

Module 105

[The following is a transcript of the recorded lecture for Module 105 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. Claim Construction

Hello. I'm Terry Fisher.

This is the fifth in a series of lectures on Patent Law. This one examines the set of rules that determine the scope of the legal rights enjoyed by a patentee.

Here's a brief review of the ground we've covered thus far – which will help to understand how the issues covered in this lecture fit into the overall subject of patent law.

The first lecture in the series, entitled Patent Fundamentals, considered: the rules governing how one acquires a patent, alternative ways of exploiting a patent, and the procedural contexts in which litigation over patents is commonly conducted.

The second examined the rapidly changing set of rules defining the kinds of products and processes that one is permitted to patent – and the kinds that one is not.

The third and fourth lectures explored the substantive requirements for obtaining a patent – utility, disclosure, novelty, and inventive step.

Lectures 5, 6, and 7 examine, from different angles, the legal rights associated with a patent.

Number 5 – the current lecture – discusses two sets of rules that, in combination, determine the ambit of a patent – namely, the rules that define the invention covered by a patent, and the rules that determine how long a patent lasts.

Number 6 will examine the rules that determine the kinds of behavior by other parties that will and will not be deemed to infringe a patent.

And Number 7 examines the remedies available to a patentee who has established that someone else has infringed her patent.

As is probably apparent, the topics of these three lectures are intertwined. The scope of a patent, the topic I'll be discussing today, cannot be fully understood without considering the activities that will be deemed to infringe that patent, which will be considered in lecture 6.

And, as the Legal Realists showed long ago, a legal right to prevent others from engaging in particular activities truly exists only to the extent that the person supposedly enjoying that right has access to effective remedies for its violation – remedies that we will be considering in Lecture 7.

In short, the topics covered in these three lectures have to be understood in combination. However, for better or worse, when confronted with a dispute between a patentee and an alleged infringer, most courts analyze the issues in the order set forth on your screen: first you determine the scope of the patent, then you decide whether the defendant has infringed it, and finally, if infringement has been established, you evaluate the remedies available to the patentee.

So I'll be taking up the issues in that order.

As we proceed through these materials, you might consider how things would change if the issues were considered in a different sequence or all at once.

Let's begin.

The heart of the statutory provision that defines the rights of a patentee in the United States is set forth on your screen.

Critical to this provision is the highlighted language: What people are forbidden to make, use, or sell is the patented invention.

Other jurisdictions use significantly different language when identifying actions that are forbidden. For example, the Patent Act of Korea provides that "A patentee shall have the exclusive right to commercially and industrially execute his/her patented invention."

while the relevant provision of the Japanese statute provides:
"A patentee shall have the exclusive right to work the patented invention as a business."

But note that both of these provisions, like the US statute, center on the concept of "the patented invention."

This way of defining the patentee's rights makes it critically important to determine what exactly is encompassed by a "patented invention."

It is commonly said that there are two general ways in which this determination might be made. The first is known as central claiming, the second is known as peripheral claiming. Both terms are a bit ambiguous, and they are used in slightly different ways by different scholars. But, roughly speaking, here's what they mean.

Under central claiming, the inventor identifies the essence or heart of her invention, but has neither the responsibility nor the authority to determine its scope.

In other words, it's not her job to determine which among various arguably similar products or services produced by other parties would be covered by the patent – and thus would be deemed to infringe it if not authorized.

Rather, a government official – typically, a judge in the course of patent litigation – determines how far the patentee's monopoly extends – in other words, the size and shape of the set of products or processes that will be deemed to encroach upon the patentee's rights. Typically, the judge, in setting that scope, takes into account the magnitude of the contribution made by the invention to the relevant field of technology or to social welfare in general.

Under peripheral claiming, by contrast, the inventor in her patent application marks the boundary of her own invention.

Like so. This is typically done in the form of formal claims, to which you were introduced in the first lecture in this series.

To be sure, the inventor also describes her invention in the application and typically provides examples of it, but those examples are just that – illustrative examples. The scope of the invention is determined, not by the examples, but by the claims.

For reasons discussed in that lecture, patent applicants commonly initially request approval of expansive claims, but the examiner commonly rejects them, for example, because the expansive claims are not adequately enabled or are anticipated by the prior art, and the applicant, to get the patent, is obliged to accept a narrowed set of claims. The upshot is that the applicant is certainly not free to determine the scope of her invention as she wishes, but she has much more responsibility in determining that scope than under central claiming.

The claims in a peripheral claiming system are sometimes analogized to the metes and bounds of a real property right – i.e., a right to land.

Publication of the patent is then loosely analogized to the posting of “no trespassing signs.”

The job of the government – in other words, judges in the course of patent litigation -- is to enforce the boundaries defined by the patentees, not to determine where those boundaries ought to be located.

No patent system relies exclusively on one approach or the other. Central claiming and peripheral claiming are always mixed to some degree. However, most of the major patent systems in the world currently rely more heavily on peripheral claiming than on central claiming.

This orientation is sometimes expressed in statutory provisions.

Article 97 of the Patent Act of Korea, for example, provides, “The scope of protection of a patented invention shall be determined by the descriptions of the claims.”

Similarly, Article 70 of the Japanese statute provides, “The technical scope of a patented invention shall be determined based upon the statements in the scope of claims attached to the application.”

Article 59 of China statute is slightly different, but points in the same direction: “For the patent right of an invention or a utility model, the scope of protection shall be confined to what is claimed, and the written description and the pictures attached may be used to explain what is claimed.”

The principle common to these various provisions is that the scope of a patent is determined by the claims, which, as you know, are written by the patentee or her agent.

Although the US patent statute does not contain a provision expressly adopting this principle, the courts have firmly established it – partly as a gloss on the statutory language (first adopted in 1870) shown on the screen.

But I hasten to add that adherence to the peripheral claiming approach does not mean that courts have no role in determining the scope of a patent. Rather, to repeat, it means that the courts understand their role to be interpretation and enforcement of the claims, rather than determination of where the boundaries should be located.

Sometimes implementation of this approach is easy. The claims are perfectly clear – and thus whether a potential defendant runs afoul of them is not in doubt.

Often, however, the claims contain ambiguities – and thus whether they cover an arguably infringing product or service is debatable. This happens especially often when, after the issuance of a patent, the field of technology continues to advance along lines unanticipated by the person who originally drafted the claims.

In situations of that sort, the claims must be interpreted. For reasons that will become apparent, it is usually a judge who must do the interpretation in the course of infringement litigation – although recently, Patent Offices have been obliged increasingly often to engage in such interpretation.

In the United States, interpreting claims is known as “claim construction.” During the next several minutes, I’ll discuss the methods that are currently employed in claim-construction process. I’ll then turn to the surprisingly complicated set of rules in the US governing who does

claim construction and when. Finally, I'll discuss the modest extent to which the approaches used in some other major jurisdictions differ.

For this purpose, I'll be relying on the general map of Patent Law that I've used in previous lectures. As usual, I will display subparts of the map on the screen as a supplement to my oral presentation. A full interactive version of the map is available through the course homepage.

Suppose a judge is presented with an important and ambiguous word or phrase in a claim. What resources might he consult in order to construe it?

The various possibilities are conventionally grouped into two categories: Intrinsic sources and extrinsic.

Intrinsic include:

- first and foremost, other language in the claims themselves;
- next, information supplied in the specification
- next, the drawings in the patent
- and finally, the various documents that were exchanged between the applicant for the patent and the examiner during the course of patent prosecution.

This last cluster is called, oddly, the file wrapper. If you want to see an example of one, follow the links in this branch of the map to see the complete file wrapper for Mr. Gatewood's patent on the improved mousetrap, which I discussed in lecture #1.

Extrinsic sources – so-called, because they require gathering and considering materials not included in the patent itself or the official documentation on which it was founded – include:

- dictionaries, both general and technical, which of course contain definitions of terms;
- relevant pieces of prior art other than the things that were identified by the applicant or the examiner in the course of patent prosecution;
- and the testimony by people who might be in a position to provide insight into the proper meaning of the ambiguous term. Such people include: experts in the relevant field of technology, patent attorneys who arguably have experience in interpreting terms, and the patentee herself, who at least in theory could testify as to what she meant by the term.

I've arranged these materials in a hierarchy. The higher in this list an item appears, generally speaking the more weight it is given in the interpretive process, the lower in the list, the less weight.

What underlies this hierarchy? Why, in other words, are some materials deemed more informative & reliable than others? There are at least three possible reasons.

The first is that an important objective of the peripheral claiming approach is to enable competitors of the patentee to ascertain the limits of the patent – and thus what the competitors may and may not do without obtaining a license. Their ability to do so will be

enhanced if judges, when called upon to interpret the claims in litigation, draw only upon kinds of material that are accessible to competitors and that competitors can reasonably be expected to consult.

The second potential basis of the hierarchy is a variant of the channeling function of formalities, which we've discussed previously. In the long run, the accuracy and efficiency of the process of interpreting claims will be enhanced if we force patentees to use standardized terms to describe the technological territory they mean to assert control – or, if they don't use standardized terms, to define the components of their idiosyncratic vocabulary explicitly. Refusing to consider extrinsic information will prompt patent applicants to put all of the information they consider relevant to the ambit of their claims into the claims themselves – which will make life easier for everyone down the road.

The third potential basis of the hierarchy is that it reflects an assessment of the relative reliability of these materials. The farther down the list you go, the more likely the information will be tainted by bias. The extreme example is testimony by a patentee concerning what she intended; the obvious hazard that her recollection will be affected by self-interest helps explain why such testimony is virtually never given any weight at all. Testimony by experts – who typically are being paid well for their testimony – is not quite so likely to be affected by bias. And so forth.

In shorthand, these three policies might be described as the notice function, the channeling function, and evidentiary value. During the next 10 minutes, as we examine more deeply the methodology of claim construction, you may find it useful to ask yourself how well each of the rules we consider advances each of these three policies.

The judge's use of these various sources is guided, to some extent, by canons of claim construction. I'll describe them – and show you some cases in which they have been invoked. But a word of warning: don't think of these canons as rules that are invariably applied. Rather, they function more like guidelines that are frequently employed.

The first canon – and the one that should be given the greatest weight – is that the judge should start with the language of the claims themselves – and that, when reading that language, should give words their ordinary or plain meanings.

“ “[W]ords will be given their ordinary and accustomed meaning unless it appears that the inventor used them differently.”

Here's an illustration of this guideline in action:

The patent at issue in the Miken Composites case pertained to an innovative bat used in the game of softball. It was invented in the 1990s when the dominant material used to make bats suitable for use in schools was aluminum. The inventor found that if you placed, inside of the main cylinder of the bat, a smaller cylinder – separated from the main one by a small gap – the

resulting combination could be made to hit a ball further. The illustration of this invention included in the patent appears on your screen. The crucial inner cylinder is identified by the number 18.

The first of the claims in which the patentee sought to capture this innovation read as follows: "A bat, comprising: a hollow tubular bat frame having a circular cross-section; and an insert positioned within the frame, the insert having a circular cross-section [and so forth]"

As you can see, the inner cylinder, the key to the invention, is described using the word "insert"— and that word recurs throughout the rest of the claim.

Now, when this double walled bat was first invented, both cylinders were made out of aluminum, which were extruded independently, and the inner cylinder was indeed "inserted" into the outer one. But some years later, bats began to be made using carbon fiber. The defendant in the Miken Composites case began manufacturing a double-walled carbon fiber bat. Carbon fiber tubes, unlike aluminum tubes, can be built in layers – and apparently that's what the defendant did. It made the inner cylinder, then constructed the outer cylinder around it. The defendant argued that, because the inner cylinder was not "inserted" into the outer one, its carbon bat was not covered by this claim. The patentee argued that the innovative feature in the patent was the use of two cylinders – one inside the other. It made no difference how the smaller one got inside the bigger one. What mattered was the final shape.

The Federal Circuit agreed with the defendant. The patentee used the term, "insert," in the claims – and that term thus determines the ambit of its patent. Here's the key passage in the court's opinion:

"We note first that nothing in the claims or specification indicates, explicitly or implicitly, that the inventor used the term in a novel way or intended to impart a novel meaning to it. To the contrary, the claims and written description of the '398 patent consistently use the term "insert" in the sense of its ordinary meaning as "something inserted or intended for insertion." Had the patentee, "who was responsible for drafting and prosecuting the patent, intended something different, it could have prevented this result through clearer drafting." Moreover, the parties have presented no evidence to suggest that the term "insert" in the context of the patent has a particular meaning differing from the ordinary and customary meaning in the field of art encompassed by the '398 patent. The term "insert" is a common term used to denote structure. To contend, however, as Wilson does, that it does not matter whether an insert is placed into a pre-existing frame or whether a frame is built around it ignores that ordinary and customary meaning, notwithstanding Wilson's attempts to categorize the term "insert" as "purely structural." The issue would have been different if the claims contained the language argued in Wilson's briefs; to wit, "internal structural member," or "multi-wall product," but they do not. It is the language of the claims not the argument that governs."

Now comes an important refinement: The Federal Circuit has frequently said that, when reading the claims (or anything else, for that matter), the judge should adopt the perspective of our old friend the PHOSITA – a person having ordinary skill in the relevant art. In other words, words should be given the meaning ascribed to them in the interpretive community of technicians, not laypeople.

Despite the frequency with which such statements appear, the number of cases in which the Federal Circuit (or any other court) makes an effort to define the PHOSITA relevant to a particular case and then to identify the difference between the way that such a person would understand a particular word and the way a layperson would understand the word, are small.

John Golden, who teaches Patent Law at the University of Texas, argues that the PHOSITA perspective would be unhelpful if the courts really began to use it. A more accessible and sensible perspective, he argues, would be that of “a patent attorney having access to the knowledge of a person of technological skill.” But I emphasize that that’s the suggestion of a scholar; the Federal Circuit has never adopted it.

The next two guidelines pertain to uses of the specification during claim interpretation. The first is that “Subject matter disclosed but not claimed is dedicated to the public.” In other words, if a patentee describes an innovation in the specification of her patent, but fails to include it in the claims, she forfeits the right to assert ownership of that innovation.

Next: “Every patentee may be his own lexicographer.” In other words, a patent applicant can override ordinary or dictionary definitions of terms by adopting, typically in the specification, unconventional definitions. This is occasionally done explicitly. Here’s an example:

The patent at issue in the *Cultor* case, decided in 2000, included in the specification the following language:

“As used herein, the expression “water-soluble polydextrose” (also known as polyglucose or poly-D-glucose) specifically refers to the water-soluble polydextrose prepared by melting and heating dextrose (also known as glucose or D-glucose), preferably with about 5-15% by weight of sorbitol present, in the presence of a catalytic amount (about 0.5 to 3.0 mol %) of citric acid.”

In litigation, the patentee argued that the term “water soluble polydextrose” should be construed more broadly.

The Federal Circuit held:

“Having explicitly defined this term as limited to that prepared with a citric acid catalyst, this effected a disclaimer of the other prior art acids. Claims are not correctly construed to cover what was expressly disclaimed.”

More often, the patentee defines a critical term inadvertently or implicitly. If, for instance,

The patentee consistently uses a word in a particular sense in the specification, that meaning will control interpretation of the same term in the claims.

Here's an illustration: In the 2005 Nystrom case, the patent at issue involved flooring material, intended for use in outdoor decks, shaped so that it both shed rainwater and was comfortable to walk on. In the specification, the patentee several times used the word "board" in a way that assumed it was made out of wood. The Federal Circuit ruled that that usage foreclosed an interpretation of the word "board" in the claims to cover decking made from materials other than wood.

The principle that a patentee can be her own lexicographer in theory would support an expansive interpretation of a term used ambiguously in the claims if the applicant consistently used the same term expansively in the specification. But cases of that sort don't seem to arise.

Here's a miscellaneous set of canons, all aimed in some way at resolving ambiguity that survives application of the interpretive techniques discussed thus far. They include:

--Avoid interpretations that lead to redundancy – in other words, that cause two or more claims to cover exactly the same territory. This guideline is sometimes referred to as the principle of claim differentiation.

--Interpret an ambiguous term so as to "secure to the patentee his actual invention" – i.e., that does not leave out of the scope of the claims the thing that the patentee in the specification describes as the principal embodiment of her invention.

--Interpret an ambiguous claim so as to preserve its validity. In other words, don't construe it in a way that will render it fatally obvious or indefinite.

--Interpret an ambiguous claim against the patentee. This guideline is loosely connected to the guideline that sometimes appears in the law of contracts: interpret an ambiguous term in a contract in a way that favors the party who did not draft it.

We come, finally, to a guideline that used to play a significant role in claim construction: Construe more broadly the claims in patents that cover a pioneering innovation than the claims in patents covering merely incremental improvements on existing technologies. You can find several old decisions announcing or assuming this principle. One of the most important was the Westinghouse case, decided by the US Supreme Court in 1898.

For better or worse, this principle figures less prominently in modern opinions.

So far, we've surveyed the various resources that judges can and do consider when interpreting ambiguous terms in patent claims and the various canons or interpretive guidelines that judges invoke when drawing upon those materials.

Unfortunately, the appellate courts in the US – and the Federal Circuit in particular – have done a poor job of providing lower-court judges guidance concerning how they should put these pieces together. Partly as a result, claim construction – at least until very recently – was highly unpredictable. Both patentees and persons who feared encroaching on others' patents had great difficulty predicting how ambiguous terms would be interpreted in litigation.

The most dramatic symptom of this problem was extraordinarily high rate at which, until recently, the Federal Circuit overturned on appeal the interpretations of ambiguous claim terms by trial judges. In an eye-opening article published in 2005, then Professor, now Judge, Kimberley Moore showed that the Federal Circuit reversed 34.5% of District Courts interpretations on claim terms. Many subsequent empirical studies confirmed her findings.

For reasons that will become apparent, the explanation for this high reversal rate is not that most District Court judges are generalists and lack both scientific training and deep knowledge of patent law. It's rather that the signals the Federal Circuit was sending them were either inconsistent or garbled.

Some Federal Circuit opinions – for example, the 1996 Vitronics case – suggested that judges should follow a strict hierarchy: begin with the ordinary meanings of the terms used in the claims themselves; look to the specification only if a term in the claim is ambiguous; look to extrinsic evidence only if the claims plus the specification was ambiguous, and so forth.

Other opinions adopted a more free-wheeling or open-ended method, in which all relevant sources could be consulted together.

In 2004, Professor Wagner and Petherbridge made a valiant effort to distill from the various Federal Circuit opinions some generalizations concerning which of the judges preferred the hierarchical approach, which they call the proceduralist approach, and which preferred the open-ended approach, which they described as "holistic."

Their conclusions are shown on your screen.

They arranged the judges in a sequence from the least likely to write or join a holistic opinion to the those most likely to write or join a holistic opinion.

Judges Dyk, Clevenger, and Linn they categorized as proceduralists.

Judges Lourie, Newman, and Bryson they categorized as holistics.

The rest they called the swing judges.

As you might imagine, the federal circuits judges themselves bridled at what they regarded as a reductionist analysis. In any event, even if Wagner and Petherbridge were right, their analysis could not mitigate the unpredictability of the doctrine, because litigants would not know until

the day their cases would be decided on appeal, which of the judges would be on the panel that decided their case.

Another source of uncertainty involved the use of dictionaries. Some Federal Circuit opinions encouraged reliance on them; others discouraged.

Criticism of the Federal Circuit's apparent inability to provide clearer guidance to judges obliged to interpret claims intensified in the early 21st century. In the 2005 Phillips decision, the judges attempted to clarify things. They heard the case en banc and solicited briefs concerning the proper approach to claim construction, not just from the litigants, but also from other interested parties.

The outcome of the case is generally regarded as a disappointment. The opinion of the Court was written by Judge Bryson. Unsurprisingly, it seemed to take a holistic line.

The key passage appears on your screen:

""[T]here is no magic formula or catechism for conducting claim construction. Nor is the court barred from considering any particular sources or required to analyze sources in any specific sequence, as long as those sources are not used to contradict claim meaning that is unambiguous in light of the intrinsic evidence. ... The sequence of steps used by the judge in consulting various sources is not important; what matters is for the court to attach the appropriate weight to be assigned to those sources in light of the statutes and policies that inform patent law. In [prior caselaw], we did not attempt to provide a rigid algorithm for claim construction, but simply attempted to explain why, in general, certain types of evidence are more valuable than others."

Bryson was joined by 8 other judges -- Chief Judge MICHEL and Circuit Judges CLEVENGER, RADER, SCHALL, GAJARSA, LINN, DYK, and PROST (who had just joined the court).

Note that this combination of judges – all signing on to what seems a holistic opinion – casts doubt on the Wagner and Petherbridge hypothesis.

Judges Lourie and Newman joined parts of the opinion, but dissented from others.

Judge Mayer dissented.

By rejecting a rigid version of the hierarchical approach, the Phillips opinion narrowed the set of acceptable methodologies somewhat. But it is still pretty vague.

Despite the Court's failure fully to eliminate the inconsistencies and ambiguities in its claim-construction jurisprudence, Phillips did have a beneficial impact. The best description of that impact is provided by a comprehensive study of the Court's decisionmaking conducted by Professors Anderson and Menell. The following graphs, all drawn from their illuminating

article, show several interesting changes in the frequency with which subsequent Federal Circuit panels of judges relied during claim construction on particular kinds of evidence.

In each graph, the vertical line in the middle marks the date on which the Phillips en banc decision was issued – so the critical comparison is between the rates to the left of the line and the rates to the right of the line.

As you can see, reliance on specifications (the top line in this graph) diminished modestly,

Reliance on material contained in file wrappers (the bottom line) diminished more substantially,

Reliance on extrinsic evidence of all sorts diminished modestly,

Reliance on dictionaries diminished sharply,

And reliance on expert testimony increased slightly, but remained infrequent.

More striking than these shifts in the kinds of material upon which the court relied when construing ambiguous terms is a dramatic reduction in the frequency with which federal circuit panels reversed the interpretation of terms adopted by trial judges.

As you can see by this graph, subsequent panels have been much less eager to overturn claim interpretations.

Nor is this increase in deference confined to a few judges; every one of the federal circuit judges has become more deferential.

Explaining this increase in deference is not easy. Because it occurred immediately, during the period in which the federal circuit was still reviewing claim interpretations made by trial judges prior to the issuance of the federal circuit opinion in Phillips, it cannot be explained on the ground that that opinion provided lower courts better guidance.

Anderson and Menell speculate, plausibly, that the briefing and argument in the Phillips case sensitized the members of the court to the seriousness of the unpredictability associated with the high reversal rate that characterized the early years of the 21st century. They argue that, troubled by this state of affairs, the members of the court tacitly, informally, adopted a more deferential stance when reviewing lower court rulings.

So that's where things currently stand in the United States with respect to the methodology of claim construction in the United States.

There remains to be considered the procedures associated with claim construction. I mentioned earlier in this lecture that, today, claim construction in the United States is done at

the trial level by judges, not juries -- and is typically done before the trial of other issues pertaining to infringement.

Both of those unusual procedural features are products of a 1996 decision by the United States Supreme Court in the *Markman* case. The key principle established by that decision is that the proper interpretation of a claim is a matter of law exclusively within the control of the trial judge and not subject to the constitutional requirement that litigants be able to demand trial by jury.

Because the issue of whether a defendant has infringed a patent is subject to the constitutional right to a jury trial, and because a growing percentage of litigants invoke that right, it has become conventional to separate the proceeding designed to inform claim construction from the main portion of an infringement trial, which is conducted before a jury.

For obvious reasons, these separate proceedings are commonly referred to as *Markman* hearings. In the large majority of cases, *Markman* hearings are held prior to the main infringement trial.

A party unhappy with the claim construction adopted by the trial judge may wish to appeal the judge's ruling immediately to the federal circuit. Generally speaking, this is not possible; the unhappy party has to wait until the entry of final judgment by the trial judge, which usually doesn't happen until after the trial.

When a claim-construction ruling is finally presented to the federal circuit, how much deference does the federal circuit give the trial judge's ruling? The relevant formal rule changed in 2015. Prior to that date, the federal circuit examined claim construction rulings under the so-called *de novo* standard of review. In other words, the federal circuit ostensibly gave the trial judge's ruling no deference whatsoever, but rather examined the issue anew. In the *Teva Pharmaceuticals* case, the Supreme Court changed the relevant standard of review. It's still the case that a trial judge's ultimate interpretation of a claim term is examined on appeal under the *de novo* standard. However, the Supreme Court ruled that, if a trial judge bases his interpretation of a term on an evaluation of extrinsic evidence – such as expert testimony concern what a word would mean to a PHOSITA – those evaluations consist of factual findings and thus should be upheld on appeal unless “clearly erroneous.”

The ruling in *Teva* is important – and will sometimes compel the federal circuit to give greater weight to claim constructions founded upon evaluations of intrinsic evidence. However, it's less revolutionary than it appears. As Professors Anderson and Menell have shown, since the 2005 *Phillips* decision, the federal circuit has been tacitly according claim construction rulings more deference than it did before that date – a posture manifested in a reduction in the rate of reversal of claim interpretations.

It's still a bit early to tell whether *Teva* will cause yet another drop in the rate at which claim constructions are overturned, but I doubt that the impact will be large.

It's possible, however, that Teva will have an unanticipated effect on the litigation strategies of patentees and defendants. Some scholars have speculated that a party who confronts a judge who seems sympathetic to the party's preferred claim construction will present extrinsic evidence in the Markman hearing, in hopes of reducing the likelihood that the judge's interpretation will be overturned on appeal, while a party who confronts a judge who seems unsympathetic will concentrate on intrinsic evidence. Maybe. My guess is that the lawyers will not attempt such complicated bank shots. But we'll see.

We turn now from claim construction methodology in the US to some other major jurisdictions. Let's start with Europe. You'll recall from lecture #1 that, in each of the member countries of the European Patent Convention, you can obtain either a national patent through the country's national patent office or a European patent through the European Patent Office. However, for the time being, both types are enforced in national courts. As yet, there is no unified European patent court.

The number of patent infringement lawsuits filed in European courts is significantly smaller than in the US. As you can see, roughly 4000 suits are filed in US courts each year. The number dipped between 2016 and 2019, but now seems to be rising again. By the way, this chart also shows the substantial percentages of such suits filed by NPEs, which, as we've discussed, are also known as patent trolls. The social benefits and costs of NPEs will be a recurring theme during the balance of this course. But, for present purposes, the central point is that roughly 4000 new suits are filed each year.

The numbers in Europe are much smaller. These are the numbers of new patent lawsuits filed in the most popular jurisdictions in 2021. As you can see, Germany has by far the most, but even in Germany the total is only about one quarter of the number filed in the US. The next most popular jurisdictions are, in order, France, the Netherlands, Italy, and the UK. The reasons underlying the surprising prominence of the Netherlands will come up when we get to remedies in lecture #7.

Prior to 1977, the courts, in those five countries, adopted substantially different approaches to claim construction. The UK approach, for example, emphasized peripheral claiming and thus was similar to the US approach. By contrast, Germany and the Netherlands were much closer to the central-claiming end of the spectrum.

The adoption of the European Patent Convention reduced this divergence considerably – by obliging all member states when construing European patents to adopt an approach that emphasized peripheral claiming. The crucial provision of the EPC was Article 69, which in its original form, provided:

“The extent of the protection conferred by a European patent or a European patent application shall be determined by the terms of the claims. Nevertheless, the description and drawings shall be used to interpret the claims.”

Unfortunately, some ambiguity in the ambit of Article 69 was introduced by the way in which the phrase “the terms of” was translated into different languages. Partly as a result, courts in some European countries continued to incorporate elements of the central claiming approach.

In 2007, Article 69 was revised slightly -- and the accompanying Protocol was revised more significantly -- in an effort to increase harmonization. The fruits are shown on your screen.

As you can see, Article 69 itself seems to adopt a pure peripheral claiming method – focusing entirely on the claims. However, the accompanying Protocol softens that commitment significantly, prescribing a position intermediate between strict fidelity to the language of the claims and a looser approach that would interpret claim language in a manner that would provide “fair protection” for the patentee.

So how did the courts in the various countries implement this instruction? Germany abandoned its traditional commitment to central claiming quickly. As you can see, the relevant statutory provision now tracks EPC 69 closely. The only shift in the language is the removal of the adjective, “European,” signifying that the method applies to the interpretation of both European patents and German national patents.

The relative weight that the German courts accord potential sources of guidance is now fairly close to that accorded by US courts.

The only significant general difference is that the German courts place more weight on finding interpretations of individual terms that will reflect and augment the coherence of the patent as a whole. One aspect of that orientation is what is known, in English, as purposive claim interpretation, under which a court attempts to attribute to each term a definition that preserves its technical function within the overall invention.

Finally, recall that, in Germany, invalidity proceedings are separate from infringement suits. This creates a risk that a patentee will advocate different claim interpretations in the two venues – a narrow one in an invalidity proceeding, and a broad one in an infringement suit. This hazard is known, oddly, as the Angora cat problem, referring apparently to the fact that Angora cats look much thinner when wet than when dry. The German courts are sensitive to this risk and use various procedures to force the patentee to adopt the same claim construction in both settings.

The French courts purport to use the same hierarchy of sources. But in practice, they rely more heavily on a central claiming approach, which they explicitly employ to ensure, among other things, that the constructions they select provide “fair protection for the patentee against the skill of the infringer to disguise infringement.”

In the same vein, they typically construe the equivalents doctrine broadly, an issue we’ll get to next week.

The Dutch courts, like the German courts, traditionally employed central claiming, in which they treated “the essence of the invention” as the starting point for their interpretation of a claim. After the adoption of the European Patent Convention, they moved away from that position, not quickly, as in Germany, but slowly, through a series of adjustments of the governing standard. The major steps in this process are shown on your screen. [pause]

Even today, the Dutch courts tend to place less weight than the German courts on the words used in a claim.

As I’ve indicated, the UK traditionally employed an approach very similar to the US – and kept that approach after adoption of the EPC. The formulas used to implement the overall methodology have varied somewhat. Here are three stages:

In the influential *Catnic* case in 1982, the key question in determining the ambit of a claim was said to be: “whether persons with practical experience of the kind of work in which the invention was intended to be used, would understand that strict compliance with a particular descriptive word or phrase appearing in a claim was intended by the patentee to be an essential requirement of the invention so that any variant would fall outside the monopoly claimed, even though it could have no material effect upon the way the invention worked.”

In the British decision in the *Improver* cases (which are included in the assigned readings), that approach was unpacked into the set of three questions shown on your screen. In combination, they tend to produce narrow interpretations.

The *Kirin-Amgen* case, by contrast, adopted a simpler approach: “What would a skilled addressee understand the patentee to have used the words in the claim to mean?”

What about the major Asian jurisdictions? All three purpose to adhere to a similar peripheral claiming approach – and to the now-dominant hierarchy of sources of guidance. But they differ significantly in the procedures through which claim construction can be conducted.

In Korea, for example, parties, including accused infringers, can seek guidance from the IP Trial and Appeal Board within the national patent office concerning whether a particular claim should be construed to cover a particular technology. These are called Confirmation of Scope proceedings. They are analogous to the IPR proceedings before the PTAB in the US, but instead of challenging the validity of claims, they seek clarification of their scope. Although the courts in infringement proceedings are not bound by their determinations, they often defer to the IPTAB’s rulings. In a 2018 decision, the Korean Supreme Court ruled that such proceedings can be initiated even after an infringement suit has been filed – and can be pursued to a final result even after judgment in the infringement action.

An analogous procedural option exists in Japan.

This concludes our survey of the different approaches used in the major jurisdictions to interpret the scope of patent claims. As you can see, since the 1970s, there has been substantial harmonization on this front, but the convergence of the countries is far from complete. Significant variations, both procedural and substantive, remain. Partly as a result, infringement suits brought in different jurisdictions against the same defendant, relying upon identical patent claims can and do come out differently. During the seminars accompanying this lecture, you will likely consider which of the dominant approaches makes the most sense.

B. Patent Duration

The second dimension of the scope of a patent is duration. Often, both the owner of a patent and competitors of the patentee care as much about how long the patent will last as they do about its technological breadth. In this portion of the lecture, I will examine the rules governing patents' temporal scope.

You could imagine a legal regime in which patents lasted forever. As I mentioned previously, trademarks are at least potentially immortal. Patents could be as well. In the United States, adoption of such a regime would require an amendment to the constitution, because, as we have seen, the constitutional clause on which patent law is based authorizes Congress to grant inventors exclusive rights to their inventions for limited times.

To be sure, in the context of copyright law, the Supreme Court has construed that phrase generously – and allowed Congress to extend copyrights, both prospectively and retroactively, for remarkably long periods. But making copyrights infinite in duration (as some authors and composers have suggested) would surely be beyond Congress' power – and the same is true for patents. In short, the creation in the US of a regime in which patents are perpetual would require modification of the Constitution, which is extremely unlikely.

That's not true elsewhere. Most other countries lack constitutional limitations on the ability of their legislatures to extend the duration of intellectual-property rights. So far, however, no legislature anywhere has made patents immortal – and there are no movements afoot to do so.

Perhaps more realistically, you could also imagine a legal regime in which patents varied in their strength or coverage over time. Justin Hughes once suggested that such a system might make sense in the context of copyright law. Specifically, he proposed an interpretation of the fair-use doctrine that would have the effect of gradually contracting, during the lifetime of a copyright, the set of activities that would be deemed to violate it. Something similar is conceivable with respect to patents. But, for better or worse, that's not the way that patent law works – in the US or anywhere else. Rather, the legal rights associated with a patent do not change during their lifetime. Like old-style light switches, they turn fully on at the moment the patent issues, and they turn fully off when the patent expires. No dimmer switches.

To assess the current rules governing their duration, it helps to have a bit of historical background.

When the patent system was first created in the United States, patents lasted for 14 years from the date the patent was issued. Somewhat more precisely, The Patent Act of 1790 authorized the Secretaries of State and War and the Attorney General to issue patents “for any term not exceeding fourteen years.” In practice, they routinely granted patents for 14 years.

The number 14 was derived from the English patent law, which, since 1623, had authorized patents “for the term of fourteen years or under.”

Why 14? Apparently, because at the time, apprentices lasted for 7 years, and it was thought that it was reasonable to give a patentee enough time to train two cohorts of apprentices in the use of the invention – which in turn was thought to be the most common way for patentees to exploit their inventions commercially.

The Patent Act of 1836 authorized discretionary extensions of this term. A newly created Board was empowered to extend the term of a patent for up to 7 years if, in the Board’s judgment, the patentee had not had sufficient opportunity to collect a reasonable remuneration. In addition, during the middle of the 19th century, Congress occasionally adopted private bills extending the duration of specific patents.

In 1861, as part of a statutory reform that, among other things, reduced the role of discretion in the patent system, this regime was replaced with a standardized term of 17 years from the date of issuance. That system remained in place for well over a century – specifically until 1995 – when it was replaced by an entirely new approach.

The primary cause of the 1995 change was that most other countries in the world had adopted systems in which patent duration was measured from the date of the application, not the date of the issuance of the patent. During the negotiations that led to the TRIPS Agreement, the United States was pressed to harmonize its regime with those of other countries. The negotiators for the US were reluctant, but in the end acquiesced. Article 33 of the TRIPS Agreement, adopted in 1994, provides, “The term of protection available shall not end before the expiration of a period of twenty years counted from the filing date.”

The US statute was amended in 1995 to comply with that obligation (as well as with other dimensions of the TRIPS Agreement.). The precise terms of the statutory reform were shaped, not just by the general obligations of Article 33, but by a bilateral deal between the US and Japan, through which the US secured an agreement that Japan would accept patent applications in the English language, something American companies badly wanted.

This regime has remained relatively stable since 1995, but had been tweaked in minor respects. Here’s how it currently works.

As I’ve indicated, the term of a patent presumptively ends 20 years after the filing date. Now, it bears emphasis that the patent still doesn’t begin until the date it’s issued. After filing but

before issuance, the applicant cannot prevent competitors from engaging in activities that, after issuance, would constitute infringement.

The upshot is that, if issuance comes 3 years after filing, then the effective life of the patent is 17 years – the same as it was under the old regime.

If issuance comes sooner, the effective life of the patent is longer.

If issuance comes more than 3 years after application, then the effective date is shorter.

One effect of this system is to put pressure on applicants to pursue patent prosecution aggressively. Indeed, that is one of the main justification for the new regime; it discourages efforts by applicants to keep their applications in limbo, waiting until competitors appear on the horizon and then surprising them with the issuance of a patent.

But it also means that the applicant is penalized if the Patent Office is slow. I'll come back to that issue in a minute.

Before doing so, we have to sharpen up the meaning of "application." If the applicant has filed a single application with the PTO and pursued it to a successful conclusion, then things are simple enough.

But what if the application that is ultimately granted invokes the procedure contained in section 120 of the statute for referring back to and claiming the priority date of another application?

In that case, the term ends 20 years after the filing of the original application, which of course shortens the effective life of the patent.

The same is true with respect to referenced divisional applications under section 121.

and with respect to prior PCT applications for the same invention that list the US as one of the countries in which patent protection will be sought.

Interestingly, however, the same is not true of patent applications in other countries, whose priority dates the US applicant invokes under the Paris Convention. The effect of this oddity, which is mandated by the Paris Convention, is to enable applicants using this approach to have their cake and eat it too – i.e., to get an earlier priority date, which, as you know, is helpful in complying with the novelty and inventive step requirements, without forfeiting any patent life.

OK, let's go back to the simpler case of an unadorned US patent application.

As I indicated, the applicant will be unhappy if the application process takes longer than usual – thereby shortening the effective life of the patent. Can she recoup any of the lost time?

Sometimes, yes.

Under the following circumstances, she can request and obtain an extension of the expiration date of her patent.

If the PTO has responded slowly to specific submissions

If the PTO takes more than 3 years to process the application – unless the delay is the applicant's fault.

And if controversies of one sort or another delay the processing of the application and the applicant eventually prevails.

The details of these extensions (including exactly how much extra time can be obtained) are of course very important to patentees, but need not concern us here. If you are curious concerning those details, consult the statutory provisions set forth on these slides.

How often are such extensions granted? Surprisingly often.

These data, assembled by Dennis Crouch, show that less than 30% of patents granted get zero term extensions. Roughly 10% get an extra one quarter year – i.e., 3 months. Another 10% get 6 months. And so forth.

Let's go back once again to the simple case.

I've indicated that, under the current regime, the term of the patent begins here and ends here.

Thus use of the technology by competitors prior to the grant does not violate the patent statute. That does not mean, however, that inventors never have any recourse under such circumstances. Sometimes they are able to invoke other bodies of law – such as trade secrecy – to punish such conduct.

What about the other end of the term? On occasion, competitors will try to get a head start on their ability with impunity to use the technology. For example, as we have seen, so-called combination patents are only violated by combination of various elements – each of which may be in the public domain. It would seem that, until the various components are actually put together, no infringement occurs. Aware of this, competitors may be tempted, prior to the expiration of the patent, to manufacture the components, test them, and even sell them to customers with instructions not to put them together until the bell rings, signaling the end of the patent.

Patentees, as you might imagine, think such conduct is cheating. It's sometimes known as "jumping the gun."

In 1984, a case of this sort, involving a combination patent on an improved system for rapidly winding toilet paper or paper towels onto rolls, came before the Federal Circuit. By a vote of 2 to 1, the court ruled that this behavior was unlawful. The key language in its opinion appears on your screen. Note the mingling of concern over the adverse impact of this strategy on the patentee's revenues with suggestions of immorality.

As Judge Nies argued in dissent, it's difficult to reconcile this ruling with the language of the statute – or, as we will see, the manner in which the Supreme Court had previously dealt with extraterritorial sales of components of a combination patent. But, for better or worse, this behavior is considered infringing.

The rules we have considered thus far govern the duration of all utility patents. Not design patents; they have a shorter term – specifically 14 years. But utility patents on all types of technology.

There is an important subsets of utility patents, however, that is also subject to an additional set of rules. It consists of patents on pharmaceutical products.

To understand how and why drug patents came to be treated differently, you need a bit more information concerning the interaction of the patent system and the drug regulatory system.

Pioneering drug companies are constantly looking for new molecules that might have therapeutic benefit. Sometimes they do this by randomly screening large numbers of compounds. Sometimes they use more targeted techniques, like asking the members of indigenous groups what plants they have found to be efficacious in addressing particular diseases.

[(The complex moral and economic issues presented by this particular strategy will be discussed by Professor Okediji in a later lecture in this series.)

When a company identifies a promising molecule, it typically soon files a patent application on that substance. Waiting to do so runs the risk that a competitor would file sooner and get priority. At that point, as you now know, the 20-year clock starts running. However, the drug is a long way from commercial viability. Typically, additional preclinical research will burn up an additional 4 years. If the compound still seems promising, the firm will commence clinical testing. This comes in three phases – first on animals, then on small groups of sick people, then on larger groups. Such testing commonly takes a total of 7 years. If all goes well, the firm will apply to the Food and Drug Administration for the right to sell drugs embodying the compound. The FDA is likely to burn roughly 2 years reviewing the application. Only if it approves, may the drugs be placed on the market.

At that point, there is likely to be only 7 years left on the clock. That's the commercial life of the patent. That's significantly shorter than the commercial life of patents on most kinds of

inventions. A short commercial life is especially problematic in the context of pharmaceutical patents because the cost of research, development, and testing is so brutally high. The firms have long argued, plausibly, that they need more time to recoup their costs.

Before discussing how Congress has sought to address their pleas, I need to highlight an additional unusual feature of drugs. In most fields of technology, once a patent expires, it's not hard for competitors to enter the field – and thus drive down the cost to consumers of the product at issue. Typically, the competitors can either reverse engineer the product – or just read the patent which should tell them how to make the product (at least if the disclosure rules are working properly). Then they can commence production and sales.

In the pharmaceutical field, those competitors are commonly known as generics. They face higher hurdles than competitors in most fields – partly because mimicking a drug is sometimes difficult, but more importantly because, at least presumptively, they have to go through the same prolonged testing and approval process as the pioneers.

In the 1970s and '80s, some generics tried to get a head start on the approval process, by commencing testing of their own versions of patented drugs prior to the expiration of the patents – so that they would be ready to enter the field as soon as the patent died. As I hope you see, this is a close analogue to jumping the gun on a combination patent – the issue we considered a minute ago.

In the important 1984 case of *Roche products v. Bolar Pharmaceutical*, the Federal Circuit ruled that this constituted “use” of the patented compound and was not excused by any exception for experimentation and was thus unlawful. (In the next lecture, we'll return to the doctrinal basis of this ruling.). For the time being, the key aspect of *Roche* is that it forced generics to wait until the end of the patent to commence testing – which of course made them unhappy.

In the Hatch-Waxman Act and some associated statutes adopted in 1984, Congress sought to address the unhappiness of both the pioneers and generics – in a way that would be less costly to the public at large.

There are many elements to the Hatch-Waxman compromise, but here are the main ones:

Pharmaceutical firms were given an extension of the terms of their patents to offset times spent in the FDA regulatory review process. The length of that extension was capped at 5 years – but most pioneers are able to secure that much. This, of course, increased the commercial life of their patents to 12 years.

On the other hand, Congress overrode the *Roche* decision. Generic firms were permitted to commence testing prior to the expiration of the (now extended) patent term. Moreover, the rules governing how much information they had to provide in order to receive FDA approval for their generic substitutes were eased considerably. Since Hatch-Waxman, generics have been

permitted to secure FDA approval by filing what's called an Abbreviated New Drug Application, popularly abbreviated ANDA.

To be successful, an ANDA must contain two things:

A demonstration of bioequivalence between the generic and the pioneer – which, in turn, enables the generic and the FDA to rely upon the clinical testing already done on the pioneer when approving the generic.

And second, a showing that approval and subsequent marketing of the generic will not violate any patents.

The generic can satisfy this second requirement in any of four ways:

- 1) By showing that The drug at issue has not been patented
- 2) By showing that, although the drug was once patented, that patent has expired
- 3) By showing that, although the patent has not yet expired, it will do so on a particular date, after which sales of the generic will begin;
- 4) Or by demonstrating that The patent on the drug is invalid or will not be infringed by the generic

The first three of these options are important, but not revolutionary.

The fourth, however, has radically altered the pharmaceutical industry, by providing generics a relatively inexpensive and risk-free way of challenging patents. Exactly how that mechanism works and how patentees have responded will be the subject of one of the discussion sessions that accompany this lecture series.

Putting aside, for the moment, the complexities associated with so-called paragraph 4 ANDAs, the regime created by the overlay of Hatch Waxman upon the general system of patent duration is widely and rightly regarded as a success. Certainly, it works much better than the system in place prior to Hatch-Waxman. Some of the credit for both the flourishing pharmaceutical industry in the US and the proliferation in the past 30 years of generic drugs should be given to this ingenious legal regime.

However, this system has one major drawback. Some kinds of drugs take longer to investigate and test than others. The premier example is drugs that address ailments that affect the central nervous system – such as depression, Alzheimer's, and schizophrenia. The scientific impediments associated with drugs aimed at such things are unusually daunting. In addition – and more relevant for present purposes – it takes much longer to demonstrate through clinical testing the safety and efficacy of such things than it does for drugs that address, for example, Hepatitis C or the flu. The reason what that matters is that, as you'll recall, the patent-term extensions available under Hatch Waxman are capped at 5 years.

Suppose, plausibly that preclinical investigation of a potential Alzheimer's drug take 8 years instead of 5, and that clinical testing of the drug takes, say, 10 years instead of 7. The result would be to reduce radically the potential commercial life of the drug – and thus to diminish the ability of the developer to recoup its costs.

This unfortunate effect is one of the reasons (not the only reason) why pharmaceutical firms in recent years have been abandoning research projects aimed at CNS disorders. Here's a comparison of the number of such projects underway in 2009 and the number underway in 2014. Since 2014, the situation has gotten worse, not better.

As Eric Budish, Ben Roin, and Heidi Williams have shown, an analogous distortion is evident in the types of cancer that pharmaceutical firms choose to target. Clinical tests that demonstrates the ability of a drug to extend by a few months the life of a person suffering from a particular form of late stage cancer can be completed much more quickly than clinical tests that show an improvement in the 5-year survival rate of a person suffering from a particular form of early-stage cancer. And tests on drugs that prevent cancer altogether take the longest of all. It is not surprising, therefore, that drug companies focus disproportionately on the former, not the latter. Although rational from the standpoint of the firms, this pattern of investment is terrible from the standpoint of public health.

How might distortions like these be mitigated? A radical solution would be to change the method by which we measure the life of a patent. Currently, as you now know, in the US and almost all other countries, the expiration of a patent is tied to the date of the application. The result, as we have seen, is to disfavor investment in fields characterized by long delays between the date of a patent application and the date on which the commercial life of the patent begins.

You could imagine changing to a system in which each patent gets a fixed commercial life. To be more concrete, imagine changing the current statutory provision to something like the following. Because this change would preserve a minimum term of 20 years from the date of the application, it would not violate the TRIPS Agreement.

To be sure, such a change would have some drawbacks. It would require the courts to develop guidelines for identifying the moment of "first commercial use" that would limit the ability of patentees to game this system. And, outside the field of pharmaceutical products (where firms have little or no incentive to postpone commencement of commercialization) it would might lead in some cases to strategic delays in launching of products. But it could save a lot of lives.

For better or worse, a statutory reform this dramatic is highly unlikely. More plausible would be extension of the terms of patents on the specific types of products that are most subject to this distortion. A few years ago, a group of scholars of which I was a member made such a proposal with respect to drugs that affect the central nervous system. The gist of our proposal is that the terms of the patents enjoyed by breakthrough CNS drugs (as well as the duration of data exclusivity protection) be extended by a specified number of years. That would of course

extend the commercial life of those breakthrough drugs and augment incentives to create them. We already employ this technique to try to stimulate additional research projects aimed at the development of new antibiotics, which are sorely needed. It could be generalized to pull investment into other areas of great social need.

If you are curious concerning the details of our proposal (including how breakthrough CNS drugs would be defined), follow the link to this article that can be found in the full version of the Patent Law map.

This concludes my discussion of the rules governing patent scope. The next lecture will focus on the topic of infringement.