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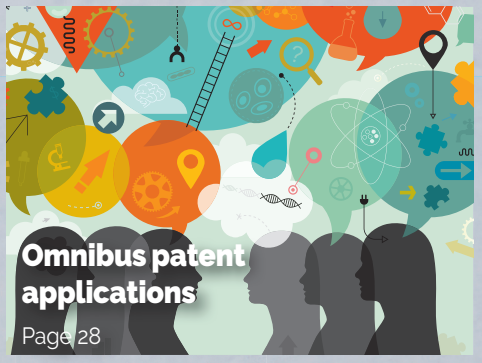



CTC Legal Media

# A potential update to the *quid pro quo* of patents? US Supreme Court to review enablement requirement in Section 112 of Patent Act

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## A *quid pro quo* system

Patent systems exist in most countries around the world and are typically codified into the law of the land. Generally, patents give their owners the legal right to exclude others from practicing (making or using) the patented invention for a limited time. This exclusivity period provides a potentially huge financial benefit to the patent owner, who may commercialize the invention and any innovations that incorporate the invention.

It begs the question: why should a government be willing to grant such power of exclusivity to a patent holder, seemingly at the expense of the free market? The answer lies in a foundational bargain between society and inventors. In the US, this covenant is expressed in Article 1, Section 8 of the Constitution:

> *The Congress shall have the 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*

But how is this to be accomplished? The American Founding Fathers recognized the value that science and the arts can play in improving society, but they left out some essential details: they didn't tell Congress how to do it.

The US Congress thereby devised a plan that has now played out for more than two centuries, driving invention and discovery to fascinating and new heights in ways that could never have been anticipated by any stretch of the imagination.

Paul Ratzmann

Melissa Chapman

For this paper, the focus returns to the basic principle, the *quid pro quo* that is expressed at the outset and addresses in some sense the "why" of things – i.e., why the patent right can be granted in the first place. The premise is simple: an inventor is granted a patent and the limited period of exclusivity that comes with it—but in exchange, the inventor must disclose their invention AND tell the world how to make and use it.

This detailed disclosure of patented inventions promotes the "Progress of Science" by driving innovation and development beyond the imagination, both during the life of the patent and after it expires. During the life of a patent, as we commonly call its "limited term of exclusivity," it may not be prudent or feasible to license or purchase the invention. In these cases, there may be motivation to figure out a new way to "design around" the patent to avoid it, while also motivating someone else to obtain their own patent on this new way of doing things.

Moreover, after the patent expires, it passes to the public domain and is free for everyone, spurring yet more innovation. Examples abound as to how groundbreaking technologies can be built upon and become ubiquitous in the larger society.

In one example, the early seeds of the now-omnipresent Global Positioning System (GPS)[1]

reach back to 1970. Today, GPS technology has made its way into the pockets of millions of people through smartphones. Not even the inventor could have imagined the impact of that invention when it was first patented. Smartphones themselves may be traced back to digital mobile phone technology developed in 1973 and patented in the US and Germany[2].

Another example is the early development of carbon fiber in Japan (which is now available everywhere) and the role that patenting and licensing[3] early in the process had in supporting and spurring development.

Les Paul, the electric guitar inventor[4], needs no introduction as an early innovator or musician. The electric guitar changed the musical world and led to a new sound and revolution in music that started in the 1960s and continues to this day.

Finally, none of us want to imagine what the world was like before the development of the simple roll of toilet paper, but in 1891 Seth Wheeler imagined a better future and invented something[5] that the world can only be grateful for.

This significant tradeoff has driven innovation and technological advancement worldwide for generations. It has brought brilliant minds to bear on the world's most challenging problems - motivating those minds to improve technology and the world at large.

It must be noted that the invention must meet other requirements, too, such as requirements of patentable subject matter; being novel (meaning it hasn't been previously patented or already known to the public); and being nonobvious (meaning that it is not readily apparent to someone working in the field of that invention). Nonetheless, a proper disclosure is a requirement, and improper disclosure (like publishing or making and selling the patented product to the public for too long before seeking patent protection) may mean you cannot obtain a patent.

1 https://patents.google.com/patent/US3789409A/en?oq=3789409

2 https://www.dpma.de/english/our_office/publications/milestones/mobile/index.html

3 https://www.wipo.int/ipadvantage/en/details.jsp?id=2909

4 https://patents.google.com/patent/US3018680A/en?oq=US3018680

5 https://patents.google.com/patent/US465588A/en?oq=US465588


## Proper disclosure

All that to say, what exactly makes a disclosure 'proper' in the US? Amongst other things, 35 USC § 112(a) sets forth the enablement requirement. This section details that patents must "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... to make and use the invention."

Thus, for an application to be complete, the description of the invention must be enabled – putting enough description into the specification that a skilled person in the art can both make and use the invention without undue experimentation (i.e., the *quid pro quo* as discussed above). The idea is that the specification must put the invention truly into the public domain, such that a skilled practitioner can understand how to make and use the invention, ensuring the public may derive a benefit from the invention once in the public domain.

Courts typically rely on several factors in determining whether an amount of experimentation is "undue." The seminal case, In *re Wands*, states that the factors include:

1. The quantity of experimentation necessary,
2. The amount of direction or guidance presented,
3. The presence or absence of working examples,
4. The nature of the invention,
5. The state of the prior art,
6. The relative skill of those in the art,
7. The predictability or unpredictability of the art, and
8. The breadth of the claims.

## Résumés

**Paul Ratzmann** is a partner at Fishman Stewart. Paul is a registered patent attorney and practices various aspects of intellectual property matters including domestic and foreign patent prosecution, due diligence, opinions, and design-around. He has an extensive background in the mechanical and electro-mechanical arts.

**Melissa Chapman** is a patent attorney at Fishman Stewart who advises clients on various aspects of intellectual property law and enjoys the dynamics of constantly changing technologies. Her practice focuses on procuring patents covering a wide range of technical fields, particularly in the mechanical arts.

In *re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988).

These principles provide clear guidance to follow so that the invention is, indeed, fully disclosed to the public.

## Supreme Court reviews enablement

Recently, the US Supreme Court granted a petition to review the enablement requirement of Section 112 of the Patent Act. The petition comes from Amgen, Inc. in response to a decision from the Federal Circuit that held two of Amgen's patents as invalid for a lack of enablement. *Amgen Inc. v. Sanofi*, 987 F.3d 1080 (Fed. Cir. 2021). With oral arguments set for March 27, 2023, and a decision expected by the end of the second quarter, companies and patent practitioners anxiously await an outcome that could significantly impact the enablement requirement and their future patent filings.

Amgen owns several patents directed to medication for treating high cholesterol. Simply stated, the body eliminates low-density lipoprotein ("LDL" or "bad cholesterol") from the body via LDL receptors in the liver. The naturally occurring protein PCSK9 may bind to and destroy these receptors, leading to an influx of bad cholesterol. Amgen's medication includes monoclonal antibodies that bind to PCSK9, blocking PCSK9 from binding to and destroying LDL receptors so that the receptors can continue eliminating bad cholesterol.

Rather than claim the structural components of the antibodies, Amgen utilized a generic or genus-claiming strategy. Genus claims typically have broader coverage – covering a family, category, or general description which may encompass more specific examples. This strategy is featured often in chemical, biotech, and pharmaceutical industries where, for instance, utilizing a variety of similar chemical structures is possible to achieve a desired claimed outcome. Genus claiming serves a role in preventing obvious modifications to a patent claim in an effort to prevent patent infringement.

In this particular instance, Amgen's patent claims are directed to what the antibody accomplishes – binding to amino acid sequences of PCSK9 to block the binding of PCSK9 to LDL receptors. The antibody may bind to several different amino acid sequences. Thus, the genus claim here does not limit the structure to a specific amino acid sequence and claims a more generic description.

After asserting claims that Sanofi and Regeneron were infringing Amgen's patents directed to cholesterol medication Praluent®, US Patent Nos. 8,829,165 ("'165 patent") and 8,859,741 ("'741 patent"), Sanofi and Regeneron counterclaimed that the claims of the '165 patent and the '741 patent were invalid for lack of enablement. A jury initially decided that the asserted claims were valid. However, the District Court overturned the decision as a judgment as a matter of law, and the Federal Circuit affirmed. *Amgen Inc. v. Sanofi*, 987 F.3d 1080 (Fed. Cir. 2021).

The Federal Circuit's affirmation was based on the requirement that the "full scope" of the claim be enabled, meaning a claim may be insufficiently enabled if it is too broad and insufficient embodiments are described in the specification. The problem for Amgen is that the Federal Circuit found that the claims of the '165 and '741 patents are not directed to a single antibody; instead, potentially millions of currently unknown antibodies fall within the scope of the claim. Additionally, the Federal Circuit held that the claims were far broader than the disclosure provided in the specification and thus would require "substantial time and effort" to "reach the full scope of the claimed embodiments." Therefore, holding that undue experimentation would be necessary to identify undisclosed embodiments encompassed by the claims, the claims were found invalid.

Amgen and those in support argue that the Federal Circuit created a heightened standard for the enablement of genus claims. According to Amgen, the "full scope" requirement asks

whether a skilled person in the art could identify and make all embodiments within the scope with minimal "time and effort." In contrast, Amgen argues that quantitatively high burdens of experimentation are not necessarily considered undue experimentation. The defendants did not establish that a skilled person in the art would have to engage in undue experimentation to make any antibody that fell within the scope of the claim, just that the quantity of experimentation required to make every antibody possible within the claim would be too much – a simple argument of quantity versus quality. Supporting amici argue that patentees need only identify a well-defined genus and provide disclosure sufficient to allow a skilled person in the art to make and use the claimed invention, per the statutory language.

## Conclusion

A heightened standard for enablement in genus claims will have severe consequences for the pharmaceutical and biotechnology industries and other fields. As the first case at the Supreme Court to consider the enablement requirement in approximately 130 years, practitioners await a decision to see if changes to the requirement will occur. The Court's decision may impact a wide range of existing patents with functional claims and may impact patent prosecution strategies in the US moving forward.

Congress' granted authority includes the requirement that a description of an invention be provided to the public in "full, clear, concise, and exact terms" to enable a skilled person to "make and use" the invention. The Supreme Court will now exercise its authority and determine if strategies like those used by Amgen are sufficient to meet the important *quid pro quo* to promote science and the useful arts as the Constitution intended.


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