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## **The Bristol and Eli Lilly cases: Creation--God or humankind?**

### **Case Comments**

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#### Law and Religion

In the debates that have arisen over the creation of the world and of humankind, there is a broad spectrum of belief starting with creationism and young earth creationism, the belief that the world was literally created in 6 days

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(William Jennings Bryan and later Henry Morris and John Whitcomb), through to theistic evolutionists, who understand evolution as an explanation of the way that God created diversity over time (Benjamin Warfield and James Orr), and on to those who hold to the concept of intelligent design (Phillip E Johnson), the belief that whilst evolution explains certain steps in the process, the intervention of a designer is needed at specific points to provide the complete picture. Further on are those agnostics, such as Darwin, who brilliantly obtained insight into the process of evolution but were unsure about the ultimate designer or creator, and finally those, such as Richard Dawkins, falling firmly into the category of atheist at the other end of the spectrum, who argue for a purely scientific explanation of creation without the involvement of God.<sup>1</sup> It is difficult to find amongst this community anyone who would argue that human beings created the world and humankind. When, however, a step is taken into the world of the patenting of biotechnical inventions and biological materials, the theological and theoretical ground starts to shift under one's feet. This commentary will consider the *Bristol* and *Eli Lilly* cases<sup>2</sup> on the patenting of biotechnical inventions and biological material in the light of the deontological and consequentialist basis of the reasoning of the Court of Justice of the European Union and the Supreme Court of the UK, respectively, to seek to discover whether a more cautious approach needs to be taken in the interpretation of the legislative provisions and case law.

According to the Agreement on Trade-Related Aspects of Intellectual Property Rights patents 'shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application'.<sup>3</sup> The grant of a patent can be refused in order to prevent the commercial exploitation of an invention on grounds of public policy or morality, including for the protection of human, animal or plant life or health or to avoid serious prejudice to the environment.<sup>4</sup> European Union patent law permits the patenting of a biotechnological invention but regards the uses of human embryos for industrial or commercial purposes as unpatentable.<sup>5</sup> It further permits the patenting of a naturally occurring gene where its industrial application is disclosed.<sup>6</sup> Thus, a patent can

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be obtained for a biotechnical invention provided it does not involve the use of human embryos and provided it is not excluded on any other public policy ground, and a patent can also be obtained for the discovery of a gene sequence or the protein which it encodes *provided* that the application discloses how it can be used. This framework can be said to accord with the Christian theological view that whilst there is a created moral order human beings have a role in exercising responsible stewardship within that order. Human creativeness and inventiveness play a legitimate role as part of that stewardship. Responsible stewardship needs, however, to operate within certain moral constraints, namely: (i) The just claims of other persons not to be harmed. (ii) The requirement that innovation serve intrinsically worthwhile ends/goals. (iii) The requirement that possible evil side effects not be rashly down played. (iv) The requirement that the benefits of innovation be justly distributed.

The *Br, stle* case concerned a challenge by Greenpeace eV to a patent held by the neuroscientist Oliver Br, stle concerning isolated and purified neural precursor cells, processes for their production from embryonic stem cells and use of neural precursor cells for treatment of neural defects. Greenpeace argued that the patent was unlawful in so far as it involved the patenting of the 'human embryo' since this was contrary to Article 6(2)(c) of Directive 98/44/ EC. On a reference from the Bundesgerichtshof, Germany, concerning, *inter alia*, whether or not human embryonic stem cells which served as base material for the patented processes constituted 'embryos' within the meaning of Article 6(2)(c) of the Directive and whether organisms from which those human embryonic stem cells could be obtained constituted 'human embryos', the Court of Justice of the European Union ruled that the term 'human embryo' had to be understood in the wide sense and included any human ovum after fertilization, any non-fertilized human ovum into which the cell nucleus from a mature human cell had been transplanted, and any non-fertilized human ovum whose division and further development had been stimulated by parthenogenesis. It left the national court to decide in the light of scientific developments whether a stem cell obtained from a human embryo at the blastocyst stage constituted a 'human embryo'. It further ruled that the exclusion from patentability of human embryos for industrial and commercial purposes also meant that a patent could not be made available for the use of human embryos for the purpose of scientific research and that likewise no patent could be granted where the technical teaching which was the subject matter of the patent application required the prior destruction of human embryos or their use as base material.

The court in its reasoning and despite its protestations to the contrary,<sup>7</sup> was to a certain extent called upon not simply to apply the letter of the law to the

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facts of the case (no mean feat in itself in a field as technical as this) but according to Recital 39 of the Directive, it was also called upon within the scope of its teleological interpretation of the legislation to ensure it was sensitive to 'ethical and moral principles recognised in a member state, respect for which is particularly important in the field of biotechnology in view of the potential scope of inventions in this field and their inherent relationship to living matter [given that] such ethical or moral principles supplement the standard of legal examinations under patent law regardless of the technical field of the invention'. The court did acknowledge Recital 16 of the Directive, this required that 'patent law must be applied so as to respect the fundamental principles safeguarding the dignity and integrity of the person'.

The decision of the Court of Justice can be seen as a triumph of deontological reasoning, already undergirded by the manner in which the legislation in this area had been formulated. The prohibition against the patenting of the human embryo for commercial or industrial purposes, including for the purposes of scientific research was absolute (only use for therapeutic or diagnostic purposes which were applied to the human embryo and were useful to it were patentable). The decision was taken by the legislators that to permit such patents was morally wrong and, therefore, an absolute prohibition was put in place. The Court of Justice by applying a wide definition to the term 'human embryo' reinforced this deontological approach. Mr Br, stle's invention had been developed in particular for patients suffering from Parkinson's disease. A consequentialist approach to this matter could, therefore, have been to argue that such great benefit would flow from the granting of the patent that a narrow definition of the term 'human embryo' should be applied, which could have resulted in the granting of the patent.

The deontological approach taken by the Court of Justice would also fit firmly into the spectrum of belief and scientific approach to creation outlined above. Creationists and atheists alike would not claim that one hu-

man being 'invented' another human being such that a patent could be granted for that 'invention'. Although at some point along that spectrum, academics would no doubt disagree as to the point at which 'creation' whether it is by divine mandate or by scientific explanation ceased and 'invention' such that humankind was entitled to claim a patent over it commenced. One's view on how creation happened, continues to happen and is sustained, necessarily affects one's view on what humankind can and cannot be said to have 'invented'. It is difficult to discern whether such concepts subconsciously informed the decision of the Court of Justice or not.

The reasoning in the *Br, stle* case provides a stark contrast to the approach taken by the Supreme Court of Justice of the UK in the *Eli Lilly* case.

The *Eli Lilly* case concerned a patent application for the discovery of a protein and the elucidation of its nucleic acid and amino acid sequences. The patent could only be granted if the discovery was 'susceptible of industrial application'. The issue in the case was how far did the applicant have to go to show that it was 'susceptible of industrial application'?<sup>8</sup> Lord Neuberger's

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reasoning is strongly consequentialist as is Lord Hope's. Lord Neuberger after considering national, European and US jurisprudence, rejected the more restrictive interpretation of the term given by the High Court and the Court of Appeal and adopted the approach of the Board of Appeal of the European Patent Office which included at point XIII, the statement that if the disclosure is 'important to the pharmaceutical industry' the disclosure of the sequences of the protein and its gene may suffice, even though its role has not 'been clearly defined.' It had to nevertheless demonstrate a 'real as opposed to a purely theoretical possibility of exploitation'.<sup>9</sup> Lord Neuberger then went on to conclude that the disclosure of the existence of the protein in question and its gene sequence and its membership of the TNF ligand superfamily should have been sufficient, taking into account the common general knowledge, to satisfy the requirements of Article 57 of the European Patent Convention that the 'invention' had to be susceptible 'to industrial application'. Lord Hope at paragraph 141 referred to 'the immense benefits in the promotion of human health, particularly in the combating of a wide range of degenerative diseases previously thought to be incurable and in the provision of techniques for the effective treatment of cancers.' Furthermore, he notes 'patent portfolios are often the most valuable asset of companies in the bioscience industry ... assessments of the value of a bioscience company's patent portfolio are likely to be a key consideration in deciding whether to acquire or invest in such a company.' He further notes at paragraph 143, that 'the bioscience industry is particularly dependent on funding for long term research and development and that in the case of the discovery such as that of the protein in question there could be a long gap between that discovery and the point at which it became susceptible to industrial application'. This leads him to conclude that the requirements for proving that an 'invention' was susceptible to industrial application were lower in the field of biological material.

With the application of consequentialist reasoning the Supreme Court is therefore able to narrow the application of legislation in order to create a more permissive legislative environment for the grant of patents in respect of biological material. This provides a direct contrast to the approach taken by the Court of Justice in the *Br, stle* case.

In both cases there were immense benefits that would flow from the research yet this did not cause the Court of Justice to waiver in its approach. One explanation for the contrast could be that because in the *Br, stle* case the court was dealing with the definition of 'human embryo' and a deontological approach was already set out in the legislation, its scope for consequentialist reasoning of any kind was limited, whilst in the *Eli Lilly* case the issue turned on whether the 'discovery' was 'susceptible to industrial application' and therefore by its very nature invited consequentialist reasoning.

There are two problems with this approach. First, it avoids the essential issue in the *Eli Lilly* case, which was at what point is it possible to say that humankind has 'created' something rather than simply 'discovered' it. Patents are, after all, awarded for inventions. Whether one takes a theistic approach or

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scientific approach to the process and the sustaining of creation, Recitals 16 and 39 of the Directive are clear--there are certain moral issues including concerns for human dignity that arise in this field. Decisions

should be taken carefully especially in those courts that create precedent for future application and those courts should perhaps allow deontological and teleological reasoning at least to have a place before focusing on the consequentialist arguments that might ultimately decide the case. If God created and sustains the world, how can humankind ever claim to have 'invented' that creation by simply discovering how it works? Whilst there still remains a requirement that there be a 'real possibility of exploitation' of the discovery, the system of granting patents for the discovery of biological material has become more permissive and it is now easier to justify patentability based on the consequentialist reasoning of the Supreme Court.

Second, it has been argued that justice in any society can be measured by the way in which that society treats its weakest and most vulnerable members.<sup>10</sup> The Swiss constitution in its preamble puts this as follows:

*We, the Swiss People and the Cantons, being mindful of our responsibility towards creation, in renewing our alliance to strengthen liberty and democracy, independence and peace in solidarity and openness towards the world, determined, with mutual respect and recognition, to live our diversity in unity, conscious of our common achievements and our responsibility towards future generations, certain that free [are] only [they] who use [their] freedom, and that the strength of a people is measured by the welfare of the weak.*

Those who have a high view of the status of the human embryo<sup>11</sup> would argue that the human embryo falls into the category of the weak and vulnerable and therefore the formulation and interpretation of law in this area should be undertaken with special care bearing in mind the effect on society of any resulting injustices in the event that the wrong decisions are taken.

<sup>1</sup> For a fuller explanation of the various theories of creation see: Nick Spencer and Denis Alexander, *Rescuing Darwin. God and Evolution in Britain Today*. (Theos 2009).

<sup>2</sup> *Brüstle v Greenpeace eV* (Case C-34/10); *Eli Lilly & Co v Human Genome Sciences Inc* [2011] UKSC 51.

<sup>3</sup> Art 27 of the Agreement on Trade-Related Aspects of Intellectual Property Rights, Annex 1C to the Agreement establishing the World Trade Organization (WTO) signed Marrakech 15 April 1994, approved by Council Decision 94/800/EC (OJ 1994 L 336, 1).

<sup>4</sup> See art 27(2).

<sup>5</sup> Parliament and Council Directive 98/44/EC of 6 July 1998 on legal protection of biotechnological inventions (OJ 1998 L213, 13) whereby inventions 'susceptible of industrial application shall be patentable even if they concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used': see art 3 of the Directive. According to art 5 of that Directive 'the human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions' but 'an element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of natural element.' According to art 6 (2) 'inventions shall be considered unpatentable where their commercial exploitation would be contrary to ordre public or morality ... in particular (c) uses of human embryos for industrial or commercial purposes' shall be considered unpatentable.

<sup>6</sup> Art 5 of Directive 98/44/EC.

<sup>7</sup> See para 30 of the Court's judgment where it explained, with reference to *Mayr v Bäckerei und Konditorei Gerhard Flöckner OHG* Case C-506/06 [2008] ECR I-1017, that it was not required by the order of reference to broach questions of a medical or ethical nature but that it should restrict itself to a legal interpretation of the relevant provisions of the relevant Directive. The *Mayr* case, however, concerned the employment rights of Ms Mayr whilst she was undergoing IVF treatment and did not concern the application of the biotech Directive. Given the nature of the area under consideration in *Brüstle* and the choices before the court, it is difficult to see how the court could avoid taking a decision based on ethical and moral principles

whether explicit or not. By insisting on a wide interpretation of the term 'human embryo' it was safeguarding the dignity and integrity of the person. This in itself provided a moral basis for its ultimate decision.

<sup>8</sup> European Patent Convention arts 52 and 57.

<sup>9</sup> See [2011] UKSC 51, para 107(5).

<sup>10</sup> A biblical basis for this can be found in Matthew 25:41-46. Famous individuals who have support this view include Winston Churchill, Pope John Paul II, Fyodor Dostoyevsky and Harry S Truman.

<sup>11</sup> For a discussion of the nature of personhood see Stephen E Lammers and Allen Verhey (eds), *On Moral Medicine* (2nd edn, William B Eerdmans Publishing Company 1998). For a discussion of respect for human life and dignity in the context of technological reproduction see Lammers and Verhey *ibid* 465-519 and for a discussion on research and experimentation see especially pages 932-41. For further discussion see also Mason and McCall Smith, *Law and Medical Ethics* (Kenyon Mason and Graeme Laurie eds, 7th edn, OUP 2006). Intellectual property law and the human body: see Ch 15, medical research: see Ch 18 and research on embryos: see Ch 19.