Institution: University of York

Unit of Assessment: 32, Philosophy

Title of case study: The Ethics of Patenting DNA

1. Summary of the impact (indicative maximum 100 words)

The Ethics of Patenting DNA was a Nuffield Council on Bioethics Report by a working party of which Thomas Baldwin was a member with responsibility for providing the ethical framework for the report. The report was published in 2002 and its initial impact occurred in the 2002-2005 period; but it has had continuing impact during the current period on legal and political debates concerning the granting of patents on DNA sequences to pharmaceutical and biotechnology companies and to universities. More generally it continues to have a significant impact on policy formation in this much disputed area.

2. Underpinning research (indicative maximum 500 words)

Thomas Baldwin has worked for many years in moral and political philosophy (see, for example: 'The Territorial State', in Jurisprudence; Cambridge Essays eds. T. R. Harrison & H. Gross, Oxford: Clarendon Press, 1992, 207-230; 'The Three Phases of Intuitionism', in Ethical Intuitionism: Re-evaluations ed. P. Stratton-Lake, Oxford: Clarendon Press, 2002, 92-112; and 'Recognition: Personal and Political', in Politics, Philosophy & Economics 8 2009, pp. 311 – 28).
He is a rational intuitionist who defends the existence of fundamental deontological truths, but also accepts that only some of these are structural and universal while others are 'practice based', that is they take their precise character from the nature of the contingent practices which moral agents find themselves in. This Idea that there can be fundamental but practice-based duties is an underlying principle in all Baldwin's work in applied ethics, allowing him to avoid both relativism and particularism while accepting that the detailed principles endorsed, about for example patenting DNA, are dependent upon the contingencies of the situation in which we find ourselves. We illustrate this point in more detail below.

Baldwin's main responsibility, as the philosophical representative on the working party assessing the ethical legitimacy of intellectual property in respect of DNA sequences, was to elucidate the normative basis of the present legal systems for intellectual property and assess the application of this system to DNA sequences. Within the report his contribution occurs largely in chapter 2 ('The patent system') and chapter 3 ('Patenting DNA'), but the group worked closely together on all aspects of the report, including the recommendations. Since the publication of the report he has continued to work in this field.

The report aimed to strike a balance between wholesale rejection of patents which involve human DNA sequences and straightforward endorsement of the practice by patent offices. While there is considerable public support for the former alternative since the very idea of patenting human genes seems repugnant, it fails to take account of the development of intellectual property (IP) law in biology during the 20th century. For that law has accepted the principle that the production of valuable compounds by innovative methods for purifying naturally occurring substances does merit patent protection where their utility has been established and disclosed. The report accepts this principle, but argues that in some cases it has not been properly applied when used to justify the grant of a patent to applications for patents on human DNA sequences. For patents on DNA sequences have been granted by patent offices, and, when challenged, confirmed by the courts, despite the facts (a) that the methods or products on which the patents were granted had not been properly assessed by the normal tests for inventiveness and utility, and (b) that in some cases the patents granted were much too broad, in that they covered speculative future applications not substantiated in the application. The report also argues that there is an important distinction between (i) the development of diagnostic tests which use discoveries concerning the significance of certain human DNA sequences and (ii) the production of synthetic proteins by novel techniques which start from discoveries concerning the human DNA sequences which are responsible for their

production in the human body. In the first case it is argued that the granting of patents for DNA sequences used in genetic diagnostic tests is contrary to the traditional invention/discovery distinction since it is only inventions that are patentable, whereas genetic diagnostic tests rely only on discoveries concerning the significance of certain DNA sequences. By contrast, the granting of patents for the production of synthetic proteins by novel techniques based on DNA sequences is in principle acceptable, but in such cases the patent should primarily cover the method of synthesis disclosed in the patent application and not the basic DNA sequence as well, since that is not an invention but a discovery.

3. References to the research (indicative maximum of six references)

The Ethics of Patenting DNA, Nuffield Council of Bioethics, London, 2002 (http://www.nuffieldbioethics.org/sites/default/files/The%20ethics%20of%20patenting%20DNA%20a%20discussion%20paper.pdf).

Evidence of research quality

Evidence of the quality of the contribution is the reception of the report by major figures working in the area, its citation in the relevant journals on this issue and major organisations dealing with biomedical issues, for example the World Health Organisation, and Baldwin's continued receipt of invitations to publish in this area (such as 'Ethics and Patents for Genetic Diagnostic Tests', in Gene Patents and Public Health, ed. G. van Overwalle, Etablissements Emile Bruylant, Brussells, 2007. pp. 45-60)

Editorial 'Putting an end to business as usual' in The Lancet, 3 August 2002 (2002 http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(02)09595-8/fulltext#)

Review 'Crackdown on DNA patents needed', The Scientist, 23 July 2002 (http://www.the-scientist.com/?articles.view/articleNo/21407/).

A report from the US National Human Genome Research Institute (part of the NIH) of their Roundtable on Genetic Patenting (December 2002) comments that 'The discussion paper, "The Ethics of Patenting DNA," by the Nuffield Council on Bioethics, is thoughtful and presents potential solutions to patenting issues' (see http://www.genome.gov/11007377)

Timothy Caulfield, Robert M. Cook-Deegan, F. Scott Kieff, John P. Walsh 'Evidence and Anecdotes: An Analysis of Human Gene Patenting Controversies', Nature Biotechnology. 2006 September; 24(9): 1091–1094. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2701726/

G. Dutfield 'DNA patenting – implications for public health research', Bulletin of the WHO 84 (2006), 388-92. http://www.who.int/bulletin/volumes/84/5/388.pdf

4. Details of the impact (indicative maximum 750 words)

The initial impact of the report occurred in the period 2002-2005 in the UK. However, its plausibility and substance – as evidence of which we quote the initial response to the report below – has led to it having a continuing international impact with important developments within the REF period with a substantial range of its expected beneficiaries, namely legislatures, the courts and policy makers in countries where genetic patenting is a substantial issue, such as the USA and the EU.

When it was published in 2002 this report was widely regarded as a major development in the discussion of the contentious issue of 'gene patents'. Maggie Ponder, chair of the Genetic Interest Group, said: "Families and individuals affected by genetic disorders wish to see the speediest development of new understanding and techniques. They also want to see the affordable application of this knowledge and technology. In the view of the Genetic Interest Group, the Nuffield Council have struck the right balance between what can be competing pressures in both research and applications." Dr Robin Lovell-Badge, Head of Development Genetics at the National Institute for Medical Research, agreed "I think this report will be very useful. I agree that in most

cases a simple DNA sequence should not be patentable. But it is not always so obvious that a particular DNA sequence causes a disease, and a considerable investment of time and resources may be involved in its discovery. In these cases it seems more reasonable that a company should be able to protect its investment and discovery with a patent." For more detailed responses at the time of publication in 2002 from the full range of potential beneficiaries, see http://www.sciencemediacentre.org/scientists-comment-on-dna-ethics-report-2/

Lawyers in particular welcomed the report's approach of using well established criteria for the validity of patents to criticise some DNA patents as unwarranted. While a wholesale denunciation of the morality of gene patents might have attracted popular support, it would not have had much practical impact. Lawyers have also taken up the report's distinction between patents based only on diagnostic tests and those based on new methods of producing therapeutic proteins. In the USA much recent interest in this issue has been aroused by the case started in 2009 by the American Civil Liberties Union (ACLU) to challenge the patents on breast cancer genes granted to the Myriad Corporation on the basis of their use in diagnostic tests for susceptibility to breast cancer. In 2010 Justice Sweet upheld the ACLU case against Myriad in the New York Federal District court on grounds similar to those articulated in the Nuffield Report. Myriad's appeal against this decision was largely upheld in the Federal Circuit Court of Appeals, but the case was sent to the US Supreme Court which reached a complex judgment in June 2013, striking down Myriad's patents on naturally occurring DNA sequences, but allowing the patentability of complementary DNA sequences which lack naturally occurring introns. In the present context, what is significant about the debates surrounding this case is the way in which the Nuffield report is still cited in discussions of the issues as an authoritative contribution and the fact that the court's emphasis on the significance of the invention/discovery test largely replicates that in the Nuffield report. Our case is that the evidence of reception of the report, continued reference to it in other contexts, and structural similarity of the reasoning, makes it plausible that this is a further evidence of its impact.

As further evidence of the report's crossing of the Atlantic to influence the legal debate there, and as a substantial impact on the legislature in the US in its own right, it is notable that the report also turns up in a US Congressional report and National Institutes of Health (NIH) briefings in the period. Further, in their 2009 submission to the Senate Standing Committee on Community Affairs Inquiry into Genes, the Australian Law Reform Commission (ALRC) referred to their report on Genes and Ingenuity: Gene Patenting and Human Health (ALRC 99, 2004). This report describes the approach to the test for inventiveness recommended in the Nuffield report (see 6.83-7 of the ALRC report) and in its conclusion it affirmed the Nuffield position (see 6.95-7). A recent briefing note by the UK Parliamentary Office of Science and Technology on this issue (taking note of the legal debates in the USA) also cites the Nuffield report in 2012.

5. Sources to corroborate the impact (indicative maximum of 10 references)

USA
The report is referred to in
(i) The 2010 US congress report on 'Current Issues in Patentable Subject Matter: Business Methods, Tax Planning Methods,and Genetic Materials' by John R. Thomas (see http://ipmall.info/hosted_resources/crs/R40681_010610.pdf),
(ii) The 2010 NIH Report on Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests by the Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS) (see http://oba.od.nih.gov/oba/SACGHS/SACGHS%20Patents%20Report%20Approved%202-5-20010.pdf).
(iii) The further 2013 NIH posting from National Human Genome Research Institute on this issue lists the Nuffield report as a source (see http://www.genome.gov/19016590).

UK
The Nuffield Report is cited in a 2012 note on by the Parliamentary Office of Science and Technology (POST) on Biomedical Patents (available at www.parliament.uk/briefing-papers/POST-PN-401.pdf)

Australia:
Genes and Ingenuity: Gene Patenting and Human Health (ALRC 99, 2004). This report describes the approach to the test for inventiveness recommended in the Nuffield report (see 6.83-7 of the ALRC report) and in its conclusion it affirmed this position (see 6.95-7). The report is supported by the 2009 report of the Senate Standing Committee on Community Affairs inquiry into Gene Patents - http://www.alrc.gov.au/senate-standing-committee-community-affairs-inquiry-gene-patents; and in 2011 the Australian Government accepted most of the recommendations in the report – see http://www.alrc.gov.au/news-media/2011/government-response-alrcs-2004-report-genes-and-ingenuity-gene-patenting-and-human-h

Some recent reviews of the legal debates which refer to the Nuffield report:
Lisa Larrimore Ouellette 'Access to Bio-Knowledge' Stanford Technology Law Review, N1 (2010) (esp. §§17-20, 23-5).

Carlo Petrini 'Ethical and legal considerations regarding the ownership and commercial use of human biological materials and their derivatives', Journal of Blood Medicine 3 (2012) 87-96

Julia Carbone, E. Richard Gold, Bhaven Sampat, Subhashini Chandrasekharan, Lori Knowles, Misha Angrist, Robert Cook-Deegan 'DNA patents and Diagnostics: Not a Pretty Picture', Nature Biotechnology, 28(8) (2010): 784–791.

Chester S. Chuang, Denys T. Lau, 'Patenting Human Genes: The Myriad Controversy', Clinical Therapeutics 32:12 (2010), 2054-6.

V. Ling 'Patently Ours? Constitutional challenges to DNA Patents', Journal of Constitutional Law 14:3 (2012), 813-48.