This issue of the Federal Circuit Review explores recent developments in the requirements for patentability set forth in 35 U.S.C. § 112. First, we will look at two cases where patentees secured a claim construction broad enough to cover the defendants’ products but then failed to overcome the resultant § 112 challenge. Next, we discuss a case in which the Federal Circuit clarified that the § 112 enablement requirement relates to the claimed invention, not a commercial embodiment. We will then examine another case where the Federal Circuit reviewed an enablement ruling and made clear that a priority date adjustment is not a cure for lack of enablement if not raised by the patentee at trial. Finally, we will explore a Federal Circuit decision that illustrates how claim construction principles govern the analysis in a § 112 indefiniteness challenge.

**Winning a Broad Claim Construction Leaves Claims Vulnerable to § 112 Challenges**

In *Eli Lilly & Co. v. Teva Pharmaceuticals USA, Inc.*, the Federal Circuit affirmed the district court’s ruling that, under the broad claim construction secured by Lilly, certain asserted patents were invalid for lack of written description. 2010 U.S. App. LEXIS 18236 (Fed. Cir. Sept. 1, 2010). Following Teva’s filing of an ANDA, Lilly alleged infringement of several of its patents for Evista®, a bone loss medication with raloxifene as the active ingredient. *Id.* at *1-2.* Two of Lilly’s asserted patents (the “Particle Size Patents”) claimed raloxifene compounds with a specified particle size, and taught that restricting raloxifene’s particle size to the claimed range resulted in consistent in vivo absorption, as well as manufacturing benefits. Following the district court’s initial claim construction, Teva notified Lilly that it had changed the particle size manufacturing specification of its bulk raloxifene in order to bring its proposed product outside the scope of the Particle Size Patents. *Id.* at *38.* Lilly contended, however, that altering the particle size in the bulk raloxifene merely created the illusion of non-infringement, because the “artificially” large particles fracture into smaller particles upon processing. Lilly thus alleged that Teva was liable for infringement because, even though Teva’s bulk raloxifene fell outside the asserted claims, the raloxifene particle size in Teva’s processed tablets fell within the range recited in the asserted claims. *Id.* at *39.*
Infringement thus turned on “whether the particle size patents claim only size measurements made on bulk raloxifene before it is formulated or, by contrast, whether the patents also claim the particle size of raloxifene within a formulated tablet.” *Id.* Lilly argued that the latter construction was proper, and the court agreed, concluding that the Particle Size Patents should be construed broadly to include both bulk and formulated raloxifene. The district court also found, however, that the broad claim construction rendered the Particle Size Patents invalid for failure to comply with the written description requirement of § 112. In particular, the court found that, after reading the patent, a person of ordinary skill would not understand how to extract raloxifene particles from the formulation in order to determine their size, and would have no indication that particle size measurements on anything other than the bulk raloxifene would be relevant to the invention. The court also noted that the patents did not disclose the concept of measuring the particle size of raloxifene extracted from a tablet, and provided no guidance as to how the tableting process could affect particle size. *Id.* at *39-40.

On appeal, Lilly argued that the district court, which issued its decision prior to the Federal Circuit’s en banc decision in *Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.*, erred in its application of the written description test by requiring the patents to disclose the necessary steps to determine infringement. The Federal Circuit agreed that district court’s decision “appear[ed] in some places to have been premised on a misunderstanding of the [written description] test,” and that the “test for written description . . . has never been whether the patent includes a description of the steps that may be used to prove infringement.” *Id.* at *41. Citing its en banc opinion in *Ariad*, the Court reiterated that the test for written description is “whether the disclosure of the application . . . reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date.” *Id.* (quoting *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc)).

Nevertheless, the Court found no clear error in the district’s court’s finding that a person of ordinary skill in the art would have understood the inventors only to have invented a “control strategy” for the particle size of bulk raloxifene. The panel observed that the specification only disclosed measurements of bulk raloxifene, and that Lilly’s own expert conceded that someone reading the specification at the time of filing would not know how particle size would be affected by the formulation process. Given that concession, the Court held that Lilly could not establish that the district court made a clearly erroneous factual finding, and affirmed. *Id.* at *42.

The Federal Circuit reviewed a somewhat similar fact pattern in the context of an enablement challenge in *Alza Corp. v. Andrx Pharmaceuticals, LLC*, 603 F.3d 935 (Fed. Cir. 2010). Alza sued Andrx, alleging that Andrx’s proposed product infringed Alza’s patent directed to a method for treating ADD or ADHD with an ascending release rate dosage form of methylphenidate. *Id.* at 936-37. Although there was no dispute that Alza had focused on osmotic dosage forms in developing its product, the district court rejected Andrx’s attempt to avoid infringement by limiting the scope of the asserted claim to osmotic dosage forms. *Id.* at 938. The Court, however, found that the claim was not infringed based on a different limitation related to an ascending release rate of the drug over time. Thus, the court’s determination that the asserted claim covered both osmotic and non-osmotic dosage forms ultimately proved irrelevant to the issue of infringement. Nonetheless, the broad claim construction provided a basis for Andrx’s assertion that the claim was not enabled. And although the parties agreed that osmotic dosage forms were enabled, the district court concluded that specification did “not enable the full scope of claim 1, which covers both osmotic and non-osmotic dosage forms.” *Id.* at 938.
On appeal, Alza argued that, at the time of filing, the specification would have enabled a person of ordinary skill in the art to create non-osmotic oral dosage forms with ascending release rates without undue experimentation. Alza asserted that creating non-osmotic dosage forms and manipulating their release rates were well-known to a person of ordinary skill in the art at the time of filing. Conceding that some iterative trial-and-error experimentation would be required to make an non-osmotic embodiment of the claimed invention, Alza contended that such experimentation was routine. *Id.* at 940.

The Federal Circuit disagreed. The Court noted that analysis of undue experimentation is a question of law (which the Court reviews *de novo*) based on underlying factual inquiries (which are reviewed for clear error). The Court explained that the factors set forth in *In re Wands* remain the relevant considerations for determining if practicing a claimed invention based on the disclosure required undue experimentation: 

“(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.” *Id.* (quoting *Wands*, 858 F.2d 731, 736-37 (Fed. Cir. 1988)). The Court observed that the district court had found that seven of the eight *Wands* factors supported a finding that undue experimentation would be required to enable the full scope of the claims and concluded that those factual findings were not clearly erroneous. *Id.*

The Court rejected Alza’s argument that evidence of the knowledge of a person of ordinary skill in the art should compel a finding that the claims were enabled. The panel emphasized that the Court “has repeatedly stated” that “the rule that a specification need not disclose what is well known in the art is ‘merely a rule of supplementation, not a substitute for a basic enabling disclosure.’” *Id.* at 940-41 (quoting *Auto. Tech. Int’l, Inc. v. BMW of N. Am., Inc.*, 501 F.3d 1274, 1282 (Fed. Cir. 2007)). The Court noted that the present case presented an “irony” it had seen in other cases: a patentee successfully argues for a broad construction of its claims, but then fails to defeat a challenge that such a claim scope was not enabled. *Id.* at 943.

**Cases Referenced:**

*Alza Corp. v. Andrx Pharmaceuticals, LLC*, 603 F.3d 935 (Fed. Cir. 2010)
*Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336 (Fed. Cir. 2010) (en banc)
*In re Wands*, 858 F.2d 731 (Fed. Cir. 1988)

**Distinguishing Commercial Embodiments From the Invention in an Enablement Challenge**

The Federal Circuit reviewed another enablement ruling in *Transocean Offshore Deepwater Drilling, Inc. v. Maersk Contractors USA, Inc.*, 617 F.3d 1296 (Fed. Cir. 2010). Transocean brought suit against Maersk alleging infringement of three patents directed to an improved apparatus for offshore drilling. The patents, which shared a common specification, claimed an oil drilling derrick with two drilling stations, a primary advancing station and an auxiliary advancing station. Because the auxiliary station can prepare lengths of drill string in advance, the main drilling station is freed from the time-consuming task of having to connect every joint in the drill string. Maersk argued that certain claim elements, the “assembly . . . operable
to transfer tubular assemblies” and “means . . . for transfer rig tubular assemblies” were not enabled. The district court agreed, relying on evidence of Transocean’s difficulty in building the first commercial embodiment. The district court concluded that the failure of the specification to include the “programming” of the transport mechanism and modifications required to use prior art transfer mechanisms failed to provide sufficient information for a person of ordinary skill in the art to take advantage of the timesaving aspect of the invention. *Id.* at 1306.

On appeal, Transocean argued that the district court erred because there were genuine issues of material fact regarding undue experimentation. Transocean first contended that methods for transferring pipe strings between derricks, including rail-mounted transport, were well-known at the time the relevant applications were filed. In addition, Transocean argued that the district court erred by requiring it to enable a commercial embodiment rather than the claimed invention.

The Federal Circuit agreed that factual issues regarding undue experimentation precluded summary judgment on the issue of enablement. The Court noted that a “patent specification only must enable one of ordinary skill in the art ‘to practice the claimed invention without undue experimentation,’” and that, unless explicitly claimed, it need not enable the “most optimized configuration.” *Id.* at 1307 (quoting *Nat’l Recovery Techs., Inc. v. Magnetic Separation Sys., Inc.*., 166 F.3d 1190, 1196 (Fed. Cir. 1999)). The Court thus held the district court in error for requiring Transocean to enable one of ordinary skill to exploit the “timesaving” aspect of the invention. In other words, the district court had required Transocean “to enable the most efficient commercial embodiment, rather than the claims.” The Federal Circuit also objected to the district court’s finding that there were no genuine issues of material fact regarding undue experimentation, noting that the specification disclosed two different pipe transfer mechanisms: a conventional crane, and a rail-mounted system. The Court found that the evidence presented by both parties raised material factual issues as to whether the development of transfer equipment required to operate the invention would be trivial. The Court thus reversed the district court’s grant of summary judgment. *Id.*

**Cases Referenced:**

*Transocean Offshore Deepwater Drilling, Inc. v. Maersk Contractors USA, Inc.*, 617 F.3d 1296 (Fed. Cir. 2010)

*Nat’l Recovery Techs., Inc. v. Magnetic Separation Sys., Inc.*, 166 F.3d 1190 (Fed. Cir. 1999)

**Priority Date Waiver as a Defense to § 112 Violations Must Be Made at Trial**

In *Ajinomoto Co. v. Intl. Trade Commission*, the Federal Circuit declined Ajinomoto’s invitation to reverse an invalidity ruling for a best mode violation through a priority date adjustment. 597 F.3d 1267 (Fed. Cir. 2010). Ajinomoto filed a complaint with the ITC, alleging § 337 violations by several Chinese companies. Ajinomoto claimed that the respondents were importing L-lysine made through its patented process. The asserted patents related to methods for producing L-lysine by cultivating E. coli bacteria that have been genetically engineered to produce greater quantities of L-lysine than naturally occurring strains. Evidence at trial, however, established that the actual strain used by the inventors to produce L-lysine had two additional genetic alterations. Those alterations were only disclosed in one of the two asserted patents and were not revealed in the Japanese application to which both claimed priority. The Administrative Law Judge (“ALJ”)
ruled that by concealing their host strain, the inventors violated the best mode requirement, and held both patents invalid.1 Id. at 1271-72. Ajinomoto petitioned the full Commission for review, but the Commission declined to overturn the ALJ’s rulings.

In its subsequent appeal, Ajinomoto argued that the ALJ improperly applied the best mode requirement to non-innovative aspects of the invention. Ajinomoto also argued that, with respect to its patent that did disclose the preferred host strain, the proper remedy was a forfeiture of its priority date, not invalidation. According to Ajinomoto, the patent should still be entitled to the priority date from a PCT application, filed a year after the Japanese application. Id. at 1273.

The Federal Circuit explained that the best mode requirement comprises a quid pro quo of the patent grant, prohibiting inventors from receiving the benefit of the right to exclude if they have concealed preferred embodiments of the inventions from the public. Id. at 1272 (citing Teleflex, Inc. v. Ficosa N. Am. Corp., 299 F.3d 1313, 1330 (Fed. Cir. 2002)). Although compliance with best mode is a question of fact, which the Court reviews for clear error, the scope of the invention to which the best mode applies is a question of law, which the Court reviews de novo. The Court stated that the best mode requirement requires an inventor to “disclose the preferred embodiment of his invention as well as preferences that materially affect the properties of the invention.” Id. (citing Bayer AG v. Schein Pharms., Inc., 301 F.3d 1306, 1312, 1320 (Fed. Cir. 2002)).

Addressing Ajinomoto’s arguments, the Court clarified that the best mode requirement is not limited to “innovative aspects” or “inventive features” of the invention and held that Ajinomoto was required to disclose its preferred host strain. Id. at 1274. The panel rejected Ajinomoto’s argument that because its right to exclude only extended to the claimed genetic modifications, it was not required to disclose the unclaimed modifications of its preferred strain. The Court pointed out that “[i]nfringement requires all claim limitations to be present, not just those that distinguish the claim from the prior art.” Id. at 1274-75. Similarly, the best mode requirement applies to all claim limitations, not just the novel ones. Because cultivating a host strain was a claimed limitation, Ajinomoto’s preference for cultivating a particular bacterium constituted a best mode of carrying out the invention and Ajinomoto was required under § 112 to disclose it. Id. at 1275.

The Court also rejected Ajinomoto’s arguments relating to the consequences of the best mode violation. The panel held that the Commission did not abuse its discretion in concluding that Ajinomoto waived its right to rely on its PCT application by failing to comply with the ALJ’s stated ground rules and raise the matter in its pretrial brief. Id. at 1277. Ajinomoto argued that it did not waive its right to assert an alternative priority date because the respondent, not Ajinomoto, had the burden of proof in challenging Ajinomoto’s effective filing date. The Court noted, however, that the asserted patent on its face claimed priority from the Japanese application, and that Ajinomoto had relied on that priority date during the ITC investigation. Id. The panel called Ajinomoto’s attempt to raise the issue of an alternative priority date for the first time during the appeal a “bait-and-switch tactic.” The Court observed that Ajinomoto’s reliance on the earlier priority date precluded the respondents from offering prior art published after the Japanese application was filed. Anjimoto’s assertion of the Japanese priority date also denied respondents an

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1 The ALJ also found that the patents were unenforceable for inequitable conduct due to this intentional act.
opportunity to attack the PCT application’s compliance with the best mode requirement. Acknowledging a patentee’s right to rely on an earlier priority date to overcome intervening prior art, and its right to argue for a different priority date at trial, the Court held that patentee cannot, as Ajinomoto had attempted, “reverse a finding of invalidity by unveiling after trial an alternative priority date on which it would now like to rely.” *Id.*

**Cases Referenced:**

Ajinomoto Co. v. Intl. Trade Commission, 597 F.3d 1267 (Fed. Cir. 2010)

Bayer AG v. Schein Pharms., Inc., 301 F.3d 1306 (Fed. Cir. 2002)


**Claim Construction Principles are Crucial in Resolving an Indefiniteness Challenge**

In *Enzo Biochem, Inc. v. Applaera Corp.*, the Federal Circuit reversed a district court’s summary judgment ruling that Enzo’s asserted claims were invalid as indefinite, and demonstrated how claim construction principles may frame an indefiniteness analysis. 599 F.3d 1325 (Fed. Cir. 2010). Enzo’s patents were directed generally to techniques for labeling and detecting nucleic acids, such as DNA and RNA. The patents purported to address known problems with prior art methods by utilizing certain non-radioactive labels as detection probes. *Id.* at 1328. The claims at issue recited a compound, or a method of using that compound as a detection probe, where a nitrogenous base is covalently attached through a “linkage group” to a chemical moiety. The claims did not include a structure for the linkage group, but instead recited the functional requirement of “not interfering substantially” with hybridization. 2 *Id.* at 1329. Applaera argued that because even a minor alteration to a single nucleotide can have profound effects on the ability of a DNA strand to hybridize, the examples in the specification were insufficient. According to Applaera, identical linkage groups could cause interference in some nucleic acid strands but not in others. Applaera argued that the lack of guidance regarding the degree of acceptable interference with hybridization rendered the claims indefinite. The district court agreed and granted Applaera’s motion for summary judgment, ruling that the claims were indefinite because the specification did not teach how to gauge what constituted substantial interference. The district court also ruled that, in the alternative, the claims were anticipated, noting that its ruling on indefiniteness didn’t affect its anticipation analysis. *Id.* at 1331.

The Federal Circuit began its analysis by noting that a “claim cannot be both indefinite and anticipated.” *Id.* at 1332. Because an anticipation analysis requires, as a first step, construing the challenged claim and, by definition, an indefinite claim cannot be adequately construed, it is not possible to perform an anticipation analysis on an indefinite claim. *Id.* (citing Honeywell Int’l, Inc. v. Int’l Trade Comm’n, 341 F.3d 1332, 1342 (Fed. Cir. 2003)).

Turning to the indefiniteness issue, the Court agreed with Enzo that the claims were not indefinite. The Court explained that indefiniteness “requires a determination of whether those skilled in the art would understand what is claimed,” and, to make that determination, “general principles of claim construction apply.” *Id.* (quoting Young v. Lumenis, Inc., 492 F.3d 1336, 1344 (Fed. Cir. 2007)). The analysis, therefore, involves consideration primarily of the intrinsic evidence: the claim language, the specification, and the

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2 The claims also required no substantial interference with detection.
prosecution history. The panel further noted that when the claim includes a “word of degree,” the claim is indefinite if the patent provides no standard for measuring that degree. *Id.* (citing *Seattle Box Co., Inc. v. Indus. Crating & Packing, Inc.*, 731 F.2d 818, 826 (Fed. Cir. 1984)). In addition, when claim limitations are defined in “purely functional terms,” the determination of whether the limitation is sufficiently definite is “highly dependent on context.” *Id.* (quoting *Halliburton Energy Servs., Inc. v. M-I LLC*, 514 F.3d 1244, 1255 (Fed. Cir. 2008)).

The Court noted that the term “hybridization,” as understood by the district court, had a definite meaning: “the binding of two separate, complementary strands of nucleic acids to form nucleic acid hybrids.” The ambiguity underlying the district court’s ruling on indefiniteness was whether a person of ordinary skill would understand when a linkage group interferes with hybridization “substantially.” The panel held that the term “substantially,” which can denote either language of approximation or language of magnitude, was used in the claims to denote magnitude—how much interference can occur during hybridization. *Id.* at 1333.

The Court first looked to the claims, concluding that certain dependent claims that recited linkage group structures provided “at least some guidance as to how much interference will be tolerated,” because a person of ordinary skill would presume that a structure recited in a dependent claim “will perform a function required of that structure in an independent claim.” *Id.* at 1334 (citing *AK Steel Corp. v. Sollac & Ugine*, 344 F.3d 1234, 1242 (Fed. Cir. 2003)). The Court thus concluded that the term “not interfering substantially” in the independent claims allowed at least the level of interference exhibited by the structures recited in the dependent claims. The Court also noted that additional examples of suitable linkage groups were provided in the specification. Moreover, the specification taught that thermal denaturation profiles and hybridization profiles could be used to measure the degree to which a linkage group interferes with hybridization. In addition, the Court found the prosecution history helpful because the applicants overcame an indefiniteness rejection related to the “not interfering substantially” language by submitting a declaration listing eight specific linkage groups that did not substantially interfere with hybridization. *Id.* at 1335.

The Court concluded that “[b]ecause the evidence here provides ‘a general guideline and examples sufficient to enable a person of ordinary skill in the art to determine [the scope of the claims],’ the claims are not indefinite even though the construction of the term ‘not interfering substantially’ defines the term without reference to a precise numerical measurement.” *Id.* The Court held that, contrary to Applera’s argument, the fact that the binding strength of DNA strands may vary based on length and sequence doesn’t mean that the choice of a linkage group is purely subjective or unrestrained. In the Court’s view, one of ordinary skill could use the denaturation profiles disclosed in the specification to compare hybridization interference with the examples in the specification to determine if a chosen linkage group substantially interfered with hybridization. The Court thus reversed the district court’s ruling that the claims were indefinite. *Id.* at 1335-36.

**Cases Referenced:**

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

*Enzo Biochem, Inc. v. Applera Corp.*, 599 F.3d 1325 (Fed. Cir. 2010)

*Halliburton Energy Servs., Inc. v. M-I LLC*, 514 F.3d 1244 (Fed. Cir. 2008)


*Seattle Box Co., Inc. v. Indus. Crating & Packing, Inc.*, 731 F.2d 818 (Fed. Cir. 1984)

*Young v. Lumenis, Inc.*, 492 F.3d 1336 (Fed. Cir. 2007)
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