

Chapter 17

PATENTING AND THE HUMAN BODY

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A. Introduction	

17.01 Access to medical treatments and medicinal products, the availability of new diagnostic tools, and the future direction of biomedical research are all profoundly influenced by the existence and exercise of intellectual property rights (IPRs). The philosophy of the intellectual property regime is disarmingly simple: the promise of a private property right to control the exploitation of a new creation—be it a drug, an artistic work or the design of a new article of commerce—encourages others to create and make their creations available to the community, all in the name of the public good. The reward to the innovator is a monopoly right, limited in time, to exclude competitors from the marketplace. The strength of the monopoly varies depending on the particular intellectual property right in question. Thus, for example, copyright only prevents direct copying of the work that is protected, whereas patent protection confers an absolute monopoly of the market making it possible to exclude even the innocent infringer who has independently and unknowingly invented the same product. Compensation for this uneven breadth of protection between these IPRs is reflected in the duration of the respective rights. Strong patent protection lasts a maximum of 20 years,¹ while weaker copyright in original works subsists for the life of the author and 70 years *post mortem auctoris*. It is clear from this that intellectual property law is about seeking a balance between a range of potentially competing interests. A host of tensions abound. On the one hand, there is the need to regulate competing private interests between property rights holders and other entrepreneurs who may, as a result, be excluded from the market. This in turn has consequences for the public interest lest excessive monopolistic control reduces consumer choice and services. Relatedly, there is the perennial problem of striking an acceptable balance between the offer of attractive and effective IPRs and the restriction on the grant and exercise of those rights when protection of them no longer serves the public good. Nowhere is the tension felt more acutely than in the realm of patent law, and it is this area of intellectual property law that impacts most directly on the provision of health

¹ Supplementary Protection Certificates are available in various jurisdictions for pharmaceuticals and agrochemicals to extend the protection period by up to five years. The rationale is that such inventions are delayed in reaching the market because of stringent safety regulations and so the actual time afforded to patentees to exploit their inventions is reduced. In Europe, see Council Regulations 1768/92 of 18 June 1992 (pharmaceuticals) and 1610/96 of 23 July 1996 (agrochemicals).

care and the carrying out of medical research.

17.02 This Chapter considers the current state of play regarding the influence on medical law of patent law and patent rights. Much recent debate has focused on the patentability of biotechnological inventions, most notably genes and gene fragments, and on the impact of aggressive patenting policies on research and the availability of diagnostic tests and therapies. Objections to patenting in the medical sphere have been directed to both (i) *absolute* grounds of objection, ie arguing that certain inventions should not be patentable at all, and (ii) *relative* grounds of objection, ie arguing that medical patents should not be exploited in a particular manner—the objection to the latter being that the exercise of the monopoly is unacceptable relative to other social values, such as access to medicines and health care. The structure of this chapter reflects these themes. Consideration is also given to the role and rights of research subjects or patients when their active participation in research has led to a patentable invention.

B. Obtaining and Exploiting a Patent

17.03 Although a range of IPRs is relevant to many aspects of a health service,² patents undoubtedly have the most direct and enduring effect on the provision of health care and the enterprise of medical research.

1. Patentability Criteria

17.04 Patents protect inventions. *Invention* is not defined in the law;³ rather a patent will be granted if a prospective patentee can overcome three significant hurdles. First, the putative invention must not be excluded from protection according to a defined list of non-patentable entities; most particularly the invention must not be a mere discovery.⁴ Second, a patent shall not be granted ‘for an invention the commercial exploitation of which would be contrary to public policy or morality’.⁵ Finally, the invention must meet a stringent set of positive criteria for patentability, namely, that the invention must be *new* (in the sense of never before having been made available to the public),⁶ it must involve an *inventive step* (ie, that the invention does not merely represent an obvious technical development to an expert in the relevant field),⁷ and it should be capable of *industrial application* (ie, it can be made or used in any kind of industry).⁸

² For example, copyright subsists in all notes, records, photographs, x-rays, prescriptions and charts because these are protected as literary or artistic works under the Copyright, Designs and Patents Act 1988, ss 3–4. Similarly, the design of many instruments or other pieces of equipment might be the subject of design rights under the Registered Designs Act 1949 or the Copyright, Designs and Patents Act 1998, Pt III, while the Trade Marks Act 1994 is the legal basis for the grant of UK trade mark rights, the existence of which is responsible for the maintenance of high prices on drugs to which a successful mark is attached. Indeed, it is a universal intellectual property policy of pharmaceutical companies to ensure that drugs are marketed under a distinctive trade mark long before any patent protection runs out. Once this occurs, after 20 years, the market share is defended by the enduring appeal of the trade mark, even although the drug itself is now available for any competitor to produce in the generics market. Further trade mark disputes affect the pricing and availability of drugs through regulation of the practice of parallel importing, see for example, Case C-143/00 *Boehringer Ingelheim KG v Swingward Ltd (joined actions)*; *Glaxo Group Ltd v Dowelhurst Ltd* [2002] 3 WLR 1697, 65 BMLR 177.

³ Patents Act 1977.

⁴ *ibid*, s 1(2)(a).

⁵ *ibid*, s 1(3).

⁶ *ibid*, s 1(1)(a).

⁷ *ibid*, s 1(1)(b).

⁸ *ibid*, s 1(1)(c).

2. Exclusions of Methods of Medical Treatment or Diagnosis

17.05 Writ large in these provisions is the role of public policy. In essence, patents should only be granted to worthy inventions that are not already available, which add substantial value to the sum total of human knowledge, and which do not offend public sensibilities. The letter of the law pays particular attention to policy concerns surrounding equitable access to health care. For example, s 4(2) of the Patents Act 1977 provides that:

An invention of a method of treatment of the human or animal body by surgery or therapy or of diagnosis practised on the human or animal body shall not be taken to be capable of industrial application.

Various practices have been denied patent protection on these grounds, including a method for operating and monitoring heart pacemakers,⁹ improved dosage regimes of established treatments,¹⁰ and a method for vaccination against disease.¹¹ The rationale is that those who practise the public good of medicine should not be hindered in their art because of the potential inaccessibility of new and improved treatment methods through the obduracy of a patent holder.¹² This rationale, however, does not extend as broadly as logic might suggest. It should be noted, for example, that the exclusion only extends to *methods* of treatment of the human or animal body. Thus, anything done to, or created from, samples *derived from* the body is patentable, so long as the substances are not to be returned to the same body.¹³ Likewise, if the method does not involve *treatment* of the human or animal body—in the sense of having a curative or prophylactic effect on a disease or malfunctioning of the body—then it is patentable. An example would be the administration of a chemical product for purely cosmetic reasons.¹⁴ It has also been established, inter alia, that pregnancy¹⁵ and infestation by lice¹⁶ are not diseases as such, and methods for their treatment have accordingly been patented. As the Court of Appeal has confirmed: '[t]he section has the limited purpose of ensuring that the actual use, by practitioners, of methods of medical treatment when treating patients should not be subject to restraint or restriction by patent monopolies. The difficulty is to decide whether the restraint concerns a method of treatment as opposed to what is available for treatment.'¹⁷

17.06 Section 4(3) of the 1977 Act ensures that 'what is available for treatment' can also be protected:

Subsection (2) ... shall not prevent a product consisting of a substance or composition being treated as capable of industrial application merely because it is invented for use in any such method.

Pharmaceuticals are the most obvious and important example of such

⁹*Tectronics/Pacemaker* [1996] OJ EPO 274.

¹⁰*Bristol-Myers Squibb v Baker Norton* [2001] RPC 1 and *Instituto Gentili SpA v Teva Pharmaceutical Industries Ltd* [2003] EWCA Civ 1545.

¹¹*Unilever's (Davis') Application* [1983] RPC 219.

¹²See Thums, D, 'Patent Protection for Medical Treatment: A Distinction between Patent and Medical Law' (1996) 27 IIC 423.

¹³European Patent Office Guidelines Pt C, ch 4.3.

¹⁴Case T-144/83 *Du Pont/Appetite Suppressant* [1987] EPOR 6. Note, however, the European Patent Office guidelines define 'surgery' to include plastic surgery, so such methods would also be excluded from protection.

¹⁵*Schering's Application* [1971] RPC 337.

¹⁶*Stafford-Miller's Application* [1984] FSR 258.

¹⁷*Bristol-Myers Squibb v Baker Norton Pharmaceuticals* [2001] RPC 1, 17.

patentable products. The inclusion of this provision is entirely due to the lobbying power of the pharmaceutical industry and its insistence on the need for strong patent protection to maintain the incentive to develop an ever-burgeoning range of drugs. The threat that innovation will dry up if patent protection is not available is a powerful argument which is used across a range of industries that avail themselves of the benefits of the patent system, but nowhere is that threat more effective than in the realm of pharmaceuticals. Although there is precious little empirical evidence that the denial of a patent has a disproportionately negative effect on innovation, the cost is thought to be too great to challenge the fixity of the pharmaceutical sector.

17.07 Some European countries such as Spain and Italy traditionally denied patent protection to pharmaceuticals for reasons similar to those that underpin the exclusion of methods of treatment. Eventually, however, these states bowed to international pressure and commitments to the European Union and brought their laws in line with other western states. And, while a number of developing and least developed countries continue to exclude patent protection in this field, their membership of the World Trade Organisation (WTO) and attendant obligations under the international TRIPS Agreement (1994) mean that this will soon change. In particular, TRIPS requires that: ‘... patents shall be available for any inventions, whether products or processes, in all fields of technology...’.¹⁸ Least developed Countries have until 2016 to provide patent protection for pharmaceutical inventions.

17.08 Further restriction on the impact of s 4(2) of the 1977 Act comes in the form of s 2(6) of the Act. This provides:

In the case of an invention consisting of a substance or composition for use in a method of treatment of the human or animal body by surgery or therapy or of diagnosis practised on the human or animal body, the fact that the substance or composition forms part of the state of the art shall not prevent the invention from being taken to be new if the use of the substance or composition in any such method does not form part of the state of the art.

Put simply, this provision ensures the patentability of a second, or even subsequent, medical use of a substance already employed in treatment or diagnosis. While the new use must be previously unknown for it to be patentable, it is irrelevant that a method of treatment is involved, or that the substance is already known and is being used (albeit to a different end), or indeed that the substance is manufactured in precisely the same way for the old and new uses.¹⁹ An example is *Wyeth’s Application*²⁰ in which the use of pharmaceutical compounds known as guanidines, which had been primarily used to lower blood pressure, was held to be patentable when employed in the manufacture of anti-diarrhoeal agents. The important qualification on claims to second or subsequent medical use is that these must be drafted in such a way as to be limited to the *manufacture* of the medicament to be used in

¹⁸ Agreement on Trade Related Aspects of Intellectual Property Rights 1994, Art 27(1). Note that Art 27(3) allows signatory states to exclude from patentability ‘diagnostic, therapeutic and surgical methods for the treatment of humans and animals’, while Art 27(2) permits exclusions from patentability of inventions ‘... the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health...’.

¹⁹ *Eisai/Second Medical Indication* Decision G 0005/83 [1985] OJ EPO 64.

²⁰ *Wyeth’s Application*; *Schering’s Application* [1985] RPC 545.

human treatment. Thus, it was not possible in *Wyeth* to claim ‘the use of guanidine in treating diarrhoea’ because this was tantamount to a claim to a method of treatment. Rather, the successful wording of the claim was to ‘the use of a guanidine in the preparation of an anti-diarrhoeal agent for treating or preventing diarrhoea’. The distinction, albeit very fine, is carefully drawn by the courts in their interpretation of patent claims. For example, the Court of Appeal recently rejected a claim for the use of taxol in cancer treatment whereby the claimants had discovered that a change of treatment regime by controlled infusion of taxol in three-hour rather than 24-hour periods could produce a similar therapeutic benefit with less suppression of the white cells of the blood. The inclusion of a claim ‘... for manufacturing a medicamentation for simultaneous, separate, or sequential application...’ did not change the essential feature of the invention; it was merely a method of treatment of the human body.²¹

17.0 This example aside, the general trend in contemporary patent law is to interpret patentability exclusions very restrictively. Indeed, the exclusion of methods of treatment and diagnosis in European patent law is now something of an anomaly. Not only has its scope been progressively reduced over the years, but its underlying logic is difficult to reconcile with other patenting practices around the globe. For example, there is no such exclusion in the United States and other jurisdictions have abandoned the provision as being no longer defensible.²² That having been said, there are no current plans to do away with the exclusion in Europe, but its impact remains marginal in the patenting of new medical technologies.

C. Biotechnological Inventions

17.10 The most controversial field of patenting in recent years is that relating to biotechnological inventions. These are inventions involving biological material, that is, ‘any material containing genetic information and capable of reproducing itself or being reproduced in a biological system’.²³ Put another way, these inventions embody, or are derived from, material taken from living organisms, be these from the plant, animal or human kingdoms. A number of objections have been raised to the application of patent law in this realm. These have often been confused and conflated under the emotive term ‘patenting life’, the use of which is unhelpful and, for the most part, has served only to muddy the waters. Rather, the objections should be treated and assessed according to their aims, of which there are broadly two. First, *absolute* grounds of objection have been raised to exclude these inventions from patent protection because it is argued either (i) they do not meet the criteria for patentability and/or (ii) they are prohibited by the exceptions in patent law itself. Second, *relative* grounds of objection have been raised challenging the effects of a biotechnological patent either because of (i) the breadth of the monopoly that has been granted, and/or (ii) the ways in which the invention is exploited under patent law. We shall consider each of these objections in turn.

²¹ Bristol-Myers Squibb v Baker Norton Pharmaceuticals [2001] RPC 1.

²² See, eg, *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1994) 122 ALR 141 (Aus) and Cuthbert, D, ‘Patent Law Reform in New Zealand: Should Methods of Medical Treatment be Patentable?’ (1997) *Patent World* May 32.

²³ Directive (EC) 98/44 of 6 July 1998 on the legal protection of biotechnological inventions [1998] OJ L213/13, Art 2(1)(a).

1. Absolute Grounds for Objection

(i) Discoveries

- 17.11** As has been already stated, the philosophy of the patent system requires that an invention is *new*, which means that it should not already be part of the state of the art (ie, available to the public by any means).²⁴ Furthermore, every patent system excludes *discoveries* from patentable subject matter.²⁵ The reasoning is self-evident: why should one party enjoy the reward of a powerful monopoly for something which she did not invent and which, in theory at least, is available to all? How, then, it is frequently asked, can naturally-occurring entities such as genes or partial gene sequences form part of a patentable invention? Why is this not merely discovery rather than invention? The answer emerges from the interpretation of patent terminology.
- 17.12** A *discovery* is the simple uncovering of a previously unrecognised substance or of a new property of a known substance. An *invention* is the production of a technical solution to a previously unsolved technical problem. It is of crucial importance to appreciate that the prohibition on discoveries relates only to discoveries *as such*.²⁶ This means that, while the mere discovery itself—for example, the discovery of the base pair sequence of a gene—cannot be the subject of a patent, applications or uses of the discovery may be patentable. And, because patent exclusions are interpreted restrictively, a discovery that can be put to use to solve a technical problem will overcome the prohibition and may itself be patentable.²⁷ Thus, locating a previously unknown gene, determining its function and making it accessible for further exploitation is an example of a technical solution to the pre-existing problem of the inaccessibility of the genetic product.²⁸ The inventiveness that is rewarded is the making available of something that was previously beyond our reach. However, any patent granted only allows control of the invention in a commercial context. It does not extend to copies of the genetic material in a natural environment, for example, within human beings.
- 17.13** The essential character of the invention is irrelevant so long as it produces a technical effect in solving a problem. Indeed, the European Patent Office Guidelines direct examiners to consider the invention as a whole and ‘to identify the real contribution which the subject-matter... adds to the known art’.²⁹
- 17.14** The European Directive on the protection of biotechnological inventions confirms that while patents are not available for ‘the human body or its parts in their natural state or for the simple discovery of one of its elements’ (Article 5(1)), patents are available for ‘elements that are isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, even if the structure of that element is identical to that of a natural element’ (Article 5(2)).³⁰ These fine distinctions have not proved un-controversial. The French Government, for example, has

²⁴ Patents Act 1977, s 1(1)(a).

²⁵ In the UK, see *ibid*, s 1(2)(a).

²⁶ *ibid*, s 1(2).

²⁷ European Patent Office Guidelines Pt C, ch IV, 2a.

²⁸ See eg *Icos Decision* OJ EPO 6/2002 293 in which it was held that the production of a purified and isolated nucleic acid having a sequence that does not exist in nature is not a discovery (although note this patent failed on other grounds including lack of inventive step and lack of industrial applicability).

²⁹ European Patent Office Guidelines Pt C, ch I V, 2.

³⁰ N 23 above, Art 5.

refused to implement the full terms of the Directive arguing that Article 5(1) and 5(2) contradict each other. The Government is still negotiating with the European Commission over implementation. It is not alone in its concerns. By December 2002 only six Member States had implemented the Directive, some two and a half years after the deadline. The Commission formally requested the remaining nine States to implement the law or face the prospect of being taken to the European Court of Justice;³¹ this occurred in July 2003 when eight States were so referred for non-implementation.³² A Group of Experts has been established to monitor and to advise on biotechnology and patenting in Europe, as was required by the Directive itself.³³ A Europe-wide public consultation³⁴ has shown that numerous points of conflict remain over the application of patent law in this field and many respondents are uneasy about the practice. Of most concern are the levels of protection given to patents of sequences or partial sequences of human genes and the patentability of human stem cells and cell lines derived from them. The Expert Group's first tasks are to examine these areas. The European Parliament, for its part, issued a resolution on the Commission's communication in November 2002 in which it stressed its support for greater public engagement with the issues surrounding biotechnology, including its protection by legal means.³⁵ In particular, the Parliament urged the Commission to revisit the text of the Directive, and especially Article 5(2), so as to exclude the total or partial sequence of a gene isolated from the body from patentability. The debate, therefore, is far from over. However, the response is monotonously repetitive from the economic perspective. It is argued that the proposed exclusions will not promote research and development activity in Europe and will put European biotechnology businesses at a competitive disadvantage because other jurisdictions, such as the United States and Japan, do not have these exclusions in their patent law.³⁶

(ii) Morality

(a) In General

17.15 In contrast to the approach adopted in the United States and in many other jurisdictions, European patent law has long contemplated a role for moral considerations in the decision-making process on the grant of patents.³⁷ The

³¹ European Commission Communication, 'Legal Protection of Biotechnological Inventions: Commission Discusses Progress with Member States and Establishes Expert Group', 28 January 2003, IP/03/127.

³² IP/03/911, 10 July 2003.

³³ This Group reported for the first time in October 2002. In essence, the Group reiterated the need, as it saw it, to maintain competitiveness through full and proper implementation of the Directive, lest Europe lose out on the enormous potential of the biotechnology market (http://europa.eu.int/comm/internal_market/en/indprop/invent/com02-2en.pdf).

³⁴ For the results of the public consultation see http://europa.eu.int/comm/biotechnology/pdf/results_en.pdf.

³⁵ For the provisional edition of the text see www3.europarl.eu.int/omk/omnsapir.so/calendar?APP=PDF&TYPE=PV2&FILE=p0021121EN.pdf&LANGUE=EN.

³⁶ Report from the Commission to the European Parliament and the Council, *Development and Implications of Patent Law in the Field of Biotechnology and Genetic Engineering*, COM (2002) 545 final, 7 October 2002.

³⁷ See also Art 27(2) of the TRIPS Agreement (1994) which permits, but does not require, signatory countries to include morality exceptions in their patent law in similar terms to those found in the EPC. In the UK s 1(3) of the Patents Act 1977 provides that: 'A patent shall not be granted for an invention the commercial exploitation of which would be contrary to public policy or morality'.

European Patent Convention embodies the common fundamentals of patent law in 27 European states, including the United Kingdom.³⁸ Article 53 provides that:

European patents shall not be granted in respect of:

(a) inventions the publication or exploitation of which would be contrary to *ordre public* or morality, provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States;

These provisions lay more or less dormant in the Convention until the advent of biotechnological patents whereupon objectors seized the opportunity to challenge the patentability of these inventions. Without exception, their efforts have been fruitless. The first problem was to persuade the patent examiners in the European Patent Office that considerations of morality were within their sphere of responsibility and competence. The issue first arose in *Harvard/Oncomouse*³⁹ in which the European Patent Office upheld a patent on a transgenic mouse bred to develop cancer as a research tool. The European Patent Office relied on the strictly utilitarian analysis that the potential benefit to mankind outweighed the suffering of the animal, and accordingly there was no bar to patent protection. Proceedings were immediately instituted against the ruling which remained unresolved for a decade, during which time the patent remained in force. A solution was eventually found in 2001 when the scope of the patent was restricted to ‘transgenic rodents containing an additional cancer gene’ rather than ‘any non-human transgenic mammal’.⁴⁰ *Harvard/Oncomouse* is significant because it established the precedent for future challenges on grounds of morality. Its crude felicific calculus has been adopted and refined in other cases, and always in the vein of interpreting the morality exclusion narrowly. Thus, for example, in *Plant Genetic Systems/Glutamine Synthetase Inhibitors*,⁴¹ the European Patent Office stated that it was only prepared to entertain challenges on grounds of morality if actual evidence of harm to society could be demonstrated. Moreover, survey evidence and opinion polls indicating distaste for patents over genetically modified organisms were insufficient evidence by which to judge the overall European moral tone. In *Howard Florey/H2 Relaxin*⁴² the Office declared that the morality measure should be applied to prevent the grant of patents only in the case of inventions which would universally be regarded as outrageous. Accordingly, it upheld the grant of a patent over a genetically engineered human protein, H2 relaxin, which is produced by women during childbirth to soften the pelvis. The patent had been objected to on a number of grounds. First, that the granting of the patent was tantamount to slavery of women because it involved the ‘dismemberment of women and the sale of their parts’; second, that it was offensive to human dignity to use pregnant women for profit; and finally that, because DNA was life itself, patenting of human DNA

³⁸ Membership as at November 2003.

³⁹ *HARVARD/Oncomouse* [1991] EPOR 525.

⁴⁰ By way of contrast the Supreme Court of Canada revoked the Harvard patent over Oncomouse itself (but not the process to manufacture it) in December 2002, claiming that, ‘[a] higher life form is not patentable because it is not a “manufacture” or “composition of matter”’: see *Harvard College v Canada (Commissioner of Patents)* [2002] SCJ No 77. This ruling cannot now be changed except by express legislation.

⁴¹ *Plant Genetic Systems/Glutamine Synthetase Inhibitors* [1995] EPOR 357.

⁴² *Howard Florey/Relaxin* [1995] EPOR 541.

was intrinsically immoral.⁴³ The Office rejected each of these claims on a narrow construction of the morality exclusion. DNA, it said, is not life, nor was the taking and modification of samples anything approximating to slavery. Importantly, the European Patent Office placed considerable store in the fact that consent had been obtained from the women to take the samples from which the patentable subject matter was derived. This, in itself, was thought to be enough to accord respect to human dignity. Interestingly, however, it is not clear what the women consented to, and in particular whether they were ever told of the prospect of patents being granted over material derived from them and the consequent economic potential.⁴⁴

(b) Consent to Patenting

17.16 This issue of consent also arose in the negotiations on the draft of the Biotechnology Directive. Initial proposals required that specific consent to patenting be obtained from individuals who provided samples that might lead to the manufacture of patentable products, but, after much lobbying from industry and the research community, no such measure appears in the body of the Directive. However, recitals in the preamble to a Directive exist as aids to interpretation of the Articles contained therein and Recital 26 of the Biotechnology Directive provides:

Whereas if an invention is based on biological material of human origin or if it uses such material, where a patent application is filed, the person from whose body the material is taken must have had an opportunity of expressing free and informed consent thereto, in accordance with national law...

While the legal status of recitals is unclear,⁴⁵ as is, in particular, whether they have the force of law in Member States, the UK implementing regulations contain nothing on this requirement for consent.⁴⁶ Moreover, the recital itself is opaque as to what consent should relate to: is it the taking of the material or the filing of the patent application? The former is merely a reflection of sound ethical research practice, while the latter is a potentially more onerous requirement, not only for the researcher who obtains consent, but also for the patentee (who will not necessarily be the same person). Indeed, the patent office itself could feel the weight of such a provision—upon whom should the onus lie to ensure the provision is complied with, and what sanction, if any, will apply if it is not? The Directive is silent on the matter, but the burden of examination for patent offices could be considerable if this became a ground on which to challenge the validity of a patent. None the less, it is the opinion of the European Group of Advisors on the Ethical Implications of Biotechnology that, when someone contributes a biological element that might later be included in an invention, then information disclosure must be ‘complete and specific’ for the consent to be valid. In particular, there must be information ‘on the potential patent application on the invention which could be made from the use of this element’.⁴⁷ The Group further opines that a

⁴³ *ibid.*

⁴⁴ See further *Moore v Regents of the University of California* (n 49 below).

⁴⁵ Case C-162/97 Criminal proceedings against Nilsson, Hagelgren and Arrborn [1998] ECR I-07477.

⁴⁶ The Patents Regulations 2000, SI 2000/2037.

⁴⁷ European Group of Advisors on the Ethical Implications of Biotechnology, *Ethical Aspects of Patenting Inventions Involving Elements of Human Origin*, Opinion No 8, 25 September 1996, para 2.4. This body was succeeded by the European Group on Ethics in Science and New Technologies which reiterated this position in its Opinion No 16 of 17 May 2002 on *Ethical Aspects of Patenting Inventions*

patent should be refused if there is evidence of disrespect for individual rights or human dignity.⁴⁸ At the time of writing the Danish Government is contemplating making consent to patenting a requirement of their law and its efforts will doubtless be keenly observed around the Union.

- 17.17** Consent and patenting have been considered together in one other famous instance, this time from across the Atlantic. In *Moore v Regents of the University of California*⁴⁹ the plaintiff failed in his attempt to claim property rights in his excised spleen cells from which his doctor and other researchers had profited after developing and patenting a cell-line using those cells. The court pointed to the hindrance to research that recognition of property rights in such material could create, and preferred instead to grant Moore remedies for lack of informed consent and breach of fiduciary duty. The court concluded that: ‘(1) a physician must disclose personal interests unrelated to the patient’s health, whether research or economic, that may affect the physician’s professional judgment; and (2) a physician’s failure to disclose such interests may give rise to a cause of action for performing medical procedures without informed consent or breach of fiduciary duty’.⁵⁰ While this is not tantamount to requiring a disclosure of an intent to patent per se, the reference to economic interests indicates that it would be sound practice to alert patients at least to the prospect. This is particularly so when ‘[t]he scope of the physician’s communication to the patient ... must be measured by the patient’s need, and that need is whatever information is material to the decision’.⁵¹ It is important to note, too, that there was no question of the court in *Moore* revoking the patent over the cell-line. It was held to be both ‘legally and factually distinct’ from the cells taken from the plaintiff’s body and the resultant financial gain was a valid reward for the inventive effort of the researchers. Thus, not only was Moore denied the recognition of property rights in his own cells but he was also deprived of the opportunity to ensure that other forms of property right did not pass to other parties.
- 17.18** Similar arguments have arisen more recently in *Greenberg v Miami Children’s Hospital Research Institute Inc.* This was a class action by families of sufferers of Canavan’s disease, a rare genetic disorder, brought against the researchers and the hospital who patented the Canavan disease gene after carrying out extensive research on samples and information provided by the families. Inter alia, arguments were advanced in conversion, lack of informed consent and breach of fiduciary duty. A motion at the behest of the defendants to strike out the action was refused, but the grounds for complaint were reduced to the unjust enrichment of the defendants at the expense of the plaintiffs,⁵² and the case subsequently settled out of court. Nonetheless, the overarching aim throughout the proceedings had been to obtain an injunction to prevent the defendants relying on the patent. It is to be regretted that a full judicial hearing did not materialise because there were always at least two reasons to suspect that the case would not blindly follow the precedent in

Involving Human Stem Cells, para 2.6.

⁴⁸ *ibid*, para 2.1.

⁴⁹ *Moore v Regents of the University of California* (1990) 51 Cal 3d 120.

⁵⁰ *ibid*, 129.

⁵¹ *Cobbs v Grant* (1972) 8 Cal 3d 229, 245.

⁵² Gorner, P, ‘Court Allows Suit on Use of Dead Kids’ DNA for Patent’, *The Chicago Tribune*, 8 June 2003, (www.chicagotribune.com).

Moore. First, the suit was being heard in Florida, whereas Moore is only binding authority in California. The tendency to assume that Moore encapsulates a universal precedent is, of course, erroneous. Second, the policy arguments are not as clear-cut as the Supreme Court of California suggested over a decade ago. Its concern, then, was to avoid erecting barriers to research and to ensure the development of, and on-going access to, medicines. The Greenberg case was representative of a groundswell of opinion against the use of patents in the medical sphere when these are used to block research by others or to limit access to health care. The owners of the Canavan patent, for example, charged a fixed royalty of \$12.50 per test and placed a limit on the number of tests that could be carried out annually by any licensee. Research uses were also tightly controlled through licensing. The plaintiffs in Greenberg were challenging the patent precisely because of these practices and not for personal profit. They did so to ensure that further research is carried out and, in this sense, the policy arguments in Moore are turned on their heads.

(c) *The European Directive*

- 17.19** The European Directive imposes certain limitations on patenting, namely that '[i]nventions shall be considered unpatentable where their commercial exploitation would be contrary to *ordre public* or morality'.⁵³ While morality is left undefined, specific exclusions are applied to the patenting of processes for cloning human beings or modifying the human germ-line, to uses of human embryos for industrial or commercial purposes, and to any processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal. The last example is a modification of the test laid down in *Harvard/Oncomouse*. The list is non-exhaustive and represents the few, most contentious, issues that all concerned could agree upon at the time of the adoption of the Directive. In so doing, it was hoped that the moral objectors would be placated while, at the same time, legislation would be passed that permitted patenting in all but a few narrowly defined realms.
- 17.20** The debate about the scope of the morality provisions nonetheless rumbles on. Although Article 6 excludes uses of human embryos from patenting, it says nothing about cells derived from embryos. Nor is it clear whether the prohibition on processes for cloning human beings relates only to reproductive cloning techniques or extends to cloning to produce stem cells for therapeutic purposes. The European Group on Ethics in Science and New Technologies reported that by 2002 over 2000 patent applications had been lodged around the world involving both human and non-human stem cells; a quarter of which related to embryonic stem cells. Over a third of all stem cell applications had been granted, as had a quarter of those related to embryonic stem cells.⁵⁴ One of the most controversial of these applications was the so-called 'Edinburgh Patent' which was originally granted by the European Patent Office over 'animal transgenic stem cells'. However, this raised considerable concern when it was suggested that this might lead to human cloning. In opposition proceedings before the Office in July 2002, however, the patent was amended to exclude human or animal embryonic cells, although it still covers modified human and animal stem cells, and the patent was upheld on this basis. The

⁵³ N 23 above, Art 6(1).

⁵⁴ European Group on Ethics in Science and New Technologies, *Ethical Aspects of Patenting Inventions Involving Human Stem Cells*, Opinion No 16, 17 May 2002, para 1.16.

European Parliament has pointed to the decision and requested Member States to recognise that this demonstrates that the Office can, and does, show due concern and respect for the ethical dimensions of patenting.⁵⁵ The European Group on Ethics, for its part, has urged a cautious approach and recommended ‘excluding the patentability of the process of creation of a human embryo by cloning for stem cells’.⁵⁶

- 17.21** It is clear, then, that despite the adoption of the Directive and the favourable rulings of the European Patent Office, the presence of a morality clause in European patent law has remained problematic for the biotechnology industry. Objections to the Directive based on moral grounds were primarily responsible for the delay in adopting the legislation, a process that took ten years. Even after its eventual adoption in July 1998, the Directive was challenged by the Netherlands, Italy and Norway before the European Court of Justice. The court took until October 2001 to uphold the validity of the law,⁵⁷ but as has been stated, a number of Member States have still to implement the Directive, some on the basis that moral objections remain.
- 17.22** The irony is that many of these objections are misguided in their aims and can never achieve what they seek. It must be borne in mind that the sole purpose of the patent system is to grant private rights to facilitate the public exploitation of inventions through monopoly control of the market. That is, a patent only gives the right to exclude others from the marketplace. The only effect of a successful challenge to a patent is the denial of this market advantage. Anyone is then at liberty to produce and exploit the invention. Those who object to patenting because they object to the invention itself therefore cannot hope to prevent the creative or exploitative process by this means. The only hope is that the absence of patent protection might act as a disincentive to invent, but there are many examples of industrial developments that never qualify for patent protection and yet are not hindered by this fact. The problem stems from a misguided desire to use the patent system as a tool for the regulation of science, industry and medicine.⁵⁸ To say that the system is ill-equipped for the task is an understatement of considerable proportions.⁵⁹
- (iii) Interpretation**
- 17.23** The most effective measures to reduce the impact of biotechnological patents have arisen in the interpretation of the criteria for patentability themselves, ie, in the need to show that an invention is new, involves an inventive step and is capable of industrial application. We have already considered the meaning of novelty in the biotechnology context and noted the vulnerability of a patent at any time in its life to challenge on the grounds of lack of novelty. The requirement of an inventive step ensures that protection is only granted when

⁵⁵ European Parliament resolution on the Commission communication on life sciences and biotechnology—A strategy for Europe, 21 November 2002, 68/PE 325.104, para 3.9.

⁵⁶ N 54 above, para 2.5. For further discussion of patenting practices relating to stem cells see Laurie, G, ‘Patenting Stem Cells of Human Origin’ [2004] EIPR 59.

⁵⁷ Case C-377/98 Netherlands v Council of the European Union and the European Parliament [2002] All ER (EC) 97.

⁵⁸ European Group of Advisors on the Ethical Implications of Biotechnology, Opinion on Ethical Questions Arising from the Commission Proposal for a Council Directive on Legal Protection for Biotechnological Inventions, Opinion No 3, 30 September 1993.

⁵⁹ In *LELAND STANFORD/Modified Animal* [2002] EPOR 2 the European Patent Office confirmed the validity of a patent for an immuno-compromised chimera mouse on the grounds that the controversial nature of the technology was insufficient on its own to deny a patent.

the invention represents a sufficiently significant advance in the field. The test asks whether the invention would be obvious to an expert who is apprised of the current state of the art and who compares what was already known to what has been invented. Thus, in *Genentech Inc's Patent*⁶⁰ the Court of Appeal considered the validity of Genentech's patent for human tissue plasminogen activator (t-PA)—a naturally occurring human protein that plays a role in the dissolution of blood clots. Genentech applied relatively standard genetic engineering techniques to reproduce sufficiently pure amounts of t-PA to develop a therapeutic agent. However, at least five other teams had embarked on the same task applying more or less the same techniques and the patent was subsequently challenged for lack of the inventive step. The Court revoked the patent holding that it was obvious to a person skilled in the art to set out to produce human t-PA by these means. The court was at pains to point out that being first, or expending considerable sums in the process of development, were not necessarily indications of inventiveness. The industry later showed concern that the decision might have raised the standard for inventiveness in the realm of biotechnological inventions. This was because the Court considered that the expert who assesses inventiveness in such industries can possess a degree of imagination and ingenuity, and that collaborative efforts within a team can also be used to assess the criterion. Normally the notional expert test contemplates an ordinarily skilled but unimaginative person. This having been said, there is no significant evidence that subsequent biotechnological patents have been subjected to a higher threshold.

2. *Relative Grounds of Objection*

(i) **Morality of Monopoly**

17.24 While it is possible to challenge the grant of a patent per se, an equally credible option is to challenge the grant of a market monopoly over inventions. The basis of this objection is that the abusive exercise of the private property right would undermine certain valued public interests. Access to medicines and diagnostic tools and the pursuit of medical research are undeniable public goods, while the control of drug and therapeutics markets and the impact on research are equally axiomatic concerns that are raised by the grant of pharmaceutical and biotechnological patents. The scene is set, then, for a classic conflict scenario. No example illustrates the problem better than the case of Myriad Genetics which owns patents worldwide over the breast cancer genes BRCA1 and BRCA2 and which are the subject of opposition proceedings before the European Patent Office. As the Nuffield Council on Bioethics states:

The opposition is aimed at curtailing any possible deleterious consequences which might stem from sanctioning the monopoly conferred on Myriad Genetics, including the possible threat to the development of research and the identification of new tests and diagnostic methods. It has also been argued that the patent will have a serious impact on equitable access to testing. It is suggested that the monopoly is antithetical to an approach to public health that is based on a commitment to the comprehensive care of patients at high-risk.⁶¹

17.25 Moreover, and as the Council goes on to point out, because of the way in which Myriad Genetics has used its patent monopolies world-wide, 'there are

⁶⁰ [1989] RPC 147 (CA).

⁶¹ Nuffield Council on Bioethics, *The Ethics of Patenting DNA*, 2002, para 4.6.

currently no other methods of diagnosing the presence of the breast cancer susceptibility gene BRCA1 that can be used without infringing the patents'.⁶²

17.26 A European Parliament resolution from October 2001 called upon the European Patent Office to reconsider the grant of patents and for amendment to the European Patent Convention which would allow the Office to revoke patents on its own initiative.⁶³ The Office replied by pointing to the role of opposition proceedings, which in Europe can be invoked by any party with a valid concern about a patent. It also stressed that its policy was not to make a special case of biotechnological inventions.⁶⁴ Certainly, the concern over monopolistic control is not restricted to these kinds of invention, and pharmaceutical patents are open to precisely the same grounds of objection. The dilemma for the Patent Office and the state in whose name patents are granted is to strike a balance between encouraging sufficient investment and research through the availability of patent protection while not being seen to prejudice, and so dissuade, patentees by setting the qualifying criteria too high. An additional problem is that wholesale challenges that go to the heart of the patent only offer an all or nothing option: either the patent stands or it does not. Other strategies are, however, available which leave more scope for balance.

(a) *Balanced Court Rulings*

17.27 The ruling of the House of Lords in *Biogen v Medeva*⁶⁵ is a good example of a search for the middle ground. This case confirmed that there is no need to prove an 'invention' in the biotechnology sphere beyond satisfying the criteria of novelty, inventive step and industrial applicability. This additional criterion had been suggested in *Genentech*, but the House of Lords stated categorically that to meet the basic patentability criteria *is* to define a patentable invention. Indeed, the general tenor of this decision is to the effect that no special case should be made of biotechnological patents, thus sharing the clear policy position of the European Patent Office. However, the court did strike down the patent on a number of technical grounds, inter alia, because the claimed monopoly was far in excess of what the invention actually contributed to the state of the art. Essentially, the House of Lords took a very measured approach in *Biogen* and sent the clear message that the criterion of inventiveness should only reward actual technical contributions to human knowledge—no more and no less. It is a frequent problem with new and emerging technologies that initial grants are pleaded broadly before the patent offices and it is left to the courts to get to grips with the true nature of the technology. *Biogen* was an early attempt to keep the United Kingdom on a straight and narrow path.

17.28 Most recently, the Court of Appeal upheld the validity of a patent over genetically engineered Erythropoietin (EPO)—a protein found in minute levels in the body which regulates the production of red blood cells—while at the same time ruling out the infringement claim of the patent holders.⁶⁶ The Court allowed a broad claim to the DNA sequence for EPO as well as to variants that performed the same function on the basis that the defendants

⁶² *ibid*, para 5.4.

⁶³ European Parliament resolution on the patenting of BRCA1 and BRCA2 ('breast cancer') genes, 4 October 2001, B5-0633, 0641, 0651 and 0663/2001.

⁶⁴ European Patent Office Declaration of 17 October 2001, AC/145/01.

⁶⁵ *Biogen v Medeva* [1997] RPC 1.

⁶⁶ *Kirin Amgen Inc v Transkaryotic Therapies Inc.* [2003] RPC 3.

could not show that the variants did not work. By the same token, the Court adopted a less abstracted interpretation of how the defendants' invention worked compared to the court of first instance and found sufficient differences with the patent in suit to hold that there had been no infringement. In many respects the decision is a good example of the balance of interests that is so crucial to the operation of a sound and socially useful patent system. It is, however, due for appeal to the House of Lords at the time of writing.

17.29 The careful policing of the boundaries of the tests for patentability is now a clear policy objective advocated in many quarters. The Nuffield Council on Bioethics, for example, has called for more stringent assessments of all criteria, and most especially the need to demonstrate inventive step.⁶⁷ The Council suspects that significant numbers of patents have been granted over biotechnological inventions that do not meet the full rigours of the test. The Council also draws attention to subtle, yet significant, differences in interpretation between the patent offices of Europe and the United States which lead to the conclusion that a lower threshold is applied in the United States, thus making biotechnology patenting easier. In both economic areas, however, revised guidance has been produced on the third criterion for patentability with special reference to genetic inventions. A biotechnological invention in the United States must now demonstrate a 'specific and substantial and credible utility', ie, it must have a clear function, although this can include a sufficiently defined theoretical use.⁶⁸ The European Directive of 1998 states that full or partial gene sequences with no known function will not be patentable,⁶⁹ and this has been confirmed by the European Court of Justice⁷⁰ and the European Patent Office which has held that the mere speculative function for a genetically engineered gene sequence is no demonstration that the product is capable of industrial application.⁷¹ Such a restrictive policy is perfectly sensible and clear: when one considers the plethora of such inventions that occur; a corresponding number of indistinct and unknowable monopolies is clearly not in the public interest.

(b) Further Limits on Monopolies

17.30 A recent report from the European Commission points to a possible role for compulsory licences in the biotechnological sector.⁷² A compulsory licence can be sought by an outside party if a patent holder refuses to grant licences for use on reasonable terms and when the patentee is not exploiting the invention herself. Compulsory licences exist, in theory at least, to ensure public availability of new inventions and they are granted when the patentee is not upholding her side of the bargain with the state. At the domestic level, the relevant patent office will decide the terms of the licence in negotiation with the parties and the patentee is entitled to 'reasonable remuneration'.⁷³ The

⁶⁷ N 61 above.

⁶⁸ While European law requires that an invention be capable of industrial application, US law focuses on the need for *utility*.

⁶⁹ N 23 above, Art 5(3) read in conjunction with Recitals 23 and 24.

⁷⁰ N 57 above, point 74 of the judgment.

⁷¹ *Ibos Decision* OJ EPO 6/2002 293.

⁷² Report from the Commission to the European Parliament and the Council, *Development and Implications of Patent Law in the Field of Biotechnology and Genetic Engineering*, COM (2002) 545 final, 7 October 2002, para 4.1.3.

⁷³ Patents Act 1977, s 48. Compulsory licences can also be granted for Crown use or as a result of a report from the Competition Commission which has found unacceptable monopolistic practices, *ibid*,

Commission also stresses the importance of the principle of exempting prior use whereby anyone already using an invention prior to the patent application, or who had made ‘effective and serious preparations for such use’, can continue in that use.⁷⁴ What the report does not highlight is the considerable antipathy with which compulsory licensing is viewed, both by patentees and patent offices alike. Also, the prior use exemption only allows on-going *private*, ie non-commercial, use and does not in that sense assist competitors.

17.31 It is also worth noting the role of research exemptions in patent law worldwide, as a result of which things done on, or to, an invention for purely experimental purposes are not considered to be an infringement of the patent. There is, for example, a long history of antipathy in the United States towards any attempt to limit the private rights of the patent holder. The so-called Bolar exemption provides protection for ‘uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products’,⁷⁵ but this only extends to measures aimed at obtaining regulatory approval for the rapid release of generics onto the market at the expiry of any existing patent. Furthermore, the scope of the common law research exemption—which as its name suggests allows research to be carried out on a patented invention without fear of an infringement suit—has been interpreted progressively more restrictively over the years. It received its strictest interpretation to date in the Federal Circuit decision on *Madey v Duke University*⁷⁶ where the court limited the scope of the exemption ‘strictly to philosophical enquiry only’. In particular, the exemption does not apply where the use ‘furthers the researcher’s legitimate business’; a concept that the court interpreted widely to exclude any use if it has the ‘slightest commercial implication’.⁷⁷ In this particular instance, the court held that the status of the defendant as a non-profit educational institution was not determinative—the research work was lucrative for the University in terms of increasing prestige and attracting further research monies and future students.

17.32 There is little clarity and no consistency of approach in Europe regarding these possible limits to patent monopolies. Bolar exemptions exist in some national systems and these are accepted as valuable in principle by the European Commission, but a harmonised way forward eludes the Union.⁷⁸ A research exemption also operates across a number of European jurisdictions but in an equally disharmonious fashion.⁷⁹ In particular, and as the Nuffield Council has observed: ‘... it is not clear whether the research exemption extends to clinical trials. Case law in some countries suggests that it does, in other countries, the

ss 51–58.

⁷⁴ Commission Report (n 72 above), 21.

⁷⁵ *Cf Roche Products, Inc v Bolar Pharmaceutical Co* (1984) 733 F2d 858 (CA Fed.) and the Act which overturned the ruling to create the ‘Bolar exemption’: the Drug Price Competition and Patent Term Restoration Act 1984 (Waxman-Hatch Act) 21 USC ss301 *et seq.*

⁷⁶ *Madey v Duke University*, 307 F 3d 1351 (Fed Cir 2002).

⁷⁷ Citing *Embrex Inc v Service Engineering Corp*, 216 F3d 1343 (Fed Cir 2000) at 1353.

⁷⁸ See, Proposal for a Regulation of the European Parliament and Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for Evaluation of Medicinal Products, COM (2001) 404 final, 26 November 2001 and Amended Proposal for a Directive of the European Parliament and Council amending Directive 2001/83/EC on the Community Code relating to medicinal products for human use, COM (2003) 163 final, 3 April 2003.

⁷⁹ See, eg, s60(5)(a) of the UK Patents Act 1977,

contrary is suggested.⁸⁰ Whatever the position in Europe, however, the exemption, where it exists, is invariably interpreted more generously than is its US counterpart.

A combination of these, and other, approaches is required to ensure a balanced and equitable way forward in the future as a host of bodies, reviews and reports has concluded.⁸¹ Additional factors to be considered include the vigilance of patent offices in carrying out thorough searches of the prior art, an on-going review of the role for imaginative licensing options, and, as we have seen above, careful application of the criteria for patentability. The OECD has indicated the difficulty of finding common solutions because of the complexity of the area, but it has nevertheless recommended that a multi-strategy approach should be considered at governmental level requiring, inter alia, review of the policies within the IP system itself, the manner by which patents are administered, and changing the behaviour of patentees in the way they exploit their monopolies.⁸² The Organisation notes in particular that the role of compulsory licences, although not popular to date, should be revisited.⁸³

D. Access to Medicines: The International Dimension

17.33 It has already been suggested that the impact of compulsory licensing schemes has been marginal in the health sector. Nonetheless, there is growing support for their use as a fair and reasonable restriction on the effects of patent monopoly control. Arguments in this respect are most advanced, although as yet not especially effective, at the international level.

The DOHA Declaration of November 2001, issued by the Council of Ministers of the World Trade Organisation, is designed to address some of the issues arising from the existence and exercise of IPRs as these relate to public health. The Declaration stresses the importance of interpreting and implementing the TRIPS Agreement⁸⁴ in ways that both promote access to existing medicines and encourage the creation of new medicines.⁸⁵ The primary effects of the Declaration, and a separate Declaration on public health,⁸⁶ make it incumbent on the TRIPS Council to address the use of compulsory licences by developing countries in the pharmaceutical realm, and to extend the deadline for least-developed countries to provide pharmaceutical patent protection under the TRIPS Agreement until 1 January 2016.⁸⁷ DOHA reiterates the underlying principle of Article 8 of TRIPS that ‘members may ... adopt measures *necessary* to protect public health and nutrition ...’. Thus, para 4 of the Declaration on the TRIPS Agreement and Public Health provides that:

⁸⁰ Nuffield Council on Bioethics (n 61 above), para 5.44, note 26.

⁸¹ For a good account, see Nuffield Council on Bioethics (n 61 above).

⁸² Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (2002), 80.

⁸³ *ibid.*, 81.

⁸⁴ N 18 above.

⁸⁵ For an account of the history of DOHA and its future direction, see World Trade Organisation, *The Road to DOHA and Beyond* (2002).

⁸⁶ Declaration on the TRIPS Agreement and Public Health, November 2001.

⁸⁷ This, of course, does not deal with the problem of individual (western) countries finding other means to ensure that developing countries provide the sort of protection they would wish, for example, by forcing the issue of bilateral treaties, linked perhaps to aid or other trade incentives, in return for ‘adequate’ patent protection.

We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all.

Such measures include restricting patentability or imposing conditions on the use of a patent, for example, by permitting compulsory licences to be granted. However, attempts to rely on these provisions⁸⁸ have met with vigorous opposition from pharmaceutical companies in some states, and most notably in the United States. This in turn led to a further round of negotiations between members of the World Trade Organisation as to the precise meaning of Article 8 TRIPS and para 4 of DOHA. When, for example, are measures *necessary* to protect public health? Who should decide this? And, how far can a state go to *promote* access to medicines for all?

17.34 The problem is particularly acute for developing and least developed countries, as is recognised by para 6 of the Declaration on Public Health:

We recognize that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement.

The stumbling block in this regard has been Article 31(f) of the TRIPS Agreement which provides that production under compulsory licence must be predominantly for the domestic market. How, then, can drugs be produced in developing countries—even with the exemption of compulsory licence protection—if those countries do not possess the infrastructure to manufacture such drugs? Moreover, how can other states assist if their own generics production should be limited to their own market?

17.35 The TRIPS Council was given the difficult task of finding an equitable solution to this problem before the end of 2002. This did not happen. Negotiations reached stalemate when the United States emerged as the sole country to reject an EU proposal to amend TRIPS so as to allow members to grant compulsory licences for the export of medicines to countries that do not have any substantial manufacturing capacity of their own.⁸⁹ The United States objected to the fact that developing countries could declare for themselves when measures were necessary, and sought to limit the regime only to medicines for the treatment of HIV/AIDS, malaria and tuberculosis. A further suggestion from the European Union that an extended list of 22 diseases should be introduced, subject to review and extension on the advice of the World Health Organisation, was also rejected.⁹⁰ The debacle demonstrates

⁸⁸ eg, the South African Medicines and Related Substances Control Amendment Act 1997 sought to improve access to medicines, and in particular treatments for HIV/AIDS, by authorising parallel imports of drugs from other countries where they are available more cheaply and by restricting the rights exercisable under a patent in respect of designated medicines. In Brazil Art 68 of the Industrial Property Law, Law No 9.279 of 14 May 1996 introduced an obligation on drug patentees to produce the patented drug in the country or face a compulsory licensing scheme, except where production was economically 'unfeasible'. This was challenged by the US as an abuse of TRIPS, the resolution being agreed negotiations between the countries should Brazil seek to invoke the licensing scheme against a US company.

⁸⁹ Currently the TRIPS Agreement, Art 31(f) restricts the legitimate use of compulsory licences to the supply of a domestic market.

⁹⁰ A Declaration from the Second Least Developed Country Trade Ministers meeting in Dhaka,

only too well the range of political agenda that influence and shape intellectual property law and policy at all levels, from the global through the regional to the local. It highlights too the serious incongruities that arise in the search for a fair balance of the interests at stake: economic and moral agenda rarely make good bedfellows. Add to the equation a political unwillingness to compromise and the prospects for change look bleak.

17.36 This having been said, a compromise was eventually reached on 30 August 2003. This takes the form of a decision to waive countries' obligations under Article 31(f) of TRIPS and to allow countries producing generics under compulsory licence to export to eligible importing countries. This is subject to the caveat that it is done in good faith and in the name of public health. Notably, there is no longer a need to show an emergency nor is there a list of qualifying diseases. It should also be pointed out, however, that 23 countries immediately declared that they would not allow importation under the waiver in what is little more than a thinly veiled act of protectionism. These include the United States, Canada, Europe, Australia and Japan. The measure has been hailed as an equitable solution to the global problem of access to medicines, but in other ways it merely widens the gap between the West and the Rest. While western companies continue to tighten their grip over their domestic markets, new markets are simultaneously opened up to them with no means to influence or control the prices of their products. In the absence of measures to ensure that generic production takes place, developing countries will have precious little option but to trade on terms driven by the intellectual property owners, thereby merely accentuating the power imbalance endemic in this area.

Footnotes

* I am indebted, as is so often the case, to my colleague Ken Mason for his comments on an earlier draft of this contribution. The usual disclaimer applies to my own efforts.

Bangladesh, 31 May–2 June 2003 contains proposals advocating, inter alia, that public health problems and the terms of compulsory licences should be the prerogative of least developed countries so long as they retain that status.