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**Enablement Issues Concerning Aggressively Broad
Generic Claims**

J. Benjamin Bai



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By J. Benjamin Bai*

I. INTRODUCTION

¶1 Most patent prosecutors would probably agree that it is our professional responsibility to obtain the broadest possible claims for our clients. This professional responsibility is often taken to mean obtaining the broadest claims possible in light of prior art. As a result, practitioners may well draft broad generic claims based on a limited number of working examples or species. In some instances, the generic claims may be so broad that they encompass millions or even billions of compounds or species.

¶2 The temptation to claim broadly is not new. For example, Samuel Morse, the inventor of the telegraph, claimed not just the telegraph, but all means of communicating electronically at a distance.¹ Similarly in the chemical arts, an inventor of a new chemical compound often attempts to claim not only the new compound, but also the entire genus to which the new compound belongs. In some cases, a generic claim encompassing millions of compounds is based on the discovery of only one or two species. But what is wrong with aggressively broad generic claims? Isn't an applicant entitled to claim as broadly as permitted by the prior art? Not exactly. In addition to being bound by the requirements that an invention be useful, novel, and non-obvious in light of prior art, patent law requires that a claim be fully enabled.² Applied to a genus type claim, which often includes multiple embodiments within the claimed genus, this means that the full scope of a generic claim must be enabled such that the scope of enablement bears a reasonable correlation to the breadth of the claimed genus.³ Is it possible for one or two species to enable an entire genus? The answer is: perhaps. This article explains some of the pitfalls of aggressively broad generic claims and possible ways to avoid them.

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¹ See *O'Reilly v. Morse*, 56 U.S. 62 (1854) (holding that Morse's claim, which was directed to all communication made electronically at a distance, was invalid because it was too broad).

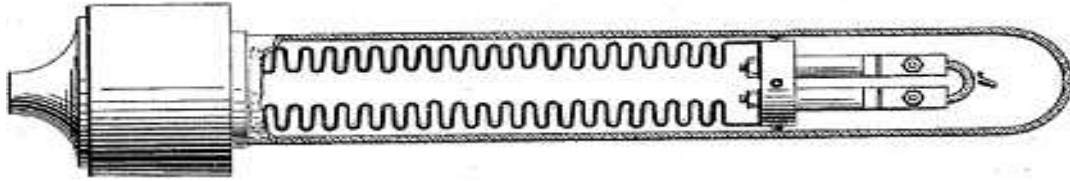
² In addition, a valid claim must meet the other requirements set forth in 35 U.S.C. § 112, including the written description and best mode requirements. While most foreign countries do not have the best mode requirement, they do have an enablement requirement. The enablement requirement in some countries is more exacting than the U.S. standard discussed herein.

³ See *In re Vaeck*, 947 F.2d 488, 495 (Fed. Cir. 1991).

II. A JOURNEY INTO HISTORY—THE INCANDESCENT LAMP PATENT

¶3 Before we delve into recent case law on enablement of generic claims, it is instructive to revisit history and examine what the U.S. Supreme Court did when faced with an aggressively broad generic claim in *Consolidated Electric Light Co. v. McKeesport Light Co.*⁴ Perhaps we will learn something from history.

¶4 In the late 1800s, Sawyer and Man discovered the use of carbonized paper in incandescent lamps. They obtained a patent entitled “Electric Light” on May 12, 1885.⁵ The following picture illustrates the Sawyer and Man lamp disclosed in the patent.



¶5 The patent includes the following four claims:

1. An incandescing conductor for an electric lamp, of *carbonized fibrous or textile material*, and of an arch or horseshoe shape, substantially as hereinbefore set forth.
2. The combination, substantially as hereinbefore set forth, of an electric circuit and an incandescing conductor of *carbonized fibrous material*, included in and forming part of said circuit, and a transparent, hermetically sealed chamber, in which the conductor is enclosed.
3. The incandescing conductor for an electric lamp, formed of *carbonized paper*, substantially as described.
4. An incandescing electric lamp consists of the following elements in combination: First, an illuminating chamber made wholly of glass hermetically sealed, and out of which all carbon-consuming gas has been exhausted or driven; second, an electric-circuit conductor passing through the glass wall of said chamber, and hermetically sealed therein, as described; third, an illuminating conductor in said circuit, and forming part thereof within said chamber, consisting of carbon made from *a fibrous or textile material*, having the form of an arch or loop, substantially as described, for the purpose specified.⁶

¶6 The lamps made according to the patent did not embody the principle of high resistance with a small illuminating surface; they did not have the filament burner of the modern incandescent lamp. Moreover, the lamp chamber was defective. Therefore, the lamp was never a commercial success.

¶7 On the other hand, Thomas Edison discovered that a particular part of the stem of bamboo was highly useful as a conductor in incandescent lamps. Thomas Edison also

⁴ 159 U.S. 465 (1895). This case is also known as “The Incandescent Lamp Patent” case. Surprisingly, this case has not been cited by the Federal Circuit in any of its opinions thus far.

⁵ U.S. Patent No. 317,676 (filed Jan. 9, 1880) (issued May 12, 1885).

⁶ *Id.* (emphasis added).

obtained a patent for his invention.⁷ The commercial Edison lamp was composed of a burner made of *carbonized bamboo* of a particular quality.

¶8 The owner of the Sawyer and Man patent filed a patent infringement suit against the manufacturer of the Edison lamp. The Supreme Court was called upon to decide whether the Edison lamp infringed the Sawyer and Man patent.

¶9 The Supreme Court framed the issue as whether the patentee was entitled to a monopoly of all fibrous and textile materials for incandescent conductors when the inventors' discovery was limited to the use of carbonized paper. In concluding that the patentee was not entitled to such a far-reaching monopoly, the Supreme Court made the following statements:

If the patentees had discovered in fibrous and textile substances *a quality common to them all*, or to them generally, as distinguishing them from other materials, such as minerals, etc., and such quality or characteristic adapted them peculiarly to incandescent conductors, such claim might not be too broad. . . . Sawyer and Man supposed they had discovered in carbonized paper the best material for an incandescent conductor. Instead of confining themselves to carbonized paper, as they might properly have done, and in fact did in their third claim, they made a broad claim for every fibrous or textile material, when in fact an examination of over 6,000 vegetable growths showed that none of them possessed the peculiar qualities that fitted them for that purpose. Was everybody, then, precluded by this broad claim from making further investigation? We think not.⁸

¶10 The Supreme Court sensed the injustice of holding otherwise because it was impressed by the evidence that showed that Thomas Edison and his assistants conducted numerous experiments, for several months, among the different species of vegetable growth, for the purpose of ascertaining the one best adapted to an incandescent conductor. Of these he found suitable for his purpose only about three species of bamboo, one species of cane from the valley of the Amazon, and one or two species of fibers from the agave family. Of the special bamboo, the walls of which had a thickness of about 3/8 of an inch, he used only about 20/1000 of an inch in thickness. In this portion of the bamboo, the fibers were almost parallel, the cell walls were relatively small, and the pithy matter between the fibers was relatively minimal. It appeared that carbon filaments could not be made of wood (i.e., exogenous vegetable growth) because the fibers were not parallel and the longitudinal fibers were intercepted by radial fibers. The wood-fiber cells were all so large that the resulting carbon was very porous and friable. Lamps made of this material proved to be of no commercial value. After trying as many as thirty or forty different woods of exogenous growth, he gave them up as hopeless. But finally, while experimenting with a bamboo strip which formed the edge of a palm-leaf fan, cut into filaments, he obtained surprising results. After microscopic examination of the material, he dispatched a man to Japan to make arrangements for securing the bamboo for further testing.⁹

⁷ U.S. Patent No. 223,898 (filed Nov. 1, 1879) (issued Jan. 27, 1880).

⁸ *Consol. Elec. Light Co.*, 159 U.S. at 472 (emphasis added).

⁹ *Id.* at 472–73.

¶11 The messenger whom Thomas Edison dispatched to different parts of Japan and China sent him about forty different kinds of bamboo, in such quantities as to enable him to make a number of lamps, and from a test of these different species he ascertained which was best for the purpose. From this it appeared very clearly that there was no quality common to fibrous and textile substances generally as to make them suitable for an incandescent conductor. Instead, the bamboo that worked best was not selected because it fit the general criteria of fibrous material, but because it contained specific peculiarities in its fibrous structure which distinguished it from every other fibrous substance.¹⁰

¶12 At the time, Rev. Stat. § 4888, the predecessor of 35 U.S.C. § 112, was the relevant patent statute and read as follows:

Before any inventor or discoverer shall receive a patent for his invention or discovery he shall make application therefor, in writing to the Commissioner of Patents, and shall file in the Patent Office a written description of the same and of the manner and process of making, constructing, compounding and using it, in such full, clear, concise, and exact terms as to *enable* any person skilled in the art or science to which it appertains, or with which it is most nearly connected, to make, construct, compound, and use the same.¹¹

¶13 In analyzing the facts of the case and applying the above statute and its own precedent, the Supreme Court asked a rhetorical question: “[H]ow would it be possible for a person to know what fibrous or textile material was adapted to the purpose of an incandescent conductor except by the most careful and painstaking experimentation?”¹² Then the Court remarked further:

If, as before observed, there were some general quality, running through the whole fibrous and textile kingdom, which distinguished it from every other, and gave it a peculiar fitness for the particular purpose, the man who discovered such quality might justly be entitled to a patent; but that is not the case here. An examination of materials of this class carried on for months revealed nothing that seemed to be adapted to the purpose; and even the carbonized paper and wood carbons specified in the patent, experiments with which first suggested their incorporation therein, were found to be so inferior to the bamboo, afterwards discovered by Edison, that the complainant was forced to abandon its patent in that particular, and take up with the material discovered by its rival. Under these circumstances, to hold that one who had discovered that a certain fibrous or textile material answered the required purpose should obtain the right to exclude everybody from the whole domain of fibrous and textile materials, and thereby shut out any further efforts to discover a better specimen of that class than the patentee had employed, would be an unwarranted extension of his monopoly, and operate rather to discourage than to promote invention. If Sawyer and Man had discovered that a certain carbonized paper would answer the purpose, their claim to all carbonized

¹⁰ *Id.* at 474.

¹¹ Rev. Stat. § 4888, ch. 230, § 26, 16 Stat. 201 (1870) (current version at 35 U.S.C. § 112 (2000)) (emphasis added).

¹² *Consol. Elec. Light Co.*, 159 U.S. at 475.

paper would, perhaps, not be extravagant; but the fact that paper happens to belong to the fibrous kingdom did not invest them with sovereignty over this entire kingdom, and thereby practically limit other experimenters to the domain of minerals.¹³

Based on the above reasoning, the Supreme Court held that claims 1, 2, and 4 of the Sawyer and Man patent were invalid.¹⁴ Because it was admitted that claim 3 was not infringed, the Supreme Court affirmed the lower court’s dismissal of the bill.

III. THE LEGAL STANDARD—“UNDUE EXPERIMENTATION” AND THE WANDS FACTORS

¶14 Now fast forward to the modern day era, where we find the enablement requirement, *inter alia*, codified at 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same¹⁵

¶15 The Federal Circuit applies the enablement requirement by asking whether one of skill in the art could make and use the invention, without undue experimentation, from the disclosure in the patent specification, coupled with information known in the art at the time the patent application was filed.¹⁶ In other words, does the specification contain sufficient detail to enable others skilled in the art to practice the claimed invention without “undue experimentation?”¹⁷

¶16 Moreover, the specification must enable one of ordinary skill in the art to practice “the full scope of the claimed invention.”¹⁸ One-to-one correlation is not required—the law does not require that

the specification itself must necessarily describe how to make and use every possible variant of the claimed invention, for the artisan’s knowledge of the prior art and routine experimentation can often fill gaps, interpolate between embodiments, and perhaps even extrapolate beyond the disclosed embodiments, depending upon the predictability of the art.¹⁹

¹³ *Id.* at 475–76 (emphasis added).

¹⁴ The Court stated that claim 1 and its dependent claims were “too indefinite to be the subject of a valid monopoly.” *Id.* at 479. While this phraseology appears to suggest that the claims were held invalid for being indefinite, the Court’s rationale seems to be premised on lack of enablement. *Id.* However, the Court did not make reference to the word “enablement” anywhere in the opinion even though the patent statute had an enablement requirement.

¹⁵ 35 U.S.C. § 112 (2000).

¹⁶ *See* PPG Indus., Inc. v. Guardian Indus. Corp., 75 F.3d 1558, 1564 (Fed. Cir. 1996); Atlas Powder Co. v. E.I. duPont de Nemours & Co., 750 F.2d 1569, 1576 (Fed. Cir. 1984).

¹⁷ *In re Vaeck*, 947 F.2d 488, 495 (Fed. Cir. 1991). *See also In re Angstadt*, 537 F.2d 498, 504 (C.C.P.A. 1976).

¹⁸ *Chiron Corp. v. Genentech, Inc.*, 363 F.3d 1247, 1253 (Fed. Cir. 2004) (citing *In re Wright*, 999 F.2d 1557, 1561 (Fed. Cir. 1993)); *In re Fisher*, 427 F.2d 833, 839 (C.C.P.A. 1970).

¹⁹ *AK Steel Corp. v. Sollac*, 344 F.3d 1234, 1244 (Fed. Cir. 2003).

All the law requires is that the “enabling disclosure of the specification be commensurate in scope with the claim under consideration.”²⁰

¶17 In determining what constitutes “undue experimentation,” the Federal Circuit emphasizes that the test is not merely quantitative, since a considerable amount of experimentation is permissible if it is merely routine or if the specification in question provides a reasonable amount of guidance with respect to the direction in which experimentation should proceed.²¹ Factors that may be considered in such evaluation include, but are not limited to:

- (1) **The breadth of the claims;**
- (2) The nature of the invention;
- (3) The state of the prior art;
- (4) The level of one of ordinary skill;
- (5) **The level of predictability in the art;**
- (6) The amount of direction provided by the inventor;
- (7) The existence of working examples; and
- (8) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.²²

The above factors, known as the eight “Wands factors,” are, however, merely illustrative, not mandatory. What is relevant to any particular “undue experimentation” analysis depends on the specific facts. Moreover, a court need not review all of the Wands factors before making an enablement determination.²³

A. *Predictability and Scope of Enablement*

¶18 While the courts do not point to any single Wands factor as dispositive, the case law suggests that the “level of predictability in the art” factor plays a significant role in virtually all enablement analyses. In addition, any enablement inquiry must necessarily take into account the “breadth of the claims” since it is scope of the claims that sets the bounds for any enablement inquiry.²⁴ These two factors—“level of predictability in the art” and “breadth of the claims”—are inversely related. As noted by the Court of Customs and Patent Appeals (CCPA),²⁵ the scope of the required enablement varies

²⁰ *In re Hyatt*, 708 F.2d 712, 714 (Fed. Cir. 1983). A related yet different issue arises when a generic claim is rejected for obviousness and the applicant tries to show unexpected results obtained from a few species to traverse the rejection. It has been well established that the applicant’s showing of unexpected results must be commensurate in scope with the claimed range. *In re Peterson*, 315 F.3d 1325 (Fed. Cir. 2003). See also *In re Greenfield*, 571 F.2d 1185, 1189 (C.C.P.A. 1978) (“Establishing that one (or a small number of) species gives unexpected results is inadequate proof, for ‘it is the view of this court that objective evidence of non-obviousness must be commensurate in scope with the claims which the evidence is offered to support.’” (quoting *In re Tiffin*, 448 F.2d 791, 792 (C.C.P.A. 1971))). Therefore, it is a double whammy for aggressively broad generic claims (which are supported only by a few species).

²¹ See *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988).

²² *Id.* (emphasis added).

²³ See *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1213 (Fed. Cir. 1991).

²⁴ See, e.g., *In re Fisher*, 427 F.2d 833, 839 (C.C.P.A. 1970) (the first paragraph of § 112 requires that the *scope of the claims* must bear a reasonable correlation to the scope of enablement provided).

²⁵ As the Federal Circuit announced in its first decision, the Federal Circuit is bound by the holdings of its predecessor courts, the CCPA and the Court of Claims. *S. Corp. v. United States*, 690 F.2d 1368, 1369

inversely with the degree of predictability involved.²⁶ The CCPA is careful to note though, that even in the unpredictable arts, a disclosure of every operable species is not required.²⁷

¶19 In cases involving predictable factors such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments may be made without difficulty and their performance characteristics may be predicted by reliance on known scientific laws.²⁸

¶20 On the other hand, in applications directed to inventions in arts where the results are unpredictable, the disclosure of a single species usually does not provide an adequate basis to support generic claims.²⁹ In cases involving unpredictable factors, such as most chemical reactions and physiological activity, more guidance may be required.³⁰

¶21 In unpredictable art areas, the Federal Circuit, like the CCPA, has refused to find broad generic claims enabled by specifications that demonstrate only one or a few embodiments and do not demonstrate with reasonable specificity how to make and use other embodiments within the full scope of the claim.³¹ This is because it is not obvious from the disclosure of one species what other species will work.

B. A Single Embodiment May Enable Broad Claims in Predictable Arts

¶22 *In re Vickers*³² is one example where the disclosure of a single embodiment enabled a broad generic claim in a predictable art, such as certain mechanical arts, if variations from the disclosed embodiment are known or obvious to one of skill in the art. There, the CCPA reversed a rejection of a generic claim directed to an oil well pumping apparatus. Claim 4 is the generic claim and reads as follows.

4. In combination, a cylinder for containing an operating liquid, a reciprocal member in said cylinder, means acting on said member for resisting the entrance of liquid to said cylinder, a motor cylinder, a reciprocal member in said motor cylinder adapted to be operably connected to the sucker rod of a pump in a well, a pressure forming means, a pilot operated shiftable means adapted to control the direction liquid under pressure through said pressure forming means and to and from said cylinders, a supply of operating liquid, unidirectional valve means connecting said supply with the inlet of said pressure forming means, valve means responsive to movement of **one** of said reciprocal members for directing pressure to said pilot operated means to shift the same, and additional valve means responsive to abnormal movement of **one** of said reciprocal members resulting in closure of the outlet port of **one** of said cylinder means, and thereby

(Fed. Cir. 1982) (en banc) (adopting decisions of the CCPA and the Court of Claims “announced before the close of business on September 30, 1982”).

²⁶ See *In re Vickers*, 141 F.2d 522, 526–27 (C.C.P.A. 1944); *In re Cook*, 439 F.2d 730, 734 (C.C.P.A. 1971).

²⁷ See *In re Vickers*, 141 F.2d 522; *In re Cook*, 439 F.2d 730.

²⁸ See *In re Fisher*, 427 F.2d at 839.

²⁹ See *In re Soll*, 97 F.2d 623, 624 (C.C.P.A. 1938).

³⁰ See *In re Fisher*, 427 F.2d at 839 (contrasting mechanical and electrical elements with chemical reactions and physiological activity).

³¹ PPG Indus. v. Guardian Indus. Corp., 75 F.3d 1558 (Fed. Cir. 1996). See also *In re Wright*, 999 F.2d 1557, 1562 (Fed. Cir. 1993); *In re Vaeck*, 947 F.2d 488, 496 (Fed. Cir. 1991).

³² *In re Vickers*, 141 F.2d 522.

cause a replenishing of liquid from said supply to said system during said delay.³³

¶23 The claimed oil well pumping apparatus includes a well operating or work cylinder and piston, an accumulator cylinder and piston, and a pump which forces liquid from one cylinder to the other under the control of a directional valve.³⁴ The apparatus also includes two pilot valves. One valve is controlled by the accumulator piston and causes normal reversal shifting of the directional valve, and the other valve is controlled by abnormal movement of the work cylinder piston which closes a port on the lower part of the work cylinder, and delays normal reversal for replenishment purposes.³⁵

¶24 The highlighted language of claim 4 calls broadly for the operation of the valves either by a single piston or by two pistons.³⁶ However, the construction of the apparatus shown in the specification requires two cylinders, the piston in one operating valve means and the piston in the other operating the other valve means.³⁷ Therefore, the Examiner rejected claim 4 for being too broad because the applicant did not disclose each specific embodiment of the claimed invention.³⁸

¶25 The CCPA reiterated the rule that ordinarily in a mechanical case, broad claims may be supported by a disclosure of a single form of the apparatus and that in such cases, an applicant may generally draw a broad claim on a single construction. Accordingly, the CCPA reversed the rejection.³⁹

¶26 There was no discussion of the predictability in the art. Rather, the court discussed the obviousness of the variations from the disclosed embodiments.⁴⁰ Where there is predictability, variations within a genus are likely known or obvious to one skilled in the art.

C. A Single Embodiment May Not Enable Broad Claims in Unpredictable Arts

¶27 *Amgen, Inc. v. Chugai Pharmaceutical Co.*⁴¹ exemplifies the Federal Circuit's strict application of the enablement requirement to broadly drawn biotechnology claims. Among the issues on appeal was the enablement of a generic claim, claim 7 of U.S. Patent No. 4,703,008, directed to erythropoietin (EPO) analogs, and more specifically to "all possible DNA sequences that will encode any polypeptide having an amino acid sequence 'sufficiently duplicative' of EPO to possess the property of increasing production of red blood cells."⁴²

¶28 In upholding the district court's finding of non-enablement, the Federal Circuit took particular note of the following facts, each of which corresponds roughly to the breadth and predictability factors discussed *supra*. First, the court noted that claim 7 is

³³ *Id.* at 523 (emphasis added).

³⁴ *Id.*

³⁵ *Id.*

³⁶ *Id.*

³⁷ *Id.* at 524.

³⁸ *Id.* at 526.

³⁹ *Id.* at 526–27.

⁴⁰ *Id.* at 524–25.

⁴¹ 927 F.2d 1200 (Fed. Cir. 1991).

⁴² *Id.* at 1212.

extremely broad. According to the district court's findings, "over 3,600 different EPO analogs can be made by substituting at only a single amino acid position, and over a million different analogs can be made by substituting three amino acids."⁴³ Each of these potential modifications in turn creates "manifold possibilities for change" in the EPO structure.⁴⁴ Such "manifold possibilities" leads to the second finding, namely, that the art is unpredictable. This conclusion was supported by the finding that even after five years of experimentation, "Amgen [was] still unable to specify which analogs have the biological properties set forth in claim 7."⁴⁵

¶29 In sum, the Federal Circuit found that in light of the "structural complexity of the EPO gene, the manifold possibilities for change in its structure, with attendant uncertainty as to what utility will be possessed by these analogs" claim 7 was not enabled.⁴⁶ In general terms then, the court articulated what is not sufficient to meet the standard for enabling a genus of genetic sequences: "It is not sufficient, having made the gene and a handful of analogs whose activity has not been clearly ascertained, to claim all possible genetic sequences that have [the claimed] activity."⁴⁷

¶30 Two years later, in *In re Wright*, a patent applicant encountered a similar problem when trying to patent a process for making and using vaccines.⁴⁸ There, the applicant appealed to the Federal Circuit from a final Patent and Trademark Office (PTO) rejection of claims covering a process to make vaccines against RNA viruses, including RNA viruses such as HIV. The specification, however, contained only one working example that described the production of immunity in chickens against one particular avian sarcoma RNA tumor virus. In upholding the district court's conclusion that the broad generic claims were not enabled by the specification, the Federal Circuit noted with approval the Examiner's observation that the art at hand is extremely unpredictable: "RNA viruses are a very diverse and genetically complex group of viruses which include, among others, acquired immunodeficiency syndrome (AIDS) viruses, leukemia viruses, and sarcoma viruses."⁴⁹

¶31 In addition to broad RNA virus vaccine claims, the applicant had also crafted a subgenus claim limited to avian RNA viruses.⁵⁰ In light of the particularly narrow teaching of the specification, and the limited knowledge in the art, these claims suffered the same fate as the broad genus claims. In essence, the court concluded that, as of February 1983, the filing date of the subject application, a skilled scientist reading the specification would not have reasonably believed that Wright's success with one particular strain of avian RNA virus could be extrapolated with a reasonable expectation of success to other avian RNA viruses.⁵¹

¶32 Similarly, in *In re Vaeck*,⁵² the claims were broadly drawn to methods of genetically engineering all types of cyanobacterium hosts to produce certain protein-

⁴³ *Id.* at 1213.

⁴⁴ *Id.* at 1214.

⁴⁵ *Id.* at 1213.

⁴⁶ *Id.* at 1214.

⁴⁷ *Id.*

⁴⁸ 999 F.2d 1557 (Fed. Cir. 1993).

⁴⁹ *Id.* at 1560.

⁵⁰ *Id.* at 1564.

⁵¹ *Id.*

⁵² 947 F.2d 488 (Fed. Cir. 1991).

based insecticides.⁵³ The specification described general techniques for such genetic transformation and explicitly referred to nine genera of cyanobacteria which are useful as hosts.⁵⁴ Two of these nine specific genera were *Synechocystis* and *Anacystis*.⁵⁵ The relevant working examples were further limited in that they only demonstrated the use of a single strain of cyanobacteria, *Synechocystis* 6803.⁵⁶

¶33 In upholding the enablement rejection of the claims directed to methods of engineering any cyanobacteria, the *Vaeck* panel focused on the Examiner's statements regarding claim breadth⁵⁷ and the unpredictability in the art given the limited knowledge in the art.⁵⁸

¶34 Interestingly, the *Vaeck* application also contained a set of sub-genus claims. These narrower claims were directed to two genera, *Synechocystis* and *Anacystis*, of the nine genera explicitly mentioned in the specification. In finding these sub-genus claims enabled, the Federal Circuit noted that "the PTO did not separately address these claims, or indicate why they should be treated in the same manner as the claims encompassing all types of cyanobacteria."⁵⁹

¶35 *In re Goodman*⁶⁰ is yet another instructive example. *Goodman* involved an appeal from a rejection of claims due to lack of enablement because the claims were broadly drawn to a method of producing mammalian peptides in any plant cell. The Federal Circuit sustained the Board's rejection, reasoning that the specification only "contains a single example of producing gamma-interferon in a dicotyledonous species, tobacco."⁶¹ The court further noted that the specification failed to address the extensive problems encountered by one attempting to apply the described methods to any type of plant other than a tobacco plant, or to any non-dicotyledonous plant.⁶² The court found it significant that in 1985, the effective filing date of the application, even the inventor's publications described a "major block" to methods of transforming monocot plants, a sentiment mirrored by other publications which described the state of the art with regard to transforming monocots as "fraught with unpredictability."⁶³

D. Nascent Technology Must Be Enabled with "Specific and Useful Teaching"

¶36 In *Chiron Corp. v. Genentech, Inc.*,⁶⁴ the Federal Circuit unambiguously declared that technology which is still nascent at the time of filing must be enabled with a specific and useful teaching. The court reasoned that such particularity is necessary since a person of ordinary skill in the art "has little or no knowledge independent from the

⁵³ *Id.* at 489.

⁵⁴ *Id.* at 490.

⁵⁵ *Id.*

⁵⁶ *Id.*

⁵⁷ *Id.* at 493 ("[T]he cyanobacteria comprise a large and diverse group . . . in some 150 different genera.").

⁵⁸ *Id.* ("The molecular biology of these organisms has only recently become the subject of intensive investigation and this work is limited to a few genera.").

⁵⁹ *Id.* at 496.

⁶⁰ 11 F.3d 1046 (Fed. Cir. 1993).

⁶¹ *Id.* at 1050.

⁶² *Id.*

⁶³ *Id.* at 1052.

⁶⁴ 363 F.3d 1247 (Fed. Cir. 2004).

patentee’s instruction.”⁶⁵ The *Chiron* panel held invalid as non-enabled claims directed to chimeric antibodies in view of a record that showed that (1) making chimeric antibodies was not routine technology at the relevant dates; and (2) an absence of any showing that any Chiron scientist “actually knew of chimeric antibodies” before the relevant date.⁶⁶ Similarly, the Federal Circuit has previously declared that pioneer inventions are not entitled to a lower enablement standard.⁶⁷

IV. RECENT FEDERAL CIRCUIT PRECEDENT

¶37 Several recent Federal Circuit cases have exemplified the enablement principles discussed herein. In *Liebel-Flarsheim Co. v. Medrad, Inc.*,⁶⁸ the Federal Circuit affirmed a district court decision that held claims directed to a front-loading fluid injector invalid for lack of enablement. On appeal, the patentee had argued that the claims had been interpreted too broadly, and thus, the resulting enablement inquiry had extended beyond the proper limits of the law. In particular, the patentee argued that “the court erroneously considered whether an injector without a pressure jacket was enabled, rather than limiting its inquiry to whether an injector with a pressure jacket was enabled.”⁶⁹ The patentee also sought to limit the claims to injectors with pressure jackets.⁷⁰

¶38 The Federal Circuit, however, disagreed: the court refused to adopt the proffered narrow construction and specifically found that the claims were “not limited to an injector with a pressure jacket, and therefore the full scope of the claimed inventions includes injectors with and without a pressure jacket. That full scope must be enabled, and the district court was correct that it was not enabled.”⁷¹ In arriving at its conclusion that the claims lacked enablement, the court looked first to the specification, finding that “nowhere does the specification describe an injector with a disposable syringe without a pressure jacket” and in fact, finding that “the specification teaches away from such an invention.”⁷² The court gave additional weight to “testimonial evidence that such a system could not have been produced at the time of filing.” In particular, the inventors had “admitted that they tried unsuccessfully to produce a pressure-jacketless system[. . .] that producing such a system would have required more experimentation and testing” and that they had “decided not to pursue such a system because it was ‘too risky.’” Consequently, the Federal Circuit sustained the district court’s finding that the full scope of the claims was not enabled.⁷³

¶39 Notably, the *Liebel* court also rejected the patentee’s attempt to rely on the fact that the invention was in a predictable art, here, the mechanical arts, and thus, that the principle “that the disclosure of a single embodiment can enable a broad claim” should apply. In particular, the court distinguished *Spectra-Physics*, stating that in *Spectra*,

⁶⁵ *Id.* at 1254.

⁶⁶ *Id.*

⁶⁷ *Plant Genetic Sys. v. Dekalb Genetics Corp.*, 315 F.3d 1335 (Fed. Cir. 2003).

⁶⁸ 481 F.3d 1371 (Fed. Cir. 2007). *See also* *Auto. Techs. Int’l, Inc. v. BMW of N. Am., Inc.*, 501 F.3d 1274, 1285 (Fed. Cir. 2007).

⁶⁹ *Liebel-Flarsheim*, 481 F.3d at 1378.

⁷⁰ *Id.*

⁷¹ *Id.* at 1379.

⁷² *Id.*

⁷³ *Id.* at 1380.

disclosure of one attachment means permitted one skilled in the art to make and use the invention as broadly as it was claimed, which included other attachment means known to one of ordinary skill in the art. In contrast, in this case, disclosure of an injector system with a pressure jacket does not permit one skilled in the art to make and use the invention as broadly as it was claimed, including without a pressure jacket.⁷⁴

Thus, even though the invention at issue in *Liebel* was directed to fluid injectors, and thus squarely fit within the “mechanical arts,” such characterization did not provide any defense against an enablement attack where the claims were not fully enabled even in view of the level of knowledge in that mechanical art.

¶40 In *Monsanto Co. v. Sygenta Seeds, Inc.*,⁷⁵ the Federal Circuit affirmed the district court’s summary judgment ruling that claims for a chimeric plant gene expressed in all plant cells are invalid due to lack of enablement.⁷⁶ The ruling was based on a finding that the claimed invention could not be applied to a subset of flowering plants, monocotyledons. The district court thus held that since “plant cells” included monocotyledons, any claim that extended to all plant cells was not fully enabled.⁷⁷

¶41 On appeal, the patentee argued that the term “plant cell” should not be read so broadly as to change “chimeric gene claims into claims directed to plants or plant cells transformed with the claimed gene”⁷⁸ However, like the district court, the Federal Circuit held that the claims use broad functional language and that there was no evidence of a gene transformation method with monocotyledons.⁷⁹ Accordingly, the Federal Circuit affirmed the finding of invalidity since the claims did not bear a reasonable correlation to the scope of enabled subject matter.⁸⁰

¶42 Similarly, in *Pharmaceutical Resources Inc. v. Roxane Laboratories Inc.*,⁸¹ the Federal Circuit affirmed a district court summary judgment ruling of invalidity for failure to meet the enablement requirement. The invention claimed was a stable flocculated suspension of megestrol acetate with any surfactant at any concentration. The district court had held that the claims were invalid because they were “extraordinarily broad” and that there were only three working species.⁸² The Federal Circuit focused its analysis on the “extraordinarily broad scope of the claims, which encompasses hundreds of surfactants, the high degree of unpredictability of the art, and the minimal guidance provided by the three working examples in the specification.”⁸³ Thus, even though the inventors had been able to create a “stable flocculated megestrol acetate suspension” with seven of the surfactants specified by the claims, such a limited showing simply failed to

⁷⁴ *Id.* at 1379 (citing *Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524 (Fed. Cir. 1987)).

⁷⁵ 503 F.3d 1352 (Fed. Cir. 2007).

⁷⁶ *Id.* at 1354.

⁷⁷ *Id.* at 1361.

⁷⁸ *Id.*

⁷⁹ *Id.*

⁸⁰ *Id.* at 1361–62.

⁸¹ 253 F. App’x 26 (Fed. Cir. 2007).

⁸² *Id.* at 29.

⁸³ *Id.* at 31.

create a genuine issue of material fact regarding enablement.⁸⁴ Accordingly, the Federal Circuit affirmed the enablement rejection.⁸⁵

V. FINAL THOUGHTS

¶43 So, the question remains: is it possible for one or two species to enable an entire genus? The answer will, of course, depend in large part on factors over which a practitioner has no control, such as the state of the art and the predictability of the field. However, one factor that is within a practitioner's control is the breadth of generic claims and the level of detail and guidance provided in the specification.

¶44 In view of the foregoing case law, there are several measures that a practitioner can take to mitigate the effects of these immutables. First, examine the relevant art with a critical eye. Analyze the art not just for its novelty-destroying effect, but also for the level of guidance that it will provide to one of skill in the art. If the technology is nascent, pay due consideration to the issues raised in *Chiron* and be sure that the application teaches any nascent technology with particularity. Also remember that pioneer inventions are not entitled to a lower enablement standard.⁸⁶

¶45 Second, if broad genus claims are appropriate in view of the art, be sure also to draft a claim set that includes several levels of protection, such as sub-genus and species claims. In other words, practitioners should describe and claim a myriad of sub-genera of varying scope. Each sub-genus is defined by a set of distinct characteristics or common qualities. In this way, even if a court finds the broadly drafted claims not enabled, secondary lines of defense will survive. In drafting generic and sub-generic claims, try to identify a common quality across the genus or sub-genus that makes the genus or sub-genus suitable for the intended purpose. Third, it is an over-simplification to say that mechanical and electrical arts are predictable, whereas chemical and biotechnology arts are not. Predictability or lack thereof may exist in any technology area. Therefore, practitioners should be vigilant in analyzing not just the predictability in a particular technology area, but also in examining the predictability of what is being claimed in evaluating the enablement of a genus.

⁸⁴ *Id.*

⁸⁵ *Id.*

⁸⁶ *See Plant Genetic Sys. v. Dekalb Genetics Corp.*, 315 F.3d 1335 (Fed. Cir. 2003).