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***247 SPLICING MORALITY AND PATENT LAW: ISSUES ARISING FROM MIXING MICE AND MEN**

Cynthia M. Ho [FN1]

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I. INTRODUCTION

The question of whether ethics and morality have a place in U.S. patent law has been resurrected by the filing of a patent application involving "chimeric embryos" that contain both human and non-human cells. [FN1] Although the application itself is confidential in accordance with present patent laws, [FN2] the subject matter of the application was publicized by biotechnology activist Jeremy Rifkin, who filed the application in conjunction with cell biologist Stuart Newman (Newman application). [FN3] In fact, they filed the application to *248 prevent others from creating what they considered to be immoral and to at least engender discussion and debate concerning whether such embryos should be patentable. [FN4]

The Patent and Trademark Office (PTO) immediately reacted by releasing a "media advisory" concerning its position on the same day that the application became publicized. [FN5] The advisory stated that "the PTO fully applies the law without discriminating against a particular field of technology" and that patents are not granted unless they "meet the strict patentability requirements set forth in patent laws." [FN6] It further stated that:

[T]he courts have interpreted the utility requirement to exclude inventions deemed to be "injurious to the well being, good policy, or good morals of society"

....

It is the position of the PTO that inventions directed to human/non-human chimera could, under certain circumstances, not be patentable because, among other things, they would fail to meet the public policy and morality aspects of the utility requirement. [FN7]

In noting that there existed "public policy and morality aspects" of the utility requirement, the PTO was resurrecting and relying on the doctrine of "moral utility." This doctrine is based on dicta from the *249 1817 case *Lowell v. Lewis*. [FN8] Although courts once relied on "moral utility" to deny patent protection for inventions used solely for gambling or fraud, no court has relied on this doctrine since the PTO Board of Appeals held that an invention used solely for gambling could be patentable in the 1977 decision of *Ex parte Murphy*. [FN9] Although courts have relied on *Lowell* in recent years, it is quoted primarily for the principle that inventions of specious utility are not patentable, rather than for the doctrine of moral utility. [FN10] In fact, courts have not raised moral utility as a bar to patentability even for inventions designed to circumvent the law. [FN11] Nonetheless, then PTO Commissioner Bruce Lehman characterized the position in the media advisory as consistent with the PTO's long-

standing policy. [FN12] In addition, he noted the necessity of the statement to make clear that "there will be no patents on monsters, at least not while I'm commissioner." [FN13]

Despite the PTO's initial suggestion that it would invoke the moral utility doctrine to reject the Newman application, it apparently abandoned that approach. Instead, the PTO rejected the application *250 for failing to claim statutory subject matter. [FN14] In particular, the PTO asserted that because the application improperly claimed a human being, it failed to claim patentable subject matter. [FN15]

This appears to be the first instance in which the PTO has rejected an application for improperly claiming a human being, although it had suggested that it would do so as early as 1987. [FN16] At that time, the PTO issued a statement clarifying that it considered "naturally occurring non-human multicellular living organisms, including animals, to be patentable subject matter." [FN17] However, the PTO qualified this statement by noting that "a claim directed to or including within its scope a human being will not be considered to be patentable subject matter under 35 U.S.C. § 101." [FN18] The PTO obliquely supported this exclusion by stating that "[t]he grant of a limited, but exclusive property right in a human being is prohibited by the Constitution." [FN19]

*251 The constitutional reference was widely presumed to refer to the Thirteenth Amendment prohibition against involuntary servitude and was criticized for failure to justify the exclusion of humans from patents. [FN20] In particular, it was noted that patents provide only a right to exclude and not an affirmative right to use an invention, let alone possess it. However, the constitutional basis, if any, for precluding patents on humans was overshadowed by the more immediate concerns of whether transgenic animals-- which were already scientifically possible--should be patentable.

The PTO may now have re-evaluated its prior reliance on the Constitution for excluding claims to humans as unpatentable subject matter. Although the PTO has not officially rescinded its prior statement, its recent rejection of the Newman application did not raise constitutional concerns. Rather, the PTO asserted that the Newman application claimed non-statutory subject matter because "Congress did not intend 35 U.S.C. [§] 101 to include the patenting of human beings." [FN21] However, this argument was previously rejected by the Supreme Court in *Chakrabarty*. [FN22] In particular, the Court stated that:

*252 [t]his Court frequently has observed that a statute is not to be confined to the 'particular application[s] ... contemplated by the legislators.' This is especially true in the field of patent law ... Congress employed broad language in drafting § 101 precisely because such inventions are often unforeseeable. [FN23]

The United States Patent Act does not exclude any particular inventions from the scope of patentable subject matter. [FN24] In addition, the patent laws consistently have been broadly interpreted with regard to the scope of patentable subject matter. [FN25] Although the PTO may be of a different opinion, its opinion does not have the force of law. This is because the PTO is charged with administering the patent laws, not with the creation of new law or the interpretation of existing law. [FN26]

However, even if the present patent laws allow chimeras such as the one in the Newman application to constitute patentable subject matter, the application nonetheless raises the important issue of whether inventions that some consider immoral or unethical should *253 be patentable. This issue will persist in the wake of new advances in biotechnology, regardless of the PTO's action on the Newman application. [FN27] Rapid advances in biotechnology seem to outstrip the public comfort level with the use of such technology. [FN28] Moreover, availability of patents for controversial technology seems to create further controversy and public unease. [FN29]

The present debate concerning the place of ethics within the patent system mirrors the previous controversy that ensued, following the PTO's first grant of a patent on a transgenic animal in 1988. [FN30] *254 Public controversy concerning such patents led to a number of legislative proposals to limit the scope of patentable subject matter, including one proposal to explicitly exclude "human beings" from patentability. [FN31] It is foreseeable that Congress will revisit prior proposals, or propose new legislation to limit patentable subject matter in light of the fact that proposals to restrict the scope of patentable subject matter often follow public controversy. [FN32] Perhaps more importantly, it is foreseeable that Congress may give undue consideration to the approach of other patent systems which appear on their face to accommodate morality.

This is particularly true because Congress is obligated to amend the patent laws within the confines of the Agreement on Trade Related Aspects of Intellectual Property (TRIPS agreement). [FN33] *255 Although TRIPS generally requires patent protection to be equally available for all inventions without regard to subject matter, it does allow some important exceptions; one such exception is that subject matter may be denied patentability if its commercial exploitation would violate "ordre public" or morality. [FN34] The scope of this exception has not been conclusively determined. However, because it mirrors the language of other patent systems, those systems thus become relevant in evaluating the interplay between morality and patentability. The two primary sources for such an evaluation are the European Patent Convention (EPC) [FN35] and the European Union's Directive on Legal Protection of Biotechnological Inventions (Biotechnology Directive). [FN36]

This Article seeks to advance the discussion of the proper role of ethics and morality in the United States patent system by examining existing models of incorporating ethics into the context of patentability. In particular, a detailed examination of the European system, is undertaken to determine whether morality can be adequately considered within patent law. Part II of this Article discusses the existing framework for considering morality within the EPC, including interpretation of article 53(a) by the European Patent Office (EPO) and its related courts. Part III of this Article considers the place of morality within future frameworks of patentability. In particular, the Biotechnology Directive is considered and applied to the Newman application to illustrate interpretative difficulties with the Directive. Moreover, this section addresses the implications of the existing frameworks, including the difficulties in their creation and application, for the United States. This section suggests that although morality has a place in other patent systems, that place stands on tenuous ground. At a minimum, existing systems that attempt to *256 incorporate morality into patent laws should not be followed blindly. Part IV concludes by noting that prior models for incorporating morality into the patent system underscore the fact that inclusion of morality within the patent laws does not necessarily resolve morality issues and may instead just create new ones. Accordingly, this part suggests that the use of controversial technologies should be addressed directly, rather than indirectly and ineffectively through the patent system.

II. EXISTING FRAMEWORK FOR CONSIDERING MORALITY

A. European Patent Convention Article 53(a)

In examining existing frameworks for considering morality in the context of the patent laws, the EPC [FN37] is the principle source to consult. Unlike the United States' Patent Act, article 53(a) of the EPC explicitly mandates that morality be considered in determining patentability. The EPC states that patents shall not be granted for "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" [FN38] Neither "ordre public" or morality are defined within the EPC. [FN39] The EPO's Guidelines for Substantive Examination provided to patent *257 examiners explain that the provision only should be invoked in "rare and extreme cases." [FN40] However, the sole example cited in the Guidelines of such a "rare and extreme case" is a letter-bomb. [FN41] Given the ambiguity of article 53(a), as well as the minimal guidance to patent examiners, it is not surprising that relatively few cases exist in which article 53(a) is considered, despite the existence of the provision since the creation of the EPC in 1973. [FN42] Nonetheless, the cases that do exist are useful in examining how considerations of morality within the patent system are applied in practice.

B. Judicial Interpretations of Article 53(a)

1. The Harvard Onco-mouse

The first time EPO courts considered article 53(a) was in the context of a patent application filed by Harvard University concerning transgenic mammals. The inventors had already been granted a United States patent in 1988. Like its United States counterpart, the EPO application claimed a transgenic non-human mammal susceptible to cancer. [FN43] Although the application claimed to be applicable to all mammals, the disclosed data primarily described the use of activated oncogenes in mice and thus the invention was referred to as the Harvard Onco-mouse.

The EPO initially rejected the application for reasons unrelated to morality. The EPO rejected the application as improper subject matter in light of the EPC prohibition against patenting animal "varieties," as well as the fact that the disclosure concerning mice did not support claims to mammals. The Examining Division of the EPO initially

noted that "ethical questions need to be considered" in light of U.S. controversy concerning animal patents that followed the *258 issuance of the first U.S. patent on transgenic mammals. [FN44] However, it ultimately concluded that "patent law is not the right legislative tool" for asking such questions--at least in the case where the invention was perceived to have a possible beneficial effect on mankind. [FN45]

The Technical Board of Appeal (TBA), on the other hand, determined that it was in fact necessary to consider and apply article 53(a). The TBA's determination was likely influenced by what it referred to as "considerable [[public] interest" in the application, including interest in the genetic manipulation of animals in general. [FN46] After determining that no per se exclusion to patenting transgenic animals existed under a separate EPC provision limiting patentability, the TBA stated that:

precisely in a case of this kind there are compelling reasons to consider the implications of article 53(a) EPC in relation to the question of patentability. The genetic manipulation of mammalian animals is undeniably problematic in various respects, particularly where activated oncogenes are inserted to make an animal abnormally sensitive to carcinogenic substances and stimuli and consequently prone to develop tumours, which necessarily cause suffering. There is also a danger that genetically manipulated animals, if released into the environment, might entail enforceable and irreversible adverse effects. Misgivings and fears of this kind have been expressed by a number of persons who have filed observations with the Board Considerations of precisely this kind have *259 also led a number of Contracting States to impose legislative control on genetic engineering. The decision as to whether or not article 53(a) EPC is a bar to patenting the present invention would seem to depend mainly on a careful weighing up of the suffering of animals and possible risks to the environment on the one hand, and the invention's usefulness to mankind on the other. It is the task of the department of first instance to consider these matters in the context of its resumed examination of the case. [FN47]

On remand, the Examining Division considered the Onco-mouse application in light of article 53(a), as ordered by the TBA. Before stating its opinion on the application of article 53(a), the Examining Division noted that "[i]n view of the extraordinary attention the present case has attracted from the public and the importance the public attaches to the question of patenting animals in light of public order and morality, ... the Examining Division considers it appropriate to make a statement on its position concerning these questions." [FN48] The Examining Division noted several patent law principles it considered essential to applying article 53(a):

- (1) a patent only provides a right to exclude others, rather than an affirmative right to use; thus, use of the patented invention may be governed and limited by other laws;
- (2) the EPC recognizes a general principle of patentability such that EPC provisions restricting patentable subject matter should be interpreted narrowly;
- (3) new technology is "normally afflicted with new risks, ... experience has also shown that these risks should not generally lead to a negative attitude vis -à-vis new technologies but rather to a careful weighing up of the risks on the one hand and the positive aspects on the other and that the result of this *260 consideration should be the determining factor in whether a new technology should be used or not." [FN49]

As mandated by the TBA, the Examining Division balanced the factors established by the TBA to determine whether the Onco-mouse invention violated article 53(a). In particular, it considered (1) the utility to mankind in remedying "widespread and dangerous diseases;" (2) the possibility of cruelty to animals; and (3) the possibility of uncontrolled release of unwanted genes into the environment. [FN50] The Examining Division found that the Onco-mouse did not violate article 53(a) as the invention's "usefulness to mankind cannot be denied;" this statement was based on the perception that the invention could lead to development of methods for treating one of the most frequent causes of death and thus benefit all of mankind. [FN51] In addition, the Examining Division determined that cruelty to animals could be considered reduced overall as fewer research animals would be needed using the invention, as compared to traditional methods. [FN52] Moreover, it considered unwanted environmental release to be a minimal risk that would only occur in cases of intentional misuse or blatant ignorance. [FN53] In addition, it commented that exclusion from patentability would not be justified merely because technology was dangerous and emphasized that regulation of dangerous material was within the scope of other *261 government bodies, rather than the EPO. [FN54]

However, the implications of the Onco-mouse decision may be limited. First, the Examining Division expressly cautioned that its considerations applied solely to the Onco-mouse application and that a different conclusion could conceivably be reached in applying article 53(a) to other cases of transgenic animals. [FN55] In addition, although

the Examining Division appeared to easily resolve the issue in favor of patentability, public controversy continued; the EPO remained embroiled in a debate concerning the application of article 53(a) to the Onco-mouse because of the substantial number of oppositions filed against the issued patent. [FN56] Accordingly, the EPO may be disinclined to grant patents on other transgenic animals.

2. Plant Genetic System's Herbicide Resistant (Transgenic) Plant

a. Opposition Division of the EPO

Article 53(a) was next raised as an issue by Greenpeace during opposition proceedings to a patent on a transgenic plant. [FN57] As one ground for its request to invalidate the plant patent, Greenpeace argued that the grant of a patent for plant life forms and the exploitation of such a patent runs per se contrary to morality and/or ordre public. [FN58] Greenpeace also alleged that a violation of article *262 53(a) was established pursuant to the Onco-mouse balancing test because the environmental risks from the release of any genetically-engineered organisms, including the Plant Genetic Systems' (PGS) invention, would be "incalculably great." [FN59]

Before addressing the appropriate standard by which to apply article 53(a), the Opposition Division explained some basic concepts of patent law. The Opposition Division emphasized the fundamental concept that a patent does not provide an affirmative and unfettered right to use an invention, as the Examining Division had noted in the Onco-mouse case. [FN60] In particular, the Opposition Division stated that

a patent does not confer a positive right to use an invention; exploitation of the patent is always subject to regulation by governmental agencies where appropriate (for example, the patenting of a potential novel medicament has no bearing on whether it will be approved for administration to patients or not, nor does the grant of a patent for a plant imply that it will be approved for field trials, let alone for large-scale industrial use). As the Opponent is aware, the grant of a patent is completely independent of the existence of possible restrictions on the use of the patented invention; moreover, denying a patent does not in itself prevent an invention being exploited. [FN61]

The Opposition Division also briefly discussed its perception of the policy behind patent protection to address Greenpeace's contention that the patent conferred an improper reward in the case of immoral subject matter. The Opposition Division noted that the primary reason for patents is to promote innovative research and that patent law was not intended to influence the types of research to be carried out. [FN62] The Opposition Division further stated that any attempt to utilize patent law in such a way would inappropriately deny a patent on ethical grounds in seeming disregard of the literal language *263 of EPC article 53(a), which expressly allows denials of patent based on ethical grounds and, furthermore, that such a denial would not necessarily prevent commercial exploitation. [FN63]

The Opposition Division rejected Greenpeaces' proposition that the balancing exercise set forth in the Harvard Onco-mouse case was necessary to determine whether article 53(a) was violated. The Opposition Division noted that "Harvard does not supercede the general approach that article 53(a) is to be invoked only in rare and extreme cases but should be regarded as an exceptional case relating only to the patenting of animals ... used as test models[,] ... where suffering is unavoidable." [FN64] The Opposition Division noted that article 53(a) "has only very seldom been invoked and its function has to be seen as a measure to ensure that patents would not be granted for inventions which would universally be regarded as outrageous." [FN65] Although the Opposition Division did not articulate when the provision has been invoked for such outrageous inventions, it seemed to easily conclude that the invention in this case was not so outrageous. Its decision appeared influenced, at least in part, by the fact that the EPO Board of Appeal had previously affirmed the patentability of transgenic plants without raising issues of morality. [FN66]

The Opposition Division rejected Greenpeace's proposition that an overwhelming majority of the public must favor exploitation of the invention for it to be patentable. [FN67] Instead, it noted that except where the Onco-mouse test is applicable, the relevant test for evaluating article 53(a) is whether an "overwhelming consensus" would be opposed to the exploitation of the invention as immoral. [FN68] *264 Moreover, it noted that the language of article 53(a) itself suggests that an invention should not be precluded from patentability merely because it is objectionable to some member of society. [FN69]

The Opposition Division determined that Greenpeace did not present sufficient evidence to establish that an

overwhelming consensus would oppose the patented invention. [FN70] The evidence presented by Greenpeace included a survey showing that over 80% of Swedish farmers opposed the patenting of genetically-engineered, herbicide-resistant plants, such as the patented invention. [FN71] The Opposition Division determined that this survey did not establish that the public in all contracting states would oppose the patent; thus, the survey failed to establish article 53(a) preclusion. [FN72] In addition, the Division found that the survey, as well as a public opinion poll, did not constitute objective evidence. [FN73] Rather, the Opposition Division characterized Greenpeace to only have presented "abstract ethical and moral arguments." [FN74]

In addition, the Opposition Division noted the practical difficulties with attempting to apply article 53(a). In particular, while it articulated that objective evidence was required to establish a bar under article 53(a), it also acknowledged that there is often no consensus on what constitutes objective morality. [FN75] In addition, it recognized that information concerning commercial exploitation necessary to make the determination would typically be unavailable during the course of usual patent examination. [FN76] Moreover, even if such information were available, the Opposition Division questioned whether patent examiners were properly qualified to examine ethical *265 information when their expertise is in technical areas; it found that particularly true in a case such as this where it perceived that there would likely be a "huge divergence of opinion" even among ethical specialists. [FN77]

Although it concluded that article 53(a) did not bar patentability in this case, the Opposition Division nonetheless reflected on what it perceived to be a tension between the application of article 53(a) and the nature of opposition proceedings. It asserted that opposition proceedings were not a proper context for determining moral questions such as the pros and cons of genetically engineered plants. [FN78] Moreover, it noted that because information concerning commercial exploitation would likely not be available until the time of opposition proceedings, article 53(a) issues would likely arise only with regard to publicly visible patents that were attached by special interest groups. [FN79]

b. Board of Appeals

Before addressing whether the patent violated article 53(a), the Board of Appeals first attempted to define the key terms of the article and set forth general principles concerning the application of article 53(a). [FN80] Although the Board acknowledged the difficulty in determining whether claimed subject matter would violate article 53(a), it noted that article 53(a) could not be disregarded. [FN81] The Board also noted that finding an invention illegal in a particular nation would not per se constitute a bar under article 53(a). [FN82] Similarly, it determined that living matter was not per se improper under article 53(a). [FN83] The Board stated that a proper interpretation of the history of *266 the EPC required that patentability be given the broadest possible interpretation; exceptions to patentability have been interpreted narrowly and article 53(a) should be as well. [FN84]

(1) Morality of Invention

The Board initially addressed the definition of the key term "morality" as the first step to determining whether the invention violated the portion of article 53(a) concerning morality. In particular, the Board noted that the invention would violate this provision if exploitation of the invention is "not in conformity with the conventionally accepted standards" of "European society and civilization." [FN85] However, the Board then abandoned application of this definition in its evaluation of the invention at issue. Instead of determining the "conventionally accepted standards," the Board compared the claimed invention to other patented but non-objectionable subject matter and thus announced the outer boundaries of what would be considered sufficiently immoral to preclude patentability. The Board declared that "[i]t would undoubtedly be against 'ordre public' or morality to propose a misuse or a destructive use of technology." [FN86] However, because traditional plant breeding could have accomplished the same end result achieved by the invention, the Board did not consider the patent a misuse or destructive use of technology. [FN87] Moreover, the Board characterized plant genetic engineering such as PGS's invention to be a "tool," similar to any other tool with both potential positive and negative purposes. [FN88] Thus, pursuant to this approach, as long as an invention *267 does not have a solely destructive use, the morality provision of article 53(a) will not bar patentability.

(2) Ordre Public

Addressing the definition of "ordre public," the Board first noted that it considered it to be "generally accepted that the concept of 'ordre public' covers the protection of public security and the physical integrity of individuals as part of society," including the "protection of the environment." [FN89] The Board further stated that inventions that would violate such a standard would be those "likely to breach public peace or social order (for example, through acts of terrorism) or to seriously prejudice the environment." [FN90] In addition, the Board noted that the requisite serious prejudice to the environment would need to be "sufficiently substantiated." [FN91] The Board suggested that without sufficient evidence of "actual disadvantages," a balancing test pursuant to Onco-mouse was unnecessary. [FN92] Moreover, even assuming such sufficient evidence exists, the Board agreed with the Opposition Division in that a balancing test was not the only method of determining an article 53(a) violation. [FN93]

In this case, the Board concurred with the Opposition Division that there was no conclusive evidence to establish serious prejudice. [FN94] The Board found that surveys and opinion polls do not necessarily reflect ordre public or moral norms; rather, they were more likely to reflect specific interests, particularly in cases such as this where the surveys were of a particular group of people. [FN95] The Board deemed survey evidence and opinion polls based on citizens of a single nation, or some subset of that nation, to be nonprobative of whether article 53(a) was violated; in particular, it noted that to be denied a *268 patent pursuant to article 53(a), an invention had to violate ordre public in all member states. [FN96] Moreover, even if the surveys and opinion polls had been reflective of all the member states, that still may not be enough to establish a violation of ordre public as the Board deemed such information inherently subject to control and influence. [FN97]

(3) Policy Issues

The above determinations were grounded on the Board's view of patent policy and how the patent office should relate to other governmental bodies. In determining that the invention did not violate ordre public, the Board repeatedly noted that a patent did not allow an invention to be exploited without regard to other laws and regulations. [FN98] In particular, the Board stated that:

A patent does not amount per se to an authorisation to exploit the invention claimed in the patent. For the latter regulatory approval must be obtained. Should the competent authorities and bodies, after having definitively assessed the risks involved, prohibit the exploitation of the invention, the patented subject matter could not be exploited anyhow. If, however, regulatory approval is given based on the finding that no risks or minimal risks are involved, then patent protection should be available. [FN99]

In the Board's view, regulatory authorities and bodies should govern properly the exploitation of technology; it noted that assessing hazards of exploiting technology was one of the important duties of such authorities and bodies. [FN100] Moreover, the Board explained that *269 any attempt to evaluate the risks of a technology during the patent process would be inherently flawed because potential risks could not be determined from a patent application. [FN101] The Board stated that realistic assessments of effectiveness are usually time-intensive and not available to patent offices during the pendency of a patent application. [FN102] The Board considered other specialized authorities to be in a better position to carry out assessment of risks. [FN103] In addition, the Board seemed unconcerned with Greenpeace's arguments because regulations existed that applied to the patented invention. [FN104] However, the Board noted the important point that even in the event that regulations contained inadequacies, the EPO would nonetheless be without authority to step into the shoes of a regulatory authority or body. [FN105]

3. Relaxin's Isolated Human Gene

Similarly, in the case of a patent concerning an isolated gene taken from a pregnant woman, the Opposition Division found article 53(a) inapplicable. The Green Party objected to the patent for several reasons under article 53(a): the use of pregnancy for profit was offensive to "human dignity"; the applicant was involved in "patenting life"; and the patenting was tantamount to slavery. [FN106] Accordingly, the Green Party requested that the patent be revoked in its entirety. [FN107]

Before addressing the specific objections of the Green Party, the *270 Opposition Division first stressed the limited applicability of article 53(a). It began its discussion by noting that "[t]he provisions of Article 53(a) have only very

seldom been invoked." [FN108] Like other boards and divisions who previously reviewed this provision, it noted that article 53(a) exists only to ensure that patents are not granted for inventions that would "universally be regarded as outrageous." [FN109] The Opposition Division quoted the EPO Guidelines for the relevant test to apply--whether it is likely that the "public in general" would consider the invention "so abhorrent" that patent rights would be "inconceivable." [FN110] Moreover, it noted that there is a general presumption of patentability to which article 53(a) is an exception that must be construed narrowly like all other exceptions. [FN111]

In dismissing all of the Green Party's objections, the Opposition Division clarified that the objections were largely misplaced. For example, the tissue was donated and the Draft Bioethics Convention of the Council of Europe explicitly approved its use in the invention. [FN112] In addition, the Opposition Division noted that DNA is a chemical substance containing genetic information, not "life" itself and, thus, not grounds for an objection to patenting life. [FN113] Finally, the Opposition Division clarified that the objections based on slavery "betray a fundamental misunderstanding of the effects of a patent" since a patent right does not grant an affirmative right to use and, moreover, would not give any rights over a human being in this instance. [FN114]

The Opposition Division also took the opportunity to comment on application of article 53(a) in general. It noted that "whether or not human genes should be patented is a controversial issue on which many persons have strong opinions [, but] ... the EPO is not the right institution to decide fundamental ethical questions." [FN115] In fact, the *271 Opposition Division concluded that "the opinion of society on the question of patenting human genes is complex and not yet definitely formed." [FN116] Therefore, applying the same standard as the PGS Board, it held that the invention did not violate article 53(a) because there was clearly no "overwhelming consensus" that exploitation or publication of the invention would be immoral. [FN117]

4. Novartis's Transgenic Plant

Article 53(a) was most recently discussed in the December 20, 1999 decision of the Enlarged Board of Appeals in *In re Novartis*. [FN118] In this case, article 53(a) was not technically an issue that was before the court; the Enlarged Board was addressing questions referred to it by the Technical Board of Appeal, seeking clarification on how to interpret article 53(b). [FN119] Although Greenpeace submitted objections to patentability based upon article 53(a), the Enlarged Board explicitly found article 53(a) outside the scope of the referred questions. [FN120] Nonetheless, the Enlarged Board discussed article 53(a) in the context of its article 53(b) analysis, thereby providing the first-ever interpretation of article 53(a) by an Enlarged Board.

The Enlarged Board first reiterated that there existed a "general principle of patentability," thereby implying that an exception such as article 53(a) should be interpreted narrowly. [FN121] In addition, the Enlarged Board noted that "[t]he EPO has not been vested with the task of taking into account the economic effects of the grant of *272 patents in specific areas and of restricting the field of patentable subject-matter accordingly." [FN122] The Enlarged Board explained that

[a]lthough the positions adopted in society on genetic engineering are controversial, there is no consensus in the Contracting States condemning genetic engineering in the development of plants under the above criteria [i.e., that the publication of exploitation of the invention is contrary to ordre public or morality]. On the contrary, the Directive ... establishes that promotion of innovation in this field is considered necessary in Europe. [FN123]

The Enlarged Board's opinion is particularly notable because it provides, for the first time, that evaluations under article 53(a) should be viewed with regard to the claimed invention, rather than an abstract conception of the invention. To explain this important distinction, the Enlarged Board applied its approach to a hypothetical invention concerning an improved copying machine. [FN124] The Enlarged Board explained that article 53(a) would not necessarily preclude patentability merely because one embodiment contained unclaimed features that would enable counterfeiting money. [FN125] In particular, it stated that there is "no reason to consider the copying machine as claimed to be excluded since its improved properties could be used for many acceptable purposes." [FN126]

While the clarification that claims should be the focus of analysis for applying article 53(a) is undoubtedly valuable, the brief discussion by the Enlarged Board on this issue is unlikely to resolve all future difficulties with applying article 53(a). For example, the opinion left several obvious open questions such as whether article 53(a) would bar patentability if an arguably immoral embodiment of an invention were actually disclosed in the patent

application itself along with non-objectionable embodiments. [FN127] The focus on the *273 claimed invention would seem to suggest that so long as only the unobjectionable matter were claimed, the application would be deemed patentable under article 53(a). However, even a claims-based focus may require an exclusion of the objectionable use to avoid an article 53(a) issue. Additionally, a more difficult question not addressed in Novartis is whether article 53(a) would preclude patentability where an invention has solely objectionable or illegal uses in one or more of the EPC countries.

Regardless of these unresolved issues, the Novartis approach is likely to be heartily applied by courts who heretofore had no real standard to apply. Although courts repeatedly emphasized that article 53(a) should be narrowly interpreted, they seemed to struggle with how to do so. However, the Novartis case now presents a framework with which the EPO and its courts are much more familiar--the claimed invention. Accordingly, it would not be surprising for the EPO to use the Novartis case to limit application of article 53(a). However, even though it may do so, there may still be some inconsistency, depending on how the claims are interpreted. As noted above, the Novartis case does leave some open issues. In addition, the EPO has previously struggled with attempting to narrowly apply exclusions from patentability even when it is utilizing a claims-based focus. [FN128] Moreover, a fundamental problem remains even after the Novartis case since the approach articulated in Novartis appears to gloss over the language in article 53(a) that requires that patents be *274 barred for the commercial exploitation of an invention that violates ordre public or morality. Because the claimed invention may not be equivalent to commercial exploitation, it could be argued that the Novartis approach is inadequate, albeit tempting to apply.

III. FUTURE FRAMEWORKS FOR CONSIDERING MORALITY

A. Beyond the EPC

In addition to the EPC model for incorporating morality into patent laws, there are two additional frameworks to consider. These additional frameworks, the TRIPS Agreement and the Biotechnology Directive, [FN129] are referred to as "future frameworks" because their application is yet to occur. Although these future frameworks contain similar language to EPC article 53(a), there is presently no case law concerning their application. A comparison of the language of each of these frameworks easily illustrates that they essentially add to EPC article 53(a), rather than create a new approach. Moreover, the TRIPS framework does not actually create any laws--it mandates that all countries who adhere to its requirements provide patent protection, with the important caveat that they may elect to exclude subject matter from patentability on the basis of article 53(a)-type concerns. [FN130] At this point however, the TRIPS framework offers little guidance other than its definitional interpretation of ordre public.

The Biotechnology directive, on the other hand, although not yet applied, does provide a supplemental framework beyond the EPC. Although the Biotechnology Directive is intended to be based upon the EPC and includes almost identical language, it goes beyond the EPC framework by setting forth specific categories of inventions *275 which per se violate EPC article 53(a). Accordingly, it is useful to analyze the Directive to examine the utility of a categorical exclusion of certain inventions, rather than the amorphous standard of article 53(a). [FN131] However, before explaining the text of the enacted Directive, a brief history of its path towards enactment will be provided to provide a full picture; this is particularly important because issues of morality were not contemplated when the Directive was first proposed.

B. The EU Directive on Patenting Biotechnology

A directive concerning patent protection for biotechnology was first conceived to provide uniformity in the area of patenting biotechnology; this in turn was intended to foster overall innovation within the European Community by ensuring the uniform application and interpretation of laws. [FN132] Issues relating to morality were actually not included in the initial proposal. [FN133] The original proposal attempted to clarify that living matter such as biotechnology could be patentable if it met the technical qualifications of patentability. [FN134] However, the initial proposal was severely criticized for failing to address issues of morality despite the fact that the Directive was intended to supplement the EPC such that article 53(a) of the EPC could nonetheless bar patentability, without inclusion of the identical language in the Directive. [FN135] The omission of morality from the initial proposal was the primary reason for the initial proposal's demise. Moreover, disagreements concerning whether morality should be addressed and how to address it within the directive loomed large during the ten year process towards enactment of the final *276 Directive. [FN136]

The enacted Biotechnology directive is based upon the EPC. Patents may be precluded if the commercial exploitation of an invention would violate "ordre public" or "morality" regardless of whether the standard patentability requirements are satisfied. [FN137] Although the Directive and the EPC differ slightly with regard to the type of exploitation that would invoke the prohibition--the EPC requires exploitation while the Directive specifies "commercial exploitation--the difference is minimal since the EPO has enacted regulations that incorporate the EU requirement into the EPC. [FN138]

The Directive, however, goes beyond the EPC and prior interpretations of the EPC, in dictating what constitutes subject matter that violates ordre public or morality in the area of biotechnology. In particular, the EU Directive sets forth four categories of subject matter which are considered per se violations and accordingly unpatentable:

- *277 (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. [FN139]

Although the Directive enumerates these specific examples, they are intended to include all possible inventions that might violate the morality provision. In particular, the preamble states that the directive merely provides an "illustrative list of inventions excluded from patentability[, and that] ... this list obviously cannot presume to be exhaustive." [FN140] Rather, the examples were intended to provide some guidance to national courts and patent offices in determining what violates ordre public and morality. [FN141]

1. Applying the Directive to the Newman Application

An attempt to apply the Directive to the facts of the Newman application highlights some of the inherent problems with the Directive. First, the invention disclosed in the Newman application does not necessarily fall within the categories that are now considered to be explicitly in violation of ordre public and morality. In fact, in attempting to determine which category, if any, the application falls within, the ambiguity of the provision is highlighted.

For example, although there is a ban on patenting use of embryos, the ban relates to uses of embryos for "industrial or commercial *278 purposes" only. [FN142] It is unclear whether the Newman application would be barred under this provision because it is unknown whether the commercial use must be one that is disclosed in the application, or whether there must be an intent to use the invention commercially. Moreover, pursuant to the Novartis approach, perhaps the only relevant inquiry is whether the claimed invention could be used for commercial purposes. However, even that inquiry is not definitive because it remains unclear whether this is determined as of the time of the filing, or at the time of opposition, or some other yet to be determined time period. In addition, it is unclear whether this provision would bar patentability of an application that disclosed several uses, only one of which was considered "commercial." Again, under the Novartis approach, patentability could conceivably be a possibility so long as only the non-commercial embodiment was claimed.

It is also unclear whether a process of creating a chimera would constitute a "process[]" for modifying the genetic identity of animals which [is] likely to cause them suffering without any substantial medical benefit to man or animal." [FN143] First, it is unclear whether the chimera is the modification of an existing animal or the creation of a new being outside the scope of this provision. Second, it is unclear how a determination could be made as to whether this multi-cellular creation would be likely to suffer. Would this inquiry only be considered at the time of creation of the chimeric embryo, or also considered with respect to the adult version of the chimeric embryo? The answer to this question might have substantial bearing on the outcome of the morality calculus, as it has been postulated that chimeric beings might be categorized as a sub-human species and thus considered to "suffer." [FN144] On the other hand, such beings could also be considered to be of "substantial medical benefit" as means for growing necessary transplant organs and enabling research that would be considered unethical for "real" humans. [FN145] Of course, the *279 word "substantial" raises issues of application since the term is undefined. The Onco-mouse analysis will not necessarily be of utility here as the Onco-mouse test did not include this requirement. Finally, it is unclear whether the substantial benefit must be actual or whether it may be probable.

Even if the Newman application does not fall squarely within any of the categorical exclusions, it could still be prohibited under the EPC or the Biotechnology Directive. In addition to the general prohibition under article 53(a), the preamble to the Biotechnology Directive contains language that appears directed to the Newman application. The preamble states that "process, the uses of which offend against human dignity, such as processes to produce chimeras from germ cells or totipotent cells of humans and animals, are obviously also excluded from patentability." [FN146] In addition, the EPO has stated that the Biotechnology Directive may be referred to as a supplemental source in evaluating EPC article 53(a). [FN147] On the other hand, this language is not directly incorporated into the EPC regulations as the EPO only specifically incorporated the articles of the Biotechnology Directive. In addition, although the preamble declares such processes to be obviously excluded, the failure to include them in the categorical list may also lend credence to the argument that there may not be sufficient objection to constitute a violation of article 53(a). Just as the EPO Boards have questioned public opinion polls, so to may they question a preamble that is not necessarily reflective of ordre public.

Perhaps the more important issue, however, is that even if commercial exploitation of an invention might violate ordre public or morality (either as a per se category or based on application of the article 53(a) provision), there is not necessarily a bar to patentability if the approach of the Novartis Board is adopted. Accordingly, if the offensive use were either not claimed, or not the only use of an invention, the EPO could avoid article 53(a) issues. This would *280 enable the EPO to avoid the difficult question of determining issues that it clearly feels ill-equipped to address. EPO courts have repeatedly emphasized that the function of the patent office is to grant patents, rather than to regulate technology, and have declined to rely on article 53(a) to deny patentability. [FN148] In addition, this would be consistent with the EPO position that the EPO is not the proper institution to decide ethical questions because a patent is not a moral instrument. [FN149]

However, the fact that the invention as claimed does not violate ordre public in the eyes of the EPC is unlikely to prevent those who object to genetic engineering from protesting. As is clear from the case law to date, third parties such as Greenpeace and Green Party are not novices to invoking Opposition proceedings. Moreover, they seem undeterred by repeated statements that patents do not confer an affirmative right to use. To avoid endless opposition proceedings, the EPO may also allow applications to lie dormant indefinitely without action, in the hopes that issues concerning morality will be resolved in other arenas. The EPO may be particularly reluctant to issue controversial biotechnology patents since it recently was subject to extreme protests over the issuance of a patent. In particular, Greenpeace activists recently stormed the EPO concerning a patent that issued with claims that could include human cloning. [FN150]

2. Additional Interpretive Issues

Ironically, although the political realities in the EU required inclusion of an ethical component, [FN151] the enactment of these *281 exclusions appears to undermine the initial purpose of the Directive, which was to ensure certainty and uniformity in the patent protection of biotechnological inventions. [FN152] In particular, uncertainty will prevail because it is unknown how the categories will be interpreted. Moreover, even if the categories could be interpreted clearly and uniformly, the EU Directive will not necessarily foster development of biotechnology, as intended, because it clearly excludes certain subject matter from patentability and does so permanently, rather than on a case-by-case basis.

In addition, the categories will continue to be declared unpatentable, regardless of whether they in fact continue to violate ordre public or morality. Commentators familiar with patent law have uniformly noted that the per se exclusions are problematic; although they are intended to clarify what is immoral, the per se categories result in unchangeable exclusions regardless of future developments. [FN153] Moreover, while it may be easy to legislatively exclude subject matter from patentability, the reverse is not necessarily true. [FN154] This is an inherent problem with exclusions based *282 on morality concerns since perceptions of morality fluctuate over time. Although a new Directive could theoretically be proposed and enacted to address such changes, considering that the present Biotechnology Directive took ten years to develop and still elicited legal objections, such changes are not promising.

C. Implications for the United States

The evolution of the morality preclusion demonstrates that including a morality component into the patentability

scheme is analogous to opening a Pandora's box. Although an EPO court first mandated consideration of article 53(a) issues to respond to public concerns, it is unclear whether the court would have done so if it had known that the provision would subsequently become a battleground for opponents of biotechnology. [FN155]

In addition, even if morality should be considered in the context of patentability, an exclusion based on commercial exploitation of the patented invention, as required under the EPC, the EU Directive, and TRIPS is problematic. The patent office would not have information regarding commercial exploitation of an invention since that information is not necessary to establish any of the requirements of patentability, as noted by several EPO boards struggling to determine *283 whether there was an article 53(a) violation. [FN156] Even if applicants were required to submit information concerning commercial exploitation, this could be unrealistic if not impossible, because patent applications are generally filed before commercial applications are known. Moreover, if an applicant waited until commercial applications were known, entitlement to a patent could be compromised as the invention might no longer satisfy the novelty requirement. [FN157]

Determining morality within the patent office is also problematic since morality is not within the technical capacity of present patent examiners. Patent examiners are generally scientists or engineers who have a technical background in the subject matter of the invention. They are required to have such a background as a condition of employment, but experience with issues of morality is not typically expected. In addition, EPO experiences indicate that such individuals likely feel ill-at-ease in making such decisions. Moreover, there is the inherent problem in that what constitutes an ethical invention is typically not a decision upon which parties would agree, thus creating problems with uniformity.

IV. CONCLUSION

Ethical and moral issues will inevitably arise in the exploitation of inventions. The more fundamental question, however, is how they should be addressed. This Article has attempted to demonstrate that grafting a morality provision into the patent laws results in an unstable merger. Although morality must be considered pursuant to EPC article 53(a) in determining patentability, the case law shows that consideration is at best cursory. Moreover, even if the EPO, or any patent office, were to take a more thorough evaluation of *284 morality, it is unlikely that all parties could ever be satisfied since issues of morality are inherently controversial.

The European experience demonstrates that as a practical matter, incorporating morality into the patent system is a challenge for every institutional actor with the system. The limited EPO case law, as well as the actual EPO decisions, underscore a reluctance to determine what constitutes an immoral invention that would bar patentability. The reluctance of patent examiners--trained to evaluate the technical merits of inventions--to evaluate morality is not surprising. On the other hand, granting controversial patents in the face of a mandatory morality consideration appears to have made the EPO a victim of special interest groups who are critical of biotechnology.

Moreover, the long history of the EU Biotechnology Directive demonstrates the difficulty in addressing the problems through a legislative approach. To reach a consensus, there must be agreement both on the fact that morality should be considered in a patent context, as well as what the consideration should entail; legislation may be stalled by the difficulties in articulating what objectionable matter should be deemed patentable. Although the EU did eventually enact a directive that incorporated a morality component, the compromise directive is not ideal for any party and may actually create more uncertainty and controversy.

Whether a new model can be crafted to adequately incorporate morality into the patent laws is questionable. First, it is notable that despite substantial consideration of this issue, the EU was reluctant to part entirely with the EPC system; rather, the EU adopted the EPC morality provision wholesale and merely added some per se exclusions. However, the EU formulation is any more effective than the original system under the EPC. In some ways, the EU formulation may in fact be less preferable because it introduces inflexible definitions of immoral and unpatentable inventions. Second, even assuming that a workable and appropriate framework could be envisioned, the type of in-depth consideration necessary prior to developing such a fundamental change to the patent system would inevitably lag behind the progression of technology and the issuance of controversial patents.

Although the patent laws, and particularly EPC article 53(a), have provided a forum for venting concerns about new applications of *285 biotechnology, the alleged problem with patenting such inventions should perhaps be re-

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examined. In large part, the root of articulated concerns can not be solved by addressing the patent system in isolation. As repeatedly pointed out by commentators, the denial of a patent does not eliminate all incentives to utilize an invention. Although a patent may accelerate or at least foster development of an invention, the grant or denial of a patent does not address the fundamental concern with the use of certain technology. Patents are at best a blunt tool to regulate controversial matter because patents are not necessary to utilize or commercialize innovations. Accordingly, the focus on patents is an incomplete one. The issue of whether researching or using biotechnology is ethical can and should be separated from the patenting question, which tends to conflate divergent issues.

Even if ethics were to be incorporated in the United States' patent laws, further study of the purpose of such an exclusion, as well as how that impacts the patent system, would have to be considered. Because the foundation of the patent laws lies in the constitutional mandate to promote the progress of useful arts, the question of considering morality must also be considered in that context. Namely, would considering morality further the goal of promoting the progress in useful arts? Not only does this require a consideration of constitutional interpretation and policy, but it also requires a consideration of the effect on the patent system of excluding arguably unethical inventions. Only if that question were answered in the affirmative should efforts then be directed to addressing what ethical considerations should be included within the patent system, and when such considerations should be made. Until that time, however, any temptation to incorporate morality into the U.S. patent laws should be tempered with the reality that a change to the patent laws may just create new issues to address, rather than addressing the issues that currently exist.

[FN1]. Assistant Professor of Law, Loyola University of Chicago School of Law. The author thanks Susan Kuo for her advice and support in the preparation of this Article, and Kelly Tautges for her able research assistance.

[FN1]. See *Morality Aspect of Utility Requirement Can Bar Patent for Part-Human Inventions*, 55 PAT. TRADEMARK & COPYRIGHT J. 555, 556 (1998) [hereinafter *Morality Requirement*] (noting that since the 1993 issuance of additional mouse patents, calls for moratoriums and the broader debate over patents on life forms had largely subsided until news of the Newman application).

[FN2]. 35 U.S.C. § 122 (1994). Although this provision was recently amended such that some patent applications will be published and, thus, publicly available, it is not retroactive and does not apply to this case. See *Domestic Publication of Foreign Filed Patent Applications Act of 1999*, Pub. L. No. 106-113, 113 Stat. 1501 (1999).

[FN3]. See, e.g., David Dickson, *Legal Fight Looms Over Patent Bid on Human/Animal Chimaeras*, 1998 NATURE 423. See also Rick Weiss, *Patent Sought on Making of Part-Human Creatures; Scientist Seeks to Touch Off Ethics Debate*, WASH. POST, Apr. 2, 1998, at A12. The application is referred to as the "Newman application" here because news sources consistently report Newman as an inventor of the application, but the sources are conflicting with regard to whether Rifkin is a co-inventor or a partial assignee of an interest in the application. See, e.g., Thomas D. Mays, *Biotech Incites Outcry*, NAT'L L.J., June 22, 1998, at C1 (stating that Newman is the inventor and Rifkin is a co-applicant); Rick Meredith, *How Will Provocative Application Fare in the PTO?*, NAT'L L.J., Oct. 19, 1998, at C32 (stating that Rifkin and Newman jointly applied for the patent); Weiss, *supra*, at A12 (stating that Newman has assigned Rifkin co-ownership).

[FN4]. Weiss, *supra* note 3, at A12. They hope to use the rights granted under a patent to exclude others from creating such human hybrids. See 35 U.S.C. § 271 (1994) (defining patent infringement); *id.* § 281 (providing for infringement remedy); *id.* § 283 (providing for injunctive relief to prevent infringement).

[FN5]. Patent and Trademark Office, *Facts on Patenting Life Forms Having a Relationship to Humans* (visited Apr. 1, 1998) <<http://www.uspto.gov/web/offices/com/speeches/98-06.htm>> [hereinafter *Media Advisory*].

[FN6]. *Media Advisory*, *supra* note 5. The "strict patentability requirements" referred to are that the invention (1) constitutes patentable subject matter and (2) meets the technical requirements for patentability, which require the invention to be new, useful, nonobvious, and timely filed. See 35 U.S.C. §§ 101-103 (1994). In addition, the application must comport with additional requirements concerning the contents of the application, as well as formalities with filing. See 35 U.S.C. §§ 111-112 (1994).

[FN7]. Media Advisory, *supra* note 5 (citations omitted).

[FN8]. *Lowell v. Lewis*, 15 F. Cas. 1018, 1019 (C.C.D. Mass. 1817) (No. 8,568). The case concerned the patentability of a water pump for which no issues of morality were noted. See *id. passim*.

[FN9]. *Ex parte Murphy*, 200 U.S.P.Q. (BNA) 801 (Bd. Pat App. & Int. 1977) (noting that while gambling could be considered injurious to public morals, there was no justification for denying a patent on a gambling device based on lack of utility and stating that the PTO should not dictate a morality standard through the utility requirement). No court has relied upon *Lowell* for the moral utility principle during the latter half of the Twentieth Century. See *infra* note 10 and accompanying text. See also DONALD S. CHISUM, *CHISUM ON PATENTS* § 4.03 (1999) (noting that the policy is a narrow one); Robert Merges, *Intellectual Property in Higher Life Forms: The Patent System and Controversial Technologies*, 47 MD. L. REV. 1051, 1062-66 (1988) (discussing earlier cases that relied on moral utility doctrine to preclude patentability where inventions were perceived as involving either fraud or gambling devices).

[FN10]. See *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1366 (Fed. Cir. 1999) (holding that an invention designed to deceive consumers is not invalid for lack of utility and further stating that "the principle that inventions are invalid if they are principally designed to serve immoral or illegal purposes has not been applied broadly in recent years"); *Tol-O-Matic, Inc. v. Proma Produkt-Und Marketing Gesellschaft*, 945 F.2d 1546, 1552- 53 (Fed. Cir. 1991) (quoting *Lowell* in discussion of whether piston-cylinder patent was invalid for lack of utility because there was a "total incapacity," without addressing issues concerning morality).

[FN11]. *Whistler Corp. v. Autotronics, Inc.*, 14 U.S.P.Q.2d (BNA) 1885, 1886 (N.D. Tex. 1988) (declining to find that the patented radar detector lacked utility even though the invention's primary purpose was to circumvent law enforcement attempts).

[FN12]. Morality Requirement, *supra* note 1, at 556.

[FN13]. *Id.*

[FN14]. See Patent Application is Disallowed as 'Embracing' Human Being, 58 PAT. TRADEMARK & COPYRIGHT J. 203 (1999) [hereinafter Application Disallowed]; Rick Weiss, U.S. Ruling Aids Opponent of Patents for Life Forms, WASH. POST, June 17, 1999, at A2. It should be noted that the PTO rejection is based on info provided by Rifkin & Neuman to the media.

[FN15]. See Application Disallowed, *supra* note 14. The PTO apparently asserted in its office action that:

[t]he claimed invention is not considered to be patentable subject matter under 35 U.S.C. [§] 101 because the broadest reasonable interpretation of the claimed inventions as a whole embraces a human being [A]pplicant's claimed invention ... is not limited to non-humans but rather includes within its scope a human being and as such falls outside the scope of protection under 35 U.S.C. [§] 101.

Id. at 203.

[FN16]. Although the PTO has not had to address the issue of claiming a human being head-on, it has been forecast by an earlier debate concerning transgenic animal patents. See, e.g., The Patent Competitiveness and Technological Innovation Act of 1990, H.R. 5598, 101st Cong. (1990) (proposing to amend § 101 of the Patent Act to state "except that human beings are not patentable subject matter"). See also Russell H. Walker, Note, Patent Law--Should Genetically Engineered Human Beings Be Patentable?, 22 MEM. ST. U. L. REV. 101, 116 (1991) (suggesting that Congress enact a new definitional section of the patent code that defines a "human being").

[FN17]. Patent and Trademark Office, *Animals--Patentability*, 1077 OFF. GAZ. PAT. OFFICE 24 (1987).

[FN18]. *Id.*

[FN19]. *Id.* The PTO assertion regarding the constitutional prohibition was made without any specific reference to the Constitution. *Id.* Nonetheless, it recommended that claims directed to non-plant multicellular organisms should

explicitly exclude humans from claims to avoid a rejection. *Id.* In fact, the first transgenic animal patent issued explicitly excluded humans from its claims. Philip Leder & Timothy Stewart, *Transgenic Non-Human Mammals*, U.S. PAT. NO. 4,736,866 (1988) (claiming a "transgenic non-human mammal" whose cells contained an activated oncogene in the broadcast issued claim) (emphasis added).

[FN20]. See, e.g., Dan L. Burk, *Patenting Transgenic Human Embryos: A Nonuse Cost Perspective*, 30 HOUS. L. REV. 1597, 1647-58 (1993) (questioning whether either the Thirteenth or Fourteenth Amendments provide valid legal justification for the PTO's assertion that patenting transgenic humans or embryos would be unconstitutional and noting that the constitutional basis for finding embryos unpatentable is particularly questionable as they may not fit well within the requirement of a "person"); Kevin D. DeBré, *Note, Patents on People and the U.S. Constitution: Creating Slaves or Enslaving Science?*, 16 HASTINGS CONST. L.Q. 221 (1989); Rachel E. Fishman, *Note, Patenting Human Beings: Do Sub-Human Creatures Deserve Constitutional Protection?*, 15 AM. J.L. & MED. 461 (1989).

[FN21]. *Application Disallowed*, supra note 14, at 204. The PTO's deputy assistant commissioner for patent policy, Stephen Kunin, is noted to have said that the PTO believes that Congress did not intend to allow patents on humans or on creatures that are essentially human when it enacted the Patent Act. Weiss, supra note 14, at A2.

[FN22]. *D Diamond v. Chakrabarty*, 447 U.S. 303, 314-15 (1980) (dismissing the suggestion that microorganisms cannot qualify as patentable subject matter under § 101 because Congress could not have foreseen genetic technology at the time it enacted the Patent Act). See also *Pioneer Hi-Bred Int'l, Inc. v. J.E.M. AG Supply, Inc.*, 200 F.3d 1374 (Fed. Cir. 2000) (rejecting argument that plants are not patentable because they were not intended to be included in the patent system).

[FN23]. *Chakrabarty*, 447 U.S. at 315-16 (citations omitted).

[FN24]. See 35 U.S.C. § 101. The only categories of subject matter "excluded" from patentability are those that fail to rise to the level of an invention such as laws of nature, physical phenomena, and abstract ideas. See *Diamond v. Diehr*, 450 U.S. 175, 185 (1981). In its first office action rejecting the Newman application, the PTO conceded that an invention that "embraces" a human being is not within a category the Supreme Court considered excluded in *Chakrabarty*. See *Application Disallowed*, supra note 14, at 204.

[FN25]. See, e.g., *Chakrabarty*, 447 U.S. at 309; *Pioneer Hi-Bred Int'l, Inc.*, 200 F.3d at 1376 (noting that the patent policy fosters application to all areas of subject matter in holding that patents could be properly considered statutory subject matter under the utility patent act despite other available forms of legal protection); *AT&T Corp. v. Excel Communications, Inc.*, 172 F.3d 1352, 1357-60 (Fed. Cir. 1999) (finding that method of indicating a telephone call recipient's primary interexchange carrier could constitute a process and accordingly constitute patentable subject matter); *State Street Bank and Trust Co. v. Signature Financial Group, Inc.*, 149 F.3d 1368, 1372-73 (Fed. Cir. 1998) (noting that the repetitive use of the term "any" in § 101 indicates Congressional intent not to place any restrictions on subject matter beyond those cited in the section); *Ex parte Allen*, 2 U.S.P.Q.2d (BNA) 1425, 1426 (Bd. Pat. App. & Int. 1987) (restating and applying *Chakrabarty* reasoning to find that genetically engineered oyster was patentable subject matter).

[FN26]. 35 U.S.C. § 6 (1994) (noting that the Commissioner of the PTO shall perform all duties required by law with respect to the granting and issuing of patents and that the Commissioner may establish regulations for the conduct of proceedings within the PTO). The PTO implicitly acknowledged its limited authority in its Media Advisory concerning the Newman application by stating that it "is charged with the responsibility of administering the patent laws of the United States, as interpreted by the Supreme Court and other courts." Media Advisory, supra note 5.

[FN27]. Even if the Newman application is considered patentable subject matter, a patent may still be denied for failure to meet the technical requirements of patentability. See supra note 6. In fact, it has been reported that the first PTO office action on this application preliminarily rejected the application as not only claiming non-statutory subject matter but also for failing to meet several technical requirements, including failure to make enabling and best mode disclosures under § 112, and anticipation under § 102(b). *Application Disallowed*, supra note 14, at 204.

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[FN28]. See, e.g., Lori B. Andrews, Legal, Ethical and Social Concerns in the Debate over Stem-Cell Research, *CHRON. HIGHER EDUC.*, Jan. 29, 1999, at B4; Peter Kendall, The Beast in the Dish: Lab Grows a Scientific and Ethical Quandry, *CHI. TRIB.*, Dec. 13, 1998, at C1. See also Rick Weiss, A Cloning Claim's Controversies, *WASH. POST*, Nov. 13, 1998, at A3 (noting that scientists, ethicists and federal regulators are "scramb[ling] to sort out the many controversial issues raised by [cloning]").

[FN29]. Although a patent does not create an affirmative right to use or constitute an endorsement by the government of the technology, confusion often arises from a misunderstanding that patents create such a right. See, e.g., *infra* Part II (noting this problem in the context of discussing the analogous issue within the European patent system). Nonetheless, because patent protection can provide an economic incentive for research and development, patents may raise ethical issues in situations where the necessary funding for research is available from other sources. This is in fact the case with research on stem cells, the primitive cells that become every other type of cells. Although federal funding is banned for such research, it has continued through the funding of private corporations, anticipating that patent protection will provide a return on their investment. See Lori P. Knowles, Property, Progeny and Patents, 29 *HASTINGS CENTER REP.* 38 (1999) (discussing research concerning stems cells derived from aborted fetuses by Geron and the related patent and policy issues); Eliot Marshall, A Versatile Cell Line Raises Scientific Hopes, Legal Questions: Stem Cells, 1998 *SCI.* 1014 (discussing a research group in the area of stem cells that plans to license related patents to the Geron Corp. to finance the research because of the possible implications of the public funding ban); Mara Bovsun, Stem Cell Studies Raise Hope for Human Patch Kits, *BIOTECH. NEWSWATCH*, Nov. 16, 1998, available in 1998 WL 8766021 (noting that university research was sponsored by private funding because government money was unavailable); Antonio Regalado, The Troubled Hunt for the Ultimate Cell: Studies on the Human Embryonic Stem Cell, *TECH. REV.*, July 17, 1998, at 34. See also Act of Nov. 13, 1997, Pub. L. No. 105-78, § 513(a), 111 Stat. 1517 (1997).

[FN30]. See, e.g., S. 2169, 101st Cong. (1990) (proposing five-year moratorium on patenting of genetically engineered animals); HR. 3247, 101st Cong. (1989) (proposing two-year moratorium on patenting transgenic animals). See also *ANIMAL PATENTS: THE LEGAL, ECONOMIC AND SOCIAL ISSUES* (William H. Lesser ed., 1989) (discussing legal and social issues concerning transgenic animal patents); Rebecca Dresser, Ethical and Legal Issues in Patenting New Animal Life, 28 *JURIMETRICS* 399, 405-24 (1988) (containing an in-depth discussion of ethical arguments concerning the patenting of higher life forms, with a focus on transgenic animals).

[FN31]. See The Patent Competitiveness and Technological Innovation Act of 1990, H.R. 5598, 101st Cong. (proposing to amend § 101 of the Patent Act to state "except that human beings are not patentable subject matter"); S. 2111, 100th Cong. (1988) (proposing that animals be unpatentable inventions).

[FN32]. In the early part of the Nineteenth Century, in an era when medicine was largely unregulated, attempts were made to exclude medical procedures, as well as medical devices. See H.R. 12451, 57th Cong. (1902) ("prohibiting patents on any "art" of treating human disease ... or upon any device adapted to be used in treatment of human disease"); William D. Noonan, Patenting Medical Inventions, *PHAROS*, Summer 1990, at 708. More recently, there was a renewed effort to exclude medical procedures from the scope of the Patent Act in response to a strong medical lobby asserting that doctors should not be liable for infringement of medical procedure patents. See Medical Procedures Innovation and Affordability Act, H.R. 1127, 104th Cong. (1995); H.R. 3814, 104th Cong. (1996); S. 1334, 104th Cong. (1995). Medical Procedures Innovation and Affordability Act and Inventor Protection Act of 1995: Hearings on H.R. 1127 and H.R. 2419 Before the Subcomm. on Courts and Intellectual Property of the House Committee on the Judiciary, 104th Cong. (1995); Public Hearing on Patent Protection For Therapeutic and Diagnostic Methods (Dep't Commerce May 2, 1996) <<http://www.uspto.gov/web/offices/com/sol/notices/diaghear.txt>>. Although these efforts did not ultimately alter the scope of patentable subject matter, the legislation Congress did enact deprives medical procedure patent owners from any remedies against doctors who infringe and may thus make the scope of patentable subject matter an empty promise for such inventions. See 35 U.S.C. § 287(c) (Supp. III 1997).

[FN33]. Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, Apr. 15, 1994, Legal Instruments--Results of the Uruguay Round, vol. 1, 33 *I.L.M.* 1125 (1994); Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade

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Organization, Annex 1C, Legal Instruments--Results of the Uruguay Round vol. 31, 33 I.L.M. 81 [hereinafter TRIPS].

[FN34]. *Id.* art. 27.

[FN35]. Convention on the Grant of European Patents, Oct. 5, 1973, 13 I.L.M. 270 [hereinafter EPC].

[FN36]. Council Directive 98/44 on Legal Protection of Biotechnological Inventions, 1998 O.J. (L 213) 13 [hereinafter Directive]. Member states should be in compliance with the Directive by July 20, 2000. *Id.* However, it should also be noted that the Biotechnology Directive is presently subject to legal challenge by several member countries. Case C-377/78, *Netherlands v. Parliament*, 1998 O.J. (C 378) 13; A. Scott, *The Dutch Challenge to the Bio-patenting Directive*, 4 EUR. INTELL. PROP. REV. 212 (1999); P. Farrant & V. Salmon, *Netherlands Seeks End to EU Biotech Directive*, IP WORLDWIDE, July/Aug. 1999, at 3.

[FN37]. The European Patent convention enables patent applicants to obtain a bundle of national patents in multiple member countries through the filing of a single application with the EPO. See EPC, *supra* note 35, art. 64(1) (providing that EP patent will have the same effect as a patent issued by a national patent office). These national patents are then subject to the enforcement laws of individual states. In determining whether a patent should issue, the EPO considers whether inventions are new, "susceptible of industrial application," and involve an "inventive step." See EPC, *supra* note 35, art. 52(1). These EPC requirements are considered to be roughly analogous to the U.S. requirements that a patentable invention be new, useful and obvious. See, e.g., TRIPS, *supra* note 33, art. 27(1)(1).

[FN38]. EPC, art. 53(a), *supra* note 35, at 286. The national laws of all member states to the EPC incorporate similar prohibitions. See, e.g., Patents Act § 1(3)(a) (U.K.) 1977 (stating that a patent will not be granted for "an invention the publication or exploitation of which would be generally expected to encourage offensive, immoral or anti-social behaviour"). Although the wording is slightly different, the U.K. Patents Act is intended to be interpreted similarly to the EPC. See *id.* preamble; see also Amanda Warren, *A Mouse in Sheep's Clothing: The Challenge to the Patent Morality Criterion Posed by "Dolly"*, 12 EUR. INTELL. PROP. REV. 445 (1998).

[FN39]. See EPC, *supra* note 35, art. 53(a).

[FN40]. European Patent Office, Guidelines for Substantive Examination, Part C, Chapter IV, § 3.1 (visited Mar. 7, 2000) <http://www.european-patent-office.org/guidelines/english/c_iv_3.htm>.

[FN41]. *Id.*

[FN42]. In fact, in most of the published opinions in which article 53(a) is at issue, those who opposed a patent raised the issue, not the EPO. See, e.g., *Relaxin*, 1995 O.J. EPO 388; *Plant Cells/Plant Genetic Systems*, T356/93-3.3.4, 1995 O.J. EPO 545 [hereinafter PGS].

[FN43]. *Harvard/Onco-mouse*, 1990 E.P.O.R. 4 [hereinafter *Onco-mouse*]; *Leder & Stuart*, *supra* note 19.

[FN44]. *Id.* at 10-11. The Examining Division perceived that the grant of the corresponding U.S. patent to have resulted in "severe criticism," citing hearings discussing the ethical ramifications and legislative proposals on this topic. *Id.* at 11. In addition, the Examining Division cited specific questions that were considered at the oral proceedings regarding concerns with respect to article 53(a): whether using non-animal models in cancer tests was desirable, the fact that the invention was aimed at producing tumors in the test animals, rather than aimed at improving any specific feature, the fact that animals were regarded as an "object," the potential danger that descendants of transgenic mammals could escape and disrupt evolution. *Id.*

[FN45]. *Id.* at 11.

[FN46]. See *id.* at 507 (noting this based on the "large number of observations by third parties" that were filed pursuant to EPC rules which allow for participation by those without a legal interest in the patent application).

[FN47]. Harvard/Onco-mouse, 1990 E.P.O.R. 501, 513 [hereinafter Onco-mouse II]. The TBA also confirmed that there was no bar to patent animals under article 53(b), which provides a bar to animal "varieties." Id. at 510-12.

[FN48]. Harvard/Onco-mouse, 1991 E.P.O.R. 525, 526 [hereinafter Onco-mouse III].

[FN49]. Onco-mouse III, 1991 E.P.O.R. at 527.

If higher life forms are involved in the new technology it is not only the risk which must be considered but also the possible harm which is done to such higher life forms. This leads one to the question of morality ... [F]or each individual invention the question of morality has to be examined and possible detrimental effects and risks have to be weighed and balanced against the merits and advantages aimed at.

Id. at 527. In addition, the court noted that "[i]f the legislator is of the opinion that certain technical knowledge should be used under limited conditions only it is up to him to enact appropriate legislation." Id.

[FN50]. Id.

[FN51]. Id.

[FN52]. Id.

[FN53]. Onco-mouse III, 1991 E.P.D.R. at 528. In particular, the Examining Division considered it relevant in the Onco-mouse case to consider that, according to the scientific community, there were no equivalent alternatives as reliable as the Onco-mouse. See id. at 527-28 (noting that "it is clear that in cancer research animal test models are at present considered indispensable" and that onco-mice, in particular, are a "powerful tool with which co-operating genes in tumorigenesis can be identified").

[FN54]. Id. at 528.

[FN55]. Id. In fact, a transgenic animal genetically modified to lose its hair and, thus, useful in the study of human baldness, was considered to have failed the balancing test of article 53(a) when the EPO warned Upjohn that it would not allow such an application. See, e.g., Robin Nott, *The Biotech Directive: Does Europe Need a New Draft?*, 12 EUR. INTELL. PROP. REV. 563, 565-66 (1995) (comparing the Upjohn-mouse with the Onco-mouse in criticizing application of article 53(a) as arbitrary because the degree that the animals suffered was identical); Steve Conner, *Patent Ban on Baldness 'Cure' Mouse*, INDEPENDENT (London), Feb. 2, 1992, at 5.

[FN56]. See, e.g., Hans-Rainer Jaenichen & Andreas Schrell, *The 'Harvard Onco-mouse' in the Opposition Proceedings Before the European Patent Office*, 9 EUR. INTELL. PROP. REV. 345 (1993).

[FN57]. *Greenpeace UK v. Plant Genetic Systems N.V.* (Opposition Div. EPO 1992), reported in 24 INT'L REV. INDUS. PROP. & COPYRIGHT L. 618 (1993) [[hereinafter *Plant Genetic Systems*]].

[FN58]. Greenpeace alleged that the patent's claimed second generation transgenic plants were improper because they did not constitute an invention under article 52 of the EPC. Id. at 619. In addition, Greenpeace argued that plants and processes for their production are per se unpatentable under article 53(b). Id. at 624-25. The Opposition Division rejected both of these grounds. See id.

[FN59]. Id. at 620.

[FN60]. Id. See supra note 49 and accompanying text.

[FN61]. *Plant Genetic Systems*, supra note 57, at 620.

[FN62]. Id.

[FN63]. Id.

[FN64]. *Id.* at 621 (emphasis omitted).

[FN65]. *Id.*

[FN66]. *Id.*

[FN67]. *Plant Genetic Systems*, supra note 57, at 623-24 (stating that "[t] here is no requirement in the EPC that patents may only be granted for inventions regarded as desirable by a majority of the public"). Inventions need not be desirable by a majority of the public to be patentable since to do so would be contrary to the general principle of patentability. *Id.* Also, the Opposition Division noted that the public is similarly incapable of assessing objective morality. *Id.* at 624.

[FN68]. *Id.* at 624 (noting that the prohibition under article 53(a) only existed in "very limited cases in which there is an overwhelming consensus that the exploitation of an invention would be immoral") (emphasis in original); see also *id.* at 624 (noting that the only ethical consideration is whether the invention belongs to "that extreme category of inventions which could be regarded as so abhorrent to the vast majority of the public as to render the granting of a patent inconceivable").

[FN69]. *Plant Genetic Systems*, supra note 57, at 621, 624.

[FN70]. *Id.* at 623.

[FN71]. *Id.*

[FN72]. *Id.*

[FN73]. See *id.* In particular, the Opposition Division considered the objection that the environmental risks rendered exploitation of the invention unethical to be unsubstantiated. *Id.* at 622. It also dismissed environmental risks as traditionally irrelevant to determination of patentability and more appropriate for regulation by bodies other than the EPO. *Plant Genetic Systems*, supra note 57, at 621.

[FN74]. *Id.* at 624.

[FN75]. *Id.*

[FN76]. *Id.*

[FN77]. *Id.* at 620-21.

[FN78]. *Id.* at 624.

[FN79]. *Plant Genetic Systems*, supra note 57, at 621.

[FN80]. *PGS*, 1995 O.J. EPO at 557. In particular, it noted that there were no European definitions of "morality" and "ordre public" contemplated by those who drafted the EPC. *Id.* (citing document IV/2767/61-E, at 7). The Board's attempt at defining the key terms will be discussed in connection with the Board's application of the morality and ordre public provisions separately.

[FN81]. *Id.* at 560.

[FN82]. *Id.* at 558.

[FN83]. *Id.* at 559 (basing its determination on both historical evidence and case law that patents can be granted on plants and animals).

[FN84]. *Id.* at 558 (citing the Onco-mouse and Lubrizol decisions for the proposition that exceptions are narrowly interpreted).

[FN85]. PGS, 1995 O.J. EPO at 557. The Board stated that morality is "related" to certain beliefs about what behavior is proper, such beliefs being founded on deeply rooted norms. *Id.*

[FN86]. *Id.* at 563.

[FN87]. *Id.* at 563-64. In particular, the Board noted that "plant biotechnology per se cannot be regarded as being more contrary to morality than traditional selective breeding because both ... are guided by the same motivation, namely to change the property of a plant" *Id.* at 562. The Board explained that genetically engineered plants were distinguishable in that they utilized more powerful and accurate techniques of genetic modifications in comparison to traditional plant breeding. *Id.*

[FN88]. PGS, 1995 O.J. EPO at 562, 563.

[FN89]. *Id.* at 557.

[FN90]. *Id.*

[FN91]. *Id.* at 566.

[FN92]. *Id.* at 569.

[FN93]. *Id.* The Board stated that "a 'balancing exercise' is not the only way of assessing patentability with regard to Article 53(a) EPC, but just one possible way" PGS, 1995 O.J. EPO at 557. See also Plant Genetic Systems, *supra* note 57, at 618.

[FN94]. *Id.*

[FN95]. PGS, 1995 O.J. EPO at 561.

[FN96]. *Id.* In this case, PGS's survey of Swedish farmers regarding their views on herbicide-resistant crops and an opinion poll on transgenic life only reflected opinions in Switzerland and provided no more than information concerning a national law regulating a particular activity. *Id.* at 560-61.

[FN97]. *Id.* at 561.

[FN98]. See *id.* at 564 (noting that "the invention claimed in a patent may only be exploited within the framework defined by national laws and regulations regarding the use of the said invention).

[FN99]. *Id.* at 568-69.

[FN100]. *Id.* at 565.

[FN101]. PGS, 1995 O.J. EPO at 561.

[FN102]. *Id.*

[FN103]. *Id.*

[FN104]. *Id.* at 565-66 (citing EC Directives 90/219 EEC and 90/220/EEC as examples).

[FN105]. *Id.* at 568.

[FN106]. Relaxin, 1995 O.J. EPO at 397-98. The application was also opposed on other grounds, namely, that it constituted a discovery rather than an invention and that there was no novelty. Id. at 389.

[FN107]. Id. In addition, the Green Party also requested that the EPO carry out a referendum to determine whether the public desired the invention to be patented, but the Opposition Division refused the request. Id. at 403. In doing so the Opposition Division noted that the opponent bears the burden of proof in opposition proceedings and, thus, could conduct such a survey on its own if desired. Id. Moreover, the Opposition Division clarified that the EPC does not require affirmative approval from the public to allow patentability since under such a standard the number of patents would arguably be "decimated." Id.

[FN108]. Relaxin, 1995 O.J. EPO at 398.

[FN109]. Id.

[FN110]. Id.

[FN111]. Id.

[FN112]. Id. at 399.

[FN113]. See id. at 400.

[FN114]. Id. at 399-400.

[FN115]. Relaxin, 1995 O.J. EPO at 402-03. The Opposition Division noted that, contrary to the suggestion of Greenpeace, there is no consensus on whether gene patents are inappropriate. Id. at 402. In support of this argument, the Opposition Division noted the disagreement among the EU regarding the Biotechnology Directive and the "turbulent state of the public debate on biotechnology." Id.

[FN116]. Id.

[FN117]. Id. at 403.

[FN118]. Transgenic Plant/Novartis II, G 001/98 (EPO Enlarged Bd. App. 1999), reprinted at <<http://www.european-patent-office.org/clg3/pdf/g986001ex1.pdf>>, at *1 [hereinafter Novartis II]. The Board was comprised of: Chairman Messerli and members Teschemacher, Davies, Jestaedt, Lancon, Saisset, and van den Berg.

[FN119]. Transgenic Plant/Novartis, T 1054/96-3.3.4, 1998 O.J. EPO 511 (1997), reprinted in I.I.C. 78 (1999). See also Robin Nott, The Novartis Case in the EPO, 21 EUR. INTELL. PROP. REV. 33 (1999); Ingeborg Voelker, Europe Won't Reverse Controversial EPO Ruling, IP WORLDWIDE, July-Aug. 1997, available at <<http://www.ljx.com/patents/7-8europa.html>>. The EPO had similarly rejected the application on the basis of article 53(b). See Novartis II, supra note 118, at *6.

[FN120]. Novartis II, supra note 118, at *30.

[FN121]. See id. (citing Decision G 05/83, 1995 O.J. EPO 64).

[FN122]. Id. Furthermore, the Enlarged Board stated that the potential of using a patent to restrict access to important breeding material was very limited. Id. at *31.

[FN123]. Id. at *30-31 (citation omitted).

[FN124]. Novartis II, supra note 118, at *21-22.

[FN125]. Id. at *22.

[FN126]. Id.

[FN127]. See id. at 22 (addressing only the case where counterfeiting would be "apparent" to a skilled person and accordingly perhaps excluding situations where counterfeiting was actually not just apparent, but explicitly disclosed in the application).

[FN128]. For example, the EPO has struggled with application of the EPC bar to patenting methods of medical treatment, which are precluded as per se lacking industrial application under EPC article 52(4). Although the language of the exclusion is clear, the EPO has nonetheless allowed some patents in this area by narrowly interpreting the claims and interpreting what conditions constitute illness and therapy within this rule. See, e.g., T 329/94, Blood Extraction Method, 1998 O.J. EPO 241, reprinted in 29 INT'L REV. INDUS. PROP. & COPYRIGHT L. 694 (1998) (finding that blood extraction method was not precluded from patentability under article 52(4) because there was no therapeutic purpose or effect where the purpose was to improve the "efficiency of taking blood from a donor"); Trigonelline, T 143/94-3.3.2, 1996 O.J. EPO 430, reprinted in 28 I.I.C. 95 (1997) (finding no prohibition from patentability under article 52(4) for a claim directed to the use of a composition in the production of a compound, even if the compound would have a therapeutic use); Contraceptive Method/British Technology Group, T 74/93-3.3.1, 1995 O.J. EPO 712, reprinted in 27 I.I.C. 99 (1996) (finding patent on a method of contraception not excluded under article 52(4) because pregnancy is not an illness, and its prevention is not therapy).

[FN129]. Council Directive 98/44 on Legal Protection of Biotechnological Inventions, 1998 O.J. (L 213) 13. The EU, a union of nations (presently fifteen countries), was founded to further political, economic, and social cooperation; formerly, the EU was known as the European Community (EC) or the European Economic Community (EEC). Unlike the EPC, the EU governs many facets of national law through a governmental structure including a Parliament, Council, and Commission that roughly represent branches of an executive government. These EU bodies can require member states to take actions through the issuance of regulations (immediately and directly binding on member states) or directives (binding as to result only and usually not immediately effective).

[FN130]. See TRIPS, supra note 33, art. 27.

[FN131]. Compare id. with EPC, article 53(a), supra note 35, at 286. See Directive, supra note 36, at 16. See also TRIPS, supra note 33, art. 6, at 18- 19.

[FN132]. Commission Proposal for a Council Directive on the Legal Protection of Biotechnological Inventions, 1989 O.J. (C 10) 6, passim [hereinafter Initial Proposed Directive]. See also Biotechnology in the Community, COM(83)672 final at E3, E5 (noting the necessity of taking actions designed to "stimulate biotechnology in the Community and to increase competitiveness in Europe's bio-industries").

[FN133]. See Initial Proposed Directive, supra note 132.

[FN134]. See id.

[FN135]. Although membership in the EPC and EU are not identical, the overlap is substantial. In addition, because all members of the EU are members of the EPC, the EPC requirements would govern EU member states as well as any regulations or directive issued by the EU.

[FN136]. The Initial Draft Directive was proposed in 1988 and, despite substantial amendments, was finally rejected in 1995. See Decision on the Joint Text Approved by the Conciliation Committee for a European Parliament and Council Directive on the Legal Protection of Biotechnological Inventions, 1995 O.J. (C 68) 26. For additional discussion of the problems encountered in enactment of the directive, see, e.g., Nigel Jones, The New Draft Biotechnology Directive, 6 EUR. INTELL. PROP. REV. 163 (1996) (discussing 1995 proposed directive and whether it adequately addressed ethical issues); Joseph Straus, Patenting Human Genes in Europe--Past Developments and Prospects for the Future, 26 I.I.C. 920, 942-46 (1995) (discussing provisions of the draft directive

that encountered opposition on grounds that they failed to adequately address ethical issues).

[FN137]. Compare EPC, art. 53(a), supra note 35, at 286 with Directive, supra note 36, art. 6, at 18-19. The language of the final Directive is actually more aligned with article 27(2) of the TRIPS Agreement, which allows (but does not require) contracting members to prohibit from patentability inventions whose commercial exploitation would interfere with ordre public or morality. Compare Directive, supra note 36, art. 6, at 18-19, with TRIPS, supra note 33, art. 27(2), at 94 (stating "[m]embers may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law").

[FN138]. Notice Dated 1 July 1999 Concerning the Amendment of and Implementing Regulations to the European Patent Convention, 1999 O.J. EPO 573 [[hereinafter EPO Biotech Regulations]. Although the members of the EPC and the EU are not identical, there is substantial overlap. See, e.g., EPO Member States (visited Mar. 13, 2000) <<http://www.european-patent-office.org/epo/members.htm>>; Information on the European Union (visited Mar. 13, 2000) <<http://www.cali.co.uk/bis/europe.htm>>. Therefore, EPC member states are either directly bound to comply with the Directive or will be indirectly impacted as patents sought through the EPO will be issued according to the same standards.

[FN139]. See Directive, supra note 36, art. 6(2), at 18-19. In addition, although not within the text of the Directive itself, other examples set forth in the preamble may be considered to also be in violation of the ordre public and morality standard. For example, the preamble states that situations that might offend human dignity "are obviously also excluded from patentability." Id. at 16. In particular, the preamble notes that a process to produce chimeras from germ cells or totipotent cells of humans and animals would offend human dignity. Id.

[FN140]. Id. at 16.

[FN141]. See id.

[FN142]. See id. art. 6(2)(c), at 18.

[FN143]. See Directive, supra note 36, art. 6(2)(d), at 19.

[FN144]. See supra note 20.

[FN145]. The Newman application cites socially beneficially uses. See Dickson, supra note 3, at 424 (noting socially beneficial uses of the invention). It is also unclear whether a "substantial" medical benefit is intended to require something more than the benefit shown in the Onco-mouse case where the court was using a balancing test that merely required a benefit to humans or animals.

[FN146]. Directive, supra note 36, at 16.

[FN147]. See EPO Biotech Regulations, supra note 138, Rule 23(b), at 576 (noting that for applications concerning biotechnological inventions, the Biotechnology Directive shall be used as a "supplementary means" of interpreting the EPC).

[FN148]. See supra Part II.

[FN149]. See Relaxin, 1995 O.J. EPO at 403.

[FN150]. See, e.g., Philip Shishkin, Greenpeace Protests Europe's Gene Study Patent, WALL ST. J., Feb. 23, 2000 (noting that the EPO Munich headquarters came under siege); Greenpeace Paralyzes Patent Office In Genetic Engineering Protest, AGENCE FRANCE PRESSE, Feb. 22, 2000, available in Lexis, Nexis library, News File (noting that Greenpeace activists shut down the EPO by bricking up the entrance and provided a written statement declaring that "[w]e shut down the EPO to prevent it from granting patents on living organisms as long as possible")

and criticizing the EPO for its practice of patenting "living beings").

[FN151]. See Robin Nott, "You Did It!:" The European Biotechnology Directive at Last, 9 EUR. INTELL. PROP. REV. 347, 349 (1998) (noting that "it was probably inevitable" that the exclusions under article 6(2) would be included in order to get necessary consensus for the Directive's approval).

[FN152]. See supra notes 132-34 and accompanying text.

[FN153]. Ironically, although germ line gene therapy may presently be considered immoral, if it became more socially acceptable and even something expected it might be considered "immoral" to deny a person access to it. See Margaret Llewelyn, Legal Protection of Biotechnological Inventions: An Alternative Approach, 3 EUR. INTELL. PROP. REV. 115, 122 (1997) ("Scientific developments will inevitably be made leading to changes in what society will accept as being morally correct in the context of biotechnology and what it will not. It is difficult to support an immutable statement of what can never be regarded as patentable in the light of this.").

[FN154]. For example, it is recognized that the prohibition against patenting plant varieties under EPC article 53(b) came into existence because of a requirement under a different law for providing plant variety protection that precluding protection under two separate systems. See, e.g., Novartis II, supra note 118, at *23-29 (describing history of EPC prohibition on plant varieties, including prior prohibition under the Strasbourg Convention which the EPC is based upon); E.S. VAN DE GRAF, PATENT LAW AND MODERN BIOTECHNOLOGY 85-86 (1997) (describing development of EPC article 53(b)). However, although that law was amended in 1991 to allow dual protection for plant varieties, the EPC bar remains. VAN DE GRAF, supra, at 91-94 (discussing both the political problem of amending article 53(b) and how courts have attempted to narrow the applicability of the provision). Accordingly, courts have struggled to interpret the EPC in a manner that is consistent with its literal meaning while recognizing present day realities and the purpose of the patent system. See id. See also Robin Nott, The Novartis Case in the EPO, 21 EUR. INTELL. PROP. REV. 33 (1999); Ulrich Schatz, Patentability of Genetic Engineering Inventions in European Patent Office Practice, 28 I.I.C. 2, 8-9 (1998) (noting confusion among the EPO courts regarding whether transgenic plants are denied patentability by article 53(b)); Ingeborg Voelker, Europe Won't Reverse Controversial EPO Ruling, IP WORLDWIDE, July/Aug. 1997 (discussing inconsistency of EPO decisions concerning the patentability of transgenic plants).

[FN155]. It should be noted that some of the negative impacts of article 53(a) would not be directly applicable to the United States because the United States does not provide third parties with an opportunity to oppose patents in the same manner; the only post-issuance proceeding provided by the PTO is re-examination of a patent based on new prior art. Although third parties may challenge the validity of patents in a judicial proceeding, the standing requirement essentially means that only defendants who are likely to be sued can do so. See, e.g., C.R. Bard, Inc. v. Schwartz, 716 F.2d 874, 879 (Fed. Cir. 1983) (noting that there must be a reasonable threat that a patentee will bring an infringement suit against the alleged infringer in order for the alleged infringer to have standing to sue for a declaratory judgment); cf. Animal Legal Defense Fund v. Quigg, 932 F.2d 920, 925 (Fed. Cir. 1991) (holding that farmers, husbandry groups, and organizations did not have standing to seek a declaration that animals are not patentable subject matter and an injunction against the issuance of animal patents). For additional discussion of this case, see David Burke, Note, Animal Legal Defense Fund v. Quigg: Renewed Challenge to Animal Patents, 59 UMKC L. REV. 409 (1991); Elizabeth Joy Hecht, Note, Beyond Animal Legal Defense Fund v. Quigg: The Controversy over Transgenic Animal Patents Continues, 41 AM. U. L. REV. 1023 (1992).

[FN156]. The patent laws contain no requirement for disclosure of such information. The only requirement that might relate to commercial application would be the utility requirement. However, this does not demand commercial utility and only considers whether there is at least one utility. See 35 U.S.C. § 101 (1994); Revised Interim Utility Examination Guidelines, 64 Fed. Reg. 71,440 (1999) (noting that a claimed invention must have a specific utility but no more than that). Therefore, it is conceivable that an invention could satisfy the utility requirement and yet have other applications that might be considered offensive.

[FN157]. See 35 U.S.C. § 102(b); EPC, art. 52, supra note 35, at 285-86.

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