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In This Issue

View from the Chair

Members:

After more than two years of exclusively virtual conferences, your Intellectual Property Law Section Council is thrilled to welcome you back to Mackinac Island for our 47th Annual IP Law Institute over July 21-23. We are grateful to our slate of great speakers who agreed to travel north this summer despite the unknowns, and of course this event would not be possible without our members and their families signing up to attend.

In addition to planning our main educational seminars, the Council has been working on Diversity, Equity, and Inclusion (DEI) initiatives and expects to have more DEI content in future seminars. The Council's DEI objectives are to help our section's members attract, and just as importantly *retain*, a diverse workforce that is valued, treated fairly, and participates fully at all levels of their organization. Achieving these goals will take more than a few presentations, but it is our hope that this effort will be a driving force and resource for continuous improvement of our members and their organizations.

Other initiatives include developing a social media presence and updated website content, continuing to support the Michigan Pro Bono Patent Project, and seeking effective ways to spread the word about I.P. to students of all ages in Michigan. We are in the process of setting up a web page that will allow our members to make contributions to endowed scholarships for Intellectual Property law students at both Wayne State University and Michigan State University law schools. Any contribution amount can be added to the endowment of choice, thus turning a one-time contribution into an enduring legacy in support of intellectual property education in Michigan.

Our section's annual meeting will take place at the Grand Hotel on Mackinac Island on Friday, July 22. It will mark the end of my role as Chair and the start of a new year for the Council with Kimberly Berger as Chair. Thank you, our members, for your support as we return to in-person programming and push forward with new initiatives and opportunities for Intellectual Property education and involvement in Michigan.

—Matthew D. Kendall

Upcoming Event

Intellectual Property Law Institute, 47th Annual:
In-person event scheduled to return to Mackinac Island THIS WEEK on July 21-23.

Join Us on Mackinac Island!

Need a change of scenery? There's still time to join us for comprehensive content in patent, trademark, and copyright law—all while basking in the beauty of Mackinac Island. Don't miss out on the elegant receptions and unparalleled networking with top-notch practitioners.

You will be able to:

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- Explore patent law's role in the "billionaire space race"
- Strategically use standards-essential patents and FRAND licenses

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The 30-Year Dissent

An Examination of Judge Newman's Dissent in *In re Wands* as Applied to Unpredictable Arts

By Lucas Peterson

Introduction

Arthur Conan Doyle is formally quoted in *Sherlock Holmes* as saying "[i]t is easy to be wise after the event."[1] Nothing is truer when looking to unpredictable arts and the desire to encompass broad genus claims in a patent application, where the goal is to claim any potential species of a genus to snuff out future inventors from obtaining success where the claimed inventor had not looked. The same can also be said of courts when a majority issues an opinion that in hindsight seems to validate a prior dissent. Hindsight gives the clearest picture of what an outcome should have been, and in the field of unpredictable arts, Judge Pauline Newman of the Court of Appeals for the Federal Circuit seems to have been right more than 30 years ago when she authored a dissenting opinion to the seminal enablement case of *In re Wands*.[2]

With the drastic advancements of technology and science, there seems to be tension on the Federal Circuit where the court routinely has to find a balance by weighing the scope of patentability with the potential for stifling innovation in the field of unpredictable arts. Significant headaches can arise in biotech cases, where the boom of the industry, particularly that of pharmaceuticals, has led to an exponential increase of granted patents over the last 30 years.[3] Perhaps because of the unprecedented growth and complexity in the field, and the struggle for the patent system to keep up,[4] some patent filers have tried to push the bounds of enablement in an attempt to try and expand their protection to broad genera. Therefore, the court routinely has to weigh the scope of patentability with the potential for stifling innovation by analyzing unpredictable arts under the lens of predictable enablement to avoid overbreadth.

The fascinating history of *Wands* demonstrates this frustration and tension as much as any case. In 1988, the Federal Circuit took this case to determine if Wands' patent application sufficiently enabled the invention covering the entire genus of antibodies with the function of binding to the Hepatitis B antigen. Although the majority ruled that the claims were enabled, Judge Newman understood the breadth of the claims at the time and understood that the majority's decision failed to see the full scope of the claims.

Over the next 33 years, the wisdom of Judge Newman's dissent has become more apparent, and the 2021 case of *Amgen Inc. v. Sanofi*[5] has drawn many similarities to her analysis in *Wands*. In *Amgen*, the court made clear that when a genus claim in the unpredictable arts covers thousands/millions of potential species that is broad in both structure and function, and the specification does not put the skilled artisan any closer to possession of species within the claim more so than just iterative trial-and-error research of the thousands/millions of potential species, then the disclosure is not enabling. Where science leaves the door open for an unknown number of species, claiming the entire genus is not allowable unless the disclosure (e.g., patent specification) provides the skilled artisan some predictability in identifying the species within the claim's limitations.

The Origins of the Enablement Requirement in Patent Law

The history of intellectual property is almost as long as the history of the United States itself. Engrained in the Constitution from ratification stands the Intellectual Property Clause, giving Congress 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."[6]

Just two short years after the Constitution was ratified, Congress enacted the first piece of patent legislation (the Patent Act of 1790) from this newly found power, where the fundamental *quid pro quo* of patent law was established. Section II of the 1790 Act states, in relevant part, that a patentee must deliver a specification to the Secretary of State that is so descriptive and complete so as to "*enable* a workman or other person skilled in the art or manufacture… to *make*, *construct*, or *use* the same" so that "the public may have the full benefit" of the invention once the term expires.[7]

The subsequent Patent Act of 1793 did not add much to this newly enacted enablement standard. The relevant language of the 1793 statute required a patentee to deliver the specification with so much detail that it enables a "person skilled in the art or *science*… to make, *compound*, and use the same."[8] The modifications to the statute did not change the fundamental understanding of the enablement requirement. The same conclusion is drawn from the later Patent Act of 1836, where the language of the enablement requirement was largely unchanged from the prior version.

The 1952 patent legislation officially codified the enablement requirement into what we now know as 35 USC §112. This section wraps in the entirety of the specification requirements into one, concise statute detailing the language required in a specification to obtain a patent. From this language came the modern case law surrounding the unpredictable arts and what it means to enable someone of ordinary skill in the art to make and use the invention where so much of the science is unpredictable and unknowable to those skilled persons. Even with this improved language, the unpredictable arts were still a challenge to the patent system.

In an attempt to harmonize judicial interpretation of the patent laws, Congress established the Court of Appeals for the Federal Circuit in 1982. The intent was to give this court express jurisdiction over patent cases consisting of a court packed with well-qualified judges to hear highly technical cases and derive fundamental and scientifically accurate case law to resolve these conflicts uniformly, something that prior courts had been unable to accomplish. This one-stop-shop for all patent and intellectual property-related matters allowed for patent jurisprudence to be communized across the United States, but again, unpredictable arts only proved to create challenges due to this rapid growth in technology.[9]

Pre-*Wands* Case Law

Enablement has not always been at the forefront of discussion amongst the various courts across the country. Before these complex unpredictable arts were paving the future, most granted patents involved mechanical devices and physical objects not on the micro-scale. Most of the discussion around these inventions centered around the other key requirements for a patent to grant: non-obviousness and novelty. With mechanical and physical-science-related inventions, enablement was rarely questioned, since the physical world we see has well-rooted science that has been universally accepted. These fields are known as the "predictable" arts, highlighting that a person of ordinary skill in the art can predict what will happen when universal physics is involved.[10]

Conversely, as stated in *Schering Corp. v. Gilbert*,[11] "organic chemistry is essentially an experimental science and results are often uncertain, unpredictable and unexpected."[12] This statement epitomizes the field of "unpredictable" arts and differentiates unpredictable science (organic chemistry, biotechnology, etc.) from that of the predictable arts dealing with rooted physical concepts and mathematics. This field of unpredictable arts has led to the emergence of enablement case law, since "slight variation[s] in a method can yield an unpredictable result or may not work at all."[13] Biologists, who are often the persons of ordinary skill in the art in these unpredictable fields, are generally unable to predict the outcome of an experiment, leaving the unknown still unknown.[14]

Even before the emergence of unpredictable arts, the Supreme Court recognized that an invention "rested in speculation or experiment… cannot avail to defeat a patent founded upon discovery or invention which was completed…."[15] Proving the success and completeness of an invention has been, and always will be, an integral part of the patent system and the enablement standard.

However, this is not to say that any amount of experimentation needed to practice an invention would necessarily render it not enabled. "[A] patent is not invalid because of a need for experimentation."[16] Routine experimentation, which is well known in the art, does not preclude the patentability of an invention. Only experimentation that is *undue* may render a patent not enabled.

In re Wands

In the unpredictable arts, experimentation required to practice an invention is almost inevitable, but at what level does it go beyond the threshold of routine experimentation? When the Federal Circuit decided *In re Wands*, it defined a high-level analysis for what kind of experimentation would render a patent specification not enabled, but as hindsight has shown, the majority ultimately failed to apply it correctly.[17]

The invention claimed in *Wands* involves immunoassay methods for detecting hepatitis B surface antigens by using high-affinity monoclonal antibodies of the IgM isotype. Antibodies have the potential to bind to the surface of molecules (i.e. an antigen). The hepatitis B virus particles contain various surface antigens (HBsAg) that are capable of serving as an antigen that triggers the body's natural response to create antibodies to fight the virus. The method for detecting or measuring the antigens by using antibodies as reagents is called an immunoassay.[18]

The inventor in *Wands* discovered that antibodies of the IgM isotypes are the better candidate for detecting HBsAg than their IgG sibling and are central to the claims in Wands' patent.

In the prior art, the use of IgM antibodies was disfavored because of their sensitivity to reducing agents and their tendency to self-aggregate and precipitate. Wands found through testing that some monoclonal IgM antibodies could be used for immunoassay of HBsAg with unexpectedly high sensitivity and specificity. In the patent application, Wands claimed an "immunoassay method utilizing *an antibody* to assay for a substance comprising hepatitis B-surface antigen (HBsAg)… wherein *said antibody* is a monoclonal high affinity IgM antibody having a binding affinity constant… of at least 10^9M^{-1}."[19] This claim essentially gave Wands control to all immunoassay methods for detecting HBsAg if the antibodies used for the detection were of the IgM isotype.

The process of generating monoclonal antibodies against a known antigen (or determinant thereof) is well known in the art at the time.[20] Generally, however, the process produces many cloned hybridoma cells, producing unique antibodies, most of which do not bind to the antigen, and significant screening of a large number of samples would be needed to determine the composition of the cloned cells. Further, performing these processes over and over again may result in vastly different antibody secretion effectiveness. What Wands tried to claim is the immunoassay method for detecting HBsAg wherein all of the binding antibodies are monoclonal high affinity (at least 10^9M^{-1}) IgM antibodies. It is ultimately argued by the Patent and Trademark Office Board of Patent Appeals (the "Board") that the patent broadly claims all immunoassay methods where the antibodies obtained fit that broad functional limitation without providing adequate data showing its predictability and does not disclose information sufficient to eliminate the need for undue experimentation, failing to put the public in a better scientific/technological position than it was before the patent.

Specifically, Wands stated that 9 samples were tested out of 143 total samples to determine the binding affinity and isotype, and of those 9 samples, 4 resulted in antibodies that fell within the claim limitation. The Board ruled that failing to test the remaining 134 samples for their binding affinity and isotype resulted in being unable to predict whether the methods described would cover the entire genus of antibodies, concluding that the actual tested success rate was a measly 2.8% (4 out of 143) which was insufficient to allow the claim as stated. The Board further stated that there is no way to prove that the remaining antibodies fell within the claim limitations and the statistics as viewed by the Board show Wands' methods were not predictable or reproducible. Essentially, the Board stated that the disclosure did not add sufficient predictability to warrant giving Wands a monopoly on the entire claimed genus of antibodies. Since the specification did not teach how to identify any other possible claimed embodiments with any predictability, excessive experimentation would still be required to determine if an antibody fell within the claim limitations. Wands, on the other hand, argued that the predictability should have been determined by the success rate of the samples tested, which would jump up to a much more respectable 44.4% (4 out of 9) which, Wands argued, would prove that the methods disclosed predictably produce an antibody within the claim limitations.

On appeal to the Court of Appeals for the Federal Circuit, the majority ultimately laid out an 8-part test for analyzing whether undue experimentation is required to practice an invention (a.k.a. the *Wands* factors): (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.[21] The majority agreed that the process for which monoclonal antibodies are obtained is well known in the art, regardless of the presented difficulty in performing the method. The majority also agreed that the process for which these obtained monoclonal antibodies were screened for their affinity constant and isotype was well known, as Wands used "a commercially available radioimmunoassay kit" and the "more laborious Scatchard analysis" to screen the samples collected.[22] The problem arose when Wands tried to claim the entire genus of IgM antibodies with a binding affinity constant of at least 10^9M^{-1} capable of binding to the Hepatitis B surface antigen. The majority ultimately ruled for Wands, taking Wands' stance that 9 tested samples resulting in 4 successful monoclonal antibodies meeting that broad functional limitation predictably enabled a person of ordinary skill in the art to practice the full scope of the invention. They came to this conclusion since all of the methods for obtaining monoclonal antibodies were well known in the art, and that the only question mark would be how to view the data presented by Wands to determine how big the full scope of the claims actually is. The majority failed to understand the full breadth of the claims, however, viewing the entire genus as that presented by Wands since there was "no evidence presented… on how many hybridomas" would need to be screened to obtain an antibody that fell within the claim limitations, further clarifying that undue experimentation would not be defined by "the number of hybridomas that were never screened."[23]

This ruling, when viewed through the prism of the full scope of the claims, was ultimately problematic. The patent system has been defined so as to give inventors an exclusive right to use, license, and sell their invention for a limited amount of time, giving them a monopoly on their invention in the market for the duration of the patent. In return, the USPTO requires that the specification of the patent be detailed enough to allow any person of ordinary skill in the art to practice the *full scope of the invention* and for the public to benefit from the scientific advancements once the term expires. In other words, the specification must detail not only the step-by-step process used to practice the invention as described, but also teach the entire range of possible variations. If a claimed invention is a completely decorated cake but practicing the specification results in only obtaining a chocolate cake with a buttercream frosting, the inventor has not *earned* the right to claim all potentially different types of decorated cakes (such as carrot cake, red velvet, pound cake, etc.). Since the specification teaches only how to make one type of cake out of the millions of possible cake combinations, the patent has not given possession of the *full scope* of the invention to the public as required by 35 USC §112 and

the *quid pro quo* of patent law. As with Wands' specification, the entire procedure to obtain the monoclonal antibodies capable of meeting the claim limitations is laid out, but in failing to analyze the scope of the genus, the majority allowed for a patent specification to gain a monopoly on a genus of antibodies where the specification gives unpredictable results as to the full scope of antibodies capable of meeting the claim limitations. In a field as complex and unpredictable as monoclonal antibody creation, predictability cannot be obtained through extrapolation, probabilities, or estimations.

In her dissent, Judge Newman took the correct approach to this problem, wherein she viewed the data as 4 successful antibodies out of the impossibly large genus of potential antibodies capable of meeting the claim limitations. She ignored Wands' plea for the court to look at how "statistical[ly]… unlikely it is that Wands selected the only [4] out of 143 that worked."[24] Judge Newman, with a Ph.D. in chemistry from Yale and professional experience as a research scientist, understood at the time that the breadth of the claims presented by Wands encompassed science that could not be verified with just 4 successful samples, and ignored the majority's stance that Wands need only provide the samples tested to sufficiently enable the entire genus. Regardless of whether the remaining 134 samples were tested, Newman's dissent indicated that the ultimate argument was invalid. Her dissent highlighted that the breadth of the claims could not be covered by 143 samples, let alone the 4 successful ones Wands presented, and that allowing the patent to issue would deprive the public of their right to the full scope of the invention. Since Wands had not shown "sufficient experimental support for the breadth of the requested claims…",[25] she would have affirmed the Board's decision in rejecting the claims as not being enabled.

Over the next 33 years, Judge Newman's analysis in *Wands* would be proven correct. As the Federal Circuit continued to hear cases in the unpredictable arts, the case law evolved to ensure the essence of the enablement requirement remains.

Post-*Wands* Case Law

After the *Wands* decision, courts began relying on the undue experimentation standard (*Wands* factors) laid out by the Federal Circuit to address challenges under enablement. Ultimately, the Federal Circuit has used the *Wands* factors to keep patent holders at bay, restricting them from claiming broad functional limitations to massive genera where the right to claim that genus has not been sufficiently disclosed. Specifically, in *Wyeth v. Abbott Laboratories*, the court held Wyeth's claimed method[26] was not enabled since the claims set forth a "new method of use of a known compound (sirolimus) *and* any other compounds that meet the construction's structural and functional requirements."[27] This ruling made it clear that the Federal Circuit would not allow for patent holders to expressly claim unfounded and unspecified boundaries of the field of invention. Without predictability as to the metes and bounds of the property right, the enablement requirement is not met.

Wyeth further controlled the decision in *Enzo Life Scis., Inc. v. Roche Molecular Sys.*, where the court ruled that the claims[28] for creating polynucleotides that are hybridizable and detectable upon hybridization encompassed not just a structure, but also a functional limitation. The functional limitation would require someone of ordinary skill in the art to undergo undue experimentation to determine if a sample falls within the claim limitation since there was, again, no predictability as to the metes and bounds of the invention. Thus, the full scope of the invention was not enabled in the specification.[29] This decision further defined that enablement requires predictability, where a person of ordinary skill in the art should not be required to undergo excessive amounts of experimentation before they create an embodiment that falls within the claim limitations. The alternative to this ruling would create an environment where one would need to test each and every creation to determine if it falls within any patent specification's functional claim limitations (i.e. undergo undue experimentation).

Additionally in *Idenix Pharms v. Gilead*, the court viewed the broad structural limitations of the compounds covered by the claims[30] to a method for treating hepatitis C virus (HCV) comprising any nucleoside that exhibits anti-HCV activity as potentially being "satisfied by *billions* of compounds"[31] which cannot be reasonably claimed in one broad functionally limited claim. The court has been firm that without adding certainty and specificity to the specification, a patentee is not entitled to claim more of the field and technology than is disclosed. However, the court has still held strong that routine experimentation does not bar patentability, and the *Wands* factors are not to be viewed as a "single, factual determination, but rather… a conclusion reached by weighing many factual considerations."[32] The court has further emphasized that enablement "serves the dual function… of ensuring adequate disclosure of the claimed invention and of preventing claims broader than the disclosed invention."[33]

Regardless, the court has seemingly taken Judge Newman's stance in these cases by limiting patentability only to those who have fully enabled their invention. *MorphoSys v. Janssen* was a groundbreaking case prior to *Amgen* that applied the *Wands* factors to functionally broad blood-cancer-fighting antibodies.[34] Experts in the case determined that there could be upwards of "10^{19} (ten quintillion)" antibodies that fall within the claimed functional limitations.[35] Ultimately, the court ruled that the *Wands* factors show that the invention in this case was not enabled, furthering the narrative that functional limitations added to claims of

broad genera generally do not support a finding of enablement without a substantial showing of empirical data and predictability proving the right to claim all potential species. The boundaries of the property right must be sufficiently disclosed and predictable; otherwise, the public would fail to gain the benefit of scientific advancement since the unknown would remain unknown until the patent expires.

These post-*Wands* cases hand down a fair legal finding of one's inability to claim all species of a given genus, and the court hit this point home when it decided *Amgen v. Sanofi*.

Amgen v. Sanofi

The technology at issue in *Amgen* is fairly similar to that of *Wands*, where the central aspect of the claims in question revolves around a genus of monoclonal antibodies, defined only by functional limitations, and the patent at issue also purports the same predicaments as the *Wands* patent. The majority in *Amgen*, unlike that of *Wands*, appreciated the breadth of the claims presented and agreed that identifying the metes and bounds of the invention was clearly lacking in the specification.

Low-density lipoprotein (LDL) cholesterol is linked to heart disease if at elevated levels. LDL receptors remove LDL cholesterol from the bloodstream by binding to the cholesterol, but the receptors are subject to degradation at the hands of the proprotein convertase subtilisin/kexin type 9 (PCSK9) enzyme, decreasing the number of receptors on the cell's surface capable of removing the cholesterol. Antibodies may bind to and block PCSK9, thus allowing LDL receptors to function uninhibited.[36] The process in which the antibodies are obtained was not at issue in this case like in *Wands*. Similar to *Wands*, though, *Amgen* claimed all antibodies that perform the function of binding to the PCSK9 enzyme.

Amgen owns two patents (the '165 and the '741 patents, both of which share the same specification) that describe antibodies that bind to the PCSK9 protein and lower LDL cholesterol levels by blocking PCSK9 from binding to LDL receptors. The specification discloses amino acid sequences for twenty-six antibodies, including one with the generic name evolocumab and marketed by Amgen as Repatha®. The '165 patent claims an "isolated monoclonal antibody" that binds to PCSK9, where the antibody "binds to at least one of the following residues: S153, I154, P155, R194, D238, A239, I369, S372, D374, C375, T377, C378, F379, V380, or S381… and… blocks binding of PCSK9 to [LDL Receptors]."[37] Other claims in the patent recite the antibody as "bind[ing] to at least two" of the listed residues, and further defines the antibody as part of a pharmaceutical composition that has a blocking efficiency (of stopping the PCSK9 enzyme from binding to LDL receptors) of "at least 80%."[38] Undeniably, these claims are broad in scope and function since they cover antibodies defined by their function and not their amino acid structure, and therefore could ultimately encompass millions of potential embodiments. The '741 patent narrows the scope of the '165 patent, however minimal the narrowing actually is, by claiming an antibody with the same function of binding to the PCSK9 enzyme but adds that the antibody may bind an epitope "comprising at least one of residues 237 or 238", is a "neutralizing antibody", and claims the epitope the antibody binds as being a "functional epitope."[39] None of these claims add any specificity or predictability to the broad scope of the invention, and thus, iterative trial and error research would still be needed to determine if a monoclonal antibody created would fall within the scope of the claims.

Mere days after the '741 patent was granted, Amgen sued Sanofi (Aventisub LLC, Regeneron Pharmaceuticals Inc., and Sanofi-Aventis U.S. LLC, collectively "Sanofi") alleging infringement of multiple patents (including the '165 and '741 patents). Sanofi challenged the validity of the patents, arguing that the specifications lacked written description and enablement. The District Court effectively overruled Sanofi's challenge to the written description by instructing the jury that a "written description can be satisfied 'by disclosure of a newly-characterized antigen… if you find that the level of skill and knowledge in the art of antibodies at the time of filing was such that *production of antibodies* against such an antigen was *conventional or routine*.'"[40] With this instruction, the jury unjustly returned a verdict for Amgen, finding that the patents were not shown to be invalid for lack of enablement or written description.

The Federal Circuit, on appeal, held that the jury instruction was clearly erroneous, among other things (including finding that the District Court's exclusion of post-priority-date evidence requires a new trial on enablement[41]), and remanded the case to the District Court for a new trial where Sanofi could introduce additional evidence. On remand, the jury again found that Sanofi failed to prove that some of the claims were invalid for lack of written description and enablement. The District Court, however, granted Sanofi's motion for JMOL for lack of enablement, finding that no reasonable jury could find that the claims enabled the full scope of the invention. The District Court clarified that "[a] person of ordinary skill in the art can only discover undisclosed claimed embodiments either (1) through trial and error, by making changes to the disclosed antibodies and then screening those antibodies for the desired binding and blocking properties, or (2) by discovering the antibodies *de novo*."[42] In laying out these two possible approaches, the District Court effectively stated that although there are methods to find undisclosed embodiments, the breadth of the claims combined with the lack of predictability in the specification as to which of the millions of possible antibodies will meet the claims' limitations equates to undue experimentation.

Essentially, the metes and bounds of the property right could not be discovered with the given specification. Naturally, Amgen appealed this holding for the Federal Circuit to determine if the claims of the patent specifications were enabled, leading to the 2021 case at issue here.

Federal Circuit's Holding in *Amgen*

In discussing the breadth of the claims in Amgen's patents, the Federal Circuit focused primarily on the number of embodiments that could be covered by the claims, and the effort that would be required to practice the full scope of the claimed embodiments. Relying on *Wyeth*, *Enzo*, and *Idenix*, the court reaffirmed its stance that "the enablement inquiry for claims that include functional requirements can be particularly focused on the breadth of those requirements, especially where predictability and guidance fall short."[43] The court expressly stated that enablement requires an analysis of the experimentation needed not just to cover the embodiments that are disclosed, but also the experimentation needed to practice the full scope of the claim. In Amgen's case, where there are potentially millions of embodiments that could fall within the claimed limitations, the court concluded that there is no possible way that the disclosure contained enough specificity and guidance for someone of ordinary skill in the art to practice the full scope of the claims without undue experimentation.

A patent specification claiming an entire genus in an unpredictable field needs to be sufficient enough to cover most, if not all, of the potential embodiments within that genus. A failure to do so results in being unable to predictably obtain an embodiment, other than the embodiment(s) disclosed, that falls within the metes and bounds set by the functional limitations. The court stated that a *Wands* analysis routinely involves a "concrete identification" of potential embodiments that are not enabled "so that breadth is shown concretely and not just as an abstract possibility."[44] "While functional claim limitations are not necessarily precluded,… such limitations pose high hurdles", especially in unpredictable fields, that a patent specification must surpass to be enabled.[45] The court furthered this narrative with Amgen's specification, stating although it does "include[e] data regarding certain embodiments," the full scope of the claimed invention cannot be "predictably… generated by the described methods."[46] In focusing on the effort required to practice the full scope of the invention, the court found that the methods disclosed were inadequately predictable.

Conclusively, the Federal Circuit upheld the District Court's ruling that Amgen's claims were invalid for lack of enablement. A claim that covers an entire genus, limited only by functional requirements, cannot be adequately predicted in this case because a person of ordinary skill in the art would still need to perform an excessive amount of experimentation to ascertain the metes and bounds of non-disclosed embodiments falling within the claim limitations. This conclusion, remarkably, is the same one that Judge Newman came to 33 years prior in *Wands*.

Post-*Amgen* Implications on Unpredictable Arts

After the February 2021 decision holding the patents invalid for lack of enablement, Amgen petitioned for a panel rehearing in the Federal Circuit *en banc*, and in June of 2021, the Federal Circuit denied the petition and issued a denial opinion to accompany. Amgen argued that requiring broad generic claims to be supported by disclosing the full scope of the claims "will make it impossible to obtain proper protection for biotechnology inventions".[47] The court shot down this plea from Amgen, sticking to the precedentially strong narrative that has manifested over the last few decades, where an inventor may still be able to claim a broad genus so long as the inventor has "invented species that constitute a genus."[48] As in *Amgen*, a specification that is so narrow and limited with guidance so as to make the "far corners of the claimed landscape" inaccessible or unascertainable is per se not enabled.[49]

Amgen further argued that the court's decision will have a devastating impact on inventors in the field and the market itself. Amgen believed that inventors will be hesitant to make the next best thing if there is no guarantee of protection and investors will not have incentives to invest in drug discovery. This fear and concern is presumably at the forefront of the Federal Circuit's mind when it hears these complex patent cases – how far should the courts restrict patentability without compromising innovation? That question is indeed hard to quantify. However, as the court states in the rehearing denial opinion, "enablement is part of our law, and for good reason."[50] Without enablement, inventors would be monopolizing vast areas of science and technology and stifling innovation by holding too much of the knowledge as a property right, effectively for ransom. Enablement is designed to give inventors an outlet to showcase their unique, specific invention and the wonders it can do for society without giving them the right to something that they have not fully fleshed out.

Imagine an airplane for example. An airplane consists of a fuselage, wings or lifting surfaces, control surfaces, engine(s), avionics, etc. Further down from all of those items exists more and more components that make each item unique and innovative, with so many different parties at play that combine their knowledge and technology to make these incredible aircraft. Imagine if the courts had allowed a single person/company to patent the concept of an aircraft, say back when the Wright brothers designed, developed, and flew the first controllable aircraft in 1903.[51] The claims could have consisted of a flying machine that performs the *function* of flight. For the next 17 years (the patent term at the time, which also

leads through WWI where there was the first boom in aircraft technology), not a single person would have been able to design and commercialize a better aircraft without paying for a license because the claims of the Wright brothers' broad patent would have covered all craft that performs the function of flight. Innovation would have been stifled by the *allowance* of a patent instead, and the world of air travel we know today may be very different. If this is the case for mechanical inventions that most of us can reasonably understand, why should the same not be true for chemical compositions and processes, especially those which are unpredictable?

The Accuracy of Judge Newman's Dissent

It seems that the court has encompassed the entirety of Judge Newman's dissent in *Wands* into the *Amgen* opinion. When Judge Newman was initially discussing predictability in *Wands*, she noted that an inventor must provide "sufficient data or authority" to show that the results of practicing the specification "are reasonably predictable within the scope of the claimed generic invention…."[52] While the majority failed to apply this standard to the invention in *Wands*, the Federal Circuit in its subsequent opinions, *Wyeth*, *Enzo*, *Idenix*, *MorphoSys*, and now *Amgen*, has proven Judge Newman's original synopsis correct and appropriately limited patent holders from seeking overly broad claims that have not predictably been disclosed because of a failure to teach the full scope of the claims.

As Newman's dissent appeared to indicate during the original boom of this type of unpredictable technology, there needs to be an enhanced appreciation and microscope placed on the breadth of a given claim. The future of innovation and patent rights are at stake in every decision handed down by the Federal Circuit interpreting patent laws. The law should be strict enough to make the public the true beneficiaries of new technologies but should also be decided case-by-case to ensure that every patent holder is treated fairly and held to a standard sufficiently indicative of the Constitutional requirement to promote science and useful arts.

Judge Newman was ultimately correct all the way back in 1988. Her dissent appears to have appreciated the potential for the chemical and biotech field and applied that level of care to the breadth of Wands' claims, labeling them as too broad to gain patent protection since the metes and bounds of the property right could not reasonably be established without undue experimentation. She seemingly understood all this because she had an education in and exposure to this type of science, and the majority decision in *Wands* seemed to brush off the potentially monumental scope of the claims and rule on probabilities instead. Over the next 33 years, Judge Newman's original analysis was proven true through case law, and it is remarkable to see the similarities between the recent majority opinions compared to a dissent from one of the most foundational cases of the enablement requirement.

Global Analysis of Unpredictable Arts in Light of Precedent

As we continue to live in a world where COVID-19 is running rampant throughout our lives, the emergence of monoclonal antibody therapy treatments may run hand-in-hand with the legal issues seen in *Wands* and *Amgen*. At the moment, there are three anti-SARS-CoV-2 monoclonal antibody treatments with FDA Emergency Use Authorization (EUA) for the treatment of COVID-19, one manufactured by Eli Lilly and Company, one by Regeneron Pharmaceuticals, and one by GlaxoSmithKline LLC.[53] In a year's time, who knows how many monoclonal antibody treatments there may be for the virus, who knows how many different ways may be created to treat the virus, and who knows how broad the companies creating these treatments may want to tread to potentially gain patent protection.

Importantly, the decision in *Amgen* allows for multiple antibody treatments to be available. If the decision had gone the other way, we could potentially be looking at a situation where one company holds the right to prevent everyone else from manufacturing antibodies that fight SARS-CoV-2. The importance of the *Amgen* decision is immediately apparent given the current global climate, and the ability for many companies to create different variations of an antibody that fights the same virus only benefits the public. What is certain is that the recent Federal Circuit precedent along with the fight against a pandemic raging across the globe will serve to guide society and policymakers in the present and future to ensure that the public remains as the sole beneficiary of scientific advancements.

Tension on the Federal Circuit

With so much technology and science still yet to be uncovered, the Federal Circuit has its work cut out going forward. The court has the duty to apply and interpret the law as necessary to promote the progress of science and useful arts by protecting the inventions of those making a difference with their innovations.

However, the Federal Circuit may be losing sight of what its intended purpose was when it was formed in 1982. Out of the nineteen total judges on the Federal Circuit (including Senior Judges), only nine have the qualifications to sit for the patent bar exam. As a court that was specifically created to hear appeals from the Patent Trial and Appeals Board, the essence of the court's function may be losing its luster. In *Wands*, the two judges in the majority were split as to their qualifications to sit for the patent bar, and in *Amgen*, two of the three judges were qualified, which makes these two cases exactly similar in terms of the judges' technical qualifications. However, that alone is the problem. As seen in *Wands*, all it took was for two judges to not fully understand the breadth of the science to make a ruling that fundamentally

goes against and alters the reality of the science at hand. A similar situation could have happened in *Amgen* and could potentially happen in future cases. Without a resolution to this problem, the Federal Circuit may be destined to lose the one thing that made it unique and vitally important to this country – its ability to hear, understand, and decide patent (and all intellectual property) cases.

The Federal Circuit has made, and will continue to make, difficult and un-quantifiable decisions. As so much of the world we know becomes more and more digitized and complex, so does the potential for more and more unpredictable inventions. One can only guess what these will be, but the Federal Circuit will be at the heart of patent disputes. A technically divided Federal Circuit may impact subsequent outcomes, but if *Amgen* says anything about the future decisions of the Federal Circuit, it is that the court will not allow for the unknown to remain unknown due to the lack of an inventor's ability to test and disclose the full scope of a claim. It is the hope of an engineer/scientist and aspiring legal professional that the Federal Circuit continues to come out on the right side of the coin in these cases moving forward by developing case law that is both legally sound and scientifically accurate. Regardless, the future looks optimistic and exciting both in the realm of scientific innovation and the emergence of new case law.

This article was prepared with assistance from Duane C. Marks, Assistant General Patent Counsel, Eli Lilly and Company, Adjunct Professor, IU Robert H. McKinney School of Law.

About the Author

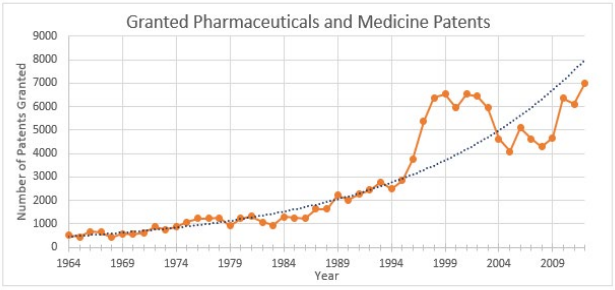
Lucas (Luke) Peterson *is a rising 4L J.D. Candidate at the Indiana University Robert H. McKinney School of Law evening program and a student representative at the IU McKinney IP Clinic. He received a B.S. in Aerospace Engineering from Embry-Riddle Aeronautical University. He worked in the aerospace and automotive industry writing software for flight simulators, turbine aircraft engines, and electric vehicle propulsion platforms before joining a Chicago-based law firm in 2022 to work in patent prosecution. This article would not have been possible without the guidance and teachings from Duane Marks, Assistant General Patent Counsel at Eli Lilly and Company and Adjunct Professor at IU Robert H. McKinney School of Law, Pervin Taleyarkhan, Legal Counsel at Whirlpool Corporation and Director of the IP Clinic at Indiana University Robert H. McKinney School of Law, and Derek Lavender, Associate Attorney at Taft, Stettinius & Hollister and Adjunct Professor at IU Robert H. McKinney School of Law.*

Endnotes

1 Sir Arthur Conan Doyle, *The Complete Sherlock Holmes*

2 *In re Wands*, 858 F.2d 731, 740 (Fed. Cir. 1988).

3 See Figure below.



4 See https://www.uspto.gov/dashboard/patents/. The USPTO reports the average first office action pendency is 16.9 months with issuance being 23.4 months on average.

5 *Amgen Inc. v. Sanofi*, 987 F.3d 1080 (Fed. Cir. 2021).

6 U.S. Const. art. I, § 8, cl. 8.

7 Patent Act of 1790, Ch. 7, 1 Stat. 109-112 (April 10, 1790) (emphasis added).

8 Patent Act of 1793, Ch. 11, 1 Stat. 318-323 (February 21, 1793) (emphasis added).

9 The subsequent, and current law today – the Patent Act of 2011, a.k.a. America Invents Act (AIA) – added no substance to the enablement requirement. Thus, the holistic view of how the enablement requirement is to be interpreted has rested upon the courts since the enablement requirement was officially codified.

10 Sean B. Seymore, *The Enablement Pendulum Swings Back*, 6 Nw. J. Tech. & Intell. Prop. 278 (2008), https://scholarlycommons.law.northwestern.edu/njtip/vol6/iss3/2

11 *Schering Corp. v. Gilbert*, 153 F.2d 428 (2nd Cir. 1946)

12 *Id.* at 433.

13 *Cedarapids, Inc. ex rel. El-Jay Div. v. Nordberg, Inc.*, 95-1529, 1997 U.S. App. LEXIS 21157 (Fed. Cir. Aug. 11, 1997)

14 Attorney-scientist Karen Canady discusses this dichotomy with a biotechnology example:

> [A]n inventor develops a strategy for solving a class of problems, but has yet to demonstrate success in all applications within that class. Although the strategy may seem logical enough that one would expect it to succeed

wherever applied, the unpredictability of biology raises doubts about this expectation. Difficulties arise because trial and error is normally required before a biologist can know which applications of a given strategy will succeed. Thus, it is difficult to distinguish between claimed inventions that solve an entire class of problems and those whose applicability is more limited.

Sean B. Seymore, *The Enablement Pendulum Swings Back*, 6 Nw. J. Tech. & Intell. Prop. 278 (2008), https://scholarlycommons.law.northwestern.edu/njtip/vol6/iss3/2 (citing Karen S. Canady, *The Wright Enabling Disclosure for Biotechnology Patents*, 69 WASH. L. REV. 455, 458 (1994)).

15 *Barbed Wire Patent*, 143 U.S. 275, 285 (1892)

16 *W.L. Gore & Assocs. v. Garlock, Inc.*, 721 F.2d 1540, 1557 (Fed. Cir. 1983)

17 Judge Newman, unlike the majority, appreciated how broad genus claims, especially in the unpredictable arts, impacted the framework for undue experimentation. For experimentation to pass into the undue realm, that usually indicates a lack of specificity or guidance as to the metes and bounds of the property right claimed.

18 *Wands,* 858 F.2d at 733.

19 U.S. Patent No. 4,879,219 (issued Nov. 7, 1989) – emphasis added.

20 See *Hybritech, Inc. v. Monoclonal Antibodies, Inc.,* 802 F.2d 1367 (Fed. Cir. 1986). See also the Kohler and Milstein's hybridoma technology.

21 *Wands,* 858 F.2d at 737.

22 *Id.* at 738.

23 *Id.* at 740.

24 *Id* at 741.

25 *Id* at 741.

26 See U.S. Patent No. 5,516,781 (issued May 14, 1996).

27 *Wyeth & Cordis Corp. v. Abbott Laboratories*, 720 F.3d 1380, 1385 (Fed. Cir. 2013).

28 See U.S. Patent No. 6,992,180 (issued Jan. 31, 2006) and U.S. Patent No. 8,097,405 (issued Jan. 17, 2012).

29 *Enzo Life Scis., Inc. v. Roche Molecular Sys.,* 928 F.3d 1340 (Fed. Cir. 2019).

30 See U.S. Patent No. 7,608,597 (issued Oct. 27, 2009).

31 *Idenix Pharms. LLC v. Gilead Scis., Inc.*, 2018 U.S. Dist. LEXIS 25663, *31 (D. Del. 2018) (emphasis added)

32 *Wands,* 858 F.2d at 737.

33 *MagSil Corp. v. Hitachi Glob. Storage Techs., Inc.,* 687 F.3d 1377, 1380-1381 (Fed. Cir. 2012)

34 *MorphoSys AG v. Janssen Biotech, Inc.*, 358 F. Supp. 3d 354 (D. Del. 2019)

35 *Id.* at 369.

36 *Amgen*, 987 F.3d at 1082-1083.

37 U.S. Patent No. 8,829,165 (issued September 9, 2014).

38 *Id.*

39 U.S. Patent No. 8,859,741 (issued October 14, 2014)

40 *Amgen Inc. v. Sanofi*, 872 F.3d 1367, 1372 (Fed. Cir. 2017) (emphasis added).

41 *Id.* at 1375.

42 *Id.* at *31-32.

43 *Amgen*, 987 F.3d at 1086.

44 *Id.* (citing *McRO, Inc. v. Bandai Namco Games Am., Inc.*, 959 F.3d 1091, 1100 (Fed. Cir. 2020)).

45 *Id.* at 1087.

46 *Id.* at 1087-1088.

47 *Amgen Inc. v. Sanofi*, 850 F. App'x 794, 796 (Fed. Cir. 2021)

48 *Id.*

49 *Id.*

50 *Id.*

51 See U.S. Patent No. 821,393 (issued May 22, 1906). This is the patent the Wright brothers received for their "new and useful Improvements in Flying-Machines", where the main feature of protection in their invention was the newly found and implemented ability to control a flying machine while it is in the air. This development in aviation technology was revolutionary at the time and gave the brothers the reputation they have today in aerospace history, but the patent did not give them the rights to an entire genus of flying machines with control surfaces that give a pilot the ability to control the flying machine in the air.

52 *Wands*, 858 F.2d at 742.

53 https://www.cdc.gov/coronavirus/2019-ncov/variants/variant-info.html#:~:text=In%20the%20United%20States%2C,%2C%2C%20and%20sotrovimab. Links to the individual fact sheets for each antibody treatment on the CDC website:

- Eli Lilly: https://www.fda.gov/media/145802/download
- Regeneron: https://www.fda.gov/media/145611/download
- GSK: https://www.fda.gov/media/149534/download

Every Word Matters in Trade Secrets Agreements

BladeRoom Group v. Emerson Electric

By Dave S. Christensen

Trade secrets are one of the oldest forms of intellectual property, with the modern version starting to appear in the early 1800's in both England and the United States[1]. In order for a trade secret owner to maintain their information as a trade secret, they must of course keep it secret. This can be difficult to do in a modern business environment where partnerships and various forms of outsourcing are commonplace and electronic communications occur with the click of a button. To maintain their trade secrets, companies often rely on agreements, sometimes referred to as confidentiality or nondisclosure agreements (NDAs) to contractually prevent employees and third parties from disclosing their information.

With the exception of purchase orders, NDAs are perhaps one of the most common contracts executed by companies today. They are so common that many companies have templates that are used freely by their employees before entering into discussions with third parties. With such common acceptance, it is easy for a company's employees to have a false sense of security about their trade secrets. Recently the company Bladeroom Group Ltd. found this out after discussions with Emerson Electric Co. were terminated[2].

What exactly are trade secrets? Since trade secret law was developed by state courts, traditionally there has not been just one definition. In general trade secrets are considered to be any information (e.g. formula, pattern, device or compilation) having independent economic value that the company derives benefit from due to it being secret.[3] A trade secret typically is related to technical information, such as the formula for Coca-Cola soft drinks or Google's search algorithm, but may also be used to protect softer business information such as compilations of customer lists or market information.

One unusual characteristic of trade secrets is that unlike patents and trademarks, there are no expirations on the protection provided that the holder takes reasonable efforts under the circumstances to keep the information secret. Once a public disclosure has occurred, however, the trade secret protections are lost. Trade secrets may be protected in a number of ways, depending on the nature of the information. As mentioned, one common method of protecting trade secrets is to use NDAs like the one executed by BladeRoom and Emerson. Both companies competed in the market to design and build data centers. In 2011, BladeRoom and Emerson entered into discussions to merge BladeRoom into Emerson's business. It should be appreciated that merger discussions often require the business being acquired to disclose many intimate details of its operation, including trade secrets such as designs, engineering methodologies. To protect itself, BladeRoom prepared and Emerson executed a nondisclosure agreement in August 2011. This agreement included the following clause, referred to as "Paragraph 12":

> The parties acknowledge and agree that their respective obligations under this agreement shall be continuing and, in particular, they shall survive the termination of any discussions or negotiations between you and [BladeRoom] regarding the Transaction, *provided that this agreement shall terminate on the date 2 years from the date hereof.* (emphasis in the opinion)

The discussions between the Bladeroom and Emerson eventually ended in July 2012 without the acquisition taking place. Based on Paragraph 12, the NDA between BladeRoom and Emerson terminated in August 2013.

Subsequent to their failed merger discussions, from July 2012 – October 2012, BladeRoom and Emerson each independently submitted proposals to Facebook for the building of a data center in northern Sweden. At the time of the initial proposal, Emerson's design was only 10% complete. In November 2013, Emerson was awarded the contract, which was signed in March 2014. Upon discovering Emerson was awarded the contract by Facebook, BladeRoom sued both Facebook and Emerson, alleging its design was copied, and that Emerson breached the nondisclosure agreement and misappropriated trade secrets. Facebook eventually settled with BladeRoom halfway through the district court trial.

At trial, the district court granted a motion to BladeRoom that prevented Emerson from arguing that Emerson had no liability for information used or disclosed after August 17, 2013[4]. The jury ultimately found Emerson liable for trade secret misappropriation and awarded BladeRoom $30 million and the district court added an additional $30 million dollars in punitive damages and $18 million in attorneys' and expert witness fees. Emerson appealed that the trial judge erred in granting BladeRoom's motion regarding arguments about the use of BladeRoom's information after August 17, 2013.

On appeal, BladeRoom argued that under Paragraph 12 any information disclosed prior to termination of the agreement was subject to the continuing obligation of confidentiality. Emerson's position was that Paragraph 12 should be interpreted as requiring confidentiality during the discussions but ended upon the two-year termination date.

Unfortunately for BladeRoom, the appeals court agreed with Emerson's interpretation. The court focused on two words "provided" and "and." The court found the term "provided" under its ordinary meaning means "on the condition, supposition, or understanding (that)." In other words, the portion of the section that was allegedly supposed to make the confidentiality provisions continuing after discussions ended was on the condition that the agreement terminated in two years. Further, the court held that because the conjunctive "and" separated the first and second clauses of Paragraph 12, the "provided" condition applied to both clauses. Thus the survivability of the confidentiality terms of the agreement after termination of the discussions or negotiations was further conditioned on the agreement terminating in two years. The court further noted that BladeRoom's interpretation "twisted the ordinary meaning of works … [and] also spawned absurdity." At trial, the jury only answered whether the breach of contract or misappropriate occurred, not when they occurred (i.e. before or after August 17, 2013). Therefore the appeals court vacated the jury's decision and remanded a new trial.

It should be noted that if, in the new trial, the disclosure of trade secret information is found to be after the termination of the nondisclosure agreement, under California law no misappropriation can occur since there was "no further obligation to protect the confidentiality of the information."[5]

What can we learn from this? In transactions involving trade secrets, make sure your agreement clearly and unambiguously states that the confidentiality provisions survive the termination of the agreement not simply the cessation of discussions. Otherwise, in addition to losing a potentially valuable business contracts, the trade secret protections may no longer protect your valuable business information.

About the Author

Dave S. Christensen, *Partner, Cantor Colburn LLP. Dave co-chairs the firm's Mechanical Engineering Patent Practice and chairs the Additive Manufacturing Practice Groups, leading teams dedicated to responsive client focused service. He focuses his practice on assisting clients in using patents and trade secrets to protect their products in both U.S. and foreign jurisdictions in a variety of technical fields, including consumer products, electrical power distribution and transmission, renewable energy, and optical measurement systems. A significant part of his practice includes assisting clients in developing cost-effective strategies for managing risk and building their brand in new product development, and in building and managing their intellectual property portfolios.*

Endnotes

1 *Vickery v. Welch*, 36 Mass. (19 Pick.) 523, 527 (1837)

2 *BladeRoom Group Ltd. v. Emerson Electric Co.,* No. 19-16583 (9th Cir. Aug. 30, 2021)

3 MCL 445.1902(d)

4 The two-year date from when the NDA was executed.

5 *BladeRoom*, No. 19-16583 (9th Cir. Aug. 30, 2021). citing to *Altavion, Inc. v. Konica Minolta Sys. Lab., Inc.*, 226 Cal. App. 4th 24, 57 (2014)

Social Media

The IP Law Section Council is excited to announce that we have created a State Bar of Michigan Intellectual Property Law Section LinkedIn group. This group was created for LinkedIn users who are members or affiliate members of the State Bar of Michigan as a means for our IP community to engage with one another on issues relevant to the IP profession. We hope that each of you take advantage of this great opportunity to connect with the Michigan IP community and support us in furtherance of our mission to provide IP education to its members and the greater community.

To Join our LinkedIn Group, go to:
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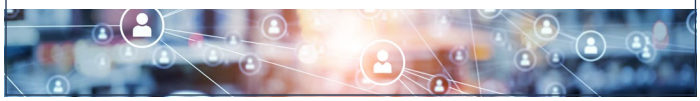

The Curious Case of *American Axle* and Patent Eligibility

By Justin J. Oliver and Joseph B. Cahill

In the early 2010s, the U.S. Supreme Court reined in the scope of patent eligible subject matter under 35 U.S.C. § 101 through the *Bilski*, *Mayo*, and *Alice* decisions. Unsurprisingly, particularly after the *Alice* decision in 2014, district courts became more willing to invalidate patent claims that involved, at least in part, laws of nature or abstract ideas. District courts routinely used patent ineligibility findings to dismiss patent infringement cases, through both motions for summary judgment and motions to dismiss on the pleadings under Rule 12(b)(6). Initially, these rulings culled patents with eligibility problems that issued from the U.S Patent and Trademark Office ("USPTO") prior to the sea change ushered in by *Alice* and its sibling cases.

Interestingly, however, district courts have continued to show little reluctance to dismiss early-stage cases on Section 101 grounds, even where the USPTO addressed *Alice* considerations in deciding whether to issue the patent. This trend raises interesting questions concerning the presumption of validity assigned to issued patents, the deference due to the USPTO's findings, and the nature of *Alice*'s two-part test for patent eligibility. Notably, the second part of *Alice*'s test implicates a factual inquiry asking if the claimed subject matter contains an inventive concept. The question of inventiveness is not the type of analysis courts have historically addressed in deciding motions to dismiss on the pleadings under Rule 12(b)(6).

A wide array of interested parties urged the U.S. Supreme Court to address these questions in connection with the *American Axle* case, where the Federal Circuit, in a split decision, upheld a decision finding a method of manufacturing driveshafts invalid under Section 101. However, the recent denial of certiorari in *American Axle* eliminates the possibility of the Supreme Court resolving Section 101 questions in the near term.

The Presumption of Validity

Under 35 U.S.C. § 282, "[a] patent shall be presumed valid" and "the burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity" with clear and convincing evidence.

Some decisions have described an "enhanced" or "added" burden where the USPTO considered the same arguments and/or evidence during prosecution before allowing the underlying patent application.[1]

Other Federal Circuit decisions have stated that the "burden" (clear and convincing evidence) does not change, but that the weight of the evidence changes, such that "it may be harder to meet the clear and convincing burden when the invalidity contention is based on the same argument … that the PTO already considered."[2] This line of Federal Circuit decisions primarily involves scenarios in which the USPTO had considered prior art, through rejections under 35 U.S.C. §§ 102 and 103, which rejections were ultimately overcome. In those cases, the challenger faced an uphill battle in convincing a district court that the USPTO erred in its judgment. But, as addressed in more detail below, for patent eligibility issues, the challenger has encountered much less resistance, statistically speaking.

When discussing the presumption of validity in the context of patent eligibility, the Federal Circuit has been less emphatic on the burden point. Specifically, in a decision addressing a dismissal under Rule 12(b)(6) even though the USPTO had explicitly confirmed patent eligibility during prosecution, the Federal Circuit merely stated: "to the extent that [plaintiff] argues that the district court should have deferred to the examiner's decision to allow the asserted claims, we have consistently held that any such deference is incorporated into the presumption of patent validity."[3]

Patent Eligibility

Under 35 U.S.C. § 101, "whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor." Excluded from patent eligibility are laws of nature, natural phenomena, and abstract ideas. For a time, applicants could obtain patents on, for instance, business methods *per se*. Post-*Alice*, such subject matter is typically characterized as an abstract idea and precluded from patent eligibility unless tied to a technical application.

Alice set forth a two-part test for determining patent eligibility. The first step "determine[s] whether the claims at issue are directed to one of [the] patent-ineligible concepts," such as a law of nature or abstract idea.[4] The second step "consider[s] the elements of each claim both individually and 'as an ordered combination' to determine whether the additional elements 'transform the nature of the claim' into a patent-eligible application."[5]

The question of patent eligibility is a question of law based on underlying facts.[6] In particular, the second step—determining whether the claim contains an inventive concept sufficient to transform the claimed abstract idea into eligible subject matter—is arguably a question of fact.[7] On this point, the dissent in *American Axle* accused the majority of substituting its own fact finding—which it called "result-oriented judicial action"—when addressing *Alice*'s second step.[8]

While *America Axle* involved an appeal of a summary judgment decision at the end of discovery, it is not uncommon for patent ineligibility rulings to occur prior to fact discovery (and expert testimony) through Rule 12(b)(6) motions. Under Rule 12(b)(6), all factual allegations in the complaint are accepted as true and the issues are viewed in a light most favorable to the plaintiff. Consequently, dismissals under Rule 12(b)(6) are not common in patent litigations.

Thus, the relative ease with which courts have been willing to decide patent eligibility issues on the pleadings raises an interesting (albeit perhaps philosophical) question concerning why courts are more comfortable deciding Section 101 questions at the early stages of a case as compared to other statutory classes of invalidity (*e.g.,* Sections 112 and 103). While Sections 101 and 103 do not present a true apples-to-apples comparison, the second step under *Alice* considers whether the claim contains an "inventive concept" that transforms the claim into patent eligible subject matter.[9] This analysis determines whether the other claim elements are "conventional."[10] Judging conventionality is arguably akin to an obviousness analysis.

For context, *Aatrix* presents a typical Rule 12(b)(6) analysis. There, the Federal Circuit reversed a patent eligibility dismissal under Rule 12(b)(6) on the basis that the amended complaint set forth concrete factual allegations concerning the second part of the Alice test, which allegations must be accepted as true.[11] This guiding principle has commonly prevented dismissals on the pleadings in patent cases. Yet, *Aatrix* aside, patent eligibility cases buck the trend in the post-*Alice* world.

A Statistical Curiosity

Since 2015 (the year following *Alice*), there have been 678 Rule 12(b)(6) motions to dismiss that, in some manner, raised issues under Section 101, of which 228 of the motions were granted (with many others being granted in part). Many of those cases involved patents that issued before the law change in *Alice*, which patents would be subject to greater scrutiny, given the law change. However, looking at the 25 most recent Rule 12(b)(6) decisions, by district courts, that addressed patent eligibility, there were 54 patents asserted by defendants to be ineligible. Of those 54 patents, only 5 survived the challenges, with the remaining 49 patents being found patent ineligible (a 90.7% success rate). Notably, of the 49 patents found to be patent ineligible, over half (25) issued *after* 2014 (the year of the *Alice* decision), which means that they would have been examined by the USPTO using the two-part *Alice* test. Indeed, at least 6 of those patents overcame explicit Section 101 rejections during prosecution (others may have overcome such rejections in parent cases). And these statistics do not even address motions for summary judgment, which would be expected to have higher success rates as compared to Rule 12(b)(6) motions.

As a comparison (and unsurprisingly), since 2015, no motions under Rule 12(b)(6) have been filed (let alone won) by defendants based on obviousness under Section 103.

Putting aside the overarching question of where to draw the line on patent eligibility, the rate at which motions to dismiss are filed and granted on Section 101 grounds is somewhat curious. Specifically, where the issue is, at least in part, a question of fact involving inventiveness, there would appear to be a significant willingness by courts to decide that issue with little development of the factual record and without regard to USPTO determinations on the subject, as compared to inventiveness questions in other contexts (*e.g.*, prior art challenges). While intense scrutiny was expected in the period directly following *Alice*, where the courts were dealing primarily with patents that issued prior to *Alice*, the recent data involving a significant number of patents issued post-*Alice* is more difficult to explain. Specifically, in a vacuum, one would expect (i) some deference to the USPTO through the presumption of validity and (ii) under Rule 12(b)(6), that factual assertions by the patent owner concerning inventiveness under the second step of *Alice* would be viewed in a light most favorable to the patent owner.

This trend coincides with ongoing complaints from patent practitioners concerning the lack of clarity on Section 101 in the post-*Alice* world. The *American Axle* dissent summed up this view by stating that Section 101 analysis seems to have evolved "into a panacea for every concern we have over an invention's patentability" and that judges may not be respecting the factual questions raised by patent eligibility analysis.[12]

The Future After *American Axle*

Many expected the U.S. Supreme Court to take up *American Axle* in order to revisit the state of patent eligibility, but the Court recently denied Certiorari. *American Axle* involved a claim directed to a method of manufacturing a driveline shaft for transmitting torque, of the type used in automobiles.[13] The relevant claim recited, in part, positioning a liner for damping vibrations, where the liner was tuned to two types of vibration.

In the majority's view, the tuning simply involved applying Hooke's law regarding frictional damping, and thus was directed to a law of nature relating to vibrational forces.[14]

Thus, under the first step in *Alice*, the claimed invention implicated ineligible subject matter, according to the majority. As to the second step, the majority took issue with the fact that a specific tuning solution was not recited in the claims.[15] The dissent viewed this as requiring the *content* of the claim itself to have an enabling disclosure (as opposed to requiring the specification to be enabling). In addition, the majority viewed the other elements of the claim as conventional, which the dissent viewed as contradicting the record below in which the patentee alleged that liners had not previously been used to reduce bending mode vibration. The dissent pointed out that the issue was one of fact which must not be judged in a vacuum on appeal.[16]

The issues teased out in the dissent made *American Axle* an interesting case for Supreme Court review. However, what may have most elevated this case in the eyes of the patent community is the way in which it shines a light on the lingering confusion over patent eligibility post-*Alice*. Specifically, practitioners have paused to consider the baseline question: could a method of manufacturing a driveshaft really be an abstract idea ineligible for patent protection?

The denied Petition for a Writ of Certiorari filed in *American Axle* presented two questions:

1. What is the appropriate standard for determining whether a patent claim is "directed to" a patent-ineligible concept under step 1 of the Court's two-step framework for determining whether an invention is eligible for patenting under 35 U.S.C. § 101?
2. Is patent eligibility (at each step of the Court's two-step framework) a question of law for the court based on the scope of the claims or a question of fact for the jury based on the state of art at the time of the patent?[17]

The U.S. Solicitor General submitted an Amicus Curiae Brief in favor of granting certiorari, which focused on the first question presented in *American Axle* and signaled a desire for a patent eligibility framework more favorable to patentees. Specifically, the U.S. noted that all mechanical inventions apply the laws of physics and, thus, implicating the use of Hook's law should not preclude patentability.[18] Further, the U.S. noted that "industrial processes," which employ concrete applications of physical phenomena, have long been accepted as patent eligible.[19] The U.S. also took issue with the Federal Circuit's analysis of *Alice*'s second step—whether there is an inventive concept that transforms the claims into eligible subject matter.[20] In the U.S.'s view, the Federal Circuit's analysis of step two is too rigid in that it applies an absolute novelty requirement to the transformation, rather than accepting that a new combination of known steps can provide the basis for patentability.[21] Despite the Supreme Court refusing to take up the case, the U.S.'s view suggests a patent eligibility framework more favorable to patentees.

The second question posed by *America Axle* could have disrupted a significant trend in lower court determinations of patent eligibility. As discussed above, district courts have shown little hesitance to decide questions of patent eligibility in the challengers' favor at the early stages of infringement cases. A ruling that the eligibility analysis is more firmly rooted in factual considerations, potentially ones for a jury's consideration, could have curtailed Rule 12(b)(6) rulings on the issue.

Without guidance from the Supreme Court, many questions about patent eligibility remain unanswered for the time being. Patent practitioners will be left to ponder the academic curiosity regarding why patent eligibility findings by the USPTO appear to be afforded less deference compared to other validity findings by the USPTO (*e.g.,* findings under Sections 112 and 103).

About the Authors

***Justin J. Oliver**, Partner, Venable LLP. Justin advises clients on all aspects of patent law. A significant part of his practice involves patent litigation and proceedings before the Patent Trial and Appeal Board ("PTAB"). In particular, Justin has handled over 100 PTAB proceedings.*

***Joseph B. Cahill**, Associate, Venable LLP. Joe practices patent law. Joe has a background in engineering and software design, having previously worked for an artificial intelligence software company.*

Endnotes

1 *Tokai Corp. v. Easton Enterprises, Inc.*, 632 F.3d 1358, 1367 (Fed. Cir. 2011); *but see Novo Nordisk A/S v. Caraco Pharmaceutical Laboratories, Ltd.*, 719 F.3d 1346, 1357 (Fed. Cir. 2013) (questioning whether any "added burden" exists).

2 *Sciele Pharma Inc. v. Lupin Ltd.*, 684 F.3d 1253, 1261 (Fed. Cir. 2012); *see also American Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1359-60 (Fed. Cir. 1984) (stating that "[w]hen the attacker simply goes over the same ground travelled by the PTO, part of the *burden* is to show that the PTO was wrong in its decision to grant the patent" and that "[d]eference is due the Patent and Trademark Office decision to issue the patent with respect to evidence bearing on validity which it considered"); *Cadence Pharmaceuticals Inc. v. Exela PharmSci Inc.*, 780 F.3d 1364, 1375 (Fed. Cir. 2015) ("since the Examiner initially rejected the claims of the [] patent for essentially the same reason as defendants now raise … the Patent Office is 'presumed

to have done its job' when it ultimately allowed the [] patent."); *Intercontinental Great Brands LLC v. Kellogg North America Company*, 869 F.3d 1336, 1350 (Fed. Cir. 2017) ("persuading a fact finder that an expert agency is incorrect on a proposition is likely to be a greater forensic challenge to the advocate than showing the proposition to be incorrect in the absence of a contrary expert-agency determination.").

3 *Cleveland Clinic Found. v. True Health Diagnostics LLC*, 760 Fed.Appx. 1013, 1021 (Fed. Cir. 2019).

4 *Alice Corp. Pty. Ltd. v. CLS Bank Intern.*, 134 S.Ct. 2347, 2355 (2014).

5 *Id.*

6 *Aatrix Software, Inc. v. Green Shades Software, Inc.*, 882 F.3d 1121, 1128 (Fed. Cir. 2018).

7 *Id.*; *see also American Axle & Manufacturing, Inc. v. Neapco Holdings LLC*, 939 F.3d 1355, 1362, 1367 (Fed. Cir. 2019).

8 *American Axle,* 939 F.3d at 1374-75.

9 *Alice*, 134 S.Ct. at 2357.

10 *Aatrix*, 882 F.3d at 1128.

11 *Id.*

12 *American Axle,* 939 F.3d at 1369, 371-72, 1375.

13 *Id.* at 1358.

14 *Id.* at 1364, 1366.

15 *Id.* at 1373.

16 *Id.* at 1364, 1370-71.

17 Petition for a Writ of Certiorari filed Dec. 28, 2020 at (i), *American Axle & Manufacturing, Inc. v. Neapco Holdings LLC.*

18 Brief for the United States as Amicus Curiae at 13-14, *American Axle & Manufacturing, Inc. v. Neapco Holdings LLC,* No. 20-892 (May 2022).

19 *Id.* at 13-14.

20 *Id.* at 16.

21 *Id.* at 17-18.

Federal Jurisdiction Not Granted Based on Possible Trademark Injury

Brooklyn Brewery Corp. v. Brooklyn Brew Shop, LLC

By Thomas J. Mango

The U.S. Court of Appeals for the Federal Circuit ("Federal Circuit") weighed in on the standing requirements under the U.S. Constitution to appeal a decision of the Trademark Trial and Appeal Board (TTAB), and it determined what a challenger in a trademark matter must show to fulfill the standing requirements. Standing is an important, but often an overlooked, part of a challenger's claim. The Federal Circuit's ruling in *Brooklyn Brewery Corp. v. Brooklyn Brew Shop, LLC,* reminds practitioners that the trademark challenger must show an injury as opposed to a possible injury and/or hypothetical injury to satisfy the standing requirements.

Background of the Brooklyn Dispute

The Brooklyn Brewery Corporation ("Brooklyn Brewery") makes and sells a number of different craft beers throughout the United States with distribution through thousands of retailers including Whole Foods Market. Since approximately 1998, Brooklyn Brewery has used the marks BROOKLYN and BROOKLYN BREWERY in connection with its various craft beers and beer-related products. Brooklyn Brewery owns U.S. Trademark Registrations for BROOKLYN BREWERY covering "Brewed malt-based alcoholic beverage in the nature of a beer" and for "Beers" in Trademark International Class 32.

The Brooklyn Brew Shop, LLC ("Brooklyn Brew") was established in 2009. Brooklyn Brew makes and sells beer-making kits, which are comprised of the necessary equipment, cleaning products, and the ingredients for making beer. Brooklyn Brew also sells accessories for beer-making, such as additional cleaning products to sanitize the equipment prior to adding the beer-making ingredients. Brooklyn Brew sells its beer-making kits throughout the United States. In addition, Brooklyn Brew sells the beer-making kits online and through retailers such as Whole Foods Market.

In February 2011, Brooklyn Brew filed a U.S. Trademark Application for the BROOKLYN BREW SHOP covering "Beer making kit" in Trademark International Class 32, in standard character, claiming use commencing in 2009, and

with "BROOKLYN BREW" disclaimed. By October 2011, Brooklyn Brew's Application had matured to Registration. In May 2014, Brooklyn Brew filed another U.S. Trademark Application for BROOKLYN BREW SHOP covering a variety of products in Trademark International Classes 5, 21, and 32, including for "Sanitizing preparations," "Beverage glassware," "Beer," and various beers, stylized, claiming use in 2012, 2011, and 2009, respectively, and with "BREW SHOP" disclaimed.

In September and December 2015, respectively, Brooklyn Brewery filed a notice of opposition against Brooklyn Brew's recently filed application and a petition to cancel against Brooklyn Brew's registration for BROOKLYN BREW SHOP. The TTAB denied the requested relief in cancellation proceeding and the TTAB awarded differing results in the opposition proceeding, and the appeal to the Federal Circuit followed.

The Federal Circuit Considers Standing

Brooklyn Brewery appealed both of the TTAB's cancellation and opposition decisions to the Federal Circuit. In opposition, Brooklyn Brew submitted that Brooklyn Brewery failed to demonstrate the proper standing requirements to appeal the TTAB's opposition decision. Specifically, Brooklyn Brew challenged Brooklyn Brewery's standing to challenge the TTAB's decision related to the cleaning and/or sanitizing products. However, Brooklyn Brew did not challenge Brooklyn Brewery's standing as to cancellation proceeding or the opposition to marks covering beer-making kits.

Brooklyn Brewery does not make or sell beer-making kits. As a result, Brooklyn Brewery does not make or sell cleaning and/or sanitizing products. Significantly, the Federal Circuit Court found that there was no evidence by Brooklyn Brewery that it had plans to expand into making and selling beer-making kits, and therefore, there also was no evidence by Brooklyn Brewery that it had plans to expand into making and selling cleaning and/or sanitizing products.

The Federal Circuit relied on the TTAB's previous determination that beer-making kits are related to beer, and, in addition, to a certain extent, beer-making kits compete with beer in the marketplace. Based on these findings, the Federal Circuit held there was enough evidence to demonstrate Brooklyn Brewery's standing to challenge the registered mark and applied-for mark covering beer-making kits.

However, the cleaning and/or sanitizing products stand on a much different footing. Because there was no evidence that Brooklyn Brewery makes or sells beer-making kits, because there was no evidence that Brooklyn Brewery makes or sells cleaning and/or sanitizing products, and because there was no evidence that Brooklyn Brewery had plans to expand into making and selling beer-making kits and therefore also cleaning and/or sanitizing products, there was no direct injury to Brooklyn Brewery. Instead, there was only a possible and/or speculative injury that might occur in the future to Brooklyn Brewery.

Ultimately, the Federal Circuit Court did not agree with the Brooklyn Brewery's claim for standing because it was too

speculative. Basically, Brooklyn Brewery submitted that it could possibly suffer injury if Brooklyn Brewery expanded its offerings to sell cleaning and/or sanitizing products. However, there was no evidence to support such expansion, and, therefore, it was merely a possible injury in the future.

In my view, and considering the likelihood of confusion factors, there is a natural expansion from beers to beer-making kits. However, there is no natural expansion from beers to cleaning and/or sanitizing products. It is simply too big of a jump, and, therefore, too speculative for the court to find a basis for its standing requirements.

The Federal Circuit's Standing Standard

When seeking jurisdiction in federal court, a party must demonstrate, *inter alia*, it has suffered an injury based on two necessary principles: (1) specific injury; and (2) measurable injury. The Federal Circuit Court said that the trademark challenger must demonstrate that (1) the parties compete in the same industry and/or business; and (2) allowing registration would likely cause a competitive injury to the trademark challenger. Further, the Federal Circuit Court found that a hypothetical and potential injury in the future is not sufficient to satisfy the standing requirements.

The Federal Circuit Court determined that Brooklyn Brewery did not demonstrate that granting a registration for Class 5 products to Brooklyn Brew would cause Brooklyn Brewery injury because beer and cleaning and/or sanitizing products are not competing products and Brooklyn Brewery would not suffer a competitive injury. Further, in my view, cleaning and/or sanitizing products could not be considered part of the Brooklyn Brewery's natural expansion of products.

Note To Practioners

Standing is a key component to the evaluation of every case and the claims that are asserted at the TTAB and on appeal to the Federal Circuit. If you plan to appeal a TTAB decision, always remember to be prepared to show how the TTAB's decision, if unchanged, will injury your client because it involves competitive products and because your client will suffer a competitive injury in the marketplace.

About the Author

Thomas J. Mango, *Partner, Cantor Colburn LLP. Tom is the Chair of the Trademark Litigation Practice at Cantor Colburn. His practice focuses on all aspects of opposition and cancellation proceedings at the Trademark Trial and Appeal Board, trademark litigation in federal courts throughout the United States, and trademark disputes for both national and international clients across a wide variety of industries. He also counsels clients regarding trademark portfolio protection, enforcement strategies, claim avoidance, and risk management.*

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