

Module 102

[The following is a transcript of the recorded lecture for Module 102 of the PatentX course. The recording of the lecture itself is available through <https://ipxcourses.org>. Stripped of the accompanying slides and other visual materials, the transcript will likely be hard to follow. It is not intended to be a free-standing document. Rather, its purpose is to assist students, who have already watched the lecture, when reviewing the material.]

A. Expansion

Hello. I'm Terry Fisher. This is the second lecture in the PatentX lecture series. The series as a whole can be accessed through the website: ipxcourses.org.

This particular lecture describes the kinds of inventions that may be patented – in the United States and in selected other countries in the world.

This topic is best addressed historically. In brief, there are three overlapping phases to the development of this field.

First, between the eighteenth century and the end of the twentieth century, the subject matter coverage of patent law in most developed countries gradually expanded. In other words, more and more types of inventions were deemed patentable.

Second, in the late twentieth century, developing countries, many of which had previously recognized fewer types of patentable inventions, were encouraged or compelled, by a coalition of upper-income countries, to modify their patent regimes to approximate the expansive coverage typical of the upper-income countries.

This process is sometimes described as international harmonization – a term that, though accurate, obscures the fact that, for the most part, the reduction of differences among countries was achieved by levelling up – in other words, by UICs pressing LMICs to modify their systems to make patent protection available to a larger set of types of invention. As we will see in later lectures, during this period LMICs countries were also pressed to enhance the entitlements enjoyed by patentees – another dimension of harmonization through levelling up.

Finally, in the 21st century, the trend toward domestic expansion and the supplementary trend toward international harmonization were reversed. Efforts to induce or force LMICs to enlarge the set of patentable inventions became both less frequent and less effective. And many UICs began to retreat – shrinking, rather than increasing the set of types of patentable inventions. The net result is that, in the US and many developed countries, the footprint of patent law is smaller today than it was 20 years ago.

In the illustration shown on your screen, I've tried to convey the fact that the three stages overlapped. How could that be? In particular, how could the set of patentable inventions be

expanding and contracting at the same time. The answer is that legal doctrine, like tidal currents, do not change direction all at once. The flood continues in some areas after the ebb has already begun in others.

It's highly unlikely that the ebb now underway will last as long as the flood tide of the twentieth century; to change metaphors, the current diminution in the subject matter coverage of the patent system will probably be regarded by future historians as a market correction, not a recession or depression. But that's just my guess; we'll have to wait to see. [Pause]

The remainder of this lecture will be divided into three parts, corresponding to the three segments of the story. In each part, I'll first sketch the relevant doctrinal developments, then consider possible explanations for the developments at issue.

If you are watching this lecture as part of the PatentX course on Patent Law and Global Public Health, the first two parts of the lecture are required, but the third (describing the recent contraction of patent law in the United States and some other developed countries) is optional. You are of course welcome to watch it. But most likely you might find it a better use of your time to watch the short recorded interview with Jayashree Watal, which in which, drawing on her first-hand experience, she discusses the origins and political economy of the TRIPS Agreement, the most important of the multilateral agreements pertaining to patent law.

OK. Let's begin.

To repeat, until the end of the 20th century, the subject matter coverage of patent law in developed countries grew at an accelerating pace. More and more things became patentable. I'll begin by describing how this occurred in the United States, then provide shorter summaries of the analogous trends in other developed countries.

If you looked only at the texts of the documents upon which US patent law is founded, you might get the misimpression that its subject matter coverage has been expansive from the very beginning.

The foundation of the US patent system is Article 1, Section 8, Clause 8 of the Constitution, which provides: "The Congress shall have Power ... To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."

As you can see, this provision gives the legislature the authority to confer temporary sets of exclusive rights upon both "authors" and "inventors."

Somewhat surprisingly, this subset of the words in the provision was originally intended to support the rights of authors – i.e., copyright law – while

this subset was originally intended to support the rights of inventors – i.e., patent law.

That's partly because the terms "science" and "arts" meant different things in the late eighteenth century than they do today – and partly because the ambitions of the drafters of this provision were not quite the same as the conventional understandings of the purposes of copyright and patent today. Later in this lecture, I'll return, briefly, to those shifts in perspective. If you want to know more concerning the original meaning of this constitutional provision, a good place to begin would be an article by Dotan Oliar entitled, "Making Sense of the Intellectual Property Clause," which was published in the Georgetown Law Journal in 2006.

For present purposes, the crucial aspect of this constitutional provision is the absence of any limitation on the types of Inventors or Discoveries to whom and to which Congress could, if it wished, extend protection. In other words, the potential scope of patent subject matter coverage in the US is very broad.

The language used by the first Congress when, in 1790, it created the first national-level patent system also seems expansive.

Here's the relevant section of the statute, with the crucial language highlighted. Again, one sees seemingly generous coverage – and the absence of any restrictions: "any useful art, manufacture, engine, machine, or device, or any improvement therein."

This statutory language has not changed fundamentally since 1790.

In 1793, when Congress adjusted the patent system, it altered the language to: "any art, machine, manufacture, composition of matter, or any new and useful improvement." The terminology is different, but was not intended to – and did not – change materially the scope of patentable inventions.

150 years later, as part of a comprehensive reform of the patent system, Congress changed one word in the identification of patentable subject matter: process was substituted for art. Again, the goal and the effect was clarification, not substantive change.

The relevant language has not been changed since. (Today, it is found in section 101 of the US Statute.)

Some of these terms are a bit archaic. You'll gradually acquire a sense of their current meanings through experience. Roughly speaking,

Art or process = a way of doing something;

Machine = an artificial structure with moving parts

Manufacture (aka, article of manufacture) = a static artificial structure – i.e., lacking moving parts

Composition of matter = chemical compound.

Graphically, these various categories might be depicted as follows.

The overall zone of the patent system is the red area.

These are processes.

These are products.

Patentable products, in turn, can be subdivided into the three zones just mentioned. As we will see, the distinction between processes and products matters in many ways. The distinctions among the subsets of product patents (depicted with dotted lines), not much.

Despite the apparent expansiveness from the beginning of the statutory definition of patentable subject matter, in practice, the ambit of the patent system during the late 18th and early 19th centuries was limited.

There weren't very many patents.

They weren't litigated very often.

Most pertained to devices to make agriculture more efficient;

The building trades

Things associated with the early stage of industrialization;

And things associated with innovative forms of transportation – like steamboats and railroads.

For the most part, this was because of the narrow range of things that inventors sought to protect.

But it may also have been due in part to the resistance of the courts to certain kinds of inventions.

Initially, the courts' skepticism was not very systematic. Modern scholars and litigants, looking backward, try to discern in the case law clearly demarcated categories of unpatentable inventions. But in truth, there were no firm categories. Rather, as Oren Bracha and Christopher Beauchamp have shown, some courts, some of the time, would refuse to recognize patent protection for inventions that appeared to seek protection for:

“principles” – in other words, the reason or reasons why something worked

“laws of nature” – such as gravity, galvanism, and magnetism

“products of nature” – things that existed prior to or independent of human intervention

If pressed concerning why such things were not patentable, they would sometimes say because they owe their origin, not to man, but to nature or God. But they were equally likely to say something more prosaic – namely, that recognizing patents in such things would confer upon the patentee an excessively large zone of monopoly power.

To repeat, the exclusion of principles, laws of nature, and products of nature from patent protection was far from consistent. Some inventions and discoveries falling into these zones passed muster. But the skepticism of some judges on these fronts – when combined with the limited set of inventions that occurred to inventors to be patentable -- curbed the ambit of the system.

Then gradually, the zone began to expand. Occasionally, this occurred through statutory change.

Sometimes, instead, it occurred quietly, behind the scenes, through generous interpretation of the patent statute by the Patent and Trademark Office.

Eventually, the liberality of the patent office would come to the surface, typically when the defendant in an infringement suit challenged an unconventional patent. In such cases, the courts sometimes held the line – but sometimes reconsidered their stances and liberalized the rules.

Through one or another of these mechanisms, the zone of coverage of the patent system gradually grew.

Here are some examples.

In 1842, Congress added to the zone of utility patents – with which, in this course, we are primarily concerned – a new set of Design Patents.

These behaved – and continue to behave – differently from utility patents. They are shorter in duration, they cover only the appearance of things, the criteria for determining when they are infringed are different from the criteria for utility patents, and so forth.

Periodically, during these lectures, I will provide additional detail concerning the special characteristics of design patents. But, for present purposes, the key point is that they increased the set of patentable inventions.

Another example: In the late 19th century, German and then US firms began for the first time to create pharmaceutical products that were effective in reducing fevers, alleviating pain, or curing diseases. Many of the US firms hesitated to seek patents on these products, in part because of the association of drug patents with charlatans, but the German firms had no such qualms and soon sought and obtained patents on their products -- and the American firms eventually followed their lead.

Many of the products on which they sought patents were purified forms of naturally occurring compounds – and thus implicated the hostility of many judges to patents on products of nature. Slowly, unevenly, the courts came to acquiesce in the granting and enforcement of such patents. One of the grounds on which they relied was the proposition that purification produced a new material. They were especially likely to take this stance if the purified form exhibited qualities not possessed by the unpurified form and/or the purified form was medicinally and thus commercially valuable.

In the 1890s, Bayer's patent on aspirin was upheld on this basis.

Later, Judge Learned Hand invoked a variant of this approach in upholding a patent on adrenalin, a purified extract from the suprarenal gland.

In the early part of the twentieth century, the production and commercialization of hormones owed much to the availability of patents, which in turn was founded on this doctrinal trend.

Yet another example: Until 1930, it was widely assumed that patents were not available for living things.

The Plant Patent Act (sometimes abbreviated PPA) overrode that assumption in one narrow field, by extending patent protection to asexually reproduced new plant varieties.

The PTO's explanation of what counts as asexual reproduction appears on your screen.

Like Design Patents, the patents available under this statute are easier to obtain than utility patents (in ways we will explore in due course) but also weaker than utility patents.

Much of the pressure that prompted Congress to adopt this statute came from the developers of new varieties of roses – and, as Petra Moser and Paul Rhode have shown, roughly half of all patents issued under the auspices of the statute went to rose growers – as you can see by comparing the dotted and solid lines in this graph.

Excluded from the 1930 Plant Patent Act were new varieties maintained through sexual reproduction – namely, through the germination of seeds. The reason was that it was not thought possible to maintain the genetic stability of a variety when it reproduced sexually. By 1970, improvement in the techniques of sexual reproduction had undermined that rationale.

Congress then adopted the Plant Variety Protection Act, which created yet another special kind of patent for sexually reproduced varieties.

These two statutes helped corrode the assumption that patents could not be obtained for living things. Meanwhile, the technologies for creating new types of micro-organisms were advancing rapidly.

In 1980, the question of whether such things were eligible for regular utility patents came to a head in the Chakrabarty case, which involved a patent on a bacterium that purportedly was capable of eating oil slicks.

The Supreme Court, by a vote of 5 to 4, upheld the patent, ruling broadly that "anything under the sun that is made by man" can be patented – plainly including large animals as well as microorganisms.

What then about new plant varieties? Were they eligible, not just for narrow protection under the PPA or PVPA, but also for the higher levels of protection provided by utility patents?

In 1985, the Board of Patent Appeals and Interferences said yes.

A few years later, in the Pioneer Hi-Bred case, which involved a patent on a new strain of corn which contained heightened levels of tryptophan, the Supreme Court agreed. If the creator of a new kind of plant could satisfy the more stringent requirements of utility patents, she was entitled to one.

Meanwhile, the commercial significance of the increasingly firm doctrine extending patent protection to purified natural substances that exhibit new, useful properties increased dramatically with the advent of biotechnology.

Starting in the 1990s, the courts, invoking this principle, consistently upheld patents on isolated gene sequences so long as the proteins for which they coded had been identified. By 2005, roughly 2600 patents on "isolated DNA" sequences – and many more patents on other innovations related to DNA – had been issued. In the opinions of some (but not all) observers, startup biotechnology firms were heavily dependent on these patents.

Other aspects of the expanding scope of patentable inventions were attributable more to the rules and practices adopted by the Patent Office than to the legislature or courts. This was not true in the beginning – because, until 1836, there either was no patent office in the United States or it had no authority to reject patent applications. To explain why requires a brief detour into institutional history.

You may have noticed, when I displayed the slide showing the crucial section of the 1790 Patent Act, that it contemplated applications being submitted, not to a government office, but directly to the

Secretary of State, Secretary of War, and Attorney General, who, unanimously or by majority vote, could decide to

issue patents on inventions they deemed sufficiently useful and important. As you might imagine, that was not a workable system, so it was soon abandoned in favor of a simple registration system.

The registration system too proved unworkable. In 1836, a Senate report concluded that the country was becoming “flooded with patent monopolies, embarrassing to bona fide patentees, whose rights are thus invaded on all sides; and not less embarrassing to the community generally.” To remedy the problem, Congress reformed and strengthened the Patent Office, giving the new commissioner the authority to hire “examining clerks,” who would evaluate applications for patentability and reject those that did not pass muster. As you know from the previous lecture, that’s essentially the system the US has now – and that most countries in the world have now.

Over time, the Patent Office began developing its own regulations and customs. These of course conformed to the rulings of the federal courts concerning the proper interpretation of the various parts of the evolving patent statute, but the courts did not cover – or did not cover right away – all aspects or possible applications of the statute. The result is that the Patent Office has had a significant amount of leeway when giving its examiners guidance concerning how to interpret patentability requirements. With respect to subject matter, the office frequently exercised that power by quietly expanding the zone of patentability – at least for a while.

The topic of diagnostic and surgical procedures provides an illustration.

Beginning in the 1950s and continuing through the mid-1990s, the PTO granted quite a few patents on procedures used by doctors either to diagnose diseases or to intervene in patients’ bodies.

An example that, as we will see later, became notorious was a method developed by Dr. Samuel Pallin for making incisions in the eyeball.

The traditional method – used, for example, in cataract surgery -- entailed making a straight cut in the surface of the eyeball,

conducting a procedure, and then stitching the incision together.

Pallin figured out that, if the surgeon instead made an angled or curved incision with particular dimensions, then she would not need to stitch it closed, because the internal pressure of the eyeball would press the edges of the cut together, thus making the incision self-healing. This new method had obvious advantages.

In 1990, Pallin applied for and, in 1992, was granted a patent on his method.

This patent was far from unique. Lots of others – most of them less elegant and useful, to be sure – had been issued in the preceding 40 years.

A similar dynamic was at work in the changing treatment of so-called business methods. For most of the 20th century, ways of conducting businesses, no matter how innovative, were considered unpatentable by most lawyers and businesspeople, on the ground that they consisted of “abstract ideas.” That attitude was reflected in and reinforced by several judicial opinions, although none of those opinions addressed the issue squarely.

Meanwhile, quietly, behind the scenes, despite this consensus, the PTO was granting patents on things that could only be considered methods of doing business. As Michael Meurer points out, these patents could be clumped into two subcategories:

administrative methods (i.e., backoffice techniques intended to increase productivity or reduce costs) and

customer service methods (i.e., new forms of or features of services that consumers value).

When one patent falling into the first of these subcategories was eventually challenged, the courts, to the surprise of many observers, upheld it. In 1998, in the *State Street Bank* case, the Federal Circuit, repudiating a long line of dicta, held that a computerized accounting system that calculated daily share values in a mutual fund, was indeed patentable just like all other new processes. Any doubt concerning the ambit of that ruling was removed a few years later, when in the *AT&T v. Excel* case, the Federal Circuit upheld a patent on a method for facilitating differential pricing by the providers of long-distance phone service. The court rejected the defendant’s contention that the patent gave AT&T control over a mathematical algorithm, reasoning that “Because the process [claimed in the patent] applies the Boolean principle to produce a useful, concrete, tangible result without pre-empting other uses of the mathematical principle, on its face the claimed process comfortably falls within the scope of § 101.”

The net effect of these two rulings was to expand dramatically the zone of patentable processes.

The Supreme Court refused to review either of the Federal Circuit’s decisions, triggering a surge of applications for and grants of patents on ways of doing business –

ranging from Amazon.com’s “one-click” checkout system,

to forms of online gambling,

to ways of distributing digital sound recordings,

to marketing techniques based on behavioral profiling.

Another, loosely related zone of expansion involved computer software. Here, the courts took the lead, while the PTO officials did their best to implement the changing stance of the judiciary. In brief, the history went as follows:

When the developers of computer software first began to seek patent protection for their creations, the Patent Office was skeptical – apparently because software seemed just a fancy form of mathematical algorithm.

The Court of Customs and Patent Appeals (which, prior to the creation of the Federal Circuit, heard appeals from PTO rejections of patents) was more favorable. In three decisions in 1969 and 1970, that court nudged the PTO to grant patents on software. Initially, the Supreme Court seemed to disagree.

In the 1970s, in a pair of highly fact-specific rulings, the Supreme Court rejected patent protection for specific instances of software. However, the Supreme Court left the door open a crack by including in the second of these rulings the statement that

“We do not hold that no process patent could ever qualify if it did not meet the requirements of our prior precedents. It is said that [our] decision precludes a patent for any program servicing a computer. We do not so hold.”

In the 1980s and 1990s, the lower courts –

most importantly, after 1982, the newly formed Federal Circuit – pushed that door further and further open – and the developers of software rushed through it in growing numbers.

The Supreme Court in another highly fact-specific ruling in 1981 seemed to acquiesce in this trend.

Finally, in 1996, the Patent Office issued a new set of guidelines, indicating that even pure software on free-standing disks was eligible for patenting.

The net result, as you might expect, was a rapid increase in applications for and grants of software patents in the United States.

The exact magnitude of the surge is controverted – in part because the Patent Office does not use a single classification for “software” and in part because innovations often integrate

software and other technologies or processes. A paper by Greg Aharonian contended that the number of software patent grants in the US had risen to roughly 21,000 per year by the end of the century. A subsequent paper by Jim Bessen and Robert Hunt agreed with the ultimate outcome, but thought that substantial numbers were being issued as early as 1976. Robert Hahn and Scott Wallsten contended that only half as many were being issued per year.

Regardless of who is right on this score, there is no question that the combination of the growth of the software industry in the closing years of the 20th century, the increasing propensity of firms to seek patents, and the increased receptivity of US courts -- led to a large increase in both absolute numbers of software patents and in the percentage of all issued patents that involved innovations in software.

Much less important economically but even more controversial was the recognition of patent protection for novel ways of reducing tax burdens. The Federal Circuit's acceptance of business method patents prompted a few enterprising accountants and tax lawyers to seek and obtain patents on novel ways of organizing their clients' affairs so as to reduce, eliminate, or defer their tax liabilities.

By the early 20th century, at least 160 of these patents had been issued. Efforts by the patentees to use the patents to stop competitors from giving their own clients the benefit of such strategies seem to have been extremely rare; typically, the patents were employed more as marketing gimmicks. But, as you might imagine, they were widely regarded as socially pernicious.

My former colleague, Bernie Wolfman, was one of the many professors of tax law who denounced this extension of the zone of patentability.

Much the same can be said for process patents on sports moves. Around the turn of the century a modest number of patents were granted on innovative ways of competing in sports. Examples included this odd way of holding a putter. Hard to imagine that this would be effective.

Most academics criticized, even mocked, these things, but a few scholars defended them – partly on the ground that they enabled people who could imagine ways of playing sports better, but who themselves had limited athletic talents, to share in the enormous incomes of pioneering athletes.

Like the patents on tax strategies, the patents on sports moves had little economic significance. I mention them rather as a sign of how far the Patent Office seemed willing to go to extend the zone of patentability.

In conclusion: here, graphically, is the ambit of the subject matter coverage of the US patent system around the end of the twentieth century.

The remarkable growth, over the course of US history, of the ambit of patent law was paralleled by comparably dramatic growth of the other two fields of intellectual property: copyright and trademark law. In case you are curious about when and how those fields grew – and, in some sectors, came to overlap with patent law, here's a short composite presentation showing, in approximate chronological order, the dimensions on which their subject-matter coverage expanded.

In this presentation, patent law will continue to be represented by the red sector. The subject-matter coverage of Copyright is shown in yellow; that of trademark law is shown in blue. So here goes.

Note how, as the three zones have grown, they have sometimes overlapped. In particular, by the end of the 20th century in the US, software was subject to both copyright and patent protection, fictional characters were subject to both copyright and trademark protection, and three-dimensional consumer products that were both useful and attractive were potentially subject to protection under all three of the principal legal regimes.

The general question spurred by this narrative is of course: why? What caused this expansion? 20 years ago, I wrote an article in which I tried to trace the main forces that drove it. I've changed my mind on a few dimensions of the story, but (for better or worse) not many. What follows is a distillation of the argument. If you want more detail, a link to the English-language translation of the article is available in the publications section of my homepage: tfisherip.org.

Perhaps the most obvious of the contributing forces was the emergence of new fields of economic activity and innovation. At the most fundamental level, between the late 18th century and the end of the 20th century, the primary basis of the US economy shifted from agriculture to industry to information processing. These transitions were accompanied by a steady increase in innovative activity. The firms leading the wave of innovation sought legal protection against competitors – and lawmakers (including judges) usually complied.

Typically, the firms seeking enhancement of their legal rights argued that it was necessary to support their infant industry and to sustain or increase the pace of innovation. Sometimes that was true, but not as always as the petitioners claimed.

Here's a small but suggestive example: The adoption of the Plant Patent Act in 1930 can be attributed in large part to intense and effective lobbying by rose growers – whom, as we saw, were the principal beneficiaries of the statute. Does this mean that, after 1930, the pace of innovation in the field of rose breeding rose? The study I mentioned earlier by Moser and Rhode concluded no. The new statute surely benefitted some growers, but does not seem to have accelerated innovation in the field.

Underlying such troubling findings is a familiar but important aspect of political economy: expansions of IP rights always benefit some groups and usually disadvantage others. Typically, those who stand to gain are innovators or the firms for which they work. They have strong,

concentrated financial interests in enhancement of their rights. The interests of those who stand to lose, by contrast, have tended to be more diluted. The largest and most important such group usually consists of consumers -- each of whom typically has had only a small stake in the content of the pertinent laws. The result is that lobbying efforts have repeatedly been biased in favor of the expansion of patentable subject matter (as well as the coverage of the other two fields of intellectual property).

The sharply different densities of the "interests" on opposite sides of intellectual-property issues, combined with the important role played by organized interest groups in American politics, means that, more often than not, the proponents of expanded entitlements will win out.

The explanation I've just outlined is an example of materialist or instrumentalist legal history -- which attributes changes in the law to the shifting needs of the economy as a whole or, more often, to particular interest groups. But the story would be radically incomplete if one did not also take into account the ideologies or belief systems that accompanied and often shaped those interests. Several components of Americans' belief systems fueled or enabled the expansion of patentable subject matter -- as well as the expansion of copyright and trademark law.

The first was the durable and widespread popular commitment in the United States to a labor-desert theory of property. The notion (commonly associated by academics with John Locke) that a person deserves to own something that he or she has created through productive labor has long had considerable currency in America. Since the late eighteenth century, this attitude has contributed to the willingness of legislators and judges first to establish and then to expand intellectual property rights. For example, in 1837 Henry Clay argued that it is "incontestable" that "authors and inventors have, according to the practice among civilized nations, a property in their respective productions . . . ; and that this property should be protected as effectually as any other property is, by law, follows as a legitimate consequence."

A second, related ideological current has been the widespread popular suspicion in the United States of governmental involvement in the process of identifying and rewarding good works of art and socially valuable inventions. This attitude crystallized later than the labor-desert theory just discussed.

Until the middle of the nineteenth century, Americans were receptive to the notion that governments could and should advance the public interest by encouraging socially valuable ventures of all sorts. This general disposition had many manifestations in early American legal and economic history -- including, for instance: selective grants of corporate charters to enterprises that promised to redound to the public welfare; "Mill Acts," which empowered landowners who wished to install mills on streams running through their property to build dams that flooded their neighbor's property (provided they paid compensation); and generous delegations by state legislatures of the power of eminent domain to private railroads.

This same general mercantilist sentiment underlay several proposals early in American history that inventors be rewarded, not with patents, but with public funds. Indeed, the first draft of what ultimately became the intellectual-property clause of the US Constitution (which I discussed at the start of this lecture) incorporated such a system of governmental awards and subsidies. Edward Walterscheid argues convincingly that this approach was ultimately rejected, not because of principled opposition to governmental involvement in the identification of worthy inventions, but because it was deemed too expensive.

By the late nineteenth century, however, this receptivity to direct governmental supervision of inventive activity had been eroded by the complex of attitudes commonly known as classical liberalism -- including, most importantly, the notion that the public and private spheres (in other words, the "state" and "civil society," respectively) were and should be distinct, combined with a general distrust of governmental tinkering with the market. In the altered ideological climate, intellectual-property rights were more palatable than governmental prizes as a way of stimulating creativity.

A third ideological current was the popularization and then persistence of heroic imagery associated with inventors and its cousin, the "romantic conception of authorship." As the late Keith Aoki observed, the celebration of inventors has very deep roots in Western culture. Grounded in "the Renaissance exaltation of the ordinary human subject as inventive genius, as embodied in Leonardo de Vinci's work," amplified by the "Enlightenment elevation of scientific geniuses such as Descartes, Leibnitz, and Newton," the glowing image of the inventor was already well established in Western culture when American patent law began to take shape.

In the United States, the attractiveness and importance of this image was reinforced by at least three cultural forces. The first was the frontier ethic, which envisions man as pitted against nature, harnessing it through ingenuity as much as through force. The second was the loosely associated "pastoral ideal," which celebrated the transformation of the wilderness into the garden. The third was the premium placed in the United States on social mobility. From that standpoint inventiveness has been seen as an important way in which a talented youth can achieve wealth and fame.

The convergence of these currents helps to explain the reverence with which Americans have treated -- and continue to treat -- our major inventors: Thomas Edison, Alexander Graham Bell, the Wright Brothers, Bill Gates, Steve Jobs, and so forth. All have been heroes in the United States -- at least until they engage in enough predatory behavior to taint their reputations.

The fourth and final force that has contributed to the growth of intellectual-property rights consists of a gradual shift in the terminology used by lawyers to describe and discuss those rights -- in a word, the "propertization" of the field. In the eighteenth century, lawyers and politicians were more likely to refer to patents and copyrights as "monopolies" than they were to refer to them as forms of "property." Gradually over the course of American history, this discourse was supplanted by one centered on the notion that rights to control the use and dissemination of information are forms of "property." One manifestation of this trend was the

growing prevalence and power of the phrase “intellectual property.” Before the Second World War, use of the phrase as shorthand for copyrights, patents, trademarks, and related entitlements was rare. Since that time, it has become steadily more common. Today, it is the standard way for lawyers and law teachers to refer to the field.

Why does the popularity of the term matter? The answer -- as the Legal Realists recognized long ago -- is that legal discourse has power. Specifically, the use of the term “property” to describe copyrights, patents, trademarks, etc. conveys the impression that they are fundamentally “like” interests in land or tangible personal property -- and should be protected with the same generous panoply of remedies.

This concludes the first portion of the lecture. Thus far, I’ve examined and tried to explain the growth of the subject matter coverage of patent law in the United States through the end of the 20th century. The second and third parts will be shorter. In the second, I’ll discuss what was going on in other countries – and, in particular, the effort to expand the reach of patent law in developing countries through the use of multilateral treaties. In the third and final part, I will return to the United States and describe the constriction of subject-matter coverage in the last 20 years.

B. Harmonization

In the previous segment of this lecture, I described and tried to explain the dramatic expansion of the subject matter coverage of patent law in the United States through the end of the 20th century. In this segment, I’ll be examining parallel developments on the international stage.

I hope you will recall from the first lecture that there is no such thing as global patent law. Each country in the world establishes and enforces its own patent system.

Recently, some regional patent systems have emerged – of which the best known is the European Patent Convention. But the majority of countries remain autonomous when creating and modifying their patent systems.

As I’ve mentioned, currently, five of these patent systems attract most of the patenting activity in the world. 90% of all patent applications are filed in the patent offices of China, the US, the European Patent Convention, Japan, or the Republic of Korea. The dominance of those five systems is likely to diminish in the future – but not rapidly.

In the 19th and early 20th centuries, the independence of the national patent systems led, as you might expect, to significant variations in patent law. On many important issues, countries adopted different rules.

For example, when determining which of two or more people who claim to have invented the same invention should get the patent on it, some countries gave priority to the claimant who could establish that she came up with the invention first, while others gave priority to the

claimant who first filed a patent application. (I'll discuss this issue in much more detail in the lecture on newness.)

Another example: Some countries published patent applications immediately after they were filed, others waited until the patents were granted, and a few even waited until the patent expired.

In some countries, patents were issued only after having been substantively examined for conformity with the statutory requirements of novelty, creativity, utility and so forth. In many, however, they were issued in the absence of such examination.

The axis of variation most relevant to the topic for today concerns subject-matter coverage. Countries differed sharply in the kinds of inventions that they deemed patentable. The combination of economic, interest-group, and ideological pressures that led to the steady expansion of subject-matter coverage in the US could be found in most other developed countries – and led to similar growth in the ambit of patent law in those jurisdictions. But the scope of patent law in most developing countries was much narrower. And even within the set of developed countries, substantial variations in the scope of the patent systems persisted.

The autonomy of the national patent systems also made it possible for countries to give preference to their own citizens or residents in various ways. An extreme example was to deny patent protection to inventors from other countries. A more moderate manifestation of this impulse were so-called “working” requirements. Many countries conditioned patent protection on the willingness of the patentee to manufacture the products at issue within the jurisdiction, thus providing employment for local residents.

To some extent, this bias resulted from simple nationalism. But it also derived partly from a recognition that, when a patent is granted to a foreign inventor – particularly one who then manufactures products covered by the patent elsewhere – most of the burden of the patent is borne by local residents (who are obliged to pay higher prices for access to the products) while both the private benefit (augmentation of the income of the patentee) and the social benefit (stimulation of inventive activity) are largely reaped by foreigners.

Although perhaps rational from the standpoint of the national governments – and beneficial, at least in the short term, to the consumers of potentially patentable products – the resultant state of affairs was increasingly problematic for private firms seeking patent protection. They of course wanted the ability to patent more kinds of inventions. They also wanted to be able to patent their inventions in many countries. Last but not least, they wanted consistency in the patent laws in various jurisdictions – to minimize the legal and administrative costs of securing protection in multiple jurisdictions.

For the most part, firms located in one country had little hope of persuading the government of another country to increase patent protection. But such firms could press their own government to enter into negotiations with the governments of other countries – with the

hope of securing treaties that would compel the governments of all participating countries to dial up their patent systems. Beginning in the middle of the 19th century, that's the strategy that growing numbers of firms pursued – and with increasing effectiveness.

The principal treaties generated by such efforts are listed on your screen. You've already encountered one of them -- the Patent Cooperation Treaty, which, as Matt Bryan showed in his lecture, has gone far toward reducing the practical impediments to securing patent protection in multiple countries.

Applicants who don't wish to use the PCT procedure and who wish instead to file separate applications in each of the jurisdictions in which they want protection, benefit from substantial standardization of the applications they must file achieved through the Patent Law Treaty. As you can see, its membership is smaller, but is likely to grow.

The principal treaties pertaining to substantive patent are the Paris Convention and the TRIPS Agreement. In combination, these two agreements have reduced substantially, but not completely, the variations in substantive patent law across jurisdictions.

As we will see, significant differences remain, and the leading firms in some, but not all, industries continue to clamor for enhanced protection – but the variation is much less today than it was 40 years ago.

I will introduce you to both of these agreements now, but I will leave to future lectures discussions of many aspects of them.

The Paris Convention was first adopted in 1884. It has been revised 6 times since, most recently in 1979. Currently, 179 countries are members.

As you can see from this map, the overwhelming majority of countries in the world are included.

Its most general and most important substantive provision is Article 2(1), which establishes the principle of “national treatment.” Here again, you need some background: There are two general ways in which treaties can be employed to curb countries' tendency to favor their own residents with respect to intellectual property protection. To illustrate them, suppose that only two countries, A and B, enter into a treaty.

The so-called “reciprocity” approach would require country A to give to the residents of country B at least as much protection as country B gives to the residents of country A.

The national treatment approach, by contrast, would require country A to give to the residents of country B the same protection that country A gives to its own residents – and country B to give to the residents of A the same protection that B accords its own residents.

The Paris Agreement (like its copyright-law cousin, the Berne Convention) incorporates the latter approach.

The relevant provision, set forth on your screen, contains some nuances not evident from the simple hypothetical example I just provided, but I won't pause to consider them.

The second most important provision is Article 4, which establishes the so-called right of priority. The most important parts of this Article are set forth on your screen. The effect of this provision is that an inventor who wishes to obtain patent protection in more than one country need not apply in all simultaneously. She can apply in one – and then apply in the others within a year – without forfeiting any rights. This right is the basis of the practice discussed in lecture #1. Many inventors obtain protection in multiple countries, not by using the PCT system, but by applying first in their home countries and then, within a year, applying directly in the other countries in which they wish patents.

A few other provisions of the Agreement – such as the soft limitations contained in Article 5 on “working requirements” – are significant, but none bears directly on our present topic.

Missing from the Paris Convention are three things that the firms who want enhanced patent protection care about. The first and, for present purposes, the most important is a requirement that each member country extend patent protection to any particular set of inventions. As you might expect, the omission of such a requirement permitted countries – especially developing countries -- to continue to deny protection to lots of things.

Joseph Straus provides the following list of the number of Paris Convention member countries that, as of 1988, denied patent protection for each of the following types of invention. Note, in particular, that over half did not recognize patent protection for pharmaceutical products.

The second missing feature was a requirement that member countries provide effective enforcement of patents.

Third and finally, the Convention contains no mechanism for forcing member countries to abide by its requirements.

These weaknesses, among others, prompted some firms to continue to agitate for stronger treaties. Chief among them were pharmaceutical firms in the US, Europe, and Japan. Frustrated by their inability to secure reforms of the sort they wanted under the auspices of the Paris Convention, they turned their attention to a seemingly unlikely forum: the trade negotiations during the so-called Uruguay Round of the General Agreement on Tariffs and Trade (commonly referred to as the GATT). When the dust settled, the overarching deal that emerged from the negotiations contained a crucial and unprecedented component: The Agreement on Trade Related Aspects of Intellectual Property Rights, now commonly known as TRIPS.

Exactly how the negotiators representing the countries in which the interested private firms were concentrated were able to secure adoption of an Agreement mandating unprecedented augmentation, not just of patent protections, but also of all other major forms of IP protection is still being contested by historians.

As Peter Yu observes, several sharply different narratives have been deployed to explain this surprising outcome. The most benign contends that, despite appearances, TRIPS benefited all countries – including the poorest. Professor Edmund Kitch is the principal proponent of this view. He argued that developing countries, by agreeing to ratchet up the levels of IP protection, were able to secure enhanced transfers of technical know-how from innovative firms in the developed world, without imposing on their residents significantly increased costs. The negotiators for the developing countries were shrewd and far-sighted enough to recognize this – and used the GATT process to outflank the interest groups within their own countries who hitherto had succeeded in blocking IP modernization.

Relatively few scholars find Kitch's argument persuasive. Many, however, subscribe to a more complex but similarly benign account. According to this narrative, low and middle-income countries, though hurt by the TRIPS Agreement, reaped offsetting benefits in other sectors. Scholars in this camp contend that the GATT as a whole represented a bargain (arguably a fair bargain) between developed and developing countries. The former gained from the heightened IP protections, while the latter received in return increased access to developed-country markets for their agricultural products and protection against unilateral trade sanctions by the US.

A third and much harsher narrative contends that the concessions made by the developed countries were insufficient to counterbalance the damage done to developing countries by TRIPS – and that the negotiators for the developing countries knew it. They nevertheless went along in the end because, to be blunt, they had no realistic alternative. Being frozen out of the emerging global free-trade system would have been catastrophic.

The final narrative contends that developing countries acquiesced in a deal that was bad for them, not because they were forced to do so, but because their negotiators were ignorant of the adverse economic and social consequences of enhanced IP protections. They were duped, in other words.

Which of the four accounts is most accurate? Answering that question is difficult, in part because not all of the reforms mandated by TRIPS have yet been implemented in developing countries and in part because measuring their actual impact is extremely difficult.

Your ability to form your own judgment on this crucial question will be enhanced by considering what exactly TRIPS compels all countries to do. With respect to patent law, here are its principal provisions:

First, it incorporates by reference all of the relevant provisions of the Paris Convention, which is important because, unlike the Paris Convention itself, TRIPS contains a mechanism capable of forcing member countries to live up to their obligations.

Like the Paris Convention, it adopts the principle of national treatment – and then goes a step further, requiring each member country to provide to the nationals of all other member countries the same set of rights it provides the nationals of any member country.

The provision most relevant to the topic of this lecture – and the provision that was most controversial at the time the agreement was adopted – is Article 27, which requires member countries to extend patent protection to all inventions that meet the basic requirements of novelty, inventive step, and capability of industrial application – regardless of the field of technology.

There are three exceptions to this obligation: Countries are free, if they wish, to deny protection to inventions monopolization of which would threaten health, morality, or the environment;

to diagnostic and surgical procedures,

and to plants and animals (so long as they protect new plant varieties using non-patent systems). We will return to these exceptions shortly.

But note that none of them appears to permit denial of protection to new pharmaceutical products.

Not only must countries recognize such things, they must provide effective mechanisms for enforcing those patents.

These and other provisions sharply increased the constraints on the freedom of each country to shape its own patent law. However, TRIPS left some important issues to the discretion of each country. These options have come to be known as the “TRIPS Flexibilities”.

Three of them I’ve already mentioned – the three permissible exclusions from the subject matter coverage of patent law. In addition, the ambiguity of the phrase, “capable of industrial application” has, as a practical matter, left countries free to deny protection to software and/or business methods.

Similarly, the absence of any detailed definition of “inventive step” has, as a practical matter, permitted some countries to be significantly more demanding than others concerning the amount of creativity necessary to warrant issuance of a patent.

With respect to the entitlements that must be accorded to patentees, countries are permitted by Article 6 to decide for themselves the degree to which selling products embodying a patent results in exhaustion of patent rights.

Other flexibilities will be considered in due course.

The general point is that TRIPS binds member countries in many ways, but is less procrustean than might at first appear.

A. Contraction

The subject-matter harmonization driven by the TRIPS Agreement did not happen all at once. Not all countries in the world were members of the GATT in 1994, and not all of the countries that were members and thus were involved in the Uruguay Round joined the WTO right away and thus became bound by TRIPS. As more countries subsequently joined the WTO and implemented TRIPs, the reach of the Agreement of course increased.

Another reason why harmonization was initially incomplete is that the TRIPS Agreement gave member countries some leeway in bringing their patent systems up to the new standard. All countries were given a year to comply. Developing countries were given another four years for most issues and nine years for enlargement of the scope of product patent protection. Least developed countries (as designated by the United Nations) were given until 2006 to comply with most of the TRIPS requirements. That deadline was subsequently put off several times and currently stands at 2021 for most issues and 2033 for extending patents to pharmaceutical products.

The countries that are currently classified as least developed – and thus are entitled to this extension – and shown in pink on this map.

The upshot is that, for many years after 1995, countries continued to enlarge the set of inventions subject to patent protection (as well as to enhance in other ways the rights of patentees) – and this process of expansion will continue in some countries for some time.

Simultaneously, however, countercurrents emerged – the net effect of which is that, around the turn of the century, the subject matter coverage of patent law began to contract.

The countercurrents were most apparent on the international stage. After the climactic adoption of the TRIPS Agreement, most efforts to secure, through multilateral treaties, increases in subject-matter coverage (or other expansions of patent rights) have failed. Some expansions were secured through bilateral agreements, but those have become less frequent.

Less obvious but equally important, since the turn of the century, most efforts to expand subject-matter coverage within either individual countries or regional patent systems have also failed.

An especially important example was the failure, after a prolonged struggle, to secure in Europe patent protection for software comparable in scope and generosity to the protection that, as I showed in the first segment of this lecture, was extended to software in the United States. The tangled history of this initiative is traced in a slide deck reachable through this branch of the full version of this map.

For present purposes, you need to know only that, despite extraordinary lobbying efforts, the proponents of augmented coverage ultimately failed.

In the US, the SM coverage of patent law not only stopped expanding around the turn of the century; it began to contract.

A few aspects of the retreat were caused by legislative action.

For example, in 2011, Congress responded to intensifying criticism of the availability of patents on tax strategies by eliminating them altogether. The language through which it did so is a bit odd – but its net effect is, prospectively, to prevent the patenting of methods for reducing taxes.

Sometimes the legislature and judiciary have worked together to narrow the scope of patentable subject matter.

The best example involves medical procedures. You will recall from Part 1 of this lecture that one of the few aspects of the subject-matter coverage of patent law that TRIPS leaves to the discretion of the member countries of the WTO is “diagnostic, therapeutic and surgical methods for the treatment of humans or animals.” Most countries that have addressed the issue have exercised that discretion by denying patent protection altogether for such things.

For example, Article 52(4) of the European Patent Directive provides: “Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body shall not be regarded as inventions which are susceptible of industrial application.”

You will recall from Part 1 this lecture that, by contrast, the PTO in the United States granted many patents on diagnostic and surgical procedures. For years, this policy received little attention, because the procedures at issue had little practical value or the patentees were not greedy in enforcing them.

Dr. Pallin’s patent on a technique for making incisions in an eyeball changed that. Because the incisions made using his technique were self-healing, they were less likely to result in distortion of the patient’s vision. Pallin took advantage of the superiority of the system by demanding license fees from other ophthalmologists – much like Hoyle Schweitzer did with his patent on the windsurfer.

Some complied, but others balked. Some of the resisters were motivated, not just by resentment of the fees, but by a belief that it was wrong for a doctor to demand such fees. Medical innovations, they thought, should be given away.

This view is widely shared – and not just by doctors. In truth, this hostility toward asserting property rights to discoveries involving medical procedures is harder to justify than it first appears. It's difficult to reconcile with the well recognized patentability of innovations involving medical devices (like MRI machines) and innovative pharmaceutical products. Inventions falling into all of these categories affect human life. But patenting a procedure for improving someone's health somehow seems worse than patenting an object related to health.

One manifestation of that attitude is the Hippocratic Oath – which all doctors in the US (as well as most other countries) pledge to obey. There are different versions of the oath, but here's the relevant portion of the most widely used:

"I will respect the hard-won scientific gains of those physicians in whose steps I walk, and gladly share such knowledge as is mine with those who are to follow."

Attitudes of these sorts prompted the American Medical Association to protest the practice brought to light by Pallin's invention. Congress responded. However, instead of eliminating such patents altogether, it sharply limited their medical and commercial significance, by immunizing both doctors and health-care providers from liability for infringing them. Here's the relevant provision.

Note the limitations of this statutory change. It carves an exception out of the remedial provisions (281 through 285), but does not alter the kinds of activities that will constitute infringement of a medical procedure patent.

. And it limits that exception to medical practitioners and related health care entities.

The result is to preserve the possibility of a successful infringement suit against a party that cannot qualify as a "health care entity."

The preservation of the possibility of enforcing a medical procedure patent against an entity other than a doctor or hospital meant that, sooner or later, the courts would be asked to consider the patentability of such things. It took a while, but eventually, such a case ended up in the US Supreme Court. The essential facts of the case were as follows.

In 1999, Hopital Sainte-Justine was granted a patent on a procedure for adjusting the dosage of a drug administered to patients suffering from some specific autoimmune diseases – such as ulcerative colitis and Crohn's disease.

It had long been known that such diseases could be controlled through administration of thiopurine drugs, but the optimal amount of the drugs varied by patient. It had also long been known that the impact of the drug on a particular patient could be assessed by measuring the amount of a metabolite in his or her blood.

The inventors, employed by the hospital, apparently determined with greater precision the lower and upper bounds of the concentration of the metabolite that reflected an appropriate dosage. They then applied for and were granted a patent on a procedure embodying that discovery.

A representative claim appears on your screen. The hospital then granted an exclusive license on the patent to Prometheus, which, in turn, exploited it by demanding license fees from companies that wanted to make use of the procedure. For a while, the Mayo Clinic was willing to pay Prometheus a license fee for the right to use a test embodying the procedure. When the Mayo executives changed their minds and began selling a very similar test without a license, Prometheus brought suit. In response, Mayo argued, among other things, that the patent was invalid.

Now, a colorable argument could be made that Mayo was and is a health care entity within the meaning of 287(c) – and thus should have been immune to suit. Indeed, one amicus made exactly this argument. But this argument was never raised by Mayo (most likely, because the Mayo lawyers concluded that Mayo was not sufficiently “related” to the doctors using the procedure as that term is defined in the statute). In any event, the courts – including, in the end, the US Supreme Court, focused their attention on the question of whether the patent fell within the zone of patentable subject matter.

The Federal Circuit said yes, but the Supreme Court unanimously said no. In an opinion written by Justice Breyer (who, as we will see, is the justice most skeptical of expansive IP rights), the Court held that ““If a law of nature is not patentable, then neither is a process reciting a law of nature, unless that process has additional features that provide practical assurance that the process is more than a drafting effort designed to monopolize the law of nature itself. ” ““Purely “conventional or obvious” “[pre]solution activity” is normally not sufficient to transform an unpatentable law of nature into a patent eligible application of such a law. ”

The fact that patients suffering from autoimmune diseases responded best to a dosage of a drug that led to metabolite levels between point X and point Y is such a “law of nature,” the Court concluded. A narrow one, to be sure. Not on the same level as $E=MC^2$. But a law nevertheless. And everything in the claim other than that law was conventional or obvious.

The ruling in Mayo has had the effect of narrowing substantially the already vestigial availability of medical procedure patents in the US. They have not been eliminated altogether, however. The reason is that, unlike the European Patent Convention, which as we have seen, forbids patents on these procedures outright, the Supreme Court rested its ruling in Mayo on an elaboration of the general principle that laws of nature are not patentable.

The attack on the patent was undoubtedly driven in part by the sentiment that medical procedures should not be patentable at all. But the Court lacks the authority to adopt that position overtly.

The net result is that the availability of patent protection for medical procedures has been significantly reduced, but not eliminated altogether. Procedures that entail less “conventional or obvious” applications of insights into the way the body functions are still patentable in the US. For example, Pallin’s patent on a technique for cataract surgery – which, as we saw, claimed a method for making a curved incision with a specific diameter, might still pass muster.

The doctrines and sentiments evident in the Supreme Court’s opinion in *Mayo* also contributed to a very important narrowing of the availability of patent protection for genetic sequences. You’ll recall from the first segment of this lecture that, in the twentieth century, both the Patent Office and the courts in the US had extended patent protection to isolated DNA sequences, justifying that stance on the ground that, while naturally occurring substances are not patentable, purified forms of those substances may be, particularly if they exhibit useful properties different from the unpurified versions. A large number of patents in the field of biotechnology had been granted on the basis of that stance. In the opinions of many observers (including me), the heavy reliance on that doctrine by an important sector of the biotechnology industry made the doctrine unassailable, however shaky it might be analytically. We were wrong.

In 2009, a case began percolating in the federal courts that would call the doctrine into question. It involved a patent on a test for determining a woman’s risk of breast cancer.

Breast cancer is a widespread and very dangerous disease. A recent paper by Ferlay et al. summarizes (and assesses) data indicating that, worldwide, there are over 1.5 million new cases of breast cancer reported each year. Only lung cancer is more common.

The death rate is not as bad as for some other cancers – such as lung, pancreatic, and ovarian. Nevertheless, half a million people (almost all of them women) die of breast cancer each year.

As one might expect, the mortality rate is substantially higher in less developed countries than in more developed countries.

The *Myriad Genetics* case arose against this grim background. For a long time, it’s been known that genetics play a role in a woman’s susceptibility to breast cancer. Scientists employed by *Myriad* discovered the precise location in the human genome of two genes, mutations in which sharply increase that susceptibility. *Myriad* capitalized on that discovery by obtaining product patents on both the naturally occurring sequences of the genes in question and the corresponding complementary DNA sequences.

(Complementary DNA or cDNA, as many of you likely know, is synthesized from messenger RNA, using techniques now well known in the field of biotechnology. Messenger RNA, in turn, is naturally generated through transcription of the DNA sequences.)

The discovery of the genes, now known as *BRCA1* and *BRCA2*, made it possible to conduct a reliable and relatively inexpensive genetic test that would determine whether a woman had

heightened risk of breast cancer. Such a test, in turn, would enable women who tested positive to employ preventive strategies to reduce that risk – and would thus save lives.

Myriad developed and marketed such a test. It then employed its patents to send cease and desist letters to other organizations offering the test – and to at least one doctor employing such a test. In other words, unlike Schweitzer or Dr. Pallin, who, as we have seen, chose to license their patented technology, Myriad adopted the first of the various techniques for exploiting a patent – namely, using it to suppress competition and thus make possible elevation of prices.

Eventually, a doctor and a firm disadvantaged by this strategy brought a declaratory judgment suit, challenging the validity of the patents. (Remember our discussion of this strategy in the first lecture.). To the surprise of many observers, including me, the District Court agreed with the challengers.

A panel of the Federal Circuit, less surprisingly, disagreed.

After some additional procedural maneuvering, the Supreme Court heard the case – and issued a ruling with two key parts:

The patents on the naturally occurring DNA sequences, it held, were invalid. Neither Myriad's initial discovery of them, nor the work it did to isolate them from the surrounding genetic material, was sufficient to lift them out of the category of unpatentable natural materials. By contrast, the patents on synthetic cDNA, because they pertained to man-made material, were valid.

In light of the potentially huge impact of the decision on the biotechnology industry, you might have expected the Supreme Court to discuss the policy implications of its ruling. For the most part, it did not. The opinion is almost entirely conceptual.

What then was its impact?

An illuminating article published in 2016 by Mateo Aboy, Kathleen Liddell, Johnathon Liddicoat & Cristina Crespo suggests that the ruling did indeed alter practices in biotechnology, but not in precisely the way you might have expected. As you can see from these graphs, taken from the article,

Applications for -- and grants of -- patents on genes have continued, even increased.

Less surprising is a change in the kinds of genetic innovations that are claimed. Even before the Court's ruling, patent applications had been shifting away from claims on isolated versions of naturally occurring genes and toward synthetic sequences. As you can see from this chart, that shift has accelerated.

Least predictable and most troubling has been a decrease in percentage of such patents granted to small and medium-sized enterprises – perhaps attributable to an increase in the cost of successful prosecution of gene patent applications.

With respect to the specific technology that generated this controversy, more companies are now offering genetic tests for breast cancer risk – and the cost of those tests has dropped. BreastCancer.org reports that, as of November 2018, at least three commercial labs (one of which is Myriad) are performing such tests, and “The cost of testing ranges from approximately \$300 to \$5,000, depending on whether you are being tested for only a specific area(s) of a gene known to be abnormal or if hundreds of areas are being examined within multiple genes.”

We come, finally, to software and business methods. You will recall, I hope, that the extensions of patent protection to software and to methods of doing business were two of the most important – and most controversial – modifications of the US patent system in the late 20th century. Although logically independent, these two extensions were intertwined in practice. In part, this was because many of the business methods for which patents were being granted consisted of relatively conventional techniques that were now being implemented using computers and software. In part, it was because they were widely criticized on similar grounds – specifically, on the ground that the kinds of innovation to which they applied would be made even without patent protection – and thus that the extension of patents to them led to social harms with no offsetting benefits.

Hostility to business method patents was especially common. Even Jeff Bezos, who as CEO of Amazon sought and obtained one of the most prominent and valuable early BMPs, soon came to doubt their social merit – and, apparently out of remorse, funded a private bounty system rewarding people who successfully challenged such things, for example on the ground that they were obvious. Indeed, one of the patents for which Bezos offered such a prize was his own.

Skepticism concerning BMPs found expression in many sectors of the patent system. In 1998, Congress created a prior-user defense (the details of which we will consider later in this lecture series) – but made it available only to defendants accused of violating BMPs.

Two years later, the Patent and Trademark Office instituted a special procedure applicable only to class 705, the designation that, until then, was most commonly used by applicants for patents on business methods. Known as “second pair of eyes”, it required that each application be approved by, not one, but two examiners. The predictable effects were both to reduce the percentage of applications approved – but also to prompt applicants to fit their claims into other categories.

In 2006, in ways I will also discuss in the last lecture, the Supreme Court made it harder to secure injunctions to remedy violations of BMPs than was true of other sorts of patents.

None of these various initiatives resulted in elimination of patent protection for business methods, but in the aggregate they made it harder to get and enforce them – and created considerable uncertainty concerning their validity and strength.

In 2010, the Supreme Court had an opportunity to clean up this mess. The *Bilski* case involved a challenge to a patent claiming a method for trading the risks associated with the impact of adverse weather events on commodity prices. The Federal Circuit, which formerly had been highly receptive to patents on analogous methods, held that this one was not eligible for patent protection on the ground that it is neither is “tied to a particular machine or apparatus” nor “transforms a particular article into a different state or thing.”

The Supreme Court agreed to hear the case. But, to the disappointment of many observers, it rejected the Federal Circuit’s so-called “machine or transformation” test as ill-suited to what the Court called the “Information Age” without offering a clear alternative. As to business method patents in particular, it refused to adopt a categorical ban on such things, but encouraged the Federal Circuit to continue to look for a “limiting principle” that would prevent excessive numbers of BMPs from “put[ting] a chill on creative endeavor and dynamic change.” Not surprisingly, this provided the District Courts, the Federal Circuit, and patent applicants little guidance in determining what was and was not patentable.

In 2014, the Supreme Court, perhaps aware that its ruling in *Bilski* had done little to mitigate the doctrinal chaos, agreed to hear yet another case involving business methods. This time, the relevant patent involved both business methods and software and thus invited the Court to clarify the law governing both of these controversial extensions.

The patent at issue pertained to the use of a computer to reduce “settlement risk” – in other words, the risk that one of the parties to a deal will be unable to make good on its promises. A bank interested in using this method sought a declaratory judgment that the patent was invalid. The District Court, conscientiously attempting to apply the Court’s prior ruling in *Bilski*, sided with the bank. The Federal Circuit, sitting en banc, affirmed the key portion of the District Court’s decision by an equally divided vote – i.e., 7 judges to 7 judges. A division of that sort within the set of judges most familiar with this body of law was a pretty clear indication that the Supreme Court had failed to make clear the governing legal standard. So the Supreme Court agreed to hear the case – and unanimously affirmed. The Court ruled that the proper way of analyzing such cases was the procedure it had laid out in its 2012 opinion in *Mayo* – which, as you will recall, concerning neither software nor business methods, but rather medical procedures. Here’s the key portion of the Court’s opinion:

In *Mayo*, we set forth a framework for distinguishing patents that claim laws of nature, natural phenomena, and abstract ideas from those that claim patent-eligible applications of those concepts. First, we determine whether the claims at issue are directed to one of those patent-ineligible concepts. If so, we then ask, “[w]hat else is there in the claims before us?” To answer that question, we consider the elements of each claim both individually and “as an ordered combination” to determine whether the additional elements “transform the nature of the

claim” into a patent-eligible application. We have described step two of this analysis as a search for an “‘inventive concept’”—*i.e.*, an element or combination of elements that is “sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the ineligible concept itself.”

In the Court’s view, both the process claims and the system claims at issue in the case clearly failed this test. All of them were drawn to the “concept of intermediated settlement” – an abstract idea – and thus the answer to the first question was yes. And they implemented that idea using a generic computer, employing “purely conventional” techniques. Thus, the answer to the second was no.

At least on its face, the ruling in *Alice* was far more definite than the Court’s ruling in *Bilski*. But the lower courts have had trouble applying it to patents involving software and business methods.

There is no question that *Alice* has made it much harder to obtain and then defend software and business method patents in the US. One indication of the magnitude of the impact is that, according to Robert Sachs, in the two years after *Alice* was decided, 36,000 patent applications were rejected by the PTO on the ground that they ran afoul the Court’s pronouncements in that case.

However, since *Alice* not all software and business methods patents have collapsed. As you can see from this typology of the subsequent case law, the courts in several cases in which patents have faced *Alice*-type challenges have answered no to the first question – and thus upheld the patent on that basis. And the courts in a few more cases have answered yes to the second question – and thus upheld the patent on that basis. In sum, whereas most of the contested cases have resulted in defeats of the patentees, not all have done so.

Looking at this situation through the eyes of a potential patentee, how can you maximize your chances? One way is to characterize your invention as a way of improving the functionality of the computer – rather than using a computer to achieve some other objective. But that will often not be possible.

At least one commentator has proposed an alternative strategy for maximizing your chances: use a lot of technical jargon. Gene Quinn, writing for the IP Watchdog, suggests:

“What this means is if you want to patent software you simply cannot write your patent applications so that an English major or History major will be able to understand the application from start to finish. If you write your application so that a technologically unsophisticated reader can understand everything from start to finish then you have failed.”

This may be sound advice, but it’s a sad state of affairs.

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To sum up, you will recall, I hope, that at the start of the 21st century, the subject-matter coverage of US patent law looked like this. Because of the various axes of contraction, it now looks like this.

Explaining this recent shrinkage is harder than explaining the expansion of eligible subject matter prior to the turn of the century.

Part of the explanation likely lies in a recent shift in the configuration and relative power of the interest groups affected by patent law. During the nineteenth and most of the 20th century, there was no well organized interest group opposed to expansion. Recently, however, there has emerged, within some industries, subsets of companies hostile to patents. The clearest example is software. It's probably fair to say that most large corporations continue to advocate generous definition of the ambit of patent protection for software, but the set of firms that now have a stake in limiting the availability of patents is growing. The result is that the signals that lawmakers get from lobbyists are less clear than they used to be.

Another potential cause of the recent contraction is the increased currency of a set of ideas that are hostile to the deployment of patent protection – either in general or in particular settings. Not only are scholars and activists singing these tunes more often, occasionally judges or other lawmakers are humming along.

Here are the principal themes:

At the most general level, recently it has become more common to describe patents as a necessary evil, than as an affirmative good. In other words, the social costs of patents have become more visible, and as a result commentators have argued with growing force that patents should not be employed anywhere they don't have to be. This is surely not a brand new idea, but its popularity has grown.

Next, one sees intensified suspicion of broad patents – either in the sense that they cover a zone that is too large in absolute terms, or in the sense that they seem excessive when compared to the contribution of the inventor to our body of knowledge. Patents on certain kinds of innovations seem more prone to this affliction than patents in others.

Next, some commentators – including, most notably, the Supreme Court – are showing increased sensitivity to that hazard that some kinds of patents will impede what is sometimes called “downstream innovation” – ie., inventive activity by people or companies who build upon the patented innovation with other innovations. Patents on abstract principles are sometimes said to be especially dangerous in this regard. If you flip this consideration around, it might provide a way of giving greater precision to the notoriously ambiguous category of abstract principle. In other words, we might classify as an abstract principle an innovation that, if patented, would be especially likely to impede downstream research.

Next, we have witnessed recently a resurgence of the attitude common in the early 19th century – that a country, when framing its own patent laws – should give precedence to its own residents or GDP and should be less focused on global social welfare. Conceivably, this could be connected to the 21st century resurgence -- in the United States as well as in other countries – of nationalism.

Next, advancements, particularly in the biological sciences, that augment our power to create or modify life have revived ancient concerns about encroaching on the domain of the gods – or unleashing things that will lead to environmental or biological catastrophe. One modest way of reducing such hazards might be to deny patent protection to especially risky types of innovation.

Finally, in the 21st century, innovators in some domains – the clearest examples are doctors and software coders – have been arguing with growing frequency that it is immoral to privatize contributions to the body of human knowledge. I mentioned the stance of the American Medical Association with respect to patents on diagnostic and surgical procedures.

Some of the highly innovative programmers associated with one or another variant of the Free Software movement make analogous arguments with respect to software.

Predicting how these various ideological currents will evolve – and how they will interact with future shifts in the configuration of interest groups is probably impossible. But you might find this catalogue helpful in spurring your own thinking concerning what ought to be the ambit of the patent system.

This concludes the lectures on patentable subject matter. In the next two lectures, we will assume that an applicant seeks a patent on a product or process that falls within the zone of eligibility. Those lectures will then address the question: What requirements must she satisfy in order to persuade an examiner to issue a patent and subsequently to defend that patent against attack?