinguish four applications of DNA sequences in relation to patent claims: for use in diagnostic tests, as research tools, in gene therapy, and in the production of therapeutic proteins. We consider each of these in turn.

Diagnostic testing

- 6.7 The identification of DNA sequences that are significantly associated with a disease can provide the basis for a diagnostic test. We take the view that the description of an association between a gene and a disease amounts to little more than a discovery. However, in general, the law in most countries has been generous in effectively allowing the applications of discoveries to be regarded as inventions provided that they are useful. We argue that allowing property rights to be asserted over all uses, or even all diagnostic uses, of DNA sequences in relation to diagnostic tests gives inventors too great a monopoly in the light of the contribution and inventiveness of their product, may hamper innovation and may not, in fact, satisfy the legal criteria for patenting. We think it likely that, if left unchanged, the patent system as it is currently applied to DNA sequences in the case of diagnostic tests will have a deleterious effect on the development and use of such tests. **We recommend that the criteria already in place within existing patent systems for the granting of patents, particularly the criterion of inventiveness, be stringently applied to applications for product patents which assert, inter alia, rights over DNA sequences for use in diagnosis. We recommend that the European Patent Office (EPO), the United States Patent and Trademark Office (USPTO) and the Japan Patent Office (JPO) together examine ways in which this may be achieved (paragraph 5.22).** If this recommendation were to be implemented, we expect that the granting of product patents which assert rights over DNA sequences for use in diagnosis would become the rare exception, rather than the norm. Where thresholds for inventiveness are low, as for example in the US, additional mechanisms may be needed. **We recommend, accordingly, that the USPTO and US lawmakers give consideration to whether patent laws need to be amended for this purpose (paragraph 5.22).**
- 6.8 One of the main concerns about asserting rights over a DNA sequence in a product patent is that the patent owner has exclusive rights to all subsequent uses of that sequence. One option that is often suggested as a way to avoid the deleterious effects that may arise as a result, is to limit patents on diagnostic tests based on DNA sequences to use patents, that is, patents which do not assert rights over the DNA sequence itself. If a use patent could be defined so that the owner of the patent is entitled to rights only to the use of the DNA sequence for his specific diagnostic test for a particular disease, and not *all* diagnostic tests

for that disease involving the use of the sequence, this could, on the one hand, provide sufficient incentive for the company to develop the test, and on the other, result in the development and marketing of a number of different tests for the same gene. **We conclude that the protection by use patents of specific diagnostic tests which are based on DNA sequences could provide an effective means of rewarding the inventor while providing an incentive for others to develop alternative tests (paragraph 5.24).**

- 6.9 Patents have already been granted on diagnostic tests that are based on genetic information. We do not support a wholesale and indiscriminate use of compulsory licensing. **Rather, in those specific cases in which the enjoyment of exclusive rights to the diagnostic use of a DNA sequence is not in the public interest, we recommend that those seeking to use the diagnostic tool or develop an alternative should seek a compulsory licence from the relevant authorities if they are refused a licence from the owner of those rights on reasonable terms, and we encourage the authorities to grant such a licence (paragraph 5.29).** We also note the suggestion made by the Organisation for Economic Co-operation and Development (OECD) of a 'clearing house' to ease the obtaining of licences for 'genetic inventions' by commercial laboratories.¹ We suggest that this concept, which might reduce transaction costs, should be explored further (paragraph 5.29).

Research tools

- 6.10 The identification of a gene may belong to the broad category of scientific findings which have no immediate commercial use in themselves but which have been dubbed 'research tools' since they can, like any other scientific information, guide the design of future research. We take the view that the exercise of a monopoly over what are now essentially discoveries of genetic information, accessible by routine methods is, in principle, highly undesirable. We consider that the development of a culture among those who carry out scientific research, whereby claims are made to naturally-occurring material which can be isolated by routine procedures and to which a weakly demonstrated or hypothetical utility may be ascribed to secure some possible future value, if endorsed by the patent offices, amounts to a misapplication of the patent system.
- 6.11 **We consider, therefore, that in general, the granting of patents which assert rights over DNA sequences as research tools should be discouraged (paragraph 5.41).** We take the view that that the best way to discourage the award of such patents is by a stringent application of the criteria for patenting, particularly that of utility. **We therefore welcome the recent Utility Guidelines for DNA sequences introduced by the United States Patent and Trademark Office (USPTO), which have, in effect, been endorsed by the European Patent Office (EPO) (paragraph 5.41).**² We suggest that there must be some evidence for the specific and substantial utility claimed in the patent application in order for it to be credible. We consider that the introduction of the Guidelines should go some way to mitigate the tendency of some patent offices to allow rights in relation to DNA sequences to be asserted when any demonstration of utility is, at best, weak. However, it is not yet certain whether they will prove to be sufficient: they have only been in operation for 18 months. **We recommend, therefore, that the United States Patent and**

¹ Organisation for Economic Co-operation and Development. Short summary report of the workshop on Genetic inventions, Intellectual property rights and licensing practices, Berlin, Germany, 24-25 January 2002. Available at <http://www.oecd.org/pdf/M00031000/M00031448.pdf>

² USPTO Utility Examination Guidelines Fed. Reg. 66: 1093. 5 Jan 2001. <http://www.uspto.gov/web/offices/com/sol/notices/utilexmguide.pdf> (20 May 2002).

Trademark Office (USPTO), the European Patent Office (EPO) and the Japan Patent Office (JPO) should monitor the impact of the Guidelines on the examination of patents to ensure that the criterion for utility is rigorously applied so that the grant of a patent more properly reflects the inventor's contribution. If this proves not to be the case, the Guidelines should be reviewed and strengthened to achieve this purpose (paragraph 5.41). Taking further corrective action (if it is needed) cannot be allowed to wait unduly long. As we observed in the case of DNA sequences as they are used in diagnosis (paragraph 5.29), we expect that if this recommendation is implemented, the result will be that patents which assert rights over DNA sequences for use in research will become the rare exception rather than the norm.

- 6.12 If rights in relation to a partial DNA sequence or EST are asserted in a patent, it is possible that the patent will also extend to the full DNA sequence, even though the full sequence may be isolated by someone else without using the EST in question. There is wide agreement that patent protection of partial DNA sequences such as ESTs should not be granted in broad terms. **We recommend that when rights are asserted in terms intended to cover all sequences that contain the EST that is the subject of the original patent, no patent should be granted (paragraph 5.38).** We also endorse the serious concerns expressed by the Human Genome Organisation (HUGO) about the possible deleterious effect on the further progress of genetic research and the successful exploitation of its results, should broad claims within patents of the so-called 'having' and 'comprising' type, be issued for ESTs. We endorse the call of HUGO to patent offices not to issue patents on ESTs without having found solutions to the problem of dependent patents (paragraph 5.38).³ (A dependent patent is one whose exploitation would encroach upon the exploitation of an earlier patent.)

Licensing DNA sequences for research

- 6.13 Many organisations, particularly universities and biotechnology companies, have already been granted patents claiming DNA sequences which have a primary use as research tools. Such organisations are often not well placed to undertake extensive product development and distribution and will often seek to realise the value of their patents through licensing. Under these and other circumstances, the risk arises that an important patent may be licensed exclusively. The resulting exclusivity may not be in the public interest: it may discourage others from working in an area which would profit from a variety of approaches or solutions. **We recommend that those public institutions which already have been awarded patents that assert rights over DNA sequences as research tools be strongly encouraged not to licence them exclusively to one or a limited number of licencees, even when, by not doing so, they may suffer some loss of revenue in the short term. We also recommend that, wherever possible, the private sector should consider non-exclusive licensing for those DNA sequences which are used in research (paragraph 5.42).**

The research exemption

- 6.14 Many researchers want to make use of patented DNA sequences in research when there is no obvious prospect of commercial development arising from that use. This situation will arise in the context of most academic research, as well as some research in industry. Research may be undertaken on inventions which have been patented, including DNA sequences.

³ HUGO. HUGO Statement on patenting of DNA sequences - In particular response to the European Biotechnology Directive. London: HUGO; 2000.

This is generally referred to as the 'research exemption'. Most patent systems have some form of exemption to enable research to be carried out on a patented invention provided it is not intended to produce commercial benefit, so as to ensure that innovative research is not stifled. **We recommend that the 'research exemption' is given a statutory basis in the US and clarified in Europe by policy-makers as a matter of urgency (paragraph 5.45). We further recommend that companies work together to extend the concept of the 'research exemption' throughout industry for DNA sequences which appear in patents and which have a use in research (paragraph 5.45).**

Gene therapy

6.15 Gene therapy aims to replace a faulty gene with a normal gene by introducing it into the body. **We consider that once a gene which is associated with a disease is identified, the use of the relevant DNA sequences in gene replacement therapy, to alleviate the effects of mutations in that gene, is obvious (particularly when such use is claimed on a purely speculative basis). Therefore, we recommend that protection by product patents should seldom be permissible (paragraph 5.49).** We can imagine other forms of gene therapy, where some innovation more complex than simply replacing a damaged gene is involved, which may constitute an inventive step. Certainly, some kind of incentive in the form of patent protection is needed to encourage the development of valid and effective gene therapy. It is a difficult area of technology which requires investment. **We believe that patent protection should be concentrated on developing safe and effective methods of appropriate gene delivery (paragraph 5.49).** This is where the real inventiveness and investment will be required, rather than in simply defining the sequence of the genes to be used in treatment.

Therapeutic proteins

6.16 Therapeutic proteins are proteins produced directly from DNA sequences (in other words, gene products) that have been developed into medicines. We conclude that patents for therapeutic proteins which include the assertion of rights over the relevant DNA sequence are justified (paragraph 5.55). **However, we take the view that while rights asserted over DNA sequences which are used to make new medicines based on therapeutic proteins are generally acceptable, they should be narrowly defined. By this we mean that the rights to the DNA sequence should extend only to the protein described (paragraph 5.56).**

Limiting the scope of product patents in relation to DNA sequences

6.17 The law in many countries, including the US and Europe, has tended to be generous in granting patents which assert rights over DNA sequences. Furthermore, the effects of many of these patents are extensive, because inventors who assert such rights obtain protection on all uses of the DNA and, sometimes, also the proteins which the DNA produces. It is a feature of DNA that one gene will often generate more than one product, for example, different proteins. Consequently, finding novel uses for DNA sequences will be a relatively common event. This is not generally the case in other areas of patenting. The effect of the recommendations which we have made so far in this Paper would be to reduce substantially the number of patents that assert rights over DNA sequences. We consider that if they are granted, there is a strong case to be made for limiting the scope of such patents. If our recommendations are not adopted, then it would be that much more important to develop a mechanism which would limit the scope of product patents. **We recommend, therefore, that the United States Patent and Trademark Office (USPTO), the European Patent**

Office (EPO), the Japan Patent Office (JPO) and other relevant bodies give consideration to the concept of limiting the scope of product patents that assert rights over naturally-occurring DNA sequences to the uses referred to in the patent claims, where the grounds for inventiveness concern the use of the sequence only, and not the derivation or elucidation of the sequence itself (paragraph 5.62).

Scrutiny of patent applications from the perspective of ethics

6.18 There are some inventions that meet the necessary legal criteria for patentability which are excluded from patenting under various international agreements. We note that the scrutiny of patent applications by reference to their being contrary to morality or '*ordre public*' requires expertise in areas that may not be represented in patent offices. These areas include moral philosophy, environmental ethics and public policy. **We recommend that the European Patent Office (EPO) should consider producing further guidance which clarifies the principles set out in Article 53(a) of the European Patent Convention (EPC) concerning patents that are contrary to morality or '*ordre public*'. We recommend that the EPO seek general guidance from the European Group on Ethics (EGE) (paragraph 3.48).**