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Whose knowledge? What values? The comparative politics of patenting life forms in the United States and Europe

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Abstract Over the past few decades, a variety of groups have begun to argue that the US and European patent systems do not adequately represent the public interest in their decision making and that they need to undergo fundamental changes to their structure and orientation. These challengers have adopted similar strategies—in terms of the venues chosen and the arguments, evidence, and rhetoric used—in each context. However, they have experienced more success in Europe than in the United States. This paper begins to explain this difference by arguing that the US and European patent policy domains have different "expertise barriers"—formal and informal rules that make it difficult for those without the knowledge that is recognized as relevant and legitimate in that domain to engage as equals.

Keywords Intellectual property · Biotechnology · Ethics · Governance · Expertise · Democracy

Over the past few decades, patent systems have become quite controversial. Some scholars and interest groups question whether the current system fulfills its intended functions, to stimulate innovation and economic growth (Benjamin and Rai 2008; Heller and Eisenberg 1998). Others offer a more fundamental challenge, arguing that given the centrality of technology in contemporary societies, patents have profound social, ethical, environmental, and health impacts that the system must consider (Bagley 2007; Kadidal 1996). In this paper, I explore the latter challenges and the responses of the US and European patent systems to these challenges, focusing on controversies over patents on life forms. As we shall see, the environmental activists, animal rights organizations, patient groups, and others advocating attention to the broad implications of patents have made their arguments by trying to introduce new forms of evidence, expertise, and reasoning into the domain; thus, this controversy provides an excellent opportunity to explore how policy domains contend with alternative forms of knowledge and reasoning. Indeed, US and European

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patent policy domains have responded quite differently. The European Parliament has passed legislation that includes some concessions to challengers, and the European Patent Office (EPO) has acknowledged challengers' arguments through its treatment of individual patents and slight shifts in its culture. In the United States, by contrast, these concerns have fallen mostly on deaf ears. Given the similarities between these two contexts, in terms of their level of economic development, the basic structures of their patent systems, and their efforts at harmonization, this difference seems surprising. What explains the contrast?

In this article, I argue that the different responses to challengers of the US and European patent systems can be explained, at least in part, by differences in what I call the "expertise barriers" of the two policy domains in the United States and Europe (Parthasarathy 2010). By expertise barrier, I mean the formal and informal rules of a policymaking domain that make it difficult for those without knowledge that is recognized as relevant and legitimate to engage as equals. The expertise barrier also shapes how a domain deals with alternative forms of evidence, expertise, and reasoning that insiders have not previously considered. While all policy domains have expertise barriers, they are particularly high in science and technology policy domains due to the technical nature of discussion and the backgrounds of the players who usually participate. Over the course of its history, and through the development of its institutions, legal and regulatory frameworks, stakeholders, rhetoric, and cultural norms and values, a policy domain establishes the types of knowledge, expertise, and reasoning that are relevant and legitimate. As this occurs, a barrier forms that makes it difficult not only for non-experts to participate in policy discussion but also for participants in the policy domain to consider seriously new forms of knowledge and expertise. The relative openness of a policy domain's expertise barrier depends on the nature of the issue in focus, the structural and cultural dimensions of its domain, and its context. We will see that in the US, the patent policy domain has developed dominant narratives, institutional arrangements, and legal and regulatory frameworks that make it difficult for insiders to consider seriously new forms of knowledge and expertise. In the European patent policy domain, by contrast, these same elements have created more opportunities for outsiders to introduce new forms of knowledge and expertise.

Scholars of the policy process have argued that policy domains invariably develop a particular "way of knowing" or "bounded rationality" that shapes the types of knowledge and expertise considered in the policy process (Feldman et al. 2006; Sabatier 2007; Schlager 2007; Yanow 2009). However, we know little about how such ways of knowing emerge, how they are maintained, and how they respond to challenge. Simultaneously, while scholars of the policy process, social movements, and science & technology studies have demonstrated that outsiders invariably try to challenge the knowledge and expertise that insiders deem legitimate when they try to influence policy domains (Brown et al. 2004; Epstein 1996; Hess 2007; Ottinger 2010; Pralle 2006), researchers have paid less attention to the nature and dynamics of resistance that outsiders face and the interactions between outsiders and insiders (one exception is: Tilly and Tarrow 2006). The "expertise barrier" concept facilitates this type of analysis by focusing our attention on how a policy domain defines relevant knowledge and also how it handles challenges to its definition of relevant knowledge. It also helps us think critically about the factors that shape the politics of knowledge in a policy domain.

This article begins with a brief introduction to the US and European patent policy domains, including attention to the formation of the expertise barriers in each. It then compares the growing challenges to patents on life forms in the United States and Europe, exploring how expertise barriers shaped the nature of these challenges. It then describes how the US and European domains have responded to these challenges. This paper is based

on qualitative case study analysis conducted from 2007 to 2010, which included over 100 interviews with US and European patent office officials, advocacy groups, and other stakeholders[1]; document analysis of patent office publications, individual patents (and associated documents, including challenges and oppositions), and transcripts of Congressional, Parliamentary, and patent office hearings; and participant observation at multiple patent office hearings and meetings.

The patent policy context

United States

Patent policy in the United States originates in the Constitution, which established a property right for inventors for a limited period of time, in return for public disclosure about the details of the invention. Congress specified the system further in the 1790 and 1793 Patent Acts, creating a transparent and easy to access system would stimulate innovation and therefore foster economic growth (Khan 2005).

Over the past two centuries, the US patent policy domain has become increasingly specialized. First, in 1836, Congress established the Patent Office (now the Patent and Trademark Office), a bureaucracy dedicated to processing patent applications (Patent Act of 1836). Although in the Patent Office's early years most examiners were legal clerks, by the end of the nineteen century they were scientifically trained personnel who received legal training once they took the position (Swanson 2009). Examiners assess the novelty, inventiveness, and utility of proposed inventions on the basis of their technical expertise and with the help of the Manual of Patent Examination Practice (which summarizes the relevant statutes and case law). As a result, in order to earn a patent today, applicants have to be aware of both the law and the scientific prior art (literature on related discoveries and inventions). Second, as the domain has become both legally and scientifically technical, the groups who participate in the policymaking process have similarly high levels of training and expertise in both of these areas. Not surprisingly, this means that the same players—patent lawyers and representatives of major universities and companies—appear over and over again as witnesses at Congressional hearings and as authors of amicus briefs to the courts. These insiders generally agree on the importance of robust and expansive patent rights. Third, while Congress established strong involvement in the Patent Office (Duffy 2000), very few committees have overseen patent-related discussions (initially the House Committee on Patents and now, the House Judiciary Committee). These committees

[1] In particular, I interviewed: (1) current and former personnel at the PTO and the EPO, including those involved in public relations and communication, mid- and high-level management, examination in controversial areas including biotechnology and traditional knowledge, patent law interpretation, and patent search activities; (2) advocacy groups involved in challenging the patent systems in the US and Europe and the patent lawyers who represent them; (3) scholars (including legal scholars) involved in debates about patent policy in the US and Europe; and (4) companies and industrial lobbying organizations involved in patent policy debates in the US and Europe. In order to determine who to interview, I began by identifying—through analysis of relevant media sources, websites, patent office proceedings, and legislative hearings, among other things—all of the individuals who might be relevant to my study. After making contact with these individuals, I was able to interview the vast majority of them. I then used a snowball sampling methodology (asking these interviewees about additional contacts) to identify additional interviewees. Again, I continued to snowball sample until I had interviewed (or tried to interview) everyone who was suggested. In sum, I interviewed: 27 stakeholders, 21 patent lawyers and scholars, and 58 current and former patent office officials.

concentrate on ensuring that the Office works properly, and rarely examine the foundations of the system itself.

Fourth, while third parties can lobby members of the Congressional committee that oversees patents, and they can contest a patent through a lengthy and costly court battle, they have limited opportunities to influence the PTO itself. Although the PTO created a "re-examination" mechanism in 1980 that allows any third party to challenge a patent on the basis of newly discovered "prior art", this re-examination was only "ex parte": once it filed its re-examination request, the third party could not participate any further in the review of the patent (the PTO would communicate solely with the patent holder). While a recent change now allows third parties to continue to submit arguments and evidence throughout the PTO's re-examination, it still restricts the scope of the challenge to prior art. Finally, judicial oversight has recently become quite narrow. Traditionally, patent cases travelled a similar path as other legal cases. District courts heard them first, they were then referred to appeals courts, and finally, the Supreme Court. Today, however, the Court of Appeals for the Federal Circuit handles all patent appeals (Adelman 1986). While this change has meant that one court could establish patent expertise, it has also restricted the number of judicial perspectives that are brought to bear on patent issues (Merz and Pace 1994). Of course, the Supreme Court still hears cases that are appealed after CAFC decisions.

In sum, the patent policy domain in the United States is made up of a few highly specialized institutions, bureaucrats, and stakeholders. Most of the players in this domain have both legal and either scientific or engineering training. Given this environment, discussions are usually narrow and highly technical, and opportunities for broad reflection are few. These structural and cultural dimensions have led to the development of a particularly strong expertise barrier. As we will see, outsiders find it extremely difficult to penetrate the domain and to introduce alternative forms of knowledge and expertise that will be considered seriously by insiders.

Europe

In many respects, the European patent policy domain looks quite similar to its US counterpart. It has similar institutions, bureaucrats, and stakeholders and has traditionally privileged the same kinds of knowledge and expertise (Drahos 2010; Jensen et al. 2005). The European Patent Office grants patents, and its personnel have scientific or engineering training and gain patent law expertise on the job. Statutes, precedents set by legal cases, and a manual of examination guidelines guide the work of examiners. The EPO is subject to both legislative and judicial oversight, and the major stakeholders are patent lawyers, large companies, and, to a lesser extent, universities and small inventors. However, there are a few differences that have led to the formation of a more porous expertise barrier in the European patent policy domain.

First, as a pan-governmental organization outside the European Union, the EPO cannot rely on other institutions to develop and maintain its political legitimacy. After decades of negotiation, seven countries signed the European Patent Convention in 1977 in order to strengthen the regional economy (now there are 37 signatories) (Consultative Assembly of the Council of Europe 1949; European Patent Convention 1973). Because it included signatories from non-EU countries, the EPC was not formally connected to the European Union and established new institutions and new governance frameworks. It created the European Patent Organization, which includes the European Patent Office and an Administrative Council that oversees it. The European Patent Office manages a centralized

patent receiving, examination, and granting system for all of its member countries, but it leaves room for national differences. Once the EPO grants a patent, the patent becomes one or more national patents (depending on the request of and fees paid by the inventor). Although patent challengers can then take advantage of the court system in each national jurisdiction, the central nature of the EPO leads many to take advantage of its internal judicial system, which allows challengers to oppose its decisions and provides two levels of appeal (the Technical Board of Appeal and the Enlarged Board of Appeal). Meanwhile, the Administrative Council, made up of representatives from the member countries, provides legislative oversight (European Patent Office 2009).

Second, the EPC also ensured respect for national differences by including a clause that states that no patent can be granted if it is contrary to "ordre public [translated from French, public policy] or morality" (Consultative Assembly of the Council of Europe 1949). Designed to ensure respect for cultural and legal differences between countries, it has appeared in numerous pan-European treaties and was uncontroversial when negotiators included it in the EPC. However, we shall see that it inadvertently created an opportunity for outsiders to introduce new forms of knowledge and expertise into the European patent policy domain.

Third, the European patent policy domain has more, and more extensive, opportunities for stakeholder involvement. In contrast to the PTO's re-examination process, the EPC established an opposition mechanism that allowed any third party to challenge a patent on any of the grounds of its issue within 9 months. Policymakers and patent offices initially established both the US and European mechanisms to provide quality control, so that competitors could challenge patents outside a slow-moving court system (Graham et al. 2002). Viewed from this perspective, the differences between the re-examination and opposition mechanisms seem minor. However, as we will see, differences between the two processes shaped the introduction of forms of knowledge and expertise that were new to the domain, and the responses of the patent systems. Challenges over novelty and inventive step, the only grounds for re-examination mechanism in the United States, usually required the invocation of scientific and/or engineering expertise. In Europe, however, because third parties could challenge patents on any grounds—including inventive step and ordre public—the EPO inadvertently invited submission of non-traditional evidence including bioethics articles, policy reports, and public opinion polls.

The final major difference between the US and European patent policy domains for the purposes of this analysis is their contexts: the politics of science and technology in the two regions. Many scholars have observed that trust in both scientific and science policy institutions has declined more rapidly in Europe than in the United States and that Europe has experienced greater mobilization against the science and technology policy establishment (Jasanoff 2007; Levidow et al. 2005). Furthermore, over the past 30 years, the US and Europe have adopted rather different logics for regulating emerging technologies including genetically modified organisms (Tickner and Wright 2003; Vogel 2004). Not only have European policymakers embraced the "precautionary principle" (placing the burden on the producers to prove that a technology is safe), but they have also begun to consider social and ecological knowledge alongside more traditional forms of quantitative scientific knowledge when trying to resolve environmental policy issues. Although these politics would not affect directly the politics of the patent policy domains in either context, one could easily imagine that participants in the European patent policy domain might be more predisposed to appreciating the value of new forms of knowledge and expertise articulated by challengers in the context of what was happening around them.

The rise of challengers

United States

Using the courts and congress

Mobilization against the patent system began in 1980, when the US Supreme Court heard the *Diamond* vs. *Chakrabarty* case. The case focused on the patentability of an oil-eating micro-organism created by Ananda Chakrabarty, a scientist at General Electric, but the Supreme Court asked a broader question: are living organisms patentable? As with previous patent cases, multiple third parties—including patent law associations, biotechnology companies, universities, and individual scientists—submitted amicus briefs discussing their interests in and opinions on the case. One of these briefs came from a coalition of groups led by Jeremy Rifkin, who had already distinguished himself as a critic and watchdog of biotechnology. This brief (People's Business Commission 1980) was different from others in a few ways. First, of the 15 briefs submitted, it was the only one opposed to patents on life forms. Second, it was submitted by groups, including environmental and development organizations, who had not intervened in patent cases before. They had no direct financial interest in the patentability of the micro-organism (or life forms more generally) and focused on the ethical, social, and ecological implications of allowing such patents. Third, they supported their arguments with evidence, expertise, and reasoning not traditionally seen in patent cases. In one section, for example, the authors argued that rather than focusing on the economic benefits that patents on life forms could bring, policymakers should adopt a deontological approach that considered the ethics of patenting life forms in and of themselves. They supported their perspective by referring to the scholarship of famous French and American philosophers and bioethicists, experts that were not traditionally seen as relevant to patent law. The other briefs responded by reinforcing the patent policy domain's expertise barrier; the Rifkin coalition's concerns, they argued, were irrelevant and betrayed a misunderstanding of how the system worked. The American Patent Law Association (1979: 21) stated, for example, "The Patent and Trademark Office well knows that its function is to *examine* inventions presented to it for compliance with the patent statutes, not to *regulate* hazardous research. [emphasis in original]." In a 5–4 decision, the Supreme Court sided with the traditional stakeholders, ruling that "anything under the sun made by man," including life forms could be patented. While it acknowledged that the coalition's concerns might have some validity, it argued that the executive and legislative branches should address them.

Despite the Supreme Court's suggestion, the US Congress did not take up the issue until 6 years later, after PTO Commissioner Donald Quigg issued a memo stating that the Office considered all non-human animals to be patentable (Quigg 1987). By this time, the PTO had already issued patents on plants and lower-order animals and had begun to receive patent applications on higher-order genetically engineered animals, including an animal genetically engineered to contract cancer (known as Oncomouse). Rifkin's coalition, which had grown and become more diverse by this time, protested the policy and urged Congress to respond (Schneider 1987). Days later, Congress asked the PTO to establish a temporary moratorium on animal patents so it could study the issue, and throughout 1987 the House Judiciary Committee held four related hearings in Washington, DC and Wisconsin (US House of Representatives 1988). As with the *Chakrabarty* case, in addition to testimony from patent lawyers, industry representatives, university officials, and individual scientists, Congress heard from farmers, animal rights activists, environmental groups, and religious

figures who had not participated in patent policymaking before and who were almost universally opposed to the expansion in patentability. The arguments made by these new participants echoed the Rifkin-led amicus brief in *Chakrabarty*, using alternative types of knowledge, expertise, and forms of reasoning. For example, they used ecological evidence and expertise to argue that animal patents could lead to a loss in species diversity, which would be bad for both agriculture and the ecosystem (US House of Representatives 1988: 104).

Just as in the *Chakrabarty* case, patent policy insiders tried to keep out any novel forms of knowledge or reasoning that would have challenged their power and the established ways of thinking about patent policymaking. They did this by classifying the contributions of outsiders as subjective "opinions" or "ethics", which had no place in this technical domain. A vice president of Integrated Genetics, a biotechnology company, noted, "We are cognizant of the differences of opinion on these matters but submit that the ethical issues raised are not germane to the question of patenting animals. Indeed, we support the view put forward by William H. Duffey (Monsanto) in his testimony of the 21st of July that the patent system is certainly the wrong place to regulate matters of ethical, social, or moral concern. [emphasis added]" (US House of Representatives 1988: 464).

The PTO ended its moratorium on patents covering higher-forms of life in April 1988, by allowing a patent on the Oncomouse (Schneider 1988). Congress chose not to respond and in 1990, the growing coalition of groups against animal patents tried again in another venue: they sued the PTO (Animal Legal Defense Fund et al. vs. Quigg 1990). They argued that Commissioner Quigg had developed the PTO's animal patent policy without any opportunity for public comment and therefore violated administrative law. However, the Court of Appeals for the Federal Circuit ruled that the challengers (led by the Animal Legal Defense Fund) had no legal standing and therefore could not sue. The challengers could not find a way in and could not force anyone to consider their arguments seriously.

Attacking the PTO

When their Congressional and judicial efforts proved unsuccessful, challengers targeted what seemed like the most closed venue of all: the PTO itself. The re-examination mechanism was quite limited, and opportunities for public comment were extremely rare and difficult for outsiders to access. However, the benefits of a successful campaign could be great, because it might force the technical bureaucracy at the center of this policy domain to rethink its rules and practices.

Challengers used the patent application process first. In 1997, Jeremy Rifkin and Stuart Newman, a developmental biologist from New York Medical College affiliated with the Council for Responsible Genetics, a watchdog group focused on biotechnologies, applied for a patent covering a chimeric embryo comprised of both human and non-human animal cells (Newman 1997). Newman and Rifkin wanted the public to see that, even when it made socially significant patent decisions, PTO considered solely the scientific context and the limits of the law. They believed that if they could expose how PTO made decisions, there would be a public uproar and pressure on the bureaucracy to develop processes that considered other forms of knowledge, expertise, and forms of reasoning that, in their eyes, better represented the public interest.

Given these goals, Newman and Rifkin immediately leaked news of their application to the media, speaking to National Public Radio, ABC News, and the Washington Post (McKenzie 1998; Weiss 1998; Zwerdling 1998). In these interviews, they explained the reasons behind the application and argued that if PTO did not do a better job of

incorporating knowledge about the implications of patents into its decision making, it would lead to these types of shocking patents (and the commercialization of these kinds of inventions). Newman, for example, emphasized that his ideal approach would include the incorporation of explicit moral reasoning developed through deliberative democratic methods (Bearden, 2005).

PTO officials responded to the invention and the accompanying publicity with anger at this interference in their expert space. They were accustomed to understanding and addressing the public interest through the lenses of their traditional stakeholders, rather than hearing from activists or the media. The PTO Commissioner at the time, Bruce Lehman, noted later that he did "not believe there should be a prohibition against a human patent…I was just deeply offended by anyone attempting to use the US Patent Office to make a point, or to stop the advancement of science. I refused to make it easy for [Rifkin and Newman]" (Dowie, 2004). While Newman and Rifkin argued that as citizens, they had as much right as anyone else to access and engage with the patent system, bureaucrats (and traditional stakeholders) responded by trying to re-emphasize the rules of participation that separated PTO decision making from the political arena. These people, and these arguments, simply did not belong. Just as the pro-patent stakeholders had argued in the Chakrabarty case and in Congressional hearings, that the evidence, expertise, and reasoning raised by the activist coalition had no place in expert discussions about patent policy, the Commissioner argued that PTO itself was a legal, economic, and scientific space not to be exposed to alternative forms of knowledge and reasoning.

In the face of mounting press coverage, PTO officials could not dismiss the issue entirely and treated it as a public relations problem. They issued a Media Advisory immediately after Newman and Rifkin began their promotional efforts, which stated that PTO would not grant a patent which it deemed to be "injurious to the well being, good policy, or good morals of society," due to a "moral utility" doctrine developed by the courts (US Patent and Trademark Office 1998; Coughlin 2006). However, PTO had never before invoked this doctrine with regard to biotechnology. It also had not figured in the Chakrabarty case, the Congressional debates over animal patents or PTO's guidelines for patent examination. It was therefore unclear what moral utility meant—how, exactly, would it be incorporated into decision-making processes, given PTO's traditional focus on legal precedent, scientific evidence, and to a lesser extent, economic concerns? Lehman had stated publicly that he would not allow patents on "monsters or other immoral" inventions (Greene 1999). This suggested that deontological reasoning might be invoked with an absolute prohibition placed on patenting certain inventions. However, PTO did not detail this reasoning (or any prohibitions) further. Thus, it seemed that this "moral utility" doctrine had been invoked purely rhetorically, to reassure the public.

Not surprisingly, PTO did not use the concept of moral utility in the actual prosecution of the Newman/Rifkin patent. Instead, Deborah Crouch, the examiner assigned to the application, simply argued that the proposed invention was unpatentable because it "embraced" a human being (Crouch and Coyne 1999). The 1987 Quigg memo, discussed earlier, had only allowed patents on "non-human" animals. (An established form of reasoning—in this case, legal—had been used to justify a boundary to patentability.) Although Crouch seemed to use the Quigg memo to avoid a discussion about moral utility, Rifkin and Newman still tried to uncover the reasoning and evidence behind PTO's definition of a human being—arguing repeatedly that the chimera invention was an animal, rather than a human. Crouch responded to these arguments by simply restating PTO's position, and not indulging the requests for more clarification regarding the office's logic

(Crouch and Coyne 1999; Coyne and Crouch 1999). Newman and Rifkin finally abandoned their application in 2005.

Since the chimera application, challenges to the PTO's decision-making processes have grown. Most of these challenges have used the PTO's re-examination mechanism, despite its limitations in terms of both the scope of the challenge and the capacity for involvement (see for examples: Public Patent Foundation 2006a; American Anti-Vivisection Society et al. 2007a). In one case, the Foundation for Taxpayer and Consumer Rights, a consumer group, filed a request for re-examination on the patents covering the methods for isolating and propagating embryonic stem cell lines (Public Patent Foundation 2006b). These patents covered virtually all human embryonic stem cell lines and therefore raised concerns about whether they would stifle research and make therapies prohibitively expensive. In its request, FTCR introduced articles from *Science* magazine and testimony from molecular biologists, in order to argue that the patents had negative consequences for both research and health care. PTO did not acknowledge these arguments but ultimately accepted that the invention was not novel because enough *scientific* prior art had been available before the patent application was filed. It revoked the patent in 2010 (Public Patent Foundation 2010).

Europe

Legislative interventions

European challengers to patents on life forms look similar to their American counterparts in many respects. They call attention to the social, ethical, and ecological implications of patents and have introduced evidence and expertise that support these challenges. However, these groups have found more opportunities to make their arguments at the European Parliament and the EPO and have achieved greater engagement with the alternative forms of knowledge and reasoning they present.

In Europe, the controversy began in the late 1980s with the consideration of a European Union Directive that would harmonize patent law regarding biotechnology across member states (Emmott 2001). The biotechnology industry strongly advocated this legislation, arguing that it would facilitate innovation and economic growth. As the European Commission began to work out the details of the proposed EU Directive on the Legal Protection of Biotechnological Inventions (known as the Biotech Patent Directive), the first step in the legislative process, the EPO quickly agreed to follow whatever legislation the European Parliament ultimately passed. The EPO did not have to accept this Directive, because it was not part of the European Union. However, acceptance would facilitate relationships with patent offices in EU countries (most of whom sat on the EPO's Administrative Council), and it would also provide some political legitimacy for its decision making in an area that was becoming controversial.

Passage of the Biotech Patent Directive quickly became difficult. Greenpeace and other challengers to patents on life forms pressured members of the Green and Catholic parties in the European Parliament to review the proposed Directive carefully and to prevent its passage in its original form (Emmott 2001). Critics of the Directive from both inside and outside Parliament demanded more explicit attention to the implications of patenting biotechnological inventions, and even sought counsel from the European Union's bioethics advisory committee, the European Group on Ethics in Science and New Technologies (Busbey et al. 2008; Plomer 2008). One of the challengers' primary demands was greater clarification of the "ordre public" language in the EPC. Despite its original meaning allowing for sensitivity to national difference, it had now created an opportunity for a

vigorous debate about the role of social, ethical, and ecological concerns in discussions about patent law. By 1995, critics had won some concessions, but they were still unsatisfied (Women's Environmental Network representative 2007). As a result, their Parliamentary allies rejected the proposed legislation.

The European Commission introduced an amended version in December 1995, which again mobilized challengers (Dinham et al. 1997; Church of Scotland 1997; Global 2000; Kein Patent Auf Leben 1997). The European Parliament debated the legislation for another 2 years and passed a revised version in July 1998 (European Parliament and Council 1998). The final Directive included some attention to critics' concerns. It specified the EPC's ordre public clause and prohibited, among other things, inventions that involved "commercialization or exploitation" of the human embryo (e.g., stem cells and methods of isolating them, embryos and methods of creating them). It outlawed patents on plant and animal varieties. It also required examiners to perform a risk/benefit "balancing" test when considering patents on animals, to ensure that the benefits to humanity outweighed the risks to the animal involved (Drahos 1999; Schneider 2009). They articulated this "weighing up" test in response to a debate brewing at the EPO over the patentability of the Oncomouse, which I describe in further detail below.

Three features of the European legislative arena made it more open to the arguments and evidence proposed by challengers and ultimately helped them achieve legislative concessions. First, as discussed above, the debates over biotechnology patents occurred as a controversy over genetically modified organisms was growing in the European context (which eventually dwarfed the size of the American GMO controversy). Indeed, many of the groups involved in the patent debate were involved in the GMO controversy as well. As a result of this debate, arguments about the social, ethical, ecological, and even global economic impacts of novel life forms had become commonplace, and European governments had begun to develop mechanisms to incorporate knowledge about these aspects of scientific and technological development into their decision making. In this context, incorporating such evidence and expertise into discussions about biotechnology patent law made sense. Second, members of the Green and Catholic parties inside the European Parliament had already advocated attention to similar kinds of concerns and expertise in the context of other related science and technology policy issues (e.g., research ethics, human biotechnology), and therefore already accepted their relevance and legitimacy (O'Neill 1997). They were willing to fight to achieve concessions in the pending legislation. Third, the Green Party had also accepted the relevance of social, ethical, and ecological concerns in the context of patent law, as demonstrated by their involvement in direct challenges to the EPO, which will be discussed in further detail below. Ultimately, the Biotech Patent Directive made the European patent policy domain's expertise barrier a little more porous; by explicitly addressing concerns about the broad implications of patents, it opened the domain up to knowledge, expertise, and reasoning relevant to those concerns.

Attacking the EPO

While they lobbied against the Directive at the Commission, Parliament, and Council, patent system challengers opened another front in their campaign: they attacked the EPO itself. Using the opposition mechanism, they began to argue that the life form patents that the EPO had begun to issue violated the ordre public clause. Although the EPC had always allowed any third party to oppose a patent on any grounds within 9 months of its issue, this was the first time that outsiders to the patent policy domain—groups who were not directly

involved in the innovation or patent process—had intervened in the EPO's decision-making processes in this way. In addition, this was the first time that opponents had argued that a patent violated the ordre public clause. As we will see, by bringing together these two elements of the EPC, they created an opportunity to force attention to their concerns. The first of these efforts began in 1987, when a number of groups including the Austrian Green Party, another Austrian organization concerned about the ethics of genetic science and technology, a German animal protection group, a Dutch organization against plant patents, and the Swedish Youth Party challenged the first patent on a genetically modified plant. These opponents suggested that the new patent would set a precedent and required extensive "ethical and social" debate (European Patent Office 1993a). Although the EPO behaved like its counterparts in the US and rejected this opposition, arguing that "patent law was never meant to be a moral instrument" (European Patent Office 1993b), it would not be able to dismiss the challengers for long.

Over the next few years, challengers regularly used the opposition mechanism to force the EPO to consider their concerns. They also organized press conferences and protest events to accompany these oppositions, to generate media and public attention to the EPO's decision-making process and their proposed alternatives. In one of the largest challenges that proved to be particularly important for the EPO, which achieved publicity among both the media and policymakers across Europe, 21 groups (including Greenpeace, Belgian and Swiss chapters of No Patents on Life, and British, German, and Austrian animal rights organizations) opposed the Oncomouse patent. The patent was controversial from the application stage: multiple groups submitted third-party observations to the EPO, urging it not to issue the patent because it violated the ordre public clause. EPO granted the patent in 1992, arguing that it passed a "weighing up" test designed to address the ordre public issue (which was eventually incorporated into the Biotech Patent Directive): it compared the benefits to humankind to the animal's suffering.

Challengers responded to the EPO by filing 21 oppositions and engaging the bureaucracy in a debate over what constituted relevant knowledge for determining a violation of the ordre public clause. They submitted hundreds of documents in support of five types of arguments. First, they claimed that the EPO had not adequately evaluated the suffering that the animal would endure (British Union for the Abolition of Vivisection and Compassion in World Farming 1993). In support, they cited articles in leading scientific and medical journals including *Cell* and *Nature* (including some published by the patent applicants themselves) that documented the extreme pain experienced by animals suffering from spontaneous tumors. They supplemented these articles with photographs of the animals. Second, they argued that the EPO and patent applicants had overstated the potential for benefit from this research, because rodent tumors do not mimic human tumors (Küng 1995). One article that they used in support of this assertion, from the *British Journal of Surgery*, stated, "Unfortunately biological behaviour and chemotherapeutic sensitivities [of mice] do not closely resemble those found in human solid tumors. Chemotherapeutic data derived from these experimental systems may therefore be misleading with the result that patients in clinical trials frequently receive ineffective agents" (Shorthouse et al. 1980). Third, opponents argued that the EPO had not considered alternative methods for testing chemotherapeutics that would result in equal benefit but lower animal suffering (Then 2001). Both Britain and the United States, they observed, had reduced animal use considerably in their research efforts and begun to develop alternative models. Scientists at the University of Cambridge, for example, had "developed an automated cell system for screening new anti-cancer drugs." (British Union for the Abolition of Vivisection and Compassion in World Farming 1993) Overall, these three arguments charged that the EPO

had weighed the suffering of the Oncomouse against the benefit to humanity in the abstract, without data of any kind to guide them. Shouldn't the EPO base its judgment on a detailed analysis supplemented by a broad array of evidence and expertise, they argued?

The last two arguments questioned whether the weighing up test was an appropriate way to measure a violation of the ordre public clause. One set challenged its utilitarian logic. Just as their American counterparts had done in both the *Chakrabarty* case and in the Congressional hearings over animal patents, challengers advocated a deontological approach that considered, in and of itself, the morality of both commodifying animals and making them suffer. To justify this argument, they relied on reports from medical ethics committees and religious documents and expertise (Evangelischen Stadtkirchenverbandes Köln 1993). The other argument suggested that the best way to assess ordre public was through public opinion. If the EPO had conducted such an analysis, opponents noted, they would have found clear opposition to the patent. They supported this claim in a few ways. They provided survey evidence from the widely respected Eurobarometer survey, performed by the European Commission on a wide variety of issues related to the European Union (British Union for the Abolition of Vivisection and Compassion in World Farming 1993). They referred to a resolution passed by the European Parliament in 1993, requesting the patent's revocation and a temporary moratorium on all animal patents "until all of the legal uncertainties have been clarified" (Koechlin and Schenkelaars 1993). Finally, they submitted petitions containing the names of thousands of European citizens who had registered their opposition to the specific patent and animal patents in general (Grain and Gen-ethisches Netzwerk 1990). Overall, opponents deployed multiple types of evidence and expertise into the EPO's decision-making processes. Some of them, including scientific articles, legal precedents, and expert declarations, were familiar to the EPO, because opponents had used them in the past. However, opponents used these documents in a new way, to demonstrate that the proposed patent violated the ordre public clause. Other types of evidence, including ethics articles and reports, photographs, petitions, and surveys, were new.

In the context of growing controversy, its difficult position between national governments and the European Union, and the existence of the ordre public clause, the EPO could not simply dismiss opponents' arguments as they had in the genetically modified plant patent case. However, in trying to engage with challengers while trying to maintain its traditional priorities and approach to the patent process, it found itself making difficult arguments. Responding to opponents' claims that it had misjudged the prospective medical benefit of the Oncomouse invention, for example, the EPO responded, "[our] assessment must be made with an element of probability and without taking into account later evidence as to the actual outcome of the exploitation. The decisive question is whether at the effective date the inventor had *bona fide* reasons to believe that his invention would have a substantial medical benefit. Thus,…the undisputed likelihood for suffering of the test animals is to be balanced against the *bona fide* belief of the inventor in a substantial medical benefit at the effective date of the patent" (European Patent Office 2003a). In order to keep opponents' evidence out, the EPO had to argue that the prospective inventor's "belief" was more relevant than empirical evidence. Of course, it would have been impossible to generate data about the risks and benefits of the invention, or related public opinion, by the date of invention.

In another example, the Opposition Division challenged the use of polls to measure public opinion. It stated, "'ordre public' and morality have to be assessed primarily by looking at laws or regulations which are common to most of the European countries because these laws and regulations are the best indicator about what is considered right or

wrong in European society. In so far as such laws or regulations concerning the relevant issue exist, it appears neither necessary nor appropriate to rely on other possible means of assessment such as public opinion polls…" (European Patent Office 2003a). Here, the EPO had to weigh different measures of ordre public. It seemed to accept that polls were a relevant "means of assessment", but decided ultimately that the legal and regulatory frameworks were better. It is not surprising that this domain, which had traditionally relied on legal precedent, chose to privilege this type of knowledge over survey data.

The Opposition Division ultimately asked the inventors to rewrite the patent to cover only rodents. Opponents saw this as a partial victory. Not only did the EPO make the patent narrower, but it had become aware of the nature and intensity of their concerns. Indeed, this would have implications far beyond Oncomouse. One high-level official recalled that period:

> …when the Oncomouse Harvard patent was granted in 1992, a big storm arose that nearly swept away the EPO, because people [here] were so strongly inward looking at this place that they didn't realize what was going on. That the work that they were doing was not just considered to be of relevance to pharmaceutical companies and other innovators, but there was a strongly social component as well. And this is the bitter lesson they had to learn… (EPO Employee a 2008)

During and after the Oncomouse controversy, challengers involved in the case and other like-minded groups filed oppositions against dozens of other patents (See, for example: Greenpeace 2001; Kein Patent Auf Leben 2010; Parthasarathy 2007). They challenged patents on genes, stem cells, genetically modified plants and animals, and methods of gene and embryo manipulation among many other things. In each case, challengers used evidence and expertise that the EPO had not traditionally considered. As they had to contend with this knowledge over and over again, EPO officials began to recognize that they had to find a way to incorporate it into their decision making. One noted:

> In general, I think that it's important for the patent system to…for people dealing with patents to keep in mind where the system comes from. What its legitimacy and its social basis are. So to really keep in mind the social contract of private benefit and public benefit and incentive for innovation on the one hand but disclosure and promoting innovation for the public good on the other hand. I think that probably has been lost… (EPO Employee c 2008)

While the US patent policy domain allowed insiders to keep out alternative forms of evidence, expertise, and reasoning, its European counterpart was not as strong. Due to a variety of structural and cultural differences, challengers were able to find a way to introduce alternative forms of knowledge and reasoning and to force insiders to consider them.

United States: responding to challengers

Participants in the US patent policy domain have not completely ignored challengers. In the mid-1990s, the PTO created the Sensitive Application Warning System (SAWS) to accompany the examination process; the purpose of the program is to provide officials with advance warning about patent applications that might generate widespread attention, so that they can both provide additional internal scrutiny and prepare for the publicity that might erupt. The SAWS is merely internal, informal, policy, however. It is not codified in

PTO's examination guidelines, linked to statutes or case law, or discussed in official training sessions. Supervisors in each technical department (known as an Art Unit) simply ask examiners to identify applications that could "generate high publicity or would potentially have a strong impact in the patent community" during the review process (Falcone et al. 2006). Although each Art Unit provides its examiners with some examples of the kinds of SAWS subject matter they might encounter, supervisors rely mostly on examiners' own judgments to assess and identify which kind of patents might fit the designation.

If an examiner finds what she believes to be an application eligible for the SAWS, she reports it to her supervisor, who reports it to her supervisor. This process continues until the report reaches the office of the Deputy Commissioner for Patent Operations and the Deputy Commissioner for Patent Examination Policy. Usually, officials at this level simply ensure that the examiner has conducted the review properly and prepare quietly for the possibility of heightened attention. On occasion, however, the PTO's personnel worry that the potential for public backlash is too great to issue the patent. An official noted that in such cases, "…the PTO will try to find some way to continue the reject the application. The PTO has lots and lots of tools…. So, essentially it is a question of finding a way to continue to reject it." (PTO Employee a 2009). It is unclear, however, how often the PTO uses the SAWS to reject patents. In sum, the SAWS provides the PTO with a mechanism to identify potentially problematic applications and conduct additional internal review, as a means of preparing for, or perhaps even avoiding, negative publicity.

In practice, the informality of the SAWS limits its impact. Multiple personnel at the PTO downplay the importance of the program, and some examiners do not even know of its existence (PTO Employee d 2009; PTO Employee f 2009). One examiner noted that in her Art Unit, examiners reported applications that were candidates for the SAWS designation in the form of light-hearted forwarded emails; if an examiner saw an application that she deemed strange, funny, or particularly interesting, she would forward it to her colleagues, and her supervisor would decide whether the application was worth pursuing (PTO Employee g 2008). In sum, while the SAWS is meant to identify proposed inventions that might capture public attention or controversy, the agency's emphasis on scientific and legal knowledge as a means of ensuring objectivity and detachment makes it difficult to implement. It requires examiners to consider the social reactions to inventions with few conceptual tools to guide them—except their own individual understandings of the world.

Europe: responding to challengers

High-level officials at the EPO have developed multiple initiatives that seem to recognize the relevance of social and ethical expertise to the patent system. Many are devoted to educating all employees, including examiners, about the issues that concern activists, national governments, and the media. In the early 1990s, *The Gazette*, the EPO's internal newsletter that is distributed to all employees, began to publish original articles about ethics and biotechnology, reprint relevant EPO press releases announcing the grassroots oppositions, and display photographs of the activist protests occurring outside of its buildings (Karet 1992). Previously, it had been mostly devoted to internal announcements, including listings of job openings, promotions, and new employees, short articles about foreign visitors to the EPO, and announcements about and reviews of (mostly social) EPO events. In 1992, for example, the Gazette announced an essay competition on "Patents and Ethics in the Context of Modern Technology" among employees at the EPO. Two winners

were awarded 15,000 and 10,000 German Marks (about 10,000 and 6,500 US dollars, respectively) with the essays published not only in the Gazette but also in major European newspapers (Financial Times, Le Monde, Neue Züricher Zeitung, and Süddeutsche Zeitung) (Patente auf Lebewesen und Gene 1993). The EPO's decision to engage its employees in discussions about the social and ethical dimensions of patenting is quite interesting. Officials could have decided that coverage of these issues would be distracting or demoralizing, or perhaps worst of all, interrupt the objectivity of their employees' work. One could easily imagine that at the PTO, officials would be reluctant to educate examiners about the growing topics of controversy. However, the EPO's officials decided the opposite. Thinking more about the issues of controversy, high-level officials seemed to believe, would make all employees do a better job.

Internal discussions about the social and ethical implications of patenting grew considerably in the 2000s, when Alain Pompidou, a trained biomedical scientist and doctor, became president of the EPO. Pompidou had long been involved in discussions about the appropriate development of biomedicine and biotechnology and sought to encourage such discussions in the Office. For example, he asked the EPO's Learning and Development Directorate (which is in charge of all personnel training efforts) to organize a series of lectures entitled, "Ethics and Science: Are They Connected?" The purpose of the nine lectures, which were simulcast in the EPO's Munich and Hague offices and held over the course of a year and a half, was to "increase staff awareness of the ethical aspects of novel technologies." (Bayrak 2007) In this way, Pompidou can be understood as a policy entrepreneur (Carpenter 2007), bringing new forms of expertise inside a bureaucracy. Pompidou suggested the list of speakers for the series, most of whom were European professors of philosophy or bioethics. He sought to use the series to teach the EPO's personnel, and examiners in particular, "that patents were no longer limited to technical and legal subject matter. It should be looked at in broader context" (EPO Employee d 2008). This training effort also emphasized the relevance of social and ethical expertise to better work output, although it was not explicitly connected to the patent decision-making process.

Perhaps the grandest attempt to change the EPO's practices was the Scenarios project, a multi-year effort initiated in 2004 to encourage strategic thinking about the future direction of the Office and the role of the patent system in global society. These efforts began with interviews of over 100 scholars and stakeholders from all over the world, who were asked to predict and discuss the different social, political, and economic pressures that the Office might face by the year 2025. A small group of personnel from the EPO—including people from all departments and levels—interviewed both traditional stakeholders and experts (e.g., from inventors organizations, patent lawyers, high-technology companies) and new players in this arena (e.g., Greenpeace, philosophers, political scientists, international development organizations). The effort was meant to expose the EPO's personnel and the public to new sources of expertise about the role of the patent system in society, while also providing external players with an opportunity to shape the future of the organization.

The EPO's team then used this interview data to construct four possible future scenarios. Although all of them touched on the grassroots challenges in some way, the "Trees of Knowledge" scenario addressed social and ethical concerns directly. In this scenario, the EPO's personnel tried to predict the kinds of dilemmas that might arise if the grassroots movements continued to grow and public trust in government, industry, science, and technology continued to erode. In particular, authors of this scenario organized the discussion around three "key" questions: "How can public and private interest in IP [intellectual property] be reconciled for the benefit of society? How are the ethical and moral

dilemmas raised by technology reflected by the patent system? Where should the limits of patentability be drawn? By whom?" (European Patent Office 2007a: 83) These were large and complicated questions, which required contemplation of issues which were quite new. Until relatively recently, they might have seemed inappropriate for deliberation by a technical bureaucracy like the EPO.

The final report of the Scenarios project was unveiled in April 2007 at a large event in Munich's EPO Office (Osterwalder 2007). Major figures in European politics and policy—including German Chancellor Angela Merkel—participated, and not surprisingly, the event was well-attended by the EPO's employees (European Patent Office 2007b). All of the EPO's attendees received copies of both the final report and a book of the interview transcripts, to expose them to new ideas. Although most examiners have day-to-day contact with inventors and patent lawyers through the examination process, they are rarely exposed, for example, to the arguments of the Church of Scotland regarding the patentability of living organisms.

Like the PTO, the EPO has also developed a Sensitive Cases, or SeCa, system, to identify and deal with sensitive applications. Unlike the SAWS, however, the SeCa system begins at the classification stage. The EPO's Receiving Section marks with a 3 × 5 inch sticker applications assigned to technical departments (known as Clusters) that have been identified by the Communication department as particularly controversial (e.g., biotechnology, nanotechnology). The sticker provides a series of prompts meant to guide examiners through an assessment of an application's sensitivity and procedures for additional review. This sticker represents two differences between the US and European systems. First, the SeCa system is more formalized than the SAWS. Although the SeCa system is not codified in official laws, it is formalized through pre-printed stickers and a systematic change in the administrative routine of the classification department and specific Clusters. Second, the kinds of applications caught by the two systems are likely to be different. While in the SAWS, the cases that examiners mark as "sensitive" can be potentially controversial or transformative in nature or simply odd, the SeCa system focuses on applications in technical fields that personnel in the Communication department recognize as publicly controversial. The EPO's SeCa system thus reminds examiners of the controversy and consequences related to their work.

When an examiner receives an application with a SeCa sticker, she must conduct an additional determination of sensitivity in addition to her evaluation of scientific and legal patentability. This determination also involves an assessment of whether the application might be in violation of the ordre public clause of the EPC and its elaboration in the EU Biotech Patent Directive. Usually, the examiner judges the sensitivity of an application using a set of examples provided by supervisors and the examiner's own intuition (EPO Employee f 2009). The only exception is the "balancing" test that examiners must perform when considering the patentability of animals. Even in these cases, however, examiners receive no training to help them perform this systematic ethical analysis; they must rely on their own judgments. One examiner explained his approach,

> It's a bit in the discretion of the examiner to decide what he thinks is [sensitive.]…But it's a balancing act between the patient and for the suffering animal. And of course in some cases, for a cat if you have cosmetic purposes and if that causes suffering. But in other cases it might be more difficult for you to decide if it has a small medical benefit and you have a lot of suffering…. (EPO Employee e 2008)

Although high-level officials at the EPO had sponsored many initiatives to emphasize the relevance and legitimacy of social and ethical knowledge, they did not train examiners

to deploy this knowledge in a systematic or rational way in patent decision making. Even when they were required by law to engage in ethical reasoning, examiners had to rely on their individual judgments. Officials seemed to assume that examiners did not require an ethics training similar to their scientific and legal training; the Office's efforts to expose its personnel to social and ethical expertise and the issues of controversy would be enough to produce appropriate decisions.

If the examiner finds it difficult to make a decision on sensitivity and, in particular, to determine whether an application violates the *ordre public* clause, she can invite additional review from a member of the patent law division. The patent lawyer advises her as to whether the application violates the *legal* precedent established for the morality exception. It is important to note that even when examiners are concerned about the *morality* of a proposed invention, they can only turn to one of the EPO's established forms of knowledge, in the form of an internal *legal* expert. Given the centrality of scientific and legal expertise in the history of the EPO, this is not surprising. However, this approach limits the degree to which other forms of knowledge or reasoning can figure in patent decision making.

If the examiner ultimately makes a determination of sensitivity, the application must be reviewed and certified by Team and Directorate supervisors and the director of the Cluster. If they agree with the examiner's assessment, it is registered in the SeCa database, which is available to all of the EPO's employees. A specially designated SeCa Advisory Board, made up of examiners, patent lawyers, and public relations personnel inside the EPO, periodically reviews the database so that they can be aware of the progress of these applications and prepare if the examiner decides to issue a patent based on that application. Meanwhile, the examiner proceeds with the review process. If she made the sensitivity determination because she believes that the application is contrary to the *ordre public* clause, she will reject it and advise the inventor about the problem. The inventor may decide to revise it to avoid the problem, or simply challenge the rejection. As with all other applications, this process continues until the patent is either issued or rejected. Overall, officials hope that the SeCa system will encourage examiners to scrutinize their work more carefully and ask themselves: "What's happening here? Do we have a quality problem? Are you granting patents you shouldn't be granting?" (EPO Employee a 2008).

The SeCa system, however, is only part of a multi-pronged crisis management system. The EPO issues press releases and fact sheets when it grants a patent that is likely to become controversial, after controversies have erupted, and in response to general areas of controversy (e.g., patents on living organisms or software)—describing the issues of public concern and the reasons behind its decision making (see for example: European Patent Office 2002; European Patent Office 2003b). By contrast, the PTO has almost never issued press releases on controversial issues or individual patents, and this practice has not changed with the rise of grassroots challenges. The EPO's external relations efforts are overseen not only by the Communications department, but also by newly created Issue Management Groups, composed of examiners, patent lawyers, and public relations specialists, all from inside the organization (EPO official a 2008). Each IMG specializes in one controversial technical area (e.g., computer-implemented inventions, biotechnology) and helps communications officials develop strategies to deal with patent applications that have been identified through the SeCa system while also helping them interact generally with stakeholders on issues that have become controversial. IMG members are often sent out as envoys to patent-related events throughout Europe, so that they can listen to the concerns of various groups and also explain the position of the Office. They also might review drafts of press releases or speak to members of the EPO's Administrative Council or the

European Union's Parliament to alert them to the impending issuance of a controversial patent. The IMGs and increased contacts with the press were created to better communicate with the public and explain the EPO's decisions, while also gathering information about issues of public concern for further discussion inside the EPO.

Conclusion

The increasing challenges to the US and European patent policy domains, particularly with regard to patents on life forms, are similar in many respects. Groups have introduced alternative types of evidence, expertise, and modes of reasoning (that are similar in both contexts) that challenge the prevailing ways of thinking about patent policy. Although challengers received some attention in the United States—in Congressional hearings, with amicus briefs, and through the media—insiders have largely dismissed their concerns. They have interpreted challengers' interventions as the articulation of irrelevant ethical issues, and have simply rejected the idea that challengers are presenting alternative forms of knowledge. PTO personnel continue to characterize themselves as offering an impartial and standardized decision making and promoting a robust patent regime as a means of stimulating economic growth. The most significant effort to consider public controversy, the Sensitive Application Warning Program (SAWS), focuses more on public relations than seriously engaging the substance of the growing concerns. By contrast, European challengers have experienced more success. The European Parliament's Biotech Patent Directive included multiple concessions to challengers, and the EPO narrowed or revoked numerous patents in response to public opposition. Finally, over the past 20 years, the EPO has begun to create spaces to allow for the consideration of new forms of knowledge, expertise, and reasoning even in the patent examination process.

These differences, I have argued, are the result of differences in the expertise barriers surrounding the patent policy domains in the two contexts. In the United States, the patent policy domain has become quite specialized and extremely difficult for outsiders to penetrate, which has limited the types of knowledge and reasoning used to influence the policy process and the level of reflection regarding the types of knowledge and reasoning that should be used in the patent policy domain. This strong expertise barrier emerged over the course of the domain's history, and today the domain's institutions, stakeholders, rules, and practices maintain it. The expertise barrier surrounding the European patent policy domain is more porous. Over the course of its shorter history, it has had to contend with a greater variety of perspectives. While the domain, like its US counterpart, privileges scientific and legal knowledge, the political position of the EPO requires it to maintain its legitimacy among national governments and the European public quite actively. Furthermore, challengers have transformed the meaning of the opposition mechanism and ordre public to force the EPO to engage with their concerns. While insiders in the US patent policy domain could simply dismiss opponents' concerns as irrelevant, insiders in the European patent policy domain are forced to engage in a conversation about what knowledge is relevant to a determination of an order public violation. Overall, the institutional positioning, the governance frameworks, and the broader politics of science and technology taking place in Europe over the past few decades forced insiders to engage with the alternative knowledge and reasoning proposed by challengers in a way that their US counterparts did not.

In the context of growing calls to ensure that knowledge plays a central role in policymaking, attention to the politics of knowledge becomes even more important. The

expertise barrier concept encourages us to consider the constraints that shape the use of knowledge in policy and encourages us to ask whether we are considering the right types of knowledge and how we determine what kinds of knowledge are relevant and legitimate. It also calls attention to the epistemological inertia that policy domains exhibit once they become established: it becomes very difficult for domains to deal with new types of knowledge, because policy officials and stakeholders are unsure how to fit it into existing practices and evaluate it. Those interested in enhancing the role of knowledge in the policy process must ensure that domains have the flexibility to consider new forms of knowledge and reasoning as well as the standardization necessary to develop legitimate policies.

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