

Patent Ethics: The Misalignment of Views Between the Patent System and the Wider Society

Ellen-Marie Forsberg¹  · Anders Braarud Hanssen¹ ·
Hanne Marie Nielsen^{2,3} · Ingrid Olesen²

Received: 2 April 2017 / Accepted: 1 August 2017 / Published online: 15 August 2017
© Springer Science+Business Media B.V. 2017

Abstract Concerns have been voiced about the ethical implications of patenting practices in the field of biotechnology. Some of these have also been incorporated into regulation, such as the European Commission Directive 98/44 on the legal protection of biotechnological inventions. However, the incorporation of ethically based restrictions into patent legislation has not had the effect of satisfying all concerns. In this article, we will systematically compare the richness of ethical concerns surrounding biotech patenting, with the limited scope of ethical concerns actually addressed in the patent system. As sources of our analyses we will use literature and document studies and a survey with important stakeholders and experts related to Norwegian patenting in the aquacultural biotechnology sector. We will structure the analyses with an ethical matrix, developed for this purpose. Showing the misalignment of the discussions within and outside the patent system, we suggest that an important reason for the ethical controversy still surrounding patenting is that ethical questions keep being framed in a narrow way within the system. Until a richer set of ethical considerations is addressed head-on within the patent system, the patent system will continue to evoke academic and interest group criticism, potentially contributing to a legitimacy crisis of the whole system.

Keywords Ethics · Patents · Biotechnology · Ordre public and morality

✉ Ellen-Marie Forsberg
Ellenmarie.Forsberg@hioa.no

¹ Research Group on Responsible Innovation, Work Research Institute, Oslo and Akershus University College, P.O. Box 4, St Olavs Plass, 0130 Oslo, Norway

² Nofima Marin, Ås, Norway

³ Seges, Copenhagen, Denmark

Introduction

Biotechnology has for many years been surrounded by ethical controversy. An OECD report prepared by Rigaud (2008) notes that ‘the development of biotechnology has triggered many ethical and social reactions from the public opinion, the media and non-governmental organisations’ (p. 5). For this reason, a new field of research, the field of Ethical, Legal and Social Implications of new technologies (ELSI) was developed in parallel with the Human Genome Project in the 1990s and, following this initiative, ELSI programs have become common companions to large scale biotechnology research programmes in all of the Western world for the last 20 years.

Patenting has become a similar companion to biotechnology. With the rising importance of the knowledge economy, patenting has become of paramount importance and even influences the development of the entire biotechnology field. Patenting also adds an additional layer of controversy to biotechnology. This is reflected in the broad policy discussions surrounding the introduction of the European Commission Directive 98/44 on the legal protection of biotechnological inventions (the Biotech Directive) in 1998 and a number of contested patenting decisions starting out with the well-known *Diamond vs Chakrabarty* ruling in the US Supreme Court in 1980 on a patent on genetically modified bacteria. The controversy is also documented by numerous scientific publications in the fields of law, ethics and social sciences, as shall be seen below.

Because of this controversy ethical concerns have been accommodated into patent law, both in the form of clarifications of patentability in the life sciences and in terms of ethical restrictions. In the European Patent Convention (EPC) this is expressed in Article 53 (Exceptions to patentability):

European patents shall not be granted in respect of:

- (a) inventions the commercial exploitation of which would be contrary to “ordre public” or morality; such 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;
- (b) plant or animal varieties or essentially biological processes for the production of plants or animals; this provision shall not apply to microbiological processes or the products thereof;
- (c) methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body; this provision shall not apply to products, in particular substances or compositions, for use in any of these methods.

Rule 28 EPC of the Implementing Regulations to the Convention on the Grant of European Patents (which incorporates the Biotech Directive into European patent law) further specifies:

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

- (a) processes for cloning human beings;
- (b) processes for modifying the germ line genetic identity of human beings;
- (c) uses of human embryos for industrial or commercial purposes;
- (d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.

These formulations appear to give quite substantial space for taking ethical concerns into account in patenting decisions. Moreover, by using the term ‘in particular’ the list of exceptions to patenting in Rule 28 EPC appears to be open-ended; opening up for continued deliberation on new technologies that should not be accepted for patenting. This would seem important in an emerging field such as biotechnology, where scientific progress takes place at a high speed. However, it is becoming evident that the ethical exceptions in the law are interpreted in a very narrow way.

In this article we will conduct an analysis of how the patent system currently is addressing the ethical concerns surrounding it. We will present an ethical tool, the ethical matrix, that is useful for systematically analysing ethically relevant concerns in biotechnology and biotechnology patenting. We will use this to show the richness of topics addressed in the literature on ethical aspects of patenting in biotechnology. We will then show that current patenting policies and practices have a much more narrow approach to ethics. This difference in ethical scope is confirmed in a small survey with stakeholders and experts related to two Norwegian patent cases. The survey shows the variation in ethical expectations to the patent system relative to the respondents’ knowledge of and experience with patenting. We will suggest that the narrow consideration of ethical concerns in current patenting practices, compared with the ethical expectations of actors outside the system, will continue to provoke negative public reactions to biopatenting, unless the patent system is made more responsive to public concerns.

A Systematic Tool for Analysing Ethical Concerns in Biotechnology Patenting

Ethical issues in biotechnology have been studied in several ELSI research programmes across the world. While human biotechnology spurred most of the early research (for instance through the mentioned Human Genome Project’s ELSI programme), the ethics of agricultural biotechnology grew in importance with the increase in public concerns about genetic modification of plants and animals. For instance, the European Society of Agricultural and Food Ethics (EurSafe) contributed to establishing ‘food ethics’ as an important research field, where the ethics of genetic modification has remained an important topic.

No standard approach to ethics has been settled, neither in the human nor non-human biotechnology field. Rather, a great variety of ethical principles, values and arguments are brought to the table. Not only are arguments made based on general ethical theories, such as utilitarianism, deontology, the ethics of care, or justice-based approaches, but many scholars argue from more specific principles, such as the precautionary principle or the principle of sustainable development, without necessarily relating to a more disciplinary ethical debate. There are also attempts to integrate ethical arguments, values and principles into approaches at a meta, or procedural, level, for instance by developing practical, ethical tools (see e.g. the Ethical Bio Technology Assessment Tools project, Beekman et al. 2006).

One such tool, the ethical matrix, has been used to outline the richness of biotechnology ethics, referring to the many substantial values and principles that figure in the discourse. This approach was developed by Ben Mepham, who first applied it to animal biotechnologies (see e.g. Mepham 2000). Later it has been applied by a great variety of researchers in a great variety of settings (see for instance Kaiser et al. 2007 and Forsberg 2007). The ethical matrix approach builds on the principle based approach in biomedical ethics [Beauchamp and Childress 2012 (1979)] and acknowledges that different ethical principles are equally valid starting points in ethics (going back to *The Right and the Good* by David Ross in 1930). The approach shows how such general ethical principles must be specified to each affected party in a specific situation. The principles may be seen as corresponding to general ethical theories (well-being refers to utilitarianism, dignity to deontology and justice to contractarian theories) (see Mepham 2005, p. 51).

An ethical matrix for food biotechnology is presented in Table 1. The point here is not to argue for each specification in the matrix, but to show the broad scope of ethical concerns that are discussed with regard to biotechnologies (see Forsberg 2007).

A similar matrix (though with different stakeholder categories and corresponding different specifications of the principles) can be designed for the context of human biotechnologies.

An ethical matrix should reflect all relevant values brought forward in the ethical discussion in a particular topic area. The purpose of developing an ethical matrix is often to make ethical discussions or decisions more transparent. After a value matrix (like the one in Table 1) is agreed upon, a consequence matrix can be developed with the same structure, showing how a particular action (for instance a technology choice) affects the values in the matrix. This allows for more clarity in discussions; for instance about whether disagreements refer to different value priorities or to different understandings of the characteristics or consequences of the action. Here, however, we will simply use the ethical matrix as an analytic tool (not as decision making support). But then we need to adapt the matrix to the topic of *biotechnology patenting*.

Discussions about the ethics of biotechnology patenting refer to ethical issues concerning the intersection between biotechnology, private ownership and innovation. Biotechnology patenting ethics includes the 'pure' bioethical or biotechnology ethics issues, but transforms them by adding the extra layer of intellectual ownership. An ethical matrix for assessing the ethical implications of *patenting* in

Table 1 An ethical matrix for food biotechnology

Stakeholders	Principles		
	Well-being	Dignity	Justice
Farmers	Safe and secure workplace and income, as well as stable social situation	Right to control of their work situation and respect for their occupation	Fair conditions for GM and non-GM farmers
Owners of food industry	Adequate profit	Acknowledgement for their part of the value chain, being heard in negotiations Protection of private initiatives	Fair terms for this industry as for the other food industries
Other users of the land	No reduction in the quality of their use of related land	Respect for their needs and their use of the land	Fair access to the resources
The producing society	Safe and profitable use of resources No health risks or added anxieties Economic growth	Freedom to manage resources and technology for the best for the society as a whole No dependencies	Fair and just living conditions for urban and rural societies, and for rich and poor
The consuming society	Guaranties for healthy food in adequate amounts Adequate nutrition No health risks	Occasion for the consumer to choose and influence the production of food products Labelling Market freedom	Food products of good quality available for different consumer groups
Future generations	No activities that threaten their health or living conditions Precaution	Not diminishing their scope of choice	The conservation of the environment and resources so that future generation will have equal opportunities as we do (biodiversity)
The biosphere—in producing and consuming areas	Health of ecosystems and animals	Harm and abuse of nature as limited as possible Respect for natural properties	The diffusion to a viable level of environmental burdens over a manifold of ecosystems (biodiversity)

biotechnology would thus be quite similar to the one for assessing the ethical implications of biotechnology applications, but would incorporate some additional issues; see Table 2.

The values in the ethical matrix refer to *prima facie* principles, which means that they each have a certain ethical force, but it may be ethically justified to infringe on some values if this has important gains for other values, *all things considered*. What

Table 2 An ethical matrix for issues related to patenting in biotechnology

Stakeholders	Principles		
	Well-being	Dignity	Justice
Inventors (industry, researchers)	Stable, predictable and good operational conditions for industry	Influence in patent issues Property rights	Fair returns on investment of resources
Competing companies	Stable and good conditions for industry	Influence in patent issues	Fair treatment of inventor and competing firms
Industry/researchers as users of the patented products/processes	Access to safe and better products/processes	Influence in patent issues	Reasonable licence conditions Fair conditions for different types of actors
Consumers/end users/etc.	Access to affordable products	Influence in patent issues The right to choose	Fair treatment of different groups Access to own resources
The human being/ human race as such	Security of basic needs No significant harms	The inherent dignity of man Informed consent Freedom to exploit naturally existing resources	Fair treatment of goods and burdens across different groups
Nations/regions	Growth, value creation, production of societal/public goods	Democracy National/regional sovereignty Respect for the desires of the populations	No privileged private gains from public resources and goods Fair distribution of rights to and benefits from resources
Future generations	Protection of resources (including biological/genetic) for future welfare Precaution	Respect for their future possibilities for choice	Fair distribution of benefits and burdens over generations
The biosphere (including animals)	Robust ecosystem services Animal welfare	Respect for animals' and the environments' dignity/inherent value	The diffusion to a viable level of environmental burdens over a manifold of ecosystems (biodiversity)

value trade-offs are justified in patent policy in general should be determined in a broad societal dialogue, and is not the topic in this article.

As a starting point the matrix spells out systematically values that are often brought forward in adjacent societal fields so we can expect them to be relevant also for patenting. In the following, we will use Table 2 to analyse the scope of ethics considered in the broader patent ethics literature in contrast to the scope revealed in primary and secondary sources on the patent system, and to analyse results from a

small survey. For our purposes the matrix will be a tool for showing the differences in what are considered ethically relevant concerns, from within the patent system and among a broader range of experts and stakeholders.

The Richness in the Scholarly Discussion

The richness of the ethically relevant concerns in biotechnology patenting can be observed in the scientific literature. Searching the EBSCO Academic Search Premier database on the terms “patent”, “ethics”, “biotechnology” and NOT “US” resulted in 98 publications.¹ These publications confirm the wide scope of the discussions of the ethics of biotechnology patents. They concern ethical topics related to the patented materials and ethical topics related to the overall design and impacts of the patent system in the context of biotechnology. It is outside the scope of this article to give a full review of these articles, but some main categories of topics addressed will be presented here. We will also consider important contributions that did not appear in the EBSCO search, but was identified by ‘snowballing’. Due to space limitations, only a few examples will be given of specific contributions within each category.

‘Patents on Life’

Many of the identified articles can be related to the so-called ‘patents on life’ discourse. One of the principal topics that is addressed, and that has raised the most societal attention, is the discussion about whether patenting parts of the human biology is ethically permissible or not infringing on basic notions of human rights or dignity (Terragni 1993). The discourse is in general related to deontological concerns about the dignity of—and non-permissibility of ownership to—human beings and living beings in general (Hettinger 1995; Adams 2003). The most prevalent topics in this category are human rights, dignitarian and sanctity of life perspectives (e.g. Frati et al. 1999; Resnik 2001; Terragni 1993; Falcone 2009).

This discourse was an important political force in the discussions preceding the introduction of the European Biotech Directive, and remained important with the continued discussions of the exception article and Rule 28 of the EPC.

These discussions revolve around the dignity principle presented in the ethical matrix (Table 2). They are relevant especially for human beings as such, and the biosphere, including animals.

Concerns About the Liberal Interpretation of Patentability and Broad Patents

The Nuffield Council of Bioethics, in its discussion paper on the ethics of patenting DNA (2002), addresses concerns regarding whether DNA technically speaking should be patentable. Crespi (2005) argues against the Nuffield report and for such

¹ After removal of duplicates. The search was carried out August 4 2016.

patentability. Reiss (2003) also argues for patenting of DNA, but notes that such patents have been granted too liberally. The concerns about the appropriate application of patentability requirements have also been raised concerning the creation of synthetic DNA (Schneider 2012). This topic is an important part of the broader debate about the ambiguities in European and international patent law and about the challenges in interpretation of the Biotech Directive. One key feature of this ambiguity revolves around how the delineation between discovery and invention applies with regard to genes. This is often not articulated as an ethical issue within patent law, but it affects ethically relevant concerns, such as the dignity of animals defined as inventions.

Broad and upstream product patents are also criticised as inhibiting the normative mandate of the patent system, namely that of promoting innovation for societal benefit (Radder 2004). It is argued that broad product patents are not adequately inventive and that they hinder further research and downstream innovation. Macer (2002) proposes specific procedures to elaborate how the criteria of novelty, nonobviousness, utility and public morality might better be used to take ethical concerns into account in the granting of patents (as well as procedures for postpatent governance).

As a more specific topic, it is discussed whether broad and upstream patents in medical research and the pharmaceutical industry specifically hinder access to medicines and treatment. Many suggest that biomedicine patents (both in Europe and in developing nations) function as a safeguard for further innovation, but may also limit equal access to important medical care (Faunce and Nasu 2008). From an ethics of care perspective it is discussed how patent law can be informed so that the current ambiguities in European patent law do not inhibit important medical research (Warren-Jones 2004).

The liberal versus strict interpretation of patentability requirements has potential consequences for the well-being of several stakeholders in the matrix. Of course, a generous attitude benefits inventors (patentees, whom the European Patent Office (EPO) calls their 'clients'). However, it may not benefit competitors, who may face patents blocking their own innovation activities, and as an implication of this, it might affect national interests if some industries are blocked. Similarly, it is pointed out that broad patents may lead to less access for users of the patented inventions, also pointing to this row of the matrix. Access to medicines affect specifically the well-being and justice for consumers/end users and human beings as such.

Openness and Sharing of Knowledge

A patent makes knowledge available for the public as the patent document describes an invention. Thus, the notion of sharing or disclosure is at the core of what patenting is as a social and legal mechanism. Still, several articles provide a critical view of how patent rights and privatisation of the bioeconomy threaten the access to important technology and data (Kluge 2003; Faunce and Nasu 2008; Santoro and Gorrie 2005; Ciliberti 1993). Contributions also discuss the topic of patent holders benefiting from publicly funded science while blocking new research and innovation (Cho et al. 2003; Hodgson 1987). In addition, strong pressures to

transfer research results to markets pose both research ethics and scientific dilemmas for scholars and institutions (Mangan 1987). It is held that increased computational power is fuelling the research ethics implications of patenting, where the commercialisation rationale of patenting may be counteracted by a data-sharing rationale assumedly more aligned with the ethos of science. The research exemption is meant to counter-act negative effects of patents on further research, but the force of this exemption is discussed by for instance Soini et al. (2008).

In genomic research, a dichotomy is raised between two strategies with regard to ownership (Marturano 2009). One is the patent-and-publish regime, the other the open-source approach. Such considerations can also be related to the Access to Knowledge (A2K) movement, as described for instance in the edited volume by Krikorian and Kapczynski (2010), who argue that the appropriation of rights on singular genes or important medicines allows privatisation of knowledge that should remain in the public domain by default. Awareness of the benefits of data sharing, supported by an infrastructure for pre- and post publication data sharing, have been proposed as measures to increase access to scientific results (Schofield et al. 2009; Toronto International Data Release Workshop Authors 2009).

Mayer (2006) points to the importance of transparency and openness in molecular biology to counteract possible conflicts of interest and biases due to patent holders maintaining research positions without disclosing a financial interest. In addition, the growing problem of failure to disclose conflicts of interest in relation to patent ownership in pharmaceutical research points to the need for particular regulation and transparency as part of a soft-law practice in these arenas (Santoro and Gorrie 2005).

The topics addressed here relate to the production of societal goods; in other words, the well-being of nations/regions and of users. Openness and sharing responds to the justice principle in the matrix, for human beings in general, for consumers more specifically, and for nations or regions. It inherently regards the relation between the inventors and industry/researchers as users of the patented products or processes, or of knowledge in general. Openness about ownership is also a precondition for informed consent and democratic decision-making.

Global Justice

The notion of justice, and distributive justice in particular, is addressed with emphasis on the uneven situation of developed versus developing nations in relation to international intellectual property (IP) regulation. Llewelyn (2002) articulates how the developing world and the developed world have drastically diverging outlooks on the current intellectual property rights (IPR) system, including patenting biological material. According to Gurry (2005), fundamental differences in economic and judicial preparedness suggest that developing nations should implement alternative protective policies to counteract global bioindustry, as they today are not sufficiently protected through the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

Another aspect of the social justice dimension regards the potential exploitation of human genetic materials from developing nations (Dickenson 2004). In

genomics, disease diagnosis and disease prevention challenge policy-makers with regard to ensuring that benefits and knowledge are equally shared across the populace and throughout regions and parts of the world. The connection between global justice and genomics pivots around the privatisation of research and innovation that could or should be a global public good (Smith et al. 2004). It is held that international governance of biomedical industries, though concerned with the distribution of costs and benefits between countries of uneven economic viability, is characterised by considerations related to awarding innovation and risk-taking by biotech corporations.

There is also a call for establishing new normative frameworks that protect genetic resources, of both plant and animal species, and counteract the risk of biopiracy. In spite of the binding Convention of Biological Diversity (CBD) requesting prior informed consent by the country of source and the Nagoya protocol, Oberthür and Rosendal (2014) highlight the underdeveloped awareness and control functions of international patent law to ensure responsible governance of patent rights in the developing world.

In the matrix, global justice is obviously related to the justice principle, in particular it is related to the fairness of distribution across the human race, and nations/regions, and across rich and poor consumers more specifically.

The Above Categorisation

It should be noted that the above categories are partly overlapping and that other categories—and other labels for, and examples of, the categories—could have been identified. Moreover, many articles address a range of topics, belonging to different categories, meaning that they could be placed in several categories. The authors have not been able to give justice to the full content of each mentioned contribution. However, the main point—to illustrate the richness of the scholarly ethical debate as a whole—should be properly documented by this presentation. The ‘ethics of biotechnology patenting’ forms a discourse both highly complex and often radically multidisciplinary. The richness both originates from the issues themselves and the disciplinary framings of the issues.

We can observe that all the rows and columns of the matrix are referred to in the literature, except for the row of future generations, which does not appear to have been given great significance in the academic discussions, perhaps due to the time-limited nature of patents. However, as patenting contributes to shaping entire fields of research it does have long-term consequences.

The Inclusion of Ethics in the Patent System

The range of values and ethically relevant arguments documented above were expressed in the discussions that have shaped current patent legislation, especially through the Biotech Directive. Sterckx and Cockbain (2012) outline the process leading up to the current version of the European Patent Convention and how societal values affected the formulation of the patentability requirements (such as

novelty, the notion of an invention, et cetera) and the exceptions to patentability. National regulations on compulsory licensing are also attempts to create flexibility in the patent system for taking societal concerns into account. However, it is becoming evident that the ethical exceptions in the law are interpreted in a very narrow way.

In particular, the interpretation of Article 53 (a) and (b) and Rule 28 (d) EPC seems to be under pressure. The NGO No Patents on Seeds! gives the following summary of the situation in the food and agriculture sector in a recent report (No Patents on Seeds! 2016):

Around 2800 patents on plants and 1500 patents on animals have been granted in Europe since the 1980s. Around 7000 patent applications for plants and around 5000 patents for animals are pending. The EPO has already granted around 180 patents that concern [...] conventional breeding and about 1400 such patent applications are filed. (p. 4)

Although many of these patents are on non-controversial applications, it is clear that the European patent system generously grants patents for both modified and conventional plants and animals.

It should also be noted that there are no examples of cases where any other technologies have been accepted as an addition to the list in Rule 28 EPC (quoted above). Sterckx and Cockbain (2012) observe that: ‘Today we increasingly find that, for things that previously belonged to the public domain, private patent rights are being issued, even though according to a serious and non-industry-biased interpretation of the law this should be impossible.’ (2012, p. 15, see also Thambisetty 2017).

Laurie (2008) makes a similar point: ‘I would suggest it is a fair summation of that jurisprudence that there has been a trend towards (a) a presumption in favour of patentability, and (b) a tendency to interpret the morality provisions in patent law very narrowly’ [p. 98, see also Milius and Townend (2008)].² Even though the inclusion of ethical concerns into patent law appears to be a sign that ethics is taken seriously in patenting practices, Parthasarathy (2015) claims that the *ordre public* clause has ‘long existed in European legal documents to little practical effect’ (p. 74). This seems to be a permanent state, as already in 1999 Drahos concluded from a broad survey of the practices of patent offices around the globe, including Europe: ‘The scope of what is regarded as patentable subject-matter has quietly expanded. This expansion has occurred in two ways. First, the scope of patentable subject matter has been given an inclusive interpretation. Secondly, the restrictions on patentability have been narrowly interpreted’ (1999, p. 442).

It should be noted that these commentators align well with the EPO’s own guidelines and guiding decisions. The EPO says that ‘according to established case law, any exception to patentability must be constructed narrowly’ (Decision of the Boards of Appeal of the European Patent Office, T1199/08, C9076.D, p. 23).

² O’Sullivan (2012) discusses Rule 28 (c) specifically and shows that this has in some cases been interpreted more broadly, but does not suggest that this implies a general broadening of the interpretation of Article 53 (a).

Moreover, the EPO states in its guidelines that the threshold for making exceptions to patenting must be high: ‘The purpose of this is to deny protection to inventions likely to induce riot or public disorder, or to lead to criminal or other generally offensive behaviour (see also F–II, 7.2). Anti-personnel mines are an obvious example. [...] This provision is likely to be invoked only in rare and extreme cases. A fair test to apply is to consider whether it is probable that the public in general would regard the invention as so abhorrent that the grant of patent rights would be inconceivable.’³ Furthermore, in the balancing act required by Rule 28 (d) the EPO requires substantial documentation of suffering in order to deny a patent, which can be difficult to produce for early stage animal biotechnology applications.⁴ Analysing the real effect of Article 53 and Rule 28 EPC on patent grant decisions is not entirely easy, though, as patent examiners may seek to deny ethically sensitive patents based on other, less ambiguous, articles in the EPC than these clauses (with the aim of avoiding time consuming oppositions and appeals).

Drahos claims that the practice of interpreting patent law articles and rules is significantly influenced by the main interest groups in the patent system, namely multinational corporations, and the expansion of patentable subject matter appears to be driven by what he calls (for instance in Drahos 2010, p. 155) ‘gaming behaviour’ by such corporations. Gaming behaviour involves creative justifications provided by the corporations’ lawyers in order to circumvent the patent from falling under the exclusion paragraphs, and may be fuelled by economic incentives for patent offices to grant a high number of patents (Staff representatives, EPO 2007). Proximity to industry is indeed institutionalised in the system, for instance, by the new pilot program ‘Closer Contact with Major Applicants’, launched by the EPO in 2015.⁵

A frequent argument used in favour of a narrow interpretation of the ethical exclusion from patentability is that patent law only protects the ownership of the invention and its concern with the moral impacts of the patented inventions should be minimal (i.e. the moral acceptability of the use of the inventions should be regulated by other laws). An assumption is that a patent is not a positive right to exercise the invention (as there may be other legislation prohibiting the use of the invention), but a negative right, i.e. a right for an inventor to hinder other actors to exploit his/her invention for a certain period of time (see for instance the statement by the EPO Boards of Appeal in point 18.2 of the Decision in the Case T 356/93).

A number of scholars also argue that the patent system is neither designed nor staffed to evaluate ethical issues (Reiss 2003; Beyleveld 2000; Crespi 1993; 2000, Zimmer and Sethmann 2005; Grünecker et al. 2005; Witek 2005). In this view, the exceptions to patenting should be designed to demarcate clear instances of technologies that are not meeting the patent criteria of inventiveness, novelty and

³ https://www.epo.org/law-practice/legal-texts/html/guidelines/e/g_ii_4_1.htm.

⁴ Information by Christoph Then, coordinator of No Patents on Seeds! in a telephone interview August 2015, commenting on an opposition case regarding The European patent EP1330552, on selection for the breeding of dairy cows by marker DNA.

⁵ http://www.iam-media.com/files/Closer_contacts_with_major_applicants.pdf.

industrial applicability and there should not be further ethical ambiguities within the patent system.

Taking a narrow approach to the interpretation of the public order or morality clause, and a liberal approach to the patentability requirements, implies focusing only on a few of the cells in the ethical matrix (Table 2); in particular, the values pertaining to the inventors and the well-being of (some) nations. The client focus of the EPO directly privileges this stakeholder in the matrix. This is an inbuilt, systematic ethical bias in the patent system. Ultimately, this protection of the inventors is supposed to lead to increased well-being for human beings and consumers in general (as they reap the benefits of increased investments in research and innovation), but whether this is indeed the case is being contested (as shown in the above literature review).

There is thus evidence that the broad range of moral concerns related to the patent system are currently not responded to within the system and that the moral stakes of other stakeholders than the industrial to a large extent are bracketed.

Study of Stakeholders' and Experts' Attitudes to Patenting

The main strategy in this paper so far has been to demonstrate the richness of ethical concerns found in a literature review on patent ethics in biotechnology, and then to give evidence of a narrow approach to ethical issues from EPO guidelines and case law, as well as from secondary sources. A familiar argument from the legal side is that the expectation that the patent system should address such a wide range of ethical concerns relies on poor understanding of the system and its intentions. In the Patent Ethics project, the validity of this argument was studied in a small survey of different stakeholders and experts in two Norwegian cases concerning aquaculture patenting.

The Patent Ethics project studied ethical dimensions of patent law in non-human biotechnology, focusing on biotechnology in aquaculture, and included two aquaculture related case studies from Norway: a case study on the processing of a patent on the AquaBounty genetically modified (GM) salmon, and a case study on a request for a compulsory license related to a patent on the Pancreas Disease (PD) virus. In the case studies we were interested in the morally relevant attitudes and judgements of different involved actors from industry, the patent office and other public offices, as well as of other interested parties and experts.

For the purpose of our attitude study, we do not need to provide any detail on the cases. It suffices to say that we interviewed a total of 16 informants, who were all interested parties in one or both of the cases studies, or had expert knowledge of the issues in question. The interviews consisted of an identical part, reported here, focusing on the respondents' general views on the patent system. In addition, there were case specific questions of a qualitative nature. All informants had higher education (12 from the natural sciences) and had positions in different organisations such as private companies, ministries, research institutions or interest groups. 15 informants were related to Norwegian organisations.

We asked the informants to score their own knowledge of patenting and to indicate whether they had been involved in applying for or processing patents. The number of respondents with different knowledge levels and involvement are given in Table 3. Three assessed themselves as having little knowledge, six as having some knowledge and seven as having comprehensive knowledge. Eight assessed themselves as having been involved in patenting, and the same number as not having been involved. We can see that respondents with little knowledge but involvement in processes were not represented in this study.

The authors cannot definitely place any particular respondent as taking the perspective ‘from the patent system’ from any of these categories. However, we may infer that if you have little knowledge of the patent system and have never been involved in patenting, you are not taking the perspective of the patent system. If you have comprehensive knowledge and have been involved in patenting, it can be assumed that you will have views that are more aligned with how the patent system works. Analysing the results based on the categories of knowledge and involvement will thus give some indications on whether we find the same difference among Norwegian stakeholders and experts in these two cases, as found in the literature and document studies presented above.

As a part of the interviews, the informants were asked to score their agreement with 15 claims about patents and the patent system, loosely corresponding to the different values presented in Table 2, on a scale from 1 (completely disagree) to 5 (completely agree). The scoring alternatives were: ‘completely disagree’, ‘disagree’, ‘neither agree nor disagree’, ‘agree’, ‘completely agree’, ‘don’t know’ and ‘not relevant’. The responses of ‘don’t know’ and ‘not relevant’ were excluded from the analysis. Where the respondent chose not to give a score (for instance if he/she believed the claim was meaningless or did not want to give a response for political reasons) the response was treated as missing and excluded from the current analysis.

The descriptive statistics of the data are given in Table 4.

The responses were analysed with a one way ANOVA (SAS statistical software package) with either knowledge or involvement in patenting as independent class variables, because adding additional variables did not improve the model significantly. A likely reason for this may be the limited number of observations and low power of the data to reveal potential additional effects. The effect of knowledge and involvement in patenting on the responses to statements were tested as differences between mean responses with Students t-tests.

Table 3 No of respondents with prior involvement in and knowledge of patenting

	Involved in patenting	Knowledge	N
	No	Little	3
	Yes	Some	3
	No	Some	3
	Yes	Comprehensive	5
	No	Comprehensive	2

Table 4 Descriptive statistics (overall means, number of respondents and standard deviation) of responses to questions in terms of agreement with the statement on a scale from 1 to 5 where 1 = completely disagree and 5 is completely agree

Statements	Mean answer from respondents	Number of respondents	Standard deviation
(a) It is important that patents protect private initiative and investment	4.4	16	0.62
(b) It is important that patents lead to more innovation	4.3	16	0.68
(c) It is important that patents contribute to creating societal goods, such as medicines or food safety	4.2	16	0.66
(d) It is important that patents contribute to sustainable development	3.6	15	0.91
(e) It is important that patents are not granted on technologies that contribute to harming human health or welfare	3.5	16	1.41
(f) It is important that patents are not granted on technologies that contribute to harming animal health or welfare	3.5	16	1.41
(g) It is important that patents contribute to protecting the environment	3.1	16	1.29
(h) It is important to take into consideration that patent processes do not contribute to increasing differences between the poor and the rich	3.3	14	1.38
(i) It is important to take into consideration how a patent may impact on future generations	2.9	14	1.44
(j) It is important that the precautionary principle is considered in the granting and management of patents	3.2	14	1.67
(k) It is important to limit the privatisation of naturally occurring biological material	4.1	15	1.36
(l) It is important to anticipate possible consequences of a patent for future innovation and the possibility for further technological development in a given field	3.7	15	1.23
(m) It is important that (more) experts can be involved in the patent examination processes in cases where it is difficult to assess the patentability requirements (such as the appropriate scope of the patent) based on the applicant's documentation	4.3	14	1.20
(n) It is important that (more) interested parties (NGOs, etc.) can be involved in the patent examination process if the patent has controversial implications for certain societal groups	3.3	16	1.53
(o) It is important that patenting within areas such as the pharmaceutical or food production sector is regulated with the aim of securing equal and open access and fair distribution	3.9	14	1.51

Results and Discussion

The highest average agreement was estimated for statements (a), (b), (c), (k), and (m) with averages above 4. Statements (a), (b) and (c) can be said to represent the ‘basic values’ of the patent system. Statements (d)–(o) represent a broader range of values, as depicted in the ethical matrix. The lowest mean agreement was found for statements from (g) to (j) as well as statement (n).

In order to study differences in perspectives from within and outside the patent system, we also broke down the answers based on knowledge of patenting (Table 5) and prior involvement in patenting (Table 6).

From Tables 5 and 6 we see that respondents more distanced from the patent system (i.e. those with little/some knowledge and those with no experience from patenting)—more than those closer to the patent system—tended to think that the patent system should not be exempt from broader societal values (e)–(o), although for several propositions the findings were not statistically significant. More details will be given on this.

When it comes to *differences in opinion* in Table 5, significant higher mean agreement ($P < 0.05$) with the statements (e), (f) and (g) was estimated for low knowledge compared to high knowledge respondents. For statement (h), the low knowledge respondents also scored higher although the difference was lower and less significant ($P < 0.10$).

With regard to *what the groups agree to* (meaning that the mean score is 4 or higher), Table 5 shows that those with comprehensive knowledge of patenting only agree to the standard views on patents [i.e. that they should protect private initiative and investment, lead to more innovation and create societal goods; statements (a)–(c)]. Those with less knowledge and/or involvement in patenting also agree that it is important that patents should not be granted for technologies that contribute to harming human (e) or animal (f) health or welfare. They also seem to agree (though the numbers are not significant) that privatisation of naturally occurring biological material should be limited (k), that (more) experts can be involved in the patent examination processes in cases where it is difficult to assess the patentability requirements (m) and that pharmaceutical and food production related patents should be regulated for fairness reasons (o). The differences between knowledge groups are smallest with regard to the importance of the basic values of the patent system (the three first statements) and statement (d).

The same trend can be seen for the effect of involvement in patenting (Table 6), but here there was a higher number of significant differences. Besides the results for the standard values of the patent system, significant *differences in opinion* were estimated for statements (e) to (j), and for statement (n). Those without prior involvement in patenting also *agreed with* statements (e) and (f) (as did the low knowledge group), as well as significantly with statements (h), (i), (j) and (n); all which was agreement that was not shared with the group with experience from patenting.

The results are reasonably similar (varies with up to 0.4) if we compare the answers given by the respondents with high knowledge and those having been

Table 5 Mean answers from respondents with little or some versus comprehensive knowledge of patenting

Statements	Mean answer from respondents with little or some knowledge of patenting (standard error)	Mean answer from respondents with comprehensive knowledge of patenting (standard error)	<i>P</i> value*
(a) It is important that patents protect private initiative and investment	4.4 (± 0.21)	4.3 (± 0.24)	n.s.
(b) It is important that patents lead to more innovation	4.1 (± 0.23)	4.4 (± 0.26)	n.s.
(c) It is important that patents contribute to creating societal goods, such as medicines or food safety	4.1 (± 0.22)	4.3 (± 0.25)	n.s.
(d) It is important that patents contribute to sustainable development	3.7 (± 0.31)	3.5 (± 0.38)	n.s.
(e) It is important that patents are not granted on technologies that contribute to harming human health or welfare	4.3 (± 0.35)	2.4 (± 0.40)	0.003
(f) It is important that patents are not granted on technologies that contribute to harming animal health or welfare	4.3 (± 0.35)	2.4 (± 0.40)	0.003
(g) It is important that patents contribute to protecting the environment	3.7 (± 0.37)	2.3 (± 0.42)	0.028
(h) It is important to take into consideration that patent processes do not contribute to increasing differences between the poor and the rich	3.8 (± 0.42)	2.4 (± 0.56)	0.072
(i) It is important to take into consideration how a patent may impact on future generations	3.4 (± 0.53)	2.4 (± 0.53)	n.s.
(j) It is important that the precautionary principle is considered in the granting and management of patents (n = 14)	3.4 (± 0.57)	2.8 (± 0.76)	n.s.
(k) It is important to limit the privatisation of naturally occurring biological material (n = 15)	4.4 (± 0.45)	3.7 (± 0.55)	n.s.

Table 5 continued

Statements	Mean answer from respondents with little or some knowledge of patenting (standard error)	Mean answer from respondents with comprehensive knowledge of patenting (standard error)	<i>P</i> value*
(l) It is important to anticipate possible consequences of a patent for future innovation and the possibility for further technological development in a given field (n = 15)	3.9 (± 0.44)	3.4 (± 0.48)	n.s.
(m) It is important that (more) experts can be involved in the patent examination processes in cases where it is difficult to assess the patentability requirements (such as the appropriate scope of the patent) based on the applicant's documentation (n = 14)	4.6 (± 0.40)	3.8 (± 0.53)	n.s.
(n) It is important that (more) interested parties (NGOs, etc.) can be involved in the patent examination process if the patent has controversial implications for certain societal groups (n = 16)	3.7 (± 0.50)	2.7 (± 0.57)	n.s.
(o) It is important that patenting within areas such as the pharmaceutical or food production sector is regulated with the aim of securing equal and open access and fair distribution. (n = 14)	4.1 (± 0.54)	3.5 (± 0.63)	n.s.

n.s. non significant at 10% level

* Significance based on one-way ANOVA

involved in patenting, and if we compare the answers of the respondents with little or some competence and those who have not been involved (varies with up to 0.6). This is explained by the situation that these groups are largely overlapping (see Table 3). The mean answers by the group who had not been involved in patenting, compared to those that had, are generally higher than the answers of the group who had low knowledge compared to the group with comprehensive knowledge.

It should be noted that the respondents' self-assessed knowledge was not validated, so the actual knowledge of the respondents within the different categories may vary. However, from knowledge of the respondents' professional background and current work, we believe that the self-assessed knowledge is quite valid.

The number of respondents and power to reveal differences is low, but the respondents represent key stakeholders and experts in Norwegian aquacultural

Table 6 Mean answers from respondents involved versus not involved in patenting

Statements	Mean answer from respondents who had not been involved in patenting cases	Mean answer from respondents who had been involved in patenting cases	<i>P</i> value*
(a) It is important that patents protect private initiative and investment	4.3 (± 0.22)	4.5 (± 0.22)	n.s.
(b) It is important that patents lead to more innovation	3.8 (± 0.16)	4.8 (± 0.16)	0.001
(c) It is important that patents contribute to creating societal goods, such as medicines or food safety	4.0 (± 0.23)	4.4 (± 0.23)	n.s.
(d) It is important that patents contribute to sustainable development	3.6 (± 0.36)	3.6 (± 0.33)	n.s.
(e) It is important that patents are not granted on technologies that contribute to harming human health or welfare	4.3 (± 0.43)	2.8 (± 0.43)	0.028
(f) It is important that patents are not granted on technologies that contribute to harming animal health or welfare	4.3 (± 0.43)	2.8 (± 0.43)	0.028
(g) It is important that patents contribute to protecting the environment	3.9 (± 0.36)	2.3 (± 0.36)	0.006
(h) It is important to take into consideration that patent processes do not contribute to increasing differences between the poor and the rich	4.0 (± 0.46)	2.6 (± 0.46)	0.048
(i) It is important to take into consideration how a patent may impact on future generations	4.0 (± 0.39)	2.1 (± 0.45)	0.009.
(j) It is important that the precautionary principle is considered in the granting and management of patents	4.4 (± 0.43)	2.0 (± 0.43)	0.002.
(k) It is important to limit the privatisation of naturally occurring biological material	4.6 (± 0.49)	3.6 (± 0.46)	n.s.
(l) It is important to anticipate possible consequences of a patent for future innovation and the possibility for further technological development in a given field	4.1 (± 0.42)	3.3 (± 0.45)	n.s.

Table 6 continued

Statements	Mean answer from respondents who had not been involved in patenting cases	Mean answer from respondents who had been involved in patenting cases	<i>P</i> value*
(m) It is important that (more) experts can be involved in the patent examination processes in cases where it is difficult to assess the patentability requirements (such as the appropriate scope of the patent) based on the applicant's documentation	4.6 (± 0.46)	4.0 (± 0.46)	n.s.
(n) It is important that (more) interested parties (NGOs, etc.) can be involved in the patent examination process if the patent has controversial implications for certain societal groups	4.0 (± 0.48)	2.5 (± 0.48)	0.045.
(o) It is important that patenting within areas such as the pharmaceutical or food production sector is regulated with the aim of securing equal and open access and fair distribution	4.4 (± 0.55)	3.3 (± 0.55)	n.s.

n.s. non significant at 10% level

* Significance based on one-way ANOVA

biotechnology, and the results are therefore interesting. However, a much more comprehensive survey should be conducted to validate the tendencies we see in this small sample, namely that those with less knowledge and experience of the patent system have higher expectations that it should reflect a broader range of societal values. Rather than being a reason for simply dismissing the views of those with less proximity to the patent system, this should be worrying for the proponents of the current system. As most citizens—and even societal interest groups—have little understanding of the highly technical field of patenting, this widespread ‘misunderstanding’ might amount to a serious legitimacy problem for the system. Citizens or interest groups may indeed resist the label of being simply misinformed and instead insist that they represent a normative stance towards what they perceive as an ethically insensitive system. Indeed, the broader values discussed here were prominent in the discussions informing the exception articles in the Biotech Directive and this political discussion cannot simply be dismissed as badly informed. That the values corresponding to statements (e) to (h) have a significantly weaker position among respondents close to the patent system is thought provoking.

This section has shown that the less one knows and the less one is involved with patenting the more one tends to expect with regard to what ethical concerns should be taken into account in patenting. This confirms the findings from the ethical

review, identifying a much richer ethical discussion outside of the system than what is reflected in the system.

The Legitimacy Problem

Above, it is suggested that the patent system's lack of anchoring in public values might amount to a legitimacy problem for the system. Borrás et al. (2007) makes the same observation:

Since the mid-1990s groups of citizens and non-governmental organizations have been heatedly questioning the granting praxis of EPO on [the biotechnology and software] areas, claiming that EPO is unjustly expanding the limits of patentability pre-defined by the European Patent Convention. For these groups, the EPO praxis is ethically and economically problematic, since it benefits specific individual economic interests rather than the wide economic and social interest. For the purpose of this article, the latter issue about social pressure needs further consideration. It is particularly important to examine the way in which the EPO has been facing the challenges of this social pressure, a social pressure that is ultimately an expression of a certain loss of social legitimacy. (p. 596)

This threat might not be obvious to the reader as indeed the overwhelming majority of people know little about the patent system or the implications of patenting, and thus do not question its legitimacy. A final reflection on the question of legitimacy is thus in order.

In a seminal article from 1995 Mark Suchman gives an overview of literature on strategic and institutionalist approaches to legitimacy. He describes legitimacy as a relation between an organisation and its environment and says that it is 'a generalized perception or assumption that the actions of an entity are desirable, proper, or appropriate within some socially constructed system of norms, values, beliefs, and definitions' (p. 574). An organisation may have pragmatic legitimacy, which 'rests on the self-interested calculations of an organization's most immediate audiences' (p. 578), i.e. patent holders/applicants, patent attorneys and industrialised states. It may also have moral legitimacy, which 'reflects a positive normative evaluation of the organization and its activities' (p. 579).⁶ Finally, it can have cognitive legitimacy when it is accepted as 'necessary or inevitable based on some taken-for-granted cultural account' (p. 582).

What is shown here is that the legitimacy of the European patent institution in the area of non-human biotechnology appears high in a restricted societal group (corporations seeking patents, patent attorneys, etc.). However, if a broader societal

⁶ Note that Forsberg (2012) argues that the term 'moral' here is slightly misleading. She argues that this dimension of legitimacy (in Suchman's definition) should rather be called 'normative' legitimacy, as it can refer to norms held by a certain community of people, but which nevertheless lack the universal character of most moral norms. In our case, however, when we discuss how the public views the moral legitimacy of the patent institution, the term 'moral' fits better as the normative evaluations here are not exclusive to certain groups' norms, but represent general societal values.

group (society in general) takes an interest, the legitimacy (at least the moral legitimacy) is likely to be perceived as significantly lower. Also, the pragmatic legitimacy may be lower, as it is unclear how the society as a whole benefits from the patent institution related to biotechnology (as discussed above). However, we would expect the cognitive legitimacy of patenting to remain high, as this is an institution we as a society may regard as self-evident, probably due to its historical anchoring. Suchman states that as long as an organisation has cognitive legitimacy (it ‘makes sense’) it can avoid questioning. However, moral legitimacy is an important safeguard against impending non-sense (ibid.). That ‘patents on life’ did not have the same self-evident status as patents on ordinary inventions, may have been the reason why the moral exception paragraphs were specified for biotechnology in the first place.

Suchman states that legitimacy is a *perception* of a social group in that an ‘organization may occasionally depart from societal norms yet retain legitimacy because the departures are dismissed as unique’, and also notes that an ‘organization may diverge dramatically from societal norms yet retain legitimacy because the divergence goes unnoticed’ (p. 574). However, if the anti-elitist tendencies we observe in Western countries extend to include resistance to a perceived alliance between ‘elitist’ state bureaucracies in the EPC member states, the EPO, and major, multi-national corporations—all far removed from ‘ordinary people’s’ interests and lives—the moral legitimacy risk may become an existential risk to the patent institution in general, as its cognitive legitimacy and self-evident character may end up being questioned.⁷

Ultimately, a narrow ethical approach may threaten the social contract of the patent system, where ‘society offers a monopoly in exchange for the release of an invention of social value’ (Drahos 2010, p. 30). If society begins to question the social value of an increasing amount of inventions, monopoly rights—at least in the field of biotechnology, and potentially other emerging technologies, such as software—may in the end be withdrawn.

Concluding Remarks

In this paper, an argument has been made based on two main sources: a review of patent ethics literature and results from a survey related to two Norwegian case studies. A large variety of ethical concerns regarding biotechnology patenting in the general patent ethics literature have been documented and it is shown that within the patent system there is only limited consideration of ethical issues, even if Article 53 EPC and Rule 28 from the Biotech Directive were intended to bring in stronger protection of ethical concerns in the system. It is also shown that there is a similar difference in what is expected of the patent system by experts and stakeholders closer to or more distanced from the patent system.

⁷ Thambisetty (2017) offers an interesting account of how the EPO through instrumental use of textualisation and other strategies tries to repair some of the legitimacy lost or revoked by civil society organisations, while at the same time maintaining its legitimacy in the eyes of the patent community.

It should be made clear that there is nothing wrong with the exceptions included in Article 53 and Rule 28 EPC. However, they only respond to a very narrow range of ethical concerns (mostly of a deontological nature) and they are in practice interpreted in a narrow fashion. Thus, they do not respond to the broader range of ethical concerns and expectations represented in society at large. One could perhaps argue that the patent system simply has a normative, value-based platform that places particular emphasis on these deontological values, and can justifiably disagree with the importance and relevance of other societal values. However, this is problematic when it is taken into account that the EPO is guided by the EPC, which is developed and in principle defended by democratic states. In none of the EPC member states have there been broad political and societal discussion on the way the EPC exception paragraphs are interpreted, and no publicly deliberated consent to exclude other ethical concerns.

In the article, it has been suggested that as long as these differences persist and the richness of ethical considerations existing among scholars and stakeholders are not addressed head-on by the actors in the patent system, the patent system will continue to evoke academic and interest group resistance. As a result, the request for open science and open access may also become stronger. Of course, actors in favour of a minimalist approach to ethics might hope that the ethicists, interest groups and the public will simply lose interest in the topic. However, with the ever-increasing technological options exploited and patented in the fields of emerging technologies, potentially touching on deeply felt ethical concerns about well-being, dignity and justice, there is reason to believe that the public interest in the patent system will grow, rather than decrease.

A greater opening for ethics within the patent system must be done in a wider dialogue with society: with legislators, politicians, a broader range of stakeholders and citizens generally. Ethical ambiguities should not be solved by reductive strategies behind closed doors, but rather faced transparently with the societies that gave a mandate for the EPC, and for biotechnology patenting, in the first place.

The so-called interactive approach to law highlights that societies' moral and legal norms should have a continuous interaction: "legislation on ethical issues should be designed in such a way that it is an effective form of communication and that, moreover, it facilitates an ongoing moral debate and an ongoing reflection on those issues, because this is the best method to ensure that the practice remains oriented to the ideals and values the law tries to realise" (Van der Burg and Brom 2000, p. 61, see also Forsberg 2011). Although Van der Burg and Brom have citizens in mind, it seems reasonable that also patent examiners and other actors within the patent system should interpret the ethical signals included in the law as guidance in their interpretation of the law and contribute in the ongoing moral reflection on how ethics can be part of patent law. Even if patent law naturally should protect the legitimate ethical interests of the inventors, this does not give carte blanche for ignoring the broader ethical side.

Acknowledgements This work has been funded by the Research Council of Norway's ELSA program, Grant No 220609/O70. We are grateful for all the discussions we have had with our good colleagues

Morten Walløe Tvedt and Nico Groenendijk in the Patent Ethics project, and we appreciate the useful feedback we received in the publication process.

References

- Adams, W. (2003). The myth of patent neutrality: Property, patents, animal rights and animal welfare in commissioner of patents V. President and fellows of Harvard College. *Canada Business Law Journal*, 39, 181.
- Beauchamp, T., & Childress, J. (2012, 1979). *The principles of biomedical ethics*. Oxford and New York: Oxford University Press.
- Beekman, V., De Bakker, E., Baranzke, H., Baune, Ø., Deblonde, M., Forsberg, E.-M., et al. (2006). *Ethical bio-technology assessment tools for agriculture and food production*. 2006/2. http://estframe.net/ethical_bio_ta_tools_project/content_2/text_2c81d261-b7a8-43e8-8f1e-d724b43e2ba3/1346076907647/et1_final_report_binnenwerk_59p.pdf. Accessed 5 Jan 2016.
- Beyleveld, D. (2000). Regulating morality through patent law. Critique of the EC Directive. *Revista De Derecho Y Genoma Humano = Law And The Human Genome Review/Cátedra De Derecho Y Genoma Humano/Fundación BBV-Diputación Foral De Bizkaia*, 12, 141–171.
- Borrás, S., Koutalakis, C., & Wendler, F. (2007). European agencies and input legitimacy: EFSA, EMEA and EPO in the post-delegation phase. *Journal of European Integration*, 29(5), 583–600.
- Cho, M. K., Illangasekare, S., Weaver, M. A., Leonard, D. G., & Merz, J. F. (2003). Effects of patents and licenses on the provision of clinical genetic testing services. *The Journal of Molecular Diagnostics*, 5(1), 3–8.
- Ciliberti, R. (1993). Biotechnological patents and ethical aspects. *Cancer Detection and Prevention*, 17(2), 313–315.
- Crespi, R. S. (1993). Ethical aspects of patenting in biotechnology. *Cancer Detection and Prevention*, 17(2), 323–327.
- Crespi, R. S. (2000). An analysis of moral issues affecting patenting inventions in the life sciences: A European perspective. *Science and Engineering Ethics*, 6(2), 157–180.
- Crespi, R. S. (2005). Ethico-legal issues in biomedicine patenting: A patent professional viewpoint. *Science and Engineering Ethics*, 11(1), 117–136.
- Dickenson, D. (2004). Consent, commodification and benefit-sharing in genetic research. *Developing World Bioethics*, 4(2), 109–124.
- Drahos, P. (1999). Biotechnology patents, markets and morality. *European Intellectual Property Review*, 21(9), 441–449.
- Drahos, P. (2010). *The global governance of knowledge. Patent offices and their clients*. Cambridge: Cambridge University Press.
- European Group on Ethics (EGE). *Opinion no. 16: Ethical aspects of patenting inventions involving human stem cells* (07/05/2002).
- Falcone, A. (2009). Genetics and new fundamental rights: From international declarations to protection of the human genome and the innovation of national constitutions: Towards a global protection of the genetic heritage of humanity. *Persona y Derecho*, 60, 271–311.
- Faunce, T. A., & Nasu, H. (2008). Three proposals for rewarding novel health technologies benefiting people living in poverty. A comparative analysis of prize funds, health impact funds and a cost-effectiveness/competitive tender treaty. *Public Health Ethics*, 1(2), 146–153. doi:10.1093/phe/phn013.
- Forsberg, E.-M. (2007). *A deliberative ethical matrix method—Justification of moral advice on genetic engineering in food production*. Dr. Art. Dissertation. Oslo, Unipub.
- Forsberg, E.-M. (2011). Inspiring respect for animals through the law? Current development in the Norwegian Animal Welfare Legislation. *Journal of Agricultural and Environmental Ethics*, 24, 351–366.
- Forsberg, E.-M. (2012). Applying instruments for regional innovation—Generating projects or legitimacy? *International Journal of Innovation and Regional Development*, 4(5), 430–445.
- Frati, L., Foà, R., & Frati, P. (1999). The patentability of living organisms between science, law and ethics. *Forum*, 9(3 Suppl 3), 8–14.
- Gurry, F. (2005). The growing complexity of international policy in intellectual property. *Science and Engineering Ethics*, 11(1), 13–20.

- Hettinger, N. (1995). Patenting life: Biotechnology, intellectual property, and environmental ethics. *Boston College Environmental Affairs Law Review*, 22(2), 267–305.
- Hodgson, C. P. (1987). Social and legal issues of biotechnology: An educational perspective. *The Ohio Journal of Science*, 87(5), 148–153.
- Kaiser, M., Millar, K., Thorstensen, E., & Tomkins, S. (2007). Developing the ethical matrix as a decision support framework: GM fish as a case study. *Journal of Agricultural and Environmental Ethics*, 20(1), 65–80.
- Kluge, E. W. (2003). Patenting human genes: When economic interests trump logic and ethics. *Health Care Analysis: HCA: Journal Of Health Philosophy And Policy*, 11(2), 119–130.
- Krikorian, G., & Kapczynski, A. (2010). *Access to knowledge in the age of intellectual property*. Zone Books. https://mitpress.mit.edu/sites/default/files/titles/free_download/9781890951962_Access_to_Knowledge_in_the_Age_of_Intellectual_Property.pdf.
- Laurie, G. (2008). Ethical aspects of patenting. In Den etiske nemnda for patentsaker. *Patentnemnd uten portefølje?* Publikasjon nr. 7. Oslo. <https://www.etikkom.no/globalassets/documents/publikasjoner-som-pdf/patentnemnd-uten-portefolje-2008.pdf>.
- Llewelyn, M. (2002). European plant intellectual property. *Journal of Herbs, Spices & Medicinal Plants*, 9(4), 389.
- Macer, D. R. J. (2002). Patent or perish? An ethical approach to patenting human genes and proteins. *The Pharmacogenomics Journal*, 2, 361–366.
- Mangan, K. S. (1987). Institutions and scholars face ethical dilemmas over pursuit of research with commercial value. *Chronicle of Higher Education*, 33(46), 11–12.
- Marturano, A. (2009). When speed truly matters, openness is the answer. *Bioethics*, 23(7), 385–393.
- Mayer, S. (2006). Declaration of patent applications as financial interests: A survey of practice among authors of papers on molecular biology in Nature. *Journal of Medical Ethics*, 32(11), 658–661.
- Mepham, T. B. (2000). A framework for the ethical analysis of novel foods: The ethical matrix. *Journal of Agricultural and Environmental Ethics*, 12, 165–176.
- Mepham, T. B. (2005). *Bioethics. An introduction for the biosciences*. Oxford: Oxford University Press.
- Milius, D., & Townend, D. (2008). Thoughts on the scope and operation of morality clauses in patent law. In Den etiske nemnda for patentsaker. *Patentnemnd uten portefølje?* Publikasjon nr. 7. Oslo. <https://www.etikkom.no/globalassets/documents/publikasjoner-som-pdf/patentnemnd-uten-portefolje-2008.pdf>. Accessed February 5, 2016.
- No Patents on Seeds! (2016). *Patents on plants and animals—Time to act for European politicians*. http://no-patents-on-seeds.org/sites/default/files/news/report_patents_on_seeds_time_to_act_2016.pdf. Accessed March 7, 2017.
- O’Sullivan, E. (2012). Is Article 53 (a) EPC still of narrow interpretation? *Journal of Intellectual Property Law & Practice*, 7(9), 680–690.
- Oberthür, S., & Rosendal, G. K. (2014). *Global governance of genetic resources: Access and benefit sharing after the Nagoya Protocol*. New York and London: Routledge.
- Parthasarathy, S. (2015). Co-producing knowledge and political legitimacy. In S. Hilgartner, C. Miller, & R. Hagendijk (Eds.), *Science and democracy: Making knowledge and making power in the biosciences and beyond* (pp. 74–93). London: Routledge.
- Radder, H. (2004). Exploiting abstract possibilities: A critique of the concept and practice of product patenting. *Journal of Agricultural and Environmental Ethics*, 17(3), 275–291.
- Reiss, M. J. (2003). The ethics of patenting DNA. *Journal of Commercial Biotechnology*, 9(3), 192–198.
- Resnik, D. B. (2001). DNA patents and human dignity. *Journal of Law, Medicine and Ethics*, 29, 152–165.
- Rigaud, N. (2008). *Biotechnology: Ethical and social debates*. <http://www.oecd.org/futures/long-termtechnologicalsocietyalchallenges/40926844.pdf>. Accessed June 13, 2016.
- Ross, D. (1930). *The right and the good*. Oxford: Clarendon Press (2002).
- Santoro, M. A., & Gorrie, T. M. (2005). *Ethics and the pharmaceutical industry*. Cambridge: Cambridge University Press.
- Schneider, I. (2012). To be or not IP? Exploring limits within patent law for the constitutionalization of intellectual property rights and the governance of synthetic biology in human health. *Revista De Derecho Y Genoma Humano = Law And The Human Genome Review/Cátedra De Derecho Y Genoma Humano/Fundación BBV-Diputación Foral De Bizkaia*, 37, 193–233.
- Schofield, P. N., Bubela, T., Weaver, T., Portilla, L., Brown, S. D., Hancock, J. M., et al. (2009). CASIMIR Rome Meeting participants. Post-publication sharing of data and tools. *Nature*, 461, 171–173.

- Smith, R. D., Thorsteinsdottir, H., Daar, A. S., Gold, E. R., & Singer, P. A. (2004). Genomics knowledge and equity: A global public goods perspective of the patent system. *Bulletin of the World Health Organization*, 82(5), 385–389.
- Soini, S., Aymé, S., & Matthijs, G. (2008). Patenting and licensing in genetic testing: Ethical, legal and social issues. *European Journal of Human Genetics*, 16, 510–550.
- Staff Representatives, EPO. (2007). *Governance of the EPO: A staff perspective*, CA/93/07. <http://www.suepo.org/public/ec07093.pdf>. Accessed September 20, 2015.
- Sterckx, S., & Cockbain, J. (2012). *Exclusions from patentability. How far has the European Patent Office eroded boundaries?*. Cambridge: Cambridge University Press.
- Suchman, M. C. (1995). Managing legitimacy: Strategic and institutional approaches. *Academy of Management Review*, 20(3), 571–610.
- Terragni, F. (1993). Biotechnology patents and ethical aspects. *Cancer Detection and Prevention*, 17(2), 317–321.
- Thambisetty, S. (2017). The construction of legitimacy in European patent law. *Intellectual Property Quarterly*, 3. ISSN 1364-906X (**In Press**).
- Toronto International Data Release Workshop Authors. (2009). Prepublication data sharing. *Nature*, 461, 168–170. doi:10.1038/461168a.
- Van der Burg, W., & Brom, F. W. A. (2000). Legislation on ethical issues: Towards an interactive paradigm. *Ethical Theory and Moral Practice*, 3, 57–75.
- Warren-Jones, A. (2004). Patenting DNA: A lot of controversy over a little intangibility. *Medical Law Review*, 12(1), 97–124.
- Zimmer, F., & Sethmann, S. (2005). The immoral gene: Does it really exist? *Science and Engineering Ethics*, 11(1), 97–104.