The unacknowledged uncertainty of biopatenting; a case study of the
Aquabounty patent in the European patent system

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Summary

The post normal science approach first launched by Funtowicz & Ravetz (1995) addresses current challenges in scientific advice; where science is practiced as the equivalent to Kuhnian normal science (NS) in situations with high uncertainties and high stakes. In this article, we apply this approach outside its usual domains, but still within the domain of science and technology policy through application of scientific knowledge: in the patent system. We show from a case study on the patent on a transgenic salmon how patenting practices and procedures related specifically to biotechnology often evade fundamental scientific, ethical and societal uncertainties. This tendency may contribute to explaining hitherto unexamined facets for the patent system’s reluctance to address the numerous controversies in the wake of recent decades’ patent opposition cases.

Keywords: ethics, patents, GMO, salmon

Introduction

The European patent system has expanded in scope and impact during the last decades. This growth may be correlated both to increase in the rate of innovation, and subsequently patenting, and to a change in policy-making related to the patent system itself (Fink et al., 2013). Many of these changes may also be correlated with a surge in biotechnology patents, and inventions based on transgenic organisms, frequently fraught with ethical controversy. With the increasing attention and prospects of the gene editing technologies (e.g. CrispR Cas9), pressing issues of ethical and societal concern may grow in significance.

Patents have existed since the dawn of the modern world. The patent system originated in the Venetian Statute of inventors of 1474, but the current form of the patent system grew out of the industrial revolution, as a system intended to protect inventions that were part and parcel of that era, such as steam engines (Farnley et al., 2004). Notwithstanding the rapid technological change in recent decades, the requirements of patentability have remained relatively unchanged and uniform. All patentable inventions, in any field of technology, must meet the requirement of novelty, inventive step and industrial applicability, including a sufficient disclosure of the invention and reference to prior-art.

Particular areas of biotechnologies challenge the boundaries to what may be patentable on ethical grounds. Simultaneously, biotechnology has been a change agent in patent law and patent policy, both in U.S. and European patent systems (Demaine & Fellmeth, 2002). In Europe particular ethical concerns are integrated into Art. 53 of the European Patent Convention (EPC) and also through the implementation of the 1998 Biotech Directive. Whereas patents might be opposed solely through the legal system in the U.S., the European model is based on a dual approach, where patents might be subject to appeals and opposition...
both through the EPO (European Patent Office) Board of Appeals and through national courts. Through the EPC, ethical evaluation is embedded into particular aspects of examination and appeal processes of the EPO, either through the decision-making and evaluation of patent examiners, or as an integral part of the work of the separate EPO Board of Appeals. Art. 53 EPC defines exceptions to patentability, as either being (through their commercial exploitation) contrary to “ordre public” or morality (Art 53(a)), being a plant or animal variety or essentially biological process (Art. 53(b)), or being methods for treatment of the human or animal body (Art. 53(c)). However, Art. 53(b) specifically states that “…this provision shall not apply to microbiological process or the products thereof” (Visser, 2015). Relevant for our purposes, the introduction of Rule 27(b) of the EPC, which represents the implemented Directive 98/44/EC (the so-called Biotech Directive), underlines the implication this has for the patentability of transgenic organisms. Rule 28(b) EPC states that such inventions shall be patentable if they concern “plants or animals if the technical feasibility of the invention is not confined to a particular plant or animal variety” (ibid).

However, the Biotech Directive’s implementation was fraught with controversy, particularly related to the patentability of genetically modified organisms (Gold & Gallochat, 2001), which also has had implications for the societal legitimacy for the patent system (Sideri, 2012, San José, 2013). Further, other commentators have also argued that the formulation of the Biotech Directive is too heavily influenced by scientific reductionist approaches, and molecular biology, in particular (Calvert & Joly, 2011). That said, the main locus of public and scholarly attention has been on particular controversial cases with specific ethical, political or societal issues at stake, such as the so-called ‘OncoMouse-case’, the Novartis-case or a range of other patents involving chimeras (Stanković, 2005), which all involved inventions relating to transgenic technologies. Common to these cases are the fact that broad moral, societal and even ontological issues were reduced to technical issues, such as whether a transgenic animal has the legal status of an invention, and whether they could or could not be confined to a particular animal variety.

Due to the complexity of new and emerging biotechnologies, and the often-ambiguous nature of patent law, many important yet more subtle issues than what may be articulated by patent law run the risk of evading public, political or legal attention in a sufficiently broad manner (Forsberg et al., 2017). Issues that are readily present in the patenting of transgenic animals include deep ontological, epistemic, ethical and societal implications that may require other or broader competencies than mere legal and technical training. Such competencies are often not present in such institutions as patent offices or courts, where decision-making processes are often dominated by various forms of what commentators have labelled reductive, self-referencing and technocratic reasoning undertaken by a community of experts with disciplinary backgrounds in engineering or the natural sciences (Kica & Groenendijk, 2011, Borrás, 2006). This feature of the European patent system and the EPO in particular has been critically diagnosed from different perspectives, both in general, and specifically in the domain of biotech patenting, from the perspective of bio- and patent ethics and from various social sciences (Forsberg et al., 2017, Plomer, 2015, Plomer & Torremans, 2009, Witek, 2005, Farnley et al., 2004). Notwithstanding the relevance of these approaches, we argue that there are normative, epistemic and institutional features of the European patent system that directly engage issues relevant to transgenic organisms and transgenic animals in particular that are rarely addressed. The central question is to what extent the current reductionist and technocratic approach to patenting transgenic organisms are informed by a scientific paradigm of scientific reductionism that do not facilitate the necessary deliberation of ethical and societal issues of great significance. Thus, our approach here is to provide a depiction of this problem based on a theoretical perspective that takes this challenge into account.

This theoretical framework of post-normal science (PNS) as put forward by Funtowicz
& Ravetz (1995) exemplify such a perspective. PNS argues that when uncertainties and decision-stakes are high, Kuhnian normal science (NS), as a problem-solving strategy, is not effective. In referring to their “Kuhnian” understanding of “normal science”, uncertainties are managed automatically, values are unspoken and foundational problems are unheard of (ibid, p. 740). In contrast to traditional views of science as producing knowledge claims entailing certainty by natural scientific communities, and only then encountering external factors (such as political interests), PNS entails the opposite. Highly uncertain knowledge claims are placed in areas of immediate social pressures in fields of conflicted political issues around emergent technology. PNS acknowledges uncertainties and high decision stakes, value plurality and societal urgency, and advocates the use of extended peer communities for decision-making in such cases.

With regard to the considerations discussed above, numerous biotechnologies, including genetically modified organisms (GMO) and genomics are inherently “post normal”, particularly with regard to defined ethical implications and biosafety considerations. Governmental policies, awareness of our way of thinking, and a more communal worldview informed by a subjective epistemology and a holistic ontology are considered as important prerequisites for developing animal breeding programs for sustainable production systems (Olesen et al., 2000). With the applications of GMOs and gene editing in animal breeding, these matters become increasingly important to address.

Additionally, a plethora of implicit and ultimately complex issues of societal impact, distributive justice and wider political, cultural and ontological considerations are also deeply embedded in the commercialization of biotechnologies. GMOs, and transgenic animal technologies, such as transgenic salmon in particular, exemplify this ‘post-normal’ nature (Benessia & Barbiero, 2016). From a post-normal perspective, the patent system needs to address these features of biotechnology. When patent examiners grant patents, they are functioning as patent advisors, or rather as de-facto decision makers in biotechnology, taking decisions that will have impact on stakeholders and potentially the public.

We will now present and discuss an example of such a patent grant process, considering the AquaBounty case (part of PatentEthics project1), in the Norwegian patent system.

Case: The AquaBounty salmon patent

The AquaBounty case in the Norwegian patent system related to the patent on a transgenic salmon filed by the U.S. company AquaBounty, and shows the process of examination of the Norwegian Industrial Property Office (NIPO) and the opinion of the Norwegian Ethics Committee for Patent Cases (from now on, Ethics Committee). In the Norwegian patent system, the Ethics Committee is involved in cases where there is doubt whether an invention should be exempted from patentability on the basis of being contrary to public order and morality anchored in § 1 in the Norwegian Patents Act (NPA). This section is equivalent to Art. 53 of EPC. Norway implemented the European Biotech Directive in 2003-2004, under the condition that certain countermeasures were implemented in order to foresee a ‘restrictive’ approach to the patentability of biotech inventions (Bioteknologinemda, 2012). The Ethics Committee on Patent Cases was one of seven such countermeasures. However, in most cases NIPO follows the general guidelines for patent examination articulated by EPO and the NPA, which is harmonized with the EPC. The AquaBounty patent represented the first and only case presented to the Ethics Committee by NIPO after it was established in 2004. In a letter of May 2006, the Ethics Committee advised that the patent should be revoked. In spite of the opinion of the committee, NIPO granted the patent in June 2006 with minor revisions in the scope and formulation of claims in the patent.
The invention filed to NIPO under patent number 19933276 includes a method for increasing the growth rate of salmonid fish. This includes a method for placing a gene encoding a salmonid growth hormone and farming of fish under conditions permitting increased growth rate. Further, the invention includes a transgenic salmonid fish that has incorporated a gene construct in its genome comprising of a type III AFP promoter and a fish growth hormone sequence (NIPO application nr. 19933276). The patent holder, AquaBounty Technologies, is a biotechnology company based in Massachusetts, USA. The patent relates to their longstanding development of the AquAdvantage™ salmon which is an Atlantic salmon with an rDNA construct that is composed of the growth hormone gene from Chinook salmon under the control of a promoter (a sequence of DNA that turns on the expression of a gene) from ocean pout.

During the deliberation in the Ethics Committee, several areas of scientific and ethical uncertainty emerged. These areas related generally to two key considerations: uncertainty about whether the fish suffered due to genetic modification, and whether there had materialized a risk of environmental damage. These considerations were applicable due to the fact that Rule 28(d) of the Biotech Directive (embedded in § 1 NPA) articulates that inventions are excepted from patentability if they include “processes for modifying the genetic identity of animals which are likely to cause them suffering without substantial medical benefit to man or animal.” Article 53 (a) of the EPC and § 1(b) in the NPA also opens for considering environmental harms of such inventions. However, this must be sufficiently documented. Based on the above considerations and the requirement of additional documentation, the applicant provided various statistical data and scientific declarations (NIPO, 2005c). Based on the enclosed documentation and scientific evidence, the Ethics Committee concluded that the aforementioned documentation was insufficient to assess both the question of suffering for the fish and potential environmental damage, and that therefore the Precautionary Principle had to be applied and the patent denied.

Such reasoning was however not compatible with the NPA nor with NIPO’s guidelines, and hence, these arguments were disregarded. However, in not taking the Ethics Committee’s opinion into full consideration NIPO also disregarded the risk assessment pivotal to the Ethics Committee’s ethical position. Notwithstanding the legal insufficiency of the documentation, the Committee’s opinion pointed to another issue of broader concern for the patentability of transgenic animals in general:

“The Committee emphasizes that there is considerable scientific uncertainty related to animal welfare and environmental effects of transgenic salmon.” (NENT 2008, p. 145th, our translation)

This reasoning by the Ethics Committee encompasses the validity of including considerations of scientific uncertainty in the assessment of § 1 (NPA). However, this reasoning was neither taken into account, nor is in any way in alignment with what is considered valid legal considerations when transgenic animals patents are examined by a patent office subject to the jurisdiction of the EPC. Valid arguments would have been there was documentation of suffering or materialized environmental damage. Since this was not demonstrated by the Ethics Committee, the AquaBounty salmon was considered patentable by virtue of meeting the requirements of novelty, inventive step and industrial applicability, and not falling under the ‘ordre public and morality’ exemption (Art. 53 EPC). This highlights a divide in the conception of what is an ethically relevant question for the expert community in the EPO, and what is considered ethically relevant among lay-people, or other expert communities including ethical experts. Actual ethical deliberation for the EPO or NIPO is by instruction restricted to an exceedingly limited area of subject matter.

A question that was not addressed in the ethical assessment, and has generally not been discussed in critical examinations of patenting of genetically modified animals, is related
to Art. 53(b), that “essentially biological processes” are exempted from patentability, while “microbiological processes” are patentable. Moreover, by virtue of Rule 27(d), a non-exhaustive list of biotechnological inventions is patentable such as “A microbiological or other technical process, or product obtained by means of such a process other than a plant or animal variety” (Rule 27(d) EPC). Evidently, the AquaBounty salmon was considered containing such a “process”. Even with sufficient understanding of biology, there is no clear scientific demarcation to be made out of the definition of the term “other technical process”, or even what constitutes an “animal variety”. Further, there is an exceedingly technical and opaque notion of what is the difference between an ‘essentially biological process’ and a ‘microbiological process’ (Kock, 2007). This non-obvious interpretation is carried out by techno-legal experts in a narrow epistemic community, with scarce attention from the broader society. Particularly for fish, the term ‘variety’ is not unambiguous, and open for controversies. Fish strains, breeding populations, stocks or breeds are all terms that are being used for a fish variety without any clear distinctions of state of evolution, genetic development or characteristics. A question to be addressed in this connection is also the allocation of credit and benefits to be shared with those who have developed a variety that is further improved through a patentable gene modification.

Conclusion

PNS argues that normal science-practices are characterized by unspoken value assumptions and a suppression of uncertainty (Saltelli & Funtowicz 2017). In contrast, numerous biotechnologies, including transgenic animals involve the manipulation of genetic material that embody irreducible uncertainty and complexity with regard to the impact on the organism and its environment (Funtowicz & Strand, 2007). The AquaBounty case provides us with an example where the assessment of competent ethical expertise was deemed mostly irrelevant. It is also an illustration of recurring themes that make up the central tenets of genetic engineering; reductionism, determinism and mechanism (Carolan, 2010); tenets that form the foundation of a normative and epistemic model of not only the bioindustry, but also its central institutions, including the patent system (Benessia & Barbiero, 2012). Current patent practices in the EPC show unwillingness to incorporate scientific uncertainty and the presence of conflicting value positions in the European public in relation to biopatents as consideration in the decision-making process, as illustrated by the consistently narrow interpretation of the scope of ethically relevant considerations from the EPO Boards of Appeal in recent years. In particular, where science to an increasing degree embrace complexity and uncertainty, patent law seems to continuously evolve towards reducing ambiguity and uncertainty (Calvert and Joly, 2011). It also illustrates a situation where decisions of vital ethical and societal significance are left to a techno-legal institution where alternative expertise or the public has little or no influence.

List of References


