Thoughts on the Scope and Operation of Morality Clauses in Patent Law

Djims Milius and David Townend

The European Patent Convention in Article 53 requires 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.” The Norwegian Patent Act prohibits the granting of patents “the use of which would be contrary to morality or public order”.

This was developed in 2003 such that the prohibition was specifically extended under section 1.b: “Inventions shall be considered unpatentable where their commercial exploitation would be contrary to ordre public or morality. Such exploitation shall not be deemed so contrary merely because it is prohibited by law or regulation”. This extension then specifies that certain applications relating to human cloning, human embryos, and genetic modification of humans and animals are prohibited under this provision.

In responding to the request to consider how a specialist ethics commission could consider the operation of these “morality clauses” or morality requirements, we have considered two things: first, how case law shows such questions have been considered by courts and tribunals; and second, whether there are broader considerations that could apply in contrast with the case law approach, particularly in relation to the nature of the grant of a patent, the underpinning presumption of private property rights, and the tendency towards a utilitarian calculus. We have used three case studies to focus our thoughts.

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3 Patent Act, Section 1, translation from the Norwegian Patent Office Website: http://www.patentstyret.no/en/english/Legal_texts/Patents_Act/ (last accessed: 10.10.2007)

4 Amended by Act number 127, 19th December 2003.

5 “On the basis of the first paragraph the following, in particular, shall not be patentable
   1. processes for cloning human beings,
   2. processes for modifying the genetic identity of human sex cells,
   3. use of human embryos for industrial or commercial purposes, and
   4. processes for modifying the genetic identity of animals, which are likely to cause them, suffering without any substantial medical benefit to man or animal, including animals resulting from such process.”

Norwegian Patents Act, as amended by Act no. 127, 19th December 2003
Part One: Morality and Ordre Public in case law

Case Study One - The Harvard Oncomouse

The facts
- The oncomouse is one of the first transgenic animals to be produced in the early 1980s. It was highly susceptible to cancer due to the introduction of an oncogene that can trigger the growth of tumours. It was conceived as a valuable means of furthering cancer research.
- Harvard College sought patent protection in the United States and several other countries.

The ethical issues
- Should patents be granted at all over animals or animal varieties which may be higher order mammals?
- What are the moral implications of suffering caused to the transgenic animal?

The resolution
- United States Patent Office (USPTO) granted patent no. 4,736,866 to Harvard College for the oncomouse claim, which explicitly excluded humans, patents on them, or modification to their genome.
- European Patent Office (EPO) considered the case at length and at different levels of Appeal until it was resolved in 2004 that patenting exclusion Articles 53(a) and (b) of the EPC suggest that the oncomouse was not an animal variety, and so did not fall within the exclusion.
- The EPO applied a utilitarian balancing test to address the ordre public and morality issues, weighing the suffering of the oncomice against the expected medical benefits to humans. Patent with modified claims limited to mice was granted on the EPO being satisfied of the tests it applied⁶.
- The Canadian patent examiner rejected claims to transgenic animals because they were not included in the definition of an invention, but allowed claim on the process for creating the oncomouse.
- The Supreme Court of Canada ruled that higher life forms were not patentable; composition of matter was understood as a combination of ingredients or substances, the body of the mouse was not; Parliament should engage in public debate to address the legislative gap⁷.

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⁶ Board of Appeal of the European patent Office, Decision of 6 July 2004, T 315/03
⁷ Harvard College v Canada (Commissioner of Patent) 2002 SCC 76
Conclusion

- The oncomouse case highlights how different jurisdictions have dealt with the basic question of whether a transgenic animal complying with patentability requirements should be considered patentable subject matter, while addressing the ethical dimensions of the oncomouse technology.
- DuPont owns the patented OncoMouse technology and grants free licences to non-profit institutions for cancer research.

Case law exploring patents and morality issues

Law and morality are connected, and the nature of that connection is being revealed in the case law relevant to patents and morality. For legal decision-making in patent law and policy, the courts have, in Europe, the European Patent Convention (EPC 1973) which at Article 53 (a) does not allow the grant of patents for “inventions the publication or exploitation of which would be contrary to 'ordre public' or morality”.

(Drahos 1999, p.441) In addition to the morality exclusion, the EPC also excludes plant and animal varieties, and processes for producing them, from patent protection.

The Article reads thus,
European patents shall not be granted in respect of
(a) inventions the publication or commercial 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.

The EPC makes provisions for a system of Appeal Boards which render judgments and makes decisions which influence European national patent laws. On judging exceptions to patentability under the EPC, Rules 23b to 23e EPC concerning biotechnological inventions gives guidance on the definition of certain terms. In addition, the European Directive 98/44/EC on the legal protection of biotechnological inventions (the Biotech Directive), was incorporated by the EPO into its rules in June 1999 as a supplementary means of interpretation.

8 Article 53 (a) reads in full:
European patents shall not be granted in respect of
(a) inventions the publication or commercial 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.

9 The Article reads thus,
European patents shall not be granted in respect of
(b) plant and animal varieties or essentially biological processes for the production of plants and animals; this provision does not apply to microbiological processes and the products thereof.

10 The EPO’s 5th edition of the Board of Appeals Case Law states that:
“Over a period of twenty-seven years (the first decision of a Board of Appeal was handedown in March 1979), a substantial body of case law on the European Patent Convention has developed. The Boards of Appeal have settled more than 21,000 cases. 85 decisions or opinions of the Enlarged Board of Appeal have clarified legal points of fundamental importance in order to ensure uniform application of the law.” (p.1)
Whilst the national patent offices and courts can express differences from the EPO, there has been a clear movement toward harmonisation of laws and practices in Europe. (Crespi 2006, p.569)

Living matter is patentable under the EPC

In principle, the case law and decisions handed down by the Board of Appeals (EPO) follow the guidance that any exceptions to patentability must be narrowly construed. Although no commentary has been made on the relevance of the EPC to possible ‘patentability exclusion’ cases previous to its coming into force, there is an indication that the patenting of living organisms began with Louis Pasteur and his isolated yeast in 1873, only a decade prior to the introduction and entry into force of the Paris Convention (1883), which made no provision for morality as it is understood today with regards to biotechnological inventions. The EPC has made no comment on the possible outcome in Europe of a case similar to the US case of Chakrabarty in which an oil-eating bacteria was granted a patent. That said, however, it is clear that living matter is not generally excluded from patentability under the EPC. A certain trend to this effect began to emerge with the judgment handed down in the Ciba-Geigy/propagating material case of 1984, in which the board, referring to Article 53(b) EPC, stated that no general exclusion of inventions in the sphere of animate nature could be inferred from the EPC.

Because exceptions to patentability must be narrowly construed, case law relating to the patentability of living matter has since further shown that:

1. the exception under Art. 53(b) EPC applies to certain categories of animals but not to animals as such;
2. a claim in which specific plant varieties are not individually claimed is not excluded from patentability under Art. 53(b) EPC, although it may embrace plant varieties

The case involving the application for the Harvard Oncomouse has resulted in a number of decisions on the principles behind permitting or excluding the patentability of living matter. Prior to the protracted series of appeals to the relevant boards that characterises this case, the application for “transgenic animals having an increased probability of developing cancer” was initially refused on the basis of Art 53(b) EPC, which prevents the patenting of animal varieties, and Art. 83 EPC, since it was unclear whether the only examples of mice provided in the application was applicable

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11 It should be noted that implementing regulations R. 23b to R. 23e EPC incorporate relating to morality questions, taken from Biotech Directive Articles 5 and 6. (REF, Nature Article)
13 From that case, it was clear that under US law, anything created by man is patentable and in the US, unlike Europe, there is no morality exception in patent law. Issues which under European provisions would raise morality concerns, in the US would be treated as matters concerning higher policy and would be likely to be passed on to Congress for deliberations and decisions.
14 OJ EPO 1984, p.112
15 T 19/90 OJ 1990, p.476
16 G 1/98 OJ 2000, p.111
to all other animals. On appeal, the argument on insufficiency of disclosure did not hold, neither did the argument advanced concerning morality and *ordre public* under Art. 53(b) EPC because it was held to apply to certain categories of animals but not to animals as such, although the Board was of the view that in a case where there was genetic manipulation of animals by insertion of an activated oncogene, there were compelling reasons for considering issues of morality as presented in Art. 53(a) EPC. (EPO 2006, p. 39) This, then, is the current view concerning patenting of living matter. As has already been noted, however, when the morality discussion was engaged, a utilitarian view prevailed.

**Inventions contrary to morality or *ordre public***

Further regulations on the implementation of the EPC specify that European patents shall not be granted under Art. 53(A) EPC for four categories of biotechnological inventions. The last of these categories provides a test for morality or *ordre public* that would consider animal suffering, medical benefit and the correspondence of the two in terms of the animal(s) concerned. (EPO 2006, p.39) The test developed to address the morality issue was based on a Rule 23d type argument to the Art. 53(a) EPC objection and included a careful weighing up of the likelihood of animal suffering and of medical benefit. The Board found that both tests were satisfied when the claims of the application were restricted to mice. (Thomas & Richards 2006, p.59; EPO 2006, p.40)

With regards to the issue of morality when addressing patents on biological materials isolated from humans, the Relaxin case gives a sense of how the case law applies in this area. The patent concerned was for the “molecular cloning and characterization of a further gene sequence coding for human relaxin”. (EPO 2006, p.40) Despite the Opposition Division rejecting the opposition on the basis that “an invention concerning a human gene did not constitute an exception to patentability because it would not be universally regarded as outrageous”, on appeal, the Board considered the new Rule 23e(2) EPC through which it was able to decide that the Relaxin

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17 Rule 23d

Exceptions to patentability Under Article 53(a), European patents shall not be granted in respect of biotechnological inventions which, in particular, concern the following:

(a) processes for cloning human beings;
(b) processes for modifying the germ line genetic identity of human beings;
(c) uses of human embryos for industrial or commercial purposes;
(d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes. Online at [http://www.european-patent-office.org/legal/epc/e/r23d.html](http://www.european-patent-office.org/legal/epc/e/r23d.html)

18 [1995] E.P.O.R. 541

19 Rule 23e

The human body and its elements

(1) 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.

(2) 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 a natural element.
subject matter was not to be considered as an exception to patentability under Art. 53(a) EPC. Aspects of the opposition relevant to morality are represented in table 1 below.

Table 1. The Relaxin Case and Morality Issues

<table>
<thead>
<tr>
<th>Challenge by the Green Party</th>
<th>Response by the EPO Opposition Division</th>
</tr>
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<tbody>
<tr>
<td>• The patent was contrary to morality or ordre public</td>
<td>• It would not be viewed by the public as too abhorrent to be patentable</td>
</tr>
<tr>
<td>• Isolating a gene from tissue taken from a pregnant woman was an offence to human dignity, as it used the pregnancy for a technical profit-oriented process</td>
<td>• The tissue was donated with consent within the framework of gynaecological operations. Many life-saving substances were isolated in this way, patented and welcomed by the public</td>
</tr>
<tr>
<td>• Patenting human genes “amounts to a form of modern slavery since it involves the dismemberment of women and their piecemeal sale to commercial enterprises”</td>
<td>• Gene patents do not confer any rights over individual human beings. There was no dismemberment of humans since the point of the invention was to synthesize the hormone</td>
</tr>
<tr>
<td>• Patenting human genes was tantamount to patenting human life, and would as such be intrinsically immoral</td>
<td>• “The patenting of a single human gene has nothing to do with the patenting of human life. Even if every gene in the human genome were cloned it would be impossible to reconstitute a human being from the sum of its genes.” No moral distinction was seen between the patenting of genes and the patenting of other important human substances, such as adrenaline.</td>
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Source: adapted from WIPO (2006a), pp.16-17

The morality issue in patenting also arises with regards to plant biotechnology. In Plant Genetic Systems the Technical Board of Appeal (TBA) of the EPO offered that:

(3) The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application. Online at http://www.european-patent-office.org/legal/epc/e/r23e.html

20 The Opposition Division refused the Opposition by the Green Party in conformity with the generally accepted principle that all exceptions to patentability are to be construed narrowly rather than broadly. They indicated that “only in those very limited cases in which there appears to be an overwhelming consensus that the exploitation or publication of an invention would be immoral may an invention be excluded from patentability under Article 53(a).” (Crespi 2006, p.570)
Plant biotechnology cannot be regarded as being more contrary to morality than traditional selective breeding
Plant cells cannot be considered to fall under the definition of a plant or a plant variety
Micro-organism includes all generally unicellular organisms with dimensions beneath the limits of vision

In considering the morality objection in depth, which was that it was immoral to own plants, which were the common heritage of mankind, the TBA considered that “there was no European definition of morality”, the same being said about _ordre public:_

“The Board considered that... ‘ordre public’ covered the protection of public security, the physical integrity of individuals, and the protection of the environment. The concept of morality was “founded on the totality of accepted norms deeply rooted in a particular culture”, which, for the EPC, was “the culture inherent in European society and civilisation”. [Thus] inventions whose exploitation was “not in conformity with conventionally accepted standards of conduct pertaining to this culture” were to be excluded from patentability as being contrary to morality.” (Crespi 2006, p.570)

In the end the Technical Board of Appeal considered the objections unjustified and rejected the opposition. More recently, advances in stem cell research have also raised questions for patenting and morality. Two cases of particular interest are the Edinburgh patent and the WARF/Stem cells case, the lessons of which are summarized below.

**Patenting Stem Cells: Morality in Future**

The Edinburgh European patent 0 695 31 was granted on 8th December, 1999. The invention was made by Professor Smith and Dr Mountford in 1993 at the Centre for Genome Research (now the Institute for Stem Cell Research). It addresses the problem of separating desired stem cells from other types of cells. The patent description lists a variety of stem cells sources for use in the method and defines the term “animal cell” very broadly to include human cells. (Crespi 2006, p.572) Although the original work was carried out on mice cells, the methods described are said to apply to embryonic stem cells generally. The patent covers methods carried out on human embryonic stem cells and also covers human embryonic stem cells which have been genetically modified so that they can be used in the selection methods. As part of 13 total objections to the patent by a number of opponents, the following issues were raised by Greenpeace and included:

- the patent could and would be read so as to embrace human cloning
- human stem cells of any sort were not suitable for patenting
- it would be contrary to morality to allow patents for such subject matter.

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21 T356/93
A 2002 decision on the case applying Art. 53(a) EPC and Rule 23d(c) stated that human embryonic stem cells and processes carried out on human embryonic stem cells are not patentable, and that claims to such inventions have been held to be contrary to morality. This decision is currently under appeal, which means that the decision could either be approved or reversed by the Technical Board of Appeal.

There is a strong possibility that future decisions handed down for the Edinburgh patent may have some influence on the patenting and funding of stem cell research in general. Despite the current policy on stem cells at the EPO, and the Biotech Directive prohibiting the patenting of “uses of human embryos for industrial or commercial purposes”, the scope of this exclusion has been interpreted differently by different Patent Offices. For instance, the UK Patent Office’s position is that

“it will distinguish between inventions that relate to totipotent stem cells on the one hand (that is, cells which are individually capable of producing an entire human body) for which patents are not being granted and pluripotent or multipotent stem cells on the other (that is, cells which are not individually capable of producing an entire human body) for which patents are being granted”

Numerous scientific and policy bodies in the UK have recognised the enormous potential of stem cell research to yield a number of treatments for various diseases. There is a large disparity in patenting practices in the area of human embryonic stem (hES) cells between the US, which to date has granted over 41 patents that claim hES cells in their application, whilst none has been granted to date in Europe. (Porter et al. 2006, p.653) The morality questions being asked concern the patenting of stem cells isolated from a human embryo and of processes involving these cells. In a submission to the Enlarged Board of Appeal of the EPO, the UK Patent Office noted that answers provided in the case of the Wisconsin Alumni Research Foundation (WARF) with regards to a patent application describing “a cell culture comprising primate [including human] embryonic stem cells” should consider that

“[t]here should be no question of this reference calling into question the patentability of human embryonic stem cells per se, if the skilled person can implement the invention without the use and destruction of human embryos, whether because of a deposit of a cell line with a recognised depository or otherwise.” (UKPO 2006, p.12)

In response to the morality objection, the UK’s position is that

“there is no reason to believe that the use of the human embryonic stem cells of the claims (e.g. by multiplication and use in research or therapy) would be regarded as contrary to conventionally accepted standards in European society as a whole…. Rather, there is a significant strand of

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23 CIPA, online at http://www.cipa.org.uk/pages/SCEurope
opinion which regards such uses as entirely moral because of their immense potential scientific and medical benefits.” (Ibid.)

In denying that there is a European consensus on the morality of the use of hES cells, the UK Patent Office is able to conclude that “[i]n cases (unlike the present) where claimed human embryonic stem cells can be made without the use or destruction of embryos, it is submitted that there will be no Art. 53(a) objection to patentability.” (Ibid., p.13) The UK sees no objection in allowing practices where the applicant or his licensee can make the claimed stem cells without the use of human embryos for industrial or commercial purposes. In the end, the UK submits that it would not be immoral for the applicant to exploit his invention of claimed embryonic stem cells. (Ibid.)

The WARF/Stem cells application was refused by the EPO Examining Division, and the Technical Board of Appeal has referred the matter to the Enlarged Board of Appeal with a set of questions it hopes to gain clarity on.25 Given that part of the rationale for issuing guidelines on the patentability of biotechnological inventions by the EU was to improve the competitiveness of the European biotech industry by clarifying and harmonizing EU biotech patent laws, the large differences in patenting policy between EU member states suggests that not only could Europe be at a disadvantage to the US in reaping the rewards of stem cell research, but that even within the EU, some members like the UK may have a competitive edge over others such as Germany, Holland and Italy who have banned research on human embryos.26

**Conclusion concerning Morality and Ordre Public and biotechnology in case law**

The case law strongly suggests a progression of judgments handed down by the EPO bodies that attempt to clarify and streamline provisions and tests for deciding on morality or ordre public objections to the patentability of living matter. A number of proposals consider that the EPO or national patent offices should only be concerned with the scope of monopoly granted and its consequences when considering the patenting of stem cells of human origin. (Laurie 2004, pp.63-5) In addition to proposing having a regulatory body handle issues of morality in this area of research, other suggestions include dealing with the morality questions in stem cell research ahead of the prospect of a Community Patent by including considerations for the diverse morality perspectives existing in the European Community. A more radical approach suggests that it is undesirable that patent law in Europe is becoming “a forum for addressing moral questions on which society at large is so divided and largely confused”, rather than separating these matters to be dealt with by the European Court of Human Rights for instance. (Beyleveld & Brownsword 1993, chap 2.) The US approach of referring such matters of high principle to Congress for consideration has stronger democratic credentials than leaving such questions in the hands of unelected public officials. That said, the democratically elected representatives must be informed by specialist scientific and ethical opinion as well as the sense of the public’s mind if the high principles are to be given appropriate consideration.

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25 WARF/Stem cells (T1374/04) [2006] E.P.O.R. 31 (EPO (Technical Bd App))
Whilst it is clear that issues of morality are increasingly relevant to patenting policy and practices, the rigid set of guidelines provided by the EPC, its Rules and the Biotech Directive seem, on occasions, to be unsuitable or confused by the body of cases exemplifying progress and the state of the art in biotechnology research today. Equally, the narrow construction of the morality question implies that the question is divorced from broader considerations about the place of biotechnology and bioscience developments in society. However, the retention of the consideration of the issue in relation to the granting of patents can imply to other fora that the issue of the morality of the inventions is being dealt with satisfactorily through the patent system for society.

**Part Two: Broader Considerations about Morality and Patents**

**Decision-making in the Public Interest**

In considering the way in which the morality clauses have traditionally been discussed in the case law, there is a strong sense that the law and process does not provide adequate tools for framing the debate and ensuring that interests and perspectives are handled equally. Part of the difficulty is that in including a morality clause, the law is requiring a judgement that ethics seems equally reluctant to supply. Whereas ethics speaks clearly about the internal structure of a particular argument, it seems less keen to make judgements about the “right answer” between competing arguments. It is then, perhaps, no surprise that there is a tendency to move towards utilitarian calculus to answer the problem, as it offers a framework within which to make decisions of competing ethics.

The difficulty for deciding questions of morality is not so much determining what a particular theoretical or compromise ethical position would suggest in a particular situation (although this is difficult enough), the difficulty is to find a framework within which the competing results from the different approaches can be evaluated and adjudicated upon. As was seen in the Oncomouse case, there can be a tendency in decision-making to adopt a strongly utilitarian balancing exercise to weigh the competing interests. It is a very attractive, pragmatic position to take. It allows all the possible interests to be voiced and given comparative values, and in this the outcome has a sense of democratic validity. However, there are concerns, well known, with the position. The first is that the value placed upon each competing element in the calculation – the weight given to each claim – is not obvious and depends in very large measure on the starting position of the decision-makers. Thus, in considering the morality of patenting the Oncomouse, the relative value placed upon human life as against animal life will differ between the humanitarian and the animal rights activist. It may, in other cases, depend upon such considerations alongside commercial interests or the interests of the advance of science. The calculation depends in part upon already determined values (or positions) which, in the utilitarian calculation as it operates in court rooms, Parliaments, and ethics committees across the world, are not spoken. The second, well known difficulty with utilitarian calculations is the

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[27] In the same way that transparency in public office requires, for example, a Member of Parliament or other public official to disclose his or her business interests and investments, a register of interests of those charged with undertaking ethics calculations could usefully indicate their ethical stance and opinion.
“tyranny of the majority”, which Mill himself identifies. (Gray, 1991) This identifies that the aggregate effect of the application of the utilitarian calculus (particularly when it is used as a framework for determining the ethics of a particular action, rather than determining a best government question\(^{28}\)) can produce devastating effects upon the minority which is, inevitably, created. Whereas this is a concern to rights-based thinking, utilitarianism requires that the benefit must prevail.

One of the further, major difficulties of the, often unidentified, reliance upon utilitarian methodology and thinking, is the aggregating effect of the calculation. When the calculation is made in terms of the adding together of the benefits to individuals and the sufferings of others, the effect can be quickly that the small benefit to a large number of individuals outweighs the large suffering to an individual or small group of individuals. Where this method is mixed with rights-based theories, this can be problematic, as utilitarianism is consequentialist and not rights-based. However, rights-based theories can often be equally quiet on how to adjudicate between competing rights. This problem will become increasingly important in future decision-making about patents in biotechnology and the biosciences, as the subject matter of the patents becomes more clearly about information relating to individuals.

When considering the removal of rights under the data protection directive (95/46/EC), Townend has argued that the way to consider the calculation and to give a greater protection to competing rights holders is to treat the question as one which concerns only competing individuals rather than aggregating the scores of many or all people (Townend, 2004). This is justifiable as the benefit to each individual within the majority is not enjoyed any the more by that individual’s claim being bundled together with the benefits of others. First, when considering the competing claims of individuals, the focus should be upon the harms. This should include a consideration of the harm of not gaining a potential. In making the calculation, the relative positions should then be considered between the actual person who stands to have his or her rights removed and the worst affected notional person if the rights of the actual person are not removed. One must first consider the reasonably foreseeable harm that is likely to occur to the actual individual if his or her rights are removed. Second, one must consider the reasonably foreseeable harms that will occur to the worst affected notional person if the rights were not removed from the actual person. In such a calculation, the rights of individuals are more protected as the calculation considers only one individual against another; and the consideration of harm, and the notion of lost benefit as harm, equally could offer a greater safeguard to individuals than the consideration of benefits against harms.

This model was devised through thinking about the situation where an actual individual’s rights (data protection rights) stand to be removed for the public benefit. The situation in applying the morality clause is somewhat different as the decision potentially involves a three-way consideration of the issue. First, there is the actual individual in the person of the applicant. But for the Article 53 consideration, an applicant who satisfies all the other criteria of an invention that is novel, has inventive step and industrial applicability (and is not falling foul of the other prohibitions, for example in relation to mathematical theory or discovery) is entitled to a patent, and the opportunity that it brings. There is a calculable harm to that individual if the

\(^{28}\) We are grateful to Dr Mark Taylor, SIBLE, for discussions on this point.
decision is that the invention is against morality. This has to be measured against the reasonably foreseeable harm to two other, notional individuals. First, the position of the worst affected potential beneficiary of the invention’s promise should be considered. What potential benefit could the invention bring in the best scenario to a notional individual, and what harm would therefore be suffered if that potential was refused? Second, the potential harm to the worst affected objector has to be calculated. What is the potential harm that is claimed by the notional representative of a particular moral or other position? This is more difficult, as it covers a range of potential harms, for example, the harm to the embryo, to animals, to individuals whose genetic data is used to create the invention, etc. Thus three potential individuals could be considered in the calculation.

There are two potential problems with this application: first, there could be a double weighting of the benefit side of the equation in considering the applicant and the worst affected beneficiary; second, the calculation still requires value judgements which are not objective. The first criticism is correct. Whereas it is possible to include the applicant in the calculation, more properly he or she should be seen as one of the potential beneficiaries of the grant of the patent, and he or she should be considered only alongside other potential beneficiaries in calculating the harm that may flow from not granting the patent. For a proper weighting of the calculation, the rights of the two potentially worst affected individuals, one from the lost benefit side, and the other from the lost moral or other position side should be considered only, making the calculation again a two-sided balance of individuals. The second criticism remains true. This does not solve the difficulty of making decisions on the basis of subjective value judgements. However, the interpretation of all rights and utility has that problem, and this method seeks to acknowledge the difficulty by requiring the calculation to be reworked into harm claims rather than the more obscure rights or utility claims.

Case Study Two - Open Model of Innovation: Access to Medicine for All

Tim Hubbard and James Love have argued²⁹ that

- The existing business model for drug development leads to high prices and unequal access
- Trade rules based on intellectual property should be modified to promote the use of alternative policy instruments to encourage innovation

Within this, they argue that:

- There is now widespread dissatisfaction with drug prices in both the developed and developing countries
- In the US, the uninsured simply cannot afford the newest medicines; In developing countries, life-saving medicines are prices beyond the reach of most people, which is a morally offensive outcome

• High drug prices are a consequence of a business model that uses a single payment to cover manufacture and research and development for the drug
• TRIPs and other IP agreements require members to implement patent systems that prevents competition from generics manufacturers
• The single payment system is an enormously inefficient of purchasing R&D

Proposition

Hubbard and Love argue that, given that spending on drug expenditure is close to 1% of GDP in most developed and developing countries worldwide, and that this contribution is enforced by trade agreements granting 20-year protection on patents,

• WHO should develop an R&D contribution ‘norm’ which would non longer be regarded as ‘free riding’; trade rules could be modified to allow countries to meet this norm by means other than the implementation of strict TRIPs IP rules, as at present
• There is an opportunity to experiment with new models based on the creation of separate competitive markets for sales and R&D; countries adopting the latter system would remove patents on final drug compounds, placing them in the public domain for the purpose of low generic prices
• Hubbard and Love’s proposal includes two distinct streams of funding represented in figure 1 regulating the R&D market, and another drugs sales market. (2004, p.149)

Figure 1. Hubbard and Love’s Proposal for R&D and Sales Markets

An alternative market-based approach is to have R&D organisations compete for rewards for specific R&D output (a prize model) perhaps a large fund set up by government and to be awarded every year; this could work with (licensing for rapid introduction of generics) or without the patent system

• There are a number of open collaborative public goods models such as those for the Human genome and the success of GNU/LINUX in software development
• Complete openness allows independent and open evaluation of R&D outputs

30 More recent comments and replies to critics by Tim Hubbard on the proposal are available at http://www.who.int/intellectualproperty/submissions/SubmissionsHubbard.pdf (last visited: 10.10.2007)
Case Study Three - Orphan Drugs and Clinical Trials

Challenges

- 40,000 cases of tsetse fly-transmitted African sleeping sickness cases each year
- More than 16 million people have Chagas’ disease (endemic in South and Ventral America) and 15% die prematurely of heart failure or other complications
- More than 12 million people have leishmaniasis (a range of diseases found throughout the tropics and sub-tropics) which includes severe skin, liver and spleen infections
- Many of the current drugs have serious side effects and would not meet current standards for safety and efficacy; Others are too expensive or become less effective because of selective resistance
- No vaccines exist to prevent these debilitating and often lethal infections

In 2005, the Wellcome Trust has awarded £8.1 million over 5 years to a team of 6 scientists from Dundee, led by Professor Mike Ferguson, to help discover new drugs to treat some of the world’s most neglected tropical diseases.\(^3\)

- The scientists’ goal is to translate basic research discoveries into candidate drugs ready for clinical trials
- The diseases investigated include African sleeping sickness, Chagas’ disease and leishmaniasis

What the research project plan to do:

- The Dundee scientists aim to bridge the gap between basic research in academic laboratories and applied research in the drug industry
- They are embarking on a programme to exploit drug targets already discovered in their basic research by adding industry-style compound screening and medicinal chemistry
- This initiative aims to marry the best of drug industry practice with academic excellence in a University environment
- The group aims to deliver at least 1 drug candidate suitable for entry into formal pre-clinical development against one neglected disease by March 2011.\(^4\)

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\(^3\) See [http://www.drugdiscovery.dundee.ac.uk/tropical/overview/](http://www.drugdiscovery.dundee.ac.uk/tropical/overview/) and [http://www.wellcome.ac.uk/assets/wtd026672.pdf](http://www.wellcome.ac.uk/assets/wtd026672.pdf)

\(^4\) With regards to the aims and goals funded by the research, it is important to note that:

- The New drug discovery programme at the University of Dundee matches the goals of both the Drugs for Neglected Diseases Initiative and the UNICEF-UNDP-Wold Bank-WHO Special Programme for Research and Training in Tropical Diseases (see [http://www.wellcome.ac.uk/doc_wtx027342.html](http://www.wellcome.ac.uk/doc_wtx027342.html))
- The Wellcome Trust is an independent research-funding charity established in 1936 under the will of tropical medicine pioneer Sir Henry Wellcome. The Trust’s mission is to promote research with the aim of improving human and animal health and it currently spends more than £400m p.a.
The Scope of the Morality Question

These two case studies pose a rather different question about the morality clause. To us, the cases suggest a very much broader interpretation of morality. Both question why limits have been placed upon morality so that it excludes the broader, general place of patenting within society. There seems to be a very strong acceptance that it is not the place of those considering the morality question to address, for example, the basis of property upon which the patent is granted. This may be, in no small part, related to the strong traditional approach that the patent is not a permission to create a product. It is merely a monopoly giving an opportunity to exploit a product on the market. The underpinning private property ownership basis of patents is not questioned within this assumption, although the effect of its operation may have high moral consequences. Equally, there is a sense that the real question of whether something is moral will be decided by the purchasing power of the market. This approach, however, stands against the imperative of Article 53, that the “publication or exploitation” of the patent would be against morality or ordre public. To us, the Article should be construed widely to understand the full moral implication of, particularly, the exploitation of the patent. This is not least the case because the inclusion of this test within the granting of the patent will imply to the purchasers in the market, and the politicians considering the appropriateness of the production of the patent, that the exploitation of the patent has been considered by experts and has been found to be not immoral, and therefore could well prejudice their approach to the question.

The work of Hubbard and Love suggests to us that the grant of a patent should reflect a wider ownership than simply that claimed by the applicant. They show that the variety of funding that comes from the community, both domestic to the patent applicant and international, means that the contributions are more sophisticated than the usual claims concerning research and development tend to be. Their work resonates, in our opinion, more closely with Robert Nozick’s interpretation of the claim to ownership following added value than with the more traditional Lockean claim that underpins the justification for much of intellectual property ownership. It is arguable that a grant of a patent that did not reflect the true funding underpinning the application and the work related to it would be immoral.

The implications of the orphan drugs case for the consideration of morality in patents is more difficult to see. There are a number of elements to consider alongside the case. First, there is the human rights context within which patents are granted. Under the Universal Declaration of Human Rights, there is a right to own property. Further, “[e]veryone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author”. Alongside this, however, “[e]veryone has the right freely to participate in the cultural life of the community, to enjoy the arts and to share in scientific advancement and its

33 Locke argues that the individual owns his or her body, and therefore the benefits of his or her work. Nozick argues that one cannot claim the benefit of the work of others, only the added value of one’s own contribution is available for ownership. See Hettinger (1989) and particularly Nozick (1974).
34 Universal Declaration of Human Rights (1949) Article 17(1).
35 Article 27(2).
benefits”). This is further supported by secondary rights to health care and welfare. The traditional approach is to interpret the property rights as private, industrial revolution style property rights, and to interpret the cultural and welfare rights as rights not to be excluded from access to these rights except for reasons of economic discrimination. However, neither position is, arguably, necessary from the language of the Declaration.

In relation to the assumption that “property” is private, industrial revolution property, there is a strong literature, particularly in the 1960s and 1970s, first, that property is open to conceptual change, and then, second, exploring the nature of the rights that are available. The implications from this work are that property changes according to the social needs of a particular time. When one considers a rights-based approach to the justification of ownership such as that presented in Byleveld and Brownsword (2002), where the basis of ownership is required to be as a secondary support for the primary right of agency, the implication for the requirements of availability of the benefits of patents become extraordinary. When one also introduces the cases such as the AIDS drugs patents into this debate, the right of patent applicants, or holders, to retain their full, but only secondary, patent rights in the face of claims that holding those property rights place in jeopardy the primary rights of agency of others becomes difficult to sustain. How this is not a matter concerning the morality of the “exploitation” of a patent is difficult to imagine.

Conclusions
The case law where the morality clauses have been considered do not show a consistent approach to considering moral and ethical questions. The narrow construction of the morality question and the utilitarian presumptions of cost and benefit seem to limit the scope of the discussion of morality; the debate does not feel to be conducted with sufficient expert consideration of the issues with an acknowledgement of individual experts’ personal starting positions. There is a strong argument that the place for the debate about the morality of an invention is not in the Patent Offices and in the hands of unelected public officials, but that rather the debate should be had in parliaments and elected fora. However, that debate must be informed by expert opinion, and it may be that an expert forum informing the Patent Office is equally good in ensuring that the morality clauses are given full and detailed discussion. A framework for that debate could be through analysing the impact of potential harms on notional, competing individuals, to avoid the tyranny of the majority and to make subjective value judgements more explicit. Most importantly,

36 Article 27(1).
37 Macpherson (1975) argues that there is a conceptual progression in property from feudal ownership, with strong elements of common ownership and ownership based upon social duty, though industrial private property, characterised by the citizenship right to easily transferable private, exclusionary property, to potential new forms relating first to the valuable commodity of welfare rights and then to political rights.
38 See, for example, Reich (1964) and Christie (1978).
39 For a discussion of the implications of this argument in relation to genetic information, see Townend (2003).
40 Where access to patented AIDS drugs has been challenged by the actions of producing generic drugs in a number of jurisdictions, notably South Africa.
the debate itself is arguably much broader than the current, narrow view taken about
the application of the morality clauses. The challenges of modern biotechnology and
bioscience require a discussion about the morality of ownership of the benefits that
flow from such advances. In this respect the morality clauses should be understood to
include both a fair reflection of the relative investment in the science and
development behind patent applications, and the need to develop the science to
deliver benefits through mechanisms beyond private profit.

List of Cases

- The Edinburgh European patent 0 695 31 (granted Dec 8, 1999)
- WARP/Stem cells (T1374/04) [2006] E.P.O.R. 31 (EPO (Technical Bd App))

References


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