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GENERAL ARTICLE

The European patent system: dealing with emerging technologies

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In light of recent controversial patent decisions in biotechnology, this article argues that the current European patent examination and opposition procedures do not suffice to balance the patent system These procedures do not provide sufficient guidance for patent examiners to deal effectively with the emerging life science technologies. The European Patent Office needs to instill more self-reflection into the patent system and foster interaction between the Office and patent stakeholders. In this respect, we propose that the EPO should establish an ex-ante, patent-granting advisory body that would consist of multidisciplinary staff drawn from various technical fields, and collaborate closely with the scientific community and other national bodies. It is expected that such an advisory body would provide an input to the existing patent system, since it would anticipate, control and reduce the possibility that patent examiners would issue low-quality patents with huge socio-economic consequences.

Keywords: European patent system; biotechnology; patent prosecution; patent assessment; third-party participation

Introduction

For many decades, the European patent system has been confined to a hermetic corner of law, a self-regulated community built on the interaction between patent applicants, patent examiners, and courts. The special structure of the "grant only" European patent system has led to this field being regulated by engineers with specialized legal and technical training, meaning that it is largely incomprehensible to the public and other stakeholders. However, the advent of new technologies, biopatents and commercial applications of biotechnology has brought many complex and controversial issues into the public sphere, leading to the desirability of greater participation in the patent system. This article analyzes the field of human genetic inventions, the controversy over patenting these inventions and the potential of different actors to translate public critique into mandatory requirements for patent authorities to limit the protection of newly emerging technologies. We argue that the European Patent Office (EPO) should make use of these actors and establish the right incentives for them to contribute to an effective patent examination process and a more transparent patent system.

In Europe, worries about stakeholder involvement within the patent system date back to 1998, when the European Union (EU) adopted the Biotechnology

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Directive (98/44/EC). The Directive brought new types of human intervention into the patent arena, often termed "biological material" and "living matter" (European Union 1998). Biotechnology has been around for long time; consider the yeast used in beer or wine and the bacteria used in cheese production. However, the influx of modern biotechnology differed from the traditional use of biological material and led to an expansion of patents granted to isolated genes, genetically modified organisms and other biological compounds (Schneider 2009b).

We can distinguish two strands of opinions on modern biotechnology and patents. On the one hand, there have been strong economic arguments from biotechnology industries and policy-makers supporting research and protection of the biotechnology inventions, as optimal tools for encouraging technology commercialization, research investments in new areas and innovation development (Johnston and Wasunna 2007). Modern biotechnology, including biomedical research, has found increasing application in healthcare, where the use biological material and gene technology has become a potential for the production of new vaccines, therapies and diagnostic tests. This has led to an increase in the number of patent applications (Majumder *et al*. 2008). However, on the other hand, technological developments in biotechnology, and especially the patenting of human genetic material, cloning and genetic testing, have drawn together a large number of activist groups, scientific bodies and civil society to challenge the legitimacy and the commercialization of genetic inventions (Jasanoff 2005). In this way, the field of biotechnology and other related innovation activities can no longer be regarded as entirely passive activities developed by inventors and used by consumers; rather, they comprise complex actors and networks involving laboratories, patients, research institutions, families, geneticists and other stakeholders (Schrell *et al*. 2007). These waves of innovation have brought the need for the patent system to ensure representation of various interests and actors. Nevertheless, this has proven to be difficult at times.

Scholars have attempted to assess the factors driving the lack of representation and stakeholder participation in the system when decisions of protecting new technologies are made. Most of them criticize the democratic deficit inherent in current technological regulatory frameworks (which tend to be driven by technocrats), and the inability of the patent system to handle socio-ethical policy considerations and open the examination process to external actors who can contribute to effective innovation outcomes (Schneider 2009a, van Pottelsberghe de la Potterie 2009). Advocates of technocracy argue that technical experts are more able to exercise professional judgment on new technologies and determine what is in the best interests of society. Some have even expressed doubts about the community's ability to understand the uncertainty of new technological developments and the complexity of innovation processes as incremental parts of science. These assumptions have led regulatory institutions into a mind-set that regards public attitudes as an obstacle to technological progress (Hagendijk and Irwin 2006). According to Cowan *et al*. (2006, pp. 32–34), such obstacles can be remedied by openness, consultation and dialogue with the public. Similar assumptions are shared by other scholars, who argue that modern societies should provide new forms of democracy which lead to improved decision-making, through communicative interaction and discursive practice, resulting in social consensual engagement with risk perception, both before and after decisions have been made (Picciotto 2001). Patent scholars add to the participatory debate, claiming that the

"chain of innovation" consists of various actors that are affected by "existing or potentially granted patents" and that it is crucial that patent offices ensure actor involvement to provide relevant information on the claimed inventions (Edfjäll 2007, Wagner 2009). However, it is only in the first phase that regulators and other actors are provided with the opportunity to "control, confine and channel *ex-ante*" the operations and successful practice of inventions (Brownsword 2008). At this point, substantive search and examination of inventions is crucial, as it represents the "first stage" of technology assessment and contributes to the validity of patents that are granted (Harhoff 2009).

Indeed, developments in the field of biotechnology and human genetics have challenged the ability of patent examiners to assess inventions and respond to socio-economic controversies. For instance, in Europe patents are granted to inventions that are new, non-obvious and have industrial application, but it is relatively difficult for gene sequences to fulfil some of these patentability standards as they already exist in nature or there is failure to prove the useful functions that these inventions could perform (Guellec and van Pottelsberghe de la Potterie 2007). Gene patent applications differ from other inventions, since broad claims[1] tend to form an intrinsic part of them, including information on nucleic acid sequences, fused cells, vectors, recombinant proteins and monoclonal antibodies (Aymé *et al*. 2008).[2] This has created intensified debates among various stakeholders on the risk of these new technologies and their effect in undermining scientific research, medical advancement and patient care. Broad claims may prevent researchers searching for cures for genetic diseases, impose unnecessary constraints on downstream innovation or cause the public to pay supracompetitive prices on patented products or processes. Furthermore, in a relatively new technical area like the field of human genetics, the general level of knowledge about prior art and the certainty about the likelihood of success of an attempted technique is low (Johnston and Wasunna 2007). Information on gene patents cannot be retrieved easily[3] and an enormous number of senior-level staff would be needed to provide sufficient qualitative expertise to patent applications involving gene sequences, which obviously is far beyond the working capacity and time-frame within which examiners operate (Ganguli 2001).

Concomitant to these concerns have been the ethical issues arising from the development and the use of genetic technologies. The complexity in biotechnology patenting is that it involves the patenting of living organisms or other products of natural origin, which normally are not patentable. Much of the controversy centers on ethical issues associated with research involving embryos and the use of genetic material. Various groups of citizens, non-governmental organizations and experts from various disciplines feel uncomfortable about the patentability of inventions that include human biological substances, claiming that these substances already belong to "humanity" or the "common heritage" and that patenting them would commodify the human body (Majumder *et al*. 2008). The European Patent Convention (EPC) and the 98/44 EC Directive have accommodated such concerns by prohibiting patents on the process of cloning humans, modification of germ line and the use of embryos for commercial purposes (European Union 1998). However, the interpretation of such exclusions is difficult in practice. The goal of patent officials is to apply the technical rules of patent law. Evaluating applications by weighing their impact on the *ordre public* and morality requires the availability of a degree of expertise that is not represented in patent offices (Nuffield Council on Bioethics 2002). These challenges have made the field of gene patents the topic of

many heated discussions focusing on the need for the patent system to reflect not only the commercial needs of the inventors but also the values of society at large.

Research aim and design

There exists a rich scholarly debate on issues related to human gene patents and on how these inventions may have impeded research and access, leading to intensified disputes and oppositions. This article aims to represent a more in-depth understanding of the interaction between the protection of new technologies, the uncertainty upon which patent officials base their decisions, and the potential of external actors to respond to the current patent controversies. In particular, we focus on the way different stakeholders at the various stages of the patent prosecution process have shaped the debate and the innovation outcomes of the current system. We argue that, in complex and socially contested technology fields, patent offices should be more aware of their activities and engage more in assessing and forecasting the impact of the claimed inventions. As such, the inclusion of various actors within the patent prosecution process is largely desirable and contingent upon the capacity of the patent system to strengthen the input-side of the patent decision-making process (Schneider 2009b).

The extent to which the European patent system currently succeeds in establishing such a participatory framework is limited. The practice under which European patents are granted has primarily followed the technocratic approach. European patent applications are examined by the EPO's Examination Division, which is staffed with technical experts, and the scope of the patents is determined by means of a regulatory process that is disguised behind the technical patentability standards (van Pottelsberghe de la Potterie 2009). After a patent is granted, parties may file their opposition to the patent. Hall *et al.* (2004) argue that the post-grant opposition procedure provides an added value to the European patent system, thus helping to contribute to a higher patent quality.[4] The primary problem with the opposition procedure, however, is the time taken for a decision to be reached. Once the opposition procedure is initiated, it takes approximately two years (if the patent is revoked) or four years (if the patent is amended) for a decision to be made (Roox *et al.* 2008). In addition, the European patent system and its post-grant opposition proceedings provide information to the public about patented inventions on which external actors may comment only after patent decisions are made. Thus, the patent examiners' dialogue with other stakeholders remains quite underdeveloped, leading to the "isolation" of patent examiners and to an increased legal uncertainty in the protection of newly emerging technologies (Hagel 2008). As a result, the EPO has been challenged by an increasing number of oppositions on the validity of the granted patents (Holzer 2005).[5]

The rest of this article is organized as follows. In the next section we discuss the function of the patent system in Europe and the controversy surrounding the implementation of the Biotechnology Directive. In the third section we extend our discussion to gene patents and the patentability of human embryonic stem cells (hESCs). In particular, we present a critical examination of three prominent patent infringement cases in Europe: the BRCA case, the Edinburgh case and the WARF case. To illuminate the participation of various actors within the patent prosecution process surrounding these cases, we have searched the Westlaw International Database and the EPO Board of Appeal Database. However, since neither of these

databases provided us with detailed data on the documents submitted (i.e. observations and oppositions) during all phases of the patent prosecution process (from the search/examination phase up to the final decision), we have searched the EPO's Register Plus and the esp@cenet Database. The evidence from these databases provides crucial information on how various entities have used the patent prosecution process as a mechanism to bring valuable inputs to examiners and influence the scope of protection for new technologies. In the fourth section we highlight the inability of the EPO and the national authorities to respond to the challenges of biotechnology inventions and assess the impact of certain products and processes. The fifth section describes how the academic debate has developed in response to current difficulties and maps the strategies they have proposed as possible solutions to foster the functioning of the European patent system and the quality of its outcomes. In the last section, we build on the gaps between current practice and academic debate, and provide recommendations on how to make the patent system more responsive and transparent. Our conclusion is that the EPO should establish an *ex-ante* patent granting advisory body, consisting of multi-disciplinary actors who collaborate closely with each other to provide prior art information and assess the implications of inventions.

The European patent system: current developments and regulatory issues

During the 1970s, the European Patent Convention established the EPO as an alternative[6] through which inventors could acquire intellectual property (IP) protection. EPO is the centerpiece of the patent system in Europe and functions as an executive arm of the EPC, whose activities are supervised by the Administrative Council. In line with Article 52 (1) EPC, EPO grants patents to inventions that are new, involve an inventive step that is not obvious to a person skilled in the art and are industrially applicable. When the patent application is filed, the EPO's Search Division draws up a Search Report relevant to the subject matter of the patent claim. In addition, a great number of patent applications undergo substantive examination by the Examination Division.[7] The EPC provisions recognize the contribution of external actors in the patent prosecution process as well. Article 115 of the EPC provides that, after the publication of the European patent application, third parties can communicate certain information or documents to the examiner in charge concerning the patentability of the invention for which an application has been filed. No fees are required for the submissions of observations and the person filing an observation may not be a party to the proceedings before the EPO. However, this mechanism continues to be used rather infrequently. The contributions of third parties are not made public and are not officially recognized by patent officials (Guellec and van Pottelsberghe de la Potterie 2007). After search and examination, EPO grants or rejects the patent, and at this point, the decisions of the EPO are open to appeal. Parties may file an opposition pursuant to Article 99 EPC or an appeal with the Technical Boards of Appeal (TBA), and in certain cases may file a petition for review with the Enlarged Board of Appeal (EBOA).

Confined as it is to this world of highly specialized, technical in-house examination, the EPO enjoyed a relatively quiet life until the 1990s (Borrás *et al.* 2007). However, after this period, certain patentability controversies attracted the public attention as the EU started to become increasingly involved in the European patent area, so as to provide greater legal certainty for new technological inventions

(particularly biotechnology- and computer-related inventions). The desire for harmonization and legislative codification of patent law in biotechnology necessitated the drafting of the EU's Biotechnology Directive (98/44/EC). The Directive and the tendency of ensuring patent rights for all forms of biotechnology dictated the involvement of a variety of actors including *the industry* (European Federation of Pharmaceutical Industries and Associations, the European Association for Bioindustries, and other industrial and trade associations part of the Forum for European Bio-Industry Coordination), *interest and environmental groups* (Greenpeace, Genetics Resources Action International, Rural Advancement Foundation International, the German Protestant Church and ActionAid), *EU institutions* (the Green Party Members of the European Parliament, the European Commission and the Council) and *citizens groups* (Thaker 2003). In this way, even though the Biotechnology Directive was initially conceived as a purely technical operation, it took 10 years for the EU institutions and a range of advocacy groups to resolve issues concerning whether human cells, genes and isolated parts of the human body (including gene sequences) should be considered patentable subject matter (Andreasen 2009).

In sharp contrast to the traditional practice of patent law, which has mainly been concerned with machines and engineering issues, the implementation of the Biotechnology Directive brought new types of human intervention into the patent arena, often termed "biological material" and "living matter". This led to various debates between the public and other stakeholders on limiting the protection of biotechnological inventions for ethical and moral reasons (Schneider 2009b). To address such concerns, the Directive for the first time specified the *ordre public* and morality exceptions, and addressed the patentability of the human body and parts isolated from it. It introduced Articles 5 and 6, which provide a list of examples of inventions that can (or cannot) be patented and of inventions for which the commercial exploitation could be considered contrary to the *ordre public* or morality (European Union 1998). These Articles were implemented through amendments by the EPC (i.e. Rules 26–29 EPC). Before the advent of the Biotechnology Directive, the patenting of higher life forms was viewed as unacceptable. The EBOA acting in accordance with Articles 52 (2) and 53(b) EPC had strictly ruled out the patentability of transgenic plant (e.g. *Greenpeace v. Plant Genetic Systems*) and animal varieties. The rulings on the patentability of transgenic plants were disputed and changed later during the *Plants*/*NOVARTIS* case,[8] when patent applicants started to use the wording of the Directive to further expand the patent eligibility (Schneider 2009a).

However, the Biotechnology Directive did not affect the basis of patent law (i.e. patent criteria, settlement of infringements), nor did it create the authority to grant patents; rather, it intended to determine explicitly which biotechnological inventions Member States shall protect under their national patent laws (Soini *et al.* 2008). The conceptualization of the Directive articles (e.g. whether "research cloning" should be classified as "cloning" or whether "embryos" should be classified as "human beings"), the scope of patents in critical fields and the interpretation of how claims may translate into potential products or processes were left to the EPO's expertise (Schneider 2009b). As such, the use of the Directive in regulating and protecting sensitive issues relating to genetic inventions has created the reverse effect of that intended. Restrictions on the scope of patentability have been strongly called for, particularly by the European Parliament with regard to gene patents and hESCs. Such restrictions have also challenged the EPO's technical expertise and patent granting practice.

Regulating new technologies: dealing with patent eligibility and scope

In this section, we illustrate the challenges that human genetic inventions have posed to the EPO's technical expertise and patent prosecution process by examining three specific cases: the BRCA case, the Edinburgh case and the WARF case. These patent cases reflect the limited resources of patent authorities in cases when patented inventions within the field of biotechnology are opposed, and the role of social and scientific groups in providing examiners with valuable inputs on the regulation of new technologies.

Case 1: the BRCA gene patent case

Between 2001 and 2004, the EPO granted patents to the Myriad Genetics Inc. covering breast and ovarian cancer genes: BRCA1 (*EP0699754, EP0705903, EP0705902*) and BRCA2 (*EP0785216, EP0858467*).[9] Prior to this decision, the UK and French genetic communities openly expressed their critiques of the commercialization of BRCA gene test. These criticisms were followed by a number of observations submitted to the EPO against the Myriad patent application. During the period of 1998–2003 numerous observations (pursuant to Article 115 EPC) were filed from research institutions, scientific societies, clinical geneticists and other European organizations representing the interests of the patients (see Table 1). These entities required the EPO to refuse patent applications since the claimed inventions were not novel, were not properly described and did not involve an inventive step. However, the EPO still decided to grant patents to Myriad (Jones 2002).

After obtaining the patents, Myriad contacted the European healthcare providers to offer them licenses for the patents. The licensing terms did not allow licensees (i.e. European laboratories engaged in genetic testing) to perform tests themselves, but mandated them to send DNA samples obtained from high-risk individuals to Myriad's laboratories in Salt Lake for analysis. Myriad's monopoly on diagnostic genetic testing and the extremely expensive licensing prices led European scientists and laboratories to file numerous oppositions (pursuant to Article 99 EPC) against the granting praxis of the EPO (Matthijs 2006). A major concern was that a monopoly on BRCA genes would benefit the specific economic interests of Myriad rather than the wider social and economic interests. The fee required from Myriad was too costly to be paid by public health insurance systems and other laboratories in the public sector, thus resulting in restrictions for patients receiving adequate care and access to medical services.[10] Furthermore, Myriad's monopoly of patent exploitation prevented European scientists and physicians from acquiring sufficient information and technical expertise on diagnostic technologies and methods, or developing more comprehensive genetic tests.[11] For these reasons, several national governments (e.g. Netherlands, Belgium and Switzerland) filed oppositions against the BRCA patents. The Members of the European Parliament joined these oppositions and adopted a resolution against the EPO's decision to grant Myriad a patent monopoly on BRCA genes (Benowitz 2002).

Besides these concerns, the opposition to the patentability of the BRCA genes addressed the failure of these inventions to fulfil the basic standards of the European patent law. The Curie Institute in Paris, followed by a coalition of 16 other French laboratories, genetic societies (from Belgium, Denmark, Germany, UK, Italy, Greece,

Table 1. Patent observations and oppositions filed by third parties against the BRCA gene patents

Observations filed pursuant to Article 115 EPC	Oppositions filed pursuant to Article 99 EPC
Scientific societies and interest groups	***(Anti) cancer research institutes and associations***
Association ECOROPA (European Ecological Action) (France)	Assistance Publique Hôpitaux de Paris
Forum Christlicher Frauen in Europa (Austria)	Azienda Ospedaliera-Mater Domini (Italy)
Genetic Interest Group (UK)	Associazione "Angela Serra" per la Ricerca sul Cancero (Italy)
Interdisziplinäre Gesellschaft für Umweltmedizin (Germany)	Deutsche Krebshilfe (Germany)
Institure for Human Genetics (UK)	Institut Curie (France)
Kommission Ökologie und Bioethik Ökumenisches (Germany)	Institut Gustave Roussy (France)
Members of German Bundestag	Italian Association for the Study of Gastrointestinal Hereditary Tumours
Publicists, Internists and Churches	Swiss Cancer Research Institute
	Vereniging van Stichtingen Klinische Genetica (Netherlands)
European organizations from the field of medicine	
Austrian Medical Association	***Environmental organizations***
Association for Glucogen Storage Disease (UK)	Greenpeace e.V. *et al.*
Alliance of Self-support Group and Human Geneticists (Germany)	
Alzheimer's Disease Society (UK)	***Patient organizations***
British Society of Human Genetics	Borstkanker Vereniging, Nederland
European Campaign Biotechnology Patents	Vlaamse Liga tegen Kanker, Belgium
EUROCHORD (Permanent Representation of Doctors in the EU)	***European governmental institutions***
German Medical Association	Belgian Government (Ministers of Public Health, of Social Affairs and of Scientific Research)
German Society of Human Genetics	
Genetic Interest Group	State of Netherlands (Dutch Minister of Health)
International Autistic Research Organization	Social Democratic Party – Switzerland
Irish Organization of Inherited Disorders	
Microcephaly Support Group (UK)	***Human genetic societies***
Neurofibromatosis Association	Austrian Society of Human Genetics
Osteogenesis Imperfecta Fédération Europe	Belgian Society of Human Genetics
PXE Support Group	British Society of Human Genetics
Society for Mucopolysaccharide Diseases (UK)	Clinical Molecular Genetic Society (UK)
Stickler Syndrome Support Group (UK)	Danish Society of Medical Genetics
UK Clinical Molecular Genetics Society	Dutch Society for Clinical Genetics
	French Society of Human Genetics
Patient organizations	Finnish Society of Medical Genetic
From Germany:	German Society of Human Genetics
Arbeitskreis Leben mit Mukoviszidose	Italian Society of Human Genetics
Arbeitsgemeinschaft der Selbsthilfe gruppen und Humangenetiker	Swiss Society of Medical Genetics
Bundesvereinigung Lebenshilfe für Menschen mit geistiger Behinderung	Czech Society of Medical Genetics

Table 1 (*Continued*)

Observations filed pursuant to Article 115 EPC	Oppositions filed pursuant to Article 99 EPC
Cystische Fibrose Bundesverband	
Deutscher diabetiker Bund	
Deutsche Hamophiliegesellschaft zur Bekampfung von Blutungskrankheiten	
Deutsche Huntington Hilfe	
Deutsche Leukämie Forschungshilfe Aktion für krebskranke Kinder	
From the UK:	
Jennifer Trust for Spinal Muscular Atrophy	
Neuro Fibromatosis Association	
Pseudoxanthoma Elasticum Support Group	
Telangiectasia Self Help Group	
Universities	
University of Edinburgh	
University of München	
University of Bonn	
University of Essen	

Source: authors' reprocessing of data retrieved from Westlaw International Database, esp@cenet and EBOA decision database.

Austria and Switzerland), research laboratories, patient associations, cancer researchers and other interest groups (see Table 1), indicated that the identification of BRCA1 was a costly effort; however it did not involve an inventive step.[12] When Myriad filed for a patent application there were already many other methods for diagnosing a predisposition to breast cancer. In addition, the French Curie Institute claimed that the BRCA patents were not inventive. The patentees had mainly benefitted from prior research conducted by an international consortium on BRCA in collaboration with patients and families, who were not acknowledged in the patents (Soini *et al*. 2008). Myriad's patents were also challenged for their lack of industrial application since the potential use of the claimed invention was not clearly specified within the application.

Following this uncommonly large number of opponents to the BRCA gene patents, in 2007 and 2008, the EPO issued a final decision on the opposition to the BRCA gene patents and related inventions, arguing that Myriad's patent claims failed to satisfy the traditional criteria for obtaining a patent.[13] The decision was a victory for the French Association of Research Institutes and Hospitals, Greenpeace and a number of genetic societies and patient organizations, scientific associations, cancer researchers and special interest groups.

The patentability of human embryonic stem cells (hESCs)

As mentioned earlier, the fight regarding patent protection in the field of human genetics has been put up not only over the patentability standards, but over ethical issues as well. This has created intensified debates among stakeholders on the scope

of protecting new inventions. In this respect, the Edinburgh and the WARF case represent the most disputed European patent cases.

Case 2: the Edinburgh patent case

In 1999, the EPO granted patents to Edinburgh University (*EP0695351*) covering techniques for generating transgenic animals from stem cells. The Edinburgh patent stated that the term animal cell was "intended to embrace all animal cells, especially of mammalian species, including human cells". This patent provoked controversy since it did not exclude the application of the patented techniques to humans. Prior to this decision, the German political authorities and environmentalists (the Ecological Democratic Party and Greenpeace), research institutions (Zoologische Staatssammlung München) and other private entities filed observations against the claimed invention. These parties required the revocation of the patent application, indicating that research on human embryos and the patenting of any sort of human stem cells were contrary to the *ordre public* or morality. However, the EPO still granted the patent to Edinburgh University (Zimmer and Sethmann 2005). The patent was licensed exclusively to an Australian company known as Stem Cell Sciences, but the patent was made public in February 2000, after Greenpeace issued a statement critical of the patent. Following this statement, Christian Gugerell, the director of biotechnology at the EPO, said that the Patent Office had not investigated the patent application with sufficient thoroughness. The Patent Office spokesperson, Rainer Osterwadter, admitted that the Munich-based Office had made an error in granting a patent to a process that could include the cloning of humans, but the Office could not immediately reverse the decision, as it had to wait for outside parties to file opposition to the patent (Tanner 2000).

In this respect, the European patent, *EP0695351*, led to a great deal of outrage and numerous questions about the future of stem cell research and bioethics. Many organizations, ranging from Greenpeace to the national governments, patent attorneys, social groups and entities from the "pro-life movement" protested against the patent (see Table 2). These groups acquired patent revocation on the grounds that the term "animal stem cells" could be extended by interpretation to include hESCs. As such, the patent was in breach of Article 53 (a) EPC, and was contrary to *ordre public* or morality.

Following these oppositions and the oral proceedings, the patent was amended in 2003 and the EPO's Opposition Division stated that the patent no longer included animal or hESCs, although it still covered modified human and animal stem cells "other than embryonic stem cells" (Baumgartner 2006).[14] This decision did not satisfy some groups, which started to speculate that the Office was refusing to deal with moral provisions, and protests continued. Responding to these concerns in 2005, the EGE (the Commission's European Group on Ethics in Science and New Technologies)[15] recommended that the EPO should make a distinction between the modified, isolated hESC (which should not be patentable) and the modified hESC (which should be). Nevertheless, the EPO's Opposition Division rejected these recommendations, asserting that it was more appropriate to interpret the EPC Rules (i.e. Rule 23d (c) and Rule 23 (e)) broadly, and deemed the human embryo and products derived therefrom as unpatentable (Zimmer and Sethmann 2005).

Table 2. Patent observations and oppositions filed by third parties against the Edinburgh patent

Observations filed pursuant to Article 115 EPC	Oppositions filed pursuant to Article 99 EPC
Political authorities, environmentalists	***European governmental institutions***
Ökologisch Demokratischen Partei (Germany)	Federal Republik of Germany
	German Bundestag – Partie des Demokratischen Socialismus
Research institutions	German Parliamentary Party Alliance
Zoologische Staatssammlung München	Bündnis 90/Die Grünen
Forschungsinstitution für zoologische Systematik	Government of the Republic of Italy
	The State of Netherlands
Private entities	***Research institutes and "pro-life" organizations***
Elber Weser Werkstatten (Für Behinderte- Gemeinnützige)	Austrian Pro-life Organization
	Aliance Pour les droirs de lavie (France)
	German Research Foundation
	Environmental organizations
	Greenpeace Germany (initiative "No patents on life")

Source: authors' reprocessing of data retrieved from Westlaw International Database, esp@cenet and EBOA decision database.

Case 3: the Wisconsin Alumni Research Foundation (WARF) patent application

In 1996, WARF filed a European patent application (*EP0770125*) with Jones Thomson as the named inventor. The application described a method by which stem cells could be produced using a process that required the use and the subsequent destruction of human embryos. Indeed, the pluripotent[16] hESCs such as those claimed by WARF did not have the potential to develop into a human being. However, disputes arose since the production of these cells required the destruction of human pre-implantation embryos and the grant of this patent allowed WARF to collect royalties on the commercial use of these cell cultures (Sterckx 2008). As such, EPO refused the WARF patent application on the grounds that the claimed invention was contrary to the EPC Rules that prohibit the patenting of biotechnology inventions that concern the uses of the human embryos for industrial or commercial purposes (i.e. Rule 28 EPC). Subsequently, WARF appealed and the TBA, which heard the appeal, referred the case with questions to the Enlarged Board. Pursuant to Article 11 (b) EPC, EBOA requested parties to provide opinions on the WARF case (Salter 2009). Following this request, third parties submitted *amicus curiae* briefs pursuant to Article 120 EPC. *Amicus curiae* briefs were filed by the Members of the European Parliament (MEPs) and patent attorneys, professional and political associations, research institutions, religious groups, environmentalists and other interest groups (see Table 3). This case is important to our study as it emphasizes the willingness of third parties to provide opinions on the patentability of human gene inventions.

In 2008 EBOA made its final decision on the WARF patent (G2/06 decision), indicating the refusal of the patent application. However, the Board has not explicitly

ruled which products or processes involving hESCs remain unpatentable and the EPO's Examination Division still has the discretion to determine whether all products or processes involving hESCs are unpatentable or whether those based on hESC cultures or cell lines are patentable (Schneider 2009b).

Distilling lessons from the biopatent controversy

What do these cases tell us? The public controversy about genetic inventions reflects a growing social awareness about the scientific limits and uncertainties upon which patent officials base their decisions. In contrast to past practices in which patenting issues were merely considered as part of a technical process, biopatent developments have acquired a social regulatory perspective. Most importantly, they indicate that technological developments are leading to new modes of governance, in which socio-ethical issues and other economic community values are bridging the gap between public outrage and professional hubris. Our empirical evidence clearly indicates that the patentability trends of new technology developments have brought together a large number of external actors to challenge the legitimacy of the EPO's granting practice, the effectiveness of the patent authorities and their accountability to public interests.

As we have seen in the BRCA case and the Edinburgh case, patent examiners have focused relatively little on the impact that exclusive ownership on genetic testing for hereditary breast cancer and the protection of techniques for generating transgenic animals from stem cells would have on society. However, during the Edinburgh patent dispute, for the first time EPO had to admit that it had made an error and could not amend the patents containing that error, as granted, without the public's support. Research institutions, national governments and other non-governmental groups have not only contributed to translating public critique into mandatory requirements for narrowing the scope of protecting new inventions, but have also

Table 3. *Amicus curiae* briefs filed by third parties on WARF patent application

MEPs and patent attorneys	***Religious groups and associations***
German Bundestag	Christian Action Research and Education
The European Parliament	Kolping diozesanverband Bamberg (Germany)
The European Centre for Law and Justice	Katholisches Buru Niedersachsen
Patent attorneys and professionals	Kolpingsfamilie St. Aloysius
Research institutions and professional organizations	***Interest and environmental groups***
Bioindustry Association (UK)	Aktion Lebensrecht für alle-Regionalverband (Germany)
Internationale Vereinigung für den schutz des geistigene eigentums (Germany)	Greenpeace, e.V.
University of Wien	Jungbauernschaft Landjugend Bezirk-Kufstein (Austria)
University of Ghent	The Environmental Protection Agency
University of Basel	Forum Info/Wien "No Patents on Life"
The Scottish Council of Human Bioethics	Women's Group–Korean Women Link
The Institute of Medical Ethics and Bioethics	***European political associations***
	Solidarieta, Liberta, Giustizia e Pace

Source: authors' reprocessing of data retrieved from esp@cenet and EBOA decision database.

served as a crucial mechanism for bringing crucial information to patent examiners with regard to the state of the art, the novelty and the industrial applicability of certain technologies. Furthermore, the patent cases mentioned above clearly emphasize that most of the oppositions lodged against gene and hESCs patents have not come from private companies or competitors, but from scientific communities and networks that involve laboratories, patients, technicians, families, geneticists and other stakeholders.

These developments in the regulation of patents in relation to new technologies demonstrate that there is a shift in the way stakeholders accept and appraise the operations of the EPO. The protection of new technologies is no longer perceived as value-neutral, merely representing an execution of the law, but rather as a policy-making process that significantly contributes to the shaping of technological pathways, to the public healthcare system and to society as a whole. In this way, the impact of the patent system and its outcomes is starting to become evident at many levels. For example, the oppositions lodged against BRCA gene patents started with the French Curie Institute, but later grew to include other governments, genetics societies, cancer researchers and interest groups (Benowitz 2002).[17] Because of this, the multitude of actors involved in biopatents has been able to address service provision and research priorities, and to turn wider concerns into regulatory challenges for technical patent examiners. Ullrich (2006) considers these activities as an exercise of devolved responsibility, which shifts centripetal governance to a centrifugal type through deregulation and the application of various policy networks.

Be that as it may, the contribution of external actors is recognized by patent authorities mostly after the decision to grant or refuse a patent has been made. According to Article 99 EPC, parties may give notice of opposition to European patents only nine months after the granting decision is published.[18] The EPO does not encourage a participatory pre-grant environment for third parties to file observations (pursuant to Article 115 EPC) on the patentability of the claimed inventions. In practice, after observations are received, the Examination Division adds them into the file and decides whether any of the observations (which provide better arguments for the case) should be considered, but third parties are not informed of any further action the Division takes in response to their observations. EPO's one-way communication with these parties has served as a disincentive for the system to effectively open up the examination process to other actors who could provide valuable inputs to patent examiners. As such, the impact of observations in the pre-grant patent prosecution process remains marginal. For instance, in the case of Myriad's BRCA gene patents, several observations were submitted to the Examination Division from a variety of actors (e.g. hospitals, scientists, research laboratories, patient organizations, see Table 1), who claimed that the patent application failed to fulfill the patentability standards. However, a patent was still granted, which led to many opposition filings, appeals and long debates until a final decision was made. Opposition filings started in 2001 and the final decision was made in 2008, corresponding to seven years of uncertainty.

The specific structure of the "grant only" European patent system has caused it to care little about providing a more responsive patent. EPO has continued its tradition of perceiving patenting as an essentially legal-technical exercise, focusing only on granting patents based on patentability criteria and not on the consequences of a patent being granted. However, since biotechnology inventions have often led to the risk of undermining scientific research, medical advancement, patient care and

health-care systems, the European patent system needs to develop more reflective and new institutional fora for public participation, which would persuade other actors and disciplines to participate in the patent prosecution process. EPO should be able to adapt to an ever-changing socio-political and scientific environment, and to focus on assessing the accuracy, safety and usefulness of certain products and processes.

Patent impact assessment: practice and theory

The EPC has left the management of patent impact assessment to the discretion of national courts and post-grant procedures (Schneider 2009a, Ullrich 2006). In principle, the national implementation process can be considered as a valuable corrective mechanism to centralized patent granting politics, even though not all countries have yet developed a reliable patent framework. To determine how national authorities deal with patent matters, we gathered data from official documents, patent law firms and IP consultants' reports[19] and from several patent officials. These data reveal that most of the national courts in the EU Member States do not have specialized patent courts, and lack the necessary technical and scientific expertise to interpret substantive patent law and assess the validity of European patents.

A specialized patent expertise is essential as it permits "fast court proceedings", "low error rates in first instance", and most importantly "fast jurisdictional feedback" to the administrators of the patent system (patent examiners) (Harhoff 2009). However, only nine EU countries (out of 27) have well-established specialized patent courts to deal specifically with patent litigation matters.[20] Furthermore, in most EU countries, national courts do not have a sufficiently well-trained staff to deal with IP cases since these courts do not require judges either to have knowledge of technical/scientific matters (e.g. to have a higher degree in such scientific subjects as chemistry or engineering) or to be professionally trained in intellectual property rights (IPRs). Only in five countries do the national courts require judges to advance their knowledge on scientific or technical matters,[21] whereas the requirement for judges to have professional legal expertise on patent issues is mandatory in 16 national courts.[22] Often, patent infringement issues are adjudicated by poorly trained staff that are unable to effectively assess the impact of new products and processes. Nevertheless, only in nine countries have national courts tried to overcome these gaps in IP and technical expertise by inviting external experts (on an *ad hoc* basis) to provide reports/opinions on sensitive patent matters.[23]

The lack of specialized expertise has resulted in differences in the application and interpretation of substantive patent law, which has often led to an ambivalent settlement of negotiations, and to a fragmented and uncertain assessment of the impact of patent claims. Although this may not be a national problem, as each country may deal with sensitive issues by applying exclusionary provisions that are in line with its own social values, problems arise when attempts are made to streamline the regional European patent system.

Acknowledging the current patentability trends and challenges, patent scholars (Burke and Reitzig 2007, Edfjäll 2007, Elsmore 2009, Shang 2009, van Pottelsberghe de la Potterie 2009, Wagner 2009, White 2004) and policy-makers (Cowan *et al*. 2006, European Commission 2008) have also attempted to provide a theoretical approach to the issue of patent impact assessment. They have proposed different mechanisms that can be used by patent offices and examiners to foster the assessment and the

quality of patents. Scholarly debates lead to four broadly defined mechanisms: administrative changes, patent law changes, technical advancement for patent examiners and better information for patent applicants and examiners.

Administrative changes

Perhaps the most complete conception on administrative changes is set forth in Wagner (2009). Wagner claims that administrative changes are of significant importance for the patent offices and examiners to cope with new technology and innovation requirements. By clearly addressing the current challenges of technology development, patent scholars argue that effective administrative reforms could be achieved if patent offices introduced supportive or other financial means to increase the number of patent examiners in specific technical fields and to encourage feedback on low-quality patents. White (2004) adds to this debate, asserting that supportive means are also important for applicants to make their applications public and to provide for "concise and precise" claims when filing patent applications. However, the analyses of Merrill *et al*. (2004) and Shang (2009) move beyond these arguments. These scholars identify other administrative strategies for improving the patent assessment, central among these being the patent examination guidelines and processes. They argue for an improved patent examination and pre-granting opposition process, and for better quality assurance techniques. In this respect, Shang (2009) contends that the inclusion of third parties (i.e. inter partes re-examination and post-grant reviews) in the examination process provides an added value to the assessment of the validity of questionable inventions.

Patent law and organizational changes

An increase in the number of patent applications, financial means, quality assurance techniques and validity claims cannot be achieved without substantive changes in patent law. To respond to the challenges of new technologies and enhance the validity of patents, patent offices should provide for efficient legislative actions and reconsider their regulatory framework, examination procedures and organizational structure (Cowan *et al*. 2006). Regarding complex technologies, Elsmore (2009) and Merrill *et al*. (2004) suggest the improvement of the requirements for defining the patentable subject matter and for applying the patentability standards. For instance, examiners should note that, in new emerging technologies (e.g. biotechnology, nanotechnology) with higher opportunities for research productivity, even the smallest efforts could lead to significant inventions, whereas in other mature technologies (chemistry or mechanics) with less technical and research opportunities, significant effort will still result in minor improvements (Guellec and van Pottelsberghe de la Potterie 2007). As such, the inventive step should be higher in the former case, since the technology evolves faster and a low inventive step will encourage simple improvements to supersede other inventions and block the development of other inventions. Under these mechanisms, patent examiners and offices will be able to achieve mutual agreements about the patentability of new technology developments. However, because patent law is a specialized field with many active players, high-quality patents will be issued only if patent offices balance the interests of active and passive users, and legislate an "open review procedure" that allows third parties to challenge patents (Wagner 2009). Additionally, patent

offices should improve their management structure and accountability, and reformulate their patent information policy (Edfjäll 2007).

Technical advancement of examiners

Patent scholars place the working performance of patent examiners at the center of a study of patent quality enhancement. Recent work by van Pottelsberghe de la Potterie (2009) indicates that backlogs and falling quality of patent applications can be easily reduced through training schemes that foster the performance of the patent examiners. In this respect, patent offices need to establish qualification mechanisms (i.e. tests, ongoing examinations and coaching services) and recruit or promote examiners based on their relevant skills.

Better patent information to patent applicants and examiners

The growing complexity of the new inventions has made it more difficult for examiners to understand these technologies, because much of the prior art is widespread to the public or other actors specialized in the field rather than in patent databases. Academic literature indicates that the assessment of patents is most often associated with the clarity of information in patent claims and the examination procedure (Cowan *et al*. 2006, Harhoff 2009). Patent information on patent claims provided by applicants contributes to the clarity of patents and leads to a more cost-effective examination process. Therefore, patent offices should allocate additional resources to examiners and ensure ongoing deliberations between applicants and patent authorities on the patentability of various subject matters. Other scholars claim that patent examiners' access to literature, i.e. scientific and patent literature and collaboration with commercial patent information providers or other institutions specialized in protecting certain industries, provides for high-quality outcomes (Elsmore 2009, White 2004). Burke and Reitzig (2007) contribute to this debate and state that patent applicants will be able to conduct thorough claim-construction analyses only if patent offices disseminate all data collection to the public, publish all patents in force and encourage better cooperation among information providers and information users.

Taken together these mechanisms suggest that the involvement of various actors and the inclusion of "external expertise in areas that are not much represented in patent offices" are crucial to ensuring legitimate patent outcomes. However, most of these mechanisms do not explain how such expertise can be incorporated into the patent prosecution process to improve the assessment of applications and encourage sustainable property rights. The EPO continues to deal with sensitive issues that require foresight and precaution on an *ad hoc* basis, as exercised by the *ad hoc* Sensitive Cases Board. This Board has not proven to be suitable for dealing with sensitive cases since it does not include members from the various disciplines who would be able to assess the impact of patents on a regular basis (Schneider 2009a).

Policy recommendations and conclusions

To improve the positive benefits of patents and reduce their negative impact, the EPO should contribute more to improving its pre-grant patent management and it

should be more aware of the consequences that its outputs (i.e. patents) may bring to the scientific community and society at large. Indeed, the Biotechnology Directive has to a certain extent settled the legality of patenting biotechnology, but it has failed to satisfy certain stakeholders, who have used the patent prosecution processes as a downstream mechanism to influence the scope of the protection of newly emerging technologies. Following the patent controversies on genes and hESCs, the EPO has admitted that it created controversy by imprudently granting patents that breached EPC provisions, in addition to the inability of the patent examiners to counter severe opposition without public support. This supports a crucial argument for extending the collaboration among these entities as a vital mechanism for managing the impact of sensitive patent matters. Policy-makers should acknowledge that, as technologies continue to evolve, so will the scientific sophistication of civil society and other professional communities, which will welcome the use of new products and processes. Therefore, policy-makers should not underestimate the ability of stakeholders and civil society groups to evaluate new technologies, but must ensure ongoing feedback and interaction with the end-users of the protected inventions. The European Parliament, along with several national expert entities and political authorities, has commented robustly on the need to develop better regulatory guidance and expertise for the granting of patents and better impact assessment procedures.[24] However, these comments do not suggest how such expertise might be incorporated into the European patent regulatory framework. For that reason, we argue that a necessary first step for the EPO is to establish a pre-grant patent advisory body that would control and reduce the probability that patent examiners would issue low-quality patents that harm the innovation process and have undesirable ethical and social consequences. In this respect, an essential starting point in implementing pre-grant patent assessment and deliberation is to decide how to provide such an advisory body and its possible composition.

The EPO patent database[25] reveals that patent applications primarily fall into 14 technical fields ranging from electricity and semiconductors, human necessities and biotechnology to vehicles and general technology, which certainly do not have the same level of innovative intensity and sensitivity. For example, even though certain industries (i.e. telecommunications and machinery) are very dynamic, as shown by the number of patent applications and grants in these fields, they are certainly not as socially sensitive as biotechnology, pharmaceuticals and medical engineering. Thus, to ensure that the pre-grant patent advisory staff have detailed information from various industries, the EPO should ensure that the advisory body includes: (a) at least one expert from each technical field in the EPO (who would represent and have knowledge about the novelty and state of the art); (b) ethicists (in the fields where they are most needed); and (c) lawyers and economists engaged in assessing the eligibility and impact of the claimed inventions.

In 2004, the EPO decided to employ a chief economist on a rotating two-year basis, which goes some way towards a multidisciplinary assessment of a patent's impact, although the EPO should certainly not focus on economic issues only (Schneider 2009a). To address various sets of interests in society, the pre-grant patent advisory body should also involve academics and scientists who would share knowledge and material with other researchers (e.g. peer review of specific patent claims), and collaborate closely with other national groups or committees to produce reports on IP regulation in response to certain ethical or social issues. Such an *ex-ante* network of cooperation, collective learning and sharing of experience and

expertise would increase awareness about the new inventions that are likely to be protected in future and improve the contribution of the patent law to the public good. It would also provide additional resources, ongoing deliberations and greater legal certainty to the patent authorities when determining the eligibility, scope and impact of inventions in which prior art and industrial applicability can hardly be understood by employing standard resources. An *ex-ante* management of the patent claims could also serve as an effective mechanism for the EPO Examination Board to make informed decisions about hiring or training patent examiners.

Most importantly, a pre-grant patent advisory body would strengthen the analytical capacities of the EPO since it would have to determine which actors need to be involved (i.e. from the scientific community, industry, NGOs or other special interest groups) so as to provide additional data to the patent advisory staff for pre-grant patent assessment decisions and evaluations. For instance, when considering the developments of the hESCs as well as the wide range of gene technologies, many countries have established Bioethics Committees[26] and Human Genetics Societies,[27] which produce reports on the regulation of new scientific developments. Biotechnology and human gene technology have attracted the attention of certain societies at the European level as well. At this point, the European Society of Human Genetics and the European Federation of Biotechnology have actively provided recommendations, research and reports on gene patenting, genetic diagnosis and public health aspects. A pre-grant patent advisory body may communicate with these committees and societies in order to receive information regarding issues that relate to biotechnology and to become acquainted with the public's perception of such technologies. This would guide patent examiners towards a multidisciplinary foresight and *ex-ante* patent impact assessment, avoiding therefore the negative implications that the newly emerging technologies could pose to wider socio-economic values.

Notes

1. Patent claims define the scope of the protection that the inventor seeks in a patent application.
2. According to the OECD definition, gene patents relate to one of the following four categories: "1) whole genes or parts of them, 2) proteins that the genes encode as well as their function in organisms, 3) vectors used for the transfer of genes from one organism to another or 4) genetically modified cells or organisms used for the making of genetically modified products and the uses of genetic sequences or proteins for genetic tests". Available from: http://www.theinnovationpartnership.org/data/ieg/documents/cases/TIP_Myriad_Legal.pdf [Accessed August, 2010].
3. Recent estimates indicate that a search of 100 sequences requires approximately 15 hours of computing time, whereas it takes 65 hours of examiner time to evaluate these search results.
4. High-quality patents should meet patentability requirements, contribute to the state of the art, offer scientific/social benefit and stand up to the most rigorous challenges in court.
5. Current estimates by Holzer (2005) and Harhoff (2009) indicate that the number of patent opposition cases in Europe is about 1260 per year, 600–700 instances of which relate to European patents. Most of the litigation comes from electrical engineering (165 cases), pharmaceuticals (149 cases), organic chemistry (including biotechnology with 141 cases) and mechanical engineering (139 cases). Cohen *et al.* (2008) add to this debate, claiming

that litigation relating to biotechnology patents is likely to increase in Europe as the industry increases in size and complexity.

6. The European patent system is not exclusive; patent applicants can also obtain strictly national patents if they are only interested in obtaining patent protection in one or a few of the EPC Contracting States.
7. Following these examinations, the EPC might provide the applicant with an opportunity to amend those claims that do not fulfill patentability requirements, whereas the Examination Division may conduct an additional examination of these amended claims.
8. During the "Plants/NOVARTIS" case, the EBOA (referring to the new Rule 23c EPC) rendered plants patentable inventions if the patentability criteria are fulfilled.
9. BRCA1 gene patents awarded Myriad exclusive ownership of genetic testing for hereditary breast cancer, exclusive rights to the isolated BRCA1 gene and to the use of genes in cancer diagnosis. BRCA2 gene patents granted rights to the detection of one specific BRCA2 mutation in a particular population.
10. See Press Office, 2001. *Institut Curie against Myriad Genetics' monopoly on tests for predisposition to breast and ovarian cancer*. Available from: http://www.curie.fr/upload/presse/myriadopposition6sept01_gb.pdf
11. See Press Release, 2002. *Institut Curie, European-wide opposition against the breast cancer patents*. Available from: http://www.curie.fr/upload/presse/europeanoppmyriad_sept02_gb.pdf
12. See note 10.
13. See Niklas Mattsson's comment on "BRCA patents in Europe", The Awapatent's IP blog, comment posted on 4 January 2010. Available from: http://www.awapatent.dk/?id = 14709&threadid = 16679
14. See also *Managing intellectual property: clash over stem cell patents in Europe*. Available from: http://www.managingip.com/Article.aspx?ArticleID = 1675644
15. EGE is an independent, multidisciplinary body that provides advice to the European Commission on ethical aspects of science and new technologies. Some of the EGE opinions have been very valuable to the development of biotechnology, but during the "Edinburgh" case EGE's opinion (Opinion no. 16) was considered inconsistent and outside patent law and Biotechnology Directive provisions. See EGE, 2008. *Opinion no 16: patentability of stem cells the view of the European Group of Ethics*. Available from: http://www.grunecker.com/download/publications/stemcells.pdf
16. Pluripotent cells mean that these cells may be different from many other cell types, but not from all possible cell types (Sterckx 2008).
17. See also note 11.
18. See *European Patent Convention 1973. Part V opposition procedure.* Available from: http://www.epo.org/patents/law/legal-texts/html/epc/1973/e/ar99.html
19. Reports from the corporate and private IP professionals on the practice of the EPO and national courts have been published in the *Intellectual asset management* magazine. Available from: http://www.iam-magazine.com
20. Austria, France, Italy, Netherlands, Germany, Spain, Sweden, the UK and Hungary.
21. Austria, Hungary, Netherlands, Sweden and the UK.
22. Austria, Belgium, Finland, France, Germany, Hungary, Ireland, Italy, Latvia, Luxembourg, Netherlands, Romania, Slovakia, Spain, Sweden and the UK.
23. Belgium, Denmark, Germany, Greece, Italy, Lithuania, Poland, Slovenia and Spain.
24. Following the gene patent controversies in 2005, the European Parliament also emphasized the need for the "EPO to establish a body that would check patents that are sensitive from an ethical point of view before they are granted" (Salter 2009).
25. According to the EPO database, there are 14 technical fields that deal with the majority of patent applications. For more information on technical fields, see *The EPO Patent Database: European patent applications per technical field and origin*. Available from: http://www.epo.org/about-us/office/statistics/applications.html
26. For more information on the National Bioethics Committees, see Salter and Salter (2007).
27. See Moses, V. et al., 2002. *Biotechnology: educating the European public – final report*. Brussels: European Commission.

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