On appeal, the Federal Circuit agreed with Finjan, stating "the use of a restrictive term in an earlier application does not reinstate that term in a later patent that purposely deletes the term, even if the earlier patent is incorporated by reference." The Court further noted that the later patents, not containing a size requirement, can refer to application programs of all sizes, including, but not limited to "small" programs. As such, the Court found "[T]hese two definitions can exist in harmony within the patent family."

As a result, The Federal Circuit reversed the district court construction and determined that "downloadable" should be defined as "an executable or interpretable application program, which is downloaded from a source computer and run on a destination computer." The Federal Circuit then remanded the case for further proceedings consistent with such definition

The *Finjan* case highlights the need for consistent use and understanding of the scope of relevant technical terms in an evolving, technologically advanced sector like information technology in general, and cybersecurity and data privacy in particular. More generally, this case reminds us that while incorporation by reference is a valuable and efficient drafting tool, it should only be used with caution and understanding of what is being so incorporated. In fact, oftentimes it is sufficient to explicitly include just a relevant portion of the supporting prior document in question without the wholesale incorporation

Certainly, the patent holder was fortunate that the Federal Circuit did not restrict the definition of downloadable to only include "small downloadables" but that was a risk avoided, and one to keep in mind when drafting patent applications in this fast-paced cybersecurity arena. This issue is of particular focus for our intellectual property and technology attorneys working in Bond's cybersecurity and data privacy practice. We know the terminology and therefore have the ability to properly protect the inventions in this space.

PATENTS

Revisiting the Quid Pro Quo Bargain of the U.S. Patent System: *Amgen Inc. v Sanofi* (Docket No. 21-757; cert. granted on November 3, 2022)

By: Amanda Rosenfield Lippes[6]

Background and History

Amgen's patents relate to treatment of high cholesterol and focus on antibodies that bind to a naturally occurring protein, namely, the proprotein convertase subsilisin/kexin type 9 (PCSK9) protein. This binding prevents PCSK9 from binding to LDL receptors and in effect allows LDL receptors to continue regulating the amount of circulating LDL cholesterol in the blood stream. If left unblocked, the PCSK9 protein interacts with LDL receptors and prevents LDL receptors from clearing the bad cholesterol that can lead to heart disease and strokes. When Amgen attempted to enforce these patents against competitors, the District Court found them invalid, and the Court of Appeals for the Federal Circuit (Federal Circuit) affirmed. Amgen appealed to the Supreme Court and the Justices agreed to intervene.

At the heart of the review by the Supreme Court is the enablement requirement, which comes from 35 U.S.C. §112(a) prescribing that a patent's specification contains "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." It has long been established that this statutory requirement dictates that a specification contain sufficient disclosure to "teach a skilled person how to make and use the full scope of the claimed invention without undue experimentation." *Genentech, Inc.*

[6] Amanda is a registered U.S. Patent and Trademark attorney. She represents clients, from startups to multinational corporations, in all phases of patent and trademark prosecution. Amanda also assists clients with patentability assessment, validity/freedom-to-operate analysis and portfolio management.

v. Novo Nordisk A/S, 108 F.3d 1361, 1365 (Fed. Cir. 1997) and, up until this case, this requirement has been reviewed by the Supreme Court only once in the current law's 70-year history.

It is the essence of the quid pro quo bargain between the inventor and the government where a temporary right to exclude others from making or using the invention is granted to the inventor in exchange for the enabling description of their invention. The enablement requirement naturally impacts how an application is drafted yet it can also affect the validity of an already issued patent. This is what happened in this case.

Sanofi and Regeneron (collectively Sanofi) developed and pursued one type of PCSK9 inhibitors and Amgen independently developed and pursued different PCSK9 inhibitors around the same time. After Amgen obtained two patents covering their cholesterol medication Repatha®, they sued Sanofi in 2014, alleging that Sanofi's competing PCSK9 antibody product infringed Amgen's patents. Crucially, the claims of Amgen's patents define their PCSK9 inhibitor antibodies by their functions (i.e., binding to sites (residues) on the PCSK9 protein and blocking the PCSK9/LDLR interaction) rather than the structures of the antibodies[7]. Amgen's patent applications support the claims by describing the structures of 26 example antibodies that perform the claimed functions. Their applications also provide guidance on how to make the antibodies using anchor antibodies and well-known screening techniques.

Before reaching the Supreme Court, the *Amgen v. Sanofi* case had a long litigation history, including two jury trials and two appeals to the Federal Circuit. After the second trial, the jury once again found that Amgen's claims were not invalid for lack of enablement and insufficient written description. But, in a post-trial decision, the district court judge granted Sanofi's motion for judgment as a matter of law (JMOL), finding the patents invalid for a lack of enablement, and the Federal Circuit affirmed.

The Federal Circuit Decision on Appeal to the Supreme Court

"To prove that a claim is invalid for lack of enablement, a challenger must show by clear and convincing evidence that a person of ordinary skill in the art would not be able to practice the claimed invention without 'undue experimentation.'" (*Alcon Research*, 745 F.3d at 1188 (quoting *In re Wands*, 858 F.2d 731, 736-37 (Fed. Cir. 1988)). *In re Wands* sets out the eight (8) factors that a court may consider when determining whether the amount of experimentation is either "undue" or sufficiently routine such that an ordinarily skilled person in the art would reasonably be expected to carry it out.[8]

In its decision, the Federal Circuit focused on four (4) of the *Wands* factors, namely, *Breadth of the Claims*, *Predictability or Unpredictability of the Art*, *Amount of Direction or Guidance Presented*, and *Quantity of Experimentation Necessary* as further described below.

Breadth of the Claims – The Federal Circuit agreed with the District Court that the scope of the claims was "indisputably broad" focusing on the "functional diversity" of the claims rather than the exact number of embodiments.

Predictability or Unpredictability of the Art – The Federal Circuit agreed with the District Court that the claimed invention is in an unpredictable field of science "with respect to satisfying the full scope of the functional limitations." Specifically, the Federal Circuit focused on the concession of one of Amgen's experts that "substitutions in the amino acid sequence of an antibody can affect the antibody's function, and testing would be required to ensure that a substitution does not alter the binding and blocking functions [claimed]."

[7] The representative claims at issue recite the following functional limitations:

> 1. An isolated monoclonal antibody, wherein, when bound to PCSK9, the monoclonal antibody binds to at least one of the following residues [a list of 15 amino acid residues], and wherein the monoclonal antibody blocks binding of PCSK9 to [LDL receptors]

[8] *Wands* factors include: (1) Quantity of Experimentation Necessary; (2) Amount of Direction or Guidance Presented; (3) Presence or Absence of Working Examples; (4) Nature of the Invention; (5) State of the Prior Art; (6) Relative Skill of Those in the Art; (7) Predictability or Unpredictability of the Art; and (8) Breadth of the Claims.

Amount of Direction or Guidance Presented – The Federal Circuit also agreed with the District Court that "[a]fter considering the disclosed roadmap in light of the unpredictability of the art, any reasonable factfinder would conclude that the patent does not provide significant guidance or direction to a person of ordinary skill in the art for the full scope of the claims."

Quantity of Experimentation Necessary – The Federal Circuit also agreed with the District Court that the required experimentation "would take a substantial amount of time and effort" noting that the only ways for a person of ordinary skill in the art to discover undisclosed claimed embodiments would be through "'trial and error, by making changes to the disclosed antibodies and then screening those antibodies for the desired binding and blocking properties' or else 'by discovering the antibodies *de novo*'".

The Federal Circuit found that the District Court did not err in finding that undue experimentation would be required to practice the full scope of the claims since "[t]he functional limitations are broad, the disclosed examples and guidance are narrow, and no reasonable jury could conclude under these facts that anything but 'substantial time and effort' would be required to reach the full scope of [the] claimed embodiments."

Notably, in its reasoning the Federal Circuit paid specific attention to footnote 2 in the *McRO* case[9] which provides: "[i]n cases involving claims that state certain structural requirements and also require performance of some function...we have explained that undue experimentation can include undue experimentation in identifying, from among the many concretely identified compounds that meet the structural requirements, the compounds that satisfy the functional requirement."

Conclusion

The Supreme Court's decision later this year is expected to clarify the enablement standard as it applies to genus claims with functional limitations, namely

- whether enablement is governed by the statutory requirement that the specification teach those skilled in the art to "make and use" the claimed invention, or whether it must instead enable those skilled in the art "to reach the full scope of claimed embodiments" without undue experimentation—i.e., to cumulatively identify and make all or nearly all embodiments of the invention without substantial "time and effort."

The crux of the issue is the balance between the scope of genus claims and their blocking effect and the patentee's requirement to properly enable others to make and use the claimed invention. Some believe if the Federal Circuit's opinion is affirmed, such a heightened "full scope of the claimed embodiments" standard would place a difficult, if not unworkable, burden on applicants when drafting patent applications not only in life sciences field, but also in other technological areas. Such full scope enablement of genus claims would require applicants to identify and describe every embodiment that falls within the scope of the claims, thus requiring to disclose and enable the entire claimed genus. A contrary view is that the heightened standard may appropriately invalidate patents with improper overbroad claiming. According to this viewpoint, in this case, Amgen impermissibly claims an entire genus via functional limitations when the specification only supports a narrower scope of anitbodies within the genus.

Until further clarification is provided from the Supreme Court, we offer the following take-aways:

1. When drafting claims, their scope must be matched by the scope of the specification and, if feasible, some subgenus claims and species claims with sufficient degree of enablement should be included.

2. Be sure to evaluate whether the claim scope as supported by the specification is worth pursuing before divulging the details necessary for the *quid pro quo* of the patent system.

[9] McRO, Inc. v. Bandai Namco Games Am. Inc., 959 F.3d 1091, 1100 (Fed. Cir. 2020)

3. When claiming inventions with functional limitations, stay within the bounds of § 112(f). In that context, broad functional limitations are interpreted to cover only those means that are equivalent to the actual means shown and/or described in the specification. While narrower in scope, these claim limitations avoid the risk of invalidation which is present for functional claim limitations outside the boundaries of § 112(f).

PATENTS

Subject Matter Eligibility Updates: The Federal Circuit Continues to Offer Insight Into Crafting Patent Applications

By: Brendan Goodwine[10]

Since the Supreme Court decided *Alice Corp. v. CLS Bank Int'l in 2014*, concerns surrounding the patentability of software and related information technologies have plagued applicants and patent practitioners alike. In its immediate aftermath, legal experts questioned whether certain computer-related inventionw would ever been considered patentable again. The framework established by *Alice* certainly imposed a stricter standard for determining patent eligibility for these inventions and made it more challenging for some inventors to obtain or successfully enforce patents for their computer-related inventions. However, over the past next nine years, we have seen the U.S. Patent and Trademark Office issue informative guidance on subject matter eligibility and have even gained some significant guidepost decisions from the Court of Appeals for the Federal Circuit (e.g., *DDR Holdings, LLC v. Hotels.com*, *Enfish, LLC v. Microsoft Corp.*, *Bascom Global Internet Servs, Inc. v. AT&T Mobility LLC*, *McRO, Inc. v. Bandai Namco Games America Inc.*, etc.).

In 2022, we continued to see the Court of Appeals for the Federal Circuit take up questions related to subject matter eligibility and provide insight into crafting patent claims that avoid the pitfalls created in the wake of the *Alice* decision. In the cases discussed here, the Federal Circuit found two more inventions that have survived the § 101 analysis under the framework established by *Alice*.

Cooperative Entertainment, Inc. v. Kollective Tech., Inc.

Our first case is *Cooperative Entertainment, Inc. v. Kollective Tech., Inc.*, which came to the Federal Circuit from the Northern District of California where Cooperative Entertainment, Inc. ("Cooperative") sued Kollective Technology, Inc. ("Kollective") over U.S. Patent No. 9,432,452 entitled "Systems and Methods for Dynamic Networked Peer-to-Peer Content Distribution." The '452 patent was originally filed as a U.S. provisional application on September 10, 2012. At the time, Netflix and other early streaming services were expanding across the global, and the inventors of the '452 patent recognized that cheaply and seamlessly delivering digital content was becoming increasingly difficult with the explosion of devices that consume such content. While some peer-to-peer (P2P) file sharing solutions had already been developed, these P2P networks were static that received content from a centralized content delivery network hub and could not handle file sizes necessary for video streaming, for example.

As a result, the inventors of the '452 patent developed dynamic P2P networks that exist outside of the "top down," static, controlled structure of a content delivery network. According to Cooperative, the inventive solution of the '452 patent "more fully opens network capacity by offloading digital content distribution to the decentralized P2P network" where "digital content could be seamlessly distributed in full" among peers.

Claim 1 of the '452 patent was identified as being representative:

1. A system for virtualized computing peer-based content sharing comprising:

[10] Brendan is a registered patent attorney, advising his clients on potential benefits and risks associated with their intellectual property. He focuses his practice on a wide variety of intellectual property matters, including patent prosecution, patent litigation and *inter partes* reviews, as well as trademark prosecution and trademark litigation.