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Patents and Allied Rights: A Global Kaleidoscope

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Patents and Allied Rights: a Global Kaleidoscope

1. Introduction

Patent law is the form of intellectual property most closely associated with technological innovation, and most often discussed in public initiatives to promote such innovation. Patents have a long history; some form of patent grant can be traced back to at least the renaissance Venetian Republic, and possibly before.¹ Initially the legal control associated with patents seems intended to either attract or perhaps misappropriate advantageous technology from foreign jurisdictions. Over time, the patent became increasingly associated with original, rather than with copied, innovations. Currently some form of patent system is found in essentially all modern states; common features of these systems are provided for by membership in the international TRIPS trade treaty that is discussed by Sam Ricketson in Part III of this volume. Thus patents have grown to be a ubiquitous feature of the global legal and technical environment.

At any given point in time, a written exposition of patent law can at best offer a snapshot of what is happening in certain jurisdictions during particular moments. Here I offer a series of such vignettes, recognizing that in a highly dynamic area of law, where the doctrine in any given jurisdiction changes on a monthly, if not a weekly, basis, and where this constant evolution of doctrine is occurring simultaneously in multiple jurisdictions, any particular example or explication of doctrine is likely to be short lived. Nonetheless my hope is that this may prove asset rather than a shortcoming. The shifting diversity of national approaches offers the opportunity to consider comparatively how characteristic themes and problems of patent law have been approached from different perspectives, and lend a sense of better, worse, and alternative solutions to the problem of prompting technical innovation. Consequently in this chapter, I have selected particular doctrinal problems in patent law, using them to illustrate certain both broad theoretical issues endemic to the patent system, tying those issues to ongoing controversies that have attracted widespread interest.

Although the diversity of patent approaches offers an opportunity for comparative scholarship and analysis, in practice it presents a series of applied challenges. The international law principle of territoriality has historically been paramount in patent law; patents are issued by particular nations and are effective only within the borders of the issuing state. At the time of this writing, no international or regional patents exist, although Member States of the European Union have

¹ LR Bradford, 'Inventing Patents: A Story of Legal and Technical Transfer' (2015) 118 *West Virginia Law Review* 267.

been slowly moving toward designation of a patent document that would be recognized as having unitary effect throughout most or perhaps even all of their territories.²

The practical necessity of securing individual patents in each of the territories where exclusive rights are desired continues to confront inventors with a stark business decision: the administrative costs of obtaining patents in every jurisdiction is prohibitive; consequently patent applicants must decide which countries are important to their business plan, and forgo protection in other nations. Typically patent applicants seek protection in major business markets with well-developed patent systems, such as the United States and nations covered by the European Patent Convention, as well as in other important markets, such as Japan and Australia. Increasingly, significant developing markets such as China and India figure in patent procurement strategies.

Certain international conventions, such as the Patent Cooperation Treaty of 1970, serve to harmonize the application mechanics by standardizing the physical and textual format of applications, as well as the procedures by which the application is examined. The European Patent Convention establishes an intergovernmental organization, the European Patent Office, that offers a unified application for obtaining patents from signatory nations. But EPO applicants emerge with a bundle of national patents that are recognized and enforced on a national, not regional, level. And even within the states of the European Patent Convention, applicants typically choose to forgo all but the three or four jurisdictions of Germany, France, the Netherlands, and the United Kingdom.

Increased global availability of patents may not be viewed universally as beneficial. Even when viewed from the most benevolent perspective, the patent system is socially costly, as it imposes extra restraints on normal commerce.³ This has historically produced a deep-seated suspicion of patents as perhaps necessary evils, but evils nonetheless. In the United States, this view shifted radically during the 1980s, when, with the ascendancy of politically conservative economic analysis of law, patents became celebrated rather than tolerated. This newer American view has increasingly become dominant in global discussions regarding patent policy, harmonization, and reform. Nonetheless, in many jurisdictions, patents are still considered at best a mixed blessing, and may still be viewed with considerable caution. Under this more cautious view of patents as extraordinary grants to the private sector, deployment of exclusive patent rights must be kept in check either by mechanisms endogenous to patent law, such as limitations or exemptions, or by external mechanisms such as competition law.

Much of the current discourse on justification of patents draws on the innovation rationale, discussed in Parts I, II and V of this volume, of providing an economic incentive for investment in the development of new technologies. This justification is common among many areas of intellectual property. But patent law entails alternative justifications that are less commonly

² CS Petersen, JH Schovsbo & T Riis, 'The Unified Patent Court (UPC) in Action: How Will the Design of the UPC Affect Patent Law?' in RM Ballardini, M Norrgård & N Bruun (eds), *Transitions in European Patent Law – Influences of the Unitary Patent Package* (Kluwer Law International 2015) 37.

³ MA Lemley, 'Property, Intellectual Property, and Free Riding' (2005) 83 *Texas Law Review* 1031.

associated with other forms of intellectual property, and which are closely related to certain idiosyncrasies of the patent system. Chief among these is the rationale of disclosure, the argument that patents are intended to induce publication, by means of the patent document, of valuable technical information that an inventor might otherwise keep concealed, either as a legal trade secret or as an actual secret.⁴ On this theory, the grant of exclusive rights under the patent system represents a bargain between the inventor and the public: in return for full disclosure to the public as to how to make and use the claimed invention, the inventor receives approximately twenty years of legal exclusivity.

It is unclear how well this theory works in practice, given that the alternative to patenting is trade secrecy. Trade secrecy lasts so long as the invention can be kept a secret, in particular, so long as third party is able to independently re-create or reverse engineer the secret. For technologies that lend themselves to such concealment, the period during which the inventor could exploit the invention might be much longer than twenty years. This suggests that the inventions for which patenting is most attractive are those that cannot be easily concealed, which is to say, inventions that would have become public knowledge without the inducement of a patent. Nonetheless, the bargain or ‘quid pro quo’ theory of disclosure permeates many aspects of patent doctrine.

2. Patent Formalities

Unlike many other forms of intellectual property, patent rights come into existence only after an administrative process of application, examination, and approval by a governmental agency. The rights conferred by the patent are thus defined by a text – a governmentally certified document – that defines the outer limits of the technology covered by the patent. Applicants for a patent are expected to submit to a designated government office a document that explains in detail the invention for which exclusive rights are sought; much of the explanation consists of written text although drawings are frequently included. The document concludes with a series of numbered statements indicating the scope of the technology over which the applicant hopes to claim exclusive rights, and is examined by an official with expertise in the relevant area of technology for compliance with the substantive and procedural requirements for a patent. The requirements for patentability include novelty, utility or industrial application, and non-obviousness or ‘inventive step.’

Often the examiner will decline to approve the application unless the applicant alters the claims to cover a more restricted or somewhat different area than that indicated in the initial application. Generally only the claims can be altered once the application is filed; altering the description of the technology would by definition mean that a different invention was under consideration than that in the original application, so that the applicant was starting over. The applicant may also have the option of responding in order to persuade the examiner, creating an epistolary record that may in some jurisdictions be used to understand the meaning or the intent behind the text of the final issued document.

⁴ DL Burk, ‘Law and Economics of Intellectual Property: In Search of First Principles’ (2012) 8 *Annual Review of Law and Social Science* 397.

Once the application is approved, and the patent issues, the patent holder enjoys a period of time, generally about 20 years, during which he is able to exercise or license exclusive rights over the invention as defined by the claims. Unauthorized activity falling within the patent claims may be the subject of legal action by the patent owner. A court enforcing the patent will look to the patent document to determine whether infringement has occurred, by comparing the accused device or activity to the claims. Accused infringers typically have the option of defending on grounds of either non-infringement or invalidity; that is, showing that either the accused activity does not fall within the scope of the patent rights, or that the patent is legally defective and so unenforceable.

Patents are thus highly intertextual: they issue on the basis of a purely textual description of an invention, with reference to other, older texts that define what the inventor may claim.⁵ The physical invention itself need never appear at any stage of the life of the patent, from application through expiration. Although it was common in the nineteenth century to require a working model of a patent to accompany a patent application, this practice has long since ceased.⁶ Indeed, in jurisdictions such as the United States, an inventor who is able to offer a sufficiently detailed textual description of his concept can secure a 'paper patent' which describes an invention that has never actually been built. Neither is the physical invention required when it comes to judging infringement: the accused device or process is judged to be infringing or non-infringing by comparison to the text of the patent document only.

Similarly, determining whether infringement has occurred, or what relationship the patent claims bear to prior art documents, is necessarily an exercise textual interpretation. Courts have adopted a range of interpretive strategies, often similar to those used in determining meaning for other legal texts, such as statutes, constitutions, or contracts. As in their interpretation of other legal texts, American courts have tended toward defined 'plain meaning' or 'literal meaning' of the words in a claim. Claim interpretation in British courts, on the other hand, has been characterized by 'purposive' readings, in which an understanding of the objective purpose of the drafter is sought: a claim means what the person having ordinary skill in the art (abbreviated PHOSITA) would understand the drafter by his or her choice of language to have intended it to mean. When a plain meaning cannot be easily determined, American courts may by contrast resort to examination of the correspondence or 'prosecution history' between the inventor and the patent issuing authority, to glean clues as to the applicant's subjective intent. Sometimes dictionaries or other external references are consulted to divine popular or likely word meanings.

Such intertextuality stands in sharp contrast to other forms of intellectual property.⁷ The detail and intensity of the application process are not found in other forms of intellectual property, nor is the reliance of patent law on the text of the published patent document. For example, in copyright there is no examination process; rights arise spontaneously with the creation of the

⁵ DL Burk & J Reyman, 'Patents as Genre: A Prospectus' (2014) 26 *Law & Literature* 163, 171-72.

⁶ A Pottage, 'Law Machines: Scale models, forensic materiality and the making of modern patent law' (2011) 41 *Social Studies of Science* 621.

⁷ DL Burk, 'Dynamic Claim Interpretation' in S Balganesch (ed), *Intellectual Property and the Common Law* (Cambridge University Press 2013) 107, 109-110.

work, and the scope of rights in the work is determined with reference to examples of the work itself, not with reference to a document that describes the work.⁸ The scope of a trademark, too, is judged with reference to the mark itself, not from a text describing the mark. The scope of copyright and trademark rights may be limited by prior works or existing marks, but nothing in these systems requires advance delineation of their ambit as in the case of patent claims.

Indeed, the application process requires the inventor to define the invention in reference to other documents – the prior art, against which the application’s compliance with statutory requirements is measured.⁹ The inventor is required to disclose any relevant prior art documents of which she is aware; the examiner will search library databases looking for relevant prior art as well. The patent document will reference any prior art documents that may bear on the patentability of the claimed invention. The applicant may be required to adjust the scope of what is claimed in the patent so as to avoid encompassing technical knowledge that is already found in references available to the public.

The current practice regarding patent claims entails yet another peculiar form of textuality, that of ‘peripheral claiming’.¹⁰ This practice evolved along with the textual practice of claiming itself. As a textual form, separate claims evolved over a period of decades, largely as a matter of informal convention in response to judicial preferences. The earliest versions of the US patent statute required only that an applicant supply what we would now call a specification to disclose the invention that was the subject of the patent.¹¹ Patents from this period contained no separate statements constituting claims, and courts determined both invalidity and infringement on the basis of the disclosure. However, in response to the need to clarify which aspects of the invention were novel and so the proper subject of the patent, patent drafters began to break out of the text a distinct, separate statement of the novel features of the invention as a one sentence ‘claim’, in order to avoid the possibility that the patent might be viewed as intended to claim everything in the full description of the invention.¹²

Once claims took the form of separate textual elements, their function and interpretation began to evolve as well, from what has been called ‘central claiming’ to the current practice of peripheral claiming. The idea behind peripheral claiming, which US patent law adopted in the 1870s, was to establish the ‘metes and bounds’ of the invention in a manner analogous to real property deeds. But before 1870, the scope of US patents was determined using a system of central claiming. Under a central claiming approach, the patentee does not delineate the outer reach of what it claims. Rather, the patentee discloses the central features of the invention – what sets it apart from the prior art – and later, for example in an infringement action, the courts determine how much protection the patent is entitled to by looking at the prior art that cabins the invention, how

⁸ JC Fromer, ‘Claiming Intellectual Property’ (2009) 76 *University of Chicago Law Review* 719.

⁹ Burk & Reyman (n 5).

¹⁰ DL Burk & MA Lemley, ‘Fence Posts or Sign Posts? Rethinking Patent Claim Construction’ (2009) 157 *University of Pennsylvania Law Review* 1743.

¹¹ KB Lutz, ‘Evolution of the Claims of U.S. Patents (pt. 1)’ (1938) 20 *Journal of the Patent Office Society* 134, 139-41.

¹² WR Woodward, ‘Definiteness and Particularity in Patent Claims’ (1948) 46 *Michigan Law Review* 755, 757-58.

important the patentee's invention was, and how different the accused device is. If the goal of peripheral claiming was to establish fence posts marking the boundary of the patent, we can think of central claiming as replacing fence posts with signposts identifying new inventions.¹³ Whereas peripheral claiming purports to mark the outermost boundary of the patentee's claims, central claiming describes the core or gist of the patentee's contribution to technology.

In some countries elements of that system remain to this day,¹⁴ and indeed there are vestiges of central claiming in the US patent system, in jurisprudential forms such as the doctrine of equivalents. Central claiming is also the norm in copyright, trademark, and trade secret law. As indicated above, these other forms of intellectual property are not defined by reference to a descriptive text, but by reference to themselves. Thus the scope of copyright in a given work is determined by looking at that work, and then determining what additional scope, such as substantially similar works, might be covered by the copyright. This is the same central claiming practice that was conducted for patentable inventions prior to the emergence of peripheral claiming.

Central patent claiming also operated as the norm in many major industrialized nations well into the late twentieth century. For example, Korea employed central claiming until a statutory change in 1980 instituted peripheral claiming; even then, courts continued to apply central claiming methods well into the 1990s.¹⁵ Central claiming was also the approach in Germany until accession to the European Patent Convention required harmonization with the peripheral approaches of other EPC member states; at that point Germany moved somewhat reluctantly to an intermediate position that continues to incorporate many aspects of central claiming.¹⁶ For the last several decades it has sought to integrate the two, using peripheral claiming as a starting point but making liberal use of the doctrine of equivalents and purposive claim interpretation.¹⁷ Nonetheless, the German Federal Supreme Court has endorsed the central claiming-based 'substantial difference' test.¹⁸

Doctrine of Equivalents

¹³ This terminology originates from WR Cornish, *Intellectual Property: Patents, Copyright, Trade Marks and Allied Rights* (Sweet & Maxwell 4th ed, 1999) 165.

¹⁴ T Takenaka, *Interpreting Patent Claims: The United States, Germany and Japan* 17 IIC Studies (Weinheim 1995) 6-9.

¹⁵ CL Kim, 'Transition from Central to Peripheral Definition Patent Claim Interpretation System in Korea' (1995) 77 *Journal of Patent & Trademark Office Society* 401.

¹⁶ W Stockmair, *The Protection of Technical Innovations and Designs in Germany* (Verlag CH Beck 1993) 93.

¹⁷ AM Soobert, 'Analyzing Infringement by Equivalents: A Proposal to Focus the Scope of International Patent Protection' (1996) 22 *Rutgers Computer & Technology Law Journal* 189, 207-11.

¹⁸ 'Moulded Curbstone' (*Formstein*) (1987) 18 IIC 795, 798 (BGH) (reporting decision in English).

Among the vestiges of central claiming found in the US system is the doctrine of equivalents.¹⁹ Claims are developed in the context of an administrative procedure, but are generally enforced by means of judicial proceedings. Claim interpretation by a court determines the applicability and scope of the patent. But at some point in the enforcement of a patent, meaning beyond the narrowest reading must be attributed to the language of the claims. If the scope of patent rights is confined to a very strict reading of the claims, infringers can easily escape the claim language by making trivial alterations to their activities; if the variants are not explicitly stated in the claims, the infringing products or processes will not literally infringe. Many nations therefore allow the patent holder to enforce the patent against infringement that is not explicit in the text of the patent claims. The doctrine of equivalents is perhaps the best known version of such expansive claim enforcement, under which a variation that is equivalent to elements of the claimed invention still triggers infringement. Equivalents have been defined as something which is known in the technological art to be a substitute, or something which performs the same function in the same way with the same result as the element it replaces in the claimed invention.

Such attribution of patent scope is of course a version of central claiming, rather than peripheral claiming, and so sits uncomfortably in the modern peripheral claiming system. In particular, such equivalents pose a problem with regard to the definiteness and notice function of claims. Peripheral claiming is often said to provide the public with a definition of the outer boundaries of the patent holder's rights, so as to warn possible infringers away from exclusively held technology. At the same time, the peripheral claim is said to provide an outer limit to the rights of the patent holder, preventing the patent holder from encroaching on technical areas outside his scope of legal exclusivity. The doctrine of equivalents potentially undermines both of these functions by providing to the patent holder a scope of exclusivity not explicitly articulated in the patent claims: patent holders then have an incentive to assert legal exclusivity over unspecified equivalents to his technology, and the public is left uncertain as to where the patent's boundaries lie.

For such reasons, Lord Hoffmann famously opined in *Kirin-Amgen* that unlike the United States, the United Kingdom recognizes no such doctrine of equivalents: while equivalence forms part of the background of facts in the light of which claims are purposively construed, it cannot be used to extend protection outside their scope.²⁰ This view has been controversial even within British patent circles; the late Sir Hugh Laddie argued that Lord Hoffmann's interpretive approach involved a misreading of UK precedent.²¹ But in any event, by focusing on what the PHOSITA would understand the drafter to have intended by his or her choice of language to claim, the British approach rejects literal claim exclusivity and supports non-literal infringement in any case in which a purposive construction of the claim produces that result.

The patent law of the UK – as well as Germany and most of its continental neighbors – is constrained by the requirements of the European Patent Convention. Article 69 of the EPC states that patent scope is to be based upon the patent's claims, in light of the description and the

¹⁹ JR Thomas, 'Claim Re-Construction: The Doctrine of Equivalents in the Post-Markman Era' (2005) 9 *Lewis & Clark Law Review* 153.

²⁰ *Kirin-Amgen v Hoechst Marion Roussel Ltd* [2005] RPC 9 (HL) 188-89.

²¹ H Laddie, 'Kirin Amgen – The End of Equivalents in England?' (2009) 40 *IIC* 3.

drawings.²² If read strictly and literally, this would seem to preclude any standalone doctrine of equivalents or other influences external to the patent document, and indeed (somewhat ironically) this is exactly how Lord Hoffmann has regarded the provision. As he has also emphasized however, it does not follow from Article 69 that patent claims are to be interpreted literally. Indeed, the agreed upon interpretive protocol that accompanies Article 69 instructs – apparently in an attempt to accommodate the traditional British and continental interpretive views – that claims are neither to be regarded as mere guidelines, nor to be regarded as rigid definition of the patent holder’s rights.²³ Rather it mandates that claims are to be read so as to combine both fair notice to the public *and* a reasonable scope of protection for the patent holder. In Lord Hoffmann’s view, purposive construction is the only way to achieve this.

Since 2007, the protocol has been amended to include a provision mandating that ‘due account’ be taken of equivalents to any element of the claims. The addition of an explicit reference in the amended protocol to ‘equivalents’ might seem to infuse an almost American meaning into Article 69, or at least recognize the primacy of the continental approach. But the protocol is guidance for interpreting the mandate of Article 69, and so might equally well be viewed as consistent with the UK approach, instructing the interpreter to consider equivalents included within the terms of the claim – perhaps in the manner suggested by Lord Hoffmann.²⁴

3. Patent Enforcement

Due to the technical nature of patent law, and not merely that of patentable subject matter, several leading jurisdictions have developed specialty courts to deal with patent issues. In the United States, the Court of Appeals for the Federal Circuit has since 1982 had exclusive appellate jurisdiction over patent cases arising in the Federal District Courts across the United States, as well as those coming from the USPTO. Within Federal District Courts, the United States has also implemented a program whereby certain judges may specialize in patent trials. In the United Kingdom, patent holders have access to both a specialty Patents Court and streamlined Intellectual Property Enterprise Court for simpler cases below a £500,000 damages cap, which also includes a small-claims track. In Germany, a Federal Patent Court sits as a court of first instances for validity challenges against issued patents, and as an appellate court hears matters that are appealed out of the patent office.

An ongoing question remains whether specialization at the level of the trial court (court of first instance) would be preferable to specialization at the appellate level, or perhaps even designation of an entirely specialized patent court system.²⁵ Many areas of law involve complex technical questions of fact that might lend themselves to expert adjudication. But it is not feasible to create separate courts for environmental, products liability, competition, health, medical malpractice,

²² Art 69 Convention on the Grant of European Patents (European Patent Convention) 1973, 1065 UNTS 255, 275-76, as amended (hereinafter EPC).

²³ Art 1 Protocol on the Interpretation of Article 69 EPC.

²⁴ N Pumfrey et al, ‘The Doctrine of Equivalents in Various Patent Regimes: Does Anybody Have It Right?’ (2009) 11 *Yale Journal of Law & Technology* 261, 284-85.

²⁵ AK Rai, ‘Specialized Trial Courts: Concentrating Expertise on Fact’ (2002) 17 *Berkeley Technology Law Journal* 877-98.

and other areas of law that routinely involve complex factual details. Patent law, however, in addition to involving technical facts, is itself highly a complex legal field, perhaps meriting specialty treatment. To the extent that the facts of patent cases are difficult, specialized trial courts might be beneficial; to the extent that the law itself poses special challenges, specialized appellate courts may be called for.

Specialized courts such as those found in the United States, the United Kingdom, and Germany accumulate experience in the intricacies of patent law, potentially giving litigants the benefit of their particularized legal expertise.²⁶ Specialized courts may also provide other benefits; for example, the Federal Circuit is widely understood to have been created by the US Congress in order to create national uniformity in patent law, so as to prevent forum shopping for adjudication that would yield a preferred outcome.²⁷ At the same time, the potential downsides of such specialty courts are also the subject of ongoing debate. Specialized fora may be subject to capture as judges begin to identify with the litigants or advocates who regularly appear before them, or they may become myopic with regard to the place of patents within the larger network of legal and social policy.²⁸

Specialized courts may also create procedural anomalies within a larger generalist judicial system. For example, in the United States the Supreme Court often uses ‘circuit splits’, which is to say conflicting decisions between inferior appellate courts, as a signal to identify issues that it needs to address via discretionary review. But because there is only one inferior appellate court that hears patent cases, this mechanism is unavailable to signal the importance (or unimportance) of patent issues.²⁹ In the absence of its usual indicator for legal importance, the Court has begun frequently asking for the views of the executive branch on patent matters, in the form of invited briefs from the Solicitor General’s office.³⁰

An alternative to judicial patent adjudication may be some form of administrative proceeding. Many jurisdictions offer the possibility of challenging the government grant of exclusivity via proceedings in the agency that issues the patent. Many jurisdictions allow such challenges in the form of opposition proceedings, some of which may occur prior to grant of the patent, but which often occur after the grant of the patent. In the United States, pre-grant opposition proceedings do not exist, but post-grant proceedings do, and are referred to as either ‘post grant review’ or ‘*inter partes* review’. The first type of (post grant) review may occur immediately after grant of the patent, for a limited period of nine months, on nearly any of the grounds related to the statutory criteria for a patent. The other type of (*inter partes*) proceeding can be initiated later in the life of the patent, on more limited grounds. These types of proceedings are relatively new in

²⁶ RC Dreyfuss, ‘Specialized Adjudication’ (1990) *Brigham Young University Law Review* 377.

²⁷ RC Dreyfuss, ‘The Federal Circuit: A Case Study in Specialized Courts’ (1989) 64 *New York University Law Review* 1.

²⁸ RC Dreyfuss, ‘The Federal Circuit: A Continuing Experiment in Specialization’ (2004) 54 *Case Western Reserve Law Review* 769.

²⁹ CA Nard & JF Duffy, ‘Rethinking Patent Law’s Uniformity Principle’ (2007) 101 *Northwestern Law Review* 1619.

³⁰ JF Duffy ‘The Federal Circuit in the Shadow of the Solicitor General’ (2010) 78 *George Washington Law Review* 518.

the United States, which adopted them in order to defray the high cost of litigating patents through the US court system.

Other countries have a longer history of experience with such oppositions, where they are often the preferred route for competitors to challenge defects in the patent grant. In the European Patent Office, opposition proceedings may be brought within 9 months of the patent grant, and offer a chance to nullify the patent with respect to all the EPC member states in which it is designated for protection. In Germany, opposition proceedings ameliorate the peculiarity of the German court system that bifurcates actions for infringement from actions regarding invalidity, requiring separate proceedings in separate courts. There too opposition proceedings can be brought within 9 months of the patents issuance, and may be appealed to the Federal Patent Court. After the 9-month period, proceedings to nullify a patent may be brought in the Federal Patent Court, but proceedings for infringement are brought in the civil district courts. The bifurcation of such issues sometimes results in the bizarre circumstance where a patent is deemed by separate proceedings ‘invalid but still infringed’.

4. Patent Eligibility

No area of patent law has received more attention in the past several decades than that of patent eligibility, which is to say, the subject matter that is properly eligible to receive a patent. The definition of proper subject matter has been the topic of copious scholarly commentary, protracted litigation, extensive judicial and administrative opinions, and has received a surprising degree of attention in the popular press. One might perhaps expect the issue to be non-existent, as Article 27 of the TRIPS Agreement requires signatories to make patents available for inventions in all fields of technology, with only a couple of allowable exceptions for patents contrary to public order, medical processes, and complex living organisms.³¹ However, the fundamental question that has repeatedly arisen is whether certain developments or discoveries constitute *inventions*, a question not addressed by the treaty. If then certain subject matter falls outside the definition of invention, or does not lie within a field of technology, Article 27 never comes into play.

The problems encountered in determining patent eligibility are well illustrated in the opinion of the Canadian Supreme Court, *Harvard College v Commissioner of Patents*, where the issue was the patent eligibility of a genetically modified mammal, the so-called ‘Oncomouse’.³² The mouse, developed as a laboratory model for cancer research, had received patents from patent offices in a number of other jurisdictions, including the USPTO and (after extended proceedings) the European Patent Office. However, the application was refused by the Canadian patent office on the grounds that a living organism was not patentable subject matter under the Canadian patent statute, which lists the categories of art, manufacture, process, machine, and composition as patent eligible subject matter.

³¹ Art 27 Agreement on Trade-Related Aspects of Intellectual Property Rights 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, THE LEGAL TEXTS: THE RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS 320 (1999), 1869 UNTS 299, 33 ILM 1197 (1994) (hereinafter TRIPS).

³² *Harvard College v Canada (Commissioner of Patents)* 2002 SCC 76.

When the case reached the Supreme Court, the majority of the Court agreed – over a strident dissent – that a complex living organism such as a mouse did not fit any of the available statutory categories. In particular, the Court reasoned that a mouse did not fit the category of ‘composition of matter’, because the common meaning of this term would not include living creatures, but only inanimate materials. Thus, according to the Court, the term Parliament used did not contemplate complex organisms, indicating that the Legislature did not have animals such as a mouse in mind when the statute was enacted. Absent new legislative direction to the contrary, a living creature was therefore excluded from any of the statutory categories.³³

The decision is particularly notable in light of a previous decision by the United States Supreme Court thirty years prior. Canada shares with its neighbor immediately to the south virtually the same statutory definitions of patentable subject matter; the language of the two countries’ statutory provisions is nearly identical. In the landmark case *Diamond v Chakrabarty*,³⁴ interpreting the same language as that interpreted by the Canadian Supreme Court in *Harvard College*, the United States Supreme Court reached the opposite conclusion: the US Court interpreted the term ‘composition of matter’ as included living organisms. According to the Court, the intent of the United States Congress was that the subject matter provisions be broad and inclusive so as to incorporate unforeseeable technologies such as a genetically modified living organism.

Canada has since effectively eviscerated the holding of the *Harvard College* case, via a subsequent Supreme Court case opining that, even if a genetically modified organism is not patentable under their statute, the genetic sequence underlying the modification may be.³⁵ Thus, rather than drafting claims to a genetically modified mouse, an inventor in Canada might do better to draft claims to the gene itself, which may happen to be situated in a mouse. But this solution to the biotechnology patent eligibility itself rests upon a controversial question of patent subject matter. Specifically, an ongoing controversy has surrounded the patent eligibility of molecules isolated and purified from their native state, and most particularly patents on genetic nucleotide sequences, or ‘genes’ drawn from living organisms.³⁶

As in Canada, the USPTO and many other national patent offices granted such patents over the latter part of the twentieth and beginning of the twenty-first century, despite questions over whether such molecules constitute ‘products of nature’ rather than human inventions. Clearly these molecules are not naturally found in a purified or isolated state that can be put to technical uses, but nonetheless some version of the molecule exists prior to human intervention. Some critics asserted that isolation and purification of an existing substance fell short of the requirement for patent eligibility.

³³ DL Burk, ‘Reflections in a Darkling Glass: A Comparative Contemplation of the *Harvard College* Decision’ (2003) 40 *Canadian Business Law Journal* 219.

³⁴ 447 US 303 (1980).

³⁵ *Monsanto Canada Inc v Schmeiser* 2004 SCC 34.

³⁶ RS Eisenberg, ‘How Can You Patent Genes?’ in D Magnus et al (eds), *Who Owns Life* (Prometheus Books 2002) 117-34.

This question was taken up by the United States Supreme Court in 2013 in *Myriad Genetics*, where in a somewhat incoherent decision, the Court held that at least some nucleotide sequences constituted ineligible products of nature.³⁷ These patent ineligible molecules displayed the same sequence found in human chromosomes. Other versions of the molecule, synthesized via laboratory processes, and having a somewhat different sequence than found in human chromosomes, were at the same time held to constitute patentable subject matter. The opinion left unclear the precise doctrinal distinction between the two types of molecules, but placed into doubt a wide array of previously accepted biotechnology patents.

Additionally, as of this writing, the *Myriad* decision appears to place the United States out of step with many of its trading partners, at least some of whom adopted laws permitting gene patents in order to harmonize their approach with the now-defunct rule in the United States. The EU Biotechnology Directive, for example, expressly includes isolated and purified genetic molecules within patentable subject matter, following the position adopted by the European Patent Office in administering the EPC, while also limiting the scope of protection for genetic products to the product when performing the specific function for which it was patented.³⁸ But in Australia, the High Court, reviewing *Myriad*'s patents to the same genetic sequences as those considered in the United States, followed suit, with a majority opining that such molecules constituted 'information' which was not of human manufacture, and were otherwise unsuited to protection having regard to the purpose and coherence of patent law.³⁹

Software Subject Matter

The second technological 'problem child' for patent subject matter has been computer software, where eligibility questions have been addressed in parallel with those in biotechnology.⁴⁰ The software cases, rather than dealing with the 'product of nature' exclusions from subject matter, have grappled with other excluded categories such as abstract ideas, mental processes, mathematical algorithms, and laws of nature. These forbidden categories are not mentioned in the US statute, but are rather the product of common law judicial interpretation of the statute. By contrast, these are explicitly set forth in the European Patent Convention as lying outside patent eligibility when claimed 'as such'.⁴¹ Software, too, is explicitly denominated by the EPC as failing patent eligibility, as are business methods and methods of playing games, when claimed 'as such'.

The explicit articulation of software and business methods as forbidden categories of subject matter under the EPC might initially appear to preclude patents that have routinely issued for

³⁷ 133 SCt 2107 (2013).

³⁸ Arts 3(2) & 9 Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions OJ L 213/13 (hereinafter *Biotech Directive*); Case C-428/08 *Monsanto Technology LLC v Cefetra BV* [2010] ECR I-06765.

³⁹ *D'Arcy v Myriad Genetics* [2015] HCA 35.

⁴⁰ DL Burk, 'Patent Law's Problem Children: Software and Biotechnology in Trans-Atlantic Context' in RL Okediji & MA Bagley, *Patent Law in Global Perspective* (Oxford University Press 2014) 187.

⁴¹ Art 52(3) EPC.

such inventions in the United States. But the EPC exclusion is subject to the qualifier ‘as such’. The meaning of this qualification has been elusive, suggesting that excluded subject matter such as software or other business methods cannot be claimed as software or business methods, but potentially could be claimed as something else. Consequently, many EPO decisions have grappled with the question of tangibility, whether the specification of some type of physical apparatus is necessary or desirable for software or business methods to constitute patentable subject matter. After periods of applying and then discarding various subject matter tests, the EPO currently seems satisfied to accept as patent eligible any invention that recites an apparatus or physical embodiment.⁴² However, inventions that pass this subject matter test may still fail patentability on other grounds, such as the requirement of non-obviousness, which the EPO assesses having regard to the technical aspects of the subject matter exclusively. For this reason, implementing a business method or other suspect process on standard computer hardware is likely to lack an inventive step.

In the United States, over the same period, decades of software subject matter cases have yielded a hauntingly similar outcome. Repeated revisiting of the software subject matter questions has culminated in the holding of *Alice Corp v CLS Bank International*, where the Supreme Court articulated a two-step test for patent eligibility: first, determine whether the patent claims an excluded category such as an abstract idea or law of nature; if it does, then determine whether the patent articulates some inventive concept that makes the claims something more than an attempt to patent the forbidden subject matter.⁴³ Each of these steps appears oriented toward fostering narrower, apparatus oriented claims. Claims are more likely to pass the first prong of the test if they are tied to a concrete embodiment, so as not to be abstract; and claims that fail the first step are most likely to pass the second when to an wedded to an unconventional implementation. In general the test appears intended to penalize and so deter overly broad and ambitious claiming. In the short period subsequent to the *Alice* decision, the trend appears to be frequent invalidation for litigated software patents, and frequent denial of software patent applications.

5. Patentability Requirements

To qualify for a patent, the invention, as defined by its written specification, must meet be judged to meet certain substantive legal criteria. The substantive requirements constitute some version of novelty, usefulness or industrial application, and inventive step or non-obviousness. Each of these poses a substantive challenge, but the last is often considered the highest barrier to patentability. The United States patent statute defines obviousness in terms of what the PHOSITA would judge to be obvious at the time the patent application was filed.⁴⁴ This metric is not unusual; Article 56 of the EPC similarly defines the inventive step in terms of what would be obvious to the person of skill in the art.⁴⁵ This standard implies that different technologies or ‘arts’ may have different levels of ordinary skill. For example, the ordinary practitioner in molecular biology may have a high degree of formal training at the PhD level, whereas some

⁴² RM Ballardini, ‘Software Patents in Europe: The Technical Requirement Dilemma’ (2008) 3 *Journal of Intellectual Property Law & Practice* 563, 567-68.

⁴³ 134 SCt 2347 (2014).

⁴⁴ 35 USC §103 (2012).

⁴⁵ Art 53 EPC.

types of mechanical arts, or for that matter software coding, may be largely self-taught. PHOSITAs in these different technologies might view innovation quite differently.

The skill of the PHOSITA is similarly linked to the universe of available information. The PHOSITA, constituting a legal construct rather than any natural person, is presumed to know all of the relevant prior art, and the obviousness of the invention is judged against the universe of prior art that the PHOSITA is presumed to know. But this of course leaves the question as to what the universe of relevant prior art should be: if the invention is, let us say, a new type of monoclonal antibody, is the relevant universe of prior art all biological knowledge? Or is it a smaller subset of knowledge, such as all immunology? Are related bodies of information, such as molecular genetics and biochemistry, included in the body of prior art or not?

This prior art question is critical to the obviousness inquiry, because a smaller, narrower body of prior art makes a finding of obviousness less likely. The larger the universe of knowledge in which the PHOSITA is presumed to operate, the more likely that references will be found that will render the claimed invention obvious. Stated differently: a smarter, more knowledgeable PHOSITA is more likely to find the invention obvious, and the definition of relevant prior art defines the knowledge of the PHOSITA. In the United States, courts have addressed the prior art question with a two step test for analogous arts: asking first whether the prior art reference is from the inventor's field of endeavor, and if not, whether the reference might nonetheless be one that was pertinent to the problem that the inventor was trying to solve.

This variation among technologies in the legal metric for innovation constitutes a central feature of the patent system. The obviousness function follows the economics of risk and decision-making, as demonstrated in pioneering work by Richard Nelson and Robert Merges on the economics of patents.⁴⁶ Merges and Nelson explained how the obviousness standard serves to reward risk-taking in technological development. The less obvious an invention would be to those of ordinary skill, the more uncertain the outcome will be when pursuing it. Increased investment into research and development of non-obvious inventions is therefore risky; the outcome is uncertain and the effort may fail. Risky research investments require a larger pay-off, or the risk will not be taken. Obviousness thus helps calibrate the patent reward to uncertainty and investment risk: the riskier and more uncertain the investment in a new technology, the higher the likelihood of receiving a patent when the risk-taking pays off.

This calibration mechanism is closely tied to the distinction that is often drawn between legal rules and legal standards.⁴⁷ The designation of rules has gone to legal imperatives that are clear-cut, bright-line, often binary requirements. The novelty and priority provisions of patent law are full of such imperatives: eg, prior art available to the public before the date a patent application is filed is considered in determining novelty, prior art available to the public after the date of filing is not. Such legal rules are fairly straightforward; their application and effect can be easily determined once the relevant criterion – such as the date of filing – is known. They are easier to

⁴⁶ RP Merges & RR Nelson, 'On the Complex Economics of Patent Scope' (1990) 90 *Columbia Law Review* 839.

⁴⁷ CM Rose, 'Crystals and Mud in Property Law' (1988) 40 *Stanford Law Review* 577.

administer, and to follow, but their simplicity and clarity often makes them rigid and inflexible, and literal application sometimes yields harsh results that might be considered unfair.

In contrast, legal imperatives designated as standards lack the binary structure of rules. Standards are typically more fact-specific and more flexible, taking specific circumstances into account. They often encompass multifactor balancing tests, incorporating diverse and complex considerations. The strengths and weaknesses of standards are reciprocal to those of rules: being more flexible, standards can be adapted to produce a customized result under any given set of factual conditions. At the same time, this flexibility makes them less predictable, so that notice of, and compliance with legal expectations becomes difficult.

In practice, few legal imperatives are pure rules or pure standards; legal provisions span a continuum anchored on one end by rules, modulating toward standards at the other. Different types of imperatives are found in different sections of the patent system. If patent novelty provisions often fall on the rules end of the continuum, then the PHOSITA standard for obviousness more closely resembles a standard. It is highly malleable depending on the facts at issue, and produces different legal outcomes for different technical situations. The technology-dependent nature of the PHOSITA offers flexibility, but also comes with the accompanying drawback that the obviousness determination often seems uncertain or vague, and is difficult to predict in advance.

The mechanisms at work in obviousness are not unique in the patent system. In work with Mark Lemley, I have argued that the PHOSITA standard provides a paradigm case of the statutory ‘policy levers’ that allow the patent system to perform its incentive function across a range of constantly changing technologies.⁴⁸ Different technological sectors have vastly different requirements for investment; developing a new pharmaceutical may cost hundreds of millions of dollars, and developing a new semiconductor device may be similarly expensive, but developing a new software product will cost orders of magnitude less. At the same time, different industries experience entirely different commercial production cycles; software and semiconductor products typically have a very short product life, measured in months or perhaps a few years, before the product is superseded and obsolete. Chemical and pharmaceutical inventions on the other hand, may be commercially viable for decades. The correspondence between inventions and products also differs; commercial products in biotechnology and chemical arts typically entail a single invention, such as a novel molecule, whereas commercial products from semiconductor manufacturers typically entail hundreds of patented inventions within a single device.

If investment is to be encouraged in all these differing industries, the incentives need to differ radically: a very substantial incentive will be needed for pharmaceuticals, much less incentive is needed for software. The policy question is how to accommodate the diverse innovation profiles of different technical fields within a single statutory scheme. One approach could be to enact specialized statutes custom tailored for each technology. Setting aside the problem of the considerable and unlikely degree of legislative attention that would be necessary to stay abreast

⁴⁸ DL Burk & MA Lemley, *The Patent Crisis and How the Courts Can Solve It* (The University of Chicago Press 2009).

of new technologies and enact statutes for them, experience teaches that specialized statutes, designed for a particular technology, do not fare well over time. There is, for example, little evidence that the European Directive on Legal Protection of Databases has promoted innovation in its specialized field.⁴⁹ The same is true for the United States' Semiconductor Chip Protection Act.⁵⁰ One clear danger of such *sui generis* systems is that they rapidly become obsolete; technology progresses, and statutes written for a particular technology require constant updating if they are not to fall into desuetude.

Instead, statutes of general technical application, such as those found in the patent system, fare much better, as they are generally designed to accommodate a wide range of technologies, including technologies not yet discovered. Standards-based 'policy levers' in patent statutes allow courts or administrative agencies to adapt the requirements of the law to the innovation profiles of existing and emerging technologies. The PHOSITA standard is one example of a number of patent doctrines that explicitly ask legal decision makers reviewing a patent to consider the invention with regard to its particular technical field. As Nelson and Merges realized, the incentive for a given invention is thus directly connected to the risks taken in that field – the risks taken and the incentive provided for software will be entirely different than those associated with pharmaceuticals, or semiconductors, or other fields of innovative endeavor.

6. Exemptions

User privileges and exemptions are on the whole less common in the patent system than they are in other areas of intellectual property, such as copyright, where jurisdictions typically recognize a wide range of exceptions to the exclusive rights of the intellectual property owner. For example, many jurisdictions include in their patent law an exception for private use much like the private use exception often found in copyright. In the United Kingdom, a statutory exception excuses unauthorized private uses of the invention, which are also to be 'non-commercial'.⁵¹ In many cases such private use exceptions complement, and sometimes overlap with an experimental use exception, which is also often codified as a statutory provision. Experimental use exceptions allow for experimentation and improvement of a patented invention, even though such activity might otherwise constitute an infringing use. Typically this exception may encompass commercial uses, as it does in the United Kingdom, Germany, and elsewhere.

However, in the United States exceptions to the exclusive rights of the patent holder are almost unknown. The United States patent statute is an outlier in this regard, as it contains no provision for private or experimental use. The United States does have a narrow statutory provision for uses related to regulatory approval of some medical and pharmaceutical inventions.⁵² There is also a separate limited common law exception recognized in some older judicial decisions. These decisions recognize an experimental use exception that resembles an exception for personal use, covering only non-commercial use of a patented invention for purely 'philosophical' and

⁴⁹ SM Maurer, PB Hugenholtz & HJ Onsrud, Europe's Database Experiment (2001) 294 *Science* 789.

⁵⁰ Burk & Lemley (n 10) 98-99.

⁵¹ S 60(5)(a) Patents Act 1977 (UK), as amended (hereinafter PA).

⁵² 35 USC §271(e) (2012).

personal investigation. Recent Federal Circuit jurisprudence has held that this exception, to the extent it may continue to be recognized at all, is so extremely narrow as to be essentially non-existent, excluding any use of the invention where money may have changed hands. Thus, for example, unauthorized use of an invention in university research would not qualify for the exception, as tuition and grant money will almost certainly be moving through university accounts.⁵³

In contrast to the US position on experimental use, it is worth briefly considering the development of the experimental use exception in Canada, another jurisdiction with a strong common law tradition. The Canadian patent statute contains explicit experimental use exemptions, but as in the United States, experimental use in Canada has been primarily the subject of judicial consideration. Unlike in the United States, in Canada experimental use has developed as a broad and robust common law doctrine that encompasses a rather wide range of testing and investigation.⁵⁴ Unauthorized uses to determine how an invention works, or to evaluate the commercial viability of an invention, or to assess whether to purchase the invention from the patent holder, all would likely fall within the broad Canadian exception.

Many jurisdictions also recognize subject matter exclusions for inventions that might disrupt morality or public order, and this is explicitly permitted under TRIPS.⁵⁵ In general such exclusions have tended to involve controversial biotechnology inventions, such as human embryonic stem cells, although harm to the environment or non-human animal welfare may also be grounds for a public order exclusion. But here again the United States differs quite substantially from its trading partners. The view of both the judiciary and the USPTO has been that judicial and administrative bodies are in a poor position to gauge morality, and that developments such as, for example gambling devices or contraceptives that are considered immoral at one point in time may be viewed as commonplace or even favorably by future generations.⁵⁶ Consequently, neither the courts nor the USPTO are inclined to invalidate patents on moral grounds, and so long as some legal utility can be found for the invention, regulation of its use is left to the legislature.

The lack of experimental use or similar provisions in the US statute has led to a series of proposals for a flexible ‘fair use’ provision in patent law similar to that found most famously in the copyright law of the United States and a handful of other jurisdictions, and discussed by Jane Ginsburg in the following Chapter of this volume.⁵⁷ Rather than a specific, defined exemption, a ‘fair use’ exemption would be a fact-specific, circumstantial standard. In the copyright context, fair use has raised some question as to whether such a flexible standard can be considered compatible with the ‘three step test’ set forth in TRIPS for exceptions to exclusive rights: the exception must be limited, must not unreasonably conflict with exploitation of the right, and

⁵³ *Madey v Duke University* 307 F3d 1351 (Federal Circuit 2002).

⁵⁴ *Dableh v Ontario Hydro (CA)* [1996] 3 FC 751.

⁵⁵ Art 27(2) TRIPS.

⁵⁶ *Juicy Whip Inc v Orange Bang Inc* 185 F3d 1364 (Federal Circuit 1999).

⁵⁷ MA O’Rourke, ‘Toward a Doctrine of Fair Use in Patent Law’ (2000) 100 *Columbia Law Review* 1177; KJ Strandburg, ‘Patent Fair Use 2.0’ (2011) 1 *University of California Irvine Law Review* 265.

must not unreasonably prejudice the legitimate interest of the rights holder.⁵⁸ However, a less punctilious reading of TRIPS suggests that exceptions that are reasonable and proportionate to a legitimate policy purpose comport with the test, whether considered as a matter of copyright or of patent.⁵⁹

Such an exemption might also ameliorate other issues. Infringement of the patent owner's exclusive rights typically involves manufacturing, selling, importing, or making other uses of the claimed invention. The scope of the rights is generally broad, and may not entail knowledge of wrongdoing; for example, the US statute does not indicate any type of intent requirement for the act of infringement. The result is effectively a regime of strict liability, where any unauthorized use of a patented invention, knowing or unknowing, is penalized.

Such a strict liability regime may lead to perverse results, particularly where modern technologies are concerned, as illustrated by the now-infamous infringement scenario advanced in the Canadian Supreme Court decision *Monsanto Canada v Schmeiser*.⁶⁰ Monsanto was the holder of patents to genetically modified, herbicide tolerant Round-Up Ready crops, including genetically modified canola plants. Schmeiser, a canola farmer, was found to be growing Monsanto's patented plants on his farm, and was sued for infringement of the Monsanto patent. Schmeiser asserted that he was unaware of how he came to be growing crops with the traits claimed in the patents; he offered the possibility that seeds had blown onto his land from a passing truck, or perhaps that the previous growing season pollen from another farm growing plants from Monsanto seed had drifted downwind and fertilized his crop, so that seed he saved from the previous year inadvertently included the genetic modifications covered by the patent.

It was clear that the trial court did not find Schmeiser's protestations credible, as there was evidence that the collection and planting of seed on Schmeiser's land was intentional. Nonetheless, even though Schmeiser failed to prove involuntary infringement, the scenario of inadvertent cross-pollination might not be implausible in other cases where living organisms are the subject of patents, and raises questions regarding not merely unintentional infringement, but non-volitional infringement. As the Canadian Supreme Court pointed out, under the Canadian statute (much like under the US statute) intent to infringe was largely irrelevant, although might provide a defense to negate elements of the act of infringement in some circumstances. A number of commentators,⁶¹ and at least one US judge,⁶² have been troubled by this potential

⁵⁸ Art 30 TRIPS.

⁵⁹ C Geiger, D Gervais, & M Senftleben, 'The Three-Step Test Revisited: How to Use the Test's Flexibility in National Copyright Law' (2014) 29 *American University International Law Review* 581.

⁶⁰ *Monsanto Canada Inc v Schmeiser* 2004 SCC 34.

⁶¹ P Heald & JC Smith, 'The Problem of Social Cost in a Genetically Modified Age' (2006) 58 *Hastings Law Journal* 87; S Munzer, 'Plants, Torts, and Intellectual Property' in T Endicott, J Getzler & E Peel (eds), *Properties of Law: Essays in Honor of Jim Harris* (Oxford University Press 2006) 189.

⁶² *Smith-Kline Beecham Corp v Apotex Corp* 403 F3d 1331 (Federal Circuit 2005) 1361 (Gajarsa J, opining that hypothetical patent liability based on the *Schmeiser* scenario 'cannot possibly be correct').

outcome, suggesting that some type of volition requirement, if not intent, should perhaps be incorporated into infringement.

7. Remedies

A patent is only as good as the rights it grants, and there are as a practical matter no rights without a remedy. Thus, the increased focus on patents around the world has led to an increasing focus on patent remedies, although they remain one of the least studied and most under-theorized areas of patent doctrine. Generally patent damages include injunctive relief and monetary damages, although the specific forms of relief vary to some degree among jurisdictions. For example, in Canada, either damages or an accounting for profits may be elected.⁶³ In the United States, due to a historical limitation on the patent statute, damages equal to lost profits or a reasonable royalty are available, but restitutionary relief is not.⁶⁴

The scope of available remedies is particularly important as a counterbalance or rectification for problems arising elsewhere in the patent system. The salience of damages is for example clear from the Canadian *Schmeiser* case mentioned previously. Having found that any use, including inadvertent and possibly even involuntary use of the genetically modified crops constituted infringement, the Court declined to award damages. Monsanto had sought an accounting for profits, or in other words, disgorgement of whatever Schmeiser had gained by his infringement. But the Canadian Supreme Court pointed out that this measure of damages entitles the patent owner only to whatever portion of the defendant's profits are attributable to use of the invention. The Court reasoned that Schmeiser had gained no profit from use of the invention; all of his profits were attributable to simply growing and selling seed, not to growing and selling genetically modified seed. Consequently, Monsanto was entitled to nothing and recovered nothing. Thus, a prudent application of remedies doctrine ameliorated a controversial finding under infringement doctrine.

Injunctions frequently issue against infringing parties once a violation of the patent holder's rights has been determined, but this may be a point where limitations or exemptions unexpectedly come into play. US courts have historically tended to issue such permanent injunctions, but have sometimes withheld them in the public interest, as for example in the famous case of *City of Milwaukee v Activated Sludge*,⁶⁵ where the inventor brought suit against a municipality for infringement of his patented method of sewage treatment. Although the city was found to be infringing, the court was reluctant to issue an injunction that would potentially shut down the sewage treatment for the city, endangering public health. The victorious patent holder was therefore limited to receiving only monetary damages – a decision that effectively conferred on the infringer a compulsory license at a royalty rate set by the court.

The incorporation of public interests into the calculus of American injunctions has been formalized by the recent decision of the United States Supreme Court in *eBay v*

⁶³ S 57(1)(b) Patent Act 1985 (Canada).

⁶⁴ 35 USC §284 (2012).

⁶⁵ 69 F2d 577 (7th Circuit 1934).

MercExchange.⁶⁶ According to the Court, the statutory requirement that permanent injunctions be issued on ‘equitable’ grounds requires consideration of factors traditionally taken into account for relief in courts of equity. Specifically, the Court held that petitions for injunctive relief must consider: first, whether an adequate remedy is available in the form of damages; second, whether the petitioner is likely to suffer irreparable harm in the absence of injunctive relief; third, the balance of hardship between the patent holder and the infringer if an injunction is granted; and finally, the public interest. The result of this balancing test has been more frequent imposition of judicially created compulsory licenses, particularly where the public interest in favor of a liability rule is compelling.

The *eBay* holding has been widely understood to constitute a judicial response to the problem of patent ‘trolling’ or of non-practicing entities (NPEs), which although troubling, and widely discussed, is largely confined to information technologies, and which to date is more typical in the United States than elsewhere.⁶⁷ The ‘trolling’ scenario involves repeated assertion of obscure and sometimes questionable patents that purport to cover basic functions of widely used technologies. Companies acquire portfolios of such patents, and then threaten nuisance lawsuits against companies that have already established businesses around the purportedly covered technologies. The threat is typically accompanied by a strategically priced offer to license or to settle at a cost far lower than the very high cost of American patent litigation.

Accused infringers who might otherwise be skeptical about the validity of the patent will tend to settle rather than incur the costs of defending a lawsuit. Additionally, unsuccessfully defending a lawsuit may be disastrous if a permanent injunction becomes a reality – such a court order can entirely shut down a company, giving the NPE enormous bargaining leverage. But if monetary gain is the goal of such lawsuits, then under *eBay* injunctions are not necessary – a damages remedy is adequate to provide money, and if money is adequate, the *eBay* factors militate against providing the additional leverage of an injunction. Consequently, injunctive relief to NPEs has fallen substantially since the *eBay* decision.⁶⁸

At the same time, perhaps the most dramatic and visible instances of the debate over injunctions have emerged amid the long series of legal disputes over mobile telecommunication devices. These so-called ‘smartphone wars’ have produced a string of judicial decisions around the globe, including multiple decisions in the United States and in Germany, and additional decisions in Korea, the Netherlands, the United Kingdom, and elsewhere. The claims asserted by the device manufacturers have encompassed assertions of patent, design protection, trademark, trade dress, and copyright. But many of the disputes have centered on standard essential patents (SEPs) which encompass exclusive rights over technologies that are required for interoperability with other devices and with telecommunications networks.

Such patents display an unusual economic profile, and so pose special remedies problems when they are enforced. Their unusual character arises from the technical necessity of interoperability.

⁶⁶ 547 US 388 (2006).

⁶⁷ CV Chien, ‘Startups and Patent Trolls’ (2014) 17 *Stanford Technology Law Review* 461.

⁶⁸ CV Chien & MA Lemley, ‘Patent Holdup, The ITC, and the Public Interest’ (2012) 98 *Cornell Law Review* 1.

Interoperable technologies such as computers or telecommunications devices tend to converge on a standard: technical commonality is necessary in order for devices to function together.⁶⁹ Technical diversity becomes less feasible in such circumstances. This convergence leads to so-called ‘network effects’: the technical standard becomes increasingly valuable as additional users adopt it, conforming to the standard.⁷⁰ In some instances, standards emerge as users naturally gravitate toward a given technology, and incompatible technologies become increasingly marginalized, often disappearing altogether as the market for the dominant standard evolves. In other cases, standards are deliberately chosen by standard setting organizations (SSOs).⁷¹ These are often private industry groups, although sometimes they are governmental or quasi-governmental organizations.

Network externalities are a particular concern when the standard chosen is subject to intellectual property rights, such as patents. Because of network effects, the adoption of the standard typically gives the standard owner enormous market leverage. The addition of exclusive legal rights in the form of a patent may greatly enhance such leverage. Competitors must adopt the chosen technical standard in order for their products to interoperate with one another; products that do not conform to the standard are technically excluded from functionality. Patents add an additional layer of exclusivity: the holder of a patent could use its exclusivity to pick and choose who is able to compete in the market for the particular technology, and possibly to exclude some potential rivals altogether.⁷²

The potential for such market leverage has lead most SSOs to require from patent holders some promise to license their patented technology on ‘fair, reasonable, and non-discriminatory’ (FRAND) terms, as a condition of adoption of their technology as a technical standard.⁷³ Once such a promise is in place, adoption and incorporation of the standard can proceed, but in a number of instances, disputes may arise either when the patent holder declines to license the technology as promised, or offers licenses that arguably require excessive royalties or other terms not taken by the licensee to constitute FRAND terms. Enforcement of the patent in such cases often leads to a finding of infringement: the defendant is likely to be using the technical standard; indeed, in order for his products to interoperate he has little choice but to employ the patented standard. At the same time, the patent holder has promised authorization for such activity, a promise that may not have been honored.

Such disputes over mobile telecommunications interoperability have repeatedly foundered on the question of injunctive relief. Many jurisdictions have adopted the routine, almost automatic grant

⁶⁹ C Shapiro & H R Varian, *Information Rules: A Strategic Guide to the Network Economy* (Harvard Business School Press 1999) 45-46.

⁷⁰ M A Lemley & D McGowan ‘Legal Implications of Network Economic Effects’ (1998) 86 *California Law Review* 479.

⁷¹ M A Carrier, *Innovation for the 21st Century: Harnessing the Power of Intellectual Property and Antitrust Law* (Oxford University Press 2009) 325.

⁷² J Farrell et al, ‘Standard Setting, Patents, and Hold-Up’ (2007) 74 *Antitrust Law Journal* 603, 616.

⁷³ J S Miller, ‘Standard Setting, Patents, and Access Lock-In: RAND Licensing and the Theory of the Firm’ (2007) 40 *Indiana Law Review* 351.

of a permanent injunction upon a finding of infringement.⁷⁴ Such reflexive grants stem from a deeply formalist stance toward intellectual property. Property regimes are characterized by a legal right to exclude – as opposed to liability regimes, which are generally characterized by a legal right to receive payment. Thus, the reasoning goes, property requires exclusive rights, which inure in the form of injunctions. If patents are indeed a form of property, then an injunction must always attend the patent. This was effectively the stance adopted by the United States Court of Appeals for the Federal Circuit prior to the Supreme Court decision in *eBay v Merc Exchange*, and a similar view has dominated UK and German courts reviewing patent cases.

A more nuanced justification for such automatic injunctions arises from the fear that refusing an injunction would promote a kind of probabilistic opportunism on the part of potential infringers: they could infringe, and if detected and successfully sued, might end up paying royalties. If the infringement were undetected, or enforcement were unsuccessful, then they might escape without payment. The worst case scenario thus entails paying the royalties that they would have paid had they sought permission in the first place, accompanied by a substantial probability of paying no royalties at all. This calculus can of course fairly easily be disrupted by adding deterrents in the form of enhanced damages, restitutionary payments, or other monetary penalties that would make the risk of successful enforcement sufficiently forbidding that bargaining for a license would seem attractive after all.

Thus, as the Mannheim regional court stated in its opinion in the FRAND licensing dispute between Motorola and Microsoft:

If the seeker of the license were in a position to successfully defend against claims for an injunction by the patent owner by arguing that the latter was obligated to grant a license anyhow, on its own volition, the patent owner would be at the mercy of any dishonest licensee, for whom there would be no more incentive to enter into licensing negotiations.⁷⁵

Consequently, in FRAND licensing cases, German courts have until recently tended to enforce the ‘Orange Book Standard’ precedent, which largely shifts the burden of compliance and demonstration of good faith onto the accused infringer.⁷⁶ Under the Orange Book Standard approach, the user of a technical standard may defend against infringement by unconditionally offering to enter into a license at a rate determined by the patent holder, and must behave as a licensee, if necessary paying reasonable royalties into an escrow account, even if the patent holder will not accept them. A patent holder who continues to refuse such munificence may be then judged to be abusing a dominant position under competition law.⁷⁷

⁷⁴ TF Cotter, *Comparative Patent Remedies* (Oxford University Press 2013) 245.

⁷⁵ Regional Court of Mannheim, 2nd Civil Division, Case 2:10-cv-01823-JLR, Document 324-6, filed 5/21/2012.

⁷⁶ (2009) *GRUR International* 747 (BGH).

⁷⁷ Cotter (n 74) 247-48.

A more utilitarian approach has been adopted elsewhere, including the United States since the *eBay* decision. Contrast the Mannheim Court's statement with that of United States federal Judge Richard Posner, sitting as a trial judge in *Apple v Motorola*:

By committing to license its patents on FRAND terms, Motorola committed to license the '898 [patent] to anyone willing to pay a FRAND royalty and thus implicitly acknowledged that a royalty is adequate compensation for a license to use that patent. How could it do otherwise? How could it be permitted to enjoin Apple from using an invention that it contends Apple *must* use if it wants to make a cell phone with UMTS telecommunications capability . . .⁷⁸

Richard Posner is of course well-known as one of the major proponents of the economic analysis of law that has become predominant in the United States; it is therefore no surprise that this view takes certain economic principles, such as network effects and revealed preference, as given. From the purely doctrinal standpoint of the *eBay* test, the legal remedy of damages is clearly adequate, because the patent holder has essentially opted into a liability regime of royalties only by promising FRAND licenses to all comers. From the standpoint of economic analysis, injunctive relief is likely to overcompensate the patent holder who has already indicated his valuation of the patent: the value of a FRAND license. Instrumentally, injunctions are often useful to place the parties in a position where they must bargain, causing public revelation of private valuations that a court otherwise would be required to estimate. But again, the patent holders' valuations have already been revealed and the bargaining has already essentially occurred when the patent holder agreed to FRAND licensing.

The German approach in SEP cases appears to have been largely rejected by the Court of Justice of the European Union, adopting something closer to the American approach.⁷⁹ This leaves some question as the extent to which European courts have the latitude to adopt an *eBay* type of approach to patent injunctions. At least some language in the Directive on Enforcement of Intellectual Property Rights suggests that such latitude exists.⁸⁰ Article 3(2) states that enforcement measures should be 'proportionate' as well as 'effective'. Article 11 of the Directive, specifically addressing injunctions, uses permissive language regarding the availability of injunctive relief: injunctions *may* issue, indicating that there are also instances in which they might not. And Article 12 of the Directive provides for 'Alternative Measures,' authorizing pecuniary compensation on the grounds of a sort of *eBay* test that takes into account the culpability of the infringer, the proportionality of the harm that might be done by an injunction, and the adequacy of monetary damages as a reasonably satisfactory remedy.

8. Related Rights

⁷⁸ 869 FSupp2d 901, 914 (ND Ill 2012) *affirmed in part* 757 F3d 1286 (Federal Circuit 2014).

⁷⁹ Case C-170/13 *Huawei Technologies Co Ltd v ZTE Corp* ECLI:EU:C:2015:477.

⁸⁰ Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights OJ L 159/16.

In many jurisdictions, the patent system exists in association with systems of similar rights, which often go by the name ‘utility model’ or ‘petty’ (from petite) patent.⁸¹ In Australia this form of intellectual property is termed the innovation model. Utility models offer a shortened term of protection, typically six years, and while novelty is still required, they entail a lower standard for inventive step than that demanded by full-fledged patents. Rather than a full examination, utility models require only registration of the invention, with perhaps a quick review to ensure compliance with formalities. Such truncated patents offer a lower level of protection in return for a quicker, simpler application process. By doing so, utility models may provide a method of encouraging sub-patentable innovation, which would not otherwise warrant the effort and expense of full patent examination.

But utility models may also point the way toward resolution of ongoing difficulties attending the grant of full patents. Full patent examination is costly and time consuming, and yet, patent applications receive relatively little scrutiny; given the thousands of applications filed every year no patent office has the resources to thoroughly examine all of them. Examiners spend only a few hours with a given application. The number of patent applications has grown enormously over the past two decades and continues to grow. Claims to obvious or inadequately disclosed inventions are inevitably allowed, and such patents become a threat to subsequent innovators, used to extract royalties where none should be available

Thus, many of the real or perceived evils of the patent system are blamed on a proliferation of bad patents, which in turn is often blamed on lackadaisical review by patent offices. Some commentators have complained that the brief scrutiny given to patents is insufficient to weed out all of the poor quality applications, which are perhaps statutorily ineligible for a patent, but nonetheless issue due to inadequate review. In the United States and elsewhere, such complaints have led to modest increases in the resources devoted to patent examination. However, detecting and filtering out the majority of poor quality applications would require substantially increasing the level of scrutiny for patent applications, which in turn would require enormous investment in hiring additional examiners and expanding patent office administration.

The prospect for such massive investment in governmental offices is unrealistic. Neither would it likely be desirable, even were the resources to be allocated for such a substantial bureaucratic expansion. Very few patents in fact turn out to be valuable enough to justify increased scrutiny: the vast majority of patents are never enforced, and appear never to be licensed. They prove to be commercial failures, or at best are stockpiled by their owners as future trading chits in business exchanges, or perhaps as a kind of insurance against being sued by someone else employing similar technology. Such patents effectively disappear after they issue, and resources spent on heightened scrutiny of unused patents would be wasted.

And yet this problem with the system may in fact be a feature, or at least a credible strategy for dealing with the vicissitudes of administrative practice – a strategy that Mark Lemley has dubbed ‘rational ignorance’.⁸² Rather than expending the resources to increase scrutiny of patents across

⁸¹ MD Janis, ‘Second Tier Patent Protection’ (1999) 40 *Harvard International Law Journal* 151.

⁸² MA Lemley, ‘Rational Ignorance at the Patent Office’ (2001) 95 *Northwestern University Law Review* 1495.

the board, it would be preferable to identify those that will prove to be valuable or important and focus greater attention on them. Time accomplishes much of this identification function. Although the majority of patents are worth very little, over time it becomes clearer which patents are valuable and which merit increased scrutiny. These patents show up in litigation; they are sufficiently valuable that their owners expend the sometimes quite considerable resources necessary to enforce them. Patent enforcement thus acts as a filter, helping to identify which patents are worth additional scrutiny.

Under this view, the patent office examination process provides a ‘quick look’ at the beginning of a patent’s life, to screen out the very most obviously unsuitable candidates, and later on the courts provide a more searching review to the valuable patents that turn up in litigation. This raises the question as to whether a simple registration system might provide nearly the same benefits, essentially doing away with the costs of providing any screening of applications on the front end. Formal examination likely screens out a number of the very worst applications, but it is not entirely clear that enough are removed to justify the cost, not only to the applicants who traverse the long and sometimes harrowing application process, but of maintaining the extensive government apparatus that conducts patent examination.

At the same time, using time as a filter is itself an expensive proposition, making attractive the attempt to identify on the front end which patents are likely to prove valuable and worthy of heightened scrutiny. As already suggested, the patent office is in a poor position to make such an assessment, even with greatly enhanced resources. Rather, the inventor or applicant is likely to be in the best position to make such an assessment, having the most information about the invention. Thus, a system for identifying valuable patents for scrutiny might best succeed by aligning the inventor’s interests with the public interest in identifying potentially valuable patents.

A related proposal has been to adopt a tiered system, with certain preferred patents, sometimes dubbed the ‘gold-plated patent’.⁸³ Under this approach, applicants who believed their inventions were likely to prove valuable, and who wished to invest in a higher degree of review for their patents, would be required to pay enhanced fees in return for a comprehensive, in-depth examination of their applications. The enhanced fees would defray the cost of more extensive examination, and would result in a patent that would be accorded a higher degree of deference in subsequent legal proceedings. Other patents would be as cursorily examined as they are today, or perhaps merely registered as utility models are. Patents issuing from regular examination, or from registration, would be accorded no deference when later scrutinized in a court proceeding. Utility models, coupled with a system of full utility patents, essentially offer such a tiered system, creating a proof of concept for tiered systems of protection.

9. Plant Breeder’s Rights

For novel plant varieties, specialized systems of plant breeders’ rights offer an alternative to patenting. Under the subject matter provisions of the TRIPS agreement, signatory nations are

⁸³ M Lemley, D Lichtman & B Sampat, ‘What to Do About Bad Patents?’ (2005-2006) *Regulation* 10.

permitted to exclude plants and animals from their patent law, but must offer some form of intellectual property protection for plant varieties, either by means of patents or by a form of intellectual property specific to patent varieties, or some combination of the two. Many signatories have chosen to satisfy this requirement by adherence to the convention of the International Convention for the Protection of New Plant Varieties, or UPOV Convention.⁸⁴ In the European Union implementation comes as a community-wide plant breeder's right, known as the Community Plant Variety Right (CPVR), which is effective in all the Member States. However, the majority Member States also maintain their own national system of plant breeders' rights, and plant breeders can opt for either the community right, or for selected national rights.

Rather than the patentability criteria of novelty, utility, and nonobviousness, UPOV requires plants to be novel, distinct, uniform, and stable. Similar to patents, UPOV compliant rights extend at least 20 years. However, UPOV differs somewhat from patent protection in offering specifically tailored exceptions to the rights of the plant breeder, including exceptions for experimental use, for breeding new varieties, and for private non-commercial uses of a covered variety. Adherents to the Convention may also provide a farmer's exemption, allowing farmers to save seed from year to year for re-planting without violating the breeder's right.

Due to historical and political reasons, the United States falls into the TRIPS category of providing intellectual property in respect of plant varieties through a combination of patents and *sui generis* law. The United States protects sexually reproducing plants by means of the Plant Variety Protection Act (PVPA), which largely conforms to the UPOV Convention. However, US Supreme Court decisions have held that utility patents subject matter extends to genetically modified plants, and that both patents and PVPA protection may simultaneously apply to the same plant variety.⁸⁵ The practical effect of this simultaneous coverage is that the research and farmers' exemptions to PVPA protection are negated by the utility patent, which has no such exemptions: farmers who save seed under the PVPA exemption would still infringe under the utility patent. Additionally, the use of PVPA protection appears to be declining since the utility patent alternative became available.⁸⁶

The European Union has addressed this matter differently, but after a long and tortuous journey seems to have arrived at the same position as the United States. Both the European Patent Convention⁸⁷ and the EU Biotechnology Directive⁸⁸ exclude plant varieties as such from patentable subject matter; they also exclude essentially biological processes for producing plants. This appeared to prevent conventionally bred plants from being encompassed within the scope of utility patents. However, the Enlarged Board of Appeal of the EPO has interpreted the language regarding plant varieties quite strictly, so that individual plants and traits covering multiple

⁸⁴ 1991 Act of the International Convention for the Protection of New Plant Varieties (UPOV Convention) 815 UNTS 89.

⁸⁵ *JEM Ag Supply Inc v Pioneer Hi-Bred International Inc* 534 US 124 (2001).

⁸⁶ MD Janis & JP Kesan, 'U.S. Plant Variety Protection: Sound and Fury...?' (2002) 39 *Houston Law Review* 727.

⁸⁷ Art 53(b) EPC.

⁸⁸ Art 4 Biotech Directive.

varieties may be patented.⁸⁹ Additionally, the products of conventional breeding have been held to be patent eligible.⁹⁰ The result appears to be that conventionally bred plants may be patented, so that the exemptions for farmers and research entailed by the CPVR would be superseded, just as in the United States.

TRIPS also allows signatories to develop their own *sui generis* alternatives to plant breeders' rights. India, for example, has developed a variation on plant breeders' rights that provides remuneration to the community in which the variety was developed. The United States offers a peculiar *sui generis* form of intellectual property protection, the plant patent, for asexually reproducing plants.⁹¹ Plant patents are situated within the same statute as the more familiar utility patents, meaning that plant patents must satisfy the same statutory criteria of novelty, utility, disclosure, and non-obviousness as more generalized patents. But this necessitates certain adaptations, as plants have certain idiosyncrasies that do not easily fit the general statute. For example, as a concession to the difficulty of textually describing vegetable inventions, the disclosure in plant patents is typically visual, such as a photograph of the claimed plant. And as a practical matter, infringement of a plant patent typically must occur by means of unauthorized grafting or sprouting of the existing plant. Thus, plant patents effectively block misappropriation or copying of vegetable material, rather than independent recreation of the plant.

10. Conclusion

The fragmentation and constant evolution of international patent regimes is both a blessing and a curse. While the changing, intersecting diversity of approaches creates enormous complexity in the patent system, recombination of different doctrines and perspectives is our best source of solutions to the innovation needs of a multifaceted global economy that is also in constant motion.

⁸⁹ G1/98 (*Transgenic Plant/NOVARTIS II*) [2000] OJ EPO 111.

⁹⁰ G2/12 (*Tomato II*) & G2/13 (*Broccoli II*) ECLI:EP:BA:2015:G000213.20150325.

⁹¹ 35 USC §§ 161-164 (2012).