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EXCLUSION BY INCLUSION? ON DIFFICULTIES WITH REGARD
TO AN EFFECTIVE ETHICAL ASSESSMENT OF PATENTING
IN THE FIELD OF AGRICULTURAL BIO-TECHNOLOGY

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ABSTRACT. In order to take ethical considerations of patenting biological material into account, the so-called “*ordre public* or morality clause” was implemented as Article 6 in the EC directive on the legal protection of biotechnological inventions, 98/44/EC. At first glance, this seems to provide a significant advantage to the European patent system with respect to ethics. The thesis of this paper argues that the *ordre public* or morality clause does not provide sufficient protection against ethically problematic uses of the patent system within the area of life. On the contrary, there are worrisome obstacles to any effective and comprehensive critical analysis of the ethical aspects of bio-patenting, especially in the field of agriculture. These obstacles can be seen as indirect consequences of the implementation of ethical considerations in form of the *ordre public* and morality clause in the EC Directive. Therefore, Article 6 of the EC Directive on the legal protection of biotechnological inventions seems to ultimately weaken the position of ethics in the debate concerning bio-patenting because the *ordre public* and morality clause is usually interpreted in an exclusively *bio-ethical* way in the sense of an “intrinsic ethics,” which is primarily interested in questions regarding the moral status of particular entities. It is argued that an important cause of this phenomenon is that the decisive reasons against bio-patenting are concerns of *social ethics*, and not *bio-ethics*.

KEY WORDS: agricultural bio-technology, EC bio-patenting directive, ethics, *ordre public* and morality clause, patents

1. INTRODUCTION

Patenting aims at promoting technological innovation and advancement expected to benefit society at large. In order to realize this end, an innovator is given a set of exclusive rights in the form of a patent to either prevent commercial use of the invention by others for a fixed period of time (usually 20 years) or to require licensing fees for the commercial use of the patented innovation. By conferring such a limited monopoly in exchange for public disclosure of the new technology, it is expected to enable the patentee to market the respective invention in a

profitable way and thus to regain the invested costs of research and development.

The rights granted in the form of a patent might thus be interpreted as sort of a reward assigned to the patent holder in exchange for introducing an innovative product or process into the public domain along with the disclosure of its specifications. Exclusion rights (rights that allow the holder to exclude other parties from the commercial use of a patented invention) have been shown, however, to contradict societal interest in an economy free from monopolies, and to also put into peril the freedom of research (see Wolfrum and Stoll, 2001). Therefore, the privileges assigned to the patent holder may need to be balanced both against the invention's expected usefulness for society at large and the inventor's efforts. In order to ensure this delicate balance of interests, patents are only granted for inventions and not for discoveries. Furthermore, the inventions need to prove to be novel and suited for commercial use, as well as being non-obvious. This is to say that an invention ought not to be so obvious as to be easily derived from the current level of technology by the average expert in the field. From an ethical point of view, both the promotion of technological advancement and the just and fair compensation of an inventor's contributions seem legitimate. Above that, the patenting system can be understood in a certain sense to work as an instrument securing commutative justice in practice: Considering the risks and costs involved with the research and development of technological innovations, and taking into account the common good arising from the public disclosure of the resulting invention, it is fair and just to reward the innovative party in an appropriate and equitable way.

But does this line of thought apply to the realm of living things as well? Or are there rather distinctive features that put into question the application of patent law to biological materials? A first glance at relevant legal texts, as well as the legal and ethical debates concerning bio-patenting, points to two findings. With regard to the current legal practice of granting patents, both the patenting of biological resources and the methods these materials are being used basically fall under the same set of requirements as for patenting non-living material. This is in accordance with Article 27(1) of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (hereafter called "TRIPS Agreement"), which states with regard to patentable subject matters that patents shall be available for any invention in *all* fields of technology. Nonetheless, despite this reasonably well-defined and clear-cut patent law, the general ethical legitimacy of bio-patenting and its specific ethical confines remain most controversial.¹ To name just one

¹ Cf., inter alia, Hermerén, 2000; Warner, 2001; Baumgartner and Mieth, 2003 on the ethical debate on bio-patenting.

example: It is argued that the identification and isolation of genes and DNA sequences do not satisfy the eligibility requirement of patentable material because it is a discovery, not an invention. Public interest usually focuses on patent applications filed on innovations in the field of bio-medical research, including such well-known patent examples as the “breast cancer genes” or the “Harvard onco-mouse.” The attention of the public has turned more recently to the ethical aspects of patenting with regard to bio-technological developments in the field of agriculture.² Discussion has revolved around such patents as those on “Golden Rice” and those on maize plants with a content of oil and oleic acids exceeding a certain threshold level.

In light of the lively discussion of the ethical aspects of patenting, ethical limitations on the patentability of biological material were explicitly included in the wording of *Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions* (“Directive” in the following). Effective the first of September 1999, the Directive was implemented in the form of the rules 23(b)–23(e) in the European Patent Convention and is now legally authoritative for the granting of patents in Europe.

2. THE *ORDRE PUBLIC* AND MORALITY CLAUSE: ETHICAL ASPECTS OF BIO-PATENTING IN THE EC DIRECTIVE

Article 6 of the Directive is the undeniable ethical heart of current EC patenting legislation. Known commonly as the *ordre public* and morality clause, it proves crucial as far as the outer ethical limitations of patentability are concerned.³

1. Inventions shall be considered unpatentable where their commercial exploitation would be contrary to *ordre public* or morality; however, exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation.
2. On the basis of paragraph 1, the following, in particular, shall be considered unpatentable:

² This article will refer to all technological developments as agricultural bio-technological developments or innovations that initially treat non-human biological material and that are applied (or employed) during food production. This comprises not only micro-biological and plant products, but also any processed product that is based on biological material originating from (non-human) animals.

³ Article 6 of the Directive does not create an entirely new patent law. It mirrors article 53(a) of the European Patent Convention that can be seen as the progenitor of article 6 of the Directive.

- (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.

By referring to “*ordre public* and morality” as ethical limits to the patentability of bio-technological innovations, the Directive ipso facto contains provisions suited for an (initial) assessment of the ethical aspects of any corresponding patent application. Such option should not be regarded as a matter of course – it is seen as the exception, rather than the rule. Patent law in the United States, for instance, does not stipulate any similar provision to Article 6.⁴

Article 6 of the Directive, at first glance, appears to be the result of an effective debate on the ethical aspects of the legal protection of technological innovations in the field of life sciences. Its practical impact, however, largely depends firstly on its judicial interpretation and secondly on its legal implementation at national and EU-level. Since the concept of *ordre public* and morality remains fairly vague, it allows for certain leeway in interpretation.⁵ According to recital 38 of the Directive, the list of processes that are contrary to the *ordre public* and morality are defined as unpatentable in Article 6(2) needs to be understood as “an illustrative list” only, one included, in the words of the Directive, “to provide national courts and patent offices with a general guide to interpreting the reference to *ordre public* and morality.” It is clearly stated that this list “obviously cannot presume to be exhaustive.” Likewise, recital 38 offers leeway of interpretation while simultaneously providing specific examples that violate the concept of human dignity, stating, “Processes, the use 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.”⁶

⁴ Cf. Bagley, 2003. Margo A. Bagley characterizes the US approach as “patent first, ask questions later,” while labeling the European approach as “ask questions first, patent later.” Bagley assesses the European inclusion of an express morality-based exclusion bar in the EC directive quite positively, particularly in comparison to the US approach.

⁵ Cf. Van Overwalle, 2003, p. 152: “[A]rticle 6 of the EU bio-technology directive is the subject of an ongoing debate. [...] [T]he principle laid down in article 6(1) raises serious interpretation problems.” An opposing point of view is presented by Tade Matthias Spranger who argues that the terminology of public order and morality “has materially been clarified by jurisdiction and law teaching to a sufficient degree so as to function as legal terms” (Spranger, 1999, p. 598).

⁶ See also the beginning of recital 16: “Patent law must be applied so as to respect the fundamental principles safeguarding the dignity and integrity of the person.”

The ethical principles on which grounds innovations are considered unpatentable are human dignity (see recitals 16 and 38) and the principle of not causing unnecessary harm or suffering to sentient animals (Article 6(2)d).⁷ But these are principles of a normative bio-ethics in the strictest sense. They are closely, even *directly*, related to the question of the “moral status” of either the to-be-patented biological material or of the animal/living being that provides the biological material in question. Keith Douglas Warner speaks in a similar context of “intrinsic ethics,” a term that for us adequately defines the narrow concept of ethics that is used in interpretation of the Directive (Warner, 2001, 309).

The predominant interpretation of Article 6(1) corresponds to this ethical point of view. Historically, it has been a general principle of patent law that exclusions from patentability are to be interpreted narrowly and inclusions broadly.⁸ Consequently, Geertrui Van Overwalle argues that it is “generally accepted that the twin concept *ordre public* and morality is used to define the utter limits of what present society tolerates and to delimit the absolutely unacceptable” (Van Overwalle, 2003, p. 152). Accordingly, Article 6 of the Directive is considered a narrow gate of entry for “the main principles underlying the legal system” (Cf. Van Overwalle, 2003, pp. 152; Godt, 2003, p. 55).⁹

Despite this markedly narrow gate of entry for the due regard of ethical considerations in patenting, Article 6 of the Directive proved significant in a decision by the European Court of Justice regarding the so-called Edinburgh patent (EP 695351). In 1999, this patent was granted to the University of Edinburgh for a method by which “animal stem cells” could be genetically modified so as to give them a survival advantage over unwanted differentiated cells, and in this way they could be cultured and isolated. On the grounds that the term “*animal stem cells*” might also be interpretatively extended to include human embryonic stem cells (which when derived from human embryos result in the destruction of the embryo), opposition to the Edinburgh patent was formally lodged by fourteen parties, including the governments of Germany, Italy, and the Netherlands. In June 2003, following an opposition hearing, the patent was amended and confined specifically to “*other than embryonic stem cells*” (see also Baumgartner and Mieth, 2006).

⁷ The discussion on the patenting of the so-called “Onco-mouse” provided the background for the inclusion of this principle into the Directive. See also Godt, 2003, p. 53.

⁸ Beyleveld and Brownsword, 2003, p. 133.

⁹ Margo A. Bagley, who assesses the European patent law quite positively, acknowledges that the *ordre public* and morality clause is “a very narrow focus” for the inquiry of the moral aspects of a patent application. Cf. Bagley, 2003, p. 519.

Due to the “dependency” of Article 6(1) of the Directive on bio-ethical principles in the stricter sense – such as human dignity or the precept not to cause needless suffering to sentient beings – the concept of public order and public morals (*ordre public* and morality) seems to be applied almost exclusively to innovations in the field of bio-medical research. This becomes most evident in a comparison of Article 6 of the EC bio-patenting directive with the corresponding text passage in the TRIPS Agreement. The TRIPS Agreement as well makes mention of the concept of *ordre public* and morality, however it is characterized as a merely available and not a mandatory criterion for the exclusion of inventions from patentability. It also applies to inventions outside the realm of living things. Unlike the case of the EC directive, this TRIPS clause is not illustrated by the examples in Article 27(2):

Members 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.

Recital 36 of the EC directive directly alludes to this passage, which, however, was not included in the operative part of the Directive.¹⁰ This bears some relevance to the question of whether the provisions provide a possibility to exclude bio-technological innovations in the field of agriculture from patentability, given that the exclusion is based on ethical deliberations only.

To sum up, one may say that Article 6 of the EC Directive provides a morally-based exclusion bar for patentability. However, the predominant interpretation of Article 6 that is to a certain degree predetermined by the text of the Directive (e.g., the strong focus on principles of an “intrinsic” bio-ethics and the omission of parts of the corresponding Article of the TRIPS Agreement) results in a very limited scope for an application of Article 6.

3. PROBLEMS CONCERNING THE ETHICAL ASSESSMENT OF PATENTING IN AGRICULTURAL BIO-TECHNOLOGY

The examples given in the Directive as a guideline to interpreting the concept of *ordre public* and morality are excluded from patentability for the reason that their application or commercial use directly and evidently

¹⁰ The operative part of a directive (the *articles*) is key to the meaning of its *recitals*. The precise nature of recitals, however, along with their legal binding force, remains controversial. “They act to provide a context for patent law provisions by which to guide legal interpretation. [...] According to prevailing opinion, they act as a ‘legally binding reference point for interpretation’” (Godt, 2003, p. 54).

violates core principles of the European value system. Hence, the reason for exclusion is inherent to the invention itself or to its (anticipated) application and is clearly not based on the granting of intellectual property rights pertaining to any specific technological innovation. “There is a strong feeling that Article 6(2) does not aim at limiting the *patent* implications of certain bio-tech inventions, but wishes to exclude certain fields of *research* as such” (Van Overwalle, 2003, p. 153. Emphases in original).

This offers substantial implications with regard to the question whether the exclusion from patentability of bio-technological developments in the field of agriculture is possible on the basis of ethical considerations. First, the bearing of Article 6 of the Directive is highly problematic because such agricultural innovations do not show any direct reference to the principle of human dignity or to the ban on causing animals suffering without any substantial *medical* benefit. This I will call the “problem of an inappropriate ethics.”

Secondly, the evaluation process of *all* ethical aspects of bio-technology as required by Article 7 of the Directive is rendered impossible by the fact that the concept of *ordre public* and morality constitutes the *sole* point of reference for any ethical assessment of patent applications.¹¹ This I will call the “problem of an impediment to comprehensive and effective ethical review through the implementation of ethical considerations into law.”

By no means do these problems prove significant only in the context of agricultural bio-technology – their particular importance in this area, however, must not be overlooked. They shall be examined further in the following paragraphs.

4. THE “PROBLEM OF AN INAPPROPRIATE ETHICS”

As has already been shown above, Article 6 of the Directive is only applicable to those technological developments that society considers ethically false *in themselves*, so that their use appears unacceptable for reasons of principle – irrespective of the question whether or not their use yields desirable results. This, from the outset, is not the case with agricultural bio-technological inventions, since they neither rely on extracted biological material that results in the destruction of human life (as was one potential outcome in the first phrasing of the so-called Edinburgh patent) nor are they closely linked with “suffering without any substantial *medical* benefit.”

¹¹ Article 7 reads, “The Commission’s European Group on Ethics in Science and New Technologies evaluates all ethical aspects of bio-technology.” The limits set for the patenting of bio-technological innovations then appear in recital 44, which, following the exact wording of article 7, states, “Whereas it should be pointed out in this connection that that Group may be consulted only where bio-technology is to be evaluated at the level of basic ethical principles, including where it is consulted on patent law.”

Nonetheless, it does not follow that the patenting of genetically modified micro-organisms, for instance, or of transgenic seed and crops is free from ethical concerns. Public discourse on the ethical permissibility and allowability of bio-patenting was initially triggered in 1980 by a micro-organism, after the US Supreme Court's landmark *Chakrabarty* decision affirmed the patentability of a genetically modified micro-organism capable of breaking down crude oil.¹² The ethical assessment of patents in the context of agricultural bio-technology, however, is based on principles beyond those specified in Article 6(2) and the recitals 16 and 38 of the Directive, and proceeds rather by criteria not immediately derived from *bio*-ethical principles in the strict sense (such as the question regarding the moral status of a specific entity). Instead, in this context, critics often address problems similar to the following kind:¹³

- Small farmers may become increasingly dependent on large seed companies due to the patenting of seed. The lion's share of patents on seed and other biological materials suited for use in agriculture is owned by a handful of transnational seed companies that control access to major agricultural resources. The present situation might mark the beginning of an oligarchic agro-business system. Viewed in this light, fears arise that future small-size farmers might only have a small number of patent-free seed cultivars at their disposal that will prove less efficient than patented seeds and produce smaller yield. Experience suggests that because of the high cost of patented seeds, small farmers would no longer be able to exist independently of large seed companies.¹⁴
- Bio-patents frequently function as instruments for exploiting developing countries. There have been instances, for example, of researchers from

¹² See Kevles, 2002 for further information. Apart from marking the start of public controversy with regard to bio-patenting, this ruling also constitutes the onset of an increase in both scope and numbers of bio-patents.

¹³ These well-known points of discussion can only be mentioned in brief here. Cf. CIDSE, 2000; Hermerén, 2000; Svatos, 2000; Warner, 2001; CIPR, 2002; Nilles, 2003; Tsioumanis et al., 2003; Van den Belt, 2003 with regard to the ethical aspects of patenting in the field of agricultural bio-technology.

¹⁴ With regard to the effect of patenting systems on developing countries, the Commission on Intellectual Property describes the danger of excluding specific groups of persons or even entire societies from the benefits of technological advance as a potential result of patenting: "The system provides the incentive for individuals and companies to invent and develop new technologies that may benefit society. But incentives work differently according to whether there is a capacity to respond to them. And, by conferring exclusive rights, costs are imposed on consumers and other users of protected technologies. In some cases, protection means that potential consumers or users, who are unable to pay the prices charged by IP [Intellectual Property] owners, are deprived of access to the innovations the IP system is intended to make available." (CIPR, 2002, p. 5).

Western bio-tech industries prospecting in Third World countries rich in natural and biological resources in order to collect samples of biological materials, which, after being modified, are then sold back in the form of patented products to the very farmers and customers in the very same developing countries. Often the seeds produced are sterilized so that farmers must buy new (expensive) seed for each harvesting season—unless they wish to gamble on re-using their traditional “old” seed, which might, however, yield less than the patented ones. The problem posed by such practices is not the same as potential patent misuse and from which it does *not* necessarily follow that bio-patents are problematic in terms of ethics. If anything, as the above two examples elucidate, the danger of patents originates in the context of the economic competition and imbalance from which they cannot be separately considered. These have far graver ethical implication than the individual patent holder’s intentions.

- Relating to the problem described in the previous paragraph, researchers and entrepreneurs from highly-industrialized countries sometimes are accused of “bio-piracy,” which is to say that they appropriate and privatize traditional knowledge of indigenous populations, particularly in the Global South. Such appropriation also occurs from local biological resources without first seeking the prior informed consent of the holder or owner of the indigenous knowledge, adding insult to injury by failing to share the benefits prospected in this process. This is in direct contrast to any number of possible schemes or rules of benefit sharing. The people whose traditional knowledge and biological resources are being appropriated do not only run the risk of being exploited, but, adding injury to insult, also might be excluded from the free use of the respective biological material if it gets patented. The products derived from the Neem tree are a prime example in this context.
- Evidence that patents on genes and gene sequences frequently affect bio-technological research and development in a negative way seems to fundamentally contradict the patenting system’s main objective to foster technological innovation. There are various reasons for this. Besides the concentration and monopolization trends already outlined above, the resulting rise in prices needs to be duly noted, as it eminently influences research in areas that require the use of already patented material. While it is true that access to information on patented research results is basically free for the *scientific community*, one needs, however, to differentiate between “free access” and “free use” in this context.¹⁵ The fact that research results published during the patenting proceedings

¹⁵ See Gertruui Van Overwalle, Contributions in the Forum Bio-ethics of the German National Ethics Council on April 23, 2003, transcript, p. 14 (Source: http://www.ethikrat.org/texte/pdf/Forum_Patent_03-04-23_Protokoll.pdf).

are freely available for study and are thus in the public domain, does not imply that the use of the respective information for one's own research is free of cost. Rather, research can be inhibited in fields characterized by a multitude of fragmented patents because of the high transaction costs of licensing earlier patents. Such research is frequently considered less (financially) viable. As a result, scientists (may) consult patent databases prior to choosing their field of research in order to assess future licensing fees and even change their field of study in the face of prohibitively high costs.¹⁶ In addition, it seems reasonable to assume that scientifically useful information is being withheld from the public until after a patent application has been filed, since an invention, if it is to remain patentable, must not have been published before.¹⁷

The questions and problems outlined here for exemplary purposes make it clear that the ethical aspects of patenting in the field of agricultural biotechnology rather pertain to the study of social ethics than to the area of an "intrinsic" bio-ethics in the above strict sense. They are closely related to questions of food security, justice, and (free) access to specific or scarce resources. These aspects simply cannot be traced back to principles such as human dignity or to the precept of not causing unnecessary harm and suffering to animals. Moreover, even if the assessment of an agricultural or bio-technological patent application was considered ethically problematic or outright wrong in light of these social concerns, it would still miss making any substantive link to the sole point of reference included in the Directive.

¹⁶ The resulting problem was termed the "tragedy of the anticommons" by Michael Heller and Rebecca Eisenberg. While in the case of the "tragedy of the commons" (Garrett Hardin), an analogy widely known in the context of environmental protection, a conflict emerges from the free unregulated access to a resource that any individual actor may use at his/her discretion, resulting in the over-exploitation of said (common) resource. The scenario characterized by Heller and Eisenberg is the exact opposite: As a result of the privatization of research and particularly due to a corresponding patenting practice, valuable resources for research run the risk of being wasted or being utilized most ineffectively because too many patent owners have the right to exclude each other from the use of vital parts of the overall resource. Competing patents of this kind lead to a decrease in the development of novel products and methods instead of an increase (Cf. Heller and Eisenberg, 1998). Provisions such as the privileged status of research ("research exemption") laid down in section 11 of the German Patent Law fail to adequately address this problem in the context of bio-technology. While the German research exemption, for instance, covers experimental acts performed *on* patented inventions and *about* them such as scientific experiments researching into the way the respective invention works (its *modus operandi*) and aiming at its further development, it does not cover experiments in which the patented invention is merely used to yield knowledge on subject matters outside the original patent – that is research *using* said patented invention. Therefore, this latter kind of research in which the patented invention is merely instrumental in use, is subject to licensing fees. This provision has serious consequences especially with regard to genes and gene sequences due to the multi-functionality of genes.

¹⁷ See Schneider (2003, pp. 185–186) for further information.

It may be the case that there is nothing in the Directive that explicitly precludes ethical considerations concerning patenting developments in the field of agricultural biotechnology. But the predominant narrow interpretation of Article 6 that is strongly suggested by the text of the directive proves to be *de facto* an effective bar. Hence, the exclusion of bio-technological innovations in the field of agriculture from patentability by referring to explicitly ethical deliberations proves difficult: Not only are they frequently considered ethically unproblematic themselves, but there is also the need for the ethical problems associated with said innovations to be of the “right kind” of ethical problems.

5. BIO-PATENTING IN LIGHT OF THEOLOGICAL CRITIQUE AND CHURCH STATEMENTS¹⁸

Does a theological approach or an explicitly theological ethics provide a way to deal with the “problem of an inappropriate ethics” adequately? There are numerous statements by representatives of religious groups and denominations, often supported by documents drawn up by church-related organizations, that assess both the potentials and problems of bio-patenting. Exemplary organizations and texts that prove relevant include, the World Council of Churches (WCC) 1982 report “Manipulating Life: Ethical Issues in Genetic Engineering;” the 1987 “Statement of Religious Leaders against Animal Patenting;” the WCC Department on Church and Society’s “Bio-technology: Its Challenges to the Churches and the World;” the “Joint Appeal against Human and Animal Patenting” that was adopted in May 1995 by church leaders representing more than 80 different groups; the European Ecumenical Commission for Church and Society (EECCS)’s 1998 document titled “EECCS and Bio-ethics;” and, finally, the “Bio-patenting and the Threat to Food Security: A Christian and Development Perspective” published in 2000 by the non-governmental organization *Coopération Internationale pour le Développement et la Solidarité* (CIDSE).

These documents are generally critical in their assessment of bio-patenting and, when taken together, basically constitute three main lines of argument or critique:

- (1) A first criticism derives from the conviction that all life and the entirety of living beings are gifts and creatures of God. Thus, due to their bonding and enduring relationship to God, a special quality (particularity) is accorded to them that is commonly referred to as the

¹⁸ Cf. CIDSE, 2000; Cole-Turner, 2000; Warner, 2001; Cunningham, 2003 for the following paragraphs.

“dignity as a creature” or God-given “sanctity.” Patent law implicitly assumes living beings, isolated parts, or genetically modified entities can be “invented” by man. This assumption is vigorously denied on grounds of the religious belief that God is the sole creator and “inventor” of all living beings and who is thus, according to this line of reasoning, the sole holder of all intellectual property rights as regards the realm of living things. R. Cole-Turner succinctly expresses this notion as follows:

In this view, as Creator, God reserves the right to determine how the knowledge of organic development is to be used. In a way, it is as if God the Creator were the first to patent genes, not to exclude us from using the knowledge, but to exclude us from excluding others. (Cole-Turner, 2000, p. 837).¹⁹

- (2) Another theological argument, based on the previous point of criticism, emphasizes said dignity of life or particularity by pointing out that a living being is being reduced to a mere substance or resource and eventually commodified through the act of patenting. The granting of bio-patents ignores the specific status inherent to living beings due to their relation to God, the same status that distinguishes them from non-living things:

The patenting of life encodes into law a reductionist conception of life which seeks to remove any distinction between living and non-living things [...] This mechanistic view directly contradicts the sacramental, interrelated view of life intrinsic to a theology of the integrity of creation.²⁰

- (3) Social ethical arguments against bio-patenting from a perspective of religious understanding are not explicitly theological ones. Rather, these aim at aspects already dealt with in the above section on the “problem of an inappropriate ethics”: the appropriation and privatization of

¹⁹ The aforementioned criticism of the notion of invention is also supported in other contexts independent of a religious background – though with a slightly different emphasis. There, the aspect of an over-compensation for the respective inventor is frequently brought forward. As has already been pointed out, the efforts performed by the inventor in advance need to be balanced in a just and fair way against the “price” society pays for the utilization of a patented innovation. In the area of bio-technology, each innovation is derived from at least three components: “Nature (creation), previous intellectual works provided by others, and the individual work (effort) of the inventor.” (Dolder, 2003, p. 3.) Therefore, the exclusive rights granted in a patent should be limited in scope to the effort contributed by the inventor: “The *factum*, which comprises the intellectual work put forward by the inventor, is to be regarded patentable, not the *genitum* which originates from nature (creation)” (ibid.). The patenting of biological resources themselves (such as transgenic seed, genetically modified organisms etc.) appears an undue reward given the significant part the *genitum* has in such invention.

²⁰ World Council of Churches, Department on Church and Society, Biotechnology: Its Challenges to the Churches and the World, quoted in Cole-Turner, 2000, p. 836. Paige Comstock Cunningham speaks in this context of an “erosion of the imago Dei” due to the patenting of human genes (Cunningham, 2003).

genetic resources found in developing countries for materialistic reasons in connection with the availability of patenting (“bio-piracy”); the increasing dependency of small-size farmers on trans-national seed companies and as a result the erosion of both bio-diversity and food security, et cetera. According to Keith Douglas Warner the principle of the universal destination of goods remains primordial towards (individual) private property rights and thus constitutes a principle that significantly limits the potential for ethically acceptable bio-patents:

The Catholic social teaching tradition and its principle of the universal destination of goods fundamentally conflicts with the negative right conferred by gene patents. The Catholic principle of the universal destination of goods implies that genes, gene sequences, and engineered crop varieties are ineligible for patent protection, although the processes to engineer these should be eligible. (Warner, 2001, p. 361).²¹

Considering the theological evaluation of bio-patenting outlined here in light of the aforementioned “problem of an inappropriate ethics,” one needs to conclude that, in a theological or religious understanding, a specific emphasis is placed on the criticism of bio-patenting through the *theologoumena* of the “sanctity” of life and of the “dignity as a creature.” The first two arguments, after all, are not conceivable without reference to theology and without such recourse prove inadequate with view to agricultural biotechnology. It appears, though, that the “strength” of theological critique is at the same time its weakest spot: Outside religious context, it proves highly problematic to argue in favor of the conviction that all living beings are accorded a specific dignity, that is particularity, that necessitates the recognition of life’s special need for protection and that negates any intellectual property rights in the realm of living things. Therefore, without further assistance, this argumentation fails to establish an appropriate basis for legislation in a pluralistic and non-biased society with its diversity of interests, convictions, and lifestyles. And irrespective of this, even for a theological ethics that specifically seeks to address the realm of (Christian) faith and community only, the notion of the “dignity as a creature” that is at its core, categorically differs from the concept of “human dignity” that is central to the EC bio-patenting directive and that tries to establish the human being as distinct and unique from other living beings.

Hence, theological critique on bio-patenting ultimately fails to provide effective answers to the problems detailed above in just the same way as any

²¹ Whether the principle of the universal destination of goods really works as an argument against bio-patenting or at least against specific forms thereof, requires, in my opinion, a thorough examination. Basically, patenting specifically aims at fostering technological innovation for the common good, whereas the granting of economic privileges to the inventor in form of exclusive rights is just a secondary goal that even can be characterized as just a means for realizing the proper end of any patenting regime.

other (non-theological) moral theory. Therefore theological ethics does not provide a solution to the “problem of inappropriate ethics” as outlined above.

6. THE “PROBLEM OF AN IMPEDIMENT TO COMPREHENSIVE AND EFFECTIVE ETHICAL REVIEW BY THE IMPLEMENTATION OF SPECIFIC ETHICAL PRINCIPLES INTO LAW”

This second problem is very closely connected to the “problem of inappropriate ethics.” Nonetheless, in my opinion, the differentiation proposed here facilitates the analysis of the problems considerably.

A patent does not confer a right to make use of the patented invention, but only the right to exclude others from using the invention. Therefore, the regulation of exploitation and use of patented innovations is considered to be outside the scope of the patent system (Cf. Beyleveld and Brownsword, 2003, p. 131). The doctrine that patent law must not regulate the use of technological inventions could be considered to be an important reason for the avoidance of social ethics in the Directive. However, this would imply significant inconsistencies, because Article 6 of the Directive would be called into question by this doctrine as well (Cf. Beyleveld and Brownsword, 2003). There is no direct link between ethical deliberations on the one hand and the question of legal protection of bio-technological inventions on the other in the Directive. The moral restrictions on bio-patenting laid down in Article 6 do not exclude certain biotechnological inventions from patentability because of patent implications, but only where the commercial exploitation of the invention in question would be contrary to *ordre public* and morality.²²

The abovementioned social-ethical problems of patenting in the field of agricultural bio-technology are more directly related to patents and their exclusive function. Nevertheless, Article 6 offers the sole point of reference in the Directive for an ethical assessment of patent applications. As already said, the given “interpretation guidelines” in the Directive in conjunction with the failure to include, as criteria for unpatentability, the protection of human, animal or plant life or health and the avoidance of serious prejudice to the environment, as has been laid out in Article 27(2) of the TRIPS Agreement, strongly suggest a very narrow interpretation of Article 6. This might even render it impossible to exclude any agricultural bio-technological innovations from patentability on the basis of ethical

²² Accordingly, Geertrui Van Overwalle proposes to amend the EC bio-patenting directive by striking out article 6(2): “[P]atent law should not interfere when *research* is ethically undesirable. Since a direct link is missing between ethics and patents in article 6(2), I take the view that this provision should be abolished and the exclusions should be treated in research regulations.” (Van Overwalle, 2003, p. 153. emphasis in original).

considerations. Against this background, there is reason to believe that the explicit inclusion of *specific* ethical principles into the legal framework of the European patent system might further *weaken* the position of ethics, particularly with a view to the bio-political debate on the legal protection of technological innovations in the field of agricultural biotechnology. The area affected by this phenomenon, which can only be roughly adumbrated here and which I like to call the “problem of an impediment to comprehensive and effective ethical review by the implementation of specific ethical principles into law,” is not limited to bio-patenting in the field of agriculture and food production but also comprises patenting in the field of bio-medicine. By taking a look at a viewpoint described by Dieter Laudien, which is held by proponents of extensive patent protection in the area of bio-technology, one may find some support for assuming so:

These ethical constraints including an explicit reference to the (German) Embryo Protection Act as a limit to patentability are widely supported by the pharmaceutical industry research. Yet, it argues that as a matter of principle the patent law definition of limits to patentability ought to be governed first and foremost by the *ordre public* clause (violation of public order and public morals) and that *no other reasons for exclusion but those given as examples in the Directive should constitute guidelines for patent examiners and courts.* (Laudien, 2003, p. 52. Emphasis by C.B.).²³

Given the “problem of an inappropriate ethics” outlined above, however, it is evident that the selective inclusion of specific ethical principles into patent law, or rather the (judicial) interpretation and implementation of legal provisions in the field of agricultural biotechnology according to such principles, proves most significant and yet, from an ethical perspective, *necessarily* renders ethics rather useless. Due to the “hermetic character” of the ethical part of the Directive that has been described before, social ethical deliberations have little to no point of reference for affecting legal practice in patent law.

²³ At the beginning of this quote, Laudien refers to the German federal government’s draft proposal on the implementation of the bio-patenting Directive issued during the fourteenth parliamentary (legislative) term (Source: Bundestagsdrucksache 14/5642 from March 23, 2001). See also the position expressed by Tade Matthias Spranger, who, while discussing ethical reservations about certain forms of bio-patenting, points to several articles of the EC directive and then apodictically concludes that no further(-reaching) standards prove necessary. (Cf. Spranger, 2003, p. 88). According to Spranger, ethical deliberations may serve as motives for legislative bills or can influence the actual wording of legal norms, they should not, however, be given an underlying role in the “practice of patenting” or carry too much weight with respect to single issues. Hence, Spranger explains, the “somewhat unfortunate phrasing” of the EC directive should “not add to expanding beyond scope the already observable discussion according to which ethical considerations ought to weaken, in content, the impartial character of patent law.” (Spranger, 1999, p. 598).

7. CONCLUSION

If under specific situations a comprehensive and critical ethical analysis of legal institutions such that the notion of the patent is necessarily rendered ineffectual as a result of law, then law itself is found to be ethically problematic. From this, however, one cannot immediately reach too quickly for ethical conclusions or demands, since the problems presented in the previous section appear at first glance to be open for interpretation as an intriguing variant of moral theory's well-known principle "ought implies can." By means of the directive 98/44/EG a European legal framework for bio-patenting was installed – perhaps unintentionally or incidentally – that offers no possible point of reference for certain kinds of ethical critique towards specific patent applications. As a result, there seems to be lacking some form of requirement to consider innovations unpatentable if ethical reservations arise or to at least limit the scope of patents where applicable.²⁴ This framework, however, is *legal* in character and thus subordinate to the paramount *ethical* or *moral* duty. (Cf. Gewirth, 1978, p. 1). The "moral point of view" is a *critical* view towards positive law, as has also been recognized by authors who share Jürgen Habermas's understanding of the relation between positive law and morality as a complementary relation. Thus they reject such natural law concepts as a hierarchy of legal orders, as epitomized by the claim, "positive law remains subordinate to, and is oriented by, the moral law." (Cf. Habermas (1996), here particularly pp. 104–118 and pp. 447–).

Against this background, "opening up" legal texts for ethical critique appears quite a natural solution to the aforementioned problem or to at least help in this regard.²⁵ Article 6 of the Directive neither constitutes a necessary nor a sufficient instrument for an adequate consideration of the ethical aspects of bio-patenting. Geertrui Van Overwalle's proposition to include all specifications of the *ordre public* and morality clause in the TRIPS agreement into the European Patent Convention and thus to bring into equilibrium bio-technology, patenting, and ethics, can also be understood in the sense of an ethically indicated "opening up" of law texts (Cf. Van Overwalle, 2003, p. 152). In addition, the potential of an ethical assessment of patent applications could be diversified by treating the recitals 26 (informed consent) and 27 (information on the geographical origin of

²⁴ The above-quoted viewpoints of Dieter Laudien and Tade Matthias Spranger seem to support this notion.

²⁵ Frans Brom (2003) articulates a similar demand but does not identify legal texts and their interpretation as a starting point but rather locates it in a comprehensive public debate on the issues in question.

biological material)²⁶ as binding prerequisites for patenting (Cf. Godt, 2003; Van Overwalle, 2003). These proposals, however, have a common problem: They can actually only provide a view on possible problems of the patenting system in specific, concrete cases that have not yet been addressed in law, but they ultimately fail to provide the much more dynamic modes of evaluation required for (relatively) novel technologies and their short innovation cycles, such as with bio-technology. Therefore, ultimately, the question proves perfectly justified whether the patent system represents an adequate instrument for the promotion of future developments in the area of bio-technology, if its essential characteristics are rather developed for a “bricks-and-mortar-world” rather than for the age of information economy (Eisenberg, 2002). It is a disputed question whether there is a need for a new protection regime *sui generis* for realizing the fostering of research and innovation, for rewarding inventions, and for the expansion of public domain knowledge and of all possibilities that could prove both more useful and more reasonable. From an ethical perspective, the answer to me seems clear.

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²⁶ Documenting the geographical origin of biological material is an important prerequisite for realizing the aim of “sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilisation of genetic resources with [those] providing such resources” (rule of benefit sharing) as specified in article 15(7) of the Convention on Biological Diversity. Despite the implementation of the EC bio-patenting directive, section 34 of the German Patent Law fails to regulate this in a satisfactory way due to the fact that each respective patent application is only “supposed” and not required to record the place of origin and that the failure to comply with said provision is not sanctioned. This has also been criticized by members of the German National Ethics Council in their “Position statement in favour of stricter requirements”: “There should be a statutory obligation to furnish evidence of the origin of the biological substances of human and non-human origin used in each case.” (GNEC, 2004, p. 38).

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