

## CHAPTER 8A

# BIOTECHNOLOGY PATENT LITIGATION\*

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## I. INTRODUCTION

What sets biotechnology<sup>1</sup> patent litigation apart from other types of patent litigation? In a nutshell, biotechnology patent litigation is characterized by the recurring theme that small changes can have big consequences. While this principle operates in many areas and goes by many names—an “unpredictable art,” a “pioneering invention,” or simply the challenge of enabling the full scope of one’s claims—the common thread in the biotechnology context is that a small change in a DNA sequence, protein sequence, or living organism can have profound and uncharted implications. A patentee relies on this unpredictability when heralding a claimed invention as a great achievement that, once demonstrated, will provide a roadmap for all who choose to follow. One challenging a patent may use this unpredictability when disputing priority or conception, or to test the sufficiency of the patent’s teaching and disclosure as measured against the full scope of the claims.

While biotechnology patent litigation shares many strategic and tactical attributes with patent litigation in other technical areas, in this chapter we focus on the aspects of patent litigation unique to this field and share some insights on how to harness the power of small changes.

## II. PATENTABLE SUBJECT MATTER: HOW MUCH IS ENOUGH?

In the process of researching and developing biotechnology products, researchers may innovate new and better methods of manufacturing and using those products. For this reason, innovation in the biotech industry can result in a variety of inventions that cover multiple aspects of the process of making a new product and methods of using the device, in addition to the new and useful product itself. For example, the development of a new therapeutic may result in patents covering the isolated DNA, a process for making a protein or antibody, the recombinantly-produced protein or antibody itself, and methods of using that product as a therapeutic. Similarly, the development of a new medical device may lead to patents covering the device, components of the device, and methods for using them. While pursuing separate patent protection for multiple inventions may be time-consuming and costly—not insignificant considerations for early-stage companies—obtaining patents on each of these separate inventions provides the broadest patent protection and the long-term ability to maintain market exclusivity (and strategic flexibility) for the greatest duration (since each patent is prosecuted separately, each often issues at a different time and carries a distinct patent term).

The question then becomes: What discoveries along the path of research and development are legally sufficient to qualify as patent-eligible subject matter? Conversely, where does an inventor invite challenge based on his or her claiming

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<sup>1</sup>“Biotechnology” is often used to refer to technology that depends in some important way on the use of living organisms, cells, or cell-derived materials. Patents in the biotechnology industry are directed to products such as isolated DNA, recombinantly-produced proteins, and monoclonal antibodies, as well as the processes for making them and methods or delivery systems for using them.

strategy? This section explores some of the benefits and pitfalls of seeking and obtaining broad coverage for biotech inventions through a panoply of claims.

Section 101 of the Patent Act provides: “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, subject to the conditions and requirements of this title.”<sup>2</sup> Although the Supreme Court has identified laws of nature, natural phenomena, and abstract ideas as categorical exceptions that are not eligible for patent protection,<sup>3</sup> patent eligibility has historically presented a relatively low bar, with other requirements of patentability, such as those set out in 35 U.S.C. §§102, 103, and 112, having more teeth. The Supreme Court in *Diamond v. Chakrabarty*, for example, interpreted the Patent Act broadly and opened the door to the patenting of living organisms.<sup>4</sup> The Court explained that “[i]n choosing such expansive terms as ‘manufacture’ and ‘composition of matter,’ modified by the comprehensive ‘any,’ Congress plainly contemplated that the patent laws would be given wide scope.”<sup>5</sup> As further support, the Court quoted Thomas Jefferson, the author of the Patent Act of 1793, to the effect that “ingenuity should receive a liberal encouragement”;<sup>6</sup> it also pointed to the Committee Reports accompanying the 1952 Act, which stated that Congress intended patentable subject matter to “include anything under the sun that is made by man.”<sup>7</sup>

Recent developments in the case law seem to have raised the bar—or at least muddied the waters—as to what constitutes patent-eligible subject matter, thus making a §101 patent challenge a more appealing defense. The two areas that have been the most in flux, and which therefore provide the most opportunity for patent challengers, are (1) patent claims directed to products of nature and (2) patent claims directed to methods of use (which can be attacked as mental processes).

### A. Patentability of Products of Nature

In *Diamond v. Chakrabarty*,<sup>8</sup> the Supreme Court began to draw nuanced distinctions between what is and what is not patentable subject matter in the biotechnology industry. The Supreme Court there considered whether products of nature could constitute patentable subject matter, and held that Chakrabarty’s invention of a man-made bacterium capable of breaking down crude oil constituted a patentable “manufacture” or “composition of matter.”<sup>9</sup> The invention was determined to be not only distinct from what is found in nature, but also to have potentially significant utility:

[T]he patentee has produced a new bacterium with markedly different characteristics from any found in nature and one having the potential for significant utility.

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<sup>2</sup>35 U.S.C. §101.

<sup>3</sup>*Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980).

<sup>4</sup>*Id.* at 308.

<sup>5</sup>*Id.*

<sup>6</sup>*Id.* at 308–09 (quoting 5 WRITINGS OF THOMAS JEFFERSON 75–76 (Washington ed., 1871)).

<sup>7</sup>*Id.* at 309 (quoting S. REP. NO. 82-1979, at 5 (1952); H. R. REP. NO. 82-1923, at 6 (1952)).

<sup>8</sup>447 U.S. 303 (1980).

<sup>9</sup>*Id.* at 309–10.

His discovery is not nature's handiwork, but his own; accordingly it is patentable subject matter under 101.<sup>10</sup>

In so holding, the Court distinguished other, earlier cases where, despite clear acts of human ingenuity and creativity, the results nonetheless failed to rise to the level of patentable subject matter. For instance, the disputed claims in the early case of *Funk Bros. Seed Co. v. Kalo Inoculant Co.* were directed to an inoculant for plants produced by selecting non-inhibiting strains of different species of bacteria.<sup>11</sup> The *Funk* Court articulated the rule that phenomena of nature—such as the qualities of these bacteria, the heat of the sun, electricity, and the qualities of metals—“are manifestations of laws of nature, free to all men and reserved exclusively to none.”<sup>12</sup> While there was an advantage to the selection of the bacteria, the claimed product was nonetheless found to be unpatentable because “[t]he combination of species produces no new bacteria, no change in the six species of bacteria, and no enlargement range of their utility. . . . They serve the ends nature originally provided and act quite independently of any effort of the patentee.”<sup>13</sup> Therefore, the subject matter of the patent claims was determined to be unpatentable phenomena of nature.<sup>14</sup>

For purposes of patentability, between the genetically-engineered living organism and the product seemingly plucked as-is from nature lie purified and isolated products of nature. The purification and isolation of these products can render them newly useful as, for example, therapeutics or testing material for use in scientific research. While patentability depends on whether a claimed composition “possesses a new or distinctive form, quality, or property” compared to the naturally-occurring product,<sup>15</sup> courts have historically maintained the validity of patents on purified and isolated products of nature. By way of example, Judge Learned Hand in *Parke-Davis & Co. v. H.K. Mulford Co.* rejected a validity challenge to patent claims directed to an adrenaline compound that had been isolated and purified from animal suprarenal glands.<sup>16</sup> Unlike the claimed invention, adrenalin in gross form as found in nature could not be used for the therapeutic properties it possessed, nor could it be administered to humans for treatment. Similarly, in *In re Bergstrom*, the Court of Customs and Patent Appeals upheld the validity of patents directed to purified prostaglandins that had been extracted from prostate glands.<sup>17</sup> The C.C.P.A. noted that these naturally-occurring products “do not exist in nature in pure form,” making such compounds patent-eligible.<sup>18</sup>

Thus, the case law distinguishes between, on the one hand, the unpatentable product of nature in an unmodified (albeit useful) form and, on the other, the patentable, man-made product or improvement (even through purification)

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<sup>10</sup>*Id.* at 310.

<sup>11</sup>*Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948).

<sup>12</sup>*Id.* at 130.

<sup>13</sup>*Id.* at 131.

<sup>14</sup>See also *Ex Parte Grayson*, 51 USPQ 413 (Pat. Off. Bd. App. 1941) (denying a patent on a beheaded and cleaned shrimp still in its shell because the shrimp, even though manipulated, was nonetheless an unpatentable product of nature).

<sup>15</sup>*American Fruit Growers v. Brodget Co.*, 283 U.S. 1, 11 (1931).

<sup>16</sup>*Parke-Davis & Co. v. H.K. Mulford Co.*, 189 F. 95 (S.D.N.Y. 1911).

<sup>17</sup>*In re Bergstrom*, 57 C.C.P.A. 1240 (C.C.P.A. 1970).

<sup>18</sup>*Id.* at 1249.

upon nature. This long-standing division between patentable and unpatentable subject matter was recently challenged in *Association for Molecular Pathology v. U.S. Patent & Trademark Office*.<sup>19</sup> In that case, a district court (for the first time) invalidated patents directed to isolated DNA and methods of analyzing gene sequences based on the conclusion that DNA (even “isolated DNA”) is an unpatentable product of nature, thereby introducing new vulnerability and uncertainty regarding claims directed to isolated and/or purified products of nature.<sup>20</sup>

The district court’s ruling in *Association of Molecular Pathology*, holding that claims to isolated DNA encoding breast cancer susceptibility genes were unpatentable, was contrary to Patent Office practice of granting patents on isolated DNA and case law upholding their validity. The court focused on whether the claimed DNA had structural or functional differences that made it “markedly distinct” from the native DNA found in nature and determined that “[t]he proper comparison is between the claimed isolated DNA and the corresponding native DNA, and the presence or absence of chromosomal proteins merely constitutes a difference in purity that cannot serve to establish subject matter patentability.”<sup>21</sup> On appeal, the Federal Circuit reversed and held that the claims drawn to isolated DNA “are drawn to patentable subject matter because the claims cover molecules that are markedly different—have a distinctive chemical identity and nature—from molecules that exist in nature.”<sup>22</sup> The court explained that human intervention in cleaving or synthesizing results in “a distinctive chemical identity” from native DNA, and that the former is not just a purified form of native DNA.<sup>23</sup> More generally, the Federal Circuit rejected the district court’s attempt to create a categorical rule excluding isolated DNA from patent eligibility, noting that such a change in the law would have to come from Congress.<sup>24</sup>

The Federal Circuit’s decision in *Association for Molecular Pathology* confirmed the patentability of isolated DNA and has been a very positive development for innovator biotechnology companies as well as the public, which benefits from the great advances these inventions contribute to the medical community. Had the district court’s decision been upheld, it would have caused significant disruption to the incentives for companies and scientists to invest significant time and effort in the discovery of new therapeutics, among other things. As this chapter goes to press, the uncertainty surrounding the patentability of isolated DNA seems, at least for now, to have abated.

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<sup>19</sup>*Association for Molecular Pathology v. U.S. Patent & Trademark Office*, 702 F. Supp. 2d 181 (S.D.N.Y. 2010).

<sup>20</sup>*Id.* at 232.

<sup>21</sup>*Id.* at 229–30. The district court also held that the patents directed to methods of analyzing and comparing gene sequences and methods of using the DNA to screen for cancer risks by comparing growth rates of cells were invalid as mental processes that failed to meet the “machine-or-transformation” test. *Id.* at 236–37. The patentability of mental processes and methods is discussed in §II.B., *infra*.

<sup>22</sup>*Association for Molecular Pathology v. U.S. Patent & Trademark Office*, No. 2010-1406, 2011 WL 3211513, at \*17, 99 USPQ2d 1398 (Fed. Cir. July 29, 2011). The Federal Circuit also reversed the district court’s holding that the method of using the DNA to screen for cancer risks failed to rise to the level of patent-eligible subject matter, ruling instead that this method is patentable because the claim contained an “inherently transformative step involving the manipulation of the cells and their growth in the medium.” *Id.* at \*23. However, the Federal Circuit affirmed the lower court’s ruling that the method claims to comparing or analyzing DNA sequences without a “transformative” step were not patent-eligible “because they claim only abstract mental processes.” *Id.* at \*21.

<sup>23</sup>*Id.* at \*17.

<sup>24</sup>*Id.* at \*18.

## B. Patentability of Mental Processes and Methods

In another recent §101 development, the Supreme Court in *Bilski v. Kappos* addressed the patentability of method claims and, in particular, claims directed to a method of hedging risk in the field of commodities trading.<sup>25</sup> While the technology at issue in *Bilski* was unrelated to the life sciences industry, the decision has important implications for the field of medical technology and methods of treatment. As part of an overall patent strategy, medical technology companies will pursue patents not only on the medical device or therapeutic product itself but also on novel methods of using the device or product.

The *Bilski* Court rejected a categorical rule that business methods are not patentable, but nonetheless affirmed the Federal Circuit's holding that the concept of hedging risk and the application of that concept to energy markets are unpatentable abstract ideas.<sup>26</sup> Significantly, the Court endorsed the machine-or-transformation test as one applicable test, but held that it was not the sole or exclusive test for patent-eligible subject matter.<sup>27</sup> The Court recognized the test as a "useful and important clue, an investigative tool, for determining" the patentability of process claims;<sup>28</sup> then, instead of providing more concrete guidance on what other tests could be applied, it directed courts simply to look to the Supreme Court's precedent to determine what would constitute an unpatentable abstract idea.<sup>29</sup> At the end of the day, the *Bilski* decision cautioned the Federal Circuit and lower courts to avoid bright-line determinations and afforded them greater flexibility in assessing patentable subject matter.

In one of the first post-*Bilski* decisions addressing §101 patentability, the Federal Circuit in *Prometheus Laboratories, Inc. v. Mayo Collaborative Services* upheld (for the second time) the validity of method claims directed to administering a drug and then determining the level of the drug's metabolites in the subject.<sup>30</sup> Since the Supreme Court did not reject the machine-or-transformation test, it is not surprising that the Federal Circuit applied this same test again on remand to reach the same conclusion. The Federal Circuit again disagreed with the district court that the steps of the claimed process were simply unpatentable correlations of natural phenomena, and also disagreed that the steps were merely unpatentable data-gathering and mental steps. Rather, the Federal Circuit found that the claims were directed "not to a law of nature, but to a particular application of naturally occurring correlations, and accordingly do not preempt all uses of the recited correlations."<sup>31</sup> The claimed methods thus satisfied the transformation prong of the machine-or-transformation test because they "transform an article

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<sup>25</sup>*Bilski v. Kappos*, 130 S.Ct. 3218 (2010).

<sup>26</sup>*Id.* at 3228, 3231.

<sup>27</sup>*Id.* at 3227. The machine-or-transformation test provides that a claimed method or process is patentable if it is tied to a particular machine or apparatus or transforms a particular article into a different state or thing.

<sup>28</sup>*Id.* at 3227.

<sup>29</sup>*Id.* at 3231.

<sup>30</sup>*Prometheus Labs, Inc. v. Mayo Collaborative Servs.*, 628 F.3d 1347 (Fed. Cir. 2010). The Federal Circuit had once before reached the same conclusion under the machine-or-transformation test (see *Prometheus Labs, Inc. v. Mayo Collaborative Servs.*, 581 F.3d 1336 (Fed. Cir. 2009)), but the Supreme Court granted Mayo Collaborative's petition for a writ of certiorari and vacated and remanded the case in light of the *Bilski* decision. *Mayo Collaborative Servs. v. Prometheus Labs, Inc.*, 130 S.Ct. 3543 (2010).

<sup>31</sup>*Prometheus Labs*, 628 F.3d at 1354.

into a different state or thing,’ and this transformation is ‘central to the purpose of the claimed process.’”<sup>32</sup> The court elaborated on this last point and stated that “method of treatment [claims] . . . are always transformative when one of a defined group of drugs is administered to the body to ameliorate the effects of an undesired condition.”<sup>33</sup> Following this decision, the Supreme Court again granted certiorari on June 20, 2011; the outcome of that review remains to be seen.

### C. Section 101 Strategies

It may be premature to alter one’s patent litigation strategy based on the non-final decisions in *Prometheus* and *Association for Molecular Pathology*, but some guideposts are emerging that may be instructive to patentees and patent challengers. While not dispositive, the machine-or-transformation test is instructive and suggests that the strongest biotechnology claims will be those directed to products that have been altered from their natural state and those directed to methods of treatment in which the body is “transformed” as a result of the treatment.

For a patentee, a straightforward pre-litigation strategy may be to draft patent claims to satisfy at least the machine-or-transformation test by tying a method or process to a particular device in broad terms or claiming isolated DNA in a vector, thus reinforcing patentability in exchange for narrower claim scope. Once the patentee has emerged from prosecution with issued patents, it can decide when facing an infringing competitor whether to assert its entire patent portfolio or, instead, to select only the strongest patent claims from a §101 perspective in order to avoid the challenge of patentable subject matter altogether.

For a patent challenger, new opportunities emerge to use the ambiguity in the law, the lack of bright-line rules, and the recent heightened §101 scrutiny to gain strategic advantage. A patent challenger may raise a §101 issue early in a case for thematic reasons as well: to minimize the significance of the claimed invention by characterizing it as a product that exists in nature or as a mere abstract idea. Moreover, a challenge to the patentability of asserted claims in this unknown environment—especially after a district court decision like that in *Association of Molecular Pathology*—poses concern for the patentee and provides more of an incentive to settle rather than take the chance that its patent claims will be invalidated. Now that the Supreme Court has eliminated *Bilski*’s machine-or-transformation test as a bright-line rule, issues of patentable subject matter are much less likely to be decided on summary judgment. They will nevertheless remain a viable defense and a source of patent vulnerability until the law is more clearly defined.

## III. DEFINING THE CLAIMED INVENTION

A biotechnology patent case, like many other types of patent cases, begins and ends with the definition of the claimed invention. In the biotech field, however, defining the claimed invention is as much an art as it is a science. What may

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<sup>32</sup>*Id.* at 1355 (quoting *In re Bilski*, 545 F.3d 943, 962 (Fed. Cir. 2008)).

<sup>33</sup>*Id.* at 1356.

be required for a patentee to conceive of an isolated DNA sequence, a genetic marker, a therapeutically effective recombinant protein, or a method of screening for a disease or condition pushes the boundaries of patent law as well as the state of the relevant art.

Pioneers are often entitled to broad claim scope,<sup>34</sup> but those who follow in the footsteps of path-breaking inventors must navigate the prior art and take care in crafting claims and making representations during prosecution in order to secure what they can without unnecessarily surrendering claim scope. Claim scope is inherently fact-bound and will depend on, among other things, the intrinsic record: the claims, the specification, and the file history. Additionally, both the patentee and the alleged infringer must play the hand that they have been dealt and either embrace or reconcile those facts when constructing their arguments.

While neither the patentee nor the alleged infringer is entirely free to write on a blank slate, drawing the metes and bounds of a claimed invention provides opportunities to introduce (or resolve) possible disputes regarding, *inter alia*, priority, conception, inventorship, written description, enablement and scope of equivalents.

#### **A. The Doctrine of Simultaneous Conception and Reduction to Practice: The Special Case of Nucleic Acids**

What is the claimed invention and what was required to conceive of it? Conception is the completion of the mental act of invention and the touchstone of inventorship.<sup>35</sup> It is well-settled law that conception of a claimed invention requires both the idea of an invention's structure and possession of an operative method for making it.<sup>36</sup> In the case of DNA and other chemical compounds, "conception does not occur unless one has a mental picture of the structure of the chemical."<sup>37</sup>

In the early 1990s, when considering claims to an isolated DNA sequence, the Federal Circuit applied the doctrine of simultaneous conception and reduction to practice.<sup>38</sup> Borrowing from a line of cases dating back to the 1940s, the Court determined that when an inventor is unable to envision the detailed structure of a DNA sequence, as well as a method for obtaining it, "conception has not been achieved until reduction to practice has occurred, *i.e.*, until after the gene has been isolated."<sup>39</sup> While not entirely limited to isolated nucleic acid claims, the doctrine has been used in the main in the consideration of DNA claims and, for good or ill, has persisted in the analysis of these claims to the present day.

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<sup>34</sup>*See, e.g.*, *Augustine Med., Inc. v. Gaymar Indus., Inc.*, 181 F.3d 1291, 1301 (Fed. Cir. 1999) ("Without extensive prior art to confine and cabin their claims, pioneers acquire broader claims than non-pioneers who must craft claims to evade the strictures of a crowded art field.").

<sup>35</sup>*Burroughs Wellcome Co. v. Barr Laboratories, Inc.*, 40 F.3d 1223, 1227–28 (Fed. Cir. 1994) (*citing* *Sewall v. Walters*, 21 F.3d 411, 415 (Fed. Cir. 1994)).

<sup>36</sup>*See* *Oka v. Youssefyeh*, 849 F.2d 581, 583 (Fed. Cir. 1988); *see also* *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1376 (Fed. Cir. 1986).

<sup>37</sup>*Amgen Inc. v. Chugai Pharmaceuticals, Inc.*, 927 F.2d 1200, 1206 (Fed. Cir. 1991).

<sup>38</sup>*Id.* *See also* *Fiers v. Revel v. Sugano*, 984 F.2d 1164 (Fed. Cir. 1993).

<sup>39</sup>*Amgen Inc.*, 927 F.2d at 1206. *See also* *Fiers*, 984 F.2d 1164 (Fed. Cir. 1993); *accord* *Smith v. Bousquet*, 111 F.2d 157 (C.C.P.A. 1940).

### 1. *Conception and Priority of DNA-Based Claims*

One consequence of applying the doctrine to biotechnological inventions is that the moment of completed conception is pushed forward in time to the moment of reduction to practice or even later. Because conception requires that an inventor appreciate what he or she has invented,<sup>40</sup> a patent challenger may argue that reduction to practice of the structure is necessary but not sufficient for full conception of the claimed invention. For example, if the claimed invention includes a recombinant protein that possesses certain properties, or a particular use of an isolated DNA sequence, complete conception may require both identification of the underlying structure (DNA or protein sequence) and confirmation of the claimed functionality.

For one challenging the validity of a patent, extending the time for conception (and simultaneous reduction to practice) opens the way for priority challenges, intervening art, or even contribution by other potential putative inventors. Conversely, defining early what is required to conceive of the claimed invention allows a patentee to anticipate and stave off invalidity challenges, as well as marshal evidence to corroborate conception and reduction to practice.

### 2. *Joint Inventorship and DNA-Based Claims*

Where the completed act of conception is pushed forward in time, the contributions of others—even in the context of simultaneous conception and reduction to practice—open the way for claims of joint inventorship (or a defense of misjoinder or non-joinder) and/or obviousness.

While a joint inventor must contribute in some significant way to the conception of the invention, there is no requirement that a joint inventor independently have a contemporaneous picture of the final claimed invention in order to qualify as a joint inventor.<sup>41</sup> The Federal Circuit has held that the doctrine of simultaneous conception and reduction to practice cannot be used to show that “because the first person did not conceive or reduce to practice the entire claimed invention, he or she did not at least contribute in some significant way to the ultimate conception.”<sup>42</sup> Therefore, the contributions of collaborators or co-workers may qualify as inventive even where the collaborator did not have “an independent mental picture of the complete compound claimed.”<sup>43</sup> For a patent challenger, a prolonged timeline to completed conception may open the door to contributions by others that may be found to be inventive. Where those contributions were made outside of common employment or an obligation to assign, they may also provide a challenger with the basis for an obviousness defense.<sup>44</sup> As several courts have noted, joint inventorship is one of the “muddiest” concepts within patent law,<sup>45</sup> providing ample fodder for a patent challenger in the life sciences field.

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<sup>40</sup>*Invitrogen Corp. v. Clontech Labs, Inc.*, 429 F.3d 1052, 1063 (Fed. Cir. 2005) (citing *Silvestri v. Grant*, 496 F.2d 593, 597 (C.C.P.A. 1974)).

<sup>41</sup>*Vanderbilt Univ. v. ICOS Corp.*, 601 F.3d 1297, 1303 (Fed. Cir. 2010).

<sup>42</sup>*Fina Oil v. Ewen v. Razavi*, 123 F.3d 1466, 1474 (Fed. Cir. 1997); see also *Vanderbilt Univ. v. ICOS Corp.*, 601 F.3d 1297, 1308 (Fed. Cir. 2010).

<sup>43</sup>*Vanderbilt Univ. v. ICOS Corp.*, 601 F.3d 1297, 1307 (Fed. Cir. 2010).

<sup>44</sup>See 35 U.S.C. §103(c).

<sup>45</sup>See *Brown v. Regents of Univ. of Cal.*, 866 F. Supp. 439, 442 (N.D.Cal. 1994) (citing *Mueller Brass Co. v. Reading Indus., Inc.*, 352 F. Supp. 1357, 1372 (E.D.Pa. 1972), *aff'd*, 487 F.2d 1395 (3d Cir.1973)).

A patentee may characterize the contributions of others as the rote lab work of a technician or a pair of lab hands acting under the guidance and supervision of the patentee. Even where the contributor is a co-worker or under a common obligation of assignment, a patentee may wish to maintain the contributor's non-inventive status not only to avoid disrupting the designation of the named inventor/inventors, but also so that the contributor may serve as a non-inventor corroborator of the invention.<sup>46</sup>

### 3. *Strategies for Conception, Priority, and Inventorship*

While both patentees and patent challengers tend to apply the doctrine by rote to DNA-based claims, it is worth considering whether doing so makes sense in light of the facts of the case at hand and the nature of the claimed invention. For both patentees and challengers, it is important to remember that the decisions first applying the doctrine of simultaneous conception and reduction to practice to DNA-based inventions are undeniably products of their time. The earliest cases reflect the state of the art in 1983–84, when a detailed method for isolating a DNA sequence, by itself, did not ensure success or certainty in obtaining the desired sequence.

The Federal Circuit has consistently declined to hold that an inventor can never conceive of an invention until reduction to practice because of the inherent unpredictability of the science.<sup>47</sup> Rather, in each of the DNA or biotech conception cases, the court ultimately relied on the date of reduction to practice because it, in effect, provided the first evidence to corroborate conception of the invention.<sup>48</sup> Today, more than 25 years after these early DNA cases, polymerase chain reaction (PCR), DNA screening libraries, and the human genome project have made the isolation and characterization of DNA sequences much more predictable, and a patentee or patent challenger may find room to distinguish the application of the doctrine and re-set the clock to an earlier date for completed conception.

## **B. Claim Scope and the Doctrine of Equivalents**

Notwithstanding a patentee's effort to define the metes and bounds of the claimed invention, he or she cannot conceive of or enable every possible permutation and may need to rely on a scope of equivalents to capture an accused infringer's activities. The doctrine of equivalents holds a special challenge for patentees in the unpredictable art of biotechnology.

On the one hand, a patentee wants to maintain his or her position that the claimed invention was a breakthrough that proved a principle, clearing the way past prior art that might otherwise be relevant. At the same time, however, argu-

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<sup>46</sup>See *Procter & Gamble Co. v. Teva Pharm. USA, Inc.*, 566 F.3d 989, 999 (Fed. Cir. 2009) (citing *Hahn v. Wong*, 892 F.2d 1028, 1032 (Fed. Cir. 1989) (An inventor "must provide independent corroborating evidence in addition to his own statements and documents."). See also *Shu-Hui Chen v. Bouchard*, 347 F.3d 1299, 1309 (Fed. Cir. 2003) ("It is well established that when a party seeks to prove conception via the oral testimony of a putative inventor, the party must proffer evidence corroborating that testimony.").

<sup>47</sup>See *Smith v. Bousquet*, 111 F.2d 157, 162 (C.C.P.A. 1940); *Amgen Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1206–07 (Fed. Cir. 1991); *Fiers v. Revel v. Sugano*, 984 F.2d 1164, 1171 (Fed. Cir. 1993); *Burroughs Wellcome Co. v. Barr Labs.*, 40 F.3d 1223, 1229 (Fed. Cir. 1994); see also *Board of Education v. American Bioscience Inc.*, 333 F.3d 1330, 1340 (Fed. Cir. 2003).

<sup>48</sup>*Id.*

ing that a small difference—in sequence, in structure, in method—may have profound consequences and constitute a patentable invention makes it all the more difficult to argue that similar small differences are properly captured by the scope of equivalents. For example, patented proteins may have hundreds or thousands of analogs (*e.g.*, by single amino acid substitution) that are not literally covered by the claims. When more than one amino acid is substituted, added, and/or deleted, the number of analogs increases exponentially. The only avenue for capturing these small changes to the claimed product may be through the doctrine of equivalents. Patentees, then, are confronted with a Hobson’s choice: Lose a scope of equivalents or open the door to obviousness.

In some cases, depending on what positions it was forced to stake out during prosecution, a patentee will have less flexibility in choosing how to frame its claims and scope of equivalents. Where the patentee has submitted a narrowing amendment to its pending claims in order to overcome a rejection related to patentability, the patentee may be estopped from asserting those claims to cover claim scope that is deemed surrendered, regardless of how minor the amendment or how close the accused product is to meeting the claim limitation. The Federal Circuit in *Glaxo Wellcome, Inc. v. Impax Laboratories, Inc.* considered a case where the patentee amended its claims in response to an enablement rejection to add a specific mechanism of action.<sup>49</sup> The court held that prosecution history estoppel attached to that amendment, and that the doctrine of equivalents could not be used to prove infringement by another agent that had an equivalent mechanism of action to the one claimed.<sup>50</sup>

Sometimes, though, a patentee can carefully thread the needle to maintain both arguments. In *Abbott Laboratories v. Dey, Inc.*, for example, the Federal Circuit considered whether the doctrine of equivalents could be applied where claims directed to a lung surfactant composition with 68.6–90.7% phospholipid were asserted against an accused product containing 94.5% phospholipid.<sup>51</sup> To determine whether the doctrine of equivalents could be applied to capture this increase in phospholipid, the court considered whether a “hypothetical claim” that literally encompassed the accused product would be allowable over the prior art.<sup>52</sup> The court determined that, even though the claim recited a specific numeric range and the prior art overlapped with that range, the doctrine of equivalents could be applied because other limitations rendered the hypothetical claim nonobvious.<sup>53</sup> Thus, the doctrine of equivalents may be applied to capture the slight changes made by an accused infringer if the prior art does not preclude such application.

While a patentee will be more successful asserting a pioneering patent where the prior art has not forced extensive narrowing amendments or novelty arguments, there remains the formidable task of deciding how to frame the claimed

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<sup>49</sup>356 F.3d 1348, 1351–56 (Fed. Cir. 2004).

<sup>50</sup>*Id.* at 1354–56. *See also* Amgen Inc. v. Hoechst Marion Roussel, Inc., 457 F.3d 1293, 1308–16 (Fed. Cir. 2006) (prosecution history estoppel precluded infringement by equivalents where the accused protein differed from the claimed protein by one amino acid).

<sup>51</sup>Abbott Labs. v. Dey, L.P., 287 F.3d 1097, 1107–08 (Fed. Cir. 2002).

<sup>52</sup>*Id.* at 1105 (*citing* Wilson Sporting Goods Co. v. David Geoffrey & Assocs., 904 F.2d 677, 684 (Fed. Cir. 1990) (“The pertinent question then becomes whether that hypothetical claim could have been allowed by the PTO over the prior art.”)).

<sup>53</sup>*Id.* at 1106–07.

invention and its scope of equivalents in a way that avoids obviousness challenges based on the assertion that small changes are similar in structure, function, and result. As with the §112 defenses discussed below, a patentee may take refuge in the patent's own disclosure. For instance, a small change whose affect is unknown or unproven presents a universe of unpredictability. However, once a patentee has tested the small change, and thus proven a principle, others practicing in the art with the benefit of that knowledge and disclosure (the patent's teaching) may be able to apply that change rotely, or to extrapolate from the principle more broadly and more predictably. In some cases, these tensions will be easier to navigate, but in all cases, navigating this conflict and deciding early in the case how to frame the invention are both thorny and critically important.

For a patent challenger, it is important to mine the prosecution history to the fullest extent, including parent and sibling histories, to look for evidence of surrendered claim scope. At the same time, the challenger should exploit the tension between nonobviousness and novelty in the claimed invention and the patentee's attempt to capture a broader scope of equivalents in its arguments and in developing its factual record.

#### IV. SECTION 112-BASED DEFENSES: WRITTEN DESCRIPTION AND ENABLEMENT

One of the most unique hallmarks of biotechnology patent litigation is that §112 invalidity defenses are often more successful than the traditional anticipation and obviousness defenses common in other types of patent litigation.<sup>54</sup> Because of the unpredictability inherent in the biotechnology field, biotechnology patents are often more prone to attack as failing to satisfy their disclosure requirements than for having been practiced or suggested by the prior art. In fact, some statistics suggest that §112 defenses are nearly twice as likely as Section 102 and Section 103 defenses to prevail in life sciences patent disputes—nearly the complete inverse of the results seen in IT patent litigation.<sup>55</sup>

##### A. Written Description Challenges

Among the various §112 defenses, written description is one of the most fruitful areas for a patent challenger to explore. This is largely because the disclosure requirement in a biotechnology patent application is held to a higher standard than its IT counterparts. As the Federal Circuit has made clear, the “level of detail required to satisfy the written description requirement varies depending on the nature and scope of the claims and on the complexity and predictability of the relevant technology.”<sup>56</sup>

To satisfy the written description requirement, a patentee must describe the invention in sufficient detail so “that one skilled in the art can clearly conclude

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<sup>54</sup>See data from the University of Houston Law Center at [www.patstats.org](http://www.patstats.org).

<sup>55</sup>*Id.*

<sup>56</sup>*Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc) (citing *Capon v. Eshhar*, 418 F.3d 1349, 1357–58 (Fed. Cir. 2005)).

that the inventor invented the claimed invention as of the filing date sought.”<sup>57</sup> Patent challenges in the life sciences based on written description come in two distinct flavors. The first mirrors a challenge to conception—i.e., an allegation that the patentee has failed to convey to an ordinarily skilled artisan that he or she was in possession of (or fully appreciated) the claimed invention at the time of filing. The second type of attack, often referred to as a “genus/species” attack, alleges that the patentee has not adequately described the full scope of the claims such that one skilled in the art would have been able to visualize the full complement of claimed embodiments. This second avenue of attack is very similar to a scope of enablement attack that can be mounted against generic (or “genus”) claims, as discussed below.

The first type of written description challenge is strikingly similar to the conception cases discussed above. In practice, the Federal Circuit has required a patentee to disclose the isolated DNA sequence for any DNA-based invention: “[A]n adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself.”<sup>58</sup> In the seminal written description case, *Regents of the University of California v. Eli Lilly & Co.*, the Federal Circuit found that a claim directed to cDNA encoding human insulin was not adequately described by the disclosure of rat insulin cDNA and a general method for obtaining human cDNA.<sup>59</sup>

While more recent cases have suggested that functional language may satisfy the written description requirement where there exists an established correlation between structure and function that is sufficiently disclosed or known in the art,<sup>60</sup> as a practical matter the Federal Circuit has continued to require a sequence or structure-based disclosure in all but a couple of outlier cases.<sup>61</sup> In fact, a patentee’s inclusion of a functional limitation may actually introduce additional description defects if a court finds that there is insufficient support for the genus of claimed structures actually possessing the recited function.<sup>62</sup>

For a patentee defending against this type of written description attack, it is critical to develop evidence showing the inventor’s contemporary appreciation and possession of the claimed invention. Evidence of possession can be bolstered by developing a record showing that correlated structures were well known or could be routinely selected in the art. A patent challenger, on the other hand, may exploit the prolonged timeline to complete conception, and thus a complete

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<sup>57</sup>*Lockwood v. American Airlines Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997).

<sup>58</sup>*Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1566–67 (Fed. Cir. 1997) (internal citations omitted).

<sup>59</sup>*See id.* at 1567 (“While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA’s relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA. Describing a method of preparing a cDNA or even describing the protein that the cDNA encodes, as the example does, does not necessarily describe the cDNA itself.”).

<sup>60</sup>*Enzo Biochem, Inc. v. Gen-Probe, Inc.*, 323 F.3d 956, 964 (Fed. Cir. 2002) (written description requirement may be satisfied if the functional characteristic is correlated to a particular structure that is sufficiently disclosed or known in the art); *see also Capon v. Eshhar*, 418 F.3d 1349 (Fed. Cir. 2005).

<sup>61</sup>*Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc); *see also Billups-Rothenberg, Inc. v. Associated Regional & Univ. Pathologists, Inc.*, 642 F.3d 1031, 1036–37 (Fed. Cir. 2011).

<sup>62</sup>*Centocor Ortho Biotech v. Abbott Labs.*, 636 F.3d 1341, 1352 (Fed. Cir. 2011); *see In re Kubin*, 561 F.3d 1351, 1353–54 (Fed. Cir. 2009).

description, in order to introduce uncertainty regarding priority, inventorship, and ultimately possession, as discussed in more detail below.

The second type of written description attack is based on a challenge to the breadth of the claimed invention. An adequate written description of a claimed genus requires “more than a generic statement of an invention’s boundaries.”<sup>63</sup> A patentee must set forth “either a representative number of species falling within the scope of the genus or structural features common to the members of the genus.”<sup>64</sup> What constitutes a “representative number of species” is inversely related to the predictability in the art, such that the Federal Circuit has noted that a single species will rarely be sufficient to adequately describe a broad claim in an unpredictable art.<sup>65</sup> Nonetheless, the ultimate determination of what constitutes disclosure sufficient to demonstrate that an inventor possessed (or conceived) of the claimed genus will be inherently fact-bound.

This written description genus/species challenge goes to the heart of a biotechnology patent case: Having made a discovery in an unpredictable field, the patentee wishes to claim more broadly than merely the specific disclosed embodiments. For an alleged infringer, the unpredictability in the art and the patentee’s allegation of nonobviousness can be powerful admissions for use in undermining the full scope of the claimed invention.

For the patentee, the real challenge in defending against a genus/species challenge lies in characterizing the breadth of the claim as a non-novel feature of the invention. For instance, having discovered and isolated the DNA sequence for human erythropoietin, a patentee may argue that appreciating the range of vectors or host cells that could be used for recombinant expression was fairly routine.<sup>66</sup> The patentee will characterize the invention as a paradigm shift and, in so doing, may argue that the claimed invention opened up a new field such that others coming later could easily follow, and that the inventor was therefore entitled to claim his or her invention broadly. Much of the evidentiary record that can help defend against a written description challenge based on claim breadth will be useful in defending against a similar breadth challenge on separate enablement grounds, as discussed below.

From the perspective of a patent challenger, much of the patentee’s evidence of nonobviousness and inventiveness may be parlayed into unpredictability in the scope of the claimed invention. The crux of the defense is to tie the unpredictability in the claimed discovery to the breadth or genus aspect of the claim.

## B. Enablement Challenges

The same unpredictability that provides the backdrop for significant and pioneering inventions in the biotechnological art can pose problems for patentees attempting to disclose and enable the full scope of their claims. The enablement defense, like written description, provides much grist for patent challengers.

From the first Patent Act up to the present, Congress has required that, in exchange for the privilege of limited exclusivity, patentees disclose and teach

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<sup>63</sup>*Ariad Pharm., Inc.*, 598 F.3d at 1349.

<sup>64</sup>*Id.* at 1350.

<sup>65</sup>*Id.*

<sup>66</sup>*Amgen v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1335 (Fed. Cir. 2003).

ordinarily skilled artisans how to make and use the claimed invention.<sup>67</sup> Today, Section 112, paragraph 1 requires the patent's specification to disclose "the manner and process of making and using [the claimed invention], in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same."<sup>68</sup> Over time, case law has elaborated on the statute to require that a patent's specification teach one of ordinary skill in the art how to make and use the claimed invention without undue experimentation.<sup>69</sup>

While it is black-letter law that a patentee need not disclose in his or her patent that which is well known in the art,<sup>70</sup> the scope of what is well known or well understood to an ordinarily skilled artisan in a rapidly advancing or unpredictable art will often be narrow and will almost certainly be the subject of some debate. And in a nascent or emerging technology, only the most incidental or minor features of the method of making or using the claimed invention may be inferred or provided by the existing knowledge in the art.<sup>71</sup>

Where a patent discloses a single example or a limited number of examples (or "species") yet claims more broadly (as in a "genus"), a patent challenger may exploit the unpredictability of the art and raise an undue breadth challenge (similar to that discussed above in the context of written description) to the claimed invention based on the separate enablement requirement of Section 112. In a series of cases decided in the early 1990s arising from appeals before the BPAI, the Federal Circuit rejected broad genus claims where only one or a limited number of working examples had been disclosed.

In *In re Vaeck*, the Federal Circuit held that claims to the use of all bacterial host cells were not enabled by a specification that provided two working examples, both using a single cyanobacteria strain as the host.<sup>72</sup> Two years later, in *In re Wright*, the court concluded that claims to certain pathogenic RNA virus vaccines were not enabled by a single working example to a specific RNA tumor virus, and further suggested that a single working example is rarely sufficient to enable a claim to a broad genus.<sup>73</sup> That same year, in *In re Goodman*, the Federal Circuit again concluded that a patentee failed to enable genus claims to genetically altered plants (both monocots and dicots) where the single working example disclosed only a genetically altered dicot (one of the species claimed).<sup>74</sup> These cases stand for the proposition that a patentee may not be able to support a broad genus claim by disclosing how to make and use one or only a limited number of species falling within the scope of the genus. The assessment of "how

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<sup>67</sup>Patent Act of 1790, Ch. 7, 1 Stat. 109-112 (Apr. 10, 1790).

<sup>68</sup>35 U.S.C. §112 para. 1.

<sup>69</sup>*In re Wands*, 858 F.2d 731, 736-37 (Fed. Cir. 1988) ("Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.'"); *Enzo Biochem, Inc. v. Calgene, Inc.*, 188 F.3d 1362, 1371-72 (Fed. Cir. 1999).

<sup>70</sup>*Hybritech v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384 (Fed. Cir. 1986) ("[A] patent need not teach, and preferably omits, what is well known in the art"); see also *Chiron Corp. v. Genentech*, 363 F.3d 1247, 1254 (Fed. Cir. 2004).

<sup>71</sup>*Genentech, Inc. v. Novo Nordisk*, 108 F.3d 1361, 1366-67 (Fed. Cir. 1997), cert. denied, 522 US 963 (1997).

<sup>72</sup>*In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991).

<sup>73</sup>*In re Wright*, 999 F.2d 1557 (Fed. Cir. 1993).

<sup>74</sup>*In re Goodman*, 11 F.3d 1046 (Fed. Cir. 1993).

much is enough” will be fact-specific, but in general the amount of disclosure courts will require will be inversely proportional to the predictability in the art and, specifically, in the field of the invention.

A patent challenger will adduce the same kinds of evidence that would support a genus/species attack on written description (as discussed above)—the limited nature of the disclosure, the lack of predictability in the art, the existence of inoperative embodiments—to maintain its challenge for lack of enablement. A patentee will again marshal evidence and argument to support its contention that once it had proven an unpredictable or unknown principle, that principle could be broadly and predictably applied. From the patentee’s perspective, however, an undue breadth challenge may be easier to combat than a written description challenge because a patentee is better able to supplement the patent’s disclosure with what was known to an ordinarily skilled artisan at the time.<sup>75</sup> For example, a patentee can develop and rely on evidence outside of the patent’s disclosure to support the enablement of the claims.<sup>76</sup> A patentee may also introduce post-filing evidence of enablement to show that the patent was enabled at the time of filing.<sup>77</sup> It is permissible for an ordinarily skilled artisan to experiment, and even to encounter inoperative embodiments within the scope of a claim, as long as the experimentation is not “undue.”<sup>78</sup> Thus, a patentee can develop evidence that one of ordinary skill in the art would have known how to select or test for appropriate or workable species from within the genus, or even that he or she could have found suitable species with some (but not undue) experimentation.

In addition to breadth and scope challenges to the enablement of a claimed invention, a patent challenger may also attempt to undermine either novelty or enablement by pointing to some later-developed technology (usually the allegedly infringing technology) that the patentee has failed to disclose and enable. Patentees are not obligated to teach how to make and use the alleged infringing technology; where the claims are tied to particular methods, however, new or different methods that are not disclosed or taught by the patentee expose enablement vulnerability for the patent. At the same time, from a thematic perspective, a patent challenger will almost always be motivated to show that its own accused product or technology is significantly different from the claimed invention and not enabled by the patent disclosure. Even where this showing is not strictly relevant to the issue of enablement, it becomes an important equitable theme in a defense against infringement.

The development of post-filing technology that falls within the scope of a claimed invention has special consequences for both the patentee and the patent challenger. For composition-of-matter claims, the law is clear that “the specification need teach only one mode of making and using a claimed composition.”<sup>79</sup>

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<sup>75</sup>See *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1336 (Fed. Cir. 2003) (“The specification need not explicitly teach those in the art to make and use the invention; the requirement is satisfied if, given what they already know, the specification teaches those in the art enough that they can make and use the invention without “undue experimentation.”) (citing *Genentech, Inc. v. Novo Nordisk, A/S*, 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997); *In re Vaeck*, 947 F.2d 488, 495, 20 USPQ2d 1438, 1444 (Fed. Cir.1991)).

<sup>76</sup>See *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1336 (Fed. Cir. 2003).

<sup>77</sup>See *id.*

<sup>78</sup>*In re Wands*, 858 F.2d 731, 736–37 (Fed. Cir. 1988).

<sup>79</sup>*Johns Hopkins Univ. v. Cellpro, Inc.*, 152 F.3d 1342, 1361 (Fed. Cir. 1998).

Thus, where the method of manufacture is immaterial to the claimed invention, enablement does not require the patentee to describe and teach methods by which the patented composition may be made that are developed after the patent is filed.<sup>80</sup>

In *Invitrogen Corp. v. Clontech Laboratories, Inc.*, for example, the patented claims described genetically engineered enzyme, reverse transcriptase (“RT”), RT without regard for the method used to mutate the genes.<sup>81</sup> The parties agreed that when the patent was filed, those skilled in the art knew several techniques for altering genetic sequences, including deletion and point mutations. The patent challenger argued that the patent only taught how to implement the invention by point mutation. The Federal Circuit focused on the fact that the claims were not limited to the method used to mutate genes and held that the patentee had fully described an operable method for achieving the claimed mutation.<sup>82</sup> Similarly, in *Amgen Inc. v. Hoechst Marion Roussel, Inc.*,<sup>83</sup> the patent claims at issue included composition claims directed to recombinant human erythropoietin (EPO), a naturally occurring hormone that controls the formation of red blood cells in bone marrow. The patent challenger argued that because the specification failed to teach the method of homologous recombination and endogenous gene activation for the production of recombinant human EPO, the specification did not enable one of ordinary skill in the art to practice the full scope of the asserted claims without undue experimentation. The Federal Circuit held that because the claims at issue did not recite a particular method for the production of EPO, the specification’s failure to disclose a later-developed endogenous gene activation technology could not invalidate the patent.<sup>84</sup>

While composition-of-matter claims may be immune to challenges based on post-filing developments, other types of claims, and specifically method claims, are not. Where a patentee asserts broad method claims, post-filing developments in the art may provide a unique opportunity for patent challengers to present thematically consistent noninfringement and nonenablement defenses. A patent challenger may build on its noninfringement defense to argue that not only is the accused method significantly different from the claimed invention, but also if the claim scope is broad enough to read on the accused method, then the patentee failed to adequately enable post-filing developments. In support of this argument, the challenger may rely on evidence from the time of filing, or even later, to demonstrate the state of the art at the time of filing, or that later developments were not enabled even after the filing date.<sup>85</sup>

In all its varieties, the determination of enablement is so fact-dependent that it is rare for a biotech patent challenger not to mount an enablement defense. Almost inevitably, both the patentee and the patent challenger must devote considerable resources to developing a factual record (both from the time of patent

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<sup>80</sup>See *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1336 (Fed. Cir. 2003) (citing *US Steel Corp. v. Phillips Petroleum Co.*, 865 F.2d 1247, 1251 (Fed. Cir. 1988); *In re Koller*, 613 F.2d 819, 824–25 (C.C.P.A. 1980)); see also *In re Hogan*, 559 F.2d 595, 606 (C.C.P.A. 1977).

<sup>81</sup>429 F.3d 1052, 1071 (Fed. Cir. 2005).

<sup>82</sup>*Id.* at 1070–72.

<sup>83</sup>*Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313 (Fed. Cir. 2003).

<sup>84</sup>*Id.* at 1334–36.

<sup>85</sup>See *id.* at 1336.

filing and beyond) from which they may present, or defend against, the breadth of enablement challenges.

## V. INJUNCTIVE RELIEF

The significance of injunctive relief—both to patentees and patent challengers—cannot be overstated. For biotechnology companies seeking to enforce their patents, the availability of injunctive relief provides an incentive to invest in the time-consuming and costly endeavor of researching and developing new products, and the award or denial of an injunction can forever change the competitive landscape. After *eBay v. MercExchange*, it was hotly debated whether the backlash against permanent injunctions would affect biotechnology cases. While permanent injunctions are no longer automatically granted after a favorable disposition on the merits, the variety of factors that courts consider to determine whether an injunction is warranted still favors injunctions in those biotechnology cases where the patented invention is available on the market and satisfies market demand. For biotechnology companies in particular, the fourth prong of the injunction inquiry—the public interest prong—has heightened significance and, post *eBay*, plays a special role in courts’ assessment of the propriety of injunctions in biotechnology patent cases.

### A. *eBay v. MercExchange*: The New Standard for Patent Cases

The Supreme Court in *eBay, Inc. v. MercExchange, L.L.C.*, determined that the traditional four-factor injunction test applies to patent cases.<sup>86</sup> Thus, to be entitled to an injunction, a patentee must demonstrate: (1) that it has suffered irreparable injury; (2) the inadequacy of monetary damages; (3) that the balance of hardships weighs in favor of an injunction; and (4) that the public interest would not be disserved by a permanent injunction.<sup>87</sup>

In setting forth this standard, the Court rejected the notion that irreparable harm may be presumed upon a finding of patent infringement and validity. In other words, patentees are no longer automatically, or almost automatically, entitled to an injunction. Instead, the Court directed trial courts to apply the traditional four-factor test in exercising their equitable discretion to grant or deny a permanent injunction, and warned against adopting categorical rules compelling the grant or denial of such relief. Accordingly, the majority opinion written by Justice Thomas emphasized that the district courts have “considerable discretion.”<sup>88</sup> In a concurring opinion, however, Chief Justice Roberts reminded district courts that “discretion is not whim” and that there is a “long tradition of equity practice” to follow.<sup>89</sup>

On remand, the district court denied the motion for permanent injunction, finding that there was no irreparable harm and that there existed an adequate remedy at law (i.e., monetary damages) where MercExchange did not practice

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<sup>86</sup>*eBay, Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2006).

<sup>87</sup>*Id.* at 391.

<sup>88</sup>*Id.* at 394.

<sup>89</sup>*Id.* at 395 (Roberts, C.J., concurring).

the claimed invention and did not have a presence in the online auction industry (*i.e.*, MercExchange was not a direct competitor of eBay). Furthermore, MercExchange's post-trial discussions regarding licensing suggested that its request for an injunction was a "litigation tactic" and did not arise from a legitimate need to protect its business. The district court's decision on remand was consistent with Justice Kennedy's concurring opinion, where he highlighted the relatively new phenomenon of patentees using their patents not to make and sell products, but rather to extract licensing fees, and stated that in these circumstances the equities may tip in favor of the infringer.<sup>90</sup> In the context of weighing the injunction factors, a non-practicing entity is less likely to suffer irreparable harm, absent an injunction, where it is seeking licensing fees or settlements in any event. In addition, the balance of hardships may favor an infringer who has a product on the market and may not even have been aware of the patent when it invested in the development and marketing of that product. On the other hand, the courts have been unsympathetic to infringers who plan to launch at risk and then complain of their hardship if enjoined.<sup>91</sup>

## B. Irreparable Harm post-*eBay*

Post-*eBay* case law suggests that the facts most determinative in establishing irreparable harm are (1) direct competition between a patentee and the accused infringer and (2) loss of sales and market share by the patentee.<sup>92</sup> Another compelling fact that courts have found to weigh in favor of irreparable harm is the patentee's protection of its right of exclusivity by declining to license its patent rights.<sup>93</sup>

A patentee who alleges these facts but fails to substantiate its claims of irreparable harm will not be entitled to an injunction. For example, the district court in *Praxair, Inc. v. ATMI, Inc.*, denied an injunction where, even though the parties were direct competitors, the patentee failed to demonstrate that the asserted patents were critical to the overall corporate success of the company.<sup>94</sup> In particular, Praxair generally argued that the presence of the infringing product would cause Praxair to "likely lose additional market share, profits, and goodwill," but didn't provide any evidence or details to substantiate its claims.

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<sup>90</sup>*Id.* at 396 (Kennedy, J., concurring).

<sup>91</sup>*MercExchange, L.L.C. v. eBay, Inc.*, 500 F. Supp. 2d 556, 584 (E.D. Va. 2007).

<sup>92</sup>*See, e.g., Novozymes A/S v. Genencor Int'l, Inc.*, 474 F. Supp. 2d 592, 613 (D. Del. 2007) (granting permanent injunction because, *inter alia*, "[t]hese are head-to-head competitors, and Novozymes has a right, granted by Congress, not to assist its rival with the use of proprietary technology"); *Fresenius Med. Care Holdings, Inc. v. Baxter Int'l, Inc.*, 2008 U.S. Dist. LEXIS 79689, at \*11 (N.D. Cal. Mar. 21, 2008) ("The law favors Baxter's right to the full value of its property, particularly the ability to keep it out of its main competitor's hands."); *Muniauction, Inc. v. Thomson Corp.*, 502 F. Supp. 2d 477, 482 (W.D. Pa. 2007) ("Plaintiff and defendants are direct competitors in a two-supplier market. If plaintiff cannot prevent its only competitor's continued infringement of its patent, the patent is of little value.") (vacated on other grounds 532 F.3d 1318); *Amgen Inc. v. Hoffmann-La Roche Ltd.*, 581 F. Supp. 2d 160, 212 (D. Mass. 2008) (granting permanent injunction where "[t]he vast majority of Roche sales would be to the exclusion of Amgen sales, resulting in lost profits, market share, and good will").

<sup>93</sup>*See, e.g., 3M Innovative Properties Co. v. Avery Dennison Corp.*, 2006 U.S. Dist. LEXIS 70263, at \*4-5 (D. Minn. Sept. 25, 2006) (Because 3M spent several years consistently refusing to license its patent rights, "[t]he Court will not disturb 3M's determination that its business interests will not be served by the licensing of this product."); *cf. IMX, Inc. v. Lendingtree, LLC*, 469 F. Supp. 2d 203, 225 (D. Del. 2007) ("Plaintiff's willingness to forego its patent rights for compensation, though certainly not dispositive, is one factor to consider with respect to whether plaintiff will suffer irreparable harm.")

<sup>94</sup>*Praxair v. Adv. Tech. Materials*, 479 F. Supp. 2d 440 (D. Del. 2007).

The district court noted that, while it was unclear what quantum of evidence is required, Praxair hadn't met its burden in any event.<sup>95</sup>

Conversely, the absence of direct competition or loss of sales and market share does not preclude a patentee from being entitled to an injunction where irreparable harm can nonetheless be established. In *Commonwealth Scientific & Industrial Research Organisation v. Buffalo Technology Inc.*, for example, the district court granted an injunction where the patentee, a non-practicing entity, spent large sums of money in the research and development of its patented technologies.<sup>96</sup> The court found it particularly compelling that CSIRO is a research institute that relies heavily on its ability to license its intellectual property to finance its research and development. If, at the end of the day, an infringer merely had to pay a royalty instead of facing a potential injunction, it would have no incentive to enter into a license agreement in the first instance rather than challenge the patents. Furthermore, if CSIRO had to pursue each infringer to enforce its patents and divert millions of dollars for each litigation, its research and development operations would be significantly delayed and hindered. Thus, since CSIRO's licensing strategy went to the core of its business model, it would be irreparably harmed absent an injunction.<sup>97</sup>

Another important consideration in assessing the propriety of an injunction is whether the patented invention is only one part of a multi-component product that is accused of infringement. In Justice Kennedy's concurring opinion, he specifically postulates that an injunction may not serve the public interest where the patented invention is but a small component of the infringing product and the threat of an injunction is used to obtain exorbitant fees.<sup>98</sup> Courts also consider whether there are non-quantifiable intangible losses, such as harm to reputation and goodwill, loss of talent, price erosion, loss of market position, and loss of market opportunities.<sup>99</sup>

Thus, the case law suggests that there is a continuum of factual paradigms with the patent troll (a non-practicing entity endeavoring to extort licensing fees for profit rather than for future research and development) on one end and the path-breaking pioneer (an innovator that practices the invention and protects its right of exclusivity while making the benefits of its invention available to the public) on the other. The more closely a patentee's situation approaches that of a pioneering and practicing inventor, the more likely it is to succeed in obtaining an injunction.

### C. Importance of the Public Interest Factor

Regarding the public interest prong of the injunction inquiry, courts are directed to consider whether an injunction would “not disserve the public inter-

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<sup>95</sup>*Id.* at 443–44.

<sup>96</sup>*Commonwealth Scientific and Industrial Research Organisation v. Buffalo Tech.*, 492 F. Supp. 2d 600 (E.D. Tex. 2007).

<sup>97</sup>*Id.* at 604–05.

<sup>98</sup>*eBay, Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 396 (2006) (Kennedy, J., concurring).

<sup>99</sup>*See, e.g., Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368 (Fed. Cir. 2006) (loss of good will and potential lay-offs evidenced irreparable harm); *Purdue Pharma L.P. v. Boehringer Ingelheim GmbH*, 237 F.3d 1359, 1368 (Fed. Cir. 2001) (price erosion and loss of market position evidenced irreparable harm); *Polymer Technologies, Inc. v. Bridwell*, 103 F.3d 970, 975–76 (Fed. Cir. 1996) (loss of market opportunities was evidence of irreparable harm).

est”—not whether it would serve the public interest. This standard is consistent with the long tradition in equity practice of favoring the status quo versus a more interventionist approach, which seems appropriate since what will or will not serve the public interest is highly speculative. For example, will a new product have beneficial effects? Will it have a positive impact on the market and/or reduce costs? In the pharmaceutical industry, the availability of a new product will not necessarily drive down costs. Given the complexities of the pricing and payment for pharmaceuticals, companies are often actually incentivized to enter the market at a higher price than a competing, established product, as customers then receive a higher government reimbursement and the company’s profit margin is increased. Accordingly, unless an infringing product would fulfill an otherwise unmet medical need, the public interest likely favors promoting investments in innovation.

On the other hand, what does it mean to “not disserve the public interest”? In the biotechnology field, if there is a pre-existing public reliance on an infringing product, or if the infringer provides the only public supply or satisfies an otherwise unmet medical need, it may disserve the public to grant an injunction. But even where an infringing medical product is already on the market, a permanent injunction may still be the appropriate remedy. For example, the district court in *Smith & Nephew, Inc. v. Synthes (U.S.A.)* granted a permanent injunction enjoining Synthes from continuing to market and sell its infringing orthopedic product where other products were available and where there was not a significant public reliance on the infringing product.<sup>100</sup> Thus, the court found that disrupting the infringing product’s distribution would not negatively impact the public interest.<sup>101</sup>

Before *eBay*, courts routinely found that there was a public interest in promoting significant investments in innovation.<sup>102</sup> This principle was reinforced by a district court post-*eBay*, which granted an injunction to prevent a competing therapeutic from entering the market, stating that “[i]f America is to continue to be an engine of medical innovation it will be because we protect the right of inventors to exploit the limited monopoly granted in the Patent Clause.”<sup>103</sup> This is particularly important in the biotechnology industry, where it takes hundreds of millions of dollars and more than decade to research, develop, obtain FDA approval and bring one successful product to market, with investments in many more failed endeavors or products along the way.

#### D. Injunction Strategies

Not surprisingly, the strategies that the patentee and patent challenger may employ, whether to obtain or to preclude the award of an injunction, will vary considerably depending on whether the patentee is a practicing or a non-practicing patentee.

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<sup>100</sup>*Smith & Nephew, Inc. v. Synthes (U.S.A.)*, 466 F. Supp. 2d 978, 985 (W.D. Tenn. 2006).

<sup>101</sup>*Id.*

<sup>102</sup>*See, e.g., Patlex Corp. v. Mossinghoff*, 758 F.2d 594, 599 (Fed. Cir. 1985) (“The encouragement of investment-based risk is the fundamental purpose of the patent grant, and is based directly on the right to exclude.”); *Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1383 (Fed. Cir. 2006).

<sup>103</sup>*Amgen Inc. v. Hoffmann-La Roche Ltd.*, 581 F. Supp. 2d 160, 227 (D. Mass. 2008).

A non-practicing patentee should be prepared to demonstrate its investment in research and development, and to show that lack of an injunction would cause irreparable harm to its business model and cycle of innovation. Where the patentee does not itself practice the invention but supplies the market with other products or services, the bright line distinctions fade and courts must look at the business model as a whole when assessing irreparable harm and public interest factors.

For an alleged infringer defending against a non-practicing patentee, it is important to develop a factual record regarding public interest and the balance of hardships. In biotechnology cases, establishing that the accused product fills an unmet need (a medical need, and not merely a cosmetic one) and demonstrating a sustained, significant investment in research and development by the alleged infringer (and the lack of such investment by the patentee) augurs in favor of denying a permanent injunction.

A practicing patentee, on the other hand, should marshal evidence to demonstrate its substantial investment in research and development, its investment in the development or cultivation of the relevant market, and its reliance on exclusivity in order to demonstrate the irreparable harm it would suffer if a new entrant were permitted in the market. At the same time, a practicing patentee will want to develop arguments both to show that an injunction favors the public interest and to defend against the inevitable arguments by the patent challenger regarding the benefit to consumers, the government, and patients of allowing an alternative or competing product or method on the market.

A patent challenger defending against a practicing patentee will need to develop evidence to challenge both the irreparable harm and the public interest factors. The complexity of that challenge will differ markedly depending on whether or not the accused product or method is already on the market at the time of adjudication. Either way, patent challengers in biotechnology cases are uniquely positioned to implicate the choice, cost, and delivery of health care when developing a record on how injunctive relief will affect the public interest. In particular, a patent challenger will seek to develop evidence of unmet medical need, consumer choice, and affordability that either are or would be addressed by permitting the accused product or method on the market. Notably, a patent challenger may be better positioned to develop its public-interest arguments where it has already entered the market; the challenger may then base arguments regarding consumer reliance or choice where some segment of the market has already adopted the accused product or method. Of course, obvious downsides to a launch-at-risk strategy are willful infringement damages and the sunk cost of market launch.

## VI. EVIDENTIARY CONSIDERATIONS: EXPERIMENTAL EVIDENCE

One significant evidentiary consideration in biotechnology cases is whether a scientific experiment can be used to prove or disprove a disputed issue. For example, a patentee may conduct scientific experiments to prove whether the accused product, process, or method meets the limitations of the asserted claims. At the same time, a patent challenger may conduct experiments to prove that the prior art meets all of the limitations of the asserted claims, or that the patentee's

preferred embodiment does not fall within the scope of the claims, thus blunting the patentee's argument that the product's commercial success is evidence of nonobviousness. Assuming such an experiment is possible, determining whether to conduct the scientific work is a difficult strategic and tactical decision given the level of variability and unpredictability in the life sciences. There is no guarantee that experiments will yield the supporting evidence the commissioning party seeks. On the other hand, a fact finder could draw a negative inference where a party had the opportunity to conduct experiments with the relevant product but failed to do so.<sup>104</sup>

The strategy points set forth below are recommended best practices for developing the most reliable experimental data with the best likelihood of getting the results of such experiments admitted into evidence.

### A. The Expert's Credibility and Expertise

Before designing or executing scientific experiments, a party must decide which expert (or independent laboratory) is going to perform the experiments and whether one or more other experts will rely on those experiments in forming their own opinions. In some cases, it makes sense for the same expert both to perform the experiments and to provide an opinion based on the results, such as where the expert's qualifications and experience make him or her uniquely qualified to do so. However, there is no requirement that the expert offering opinions based on the experimental evidence have a hands-on role in conducting the experiments, and there may be important reasons to shield a testifying expert from the experiments until they are completed.<sup>105</sup> In any case, it is imperative that the expert performing or relying on the experiments have the appropriate—and hopefully impressive—credentials to do so.<sup>106</sup> Investing the time and resources required to conduct experimental testing is no small feat, and it is not worth the risk of having the resulting evidence excluded by relying on an expert whose expertise is only marginally relevant.

There are benefits in retaining two or more experts and keeping the roles distinct. First, different experts may be best qualified for different roles. For example, the principal expert (*i.e.*, the one offering ultimate opinions in the case) may need a broad background and a broad array of experiences in order to be qualified to address all the issues relevant to an ultimate legal issue in the case, such as infringement or validity. On the other hand, the expert (or independent laboratory) best qualified to conduct the experiments may need specific expertise and laboratory experience. Early attention to each expert's credentials and experience only serves to enhance the reliability and credibility of the testimony and opinions offered.

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<sup>104</sup>*Medtronic, Inc. v. Boston Scientific Corp.*, 2002 U.S. Dist. LEXIS 28355, at \*55 (D. Minn. Aug. 8, 2002) (finding experiments performed by accused infringer's expert not adequate substitutes for testing the accused product itself and noting that the accused products "were available to him from his own client and/or on the open market").

<sup>105</sup>*Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 592 (1993) ("[A]n expert is permitted wide latitude to offer opinions, including those that are not based on firsthand knowledge or observation.").

<sup>106</sup>Federal Rule of Evidence 702 requires a witness to be "qualified as an expert by knowledge, skill, experience, training, or education."

Second, keeping in mind the potentially variable and unpredictable nature of life sciences work, it may be advisable to keep the principal or testifying expert shielded from preliminary experimental work until the results of such tests are known and are determined to be reliable and relevant to the issues in the case. If this avenue is taken, however, it is critical to get the principal expert's input—by, for example, helping to design, even in the abstract, a well-controlled and reliable experiment that in the expert's view proves the relevant point, including appropriate tests to perform and protocols to follow. This early consultation avoids the risk of performing an experiment only to find that the principal expert is unwilling to rely on the results.

Third, separating the role of testifying expert from that of experiment-conductor adds another layer of quality control and objectivity to the scientific work. This may be especially true where the scientific work is done by a commercial laboratory that is in the business of performing such tests. Even though the independent laboratory is commissioned by, and profits from, the party seeking to rely on the experimental results, the scientists undertaking the work will be one step removed from the issues and disputes in the case, and will be following established protocols and quality control procedures.

## **B. Design and Execution of Experiments**

To be admitted into evidence, an expert's testimony must be "relevant to the task at hand" and rest "on a reliable foundation."<sup>107</sup> The Supreme Court in *Daubert v. Merrell Dow Pharmaceuticals, Inc.* held that when expert scientific testimony is proffered, "a preliminary assessment [must be made] of whether the reasoning or methodology underlying the testimony is scientifically valid, and whether that reasoning or methodology properly can be applied to the facts in issue."<sup>108</sup> Thus, when experimental evidence is proffered, it must be based on scientifically sound methodologies and designed to test for the specific claim limitation in dispute (for example, whether an accused product has a specific recited biological activity, or whether an accused method of treatment results in the recited biological effect).

A scientific technique or method that has been subjected to peer review and publication and generally accepted by the relevant scientific community is indicative, though not dispositive, of scientific validity.<sup>109</sup> Conversely, it is difficult to prove that a scientific technique or methodology that has been widely criticized or abandoned by the relevant scientific community is scientifically sound and valid.

As to relevancy, one should consider conducting the test or experiment set forth in the patent claim, if one is recited, or disclosed in the patent specification. It would be difficult for the opposing party to exclude results proving or disproving the existence of a characteristic where the same tests were used and described by the patentee to characterize his or her invention. While this is the recommended approach, using a different but comparable test may be sufficient—if the tests

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<sup>107</sup>*Daubert*, 509 U.S. at 584–87.

<sup>108</sup>*Id.* at 592–93.

<sup>109</sup>*Id.* at 594.

are in fact comparable.<sup>110</sup> When executing experiments used at the time of the invention and/or described in the patent specification, it is important to follow the same protocol and use the same conditions, as far as possible, that were used at the time of the invention. Furthermore, failing to follow scientific procedures and protocols ordinarily exercised by scientists in the field could be detrimental to the admissibility of an expert's testimony.<sup>111</sup>

### C. Admitting Experimental Data Into Evidence

If the experimental results are highly compelling, the opposing party will use any admissibility challenge available to keep them out of evidence and prevent them from being relied upon. For this reason, in addition to using qualified experts and following standard and well-accepted scientific methodologies, as discussed above, it is critical to make complete and timely disclosure of the experiments and results.

Federal Rule of Civil Procedure 26 requires a party seeking to offer expert testimony to disclose “(i) a complete statement of all opinions the witness will express and the basis and reasons for them; [and] (ii) the facts or data considered by the witness in forming them.”<sup>112</sup> To prepare for complete disclosure, every aspect of the scientific work—the chain of custody for all of the testing materials, the receipt and storage of materials, preparatory steps, performance of the experiments, the interpretation of test results, and quality control measures—should be documented contemporaneously with the work to ensure an accurate and complete record. Comprehensive documentation and disclosure adds to the credibility of the results because it allows the opposing party (and the court) to evaluate, scrutinize, and test the data sought to be relied upon. Furthermore, a misstep or incomplete disclosure involving any phase of the scientific work can render the experimental evidence inadmissible in its entirety.

Lastly, to safeguard against an inadmissibility ruling based on untimely production, a party should ordinarily err on the side of over-inclusiveness in disclosing the documentation related to the experiments, underlying data, and results before the deadline for expert discovery expires. However, if there is a stipulation in place protecting from disclosure draft documents or communications between counsel and the expert(s), then care should be taken *not* to produce these materials, so as not to waive the stipulated protection. Otherwise, full disclosure is the safest way to get the experimental data admitted into evidence and, at the same time, protect your credibility and that of your expert.

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<sup>110</sup>*Compare* Union Carbide Chems. & Plastics Tech. Corp. v. Shell Oil Co., 425 F.3d 1366, 1374–75 (Fed. Cir. 2005) (affirming infringement where patentee established that a limitation was met by a formula allegedly different from, but found to be comparable to, the test required by the claims), *with* Genentech, Inc. v. Wellcome Found. Ltd., 29 F.3d 1555, 1566 (Fed. Cir. 1994) (affirming noninfringement where patentee's expert offered evidence of a test different from and not comparable to the test required by the claims in order to establish that the specific activity limitation was met).

<sup>111</sup>*Medtronic, Inc. v. Boston Scientific Corp.*, 2002 U.S. Dist. LEXIS 28355, at \*55–56 (D. Minn. Aug. 8, 2002) (concluding that the expert's “failure to test or validate his hypothesis, and his apparent *departure from the level of intellectual rigor that characterizes his work in his usual professional practice*, render his proposed opinion testimony . . . inadmissible under Rule 702” (emphasis added)). Scientific procedures and protocols followed by a scientific community could include specific quality control measures such as using negative and positive controls or conducting a blind study.

<sup>112</sup>FED. R. CIV. P. 26(a)(2)(B) (2010).

