

INTELLECTUAL PROPERTY SURVEYOR

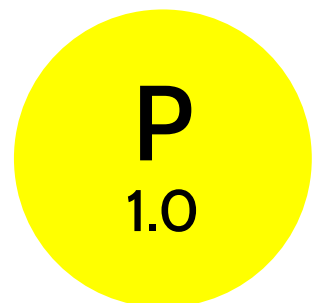
IP Surveyor

Volume: Patent

VERSION 1.0
MUSEUM EDITION



An open casebook anthology
compiled and edited by Eric E. Johnson



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Intellectual Property Surveyor

Volume: Patent

VERSION 1.01

MUSEUM EDITION

an open casebook anthology

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likely some errors and mistakes. So if you've got a real-world legal problem, you should look elsewhere for advice.

-EEJ

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–EEJ

Editing Notes

The superscript tilde ([~]) indicates omitted material. I know it's unconventional, but I like it better than the three dots because it is relatively unobtrusive.

I used square brackets to indicate insertions, which may also include a corresponding deletion in the same place.

Within judicial opinions I have liberally removed footnotes, footnote references, and citations. I've changed typography and formatting, and may have changed paragraph breaks and done some slight editing/re-writing work to put footnote material into the main body ("above the line") text. Case text—as well as statutory, regulatory, and agency guidance text—should not be considered authoritative. I've bent text as I felt appropriate to serve educational purposes. Consult the official versions of documents if you have anything else in mind.

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I have been quite liberal in editing CRS materials included in this volume. I've tried to indicate this as a general matter by using the phrase "Adapted from" or similar in connection with individual sections of text within the chapters. I may have sometimes used a superscript tilde ([~]) to indicate an ellipsis. But I've also removed various material without indication.

Typography, styling, and formatting, including levels of headings, have been changed. Paragraph breaks may have been changed. I've generally removed all footnotes and footnote references without leaving any specific indication. Sometimes footnote material has been worked into the main text without specific notation.

In places I've added words or changed phrasing to adapt the text to suit the purposes of this volume. For instance, I changed "a decade ago" to "the

2010s” to make the text understandable without being anchored to the time it was published. I removed the word “also” from a first sentence of a section of CRS text, because I hadn’t included the preceding text to which the word “also” referred. And so on.

—EEJ

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P-0: Patent Law Orientation

This chapter was authored by Eric E. Johnson.
Please see “Rights, Licensing, Etc.” at the end
of this chapter.

Key Terminology and Abbreviations

art – In the patent context, “art” can usually be translated as “technology” or something like “the public state of knowledge of technology.” This is an old-fashioned meaning of the word. And while saying “art” to mean “tech” is mostly gone from contemporary language, the term carries over to today in the word “artisan,” the phrase “state of the art,” and the jargon of patent law.

prior art – The term “prior art” means a body of non-secret technological knowledge before some crucial date (archetypally the application filing date) that will be compared to patent claims as a way of judging patentability—most notably with regard to novelty and nonobviousness.

USC – United States Code. (Title 35 is the patent title.)

CFR – Code of Federal Regulations. (Title 37 contains patent regulations.)

USPTO – United States Patent and Trademark Office.

PTO – the patent office. In the U.S. context, “PTO” is shorthand for USPTO, which is the United States Patent and Trademark Office.

MPEP – Manual of Patent Examining Procedure. The MPEP is a giant instruction book for how patent examiners are to do their job in examining patent applications. It is a very important resource for patent agents and patent attorneys.

“provisional patent” – There is no such thing as a “provisional patent.” But there is such a thing as a provisional patent application. Read on.

provisional patent application – A provisional patent application is an informal sort of application filed with the USPTO. It can't result in a patent—that takes a *non*provisional patent application. But a provisional application, if it completely describes the invention, can establish an early effective filing date for a later-filed nonprovisional patent application. And provisional patent applications can be easier to put together and file, since they have less stringent requirements. If a provisional patent application is going to do the applicant any good, it generally must be followed by a nonprovisional application within 12 months.

nonprovisional patent application – a regular patent application. A “nonprovisional” patent application is the regular sort of patent application that can result in a patent.

patent application – When someone says “patent application,” you generally can assume they are talking about a nonprovisional patent application, unless the context provides otherwise.

file wrapper – In patent lingo, “file wrapper” is a nickname for all of the documents associated with one patent application in the files of the USPTO. It includes the application itself along with written communications between the applicant and the PTO. It is similar to the phrase “case file.” The file wrapper serves as a history or timeline of the progress and evolution of a patent application during prosecution. The term “file wrapper” is sometimes used as a metonym for “prosecution history.” Two kinds of documents you might find in the file wrapper would be one or more “office actions” and a “notice of allowance.”

office action – In general, an “office action” is an instance of written correspondence from the patent examiner to the patent applicant, taking some action with regard to the patent application other than providing the straight-up good news that everything in the application is fine as it is. An office action typically includes rejections and objections to the application. It isn't necessarily a death knell for the application, but an office action does require a written response if the prosecution is going to go forward. Often some amendment to the claims will be necessary to adequately respond to an office action.

notice of allowance – A “notice of allowance” is analogous to an office action—but instead of stating what is rejected or objected to, a notice of allowance is the good news that the PTO is “allowing” (i.e., approving) a patent application, clearing the way for a patent to be issued.

claims – The claims of a patent are the stilted, technical-sounding sentences at the end of a patent document that set out the boundaries of the protected invention. In so doing, a claim sets its own test for infringement. A patent typically includes a mix of narrower and broader claims. Each claim functions as a miniature statute that sets out what members of the public are not allowed to do—lest they be sued for infringement. As such, each claim forms an independent basis for an infringement suit, such that a plaintiff only need to prove infringement of one claim to win a lawsuit.

specification – the written portion of the patent that describes the invention, explains how to build and use it, and points out how it is distinct from other art. (As a technical matter, the patent statute refers to the claims as a part of the specification. 35 U.S.C. § 112 (b). But courts and practitioners commonly use the term “specification” in contradistinction to a patent’s claims.)

Nanotreatise on Patent Law

Nanotreatise on Patent Law in the United States

by Eric E. Johnson

Rev. Date: September 25, 2022

This is a very brief primer on U.S. patent law aimed at law students and lawyers.

What is a patent?

The usual, most well-known kind of patent is what is technically called a “utility patent.” It’s a government-granted exclusive entitlement on a certain invention.

When someone says “patent,” without specifying otherwise, they are almost certainly referring to a utility patent. Under U.S. law, however, there are two other kinds of patents: design patents, which concern ornamental designs (although “ornamental” can be interpreted quite broadly) and plant patents, which concern asexually reproducing plants. Going forward, this

document will only talk about utility patents; so “patent” means “utility patent.”

Where does patent law come from?

U.S. patent law is federal law, with federal courts having exclusive jurisdiction. Congress gets its power to grant patents from the Progress Clause of the Constitution (“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.” U.S. Const. art. I, § 8, cl. 8.).

Patent law is codified as Title 35 of the United States Code. The statute that forms the basis of current patent law is the Patent Act of 1952, which starts at § 101 in Title 35. There were important substantive amendments made with the Leahy-Smith America Invents Act of 2011 (AIA). The most important effective date for the AIA is March 16, 2013. AIA changes apply to applications filed on or after that date, as well as patents that result from those applications. Pre-AIA law applies to many in-force patents and perhaps some pending applications.

Patents on inventions under Anglo-American law can be traced back to the 1623 Statute of Monopolies, which sought to shut down the practice of the English monarch handing out favors in the form of monopolies on certain products in certain territories. That statute didn’t bar patents entirely, however. It carved out an exception that would allow new patents to issue to create government-granted monopolies for novel inventions.

While a U.S. modern patent can be described as a government-granted monopoly, a patent does not necessarily provide a “monopoly” in the sense in which modern antitrust law uses the term. That is to say, any given patent may or may not create market power that allows a patent holder to raise prices above competitive levels. Whether that happens will depend on consumer preferences and the existence of alternatives to the patented invention. Certainly, however, it is part of the intent of the patent system as a whole that patents can create the power to raise prices above the level that would prevail if competition were allowed. Indeed, that is crucial to the policy rationale for patent law.

What is the policy rationale for patents?

The underlying rationale for patents is generally understood to be a bargain between society and the inventor. In return for inventing something useful and disclosing exactly how to build and use it, and also to help along the invention's development and commercialization, the government grants the inventor exclusive rights over the invention for a limited time. This allows the owner to potentially derive monopoly profits, for a time, by being the exclusive manufacturer or licensor of the patented technology.

Unlike copyrights, trademarks, trade secrets, and publicity rights, patent rights cannot arise without bureaucratic intervention. The only way patent protection comes about in the United States is if the U.S. Patent and Trademark Office (USPTO) issues a patent after favorably reviewing an application. Once issued, a patent lasts until 20 years from the date of the filing of the application. So if the application takes three years to go through, that would be an in-force patent term of 17 years. There is the possibility of certain extensions for delays in issuance attributable to the USPTO, and there are special opportunities for extensions on pharmaceutical patents having to do with the length of the approval process of the Food and Drug Administration.

What rights does a patent give you?

A patent essentially gives the owner only one right: The right to sue others for money and an injunction in an action for infringement.

A patent does not give the owner the right to practice (meaning to make or use) the invention. In fact, it is quite common that patent owners cannot make their claimed invention. Doing so might violate industrial-safety rules, run afoul of product-safety regulations, or even infringe on someone else's patent. For instance, if someone invents an improvement on a patented invention, then the inventor of the improvement cannot practice the invention without getting a license from the owner of the patent on the underlying invention. And the owner of the patent on the original invention cannot make the improved version without a license from the owner of the improvement patent. That's a situation frequently referred to as "blocking patents." Thus, the legal entitlement a patent provides is really negative one: to exclude others from practicing the invention.

Anatomy of patents: the claims and the specification

A patent is a document. A common length would be around a dozen pages or so (though some are extremely long). They are public documents and easy to find online. If you like, you can download a patent, look at it, even print it out.

Each patent has a number, and the numbers are issued sequentially. To find examples of patents, you can try searching online for "us patent NNNNNNN" – but replace "NNNNNNN" with a seven-digit number. Most numbers starting with a 7, 8 or 9 should get you a fairly recent patent. You can also try an eight-digit number starting with 10. (As of the date of this nanotreatise, new patents are being issued with numbers beyond 11,000,000.)

As a document, a patent has two important parts: the claims and the specification. Understanding the role of the claims and the specification is crucial to understanding anything else about how patents work.

Technically, the patent statute says the claims are part of the specification. 35 U.S.C. § 112 (b). But the term "specification" is commonly used in contradistinction to the claims, and that's how we'll use the word here.

The specification is the bulk of the patent. It generally contains a fair amount of text, and that text is written in normal prose—at least sort of normal. The specification's job is to carefully describe the invention, explain with precision how to build and use it, and point out how it is distinct from other inventions. The specification also generally attempts to "sell" the patentability of the invention, conveying how it is useful, new, and nonobvious.

The claims are the pointy end of the patent. You'll find them as a numbered list at the end of the patent document. The claims set out in exact language what it is that others cannot make or use. In a lawsuit, the claims form the core of the test for patent infringement.

A patent typically has multiple claims. Different claims may cover different versions of the invention, and different claims tend to be purposefully designed to be narrower or broader.

Each claim is an individual legal entitlement that can form the basis for an infringement lawsuit. If a patent has 10 claims, a plaintiff might sue a defendant on claims 4, 6, and 7. And even if the defendant wins on claims 4

and 6, for instance, the plaintiff could prevail in the lawsuit and get a money award and injunction just based on claim 7.

Claims use funny language and they consist of individual elements, all of which together define a product or process that would fall within the claim's exclusive rights and thus form the basis for an infringement action. Let's use water as an example:

I claim:

1. A molecule consisting of an oxygen atom,
a first hydrogen atom covalently bonded to said oxygen atom, and
a second hydrogen atom covalently bonded to said oxygen atom.
2. The molecule according to claim 1, wherein each hydrogen atom has a nucleus consisting of one proton and one neutron.

Notice that in this example, claim 2 is more specific and more narrow than claim 1. If a water molecule has hydrogen atoms with nuclei consisting only of protons, with no neutrons, then that water molecule would be within the scope of claim 1 but not claim 2.

Five requirements for a valid patent – for issuance and infringement litigation

It is useful to focus on five crucial things that must be present for an invention to be validly patented:

1. patentable subject matter
2. utility (usefulness)
3. novelty (newness)
4. nonobviousness
5. disclosure

These are the crucial five things that an inventor must have in order to get a patent issued in first place. And these are the crucial five things the patent owner must be prepared to uphold when the patent is attacked by the defendant in an infringement lawsuit.

Technically speaking, there's more required than just these five things to get a patent. For instance, there are fees that need to be paid and paperwork

that must be filed. But the list above is the big five for doing the substantive analysis on whether an invention is patentable.

And while there are myriad ways for a defendant to prevail in a patent lawsuit, a key battleground in litigation is the affirmative defense of invalidity. And a defendant can win on invalidity by knocking out any of those five requirements.

All claims of a patent are evaluated individually on all of these things. So in a patent with 10 claims, claim 1 might be determined to be invalid for a lack of novelty, while claim 2 might be determined to be invalid for a lack of nonobviousness. And claim 3 might be determined to be valid, while claim 4 is held invalid for not meeting a disclosure requirement. And so on. The fact that some claims might perish while others survive attack is one of the reasons inventors pursue a patent with multiple claims.

Key requirement 1: Patentable subject matter

This requirement is easy for most inventions. Section 101 provides that any “process, machine, manufacture, or composition of matter, or any new and useful improvement thereof” is patent-eligible subject matter. The categories of “machine, manufacture, or composition of matter,” cover essentially anything that is artificially produced and is tangible. Tangible substances and devices are generally easy cases for patent-eligible subject matter.

Where the invention is claimed as a “process,” things can get more complicated. Of particular note, a number of recent U.S. Supreme Court decisions have focused on the dividing line between what is in and what is out when it comes to things like software, business methods, and medical diagnostics.

Patent-eligible subject matter can be a big issue in the fields of internet services, computer programming, biotechnology, and healthcare services. But for a huge swath of inventions, patentable subject matter is a slam dunk.

Key requirement 2: Utility

The utility requirement is that the invention must be useful. This too is an easy requirement for most inventions.

Utility can, however, be a problem for inventions that are suspected of not actually working. An invention that seems to violate known laws of

physics will draw a rejection on the basis of a lack of utility. So if you are applying for a patent on a machine that endlessly produces electricity without any energy inputs – something that is inconsistent with the Second Law of Thermodynamics – you not going to get a patent. That is unless, I suppose, you can stun everyone with a successful in-person demonstration at the USPTO.

The utility requirement has been used historically to reject inventions that were deemed contrary to good morals. This doctrine of “moral utility,” however, seems to be dead letter at this point.

Of substantial economic and industrial importance is the employment of the utility requirement to reject patent applications for newly synthesized substances. If you are a pharmaceutical company or chemical company that’s synthesized a new molecule – but you don’t know what it is good for yet – the utility requirement is going to be a problem for you. Research pharma firms often use the results of animal testing to show specific pharmacological effects in order to surmount the utility requirement.

Key requirement 3: Novelty

The novelty requirement means that the invention must be new.

The key phrase used in talking about novelty is “prior art.” To be able to talk knowledgably about patents, you’ll need to get comfortable with this phrase. If a claimed invention can be found among the prior art, then it is not novel. And that means you cannot get a patent on it.

One thing that is funny – to modern ears, at least – with the phrase “prior art” is the use of the word “art.” In patent talk, “art” does not refer to the kind of thing you’d find hanging on the walls in an art museum – such as oil paintings of mythical deities. Instead, in the phrase “prior art,” the word “art” can be translated as “technology.” It is, in fact, the same sense of the word “art” that is used in the phrase “state of the art.”

Prior art, in general, constitutes all the non-concealed documents, writings, publications, public displays, public uses, etc. out there in the world – that is, the things that delineate the state of society’s technical knowledge – that were in existence *before* the applicant’s invention. Generally the date of the applicant’s invention is considered to be the date of filing of the patent

application. Thus, to simplify, everything in the public sphere before the filing date is the prior art.

A claim that covers an invention already in the prior art is said to be “anticipated,” and thus non-novel.

Beyond anticipation, there are other senses in which an invention must be new. The inventor must not have waited too long after publicly using the invention before filing an application. The inventor must have priority if there are multiple applicants with pending applications on the same invention. And the inventor must not have derived the invention from someone else’s work.

Novelty is governed by § 102. Importantly, that section was completely re-written by the AIA. The most basic concepts of § 102 persist after the AIA, but the details differ in important ways.

Key requirement 4: Nonobviousness

Even if a claimed invention cannot be found in the prior art and is deemed novel, the invention can still be rejected by the USPTO if the difference over the prior art is so minor that the change would be obvious to a person having ordinary skill in the art.

The touchstones for nonobviousness are the prior art – discussed above with regard to novelty – and the level of ability of the hypothetical person having ordinary skill in the art, frequently referred to by the convenient acronym “phosita.” In other words, if the phosita could have or would have done what you did, then you aren’t entitled to a patent on it.

Key requirement 5: Disclosure

The disclosure requirement is more precisely thought of as a multiple requirements, which are found in § 112(a). That section says, “The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.”

Analysis of the disclosure requirement, as with nonobviousness, revolves around the hypothetical person known as the phosita.

There are at least two key reasons for the § 112(a) disclosure requirements. First, the disclosure requirements force the inventor to show that they have actually invented the invention that they are claiming. Second, the disclosure requirements force the inventor to honor the essential, implicit bargain of the patent system – that in return for exclusive rights for a limited period of time, the inventor enriches the state of the art and benefits society at large by providing clear and complete instructions on how to make and use the invention. That way, the invention will be free and useful to all when the patent expires.

Patent prosecution

The process of applying for a patent and dealing with the USPTO to get it issued is referred to as “patent prosecution.” The inventor, patent attorney, or patent agent drafts the specification and claims, and files them with the USPTO. At the USPTO, an examiner reviews the application and responds. The response can be a rejection of claims, accompanied by stated reasons. Or the response could be a notice of allowance – signifying that the application is successful. For a claim that is rejected, the applicant can amend the claim, present reasons why the examiner should allow it, or abandon the claim – perhaps choosing to pursue other claims within the application that are more promising. The text and drawings of a successful patent application end up becoming the text and drawings of the issued patent.

A final rejection from a patent examiner can be appealed to the USPTO’s Patent Trial and Appeal Board, known as the “PTAB” (pronounced “pee-tab”) Decisions of the PTAB can be appealed to the U.S. Court of Appeals for the Federal Circuit.

To practice patent prosecution – that is, to prepare patent applications for and represent applicants before the USPTO – you must be admitted to practice before the USPTO, sometimes informally referred to as the “patent bar.”

Post-issuance adversarial proceedings at the USPTO

There are litigation-like proceedings that can be brought at the USPTO after a patent has been issued. These can be used as a way for third parties to attack a patent and thus pre-empt infringement litigation. Such proceedings include “post grant review” and “inter partes review.” Representing clients in

these proceedings requires admission to practice before the USPTO (the so-called “patent bar”).

Patent infringement litigation

Section 271 provides a cause of action for patent infringement against whoever “makes, uses, offers to sell, or sells ... or imports” any invention covered by an unexpired patent. Patent infringement suits must be brought in federal district court. Patent infringement actions – regardless of what regional circuit covers the particular district court – are appealed to the Federal Circuit.

Attorneys representing litigants in infringement litigation need only be admitted to practice before the federal court in which the litigation is taking place – admission to the “patent bar” is unnecessary.

Acknowledgments: I extremely am grateful to Professor Saurabh Vishnubhakat for helping me with a particular example I used in this document. But he didn't review anything other than a sliver of this whole document. Any and all errors are most certainly mine and mine alone!

Rights, Licensing, Etc.

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-EEJ

P-1: Patent Anatomy and Claims

This chapter was authored by Eric E. Johnson.
Please see “Rights, Licensing, Etc.” at the end
of this chapter.

Patent Anatomy

Patents are documents

A patent is a document. And to understand patent law and patent rights, it helps to keep that centrally in mind. Moreover, a patent is a particular kind of document: It’s a document issued by the government that serves as a vehicle for a legal entitlement bestowed on a private person.

The word “patent” means “open.” Going back hundreds of years “letters patent” were open letters issued by the government specifying that some private person had some government-granted entitlement. The entitlement was delineated by and brought into being by the document.

What we call “patents” today are very much in that tradition. They are open, public documents that are vehicles for bestowing legal entitlements on private persons, and patents delineate and bring into being those legal entitlements.

Since patents are documents, a good place to begin the study of patent law is to get familiar with the patent document—its structure and its various parts. That is the point of this chapter.

Different kinds of patents, and the terms “patent” and “patent application”

In the United States there are three different kinds of patents: utility patents, design patents, and plant patents. Nearly all the time when someone

says “patent” without specifying more, they mean a “utility patent.” You can expect that shorthand in this book as well.

There are two kinds of utility patent applications: provisional patent applications and nonprovisional patent applications. Nearly all the time when someone says “patent application,” they mean “nonprovisional utility patent application.” And that is true for this book as well.

There is one kind of shorthand, sometimes used by persons without legal training, that must be called out as not okay. Sometimes I’ve heard scientists called patent applications “patents”—for instance referring to patent applications on a CV or list of accomplishments as “patents.” To speak that way is to misrepresent things. Filing a patent application doesn’t really mean anything other than the fact that you’ve paid a filing fee. Having a “patent” means the government has examined your application and determined that you have invented something novel, nonobvious, and useful. Now, that doesn’t mean it’s a stupendous accomplishment. Indeed, many patents are rather dubious achievements. But a patent is a different creature from a patent application in the same way that a law is different from a bill.

Anatomical relation of a patent application to a patent

Just as a bill can become a law—and when it does, its text carries forward into its next evolution—a (nonprovisional) patent application can become a patent, with its text and drawings carrying forward into the resulting patent document. So you can think of a patent as an approved and engrossed application. Thus, when the readings below speak to the parts of a patent application, they are also explaining the resulting parts of a patent.

Patents and Their Parts

Adapted from Congressional Research Service, Patent Law: A Handbook for Congress, R46525, September 16, 2020. (See “Editing Notes” section at the beginning of the volume on the editing of CRS materials.)

What Is a Patent?

The Constitution empowers Congress to “promote the Progress of Science and useful Arts, by securing for limited Times to ... Inventors the exclusive Right to their respective ... Discoveries.” Since 1790, Congress has

enacted patent laws pursuant to this power, granting inventors certain exclusive rights in their inventions for a period of time. Broadly speaking, those exclusive rights are granted in return for the inventor's public disclosure of the invention. Thus, patents represent a "quid pro quo": in return for the inventor's public disclosure, the inventor receives those time-limited exclusive rights. (See *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 142 (2001).) Many of the specific doctrines underlying patent law can be explained by that rationale.

Parts of a Patent

Before describing the exclusive rights granted by a patent and related issues (such as how to obtain, enforce, and lose a patent), it is helpful to understand the basic parts of a patent. For example, before describing the legal requirements for patent claims, it is important to understand what patent claims *are*. A recently issued patent provides a good illustration of a patent's format.

A patent's cover page provides basic information about the patent, including the name(s) of the inventor(s), the title of the patent, the date that the patent issued, an abstract briefly summarizing the invention, and a representative drawing. The cover page is followed by drawings illustrating background technology; various aspects of the invention; or different implementations of the invention.

Following the drawings is the *specification*, a textual description of the invention set out in two-column pages. The textual description must meet specific legal requirements in order for the patent to be valid.

Following this textual description (and concluding the patent) are the patent *claims*, a series of numbered paragraphs setting forth what the inventor regards as his invention. These claims form the metes and bounds of the patent right; in other words, the claims define the scope of the invention, and thus the scope of the legal rights granted by the patent. Some of U.S. Patent No. 10,000,000 (the '000 patent) appear below:

What is claimed is:

- 1. A laser detection and ranging (LADAR) system, comprising:
a two-dimensional array of detector elements, each detector
element within the array including:**

- a photosensitive region configured to receive return light reflected from a target and oscillating local light from a local light source, and
- local processing circuitry coupled to an output of the respective photosensitive region and configured to receive an analog signal on the output and to sample the analog signal a plurality of times during each sample period clock cycle to obtain a plurality of components for a sample during each sample period clock cycle;
- a data bus coupled to one or more outputs of each of the detector elements and configured to receive the plurality of sample components from each of the detector elements for each sample period clock cycle; and
- a processor coupled to the data bus and configured to receive, from the data bus, the plurality of sample components from each of the detector elements for each sample period clock cycle and to determine an amplitude and a phase for an interfering frequency corresponding to interference between the return light and the oscillating local light using the plurality of sample components.

2. The system according to claim 1, wherein the two-dimensional array of detector elements comprises a large format array.

The individual clauses within each patent claim are *limitations* that serve to define the invention. Those limitations, taken together, set forth what has been invented. *Independent claims* generally do not reference other claims; for example, claim 1 of the '000 patent is an independent claim. *Dependent claims*, on the other hand, reference and incorporate the limitations of previous claims; for example, claims 2 and 3 of the '000 patent are dependent claims. Patent claims have specific legal requirements, which are explained in more detail later in the report.

Patent Application Requirements

Claim Clarity

Under 35 U.S.C. § 112(b), the claims appearing at the end of the patent must “particularly point[] out and distinctly claim[] the subject matter which the inventor or a joint inventor regards as the invention.” This is sometimes

referred to as the *definiteness requirement*. Patent claims meet this requirement by being clear enough to “inform those skilled in the art about the scope of the invention with reasonable certainty.” If a claim fails to meet this standard, it is “indefinite” and therefore invalid. The Supreme Court has described this requirement as “essential” to the quid pro quo underlying the patent grant; it “enables efficient investment in innovation” because “[a] patent holder should know what he owns, and the public should know what he does not.” The definiteness requirement thus fosters the “delicate balance the law attempts to maintain between inventors, who rely on the promise of the law to bring the invention forth, and the public, which should be encouraged to pursue innovations, creations, and new ideas beyond the inventor’s exclusive rights.”

Specification Contents

The specification must also meet certain requirements. The specification must provide “a written description of the invention, and of the manner and process of making and using it,” which is referred to as the *written description requirement*. The written description requirement is met when the specification “reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date” of the patent. Because “the invention” is defined by the patent claims, the practical analysis is whether the specification conveys possession of the subject matter of a particular claim or claims. The Federal Circuit has explained that whether an inventor had possession of the invention “requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art” and requires the specification to “describe an invention understandable to that skilled artisan and show that the inventor actually invented the invention claimed.” If a patent claim is not adequately described in the specification, then that claim is invalid. The specification must also provide sufficient detail to “enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use” the invention, referred to as the *enablement requirement*. Because, again, the “invention” is defined by the patent claims, the practical analysis is whether the specification enables a person skilled in the art to make and use the full scope of a particular claim. Thus, the enablement requirement is met when the specification teaches “those skilled in the art how to make and use the full scope of the claimed invention without ‘undue experimentation.’” If the full scope of a claim is not enabled, then that claim is invalid. The specification

must also specify the “the best mode contemplated by the inventor or joint inventor of carrying out the invention.” The *best mode requirement* means that if inventors possess a best mode for practicing the invention, they must disclose in the specification “sufficient information such that one reasonably skilled in the art could practice the best mode.” Unlike the written description and enablement requirements, however, claims may not be held invalid for a failure to disclose the best mode.

Prof. EEJ on USPTO “Filing Guide” Excerpt

The following excerpt, from material on the USPTO website, is a bit obtuse. Despite being labelled a “guide,” it is short on actual “guidance”—i.e., helpfully directing someone who is trying to successfully navigate the difficult task of drafting a patent application. Instead, the “filing guide” concentrates on a formalistic listing things you have to get done as an applicant. The unvoiced message to pro se inventors seems to be to hire a patent agent or patent attorney, or else just give up.

But this selection is helpful in orienting law students to the patent application process, pointing out the different parts of a patent application, and providing insight into the different parts of an issued patent.

I’d suggest that, as you read this selection, you refer back and forth to an issued patent. Doing that will go a long way in helping you learn your way around patents qua documents. You will also better see how an issued patent relates to the application that preceded it.

USPTO “Filing Guide” on Patent Applications

*Excerpted from Nonprovisional (Utility) Patent Application Filing Guide (January 2014), at <https://www.uspto.gov/patents/basics/types-patent-applications/nonprovisional-utility-patent> [Note: This has been edited in a way to allow law students to get a feel for what goes into a patent application. **Much minutiae has been removed. But, of course, if you were actually filing a patent application, the minutiae would be very important!** I’ve used the superscript tilde ([~]) indicates an ellipsis. Hyperlinks have been unbolded and delinked. –EEJ]*

Introduction

The United States Patent and Trademark Office (USPTO or Office) is the government agency responsible for examining patent applications and

issuing patents. A patent is a type of property right. It gives the patent holder the right, for a limited time, to exclude others from making, using, offering to sell, selling, or importing into the United States the subject matter that is within the scope of protection granted by the patent. The USPTO determines whether a patent should be granted in a particular case. However, it is up to the patent holder to enforce his or her own rights if the USPTO does grant a patent.

The purpose of this guide is to provide you with basic information about filing a utility patent application. A patent application is a complex legal document, best prepared by one trained to prepare such documents. Thus, after reviewing this guide, you may wish to consult with a registered patent attorney or agent.

There are three types of patents: utility, design, and plant. There are two types of utility and plant patent applications: provisional and nonprovisional. A provisional application is a quick and inexpensive way for inventors to establish a U.S. filing date for their invention, which can be claimed in a later-filed nonprovisional application. A provisional application is automatically abandoned 12 months after its filing date and is not examined. An applicant who decides to initially file a provisional application must file a corresponding nonprovisional application during the 12-month pendency period of the provisional application in order to benefit from the earlier provisional application filing. A nonprovisional application is examined by a patent examiner and may be issued as a patent if all the requirements for patentability are met. Each year the USPTO receives more than 500,000 patent applications. Most of the applications filed with the USPTO are nonprovisional applications for utility patents.

This guide contains information to assist you in filing your nonprovisional utility patent application. It specifies the required parts of the utility patent application and identifies some of the forms you may use (available on the USPTO website at www.uspto.gov). This information is generally derived from patent laws and regulations found at Title 35 of the United States Code (U.S.C.), and Title 37 of the Code of Federal Regulations (CFR). These materials, as well as the *Manual of Patent Examining Procedure* (MPEP), are available at the USPTO website, at PTRCs, and at most law libraries.

Nonprovisional Utility Patent

Filing Options

A nonprovisional utility patent application can be filed with the USPTO through the Office's electronic filing system called EFS-Web, delivery by U.S. mail, or hand delivery to the Office in Alexandria, Virginia. By far, most patent applications filed at the USPTO are utility applications. Effective November 15, 2011, any regular nonprovisional utility application filed by mail or hand-delivery will require payment of an additional \$400 fee called the "non-electronic filing fee," which is reduced by 50 percent to \$200 for applicants that qualify for small entity status under 37 CFR § 1.27(a) or micro entity status under 37 CFR 1.29(a) or (d).⁷

Application Requirements

When filing a nonprovisional utility patent application, it must be submitted in the English language or be accompanied by a translation in the English language, a statement that the translation is accurate, and have payment of the fee set forth in 37 CFR § 1.17(i).⁷

A nonprovisional utility patent application must include a specification, including a description and a claim or claims; drawings, when necessary; an oath or declaration; and the prescribed filing, search, and examination fees.

EFS-Web accepts electronic documents formatted in Portable Document Format (PDF). The specification (description and claims) can be created using a word processing program such as Microsoft® Word or Corel® WordPerfect. The document containing the specification can normally be converted into PDF format by the word processing program and can be included as an attachment when filing the application via EFS-Web. Other application documents, such as drawings and a hand-signed declaration, may have to be scanned as a PDF file for filing via EFS-Web.

[Omitted: various minutiae about margins, page numbering, etc.]

A complete nonprovisional utility patent application should contain the elements listed below, arranged in the order shown. Description of these elements is provided in the following sections:

- Utility Patent Application Transmittal Form or Transmittal Letter
- Appropriate Fees

- Application Data Sheet (see 37 CFR § 1.76)
- Specification (with at least one claim)
- Drawings (when necessary)
- Executed Oath or Declaration
- Nucleotide and Amino Acid Sequence Listing (when necessary)
- Large Tables or Computer Listings (when necessary)

Utility Patent Application Transmittal Form or Transmittal Letter

~The form identifies the applicant(s), the type of application, the title of the invention, the contents of the application, and any accompanying enclosures.~

Appropriate Fees

You can electronically submit the required filing, search, and examination fees using a credit card or electronic funds transfer.~

[The USPTO's fee schedule can be interesting to look over. It is here: <https://www.uspto.gov/learning-and-resources/fees-and-payment/uspto-fee-schedule> —EEJ]

Fee Discounts Based on Establishment of Small or Micro Entity Status

Most patent applicants pay regular undiscounted patent fees. However, fees for filing, searching, examining, issuing, appealing, and maintaining patent applications and patents are reduced by 50 percent for any small entity that qualifies for reduced fees under 37 CFR § 1.27(a), and are reduced by 75 percent for any micro entity that files a certification that the requirements under 37 CFR § 1.29(a) or (d) are met.~

Application Data Sheet

Submission of an application data sheet (ADS) should be routine for all nonprovisional applications and is required in certain instances. For example, for applications filed on or after September 16, 2012, any domestic benefit claim(s) and any foreign priority claim(s) must be made in an ADS within four months from filing or 16 months from the filing date of the prior-filed application, whichever is later.~

Specification

The specification is a written description of the invention and of the manner and process of making and using the invention that concludes with the claims to the invention, which must begin on a new page. The specification must be in clear, full, concise, and exact terms to enable any person skilled in the art or science to which the invention pertains to make and use the same.

For inventions involving computer programming, computer program listings may be submitted as part of the specification as set forth in 37 CFR § 1.96(b) and (c). Other than for a reissue application or reexamination proceeding, the pages of the specification (but not the transmittal letter sheets or other forms), including claims and abstract, must be numbered consecutively, starting with 1, the numbers being centrally located above or preferably below, the text. The lines of the specification must be 1.5 or double spaced (lines of text not comprising the specification need not be 1.5 or double spaced). It is desirable to include an indentation at the beginning of each new paragraph and for paragraphs to be numbered (e.g., [0001], [0002], [0003], etc.).

For an invention made with United States government support and for which the United States government has certain rights, 35 U.S.C. 202(c)(6) and 37 CFR 401.14(f)(4) requires the specification to contain a statement specifying that the invention was made with United States government support and that the United States government has certain rights in the invention. For example, the following language may be used: "This invention was made with government support under [IDENTIFY THE CONTRACT] awarded by [IDENTIFY THE FEDERAL AGENCY]. The government has certain rights in the invention."

It is preferable to use all of the section headings described below to represent the parts of the specification. Section headings should use upper case text without underlining or bold type. If the section contains no text, the phrase "Not Applicable" should follow the section heading.

Title of Invention

The title of the invention (or an introductory portion stating the name, citizenship, residence of each applicant, and the title of the invention) should appear as the heading on the first page of the specification. Although a title

may have up to 500 characters, the title must be as short and specific as possible.

Cross-Reference to Related Applications

Any nonprovisional utility patent application filed after September 16, 2012 claiming the benefit of one or more prior-filed copending nonprovisional applications (or international applications designating the United States of America) under 35 U.S.C. §§ 120, 121, or 365(c), or to a provisional patent application under 35 U.S.C. § 119(e), must present the reference to the earlier application in an application data sheet under 37 CFR § 1.76. See 37 CFR § 1.78. Cross-references to other related patent applications may be made when appropriate.

Statement Regarding Federally Sponsored Research or Development (if Applicable)

This section should contain a statement as to rights to inventions made under federally sponsored research and development (if any). See MPEP §310 for more information.

Reference to Sequence Listing, a Table, or a Computer Program Listing Compact Disc Appendix (if Applicable)

[Omitted: explanation of the use of compact discs to contain large amounts of data for computer code, gene sequences, and table of information.]

Background of the Invention

This section should include a statement of the field of endeavor to which the invention pertains. This section may also include a paraphrasing of the applicable U.S. patent classification definitions or the subject matter of the claimed invention.

Also, it should contain a description of information known to you, including references to specific documents related to your invention. It should contain, if applicable, references to specific problems involved in the prior art (or state of technology) that your invention is drawn toward. See MPEP § 608.01(c) for more information.

Brief Summary of the Invention

This section should present the substance or general idea of the claimed invention in summarized form. The summary can include the advantages of

the invention and how it solves previously existing problems. Preferably, problems are identified in the **Background of the Invention** section. A statement of the object of the invention may also be included. See MPEP § 608.01(d) for more information.

Brief Description of the Several Views of the Drawing

Where there are drawings, you must include a listing of all figures by number (e.g., Figure 1A) and with corresponding statements explaining what each figure depicts.

Detailed Description of the Invention

In this section, the invention must be explained along with the process of making and using the invention in full, clear, concise, and exact terms. This section should distinguish the invention from other inventions and from what is old. It should also describe completely the process, machine, manufacture, composition of matter, or improvement invented. In the case of an improvement, the description should be confined to the specific improvement and to the parts that necessarily cooperate with it or that are necessary to completely understand the invention.

It is required that the description be sufficient so that any person of ordinary skill in the pertinent art, science, or area could make and use the invention without extensive experimentation. The best mode contemplated by the inventor of carrying out the invention must be set forth in the description. Each element in the drawings should be mentioned in the description. See MPEP § 608.01(g) for more information.

Claim or Claims

The claim or claims must particularly point out and distinctly claim the subject matter that the inventor or inventors regard as the invention. The claims define the scope of the protection of the patent. Whether a patent will be granted is determined, in large measure, by the scope of the claims.

A nonprovisional application for a utility patent must contain at least one claim. The claim or claims section must begin on a separate physical sheet or electronic page. If there are several claims, they must be numbered consecutively in Arabic numerals.

One or more claims may be presented in dependent form, referring back to and further limiting another claim or claims in the same application. All

dependent claims should be grouped together with the claim or claims to which they refer to the extent practicable. Any dependent claim that refers to more than one other claim (multiple dependent claim) shall refer to such other claims in the alternative only. Each claim should be a single sentence, and where a claim sets forth a number of elements or steps, each element or step of the claim should be separated by a line indentation.

Abstract of the Disclosure

The purpose of the abstract is to enable the USPTO and the public to quickly determine the nature of the technical disclosures of your invention. The abstract points out what is new in the art to which your invention pertains. It should be in narrative form and generally limited to a single paragraph, and it must begin on a separate page. An abstract should not be longer than 150 words. See MPEP § 608.01(b) for more information.

Drawings

A patent application is required to contain drawings if drawings are necessary to understand the subject matter to be patented. Most patent applications contain drawings. The drawings must show every feature of the invention as specified in the claims. A drawing necessary to understand the invention cannot be introduced into an application after the filing date of the application because of the prohibition against new matter. Please see the detailed **Drawing Requirements** section.

Oath or Declaration

An oath or declaration is a formal statement that must be made by the inventor in a nonprovisional application, including utility, design, plant and reissue applications. Each inventor must sign an oath or declaration that includes certain statements required by law and the USPTO rules, including the statement that he or she believes himself or herself to be the original inventor or an original joint inventor of a claimed invention in the application, and the statement that the application was made or authorized to be made by him or her.

Sequence Listing (if Applicable)

This section, for the disclosure of a nucleotide or amino acid sequence, should contain a listing of the sequence complying with 37 CFR §1.821 through 37 CFR §1.825 and may be in paper or electronic form.

Obtaining a Receipt for Documents Mailed to the USPTO

[Omitted.]

Drawing Requirements

[Omitted: More than 2900 words discussing the technical requirements of drawings.]

CFR on Claims

37 CFR 1.75 Claims.

- (a) The specification must conclude with a claim particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention or discovery.
- (b) More than one claim may be presented provided they differ substantially from each other and are not unduly multiplied.
- (c) One or more claims may be presented in dependent form, referring back to and further limiting another claim or claims in the same application. Any dependent claim which refers to more than one other claim ("multiple dependent claim") shall refer to such other claims in the alternative only. A multiple dependent claim shall not serve as a basis for any other multiple dependent claim. For fee calculation purposes under § 1.16, a multiple dependent claim will be considered to be that number of claims to which direct reference is made therein. For fee calculation purposes also, any claim depending from a multiple dependent claim will be considered to be that number of claims to which direct reference is made in that multiple dependent claim. In addition to the other filing fees, any original application which is filed with, or is amended to include, multiple dependent claims must have paid therein the fee set forth in § 1.16(j). Claims in dependent form shall be construed to include all the limitations of the claim incorporated by reference into the dependent claim. A multiple dependent claim shall be construed to incorporate by reference all the limitations of each of the particular claims in relation to which it is being considered.

(d)

(1) The claim or claims must conform to the invention as set forth in the remainder of the specification and the terms and phrases used in the claims must find clear support or antecedent basis in the description so that the meaning of the terms in the claims may be ascertainable by reference to the description (See § 1.58(a).)

(2) See §§ 1.141 to 1.146 as to claiming different inventions in one application.

(e) Where the nature of the case admits, as in the case of an improvement, any independent claim should contain in the following order:

(1) A preamble comprising a general description of all the elements or steps of the claimed combination which are conventional or known,

(2) A phrase such as "wherein the improvement comprises," and

(3) Those elements, steps, and/or relationships which constitute that portion of the claimed combination which the applicant considers as the new or improved portion.

(f) If there are several claims, they shall be numbered consecutively in Arabic numerals.

(g) The least restrictive claim should be presented as claim number 1, and all dependent claims should be grouped together with the claim or claims to which they refer to the extent practicable.

(h) The claim or claims must commence on a separate physical sheet or electronic page. Any sheet including a claim or portion of a claim may not contain any other parts of the application or other material.

(i) Where a claim sets forth a plurality of elements or steps, each element or step of the claim should be separated by a line indentation.

MPEP on Form of Claims

From the Manual of Patent Examining Procedure. [Note: Hyperlinks have been removed and boldface type made nonbold.]

608.01(m) Form of Claims [R-10.2019]

The claim or claims must commence on a separate physical sheet or electronic page and should appear after the detailed description of the

invention. Any sheet including a claim or portion of a claim may not contain any other parts of the application or other material. While there is no set statutory form for claims, the present Office practice is to insist that each claim must be the object of a sentence starting with "I (or we) claim," "The invention claimed is" (or the equivalent). If, at the time of allowance, the quoted terminology is not present, it is inserted by the Office of Data Management. Each claim begins with a capital letter and ends with a period. Periods may not be used elsewhere in the claims except for abbreviations. See *Fressola v. Manbeck*, 36 USPQ2d 1211 (D.D.C. 1995). Where a claim sets forth a plurality of elements or steps, each element or step of the claim should be separated by a line indentation, 37 CFR 1.75(i).

There may be plural indentations to further segregate subcombinations or related steps. In general, the printed patent copies will follow the format used but printing difficulties or expense may prevent the duplication of unduly complex claim formats.

Reference characters corresponding to elements recited in the detailed description and the drawings may be used in conjunction with the recitation of the same element or group of elements in the claims. The reference characters, however, should be enclosed within parentheses so as to avoid confusion with other numbers or characters which may appear in the claims. Generally, the presence or absence of such reference characters does not affect the scope of a claim.

Many of the difficulties encountered in the prosecution of patent applications after final rejection may be alleviated if each applicant includes, at the time of filing or no later than the first reply, claims varying from the broadest to which he or she believes he or she is entitled to the most detailed that he or she is willing to accept.

Claims should preferably be arranged in order of scope so that the first claim presented is the least restrictive. All dependent claims should be grouped together with the claim or claims to which they refer to the extent practicable. Where separate species are claimed, the claims of like species should be grouped together where possible. Similarly, product and process claims should be separately grouped. Such arrangements are for the purpose of facilitating classification and examination.

When two claims in an application comply with the requirements of 35 U.S.C. 112(d) but are duplicates, or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other claim under 37 CFR 1.75 as being a substantial duplicate of the allowed claim. Note however, that court decisions have confirmed applicant's right to restate (i.e., by plural claiming) the invention in a reasonable number of ways. Indeed, a mere difference in scope between claims has been held to be enough. Form paragraphs 7.05.05 and 7.05.06 may be used where duplicate claims are present in an application.

See MPEP § 608.01(n), subsection II, for rejections under 35 U.S.C. 112(d) of dependent claims that do not specify a further limitation of the subject matter claimed. See MPEP § 804 for double patenting rejections of claims in different applications that are not patentable over each other.

The form of claim required in 37 CFR 1.75(e) is particularly adapted for the description of improvement-type inventions. It is to be considered a combination claim. The preamble of this form of claim is considered to positively and clearly include all the elements or steps recited therein as a part of the claimed combination.

Advice on Claim Drafting

This section was created by taking text from presentation slides prepared by USPTO personnel and then liberally restructuring, rearranging, and re-writing it, resulting in something that is more like book-type prose. The slides were associated with the Invention-Con 2019 Pre-Conference Session on September 12, 2019. They were obtained from: <https://www.uspto.gov/sites/default/files/documents/Claim%20drafting.pdf>.

Prior to writing claims answer these questions:

- What is the invention?
- What are the elements that make up the invention?
- How do the elements relate to one another?
- Are there multiple embodiments of the same invention?

What the law says: A nonprovisional patent application must have at least one claim particularly pointing out and distinctly defining the invention. A claim may be written in *independent* or *dependent* form. An independent claim is a standalone claim that contains all the limitations necessary to define

an invention. A dependent claim refers to a previously set forth claim adds some further limit on that claim.

What the MPEP says: A claim in dependent form incorporates by reference all the limitations of the claim to which it refers. Claims must be fully supported and enabled by the disclosure. Claims must be drafted as a single sentence. Claims should be arranged in order of scope so the first claim presented is the broadest. Consistent terminology should be used in both the patent disclosure and the claims.

Claims define the invention and what aspects are legally enforceable. Terms and phrases used in the claims must find clear support or antecedent basis in the description portion of the patent so that the meaning of the terms in the claims are clearly understood by reference to the description portion.

Types of claims – invention categories:

- Product – A claim that is directed to elements that can be: a device, apparatus, machine, composition of matter or article of manufacture.
- Method (process) – A claim that describes/defines a series of acts or steps for performing a desired function or accomplishing an intended result.

Types of claims - independent & dependent: A claim may be written in independent or dependent form. An independent claim refers to a stand-alone claim that contains all the limitations necessary to define an invention. A dependent claim refers to a previous claim and must add a further limitation to the previous claim. A claim in dependent form incorporates by reference all the limitations of the claim to which it refers.

Claim formalities:

- The claim starts with the heading “The invention claimed is ... ” or “I claim ... ” or some equivalent phrase.
- Each claim is a single sentence (beginning with a capital letter and ending with a period).
- Claims are numbered consecutively in ascending order.

Patent claim structure:

A claim in a utility application or patent has three parts:

- The ***preamble*** provides context for the claimed invention. Preamble language may or may not limit the claimed invention.
- The ***transitional phrase*** establishes whether the claim is “open,” “closed” or “partially open.” In other words, the transitional phrase indicates the degree to which a claim is limited to only those elements recited in the claim body.
- The ***claim body*** recites the limitations (structure and/or acts in clear, full, concise terms) necessary to define the invention.

Basic rule #1, the preamble: Every claim needs a preamble, which is the introductory phrase in a claim. The general rule is that the preamble of a claim does not limit the scope of the claim, but try to stay away from functional language. Try “A shovel ... ” instead of “A shovel for digging ... ”

Basic rule #2, the transition: Every claim needs a transition. The most common transitions are: “comprising” “consisting essentially of” and “consisting of.” “Comprising” is by far the most common because it means the invention includes but is not limited to the elements identified in the claim. “Consisting essentially of” limits the scope of a claim to the specified materials or steps “and those that do not materially affect the basic and novel characteristic(s)” of the claimed invention. “Consisting of” is closed and means that the invention is limited to the elements identified in the claim.

Basic rule #3 antecedent basis: The first time you introduce a limitation (e.g., an element, characteristic, internal reference, etc.) you **MUST** introduce it with either “a” or “an”, as is grammatically appropriate. (e.g., primary antecedent basis). Subsequently you refer to the already introduced limitation by either “said” or “the.” (e.g., secondary antecedent basis). For example, a lack of clarity could arise where a claim refers to “said lever” or “the lever,” where the claim contains no earlier recitation or limitation of a lever and where it would be unclear as to what element the limitation was making reference. Similarly, if two different levers are recited earlier in the claim, the recitation of “said lever” in the same or subsequent claim would be unclear where it is uncertain which of the two levers was intended.

Example of an independent device claim:

1. A headgear apparatus comprising:
a headband member having a frontal portion;

a visor member removably secured to said frontal portion of said headband; and

an eye shield member removably secured to said frontal portion of said headband.

Examples of dependent device claims:

(These are from US Patent No. 6,009,555, titled "Multiple Component Headgear System.")

2. A headgear apparatus as in claim 1, wherein said eye shield member is adjustable with respect to said headband member.

3. A headgear apparatus as in claim 1, wherein said visor member and said eye shield member are secured to said frontal portion of said headband member by a set of rivets.

4. A headgear apparatus as in claim 2, wherein said headband member is made of neoprene fabric.

5. A headgear apparatus as in claim 3, wherein said headband member comprises a continuous bead of sealant material.

Example of an independent method claim:

(This is from US Patent No. 6,635,133.)

1. A method of making a ball, comprising:

forming an inner sphere by forming an outer shell with a fluid mass center;

forming a plurality of core parts;

arranging and joining the core parts around the inner sphere to form an assembled core;

molding a cover around the assembled core.

Examples of dependent method claims:

2. The method of claim 1, further comprising molding nonplanar mating surfaces on the core parts, wherein the core parts comprises meshing the mating surfaces.

3. The method of claim 1, wherein forming the inner sphere comprises freezing a sphere of a fluid.

4. The method of claim 1, wherein the forming of the core parts comprises compression molding the core parts.

Strategies for writing claims: When you write a claim you want to introduce all of the components and characterizations of the components that are necessary for the invention to work and for it to be different than what is already in the public domain.

Try something like this (letters represent either components or characteristics of the components):

1. A [insert title] comprising: A, B and C.
2. The invention of claim 1 further comprising D, which is [insert connection/relation].
3. The invention of claim 2 further comprising E, which is [insert connection/relation].
4. The invention of claim 3 wherein D is [insert a specific characterization].
5. The invention of claim 4 wherein E is [insert specific characterization].

In the examples above, notice the dependent transitions. When you are adding a component you use "further comprising" and then explain how the component is connected to or relates with the components already introduced. When you are further describing something that has already been introduced you use "wherein."

One possible approach: Try focusing on the inventive concept. Ask yourself: What features set the invention apart from prior inventions? Then, identify fundamental elements. Omit unnecessary elements. But include elements as necessary to distinguish what you are claiming over the prior art. Consider the terms you are using to describe parts of the invention and interrelationships among those parts. Try selecting broad terms and carefully identifying their relationship. Review the claim and revise, removing unnecessary claim elements.

Aim for claims that are neither too broad/general, nor too specific/narrow.

The more specific/narrow a claim is, the more easily patentable it will be. But a claim that is too specific/narrow may not be valuable. A claim with a narrower scope is easier for others to not infringe.

The more general/broad a claim is, the more valuable it will be, because it will sweep up a wider scope of potential infringement. But a claim that is too general/broad, may not be patentable. A claim with a broader scope is more likely to be non-novel. And even if a claim is determined by the USPTO to be patentable, the broader it is, the more vulnerable it will be to an invalidity challenge by a defendant in a patent infringement suit.

A claim that may be too broad:

Claim 1. A vehicle comprising: a frame body;
a first and second front wheel and a first and second back wheel aligned and spaced from the first and second front wheel, each wheel rotatably connected to the frame body;
a seat connected to the frame body; and
a removable top portion made of cloth connected to the frame body.

A claim that may be overly specific:

Claim 1. A vehicle comprising:
a motor;
a yellow frame body including a plurality of hinged doors;
a first and second front wheel and a first and second back wheel and aligned and spaced from the first and second front wheel, each wheel rotatably connected to the frame body and made of rubber;
a seat connected to the frame body;
a plurality of glass windows connected to the frame body;
two red lights connected to the frame body;
two metal bumpers connected to the frame body; and
a removable top portion made of cloth.

Claim drafting things you should do: Consider drafting your specification first and then your claims based on terms used in the specification. Think about what legal protection you want for your invention and tailor your claims accordingly. Look at the claims in patents issued in your

field of technology. Particularly point out and distinctly claim the subject matter regarded as the invention. Within the claims, ensure that dependent claims further limit the claim from which they depend. Review and reconcile both the specification and claims, making necessary additions and corrections so that the claim terms find support (antecedence) in the specification. Check for antecedent basis issues.

Claim drafting things you should *not* do: Don't use claims covering multiple statutory classes of invention (“A widget and method for using same ...”). Don't use non-standard transitional phrases, which may raise questions of interpretation. Don't refer back to only a portion of another claim in a dependent claim (e.g., “The widget of the apparatus of claim 1...”). Don't use a dependent claim to remove/replace an element from a previously presented claim from which it depends (e.g., “The vehicle of claim 1 where the removable top portion is non-removable.”). Don't use trademarks or tradenames in the claims, instead use generic terms, e.g., “hook and loop fastener” instead of Velcro®. Don't use language that merely suggests, makes optional and, thus, does not limit the claim.

Editing Notes

Regarding edits generally, see “Editing Notes” section at the beginning of the volume. Those notes also specifically speak to text sourced from the Congressional Research Service (CRS).

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–EEJ

P-2: Patent Subject Matter

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CRS on Patentable Subject Matter

The following adapts and combines text from two CRS sources: Congressional Research Service, Patent Law: A Handbook for Congress, R46525, September 16, 2020. Congressional Research Service, Patent-Eligible Subject Matter Reform in the 116th Congress, R45918, September 17, 2019. (See “Editing Notes” section at the beginning of the volume on editing of CRS materials.)

Section 101 of the Patent Act (Section 101) states that “any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof” is patentable if the invention meets other requirements. Despite the seemingly broad scope of this provision, however, the Supreme Court “has long held that this provision contains implicit exceptions. Specifically, “laws of nature, natural phenomena, and abstract ideas’ are not patentable.”

The statutory definition of patent-eligible subject matter under Section 101 of the Patent Act has remained essentially unchanged for over two centuries. As a result, the scope of patentable subject matter—that is, the types of inventions that may be patented—has largely been left to the federal courts to develop through “common law”-like adjudication. In the 20th century, the

U.S. Supreme Court established that three main types of discoveries are categorically patent-ineligible: laws of nature, natural phenomena, and abstract ideas.

The law of patentable subject matter received less attention than the other patent requirements until the 2010s, when the Supreme Court began to show renewed interest in the doctrine. Over a five-year period, the Supreme Court rejected, as ineligible, patents on a business method for hedging price-fluctuation risk; a method for calibrating the dosage of a particular drug; isolated human DNA segments; and a method of mitigating settlement risk in financial transactions using a computer. These cases established a new two-step test, known as the *Alice/Mayo* framework, for determining whether a patent claims ineligible subject matter.

The first step of the *Alice/Mayo* test addresses whether the patent claims are "directed to" a law of nature, natural phenomenon, or abstract idea. If not, the invention is patentable. If the claims are directed to one of the ineligible categories, then the second step of the analysis asks whether the patent claims have an "inventive concept." To have an inventive concept, the patent claim must contain elements that transform the nature of the claim into a patent-eligible application of the ineligible concept, so that the claim amounts, in practice, to something "significantly more" than a patent on the ineligible concept itself. If the invention fails the second step of *Alice/Mayo*, then it is patent-ineligible.

The Supreme Court's decisions have been widely recognized to effect a significant change in the scope of patentable subject matter, restricting the sorts of inventions that are patentable in the United States. The *Alice/Mayo* test has been the subject of criticism, with some stakeholders arguing that the *Alice/Mayo* framework is vague and unpredictable, unduly restricts the scope of patentable subject matter, reduces incentives to invest and innovate, and harms American industry's competitiveness. In particular, the *Alice/Mayo* test has created uncertainty in the computer technology and biotechnology industries as to whether innovations in medical diagnostics, personalized medicine, methods of treatment, computer software, and artificial intelligence are patent-eligible.

Case: Mayo v. Prometheus Labs

This edited case text obtained/adapted from James Grimmelmann's Patterns of Information Law. See notes on editing, licensing etc. at the end of this chapter.

Mayo Collaborative v. Prometheus Labs

Supreme Court of the United States
566 U.S. 66 (2012)

Section 101 of the Patent Act defines patentable subject matter. The Court has long held that this provision contains an important implicit exception. Laws of nature, natural phenomena, and abstract ideas are not patentable.

I

A

The patents before us concern the use of thiopurine drugs in the treatment of autoimmune diseases, such as Crohn's disease and ulcerative colitis. When a patient ingests a thiopurine compound, his body metabolizes the drug, causing metabolites to form in his bloodstream. Because the way in which people metabolize thiopurine compounds varies, the same dose of a thiopurine drug affects different people differently, and it has been difficult for doctors to determine whether for a particular patient a given dose is too high, risking harmful side effects, or too low, and so likely ineffective.

At the time the discoveries embodied in the patents were made, scientists already understood that the levels in a patient's blood of certain metabolites, including, in particular, 6-thioguanine and its nucleotides (6-TG) and 6-methyl-mercaptopurine (6-MMP), were correlated with the likelihood that a particular dosage of a thiopurine drug could cause harm or prove ineffective. But those in the field did not know the precise correlations between metabolite levels and likely harm or ineffectiveness. The patent claims at issue here set forth processes embodying researchers' findings that identified these correlations with some precision.

More specifically, the patents – U.S. Patent No. 6,355,623 (623 patent) and U.S. Patent No. 6,680,302 (302 patent) – embody findings that concentrations in a patient's blood of 6-TG or of 6-MMP metabolite beyond a certain level (400 and 7000 picomoles per 8×10^8 red blood cells, respectively) indicate that the dosage is likely too high for the patient, while concentrations

in the blood of 6-TG metabolite lower than a certain level (about 230 picomoles per 8×10^8 red blood cells) indicate that the dosage is likely too low to be effective.

The patent claims seek to embody this research in a set of processes. Like the Federal Circuit we take as typical claim 1 of the 623 Patent, which describes one of the claimed processes as follows:

A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising:

- (a) administering a drug providing 6-thioguanine to a subject having said immune-mediated gastrointestinal disorder; and
- (b) determining the level of 6-thioguanine in said subject having said immune-mediated gastrointestinal disorder,

wherein the level of 6-thioguanine less than about 230

pmol per 8×10^8 red blood cells indicates a need to increase the amount of said drug subsequently administered to said subject and

wherein the level of 6-thioguanine greater than about 400

pmol per 8×10^8 red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.

B

Respondent, Prometheus Laboratories, Inc. (Prometheus), is the sole and exclusive licensee of the 623 and 302 patents. It sells diagnostic tests that embody the processes the patents describe. For some time petitioners, Mayo Clinic Rochester and Mayo Collaborative Services (collectively Mayo), bought and used those tests. But in 2004 Mayo announced that it intended to begin using and selling its own test—a test using somewhat higher metabolite levels to determine toxicity (450 pmol per 8×10^8 for 6-TG and 5700 pmol per 8×10^8 for 6-MMP). Prometheus then brought this action claiming patent infringement.

The District Court found that Mayo's test infringed claim 7 of the 623 patent. In interpreting the claim, the court accepted Prometheus' view that the toxicity-risk level numbers in Mayo's test and the claim were too similar to render the tests significantly different. The number Mayo used (450) was too close to the number the claim used (400) to matter given appropriate margins

of error. The District Court also accepted Prometheus' view that a doctor using Mayo's test could violate the patent even if he did not actually alter his treatment decision in the light of the test. In doing so, the court construed the claim's language, "indicates a need to decrease" (or "to increase"), as not limited to instances in which the doctor actually decreases (or increases) the dosage level where the test results suggest that such an adjustment is advisable.

II

Prometheus' patents set forth laws of nature – namely, relationships between concentrations of certain metabolites in the blood and the likelihood that a dosage of a thiopurine drug will prove ineffective or cause harm. Claim 1, for example, states that if the levels of 6-TG in the blood (of a patient who has taken a dose of a thiopurine drug) exceed about 400 pmol per 8×10^8 red blood cells, then the administered dose is likely to produce toxic side effects. While it takes a human action (the administration of a thiopurine drug) to trigger a manifestation of this relation in a particular person, the relation itself exists in principle apart from any human action. The relation is a consequence of the ways in which thiopurine compounds are metabolized by the body – entirely natural processes. And so a patent that simply describes that relation sets forth a natural law.

The question before us is whether the claims do significantly more than simply describe these natural relations. To put the matter more precisely, do the patent claims add enough to their statements of the correlations to allow the processes they describe to qualify as patent-eligible processes that apply natural laws? We believe that the answer to this question is no.

A

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. A patent, for example, could not simply recite a law of nature and then add the instruction "apply the law." Einstein, we assume, could not have patented his famous law by claiming a process consisting of simply telling linear accelerator operators to refer to the law to determine how much energy an amount of mass has produced (or vice versa). Nor could Archimedes have secured a patent for his famous principle of

flotation by claiming a process consisting of simply telling boat builders to refer to that principle in order to determine whether an object will float.

What else is there in the claims before us? The process that each claim recites tells doctors interested in the subject about the correlations that the researchers discovered. In doing so, it recites an “administering” step, a “determining” step, and a “wherein” step. These additional steps are not themselves natural laws but neither are they sufficient to transform the nature of the claim.

First, the “administering” step simply refers to the relevant audience, namely doctors who treat patients with certain diseases with thiopurine drugs. That audience is a pre-existing audience; doctors used thiopurine drugs to treat patients suffering from autoimmune disorders long before anyone asserted these claims. In any event, the prohibition against patenting abstract ideas cannot be circumvented by attempting to limit the use of the formula to a particular technological environment.

Second, the “wherein” clauses simply tell a doctor about the relevant natural laws, at most adding a suggestion that he should take those laws into account when treating his patient. That is to say, these clauses tell the relevant audience about the laws while trusting them to use those laws appropriately where they are relevant to their decisionmaking (rather like Einstein telling linear accelerator operators about his basic law and then trusting them to use it where relevant).

Third, the “determining” step tells the doctor to determine the level of the relevant metabolites in the blood, through whatever process the doctor or the laboratory wishes to use. As the patents state, methods for determining metabolite levels were well known in the art. Indeed, scientists routinely measured metabolites as part of their investigations into the relationships between metabolite levels and efficacy and toxicity of thiopurine compounds. Thus, this step tells doctors to engage in well-understood, routine, conventional activity previously engaged in by scientists who work in the field. 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 prohibition against patenting abstract ideas cannot be circumvented by adding insignificant post-solution activity.

Fourth, to consider the three steps as an ordered combination adds nothing to the laws of nature that is not already present when the steps are considered separately. Anyone who wants to make use of these laws must first administer a thiopurine drug and measure the resulting metabolite concentrations, and so the combination amounts to nothing significantly more than an instruction to doctors to apply the applicable laws when treating their patients.

The upshot is that the three steps simply tell doctors to gather data from which they may draw an inference in light of the correlations. To put the matter more succinctly, the claims inform a relevant audience about certain laws of nature; any additional steps consist of well-understood, routine, conventional activity already engaged in by the scientific community; and those steps, when viewed as a whole, add nothing significant beyond the sum of their parts taken separately. For these reasons we believe that the steps are not sufficient to transform unpatentable natural correlations into patentable applications of those regularities.

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I am very grateful to James Grimmelmann for his generosity in sharing his excellent materials!

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–EEJ

P-3: Patent Utility

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CRS on the Utility Requirement

The following adapts text from Congressional Research Service, Drug Prices: The Role of Patents and Regulatory Exclusivities, R46679, February 10, 2021. (See “Editing Notes” section at the beginning of the volume on editing of CRS materials.)

An invention must be *useful* to be patentable, which means that it must have a specific and substantial utility. The utility requirement derives from the IP Clause’s command that patent laws exist to “promote the Progress of . . . *useful* Arts.” The constitutional purpose of patent law thus requires a “benefit derived by the public from an invention with substantial utility,” where the “specific benefit exists in currently available form.” The bar for utility, however, requires only that the claimed invention have some “significant and presently available benefit to the public” that “is not so vague as to be meaningless.”

MPEP on Utility

*From the USPTO’s **Manual of Patent Examining Procedure** (rev. Nov. 2013).*

*This MPEP text obtained/adapted from James Grimmelmann’s *Patterns of Information Law*. See notes on editing, licensing etc. at the end of this chapter.*

§ 2107 Guidelines for Examination of Applications for Compliance with the Utility Requirement

A claimed invention must have a specific and substantial utility. This requirement excludes “throw-away,” “insubstantial,” or “nonspecific” utilities, such as the use of a complex invention as landfill.

Credibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record (e.g., test data, affidavits or declarations from experts in the art, patents or printed publications) that is probative of the applicant’s assertions. An applicant need only provide one credible assertion of specific and substantial utility for each claimed invention to satisfy the utility requirement.

§ 2707.01 General Principles Governing Utility Rejections.

I. Specific and Substantial Requirements

Courts have recognized that the term “useful” used with reference to the utility requirement can be a difficult term to define. Where an applicant has set forth a specific and substantial utility, courts have been reluctant to uphold a rejection under 35 U.S.C. § 101 solely on the basis that the applicant’s opinion as to the nature of the specific and substantial utility was inaccurate.

Practical considerations require the Office to rely on the inventor’s understanding of his or her invention in determining whether and in what regard an invention is believed to be “useful.” Because of this, Office personnel should focus on and be receptive to assertions made by the applicant that an invention is “useful” for a particular reason.

A. Specific Utility

A “specific utility” is specific to the subject matter claimed and can “provide a well-defined and particular benefit to the public.” *In re Fisher*, 421 F.3d 1365 (Fed. Cir. 2005). This contrasts with a general utility that would be applicable to the broad class of the invention. Office personnel should distinguish between situations where an applicant has disclosed a specific use for or application of the invention and situations where the applicant merely indicates that the invention may prove useful without identifying with specificity why it is considered useful. For example, indicating that a compound may be useful in treating unspecified disorders, or that the compound has “useful biological” properties, would not be sufficient to define

a specific utility for the compound. Similarly, a claim to a polynucleotide whose use is disclosed simply as a “gene probe” or “chromosome marker” would not be considered to be specific in the absence of a disclosure of a specific DNA target. See *Fisher* (“Any EST [expressed sequence tag] transcribed from any gene in the maize genome has the potential to perform any one of the alleged uses. Nothing about applicant’s seven alleged uses set the five claimed ESTs apart from the more than 32,000 ESTs disclosed in the application or indeed from any EST derived from any organism. Accordingly, we conclude that applicant has only disclosed general uses for its claimed ESTs, not specific ones that satisfy § 101.”). A general statement of diagnostic utility, such as diagnosing an unspecified disease, would ordinarily be insufficient absent a disclosure of what condition can be diagnosed. Contrast the situation where an applicant discloses a specific biological activity and reasonably correlates that activity to a disease condition. Assertions falling within the latter category are sufficient to identify a specific utility for the invention. Assertions that fall in the former category are insufficient to define a specific utility for the invention, especially if the assertion takes the form of a general statement that makes it clear that a “useful” invention may arise from what has been disclosed by the applicant.

B. Substantial Utility

“[A]n application must show that an invention is useful to the public as disclosed in its current form, not that it may prove useful at some future date after further research. Simply put, to satisfy the ‘substantial’ utility requirement, an asserted use must show that the claimed invention has a significant and presently available benefit to the public.” *Fisher*. The claims at issue in *Fisher* were directed to expressed sequence tags (ESTs), which are short nucleotide sequences that can be used to discover what genes and downstream proteins are expressed in a cell. The court held that “the claimed ESTs can be used only to gain further information about the underlying genes and the proteins encoded for by those genes. The claimed ESTs themselves are not an end of [applicant’s] research effort, but only tools to be used along the way in the search for a practical utility. Applicant does not identify the function for the underlying protein-encoding genes. Absent such identification, we hold that the claimed ESTs have not been researched and understood to the point of providing an immediate, well-defined, real world benefit to the public meriting the grant of a patent.” Thus a “substantial utility” defines a “real

world” use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a “real world” context of use are not substantial utilities. For example, both a therapeutic method of treating a known or newly discovered disease and an assay method for identifying compounds that themselves have a “substantial utility” define a “real world” context of use. An assay that measures the presence of a material which has a stated correlation to a predisposition to the onset of a particular disease condition would also define a “real world” context of use in identifying potential candidates for preventive measures or further monitoring. On the other hand, the following are examples of situations that require or constitute carrying out further research to identify or reasonably confirm a “real world” context of use and, therefore, do not define “substantial utilities”:

- (A) Basic research such as studying the properties of the claimed product itself or the mechanisms in which the material is involved;
- (B) A method of treating an unspecified disease or condition;
- (C) A method of assaying for or identifying a material that itself has no specific and/or substantial utility;
- (D) A method of making a material that itself has no specific, substantial, and credible utility; and
- (E) A claim to an intermediate product for use in making a final product that has no specific, substantial and credible utility.

Office personnel must be careful not to interpret the phrase “immediate benefit to the public” or similar formulations in other cases to mean that products or services based on the claimed invention must be “currently available” to the public in order to satisfy the utility requirement. Rather, any reasonable use that an applicant has identified for the invention that can be viewed as providing a public benefit should be accepted as sufficient, at least with regard to defining a “substantial” utility.

C. Research Tools

Some confusion can result when one attempts to label certain types of inventions as not being capable of having a specific and substantial utility based on the setting in which the invention is to be used. One example is inventions to be used in a research or laboratory setting. Many research tools

such as gas chromatographs, screening assays, and nucleotide sequencing techniques have a clear, specific and unquestionable utility (e.g., they are useful in analyzing compounds). An assessment that focuses on whether an invention is useful only in a research setting thus does not address whether the invention is in fact “useful” in a patent sense. Instead, Office personnel must distinguish between inventions that have a specifically identified substantial utility and inventions whose asserted utility requires further research to identify or reasonably confirm. Labels such as “research tool,” “intermediate” or “for research purposes” are not helpful in determining if an applicant has identified a specific and substantial utility for the invention.

II. Wholly Inoperative Inventions; “Incredible Utility”

An invention that is “inoperative” (i.e., it does not operate to produce the results claimed by the patent applicant) is not a “useful” invention in the meaning of the patent law. However, as the Federal Circuit has stated, “[t]o violate 35 U.S.C. § 101 the claimed device must be totally incapable of achieving a useful result.” *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 997 F.2d 1555 (Fed. Cir. 1992). *See also E.I. du Pont De Nemours and Co. v. Berkley and Co.*, 620 F.2d 1247 (8th Cir. 1980). (“A small degree of utility is sufficient. The claimed invention must only be capable of performing some beneficial function. An invention does not lack utility merely because the particular embodiment disclosed in the patent lacks perfection or performs crudely. A commercially successful product is not required. Nor is it essential that the invention accomplish all its intended functions or operate under all conditions, partial success being sufficient to demonstrate patentable utility. In short, the defense of non-utility cannot be sustained without proof of total incapacity.”) If an invention is only partially successful in achieving a useful result, a rejection of the claimed invention as a whole based on a lack of utility is not appropriate.

Situations where an invention is found to be “inoperative” and therefore lacking in utility are rare, and rejections maintained solely on this ground by a Federal court even rarer. In many of these cases, the utility asserted by the applicant was thought to be incredible in the light of the knowledge of the art, or factually misleading when initially considered by the Office. Other cases suggest that on initial evaluation, the Office considered the asserted utility to be inconsistent with known scientific principles or speculative at best as to whether attributes of the invention necessary to impart the asserted utility

were actually present in the invention. However cast, the underlying finding by the court in these cases was that, based on the factual record of the case, it was clear that the invention could not and did not work as the inventor claimed it did. Indeed, the use of many labels to describe a single problem (e.g., a false assertion regarding utility) has led to some of the confusion that exists today with regard to a rejection based on the “utility” requirement. Examples of such cases include: an invention asserted to change the taste of food using a magnetic field, a perpetual motion machine, a flying machine operating on “flapping or flutter function,” a “cold fusion” process for producing energy, a method for increasing the energy output of fossil fuels upon combustion through exposure to a magnetic field, uncharacterized compositions for curing a wide array of cancers, and a method of controlling the aging process. These examples are fact specific and should not be applied as a *per se* rule. Thus, in view of the rare nature of such cases, Office personnel should not label an asserted utility “incredible,” “speculative” or otherwise unless it is clear that a rejection based on “lack of utility” is proper.

Rights, Licensing, Attribution, Disclaimers, and More

The following was written by Eric E. Johnson:

This chapter P-3, “Patent Utility,” was put together by Eric E. Johnson by incorporating text from various sources. Each section, above, indicates the source.

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Regarding text sourced from *Patterns of Information Law: Intellectual Property Done Right* (version 1.1, August 2017) authored by **James Grimmelmann**: I did not find a copyright notice in the book, but I believe the correct one is: © 2017 James Grimmelmann. The book is licensed under the Creative Commons Attribution International License 4.0 (CC-BY 4.0) license, available at <https://creativecommons.org/licenses/by/4.0/>. That license contains a disclaimer of warranties and a statement of limitation of liability. The original work is available at <https://james.grimmelmann.net/ipbook/>. On page 34, Prof. Grimmelmann writes: “All of my own contributions to these materials – including any original writing, edits to existing materials, and the selection and arrangement of those materials – are

hereby made available for free reuse under the terms of the Creative Commons Attribution 4.0 International license. Credit is not important to me, but I do care that you preserve the license notice if you redistribute these materials.” Regarding his editing, on page 32, Prof. Grimmelmann writes: “My editorial technique is borrowed from Sweeney Todd: extensive and shocking cuts. These are pedagogical materials, not a legal brief. I have not put words in anyone else’s mouth, but I have been unconcerned with the usual editorial apparatus of ellipses and brackets. I drop words from sentences, sentences from paragraphs, paragraphs from opinions – all with no indication that anything is gone. I also reorder paragraphs and sometimes sentences as needed to improve the readability of a passage. My goal is to make it easy for the reader. If it matters to you what the original said, consult the original.” And he says a bit more along these lines. As for my own editing in bringing his material into this volume, I’ve made various tweaks, including formatting changes, adding and re-wording headers and source information, and bringing material into the main text that he put in page margins. In this chapter and others, an effort was made to correct some typos/mistakes in the text of readings. I probably haven’t gone nearly as far as he did in editing others, but for the sake of prudence, assume I’ve done unto him as he’s done unto others.

I am very grateful to James Grimmelmann for his generosity in sharing his excellent materials!

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–EEJ

P-4: Patent Novelty

This chapter was put together by Eric E. Johnson primarily using a swath of text from *Patterns of Information Law: Intellectual Property Done Right* (version 1.1, August 2017) authored by **James Grimmelmann**. Some tweaks were made. The two sections at the beginning of this chapter (statute and CRS) were added.

Please see “Rights, Licensing, Attribution, Disclaimers, and More” at the end of this chapter.

35 U.S.C. § 102. Conditions for patentability; novelty.

[As amended by the America Invents Act of 2011.

Effective for applications filed on or after March 16, 2013.]

(a) NOVELTY; PRIOR ART. – A person shall be entitled to a patent unless –

(1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention; or

(2) the claimed invention was described in a patent issued under section 151, or in an application for patent published or deemed published under section 122(b), in which the patent or application, as the case may be, names another inventor and was effectively filed before the effective filing date of the claimed invention.

(b) EXCEPTIONS. –

(1) DISCLOSURES MADE 1 YEAR OR LESS BEFORE THE EFFECTIVE FILING DATE OF THE CLAIMED INVENTION. – A disclosure made 1 year or less before the effective filing date of a claimed invention shall not be prior art to the claimed invention under subsection (a)(1) if –

(A) the disclosure was made by the inventor or joint inventor or by another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor; or

(B) the subject matter disclosed had, before such disclosure, been publicly disclosed by the inventor or a joint inventor or another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor. ...

CRS on Novelty

Adapted from Congressional Research Service, Patent Law: A Handbook for Congress, R46525, September 16, 2020. (See “Editing Notes” section at the beginning of the volume on editing of CRS materials.)

An applicant may not receive a patent on something that is not new. Thus, if the claimed invention was, among other things, in public use, on sale, or described in a publication prior to the filing date of the patent application, then it is ineligible for a patent. The requirement that the invention be different from what came before is referred to as the *novelty requirement*. To establish a lack of novelty, the PTO examiner (or, in post-issuance proceedings, another party challenging the patent) relies on the “prior art”—references, such as publications and other patents, that establish what was known in the art at the time of the applicant’s alleged invention. To demonstrate a lack of novelty (or, in other words, to demonstrate that a patent claim is “anticipated”), a single reference (usually, a patent or publication) must disclose all of the limitations in a patent claim. Notably, the statutory provision governing novelty states that an applicant “shall be entitled to a patent unless” the invention is not novel. Thus, the statute places the burden on the PTO to demonstrate that the invention is not novel.

Under the statute, certain references do not qualify as prior art that would serve to prevent patenting. For example, disclosures by the inventor or a joint

inventor made one year or less before the filing date of the patent application do not qualify as prior art. This establishes a one-year “grace period” for inventors to disclose information regarding the invention without losing the opportunity to receive a patent.

Prof. James Grimmelmann on Priority and Novelty

From James Grimmelmann’s Patterns of Information Law (v 1.1, 2017). See notes on editing, licensing etc. at the end of this chapter.

Priority rules determine which of competing claimants is entitled to an IP right based on an earlier claim. It is rarely as simple as “first in time” because what counts as “first” could be assessed in different ways. Priority rules select one of these ways of determining who is “first” and determine the consequences of this fact. As we shall see, U.S. patent law mostly creates priority by preventing all but one – or sometimes all – of the potential claimants from obtaining a patent. As we shall also see, the AIA dramatically changed the priority rules of U.S. patent law; this was the single biggest change made by the AIA.

Under Section 102, an applicant “shall be entitled to a patent unless” someone somewhere has done something that makes the invention not patentable. That something is called a *prior art reference* and it is said to *anticipate* the applicant’s invention. Conceptually, any such rule raises three questions:

- What makes a prior art reference sufficiently *similar* to the applicant’s “claimed invention” to make it unpatentable? If Alfie applies to patent an oven, Beth’s previous work on metalworking is irrelevant to the novelty of Alfie’s oven. Patent law has settled on a remarkably elegant test to capture this idea: the test for anticipation is simply the test for infringement plus the test for enablement. A claim is anticipated by an enabling prior art reference (and hence not novel) if that reference would infringe the claim. *Peters v. Active Mfg. Co.*, 129 U.S. 530 (1889). “That which infringes, if later, would anticipate, if earlier.”
- Which kinds of *activities* count as prior art? The present section 102 uses the words “patented, described in a printed publication, or in public use, on sale, or otherwise available to the public.” They are broad, but they do not exhaust the universe of human activity. If Alfie files for a

patent on an oven of a type that Beth once built and then demolished without using or telling anyone else, Beth's secret use does not qualify as prior art and will not stand in the way of Alfie's application. Extensive caselaw glosses the meanings of these phrases, which are far subtler than they may appear at first glance, and which have changed substantially over time.

- *When* must an activity have taken place to qualify as prior art? The present section 102 uses the words "before the effective filing date of the claimed invention," so the patent applicant must not only think of the invention and make it work but must also make it to the Patent Office before anyone else goes public with the same idea. If Alfie invents in January and files in March but Beth publishes (or worse, files her own application) in February, Alfie is out of luck. This is one of the major changes in the America Invents Act: under pre-AIA law, Alfie's March application based off a January invention date would have been good enough. As we dig into the text of the AIA, we will see why it is said to create a rule of "first inventor to file."

Not coincidentally, these are the same kinds of questions one must also ask about *infringement*: what kinds of conduct are prohibited, what makes a defendant's use too similar, and when does it fall within the term of the plaintiff's rights? This symmetry is baked into patent law, as it is to many other fields of intellectual property law.

MPEP on Anticipation

From the USPTO's Manual of Patent Examining Procedure.

This MPEP text obtained/adapted from James Grimmelmann's Patterns of Information Law. See notes on editing, licensing etc. at the end of this chapter.

§ 2131 Anticipation—Application of 35 U.S.C. § 102

A claimed invention may be rejected under 35 U.S.C. 102 when the invention is anticipated (or is "not novel") over a disclosure that is available as prior art. To anticipate a claim, the disclosure must teach every element of the claim.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. "When a claim covers several structures or compositions, either

generically or as alternatives, the claim is deemed anticipated if any of the structures or compositions within the scope of the claim is known in the prior art.” *Brown v. 3M*, 265 F.3d 1349 (Fed. Cir.2001) (claim to a system for setting a computer clock to an offset time to address the Year 2000 (Y2K) problem, applicable to records with year date data in “at least one of two-digit, three-digit, or four-digit” representations, was held anticipated by a system that offsets year dates in only two-digit formats). The elements must be arranged as required by the claim, but this is not an *ipsissimis verbis* test, i.e., identity of terminology is not required.

A generic claim cannot be allowed to an applicant if the prior art discloses a species falling within the claimed genus. The species in that case will anticipate the genus.

§ 2131.02 Genus-Species Situations.

A genus does not always anticipate a claim to a species within the genus. However, when the species is clearly named, the species claim is anticipated no matter how many other species are additionally named. *See Ex parte A* 17 USPQ 2d 1716 (BPAI 1990) (“The tenth edition of the *Merck Index* lists ten thousand compounds. In our view, each and every one of those compounds is ‘described’ as that term is used in [pre-AIA] 35 U.S.C. § 102(a), in that publication.”).

Whether a generic disclosure necessarily anticipates everything within the genus depends on the factual aspects of the specific disclosure and the particular products at issue. How one of ordinary skill in the art would understand the relative size of a genus or species in a particular technology is of critical importance.

In *In re Petering*, 301 F.2d 676 (CCPA 1962) the prior art disclosed a generic chemical formula “wherein X, Y, Z, P, and R’- represent either hydrogen or alkyl radicals, R a side chain containing an OH group.” The court held that this formula, without more, could not anticipate a claim to 7-methyl-9-[d, l’-ribityl]-isoalloxazine because the generic formula encompassed a vast number and perhaps even an infinite number of compounds. However, the reference also disclosed preferred substituents for X, Y, Z, P, R, and R. The court determined that this more limited generic class consisted of about 20 compounds. The limited number of compounds covered by the preferred formula in combination with the fact that the number of substituents was low

at each site, the ring positions were limited, and there was a large unchanging structural nucleus, resulted in a finding that the reference sufficiently described “each of the various permutations here involved as fully as if he had drawn each structural formula or had written each name.” The claimed compound was 1 of these 20 compounds. Therefore, the reference “described” the claimed compound and the reference anticipated the claims.

When the reference relied on expressly anticipates or makes obvious all of the elements of the claimed invention, the reference is presumed to be operable. Once such a reference is found, the burden is on applicant to provide facts rebutting the presumption of operability.

§ 2121 Prior Art; General Level of Operability Required to Make a Prima Facie Case.

A prior art reference provides an enabling disclosure and thus anticipates a claimed invention if the reference describes the claimed invention in sufficient detail to enable a person of ordinary skill in the art to carry out the claimed invention; proof of efficacy is not required for a prior art reference to be enabling for purposes of anticipation.

Case: Titanium Metals v. Banner (novelty excerpt)

This case text obtained/adapted from James Grimmelmann’s Patterns of Information Law. See notes on editing, licensing etc. at the end of this chapter.

Titanium Metals Corp. of America v. Banner

U.S. Court of Appeals for the Federal Circuit
778 F.2d 775 (Fed. Cir. 1985)

This appeal is from an Order of the United States District Court for the District of Columbia in a civil action brought pursuant to 35 U.S.C. § 145 against Donald W. Banner as Commissioner of Patents and Trademarks authorizing the Commissioner to issue to appellee a patent containing claims 1, 2, and 3 of patent application serial No. 598,935 for “TITANIUM ALLOY.”

The inventors, Loren C. Covington and Howard R. Palmer, employees of appellee to whom they have assigned their invention and the application thereon, filed an application on March 29, 1974, serial No. 455,964, to patent an alloy they developed. The application involved in this appeal contains the

three claims on appeal. The alloy is made primarily of titanium (Ti) and contains small amounts of nickel (Ni) and molybdenum (Mo) as alloying ingredients to give the alloy certain desirable properties, particularly corrosion resistance in hot brine solutions, while retaining workability so that articles such as tubing can be fabricated from it by rolling, welding and other techniques. The inventors apparently also found that iron content should be limited, iron being an undesired impurity rather than an alloying ingredient. They determined the permissible ranges of the components, above and below which the desired properties were not obtained. A precise definition of the invention sought to be patented is found in the claims, set forth below, claim 3 representing the preferred composition, it being understood, however, that no iron at all would be even more preferred.

1. A titanium base alloy consisting essentially by weight of about 0.6% to 0.9% nickel, 0.2% to 0.4% molybdenum, up to 0.2% maximum iron, balance titanium, said alloy being characterized by good corrosion resistance in hot brine environments.
2. A titanium base alloy as set forth in Claim 1 having up to 0.1% iron, balance titanium.
3. A titanium base alloy as set forth in Claim 1 having 0.8% nickel, 0.3% molybdenum, up to 0.1% maximum iron, balance titanium.

The examiner's final rejection, repeated in his Answer on appeal to the Patent and Trademark Office (PTO) Board of Appeals (board), was on the grounds that claims 1 and 2 are anticipated (fully met) by, and claim 3 would have been obvious from, an article by Kalabukhova and Mikheyew, *Investigation of the Mechanical Properties of Ti-Mo-Ni Alloys*, RUSSIAN METALLURGY (METALLY) No. 3, pages 130-133 (1970) (in the court below and hereinafter called "the Russian article") under 35 U.S.C. §§ 102 and 103, respectively. The board affirmed the examiner's rejection.

The Russian article is short (3 pages), highly technical, and contains 10 graphs as part of the discussion. As its title indicates, it relates to ternary Ti-Mo-Ni alloys, the subject of the application at bar. The examiner and the board both found that it would disclose to one skilled in the art an alloy on which at least claims 1 and 2 read, so that those claims would not be allowable under the statute because of lack of novelty of their subject matter. Since the article does not specifically disclose such an alloy in words, a little thinking is

required about what it would disclose to one knowledgeable about Ti-Ni-Mo alloys. The PTO did that thinking as follows:

Figure 1c [a graph] shows data for the ternary titanium alloy which contains Mo and Ni in the ratio of 1:3. Amongst the actual points on the graph is one at 1% Mo + Ni. At this point, the amounts of Mo and Ni would be 0.25% and 0.75% respectively. A similar point appears on the graph shown in Figure 2 of the article.

Appellants do not deny that the data points are disclosed in the reference. In fact, the Hall affidavit indicates at least two specific points (at 1% and 1.25% Mo + Ni) which would represent a description of alloys falling within the scope of the instant claims.

On that basis, the board found that the claimed alloys were not new, because they were disclosed in the prior art. It having been argued that the Russian article contains no disclosure of corrosion-resistant properties of any of the alloys, the board held: "The fact that a particular property or the end use for this alloy as contemplated by appellants was not recognized in the article is of no consequence." It therefore held the Russian article to be an anticipation, noting that although the article does not discuss corrosion resistance, it does disclose other properties such as strength and ductility. The PTO further points out that the authors of the reference must have made the alloys to obtain the data points.

Being dissatisfied with the decision of the board, Titanium Metals Corporation of America, as assignee of the Covington and Palmer application, then brought an action in the District Court for the District of Columbia against the Commissioner pursuant to 35 U.S.C. § 145.

The case came on for trial on January 24, 1980, before the Honorable John G. Penn and was concluded in two and a half hours. The testimony of one witness was heard by the court, Dr. James C. Williams, professor at Carnegie-Mellon University in Pittsburgh and an expert in titanium metallurgy.

The court then concluded that claims 1-3 were not anticipated and that claim 3 was wrongly rejected as directed to obvious subject matter. In the court's view, Dr. Williams' testimony tipped the scales in favor of issuing a patent.

We are left in no doubt that the court was impressed by the totality of the evidence that the applicants for patent had discovered or invented and disclosed knowledge which is not to be found in the reference, nor do we have any doubt about that ourselves. But those facts are beside the point. The patent law imposes certain fundamental conditions for patentability, paramount among them being the condition that what is sought to be patented, as determined by the claims, be new. The title of the application here involved is "Titanium Alloy," a composition of matter. Surprisingly, in all of the evidence, nobody discussed the key issue of whether the alloy was new, which is the essence of the anticipation issue, including the expert Dr. Williams. Plaintiff's counsel, bringing Dr. Williams' testimony to its climax, after he had explained the nature of the ingredients, the alloys made therefrom, and their superior corrosion resistance in hot brine, etc., repetitively asked him such questions as "Does the [Russian] article *direct you* as one skilled in the art to a titanium alloy having nickel present in an amount between .6 and .9 percent molybdenum in an amount between .2 and .4 percent?" (emphasis ours) followed by "Is there anything mentioned in the article about corrosion resistance?" Of course, the answers were emphatically negative. But this and like testimony does not deal with the critical question: do claims 1 and 2, to which the questions obviously relate, read on or encompass an alloy which was already known by reason of the disclosure of the Russian article?

Section 102, the usual basis for rejection for lack of novelty or anticipation, lays down certain principles for determining the novelty [of an invention], among which are the provisions in § 102(a) and (b) that the claimed invention has not been "described in a printed publication in this or a foreign country," either (a) before the invention by the applicant or (b) more than one year before the application date to which he is entitled (strictly a "loss of right" provision similar to novelty). Either provision applies in this case, the Russian article having a date some 5 years prior to the filing date and its status as "prior art" not being questioned. The question, therefore, is whether claims 1 and 2 encompass and, if allowed, would enable plaintiff-appellee to exclude others from making, using, or selling an alloy described in the Russian article.

To answer the question we need only turn to the affidavit of James A. Hall, a metallurgist employed by appellee's TIMET Division, who undertook to analyze the Russian article disclosure by calculating the ingredient percentages shown in the graph data points, which he presented in tabular

form. There are 15 items in his table. The second item shows a titanium base alloy containing 0.25% by weight Mo and 0.75% Ni and this is squarely within the ranges of 0.2-0.4% Mo and 0.6-0.9% Ni of claims 1 and 2. As to that disclosed alloy of the prior art, there can be no question that claims 1 and 2 read on it and would be infringed by anyone making, using, or selling it. Therefore, the statute prohibits a patent containing them. This seems to be a case either of not adequately considering the novelty requirement of the statute, the true meaning of the correlative term “anticipation,” or the meaning of the claims.

By reason of the court’s quotations from cases holding that a reference is not an anticipation which does not enable one skilled in the art to practice the claimed invention, it appears that the trial court thought there was some deficiency in the Russian article on that score. Enablement in this case involves only being able to make the alloy, given the ingredients and their proportions without more. The evidence here, however, clearly answers that question in two ways. Appellee’s own patent application does not undertake to tell anyone how to make the alloy it describes and seeks to patent. It assumes that those skilled in the art would know how. Secondly, appellee’s expert, Dr. Williams, testified on cross examination that given the alloy information in the Russian article, he would know how to prepare the alloys “by at least three techniques.” Enablement is not a problem in this case.

As we read the situation, the court was misled by the arguments and evidence to the effect that the inventors here found out and disclosed in their application many things that one cannot learn from reading the Russian article and that this was sufficient in law to justify granting them a patent for their contributions—such things as what good corrosion resistance the claimed alloys have against hot brine, which possibly was not known, and the range limits of the Ni and Mo content, outside of which that resistance diminishes, which are teachings of very useful information. These things the applicants teach the art and the Russian article does not. But throughout the trial counsel never came to grips with the real issues: (1) what do the claims cover and (2) is what they cover new? Under the laws Congress wrote, they must be considered. Congress has not seen fit to permit the patenting of an old alloy, known to others through a printed publication, by one who has discovered its corrosion resistance or other useful properties, or has found out to what extent one can modify the composition of the alloy without losing such properties.

For all of the foregoing reasons, the court below committed clear error and legal error in authorizing the issuance of a patent on claims 1 and 2 since, properly construed, they are anticipated under § 102 by the Russian article which admittedly discloses an alloy on which these claims read.

Prof. James Grimmelmann on Categories of Prior Art

This section is text from James Grimmelmann's Patterns of Information Law (v 1.1, 2017). See notes on editing, licensing etc. at the end of this chapter. The text taken from Prof. Grimmelmann's book includes the cases and MPEP text within this section.

Under the new § 102(a)(1), “A person shall be entitled to a patent unless the claimed invention was *patented, described in a printed publication, or in public use, on sale, or otherwise available to the public* before the effective filing date of the claimed invention.” Most of the caselaw bearing on these phrases was developed under the old § 102; significant relevant differences will be noted.

Prior art category 1: “patented”

U.S. patents pose few conceptual or practical difficulties; they are prior art as of the day they issue. It is not always so easy to tell whether a foreign right is a “patent” within the meaning of § 102. *In re Carlson*, 983 F.2d 1032 (Fed. Cir. 1992) held that a German Geschmacksmuster counted as a patent for prior art purposes. A person may obtain one by “depositing with a local office an application with a drawing, photograph or sample of the article.” That was enough, even though “Geschmacksmuster on display for public view in remote cities in a far-away land may create a burden of discovery for one without the time, desire, or resources to journey there in person or by agent to observe that which was registered and protected under German law.” Such is life.

Prior art category 2: “described in a printed publication”

In re Klopfenstein

U.S. Court of Appeals for the Federal Circuit
380 F.3d 1345 (Fed. Cir. 2004)

Carol Klopfenstein and John Brent appeal a decision from the Patent and Trademark Office's Board of Patent Appeals and Interferences (“Board”)

upholding the denial of their patent application. The Board upheld the Patent and Trademark Office's ("PTO's") initial denial of their application on the ground that the invention described in the patent application was not novel under 35 U.S.C. § 102(b) because it had already been described in a printed publication more than one year before the date of the patent application. We affirm.

Background

The appellants applied for a patent on October 30, 2000. Their patent application, Patent Application Serial No. 09/699,950 ("the '950 application"), discloses methods of preparing foods comprising extruded soy cotyledon fiber ("SCF"). The '950 application asserts that feeding mammals foods containing extruded SCF may help lower their serum cholesterol levels while raising HDL cholesterol levels. The fact that extrusion reduces cholesterol levels was already known by those of ordinary skill in the art that worked with SCF. What was not known at the time was that double extrusion increases this effect and yielded even stronger results.

In October 1998, the appellants, along with colleague M. Liu, presented a printed slide presentation ("Liu" or "the Liu reference") entitled "Enhancement of Cholesterol-Lowering Activity of Dietary Fibers By Extrusion Processing" at a meeting of the American Association of Cereal Chemists ("AACC"). The fourteen-slide presentation was printed and pasted onto poster boards. The printed slide presentation was displayed continuously for two and a half days at the AACC meeting.

In November of that same year, the same slide presentation was put on display for less than a day at an Agriculture Experiment Station ("AES") at Kansas State University.

Both parties agree that the Liu reference presented to the AACC and at the AES in 1998 disclosed every limitation of the invention disclosed in the '950 patent application. Furthermore, at neither presentation was there a disclaimer or notice to the intended audience prohibiting note-taking or copying of the presentation. Finally, no copies of the presentation were disseminated either at the AACC meeting or at the AES, and the presentation was never catalogued or indexed in any library or database.

DISCUSSION

B.

The appellants argue on appeal that the key to establishing whether or not a reference constitutes a “printed publication” lies in determining whether or not it had been disseminated by the distribution of reproductions or copies and/or indexed in a library or database. They assert that because the Liu reference was not distributed and indexed, it cannot count as a “printed publication” for the purposes of 35 U.S.C. § 102(b). To support their argument, they rely on several precedents from this court and our predecessor court on “printed publications.” They argue *that In re Cronyn*, 890 F.2d 1158 (Fed. Cir. 1989), *In re Hall*, 781 F.2d 897 (Fed. Cir. 1986), *Massachusetts Institute of Technology v. AB Fortia*, 744 F.2d 1104 (Fed. Cir. 1985) and *In re Wyer*, 655 F.2d 221 (CCPA 1981) among other cases, all support the view that distribution and/or indexing is required for something to be considered a “printed publication.”

We find the appellants’ argument unconvincing and disagree with their characterization of our controlling precedent. Even if the cases cited by the appellants relied on inquiries into distribution and indexing to reach their holdings, they do not limit this court to finding something to be a “printed publication” only when there is distribution and/or indexing. Indeed, the key inquiry is whether or not a reference has been made “publicly accessible.”

The statutory phrase “printed publication” has been interpreted to mean that before the critical date the reference must have been sufficiently accessible to the public interested in the art; dissemination and public accessibility are the keys to the legal determination whether a prior art reference was “published.”

For example, a public billboard targeted to those of ordinary skill in the art that describes all of the limitations of an invention and that is on display for the public for months may be neither “distributed” nor “indexed” – but it most surely is “sufficiently accessible to the public interested in the art” and therefore, under controlling precedent, a “printed publication.”

Furthermore, the cases that the appellants rely on can be clearly distinguished from this case. *Cronyn* involved college students’ presentations of their undergraduate theses to a defense committee made up of four faculty members. Their theses were later catalogued in an index in the college’s main library. The index was made up of thousands of individual cards that

contained only a student's name and the title of his or her thesis. The index was searchable by student name and the actual theses themselves were neither included in the index nor made publicly accessible. We held that because the theses were only presented to a handful of faculty members and had not been catalogued or indexed in a meaningful way, they were not sufficiently publicly accessible for the purposes of 35 U.S.C. § 102(b).

In *Hall*, this court determined that a thesis filed and indexed in a university library did count as a "printed publication." The *Hall* court arrived at its holding after taking into account that copies of the indexed thesis itself were made freely available to the general public by the university more than one year before the filing of the relevant patent application in that case. But the court in *Hall* did not rest its holding merely on the indexing of the thesis in question. Instead, it used indexing as a factor in determining "public accessibility." As the court asserted:

The "printed publication" bar is grounded on the principle that once an invention is in the public domain, it is no longer patentable by anyone. Because there are many ways in which a reference may be disseminated to the interested public, "public accessibility" has been called the touchstone in determining whether a reference constitutes a "printed publication" bar under 35 U.S.C. § 102(b).

In *MIT*, a paper delivered orally to the First International Cell Culture Congress was considered a "printed publication." In that case, as many as 500 persons having ordinary skill in the art heard the presentation, and at least six copies of the paper were distributed. The key to the court's finding was that actual copies of the presentation were distributed. The court did not consider the issue of indexing. The *MIT* court determined the paper in question to be a "printed publication" but did not limit future determinations of the applicability of the "printed publication" bar to instances in which copies of a reference were actually offered for distribution. [FOOTNOTE: With regard to scientific presentations, it is important to note that an entirely oral presentation at a scientific conference that includes neither slides nor copies of the presentation is without question not a "printed publication" for the purposes of 35 U.S.C. § 102(b). Furthermore, a presentation that includes a transient display of slides is likewise not necessarily a "printed publication." See, e.g., *Regents of the Univ. of Cal. v. Howmedica, Inc.*, 530 F.Supp. 846 (D.N.J. 1981) (holding that "the projection of slides at the lecture that was

limited in duration and could not disclose the invention to the extent necessary to enable a person of ordinary skill in the art to make or use the invention” was not a “printed publication”).]

Finally, the *Wyer* court determined that an Australian patent application kept on microfilm at the Australian Patent Office was sufficiently accessible to the public and to persons skilled in the pertinent art to qualify as a “printed publication.” The court so found even though it did not determine whether or not there was “actual viewing or dissemination” of the patent application. *Id.* It was sufficient for the court’s purposes that the records of the application were kept so that they could be accessible to the public. [FOOTNOTE: *Id.* Unlike in *Cronyn*, it was the actual patent application — and not just an index card searchable by author name only — that was made publicly accessible.] According to the *Wyer* court, the entire purpose of the “printed publication” bar was to “prevent withdrawal” of disclosures already in the possession of the public by the issuance of a patent.

Thus, throughout our case law, public accessibility has been the criterion by which a prior art reference will be judged for the purposes of § 102(b). Oftentimes courts have found it helpful to rely on distribution and indexing as proxies for public accessibility. But when they have done so, it has not been to the exclusion of all other measures of public accessibility. In other words, distribution and indexing are not the only factors to be considered in a § 102(b) “printed publication” inquiry.

C.

In this case, the Liu reference was displayed to the public approximately two years before the ’950 application filing date. The reference was shown to a wide variety of viewers, a large subsection of whom possessed ordinary skill in the art of cereal chemistry and agriculture. Furthermore, the reference was prominently displayed for approximately three cumulative days at AACCC and the AES at Kansas State University. The reference was shown with no stated expectation that the information would not be copied or reproduced by those viewing it. Finally, no copies of the Liu display were distributed to the public and the display was not later indexed in any database, catalog or library.

The duration of the display is important in determining the opportunity of the public in capturing, processing and retaining the information conveyed by the reference. The more transient the display, the less likely it is to be

considered a “printed publication.” Conversely, the longer a reference is displayed, the more likely it is to be considered a “printed publication.” In this case, the Liu reference was displayed for a total of approximately three days. It was shown at the AACCC meeting for approximately two and a half days and at the AES at Kansas State University for less than one day.

The expertise of the intended audience can help determine how easily those who viewed it could retain the displayed material. As Judge Learned Hand explained in *Jockmus v. Leviton*, 28 F.2d 812 (2d Cir. 1928) a reference, “however ephemeral its existence,” may be a “printed publication” if it “goes direct to those whose interests make them likely to observe and remember whatever it may contain that is new and useful.” In this case, the intended target audience at the AACCC meeting was comprised of cereal chemists and others having ordinary skill in the art of the ’950 patent application. The intended viewers at the AES most likely also possessed ordinary skill in the art.

Whether a party has a reasonable expectation that the information it displays to the public will not be copied aids our § 102(b) inquiry. Where professional and behavioral norms entitle a party to a reasonable expectation that the information displayed will not be copied, we are more reluctant to find something a “printed publication.” This reluctance helps preserve the incentive for inventors to participate in academic presentations or discussions. Where parties have taken steps to prevent the public from copying temporarily posted information, the opportunity for others to appropriate that information and assure its widespread public accessibility is reduced. These protective measures could include license agreements, non-disclosure agreements, anti-copying software or even a simple disclaimer informing members of the viewing public that no copying of the information will be allowed or countenanced. Protective measures are to be considered insofar as they create a reasonable expectation on the part of the inventor that the displayed information will not be copied. In this case, the appellants took no measures to protect the information they displayed — nor did the professional norms under which they were displaying their information entitle them to a reasonable expectation that their display would not be copied. There was no disclaimer discouraging copying, and any viewer was free to take notes from the Liu reference or even to photograph it outright.

Finally, the ease or simplicity with which a display could be copied gives further guidance to our § 102(b) inquiry. The more complex a display, the

more difficult it will be for members of the public to effectively capture its information. The simpler a display is, the more likely members of the public could learn it by rote or take notes adequate enough for later reproduction. The Liu reference was made up of 14 separate slides. One slide was a title slide; one was an acknowledgement slide; and four others represented graphs and charts of experiment results. The other eight slides contained information presented in bullet point format, with no more than three bullet points to a slide. Further, no bullet point was longer than two concise sentences. Finally, as noted earlier, the fact that extrusion lowers cholesterol levels was already known by those who worked with SCF. The discovery disclosed in the Liu reference was that double extrusion increases this effect. As a result, most of the eight substantive slides only recited what had already been known in the field, and only a few slides presented would have needed to have been copied by an observer to capture the novel information presented by the slides.

Upon reviewing the above factors, it becomes clear that the Liu reference was sufficiently publicly accessible to count as a “printed publication” for the purposes of 35 U.S.C. § 102(b). The reference itself was shown for an extended period of time to members of the public having ordinary skill in the art of the invention behind the ’950 patent application. Those members of the public were not precluded from taking notes or even photographs of the reference. And the reference itself was presented in such a way that copying of the information it contained would have been a relatively simple undertaking for those to whom it was exposed — particularly given the amount of time they had to copy the information and the lack of any restrictions on their copying of the information. For these reasons, we conclude that the Liu reference was made sufficiently publicly accessible to count as a “printed publication” under § 102(b).

Prior art category 3: “in public use”

The old § 102 got at this concept in two different ways. It denied a patent where the invention was “known or used by others” before the *date of invention* (a “novelty” rule) or where it was “in public use” more than a year before the *filing date* (a “statutory bar”). While the two provisions differed in their timing (more on this in the Priority section below), the most fundamental distinction was that “known or used by others” only applied to

uses made by *third parties*, whereas “in public use” also could be triggered by anyone, *including the inventor*.

Egbert v. Lippman

Supreme Court of the United States

104 U.S. 333 (1881)

This suit was brought for an alleged infringement of the complainant’s reissued letters-patent, No. 5216, dated Jan. 7, 1873, for an improvement in corset-springs.

The original letters bear date July 17, 1866, and were issued to Samuel H. Barnes. The reissue was made to the complainant, under her then name, Frances Lee Barnes, executrix of the original patentee.

The specification for the reissue declares:

This invention consists in forming the springs of corsets of two or more metallic plates, placed one upon another, and so connected as to prevent them from sliding off each other laterally or edgewise, and at the same time admit of their playing or sliding upon each other, in the direction of their length or longitudinally, whereby their flexibility and elasticity are greatly increased, while at the same time much strength is obtained.

The second claim is as follows:

A pair of corset-springs, each member of the pair being composed of two or more metallic plates, placed one on another, and fastened together at their centres, and so connected at or near each end that they can move or play on each other in the direction of their length.

[The patent statute in force at the time had a two-year statutory bar, whose] effect is to render letters-patent invalid if the invention which they cover was in public use, with the consent and allowance of the inventor, for more than two years prior to his application.

The evidence on which the defendants rely to establish a prior public use of the invention consists mainly of the testimony of the complainant.

She testifies that Barnes invented the improvement covered by his patent between January and May, 1855; that between the dates named the witness and her friend Miss Cugier were complaining of the breaking of their corset-

steels. Barnes, who was present, and was an intimate friend of the witness, said he thought he could make her a pair that would not break. At their next interview he presented her with a pair of corset-steels which he himself had made. The witness wore these steels a long time. In 1858 Barnes made and presented to her another pair, which she also wore a long time. When the corsets in which these steels were used wore out, the witness ripped them open and took out the steels and put them in new corsets. This was done several times.

It is admitted, and, in fact, is asserted, by complainant, that these steels embodied the invention afterwards patented by Barnes and covered by the reissued letters-patent on which this suit is brought.

Joseph H. Sturgis, another witness for complainant, testifies that in 1863 Barnes spoke to him about two inventions made by himself, one of which was a corset-steel, and that he went to the house of Barnes to see them. Before this time, and after the transactions testified to by the complainant, Barnes and she had intermarried. Barnes said his wife had a pair of steels made according to his invention in the corsets which she was then wearing, and if she would take them off he would show them to witness. Mrs. Barnes went out, and returned with a pair of corsets and a pair of scissors, and ripped the corsets open and took out the steels. Barnes then explained to witness how they were made and used.

The question for our decision is, whether this testimony shows a public use within the meaning of the statute.

We observe, in the first place, that to constitute the public use of an invention it is not necessary that more than one of the patented articles should be publicly used. The use of a great number may tend to strengthen the proof, but one well-defined case of such use is just as effectual to annul the patent as many. For instance, if the inventor of a mower, a printingpress, or a railway-car makes and sells only one of the articles invented by him, and allows the vendee to use it for two years, without restriction or limitation, the use is just as public as if he had sold and allowed the use of a great number.

We remark, secondly, that, whether the use of an invention is public or private does not necessarily depend upon the number of persons to whom its use is known. If an inventor, having made his device, gives or sells it to another, to be used by the donee or vendee, without limitation or restriction, or

injunction of secrecy, and it is so used, such use is public, even though the use and knowledge of the use may be confined to one person.

We say, thirdly, that some inventions are by their very character only capable of being used where they cannot be seen or observed by the public eye. An invention may consist of a lever or spring, hidden in the running gear of a watch, or of a ratchet, shaft, or cog-wheel covered from view in the recesses of a machine for spinning or weaving. Nevertheless, if its inventor sells a machine of which his invention forms a part, and allows it to be used without restriction of any kind, the use is a public one. So, on the other hand, a use necessarily open to public view, if made in good faith solely to test the qualities of the invention, and for the purpose of experiment, is not a public use within the meaning of the statute. *City of Elizabeth v. American Nicholson Pavement Co.*, 97 U.S. 126 (1878).

Tested by these principles, we think the evidence of the complainant herself shows that for more than two years before the application for the original letters there was, by the consent and allowance of Barnes, a public use of the invention, covered by them. He made and gave to her two pairs of corset-steels, constructed according to his device, one in 1855 and one in 1858. They were presented to her for use. He imposed no obligation of secrecy, nor any condition or restriction whatever. They were not presented for the purpose of experiment, nor to test their qualities. No such claim is set up in her testimony. The invention was at the time complete, and there is no evidence that it was afterwards changed or improved. The donee of the steels used them for years for the purpose and in the manner designed by the inventor. They were not capable of any other use. She might have exhibited them to any person, or made other steels of the same kind, and used or sold them without violating any condition or restriction imposed on her by the inventor.

According to the testimony of the complainant, the invention was completed and put to use in 1855. The inventor slept on his rights for eleven years. Letters-patent were not applied for till March, 1866. In the mean time, the invention had found its way into general, and almost universal, use. A great part of the record is taken up with the testimony of the manufacturers and venders of corset-steels, showing that before he applied for letters the principle of his device was almost universally used in the manufacture of corset-steels. It is fair to presume that having learned from this general use that there was some

value in his invention, he attempted to resume, by his application, what by his acts he had clearly dedicated to the public.

An abandonment of an invention to the public may be evinced by the conduct of the inventor at any time, even within the two years named in the law. The effect of the law is that no such consequence will necessarily follow from the invention being in public use or on sale, with the inventor's consent and allowance, at any time within two years before his application; but that, if the invention is in public use or on sale prior to that time, it will be conclusive evidence of abandonment, and the patent will be void.

City of Elizabeth We are of opinion that the defence of two years' public use, by the consent and allowance of the inventor, before he made application for letters-patent, is satisfactorily established by the evidence.

Mark A. Lemley

Does "Public Use" Mean the Same Thing It Did Last Year?

93 TEX. L. REV. 1119 (2015)

An inventor can obtain a patent only if the invention is "novel" – that is, that no one has done the same thing before. Rather than adopting an absolute novelty rule, however, patent law has traditionally required that most categories of prior art be "accessible to the public." Thus, while [old] 35 U.S.C. § 102(a) bars a patent if the invention was "known or used by others" before the applicant invented it, courts have interpreted that term to mean "publicly known or used." At the same time, the public accessibility requirement does not require that the public have a realistic chance of accessing the information; "public" seems to mean merely "not secret." An invention performed underground on private property in a rural area, an invention found only inside the walls of a safe, and a single copy of a graduate thesis in the basement of a library in Germany have all been held sufficiently "public" to constitute prior art.

In addition to novelty, the Patent Act of 1952, like its predecessors, created a series of "statutory bars" designed to prevent inventors from making commercial use of their invention while keeping it secret. [Old] section 102(b) provides that even a true first inventor is not entitled to a patent if the invention has been "on sale" or "in public use" more than a year before the

inventor files her patent application. As with [old] section 102(a), the courts have interpreted the word “public” quite loosely, so that even uses that are extremely unlikely to be viewed by the public are nonetheless classed as “public uses” so long as they are not affirmatively secret. In the most extreme example, the Supreme Court held that a woman engaged in a public use of a corset invented by her fiancé when she wore it under her clothing.

But even a very broad definition of “public” left a significant loop-hole – an inventor could avoid the one-year statutory bar by commercializing his invention but treating it as a trade secret. Because a secret use is by definition not a public use, a company could make commercial use of an invention indefinitely without triggering the one-year period for filing. To solve this problem, courts for more than seventy years have created a special rule for secret commercial uses: a secret commercial use is not prior art that bars a third party from later obtaining a patent, but it does start the one-year clock running for the user. This rule originated in a 1940 opinion by Judge Learned Hand in *Metallizing Engineering v. Kenyon Bearing & Auto Parts*, 153 F.2d 516 (2d Cir. 1946). The court acknowledged that interpreting the same term (“public use”) to have different meanings was hard to reconcile with the statute. But Judge Hand reasoned that it was not the intent of the statute to encourage secrecy, but instead to encourage disclosure. *Metallizing’s* split interpretation of public use served that goal in two ways. First, it encouraged inventors to file a patent quickly rather than relying in trade secrecy, because they would lose the right to patent if they waited longer than a year. Second, the fact that a secret commercial use wouldn’t prevent a later patent from issuing to a third party adds to the disclosure incentive, because an inventor who opts for trade secrecy may find that a later inventor has patented their own idea and there is nothing they can do to stop it.

Lough v. Brunswick Corp.

U.S. Court of Appeals for the Federal Circuit
83 F.3d 1113 (Fed. Cir. 1996)

[Lough designed an improved seal for outboard motors.] After some trial and error with his grand-father’s metal lathe, he made six usable prototypes in the spring of 1986. He installed one prototype in his own boat at home. Three months later, he gave a second prototype to a friend who installed it in his boat. He also installed prototypes in the boat of the owner of the marina where

he worked and in the boat of a marina customer. He gave the remaining prototypes to longtime friends who were employees at another marina in Sarasota. Lough did not charge anyone for the prototypes. For over a year following the installation of these prototypes, Lough neither asked for nor received any comments about the operability of the prototypes. During this time, Lough did not attempt to sell any seal assemblies.

On June 6, 1988, Lough filed a patent application entitled “Liquid Seal for Marine Stern Drive Gear Shift Shafts,” which issued as [U.S. Patent No. 4,848,775A] on July 18, 1989.

One is entitled to a patent unless, *inter alia*, “the invention was ... in public use ... in this country, more than one year prior to the date of the application for patent in the United States.” We have defined “public use” as including any use of the claimed invention by a person other than the inventor who is under no limitation, restriction or obligation of secrecy to the inventor. An evaluation of a question of public use depends on how the totality of the circumstances of the case comports with the policies underlying the public use bar. These policies include: (1) discouraging the removal, from the public domain, of inventions that the public reasonably has come to believe are freely available; (2) favoring the prompt and widespread disclosure of inventions; (3) allowing the inventor a reasonable amount of time following sales activity to determine the potential economic value of a patent; and (4) prohibiting the inventor from commercially exploiting the invention for a period greater than the statutorily prescribed time.

Neither party disputes that Lough’s prototypes were in use before the critical date. Thus, both parties agree that the issue presented on appeal is whether the jury properly decided that the use of Lough’s six prototypes in 1986, prior to the critical date, constituted experimental use so as to negate the conclusion of public use.

“The use of an invention by the inventor himself, or of any other person under his direction, by way of experiment, and in order to bring the invention to perfection, has never been regarded as [a public] use.” *City of Elizabeth*. This doctrine is based on the underlying policy of providing an inventor time to determine if the invention is suitable for its intended purpose, in effect, to reduce the invention to practice. *See id.* (“It is sometimes said that an inventor acquires an undue advantage over the public by delaying to take out a patent,

but this cannot be said with justice when the delay is occasioned by a bona fide effort to bring his invention to perfection, or to ascertain whether it will answer the purpose intended.”). If a use is experimental, it is not, as a matter of law, a public use within the meaning of section 102.

To determine whether a use is “experimental,” a question of law, the totality of the circumstances must be considered, including various objective indicia of experimentation surrounding the use, such as the number of prototypes and duration of testing, whether records or progress reports were made concerning the testing, the existence of a secrecy agreement between the patentee and the party performing the testing, whether the patentee received compensation for the use of the invention, and the extent of control the inventor maintained over the testing.

In order to justify a determination that legally sufficient experimentation has occurred, there must be present certain minimal indicia. The framework might be quite formal, as may be expected when large corporations conduct experiments, governed by contracts and explicit written obligations. When individual inventors or small business units are involved, however, less formal and seemingly casual experiments can be expected. Such less formal experiments may be deemed legally sufficient to avoid the public use bar, but only if they demonstrate the presence of the same basic elements that are required to validate any experimental program.

It cannot be reasonably disputed that Lough’s use of the invention was not “experimental” so as to negate a conclusion of public use. It is true that Lough did not receive any compensation for the use of the prototypes. He did not place the seal assembly on sale before applying for a patent. Lough’s lack of commercialization, however, is not dispositive of the public use question in view of his failure to present objective evidence of experimentation. Lough kept no records of the alleged testing. Nor did he inspect the seal assemblies after they had been installed by other mechanics. He provided the seal assemblies to friends and acquaintances, but without any provision for follow-up involvement by him in assessment of the events occurring during the alleged experiments, and at least one seal was installed in a boat that was later sold to strangers. Thus, Lough did not maintain any supervision and control over the seals during the alleged testing.

Lough argues that other evidence supports a finding that his uses were experimental, including his own testimony that the prototypes were installed for experimental purposes and the fact that the prototypes were used in such a manner that they were unlikely to be seen by the public. However, the expression by an inventor of his subjective intent to experiment, particularly after institution of litigation, is generally of minimal value. In addition, the fact that the prototypes were unlikely to be seen by the public does not support Lough's position. As the Supreme Court stated in *Egbert*:

Some inventions are by their very character only capable of being used where they cannot be seen or observed by the public eye. An invention may consist of a lever or spring, hidden in the running gear of a watch, or of a ratchet, shaft, or cogwheel covered from view in the recesses of a machine for spinning or weaving. Nevertheless, if its inventor sells a machine of which his invention forms a part, and allows it to be used without restriction of any kind, the use is a public one.

Moreover, those to whom he gave the prototypes constituted "the public," in the absence of meaningful evidence of experimentation.

We therefore hold that the jury had no legal basis to conclude that the uses of Lough's prototypes were experimental and that the prototypes were not in public use prior to the critical date. Our holding is consistent with the policy underlying the experimental use negation, that of providing an inventor time to determine if the invention is suitable for its intended purpose, i.e., to reduce the invention to practice. Lough's activities clearly were not consistent with that policy. We do not dispute that it may have been desirable in this case for Lough to have had his prototypes installed by mechanics of various levels of skill in boats that were exposed to different conditions. Moreover, Lough was free to test his invention in boats of friends and acquaintances to further verify that his invention worked for its intended purpose; however, Lough was required to maintain some degree of control and feedback over those uses of the prototypes if those tests were to negate public use.

*Prior art category 4: “on sale”****MPEP § 2150.02(d) On Sale****[Manual of Patent Examining Procedure (Rev. Nov. 2013)]*

The pre-AIA case law indicates that on sale activity will bar patentability if the claimed invention was: (1) the subject of a commercial sale or offer for sale, not primarily for experimental purposes; and (2) ready for patenting. *See Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55 (1998). Contract law principles apply in order to determine whether a commercial sale or offer for sale occurred.

§ 2133.03(b) “On Sale” (describing pre-AIA law)

A sale is a contract between parties wherein the seller agrees “to give and to pass rights of property” in return for the buyer’s payment or promise “to pay the seller for the things bought or sold.” A contract for the sale of goods requires a concrete offer and acceptance of that offer. *See, e.g., Linear Tech. Corp. v. Micrel, Inc.*, 275 F.3d 1040 (Fed. Cir. 2001) (Court held there was no sale where prospective purchaser submitted an order for goods at issue, but received an order acknowledgement reading “will advise-not booked.” Prospective purchaser would understand that order was not accepted.).

An assignment or sale of the rights in the invention and potential patent rights is not a sale of “the invention.” *In re Kollar*, 286 F.3d 1326 (Fed. Cir. 2002) distinguishes licenses which trigger the on-sale bar (e.g., a standard computer software license wherein the product is just as immediately transferred to the licensee as if it were sold), from licenses that merely grant rights to an invention which do not per se trigger the on-sale bar (e.g., exclusive rights to market the invention or potential patent rights).

The Supreme Court’s “ready for patenting” prong applies in the context of both the on sale and public use bars.

§ 2133.03(c) The “Invention” (describing pre-AIA law).

“Ready for patenting,” the second prong of the *Pfaff* test, may be satisfied in at least two ways: by proof of reduction to practice before the critical date; or by proof that prior to the critical date the inventor had prepared drawings or other descriptions of the invention that were sufficiently specific to enable a person skilled in the art to practice the invention. [In one case, a] patent was held invalid because the invention for a computer chip socket was “ready for patenting” when it was offered for sale more than one year prior to the

application filing date. Even though the invention had not yet been reduced to practice, the manufacturer was able to produce the claimed computer chip sockets using the inventor's detailed drawings and specifications, and those sockets contained all elements of invention claimed in the patent.

Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc.

U.S. Court of Appeals for the Federal Circuit
855 F.3d 1356 (Fed. Cir. 2017)

Helsinn, the government, and other amici argue that the AIA changed the law by adding the “otherwise available to the public” phrase. They argue that the on-sale bar now does not encompass secret sales and requires that a sale make the invention available to the public in order to trigger application of the on-sale bar. Apart from the additional statutory language, this argument primarily relies on floor statements made by individual members of Congress.

We decline the invitation by the parties to decide this case more broadly than necessary. At most the floor statements show an intent “to do away with precedent under current law.” (remarks of Sen. Leahy). Such precedent had held certain secret uses to be invalidating under the “public use” prong of § 102(b). Each of those cases involved a public use where the invention was not, as a result of the use, disclosed to the public. This public use issue is not before us, and we decline to address it.

The floor statements do not identify any *sale* cases that would be overturned by the amendments. Even if the floor statements were intended to overrule those secret or confidential sale cases, that would have no effect here since those cases were concerned entirely with whether the existence of a sale or offer was public. Here, the existence of the sale— i.e., the Supply and Purchase Agreement between Helsinn and MGI – was publicly announced in MGI's 8-K filing with the SEC.

Our prior cases have applied the on-sale bar even when there is no delivery, when delivery is set after the critical date, or, even when, upon delivery, members of the public could not ascertain the claimed invention. There is no indication in the floor statements that these members intended to overrule these cases.

Prior art category 5: “otherwise available to the public”

The old § 102 had a closed list of prior art categories. The open-ended language “otherwise available to the public” is new with the AIA. In the PTO’s view, “This ‘catch-all’ provision permits decision makers to focus on whether the disclosure was ‘available to the public,’ rather than on the means by which the claimed invention became available to the public or whether a disclosure constitutes a ‘printed publication’ or falls within another category of prior art.”

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The following was written by Eric E. Johnson:

This chapter P-4, “Patent Novelty,” was put together by Eric E. Johnson by taking a swath of text from *Patterns of Information Law: Intellectual Property Done Right* (version 1.1, August 2017) authored by **James Grimmelmann**. I added the § 102 statute at the beginning and the CRS section after that. (Regarding CRS text, see “Editing Notes” section at the beginning of the volume on editing of CRS materials.) The rest of the chapter is material from Prof. Grimmelmann’s book with minor tweaks.

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technique is borrowed from Sweeney Todd: extensive and shocking cuts. These are pedagogical materials, not a legal brief. I have not put words in anyone else's mouth, but I have been unconcerned with the usual editorial apparatus of ellipses and brackets. I drop words from sentences, sentences from paragraphs, paragraphs from opinions – all with no indication that anything is gone. I also reorder paragraphs and sometimes sentences as needed to improve the readability of a passage. My goal is to make it easy for the reader. If it matters to you what the original said, consult the original.” And he says a bit more along these lines. As for my own editing in bringing his material into this volume, I've made various tweaks, including formatting changes, adding and re-wording headers and source information, and bringing material into the main text that he put in page margins. In this chapter and others, an effort was made to correct some typos/mistakes in the text of readings. I probably haven't gone nearly as far as he did in editing others, but for the sake of prudence, assume I've done unto him as he's done unto others.

I am very grateful to James Grimmelmann for his generosity in sharing his excellent materials!

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–EEJ

P-5: Patent Nonobviousness

This chapter was put together by Eric E. Johnson. It uses edited case readings from from *Patterns of Information Law: Intellectual Property Done Right* (version 1.1, August 2017) authored by **James Grimmelmann**.

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35 U.S.C. § 103. Conditions for patentability; non-obvious subject matter.

[As amended by the America Invents Act of 2011.

Effective for applications filed on or after March 16, 2013.]

A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

CRS on Nonobviousness

Adapted from Congressional Research Service, Patent Law: A Handbook for Congress, R46525, September 16, 2020. (See notes at end of chapter on editing of CRS materials.)

An applicant may not receive a patent on an invention that is an obvious extension of the prior art. Thus, “if the differences between the claimed

invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention,” then the applicant may not receive a patent. The Supreme Court has directed that four factors must be considered when determining whether the prior art renders a claimed invention obvious:

1. the scope and content of the prior art;
2. the differences between the prior art and the claimed invention;
3. the level of ordinary skill of the art; and
4. any secondary considerations (also referred to as *objective indicia*) of nonobviousness.

Secondary considerations/objective indicia that may be considered in evaluating obviousness include commercial success, long-felt but unsolved needs, and failure of others, which might provide evidence regarding whether the invention would have been obvious at the time of invention.

While a single prior art reference is generally used to demonstrate lack of novelty, multiple references may also be used to establish that a claim would have been obvious. Simply demonstrating that all of the limitations in a claim were disclosed across several references, however, is insufficient to establish that an invention would have been obvious. Instead, the party challenging the patent must further prove that a person of ordinary skill would have had some reason to combine the different references. For example, a party may argue that a person of ordinary skill would have had a reason to modify the system disclosed in one reference by incorporating a part disclosed in another reference.

Case: KSR v. Teleflex

This edited case text obtained/adapted from James Grimmelmann's Patterns of Information Law. See notes on editing, licensing etc. at the end of this chapter.

KSR Intern. Co. v. Teleflex Inc.

Supreme Court of the United States
550 U.S. 398 (2007)

The patent at issue, United States Patent No. 6,237,565 B1, is entitled “Adjustable Pedal Assembly With Electronic Throttle Control.” Supplemental App. 1. The patentee is Steven J. Engelgau, and the patent is referred to as “the

Engelgau patent.” Claim 4 of the Engelgau patent describes a mechanism for combining an electronic sensor with an adjustable automobile pedal so the pedal’s position can be transmitted to a computer that controls the throttle in the vehicle’s engine.

In *Graham v. John Deere Co.*, 383 U.S. 1 (1966) the Court set out a framework for applying the statutory language of § 103:

Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented.

If a court, or patent examiner, conducts this analysis and concludes the claimed subject matter was obvious, the claim is invalid under § 103.

Seeking to resolve the question of obviousness with more uniformity and consistency, the Court of Appeals for the Federal Circuit has employed an approach referred to by the parties as the “teaching, suggestion, or motivation” test (TSM test), under which a patent claim is only proved obvious if “some motivation or suggestion to combine the prior art teachings” can be found in the prior art, the nature of the problem, or the knowledge of a person having ordinary skill in the art. KSR challenges that test, or at least its application in this case.

I

A

In car engines without computer-controlled throttles, the accelerator pedal interacts with the throttle via cable or other mechanical link. The pedal arm acts as a lever rotating around a pivot point. In a cable-actuated throttle control the rotation caused by pushing down the pedal pulls a cable, which in turn pulls open valves in the carburetor or fuel injection unit. The wider the valves open, the more fuel and air are released, causing combustion to increase and the car to accelerate. When the driver takes his foot off the pedal, the opposite occurs as the cable is released and the valves slide closed.

In the 1990's it became more common to install computers in cars to control engine operation. Computer-controlled throttles open and close valves in response to electronic signals, not through force transferred from the pedal by a mechanical link. Constant, delicate adjustments of air and fuel mixture are possible. The computer's rapid processing of factors beyond the pedal's position improves fuel efficiency and engine performance.

For a computer-controlled throttle to respond to a driver's operation of the car, the computer must know what is happening with the pedal. A cable or mechanical link does not suffice for this purpose; at some point, an electronic sensor is necessary to translate the mechanical operation into digital data the computer can understand.

Before discussing sensors further we turn to the mechanical design of the pedal itself. In the traditional design a pedal can be pushed down or released but cannot have its position in the footwell adjusted by sliding the pedal forward or back. As a result, a driver who wishes to be closer or farther from the pedal must either reposition himself in the driver's seat or move the seat in some way. In cars with deep footwells these are imperfect solutions for drivers of smaller stature. To solve the problem, inventors, beginning in the 1970's, designed pedals that could be adjusted to change their location in the footwell. Important for this case are two adjustable pedals disclosed in U.S. Patent Nos. 5,010,782 (filed July 28, 1989) (Asano) and 5,460,061 (filed Sept. 17, 1993) (Redding). The Asano patent reveals a support structure that houses the pedal so that even when the pedal location is adjusted relative to the driver, one of the pedal's pivot points stays fixed. The pedal is also designed so that the force necessary to push the pedal down is the same regardless of adjustments to its location. The Redding patent reveals a different, sliding mechanism where both the pedal and the pivot point are adjusted.

We return to sensors. Well before Engalgau applied for his challenged patent, some inventors had obtained patents involving electronic pedal sensors for computer-controlled throttles. These inventions, such as the device disclosed in U.S. Patent No. 5,241,936 (filed Sept. 9, 1991) ('936), taught that it was preferable to detect the pedal's position in the pedal assembly, not in the engine. The '936 patent disclosed a pedal with an electronic sensor on a pivot point in the pedal assembly. U.S. Patent No. 5,063,811 (filed July 9, 1990) (Smith) taught that to prevent the wires connecting the sensor to the computer from chafing and wearing out, and to avoid grime and damage from the

driver's foot, the sensor should be put on a fixed part of the pedal assembly rather than in or on the pedal's footpad.

In addition to patents for pedals with integrated sensors inventors obtained patents for self-contained modular sensors. A modular sensor is designed independently of a given pedal so that it can be taken off the shelf and attached to mechanical pedals of various sorts, enabling the pedals to be used in automobiles with computer-controlled throttles. One such sensor was disclosed in U.S. Patent No. (filed Dec. 18, 1992) ('068). In 1994, Chevrolet manufactured a line of trucks using modular sensors attached to the pedal support bracket, adjacent to the pedal and engaged with the pivot shaft about which the pedal rotates in operation.

The prior art contained patents involving the placement of sensors on adjustable pedals as well. For example, U.S. Patent No. 5,819,593 (filed Aug. 17, 1995) (Rixon) discloses an adjustable pedal assembly with an electronic sensor for detecting the pedal's position. In the Rixon pedal the sensor is located in the pedal footpad. The Rixon pedal was known to suffer from wire chafing when the pedal was depressed and released.

This short account of pedal and sensor technology leads to the instant case.

B

Engelgau filed the patent application on August 22, 2000 as a continuation of a previous application for U.S. Patent No. 6,109,241, which was filed on January 26, 1999. He has sworn he invented the patent's subject matter on February 14, 1998. The Engelgau patent discloses an adjustable electronic pedal described in the specification as a "simplified vehicle control pedal assembly that is less expensive, and which uses fewer parts and is easier to package within the vehicle." Claim 4 of the patent, at issue here, describes:

A vehicle control pedal apparatus comprising:
a support adapted to be mounted to a vehicle structure;
an adjustable pedal assembly having a pedal arm moveable in for[e] and aft directions with respect to said support;
a pivot for pivotally supporting said adjustable pedal assembly with respect to said support and defining a pivot axis; and

an electronic control attached to said support for controlling a vehicle system;

said apparatus characterized by said electronic control being responsive to said pivot for providing a signal that corresponds to pedal arm position as said pedal arm pivots about said pivot axis between rest and applied positions wherein the position of said pivot remains constant while said pedal arm moves in fore and aft directions with respect to said pivot.

We agree with the District Court that the claim discloses “a position-adjustable pedal assembly with an electronic pedal position sensor attached to the support member of the pedal assembly. Attaching the sensor to the support member allows the sensor to remain in a fixed position while the driver adjusts the pedal.”

Before issuing the Engalgau patent the U.S. Patent and Trademark Office (PTO) rejected one of the patent claims that was similar to, but broader than, the present claim 4. The claim did not include the requirement that the sensor be placed on a fixed pivot point. The PTO concluded the claim was an obvious combination of the prior art disclosed in Redding and Smith, explaining:

Since the prior art references are from the field of endeavor, the purpose disclosed would have been recognized in the pertinent art of Redding. Therefore it would have been obvious to provide the device of Redding with the means attached to a support member as taught by Smith.

In other words Redding provided an example of an adjustable pedal and Smith explained how to mount a sensor on a pedal’s support structure, and the rejected patent claim merely put these two teachings together.

Although the broader claim was rejected, claim 4 was later allowed because it included the limitation of a fixed pivot point, which distinguished the design from Redding’s. Engalgau had not included Asano among the prior art references, and Asano was not mentioned in the patent’s prosecution. Thus, the PTO did not have before it an adjustable pedal with a fixed pivot point. The patent issued on May 29, 2001 and was assigned to Teleflex.

C

The District Court determined, in light of the expert testimony and the parties' stipulations, that the level of ordinary skill in pedal design was "an undergraduate degree in mechanical engineering (or an equivalent amount of industry experience) and familiarity with pedal control systems for vehicles." Following *Graham's* direction, the court compared the teachings of the prior art to the claims of Engelgau. It found "little difference." Asano taught everything contained in claim 4 except the use of a sensor to detect the pedal's position and transmit it to the computer controlling the throttle. That additional aspect was revealed in sources such as the '068 patent and the sensors used by Chevrolet.

Under the controlling cases from the Court of Appeals for the Federal Circuit, however, the District Court was not permitted to stop there. The court was required also to apply the TSM test. The District Court held KSR had satisfied the test. It reasoned (1) the state of the industry would lead inevitably to combinations of electronic sensors and adjustable pedals, (2) Rixon provided the basis for these developments, and (3) Smith taught a solution to the wire chafing problems in Rixon, namely locating the sensor on the fixed structure of the pedal. This could lead to the combination of Asano, or a pedal like it, with a pedal position sensor.

The conclusion that the Engelgau design was obvious was supported, in the District Court's view, by the PTO's rejection of the broader version of claim 4. Had Engelgau included Asano in his patent application, it reasoned, the PTO would have found claim 4 to be an obvious combination of Asano and Smith, as it had found the broader version an obvious combination of Redding and Smith. As a final matter, the District Court held that the secondary factor of Teleflex's commercial success with pedals based on Engelgau's design did not alter its conclusion.

With principal reliance on the TSM test, the Court of Appeals reversed. It ruled the District Court had not been strict enough in applying the test, having failed to make "findings as to the specific understanding or principle within the knowledge of a skilled artisan that would have motivated one with no knowledge of the invention to attach an electronic control to the support bracket of the Asano assembly." The Court of Appeals held that the District Court was incorrect that the nature of the problem to be solved satisfied this

requirement because unless the “prior art references address[ed] the precise problem that the patentee was trying to solve,” the problem would not motivate an inventor to look at those references.

Here, the Court of Appeals found, the Asano pedal was designed to solve the “constant ratio problem” – that is, to ensure that the force required to depress the pedal is the same no matter how the pedal is adjusted—whereas Engelgau sought to provide a simpler, smaller, cheaper adjustable electronic pedal. As for Rixon, the court explained, that pedal suffered from the problem of wire chafing but was not designed to solve it. In the court’s view Rixon did not teach anything helpful to Engelgau’s purpose. Smith, in turn, did not relate to adjustable pedals and did not “necessarily go to the issue of motivation to attach the electronic control on the support bracket of the pedal assembly.” When the patents were interpreted in this way, the Court of Appeals held, they would not have led a person of ordinary skill to put a sensor on the sort of pedal described in Asano.

That it might have been obvious to try the combination of Asano and a sensor was likewise irrelevant, in the court’s view, because “‘obvious to try’ has long been held not to constitute obviousness.”

II

A

We begin by rejecting the rigid approach of the Court of Appeals. Throughout this Court’s engagement with the question of obviousness, our cases have set forth an expansive and flexible approach inconsistent with the way the Court of Appeals applied its TSM test here. To be sure, *Graham* recognized the need for “uniformity and definiteness.” Yet the principles laid down in *Graham* reaffirmed the “functional approach” of *Hotchkiss v. Greenwood*, 52 U.S. 248 (1851).

Neither the enactment of § 103 nor the analysis in *Graham* disturbed this Court’s earlier instructions concerning the need for caution in granting a patent based on the combination of elements found in the prior art. For over a half century, the Court has held that a patent for a combination which only unites old elements with no change in their respective functions obviously withdraws what is already known into the field of its monopoly and diminishes the resources available to skillful men. This is a principal reason for declining to allow patents for what is obvious. The combination of familiar elements

according to known methods is likely to be obvious when it does no more than yield predictable results. Three cases decided after *Graham* illustrate the application of this doctrine.

In *United States v. Adams*, 383 U.S. 39 (1966) a companion case to *Graham*, the Court considered the obviousness of a “wet battery” that varied from prior designs in two ways: It contained water, rather than the acids conventionally employed in storage batteries; and its electrodes were magnesium and cuprous chloride, rather than zinc and silver chloride. The Court recognized that when a patent claims a structure already known in the prior art that is altered by the mere substitution of one element for another known in the field, the combination must do more than yield a predictable result. It nevertheless rejected the Government’s claim that Adams’s battery was obvious. The Court relied upon the corollary principle that when the prior art teaches away from combining certain known elements, discovery of a successful means of combining them is more likely to be nonobvious. When Adams designed his battery, the prior art warned that risks were involved in using the types of electrodes he employed. The fact that the elements worked together in an unexpected and fruitful manner supported the conclusion that Adams’s design was not obvious to those skilled in the art.

In *Anderson’s-Black Rock, Inc. v. Pavement Salvage Co.*, 396 U.S. 57 (1969) the Court elaborated on this approach. The subject matter of the patent before the Court was a device combining two preexisting elements: a radiant-heat burner and a paving machine. The device, the Court concluded, did not create some new synergy: The radiant-heat burner functioned just as a burner was expected to function; and the paving machine did the same. The two in combination did no more than they would in separate, sequential operation. In those circumstances, “while the combination of old elements performed a useful function, it added nothing to the nature and quality of the radiant-heat burner already patented,” and the patent failed under § 103.

Finally, in *Sakraida v. Ag Pro, Inc.*, 425 U.S. 273 (1976) the Court derived from the precedents the conclusion that when a patent “simply arranges old elements with each performing the same function it had been known to perform” and yields no more than one would expect from such an arrangement, the combination is obvious.

The principles underlying these cases are instructive when the question is whether a patent claiming the combination of elements of prior art is obvious. When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability. For the same reason, if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill. *Sakraida* and *Anderson's Black-Rock* are illustrative – a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions.

Following these principles may be more difficult in other cases than it is here because the claimed subject matter may involve more than the simple substitution of one known element for another or the mere application of a known technique to a piece of prior art ready for the improvement. Often, it will be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. To facilitate review, this analysis should be made explicit. As our precedents make clear, however, the analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.

B

When it first established the requirement of demonstrating a teaching, suggestion, or motivation to combine known elements in order to show that the combination is obvious, the Court of Customs and Patent Appeals captured a helpful insight. As is clear from cases such as *Adams*, a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. Although common sense directs one to look with care at a patent application that claims as innovation the combination of two known devices according to their established functions, it can be important to identify a reason that would have

prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. This is so because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.

Helpful insights, however, need not become rigid and mandatory formulas; and when it is so applied, the TSM test is incompatible with our precedents. The obviousness analysis cannot be confined by a formalistic conception of the words teaching, suggestion, and motivation, or by overemphasis on the importance of published articles and the explicit content of issued patents. The diversity of inventive pursuits and of modern technology counsels against limiting the analysis in this way. In many fields it may be that there is little discussion of obvious techniques or combinations, and it often may be the case that market demand, rather than scientific literature, will drive design trends. Granting patent protection to advances that would occur in the ordinary course without real innovation retards progress and may, in the case of patents combining previously known elements, deprive prior inventions of their value or utility.

C

One of the ways in which a patent's subject matter can be proved obvious is by noting that there existed at the time of invention a known problem for which there was an obvious solution encompassed by the patent's claims.

The first error of the Court of Appeals in this case was to foreclose this reasoning by holding that courts and patent examiners should look only to the problem the patentee was trying to solve. The Court of Appeals failed to recognize that the problem motivating the patentee may be only one of many addressed by the patent's subject matter. The question is not whether the combination was obvious to the patentee but whether the combination was obvious to a person with ordinary skill in the art. Under the correct analysis, any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed.

The second error of the Court of Appeals lay in its assumption that a person of ordinary skill attempting to solve a problem will be led only to those elements of prior art designed to solve the same problem. The primary purpose

of Asano was solving the constant ratio problem; so, the court concluded, an inventor considering how to put a sensor on an adjustable pedal would have no reason to consider putting it on the Asano pedal. Common sense teaches, however, that familiar items may have obvious uses beyond their primary purposes, and in many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle. Regardless of Asano's primary purpose, the design provided an obvious example of an adjustable pedal with a fixed pivot point; and the prior art was replete with patents indicating that a fixed pivot point was an ideal mount for a sensor. The idea that a designer hoping to make an adjustable electronic pedal would ignore Asano because Asano was designed to solve the constant ratio problem makes little sense. A person of ordinary skill is also a person of ordinary creativity, not an automaton.

The same constricted analysis led the Court of Appeals to conclude, in error, that a patent claim cannot be proved obvious merely by showing that the combination of elements was obvious to try. When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103.

III

When we apply the standards we have explained to the instant facts, claim 4 must be found obvious.

B

The District Court was correct to conclude that, as of the time Engelgau designed the subject matter in claim 4, it was obvious to a person of ordinary skill to combine Asano with a pivot-mounted pedal position sensor. There then existed a marketplace that created a strong incentive to convert mechanical pedals to electronic pedals, and the prior art taught a number of methods for achieving this advance. The Court of Appeals considered the issue too narrowly by, in effect, asking whether a pedal designer writing on a blank slate would have chosen both Asano and a modular sensor similar to the ones used in the Chevrolet truckline and disclosed in the '068 patent. The proper

question to have asked was whether a pedal designer of ordinary skill, facing the wide range of needs created by developments in the field of endeavor, would have seen a benefit to upgrading Asano with a sensor.

In automotive design, as in many other fields, the interaction of multiple components means that changing one component often requires the others to be modified as well. Technological developments made it clear that engines using computer-controlled throttles would become standard. As a result, designers might have decided to design new pedals from scratch; but they also would have had reason to make pre-existing pedals work with the new engines. Indeed, upgrading its own pre-existing model led KSR to design the pedal now accused of infringing the Engelgau patent.

For a designer starting with Asano, the question was where to attach the sensor. The consequent legal question, then, is whether a pedal designer of ordinary skill starting with Asano would have found it obvious to put the sensor on a fixed pivot point. The prior art discussed above leads us to the conclusion that attaching the sensor where both KSR and Engelgau put it would have been obvious to a person of ordinary skill.

The '936 patent taught the utility of putting the sensor on the pedal device, not in the engine. Smith, in turn, explained to put the sensor not on the pedal's footpad but instead on its support structure. And from the known wire-chafing problems of Rixon, and Smith's teaching that "the pedal assemblies must not precipitate any motion in the connecting wires," the designer would know to place the sensor on a nonmoving part of the pedal structure. The most obvious nonmoving point on the structure from which a sensor can easily detect the pedal's position is a pivot point. The designer, accordingly, would follow Smith in mounting the sensor on a pivot, thereby designing an adjustable electronic pedal covered by claim 4.

Just as it was possible to begin with the objective to upgrade Asano to work with a computer-controlled throttle, so too was it possible to take an adjustable electronic pedal like Rixon and seek an improvement that would avoid the wire-chafing problem. Following similar steps to those just explained, a designer would learn from Smith to avoid sensor movement and would come, thereby, to Asano because Asano disclosed an adjustable pedal with a fixed pivot.

Like the District Court, finally, we conclude Teleflex has shown no secondary factors to dislodge the determination that claim 4 is obvious. Proper application of Graham and our other precedents to these facts therefore leads to the conclusion that claim 4 encompassed obvious subject matter. As a result, the claim fails to meet the requirement of § 103.

IV

We build and create by bringing to the tangible and palpable reality around us new works based on instinct, simple logic, ordinary inferences, extraordinary ideas, and sometimes even genius. These advances, once part of our shared knowledge, define a new threshold from which innovation starts once more. And as progress beginning from higher levels of achievement is expected in the normal course, the results of ordinary innovation are not the subject of exclusive rights under the patent laws. Were it otherwise patents might stifle, rather than promote, the progress of useful arts.

Case: Titanium Metals v. Banner (nonobviousness excerpt)

Note: A longer excerpt appeared previously in the chapter on patent novelty. This edited case text obtained/adapted from James Grimmelmann's Patterns of Information Law. See notes on editing, licensing etc. at the end of this chapter.

Titanium Metals Corp. of America v. Banner

U.S. Court of Appeals for the Federal Circuit
778 F.2d 775 (Fed. Cir. 1985)

Little more need be said in support of the examiner's rejection of claim 3, affirmed by the board, on the ground that its more specific subject matter would have been obvious at the time the invention was made from the knowledge disclosed in the reference.

As admitted by appellee's affidavit evidence from James A. Hall, the Russian article discloses two alloys having compositions very close to that of claim 3, which is 0.3% Mo and 0.8% Ni, balance titanium. The two alloys in the prior art have 0.25% Mo-0.75% Ni and 0.31% Mo-0.94% Ni, respectively. The proportions are so close that prima facie one skilled in the art would have expected them to have the same properties. Appellee produced no evidence to

rebut that prima facie case. The specific alloy of claim 3 must therefore be considered to have been obvious from known alloys.

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The following was written by Eric E. Johnson:

This chapter P-5, “Patent Nonobviousness,” was put together by Eric E. Johnson. It uses edited case readings from using a swath of text from *Patterns of Information Law: Intellectual Property Done Right* (version 1.1, August 2017) authored by **James Grimmelmann**.

Regarding CRS text, see “Editing Notes” section at the beginning of the volume on editing of CRS materials.

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–EEJ

P-6: Patent Disclosure

by James Grimmelmann

This chapter is the writing of James Grimmelmann, taken from his book *Patterns of Information Law: Intellectual Property Done Right* (version 1.1, August 2017). It has been lightly edited, but not combined with other sources. It is all his work.

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35 U.S.C. § 112(a). Specification, in general.

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.

Explanation

[Section 112(a)’s] language has been interpreted by the courts to create three distinct disclosure requirements: *enablement*, *written description*, and *best mode*. Of the three, enablement is the most practically significant.

Enablement

O'Reilly v. Morse

Supreme Court of the United States
56 U.S. 62 (1853)

[Morse sued O'Reilly for infringing his patent on the telegraph. The Supreme Court found that Morse was the inventor of the technology and found that O'Reilly's "Columbian Telegraph" infringed. But it narrowed Morse's patent by striking its now-famous eighth claim:]

Eighth. I do not propose to limit myself to the specific machinery or parts of machinery described in the foregoing specification and claims; the essence of my invention being the use of the motive power of the electric or galvanic current, which I call electro-magnetism, however developed for marking or printing intelligible characters, signs, or letters, at any distances, being a new application of that power of which I claim to be the first inventor or discoverer.

It is impossible to misunderstand the extent of this claim. He claims the exclusive right to every improvement where the motive power is the electric or galvanic current, and the result is the marking or printing intelligible characters, signs, or letters at a distance.

If this claim can be maintained, it matters not by what process or machinery the result is accomplished. For aught that we now know some future inventor, in the onward march of science, may discover a mode of writing or printing at a distance by means of the electric or galvanic current, without using any part of the process or combination set forth in the plaintiff's specification. His invention may be less complicated—less liable to get out of order—less expensive in construction, and in its operation. But yet if it is covered by this patent the inventor could not use it, nor the public have the benefit of it without the permission of this patentee.

Nor is this all, while he shuts the door against inventions of other persons, the patentee would be able to avail himself of new discoveries in the properties and powers of electro-magnetism which scientific men might bring to light. For he says he does not confine his claim to the machinery or parts of machinery, which he specifies; but claims for himself a monopoly in its use, however developed, for the purpose of printing at a distance. New discoveries

in physical science may enable him to combine it with new agents and new elements, and by that means attain the object in a manner superior to the present process and altogether different from it. And if he can secure the exclusive use by his present patent he may vary it with every new discovery and development of the science, and need place no description of the new manner, process, or machinery, upon the records of the patent office. And when his patent expires, the public must apply to him to learn what it is. In fine he claims an exclusive right to use a manner and process which he has not described and indeed had not invented, and therefore could not describe when he obtained his patent. The court is of opinion that the claim is too broad, and not warranted by law.

Case: Wyeth & Cordis v. Abbott Labs

Wyeth & Cordis Corp. v. Abbott Labs

U.S. Court of Appeals for the Federal Circuit
720 F.3d 1380 (Fed. Cir. 2013)

Wyeth and Cordis Corporation (Wyeth) appeal from the U.S. District Court for the District of New Jersey’s grant of summary judgment that claims 1 and 2 of U.S. Patent No. 5,516,781 (’781 patent) and claim 1 of U.S. Patent No. 5,563,146 (’146 patent) are invalid for nonenablement. Because we hold that there is no genuine issue of material fact that the specification does not enable one of ordinary skill to practice the asserted claims without undue experimentation, we affirm.

Background

The patents-in-suit relate to the use of rapamycin for the treatment and prevention of restenosis, which is the renarrowing of an artery. To open a blocked artery, a physician guides a balloon catheter to the site of accumulated plaque, and then inflates the balloon to crush the plaque. As the balloon inflates, however, it may cause injury to the arterial wall. That vascular injury causes smooth muscle cells to proliferate, which thickens the arterial wall, and, in turn, leads to restenosis.

The claims recite a method of treating or preventing “restenosis in a mammal ... which comprises administering an antirestenosis effective amount of rapamycin to said mammal.” In general, “rapamycin” may refer to a class of compounds. While the patents-in-suit use the term “rapamycin,” the parties

agree that the shared specification discloses only one rapamycin species called sirolimus. Sirolimus is naturally produced by a bacterium called *Streptomyces hygroscopicus*. [Sirolimus's chemical structure has two relevant features: a "macro-cyclic triene ring" and a specific "substituent group."]

The parties do not dispute that the effective filing date of both patents is January 9, 1992. At that time, it was known that sirolimus acts in part by binding two proteins at sites within the macrocyclic ring. It was also known that there were four additional compounds with the same macrocyclic ring as sirolimus, but different substituent groups.

The parties also do not dispute that the specification discloses the immunosuppressive and antirestenotic properties of sirolimus. The specification discloses *in vitro* test data indicating that sirolimus inhibits rat smooth muscle cell proliferation. It also discloses *in vivo* test data indicating that intraperitoneal injection of sirolimus in rats reduced the thickening of the arterial wall following vascular injury.

In two separate actions, Wyeth sued the defendants for infringement of the patents-in-suit. The defendants market stent products that elute everolimus and zotarolimus, two drugs that have the same macrocyclic ring as sirolimus but different [substituent groups]. After briefing and a hearing, the district court adopted Wyeth's proposed construction of "rapamycin" as "a compound containing a macrocyclic triene ring structure produced by *Streptomyces hygroscopicus*, having immuno-suppressive and anti-restenotic effects." Based in part on that construction, the court granted defendants' joint motions for summary judgment of invalidity for nonenablement and lack of written description.

Discussion

I.

A patent's specification must describe the invention and "the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains ... to make and use the same." 35 U.S.C. § 112(a). Claims are not enabled when, at the effective filing date of the patent, one of ordinary skill in the art could not practice their full scope without undue experimentation.

II.

The central issue on appeal is whether practicing the full scope of the claims requires excessive—and thus undue—experimentation. The district court held that it does. It found that the claims cover any structural analog of sirolimus that exhibits immunosuppressive and antirestenotic effects. The court also found that, while the specification describes assays to ascertain whether a potential rapamycin compound exhibits the recited functional effects, the only species disclosed is sirolimus. In further support of its holding of nonenablement, the court relied on the unpredictability of the chemical arts, the complexity of the invention, and the limited knowledge of treatment of restenosis using sirolimus at the time of the invention.

Wyeth argues that the district court ignored evidence that practicing the full scope of the claims would have required only routine experimentation. First, a skilled artisan could ascertain whether a candidate rapamycin compound has the same macrocyclic ring as sirolimus. Second, a skilled artisan could routinely determine whether a candidate has immunosuppressive and antirestenotic effects using the assays disclosed in the specification.

Regarding the amount of experimentation, Wyeth acknowledges that one of its experts testified that there could be millions of compounds made by varying the substituent groups outside of sirolimus's macrocyclic ring. Wyeth counters that the same expert testified that the number of compounds that would exhibit the recited functional effects would be significantly smaller. [Wyeth's expert argued that a PHOSITA would have known that only compounds permeable across cell membranes, typically having molecular weights below 1,200 Daltons would need to be considered. For purposes of summary judgment, the court accepted this claim as true, and also the claim that the assays would effectively confirm whether a candidate compound had the desired immunosuppressive and antirestenotic effects.]

We agree with Appellees and the district court that there is no genuine dispute that practicing the full scope of the claims, measured at the time of filing, would require excessive experimentation. The scope of the claims at issue is broad. Under the district court's unchallenged construction of "rapamycin," the invention is a new method of use of a known compound (sirolimus) and any other compounds that meet the construction's structural and functional requirements. We also agree that there is no genuine dispute

that the specification's guidance is limited to disclosures of the immunosuppressive and antirestenotic properties of sirolimus and assays to screen for those properties.

Yet, even accepting Wyeth's assertions, we find no genuine dispute that practicing the full scope of the claims would require more than routine experimentation for two reasons.

First, there is no dispute that, even if potential rapamycin compounds must have a molecular weight below 1,200 Daltons, there are still at least tens of thousands of candidates. The specification is silent about how to structurally modify sirolimus, let alone in a way that would preserve the recited utility. Second, there is no genuine dispute that it would be necessary to first synthesize and then screen each candidate compound using the assays disclosed in the specification to determine whether it has immunosuppressive and antirestenotic effects. There is no evidence in the record that any particular substitutions outside of the macrocyclic ring are preferable. Indeed, a Wyeth scientist confirmed the unpredictability of the art and the ensuing need to assay each candidate by testifying that, "until you test [compounds], you really can't tell whether they work or not [i.e., have antirestenotic effects]." In sum, there is no genuine dispute that practicing the full scope of the claims would require synthesizing and screening each of at least tens of thousands of compounds.

The remaining question is whether having to synthesize and screen each of at least tens of thousands of candidate compounds constitutes undue experimentation. We hold that it does. Undue experimentation is a matter of degree. Even a considerable amount of experimentation is permissible, as long as it is merely routine or the specification provides a reasonable amount of guidance regarding the direction of experimentation. Yet, routine experimentation is not without bounds.

Our cases have described limits on permissible experimentation in the context of enablement. For example, in *ALZA Corp. v. Andrx Pharmaceuticals, LLC*, 603 F.3d 935 (Fed. Cir. 2010) we affirmed a judgment of nonenablement where the specification provided "only a starting point, a direction for further research." We concluded that one of ordinary skill "would have been required to engage in an iterative, trial-and-error process to practice the claimed invention even with the help of the specification." Finally,

in *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991) we affirmed the PTO's nonenablement rejection of claims reciting heterologous gene expression in as many as 150 genera of cyanobacteria. The specification disclosed only nine genera, despite cyanobacteria being a "diverse and relatively poorly understood group of microorganisms," with unpredictable heterologous gene expression. Here, the specification similarly discloses only a starting point for further iterative research in an unpredictable and poorly understood field. Synthesizing candidate compounds derived from sirolimus could, itself, require a complicated and lengthy series of experiments in synthetic organic chemistry. Even putting the challenges of synthesis aside, one of ordinary skill would need to assay each of at least tens of thousands of candidates. Wyeth's expert conceded that it would take technicians weeks to complete each of these assays. The specification offers no guidance or predictions about particular substitutions that might preserve the immunosuppressive and antirestenotic effects observed in sirolimus. The resulting need to engage in a systematic screening process for each of the many rapamycin candidate compounds is excessive experimentation. We thus hold that there is no genuine dispute that practicing the full scope of the claims, measured at the filing date, required undue experimentation.

Plastic Dye Problem

You are drafting claims for a patent application for an industrial dye that turns certain plastics an attractive shade of blue. Your client has tested it, with success, on PETE, HDPE, PEEK, and PVDC (all semi-crystalline plastics). You could draft a broad claim that refers to "plastic" or you could draft a narrow claim that refers to "a plastic selected from the group of PETE, HDPE, PEEK, and PVDC." What are the advantages and disadvantages of each approach?

Written Description

Case: Ariad Pharmaceuticals v. Eli Lilly

Ariad Pharmaceuticals, Inc. v. Eli Lilly and Co.

U.S. Court of Appeals for the Federal Circuit
598 F.3d 1336 (Fed. Cir. 2010) (en banc)

Since its inception, this court has consistently held that § 112, first paragraph, contains a written description requirement separate from enablement, and we have articulated a fairly uniform standard, which we now affirm. Specifically, the description must clearly allow persons of ordinary skill in the art to recognize that the inventor invented what is claimed. In other words, the test for sufficiency is whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date.

The term “possession,” however, has never been very enlightening. It implies that as long as one can produce records documenting a written description of a claimed invention, one can show possession. But the hallmark of written description is disclosure. Thus, “possession as shown in the disclosure” is a more complete formulation. Yet whatever the specific articulation, the test requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art. Based on that inquiry, the specification must describe an invention understandable to that skilled artisan and show that the inventor actually invented the invention claimed.

We have made clear that the written description requirement does not demand either examples or an actual reduction to practice; a constructive reduction to practice that in a definite way identifies the claimed invention can satisfy the written description requirement. Conversely, we have repeatedly stated that actual “possession” or reduction to practice outside of the specification is not enough. Rather, as stated above, it is the specification itself that must demonstrate possession. And while the description requirement does not demand any particular form of disclosure, or that the specification recite the claimed invention *in haec verba*, a description that merely renders the invention obvious does not satisfy the requirement.

Best Mode

MPEP on Best Mode

*From the USPTO's **Manual of Patent Examining Procedure** (rev. Nov. 2013).*

§ 2165 The Best Mode Requirements

The best mode requirement is a safeguard against the desire on the part of some people to obtain patent protection without making a full disclosure as required by the statute. The requirement does not permit inventors to disclose only what they know to be their second-best embodiment, while retaining the best for themselves.

Determining compliance with the best mode requirement requires a two-prong inquiry. First, it must be determined whether, at the time the application was filed, the inventor possessed a best mode for practicing the invention. This is a subjective inquiry which focuses on the inventor's state of mind at the time of filing. Second, if the inventor did possess a best mode, it must be determined whether the written description disclosed the best mode such that a person skilled in the art could practice it. This is an objective inquiry, focusing on the scope of the claimed invention and the level of skill in the art. All applicants are required to disclose for the claimed subject matter the best mode contemplated by the inventor even if the inventor was not the discoverer of that mode.

Failure to disclose the best mode need not rise to the level of active concealment or inequitable conduct in order to support a rejection. Where an inventor knows of a specific material or method that will make possible the successful reproduction of the claimed invention, but does not disclose it, the best mode requirement has not been satisfied.

Section 15 of the Leahy-Smith America Invents Act (AIA) did not eliminate the requirement for a disclosure of the best mode, but effective September 16, 2011, it amended 35 U.S.C. 282 (the provision that sets forth defenses in a patent validity or infringement proceeding) to provide that the failure to disclose the best mode shall not be a basis on which any claim of a patent may be canceled or held invalid or otherwise unenforceable. As this change is applicable only in patent validity or infringement proceedings, it does not alter current patent examining practices as set forth above for

evaluation of an application for compliance with the best mode requirement of 35 U.S.C. 112.

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P-7: Patent Infringement

This chapter was authored by Eric E. Johnson.
Please see “Rights, Licensing, Etc.” at the end
of this chapter.

Key Points About Infringement

Section 271 provides a cause of action for patent infringement against whomever “makes, uses, offers to sell, or sells ... or imports” any invention covered by an unexpired patent.

The tangible thing that sits at the center of controversy—the thing that defendant made, used, offered for sale, sold, or imported—is commonly called the “accused product.” (For convenience, I’ll talk about infringement with regard to accused products. Of course, many patent claims are directed to methods. But the situation is the same either way.)

While it’s common to say “patent infringement,” a patent owner doesn’t really sue on the basis that the *patent* is infringed. Rather, an action for infringement is based on the allegation that the defendant has infringed one or more of the patent’s *claims*. In infringement litigation, each claim is an independent basis for liability, and each claim sets out its own test for infringement. The plaintiff must show that the accused product has each element (or “limitation”) of a claim. The phrase “reads on” is sometimes used to describe this. So one might say that infringement requires that the accused product reads on each element of a claim.

The regular, ordinary infringement allegation is based on what is called “literal infringement,” where the plaintiff must prove by a preponderance of the evidence that the defendant’s accused product literally and exactly includes each element of the sued-upon claim.

If literal infringement won’t work because one or more elements are not literally and exactly included in the accused product, then a plaintiff can try to

use the so-called *doctrine of equivalents*. To use the doctrine of equivalents on a given claim element, the plaintiff must show that the accused product has the “substantial equivalent” of that element—meaning that it performs substantially the same function in substantially the same way so as to produce substantially the same result.

Patent litigation defense for a given claim generally proceeds along two paths: (1) pointing out that the accused product does not read on at least one element of the claim; (2) showing that the claim at issue is invalid.

Invalidity is an affirmative defense. The plaintiff is entitled to the presumption that all claims of patent are valid, since the USPTO has approved them in the examination process. But defendants can attempt to persuade the jury that the USPTO’s determination was incorrect. For instance, the defendant might uncover a piece of prior art that the USPTO’s examiner didn’t consider, and the defendant can then argue that this newly found piece of prior art is anticipating. A claim that is anticipated by a prior art reference is not novel, and is thus invalid.

An invalidity defense could be attempted against an entire patent, but it typically is pursued as needed on a claim-by-claim basis. So, for example, if sued on three claims, a defendant can win the lawsuit by invalidating the first claim on novelty grounds, invalidating the second claim as obvious, and showing that the accused product doesn’t read on one of the elements of the third claim.

CRS on Patent Rights, Appeals, and Infringement

Adapted from Congressional Research Service, Patent Law: A Handbook for Congress, R46525, September 16, 2020. (See “Editing Notes” section at the beginning of the volume on editing of CRS materials.)

Rights Conferred by a Patent

A patent confers certain legal rights on its owner. Specifically, the patent owner may exclude others from making, using, importing, offering for sale, or selling the invention (collectively, “practicing the invention”). Notably, the patent includes only *negative* rights to *exclude* others from practicing the invention; the patent grant does not include the positive right for the patent owner to do so. In other words, a patent allows the owner to prevent others from making, using, importing, offering for sale, or selling the invention, but

does not give the patent owner the power to perform those acts affirmatively. In some circumstances, a patented invention when practiced in a particular manner may itself infringe another patent. The infringed patent is referred to as a *blocking patent* because it blocks practice of the patented invention. Blocking patents may arise, for example, when a patent's claims are directed to an improvement on another patented invention. In that case, the original patent may "block" practice of the patent on the improvement.

The exclusive rights granted by the patent begin on the date that the patent issues, and generally expire twenty years from the date that the patent application was filed with the PTO. The patent term may be extended under certain circumstances; for example, to compensate for time spent in regulatory review (such as before the Food and Drug Administration (FDA) in the context of pharmaceutical patents) or for delays due to certain PTO procedural failures.

Patents "have the attributes of personal property." Accordingly, although title in an invention initially vests with the inventor, that interest may be transferred or assigned to others. It is common for employment contracts to include provisions under which an employee assigns his interest in any patents developed in the course of employment to the employer. Similarly, patents may be sold from one party to another. A patent owner may also form a contract with another party permitting the other party to make, use, import, or sell a patented invention in return for compensation (e.g., a lump sum payment or a continuing royalty). Such a contract is referred to as a *license*.

Patent Appeals

Unlike most cases in federal court, appeals involving patent law are heard by a single appellate court—the U.S. Court of Appeals for the Federal Circuit (Federal Circuit). (Appeals from decisions of U.S. district courts in most nonpatent cases are heard by the various U.S. Courts of Appeals for different geographical regions or circuits.) Sitting in Washington, DC, Congress created the Federal Circuit in 1982 in an effort to unify and standardize patent law. Although the Supreme Court left the Federal Circuit's interpretations of patent law essentially undisturbed during the first two decades of the Federal Circuit's existence, in recent years the Supreme Court has taken more interest in patent law cases. In many of those cases, the Supreme Court has reversed the Federal Circuit's interpretation of patent law. Nevertheless, Federal Circuit

decisions play a large role in the acquisition and enforcement of patent rights in the United States.

Proving Patent Infringement

Patent infringement primarily takes two forms: *direct infringement*, where a party itself makes, uses, imports, sells, or offers to sell a patented invention without authorization; and *indirect infringement*, where a party in some culpable way causes direct infringement by another.

Direct Infringement

A party directly infringes a patent by itself making, using, importing, selling, or offering for sale the claimed invention. To determine whether a party infringes, the patent claims are construed and then compared to the product or method accused of infringement. There are two ways a patentee can prove that an element of an accused product or method meets a patent claim limitation. First, an element of an accused product or method may exactly match (or “meet”) the claim limitation. This is referred to as an element “literally” meeting the claim limitation. For example, if the limitation at issue requires a wooden doorknob and the accused product includes a wooden doorknob, the accused product literally meets the limitation.

An element may also meet a claim limitation under the *doctrine of equivalents*; in other words, even if the accused product or method does not literally meet a claim limitation, that limitation may be met if the accused product or method includes an element that is equivalent to the claim limitation. Under the doctrine of equivalents, an element is equivalent to a claim limitation if it performs the same function, in the same way, to reach the same result. For example, if the limitation at issue requires a wooden doorknob and the accused product includes a steel doorknob, the accused product would not *literally* meet that claim limitation, but might meet the limitation under the doctrine of equivalents.

Indirect Infringement

Indirect infringement refers to conduct where a party does not itself directly infringe a patent, but causes another party to infringe directly. There are two main types of indirect infringement: *induced infringement* and *contributory infringement*.

Induced Infringement

Under the patent statute, “[w]hoever actively induces infringement of a patent shall be liable as an infringer.” To induce infringement, a party must take an affirmative action to encourage another to perform direct infringement of a patent, knowing that those actions would constitute infringement. Thus, a finding of induced infringement requires proof that “(1) a third party directly infringed the asserted claims of the ... patents; (2) [the defendant] induced those infringing acts; and (3) [the defendant] knew the acts it induced constituted infringement.”

Contributory Infringement

Broadly speaking, contributory infringement bars selling or importing a material component of a patented invention, where the component has no substantial noninfringing use. To prove contributory infringement, a patent owner must prove (1) “that there is direct infringement”; (2) “that the accused infringer had knowledge of the patent”; (3) “that the component has no substantial noninfringing uses”; and (4) “that the component is a material part of the invention.”

Enforcing a Patent

Patent owners can enforce their patents in two main ways. First, the patent owner may file a civil action in a federal district court alleging direct or indirect patent infringement. Second, if the patent owner believes that another party is importing articles that infringe its patent, it may file a complaint in the International Trade Commission.

District Court Enforcement

The primary method of patent enforcement is to file a civil action in federal district court. The process begins when a patent owner files a complaint alleging that another person has infringed its patent. Generally speaking, the three primary issues in district court litigation will be *claim construction*, *infringement*, and *validity*. For claim construction, the parties will litigate any disputed patent claim constructions—that is, the manner in which a patent claim is interpreted—and the assigned judge will issue an order ruling how the disputed claim terms will be construed. Following claim construction by the judge, whether the accused product(s) infringe the patent claims, as construed by the judge, is

generally tried to a jury. In defense, the party accused of infringement may argue that the patent did not, in fact, meet the statutory requirements for patenting when it issued. This is referred to as an argument that the patent is “invalid.” Because an invalid patent is not legally enforceable, a judgment that the patent is invalid will lead to a finding of no liability. The issue of invalidity is also typically tried to a jury.

If the jury finds that the patent is infringed and not invalid, then the patent owner is entitled to a remedy. Available remedies include money damages and a court order that the infringer cease infringement (an “injunction”). The minimum amount of money damages is a “reasonable royalty,” generally set at the amount that the parties would have agreed to for the infringer to license the patent at the time infringement began. In certain circumstances, the patent owner may also be entitled to recover any profits she can prove were lost due to the infringement. If the infringing behavior was “egregious,” moreover, then the damages award may be increased up to triple the amount awarded by the jury. To receive an injunction, a patentee must prove (1) that it has suffered an irreparable injury; (2) that monetary damages are inadequate to compensate for that injury; (3) that the balance of hardships favors an injunction; and (4) that an injunction is in the public interest.

In “exceptional” cases, the trial judge may also, in her discretion, award the prevailing party its attorney’s fees. The Supreme Court has held that an exceptional case is one that “stands out from others with respect to the substantive strength of a party’s litigating position (considering both the governing law and the facts of the case) or the unreasonable manner in which the case was litigated.”

International Trade Commission Enforcement

The U.S. International Trade Commission (ITC)—an independent federal agency—administers Section 337 of the Tariff Act of 1930 (Section 337), among other statutes, which allows it to “investigate and issue decisions on unfair methods of competition and unfair acts in the importation and/or sale of imported articles.” Section 337 establishes that the importation into, or sale within the United States of articles that infringe a valid U.S. patent, copyright, or trademark are unlawful actions the ITC may address. Although Section 337 investigations are not limited to behavior arising from IP, in

recent years many such investigations “have focused on either patent, unregistered trademark, or trade secret claims.”

Section 337 investigations are somewhat similar to civil infringement actions in district court, with some important differences. Unlike infringement actions in district court, where the court primarily adjudicates disputes between the parties, in Section 337 investigations the ITC itself investigates whether there were unfair methods of competition or unfair acts in importation. Thus, an investigative attorney from the ITC’s Office of Unfair Import Investigations participates as a party in the process, along with the complainant and respondent. ~

Section 337 investigations are evaluated based on the complaint filed by a private party.~ If a Section 337 violation is established, possible remedies include (1) a general exclusion order, which forbids importation of products regardless of the source; (2) a limited exclusion order, which forbids importation of those products by specific companies designated in the complaint; (3) cease-and-desist orders that enjoin activities by U.S. entities; (4) temporary exclusion or cease-and-desist orders during the pendency of the investigation; and (5) consent orders, where the parties agree to an outcome. The U.S. President may disapprove any exclusion or cease-and-desist order within sixty days of issuance; if he does not, then the order goes into effect.

Case: Larami v. Amron

[Editing notes: Ellipses are indicated with a superscript tilde (~). Footnotes, citations, and portions of citations were removed without indication. Paragraph indentation or lack thereof was done for this edit and is not a reflection of the original. The all-caps phrase “SUPER SOAKER” was changed to “Super Soaker” for readability. -EE]]

Larami Corp. v. Amron

U.S. District Court for the Eastern District of Pennsylvania
27 U.S.P.Q.2d 1280 (E.D. Pa. 1993)

Judge Lowell A. REED, Jr.:

This is a patent case concerning toy water guns manufactured by plaintiff Larami Corporation (“Larami”). Currently before me is Larami’s motion for partial summary judgment of noninfringement of United States Patent No. 4,239,129 (“the ’129 patent”) (Document No. 23).~

I. BACKGROUND

Larami manufactures a line of toy water guns called “Super Soakers.”~ All use a hand-operated air pump to pressurize water and a “pinch trigger” valve mechanism for controlling the ejection of the pressurized water. All feature detachable water reservoirs prominently situated outside and above the barrel of the gun.~

Defendants Alan Amron and Talk To Me Products, Inc. (hereinafter referred to collectively as “TTMP”) claim that the Super Soaker guns infringe on the ’129 patent which TTMP obtained by assignment from Gary Esposito (“Esposito”), the inventor. The ’129 patent covers a water gun which, like the Super Soakers, operates by pressurizing water housed in a tank with an air pump. In the ’129 patent, the pressure enables the water to travel out of the tank through a trigger-operated valve into an outlet tube and to squirt through a nozzle. Unlike the Super Soakers, the ’129 patent also contains various electrical features to illuminate the water stream and create noises. Also, the water tank in the ’129 patent is not detachable, but is contained within a housing in the body of the water gun.

The “Background of the Invention” contained in the ’129 patent reads as follows:

Children of all ages, especially boys, through the years have exhibited a fascination for water, lights and noise and the subject invention deals with these factors embodied in a toy simulating a pistol.

An appreciable number of U.S. patents have been issued which are directed to water pistols but none appear to disclose a unique assemble of components which can be utilized to simultaneously produce a jet or stream of water, means for illuminating the stream and a noise, or if so desired, one which can be operated without employing the noise and stream illuminating means. A reciprocal pump is employed to obtain sufficient pressure whereby the pistol can eject a stream an appreciable distance in the neighborhood of thirty feet and this stream can be illuminated to more or less simulate a lazer [sic] beam.

A diagram adapted from the ’129 patent illustrating its design is attached hereto as Diagram A. Also, diagrams illustrating four of the Super Soakers are attached hereto: Diagram B illustrates the design of Super Soakers 30 and 50, and Diagram C illustrates the design of Super Soakers 100 and 200.

Larami brought this action seeking a declaration that the “Super Soaker” does not infringe the ’129 patent (Count I).

Larami has moved for partial summary judgment of noninfringement of the ’129 patent (Count I).

II. DISCUSSION

A. *Summary Judgment Standard*

Summary judgment is as appropriate in a patent case as it is in any other. In this case, Larami seeks a declaratory judgment that the Super Soaker water guns do not infringe the ’129 patent. At trial, the patent holder would have the burden of proving infringement by a preponderance of the evidence. *Intellicall, Inc. v. Phonometrics, Inc.*, 952 F.2d 1384, 1389 (Fed. Cir.1992). Accordingly, on this motion for partial summary judgment, Larami need only point out the absence of evidence supporting a finding of infringement. *Id.* To resist this motion, TTMP must then come forward with specific evidence showing that there is a genuine issue of material fact for trial as to whether the ’129 patent is infringed. *Id.*

B. *Infringement and Claim Interpretation*

A patent owner’s right to exclude others from making, using or selling the patented invention is defined and limited by the language in that patent’s claims. Thus, establishing infringement requires the interpretation of the “elements” or “limitations” of the claim and a comparison of the accused product with those elements as so interpreted. *Key Mfg. Group, Inc. v. Microdot, Inc.*, 925 F.2d 1444, 1448 (Fed. Cir.1991). Because claim interpretation is a question of law, it is amenable to summary judgment.

The words in a claim should be given their “ordinary or accustomed” meaning. An inventor’s interpretations of words in a claim that are proffered after the patent has issued for purposes of litigation are given no weight. *Id.*; *Lear Siegler, Inc. v. Aeroquip Corp.*, 733 F.2d 881, 889 (Fed. Cir.1984) (“The litigation-induced pronouncements of [the inventor] ... have no effect on what the words of [the patent] in fact do convey and have conveyed during its term to the public.”), *quoted in Intellicall*, 952 F.2d at 1388.

A patent holder can seek to establish patent infringement in either of two ways: by demonstrating that every element of a claim (1) is literally infringed or (2) is infringed under the doctrine of equivalents. To put it a different way,

because every element of a claim is essential and material to that claim, a patent owner must, to meet the burden of establishing infringement, “show the presence of every element *or* its substantial equivalent in the accused device.” *Key Mfg. Group, Inc.*, 925 F.2d at 1447 (emphasis added). If even *one* element of a patent’s claim is missing from the accused product, then “[t]here can be no infringement as a matter of law ...” *London v. Carson Pirie Scott & Co.*, 946 F.2d 1534, 1538–39 (Fed. Cir.1991).

Larami contends, and TTMP does not dispute, that twenty-eight (28) of the thirty-five (35) claims in the ’129 patent are directed to the electrical components that create the light and noise. Larami’s Super Soaker water guns have no light or noise components. Larami also contends, again with no rebuttal from TTMP, that claim 28 relates to a “poppet valve” mechanism for controlling the flow of water that is entirely different from Larami’s “pinch trigger” mechanism. Thus, according to Larami, the six remaining claims (claims 1, 5, 10, 11, 12 and 16) are the only ones in dispute. Larami admits that these six claims address the one thing that the Super Soakers and the ’129 patent have in common—the use of air pressure created by a hand pump to dispense liquid. Larami argues, however, that the Super Soakers and the ’129 patent go about this task in such fundamentally different ways that no claim of patent infringement is sustainable as a matter of law.

In its memorandum of law in opposition to Larami’s motion for partial summary judgment, TTMP points to evidence to support its assertion that only Super Soaker 20 literally infringes claim 1 and that Super Soakers 20, 30, 50, 100 and 200 infringe claim 10 under the doctrine of equivalents. TTMP has neither produced nor referred to evidence contradicting facts averred by Larami on all other claims of the ’129 patent. I conclude, therefore, that TTMP has not met its burden of coming forward with specific evidence showing that there is a genuine issue of material fact as to these claims. Accordingly, this memorandum will address only claims 1 and 10.

1. *Literal Infringement of Claim 1*

TTMP claims that Super Soaker 20 literally infringes claim 1 of the ’129 patent. Claim 1 describes the water gun as:

[a] toy comprising an elongated housing [case] having a chamber therein for a liquid [tank], a pump including a piston having an exposed rod [piston rod] and extending rearwardly of said toy

facilitating manual operation for building up an appreciable amount of pressure in said chamber for ejecting a stream of liquid therefrom an appreciable distance substantially forwardly of said toy, and means for controlling the ejection.

U.S. Patent No. 4,239,129 (bracketed words supplied).

Claim 1 requires, among other things, that the toy gun have “an elongated housing having a chamber therein for a liquid.” The Super Soaker 20 water gun, in contrast, has an external water reservoir (chamber) that is detachable from the gun housing, and not contained within the housing. TTMP argues that Super Soaker 20 contains a “chamber therein for a liquid” *as well as* a detachable water reservoir. It is difficult to discern from TTMP’s memorandum of law exactly where it contends the “chamber therein” is located in Super Soaker 20. Furthermore, after having examined Super Soaker 20, I find that it is plain that there is no “chamber” for liquid contained within the housing of the water gun. The only element of Super Soaker 20 which could be described as a “chamber” for liquid is the external water reservoir located atop the housing. Indeed, liquid is located within the housing only when the trigger causes the liquid to pass from the external water reservoir through the tubing in the housing and out of the nozzle at the front end of the barrel. Super Soaker 20 itself shows that such a transitory avenue for the release of liquid is clearly not a “chamber therein for liquid.” Therefore, because the absence of even one element of a patent’s claim from the accused product means there can be no finding of literal infringement, *London*, 946 F.2d at 1538–39, I find that Super Soaker 20 does not infringe claim 1 of the ’129 patent as a matter of law.

2. Infringement by Equivalents of Claim 10

TTMP claims that all five of the Super Soaker water guns infringe claim 10 of the ’129 patent. Claim 10 describes the arrangement of several components of the water gun as follows:

A toy simulating a pistol comprising wall structure forming an elongated barrel of appreciable cross-section dimensions [case], a tank in the barrel for a liquid [water tank] and a hollow handle, a cylinder disposed axially in said tank and provided with a check valve, a piston mounted in said cylinder for manual reciprocation for pumping air into said tank [air pump], conduit means [discharge tube] connected

to said tank and having an outlet located at the front of said barrel [outlet nozzle], valve means interposed in said conduct means, and a trigger operable independently of said piston carried by said handle for operating said valve means [trigger-operated valve] for controlling the forced flow of liquid through said outlet.

U.S. Patent No. 4,239,129 (bracketed words supplied; *see* Diagram A, the '129 patent, attached hereto).

To show infringement under the doctrine of equivalents, the patent owner bears the burden of proving that the accused product has the “substantial equivalent” of *every* limitation or element of a patent claim. *Intellicall*, 952 F.2d at 1389. Put another way, the patent owner must show that the accused product “performs substantially the same overall function or work, in substantially the same way, to obtain substantially the same overall result as the claimed invention.” *Wilson Sporting Goods Co. v. David Geoffrey & Assoc.*, 904 F.2d 677, 683 (Fed. Cir.1990) (quoting *Pennwalt Corp. v. Durand-Wayland, Inc.*, 833 F.2d 931, 934 (Fed. Cir.1987)).

The doctrine of equivalents is used to hinder “the ‘unscrupulous copyist’ who could otherwise imitate a patented invention as long as [s/he] was careful not to copy every inconsequential detail of the claimed inventions, or to make some ‘unimportant and insubstantial’ change to the claimed invention.” *Lear Siegler, Inc. v. Sealy Mattress Company*, 873 F.2d 1422, 1425 (Fed. Cir.1989). The doctrine is reserved for the exceptional case. As the U.S. Court of Appeals for the Federal Circuit, recently stated:

[I]f the public comes to believe (or fear) that the language of patent claims can never be relied on, and that the doctrine of equivalents is simply the second prong of every infringement charge, regularly available to extend protection beyond the scope of the claims, then claims will cease to serve their intended purpose. Competitors will never know whether their actions infringe a granted patent.

London, 946 F.2d at 1538. Thus, failure to produce evidence on any one of a claim’s elements can result in a grant of summary judgment against the patent owner on the infringement claim.

Claim 10 of the '129 patent has been previously litigated in *Talk To Me Products, Inc. v. Lanard Toys, Inc.*, 1992 U.S. Dist. LEXIS 20706 (E.D.N.Y. Dec. 18 1992). In that case, as here, TTMP argued that

[c]laim 10 “defines” a novel relationship among three components to any air pressurized water gun: the tank, air pump and outlet nozzle. TTMP asserts that Claim 10 provides that the tank, air pump and outlet nozzle be situated along the same axis. TTMP alleges that axial arrangement of these three components is novel because the prior art describes water guns with outlet nozzles located higher than their tanks.

Id. at *6. TTMP claims that, although the ’129 patent water gun has the ability to illuminate light and create noise, its most significant feature is this axial arrangement of the components which obviates the need to overcome the force of gravity upon the water. According to TTMP, Larami’s Super Soaker series has simply taken the construction of the ’129 patent and relocated the water tank from inside the housing to the top of the housing which changes the look of the gun but does not affect its unique operating characteristics.

As Judge Bartels of the Eastern District of New York found in *Talk To Me Products, Inc.*, it is clear that claim 10 does not require the positioning of the tank, air pump and outlet nozzle on the same axis. Indeed, the outlet nozzle could be placed higher or lower than the air pump and/or tank and still be consistent with claim 10. And, although the diagram of the ’129 patent depicts an outlet nozzle located along the same axis as the air pump and tank, “no invention can be saved by features which appear only in the figures, and are not mentioned in the test.” *Id.* at *8. Thus, axial placement of the outlet nozzle, water tank and air pump in the Super Soakers cannot infringe claim 10 of the ’129 patent because there is nothing in the language of claim 10 to which it could be substantially equivalent.

Furthermore, even if claim 10 were to require that the outlet nozzle be placed on the same axis as the water tank and air pump, at least one other element of the ’129 patent is absent from the Super Soaker water guns. Claim 10 requires, among other things, “a tank in the barrel for a liquid.” As discussed above with regard to claim 1, the Super Soaker water guns have external water reservoirs that are detachable from the gun housing, and not contained within the housing or barrel. No Super Soaker water gun has a “tank in the barrel for a liquid” as described in claim 10 of the ’129 patent. To establish that a water tank outside of the housing or barrel is the substantial equivalent of a water tank inside the housing or barrel, TTMP must muster evidence which would create a genuine issue of material fact as to whether the

outside tank would have a substantially similar function and use substantially similar means to yield a substantially similar result as the inside tank.

TTMP claims that the “movement of the water reservoir upwardly simply serves as a cosmetic alteration for the aesthetic looks of the water gun, and does not alter the novel operational characteristics of the water gun [covered by the ’129 patent].” TTMP’s Memorandum of Law, at 9. The evidence, however, is to the contrary. The Super Soaker design improved on the ’129 patent and other prior art by locating the tank outside the housing. First, the external and detachable tank makes manufacturing the device simpler because it is not necessary to make the entire housing pressure tight. Second, this design makes it easier for the consumer to fill the tank because it is detachable. *Id.* Third, the size and volume of the external water reservoirs are not limited by the size of the housing. Fourth, the external tanks are replaceable if they should become damaged without replacing the entire toy. Finally, users of the Super Soakers can carry additional, filled tanks on a belt or backpack and replace an empty tank without going back to a source of water. Thus, the external tanks at least function in a very different manner from the ’129 patent.

For these reasons, I conclude that there remains no genuine issue of material fact as to whether Super Soakers 20, 30, 50, 100 and 200 infringe claim 10 of the ’129 patent under the doctrine of equivalents.

III. CONCLUSION

In patent cases, summary judgment is appropriate where the accused product does not literally infringe the patent and where the patent owner does not muster evidence that is “sufficient to satisfy the legal standard for infringement under the doctrine of equivalents.” *London*, 946 F.2d at 1538. Thus, and for the foregoing reasons, Larami’s motion for partial summary judgment of noninfringement of the ’129 patent will be granted.

An appropriate Order follows.

ORDER

AND NOW, this 11th day of March, 1993, it is hereby ORDERED that the motion is GRANTED.

JUDGMENT IS HEREBY ENTERED in favor of plaintiff Larami Corporation and against defendants Alan Amron and Talk To Me Products, Inc. on plaintiff’s claim of noninfringement of United States Patent No.

4,239,129 (Count I) and on defendants' counterclaim of infringement of United States Patent No. 4,239, 129.

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–EEJ

P-8: Patents, Regulatory Exclusivities, and Pharmaceuticals

This chapter—for what it’s worth, there’s not much to it other than copying public domain sources—was authored by Eric E. Johnson.

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CRS on Drug Prices: The Role of Patents and Regulatory Exclusivities

Taken from the “Summary” portion of Congressional Research Service, Drug Prices: The Role of Patents and Regulatory Exclusivities, R46679, February 10, 2021. (See “Editing Notes” section at the beginning of the volume on editing of CRS materials.)

Intellectual property (IP) rights play an important role in the development and pricing of prescription drugs and biologics. To encourage innovation, IP law grants inventors exclusive rights in a particular invention or product, potentially enabling them to charge higher-than-competitive prices. IP rights are typically justified as necessary to allow pharmaceutical manufacturers the ability to recoup substantial costs in research and development, including clinical trials and other tests necessary to obtain regulatory approval from the U.S. Food and Drug Administration (FDA). However, IP rights have been criticized as contributing to high prices for pharmaceutical products in the United States by operating to deter or delay competition from generic drug and biosimilar manufacturers.

Two main types of IP rights may protect pharmaceutical products: patents and regulatory exclusivities. Patents, which are available for a wide

range of technologies beyond pharmaceuticals, are granted by the U.S. Patent and Trademark Office. Patents may claim chemical compounds in the pharmaceutical product, a method of using the product, a method of making or administering the product, or a variety of other patentable inventions relating to a drug or biologic. The holder of a valid patent generally has the exclusive right to make, use, sell, and import the invention for a term lasting approximately 20 years. Pharmaceutical patent disputes are subject to certain specialized procedures under the Hatch-Waxman Act and the Biologics Price Competition and Innovation Act, which can affect when generic and biosimilar manufacturers can market their follow-on products.

In addition to patent protection, certain pharmaceuticals, such as innovative products or those that serve particular needs, may qualify for periods of regulatory exclusivity when they are approved or licensed by FDA. Pharmaceutical products may only be sold in the United States after FDA has determined they are safe and effective, based on submitted data, and has approved or licensed them. FDA generally may not accept and/or approve a generic drug or biosimilar if the pharmaceutical product being used as a reference to show the follow-on product is safe and effective is covered by an unexpired regulatory exclusivity. Regulatory exclusivities vary in length from six months to 12 years, depending on the basis for the exclusivity.

Because the exclusivity that IP law provides may enable the rights holder (e.g., a brand-name drug manufacturer) to charge higher-than-competitive prices for a period of time, rights holders may have an incentive to lengthen that time period as much as possible. Some commentators allege that certain brand-name drug manufacturers (brands) have engaged in patenting practices that unduly extend the period of exclusivity. Critics argue that these patenting practices are used to keep drug prices high, without any benefit for consumers or innovation. Such patenting practices include so-called (1) patent “evergreening,” (2) “product hopping,” (3) “patent thickets,” and (4) “pay-for-delay” settlements. Patent “evergreening” is the alleged practice of filing for new patents on secondary features of a pharmaceutical as earlier patents expire, thereby extending effective patent exclusivity past the original 20-year term. “Product hopping” is the alleged practice of a brand manufacturer attempting to switch the market to a new, similar product covered by later-expiring patents before IP rights on an existing product expire. “Patent thickets” refer to portfolios of numerous, overlapping patents on the same pharmaceutical,

which allegedly deter competition due to the risk of infringement and the high cost of patent litigation. “Pay-for-delay” or “reverse payment” settlements resolve patent litigation through payments from a brand to a generic or biosimilar manufacturer to delay generic market entry; in some cases, they may be anticompetitive because they allow the brand to continue to charge high prices without risking invalidation of its patent.

Drug manufacturers counter that their patenting practices protect new, innovative inventions as Congress intended when it created the patent system. In their view, the terms for these practices are unfairly pejorative, or, at most, describe outlier behavior by a few companies. Defenders of these patenting practices reject their characterization as anticompetitive and emphasize that strong patent rights encourage innovation and life-saving research and development efforts.

In recent years, some Members of Congress have introduced bills to address these and other IP-related issues that some perceive as contributing to high pharmaceutical prices.

CRS on Pharmaceutical Patenting Practices

Taken from Kevin T. Richards, Legislative Attorney, Congressional Research Service, Pharmaceutical Patenting Practices: A Legal Overview, IF11561 (version 2), June 1, 2020. (See “Editing Notes” section at the beginning of the volume on editing of CRS materials.)

Pharmaceutical manufacturers frequently obtain intellectual property (IP) rights in their products. IP law provides exclusive rights in a particular invention or product for a certain time period, potentially enabling the rights holder (e.g., a brand-name drug manufacturer) to charge higher-than-competitive prices. If rights holders are able to charge such prices, they may have an incentive to lengthen the period of exclusive rights. Some commentators allege that pharmaceutical manufacturers have engaged in patenting practices that unduly extend the period of exclusivity. These critics argue that these patenting practices are used to keep drug prices high, without any benefit for consumers or innovation. Defenders of these patenting practices contend that patents are generally necessary to allow manufacturers to recoup their investments in research, development, and regulatory approval, and that concerns regarding these practices are either overstated or unjustified.

This In Focus provides an overview of the relevant legal background and describes four such alleged patenting practices.

Legal Background

FDA Regulation of Pharmaceutical Products

The U.S. Food and Drug Administration (FDA) must approve new drugs and biologics (i.e., pharmaceutical products derived from biological materials, such as a virus or blood component) prior to their being marketed in interstate commerce. The approval processes for drugs and biologics are similar, but distinct.

To obtain FDA approval, a drug manufacturer must submit a new drug application (NDA) that demonstrates, among other things, that the drug is safe and effective for its intended use. The clinical studies necessary to establish safety and efficacy are often expensive and lengthy; the average cost to develop a new drug has been generally estimated to be between \$1 billion to \$3 billion, and the average length of the FDA approval process is over twelve years. To encourage competition and lower drug prices through generic drug entry, the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman) created a streamlined approval process that allows generic drugs to be approved through an abbreviated new drug application (ANDA) that establishes the drug's safety and efficacy by relying on FDA's prior approval of a drug with the same active ingredient. In certain circumstances, the generic's ANDA filing constitutes an act of "artificial" patent infringement, allowing the brand manufacturer to sue the generic drug manufacturer.

Similarly, a biologic may only be marketed in the United States after FDA approves a biologics license application (BLA). To approve a BLA, FDA must determine that the biologic is "safe, pure, and potent," and that the production and distribution processes are designed to ensure the same. Like Hatch-Waxman, the Biologics Price Competition and Innovation Act of 2009 (BPCIA) created an abbreviated process to encourage early market entry of sufficiently similar biologics by relying on FDA's prior approval of a biologic. A biological product is sufficiently similar if it is "biosimilar" to or interchangeable with an approved biologic. The BPCIA also created a process for biologic and biosimilar manufacturers to resolve patent disputes following the filing of an abbreviated BLA.

Patent Law Basics

Patents, which are available for a wide variety of inventions beyond pharmaceuticals, grant the patent holder the right to exclude others from making, using, selling, or importing a patented invention within the United States for a defined term of years (generally, twenty years from the date a patent application was filed). A person who does so without the patent holder's permission infringes the patent and is potentially liable for monetary damages and other legal remedies. Patent exclusivity allows the patent holder to recoup any expenses incurred during research and development, and is intended to incentivize innovation. The exclusivity may also shield patentees from competition, thus allowing them to charge higher-than-competitive prices for goods protected by patents. Patent incentives are said to be particularly necessary for products like pharmaceuticals, which are costly to develop but may be easily copied once marketed.

Pharmaceutical patents may cover many different features of a drug or biologic beyond the active ingredient itself. Such “secondary patents” may claim, among other things:

1. formulations of the drug or biologic (e.g., an administrable form or dosage);
2. methods of using the pharmaceutical (e.g., to treat a particular disease);
3. methods of manufacturing or technologies used to make the pharmaceutical;
4. methods or technologies for administering the pharmaceutical; or
5. other chemicals related to the active ingredient, such as intermediaries.

Pharmaceutical Patenting Practices

From the patent holders' perspective, the practices described below are appropriate uses of the legal rights granted by their patents. Critics, however, view these practices as harmful strategies that exploit the patent system in ways that Congress did not intend.

“Evergreening”

Evergreening, also known as patent “layering” or “life-cycle management,” is a practice by which drug innovators allegedly seek to prolong their patent monopoly on pharmaceuticals by obtaining additional patents as

former patents expire. Because different aspects of pharmaceutical products are patentable, dozens of patents can protect a single pharmaceutical product from competition.

Critics of evergreening maintain that secondary patents are often for minor improvements or ancillary aspects of a pharmaceutical product, and effectively extend patent protection of the original product beyond the term set by Congress. Defenders contend that any additional patents cover important innovations and/or improvements to existing products, and that so-called secondary patents must meet the same patentability requirements and examination procedures as any other patent.

“Product Hopping”

“Product hopping” is the process by which a brand manufacturer uses its current dominant market position to encourage doctors, pharmacists, and consumers to “hop” from one drug, protected by soon-expiring patents, to a newer version of the same (or similar) drug with later-expiring patents. The new version of the product may be, for example, an extended release form, a new dosage, a different route of administration (e.g., capsules to tablets), or a minor chemical change. The brand manufacturer may encourage the transition through a marketing campaign or discounts and rebates. Product hopping tends to take one of two forms: a “hard switch,” where the brand manufacturer removes the original product from the market, or a “soft switch,” where the brand manufacturer leaves the original product on the market.

Critics of product hopping contend that the new product usually adds little or no clinical benefit, and the change occurs only to avoid generic competition by eliminating the market for the original product by the time of expected generic entry. Defenders maintain that manufacturers have legitimate reasons to create and patent new products, and that the new products often do have clinical benefits (for example, fewer side effects or better patient compliance).

“Patent Thickets”

In the pharmaceutical context, the term “patent thickets” describes a brand manufacturer’s practice of amassing a large number of patents relating to a single product, thereby discouraging competitors from entering the market, or making it too costly and risky to do so. For example, one recent

study of the top twelve drugs by gross U.S. revenue found that manufacturers obtained an average of seventy-one patents on each drug. Concerns about patent thickets have commonly been raised regarding biologics, as compared to small molecule chemical drugs. This may be, at least in part, because manufacturing a pharmaceutical using living cells is often complicated, offering many potential opportunities for patenting innovative processes or tools (although the underlying naturally occurring biological material itself might not be patentable). For example, a company producing a biologic could attempt to patent the use of a different medium for cell growth or an adjustment to the dosing.

Critics contend that these patent thickets are created by patenting minor or secondary innovations, yet effectively delay competition because generics or biosimilars must challenge or design around every patent, which can be expensive or difficult. Defenders maintain that the patents on these products reflect the type of innovations that the patent laws were designed to incentivize, and that each patent has been determined to be valid through the patent examination process.

“Pay-for-Delay” Settlements

Through the procedures established by Hatch-Waxman and the BPCIA, brand manufacturers may initiate patent litigation when generic (or biosimilar) manufacturers submit abbreviated applications for products covered by certain unexpired patents. Some brand manufacturers have settled such litigation by paying (or otherwise compensating) generic manufacturers in return for the generic manufacturers agreeing to delay market entry. The Supreme Court has held that this practice, referred to as a “reverse payment” or “pay-for-delay,” may in certain circumstances be a valid exercise of patent exclusivity, but in other circumstances may violate the antitrust laws.

Critics allege that brand manufacturers use pay-for-delay to protect weak patents from invalidation; because pay-for-delay agreements terminate the litigation, questions of patent validity and infringement remain open. Thus, critics contend that pay-for-delay adversely affects competition by allowing the brand manufacturer to (1) avoid the risk that its patents will be invalidated, (2) delay the market entry of generic competition, and (3) effectively extend its exclusive right to market the listed drug. Defenders maintain that these settlements are a legitimate way to reduce the cost and risk associated with

litigation; they point out that the overwhelming majority of lawsuits settle across all areas of the law. Moreover, defenders argue that the litigation could end with the brand manufacturer prevailing, which would generally bar competition until the end of the patent term. By settling the litigation, defenders contend, generic entry before the end of the patent term is often guaranteed.

Combinations of Practices

Although presented here separately, critics contend that these practices are sometimes used concurrently. For example, some brand manufacturers may combine product hopping with pay-for-delay settlements, by using a pay-for-delay settlement to delay generic entry while the brand manufacturer switches the market to a new product protected by patent exclusivity.

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–EEJ

Volume Revision Notes

All version numbers beginning with “1.0” (e.g., 1.00 and 1.01) are interchangeable from a teaching/learning/assigning standpoint. Only minor typo-level errors are corrected, and there are no changes to pagination. In support of the point about interchangeability, a detailed specification is presented:

A revision date for a reprinted document, erroneously listed as August 16, 2022, was corrected to September 25, 2022 (page 18); the word “is” was inserted into “typically is pursued” (page 125); a section-numbering letter in quoted statutory text that was stranded across a page break from its associated text was reunited with its text (pages 42 & 43); section symbols stranded across a line break from their associated numbers were reunited with those numbers (pages 42, 82, 94); various numerals in parentheses stranded across line breaks from their associated clauses were reunited with those clauses (pages 90, 103, 130, 145) a nonbreaking hyphen replaced a hyphen that was awkwardly breaking a word across a line (page 94); an extra period was removed (page 105); extra spaces were removed (page 139, 141, 143, 145, 146). The version number was changed from 1.00 to 1.01 on pages 3 and 4. On page 4 the boxed paragraph was added, and on that same page a parenthetical about the 1.01 version being posted in 2023 was inserted. The Volume Revision Notes (that you are reading now) were added.

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