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This issue of the *Federal Circuit Review* will discuss recent decisions of the Federal Circuit concerning the patent specification requirements of 35 U.S.C. § 112. First, we will review decisions involving the written description requirement for claims that are directed to genus of compounds, that contain a negative limitation, or that are directed to just one of two solutions presented together in the specification. Next, we discuss the enablement requirement in the context of claims reciting an open-ended range limitation. We will review a case concerning the heightened disclosure requirements for means-plus-function claims implemented using a special-purpose computer. Finally, we note recent amendments affecting the format of Section 112 and eliminating failure to disclose a best mode as grounds for invalidity.

WRITTEN DESCRIPTION

Section 112 requires that the specification contain a written description of the invention. An adequate written description “reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date.” *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc). Recent cases highlight the written description requirement in the context of claims directed to a genus of compounds, and for claims having a negative limitation. A further case discusses a validity challenge in which the specification disclosed employing two solutions at the same time to solve related problems, but claims covered employing just one solution.

DISCLOSING A GENUS OF COMPOUNDS

“[A] sufficient description of a genus requires the disclosure of either a representative number of species falling within the scope of the genus or structural features common to the members of the genus so that one of skill in the art can ‘visualize or recognize’ the members of the genus.” *Ariad*, 598 F.3d at 1350. However, there is no bright-line rule governing how many species, and how much detail, is necessary, as this differs depending on the invention and the state of the art. *See id.*

In *Boston Scientific Corp. v. Johnson & Johnson*, 647 F.3d 1353 (Fed. Cir. 2011), the Federal Circuit affirmed the judgment of the district court that claims directed to a compound and certain analogs defined and described primarily with respect to their function, rather than their structural characteristics, were insufficiently described. The case concerned patents directed to coronary stents containing drugs for the prevention of restenosis, or a narrowing in the arteries. One family of patents, dating from 1997 (the “1997 patents”), claimed stents utilizing rapamycin or a macrocyclic lactone analog thereof. *Id.* at 1358. The shared specification of the 1997 patents did not disclose any particular drug ingredients or coatings. It noted that rapamycin was of particular interest due to its known effect of inhibiting inflammation due to stent implantation, but also that the precise mechanism of rapamycin was still under investigation and that an ideal agent had not yet been identified. *Id.*

A further patent (the “’662 patent”) claimed stents utilizing rapamycin or a macrocyclic triene analog thereof, but provided only a brief and general discussion of rapamycin analogs as a whole. *Id.* at 1359. Notably, the ‘macrocyclic lactone analog’ and ‘macrocyclic triene analog’ claim limitations did not appear in the original patent applications, but were added during prosecution after a competitor obtained European approval to sell a stent containing everolimus, a macrocyclic lactone and triene analog of rapamycin. *Id.* at 1358–59.

In the district court, the declaratory-judgment plaintiff asserted that the 1997 patents and the ‘662 patent were invalid for lack of written description and lack of enablement. The patentees countered with evidence that the structure and mechanisms of rapamycin analogs were known in the art and that one of ordinary skill would understand that the claimed analogs must have the particular function of inhibiting cell-cycle progression. Nonetheless, the district court found that the shared specification of the 1997 patents failed to provide any definitions, examples, or other criteria for determining whether a compound was a claimed analog without testing its properties. *Id.* at 1360. It concluded that a functional description of a genus of analogs did not serve to adequately describe the analogs themselves to one of ordinary skill. *Id.* at 1360. As for the ‘662 patent, the district court found that the specification explicitly disclosed the function of macrocyclic triene analogs, but again left one of ordinary skill to “guess and check” which analogs could potentially work. *Id.* at 1360–61. The district court granted summary judgment of invalidity for lack of written description without reaching the question of enablement.

In affirming the district court, a panel of the Federal Circuit found that the 1997 patent specification disclosures demonstrated possession of a stent containing rapamycin, but not the genus of analogs claimed. *See id.* at 1364. It noted that the 1997 patent specification contained “virtually no information” regarding the claimed macrocyclic lactone analogs, no examples using these analogs, and no guidance on how to properly determine whether a compound was in fact a macrocyclic lactone analog aside from it being ‘structurally similar’ to rapamycin. *Id.* The panel observed that rapamycin was a complex molecule containing over a hundred different atoms, and that the universe of structurally similar compounds was potentially limitless. Although “functional claim language can meet the written description requirement if there is an established correlation between structure and function,” the

Federal Circuit concluded that the patentees had not shown that such a correlation was disclosed in the specification or otherwise known in the art. *Id.* at 1366–67. The Federal Circuit gave little weight to the patentees’ disputed assertion that analogs were well understood in the art. It appeared that at most a small number of analogs were known, yet the claims covered all analogs, and the specification provided no guidance for identifying those that would work in the invention. *Id.* at 1365.

The Federal Circuit affirmed the district court’s finding of inadequate written description as to the ’662 patent as well. It reasoned that while the specification disclosed the genus of rapamycin analogs, the specification did not describe the sub-genus of macrocyclic triene analogs. Again, the state of the art was not so advanced that functional descriptions sufficed to describe sub-genus. *See id.* at 1367–68.

Judge Gajarsa, while concurring in the judgment, wrote separately to express concern that the panel had blurred the lines between the written description requirement and enablement, a distinct Section 112 requirement discussed in the next section. In Judge Gajarsa’s view, the record concerning the 1997 patents was sufficient to affirm the judgment on enablement grounds, although the district court had not formally reached this question. *Id.* at 1369–70 (Gajarsa, J., concurring in part). He noted that the enablement analysis was simpler and avoided factual complexities that led the panel majority to “further extend[] the written description requirement into the realm of enablement.” *Id.*

#### SUPPORTING A NEGATIVE LIMITATION BY DISCLOSING A REASON TO EXCLUDE

Claims may include negative limitations, which specifically exclude subject matter, such as certain steps or ingredients, from the scope of the claim. The panel decision in *Santarus, Inc. v. Par Pharma., Inc.*, 694 F.3d 1344 (Fed. Cir. 2012) (per curiam) clarifies that the written description requirement may be satisfied with respect to a negative limitation when the specification discloses a reason to exclude the particular subject matter from coverage. However, a partial concurrence by Judge Newman calls into question whether a reason to exclude is necessary to support a negative limitation.

The patent-in-suit was directed to a method for treating a gastrointestinal disorder by administering an omeprazole pharmaceutical composition lacking sucralfate, among other limitations. *Id.* at 1350. The specification disclosed that no-sucralfate compositions were preferable to compositions having sucralfate, and incorporated by reference a parent patent that disclosed disadvantages of sucralfate. *Id.* The defendant argued that these teachings did not satisfy the written description requirement with respect to the no-sucralfate limitation. Plaintiffs maintained that one of ordinary skill in the field would have known the properties and effects of sucralfate, and would have understood that disadvantages of sucralfate could be avoided by using the claimed formulation. *Id.* at 1350–51.

Reversing the district court, a panel of the Federal Circuit agreed with plaintiffs that the specification disclosures were sufficient. According to the panel, “[n]egative claim limitations are adequately supported when the specification describes a reason to exclude the relevant limitation. Such written description support need not rise to the level of disclaimer . . . .” *Id.* at 1351. The no-sucralfate limitation was “adequately supported by statements in the specification expressly listing the disadvantages of using sucralfate.” *Id.*

Concurring in this result, Judge Newman wrote separately to address what she viewed as a new and inappropriate test for negative limitations. According to Judge Newman, “[n]egative claim limitations may often be appropriately stated in claims although the reason for the limitation is not set forth in the specification.” *Id.* at 1358–59 (Newman, J., concurring in part, dissenting in part). She observed that a negative limitation may arise during prosecution to distinguish prior art or otherwise respond to an examiner’s rejection. In any event, Judge Newman noted, the patent-in-suit did disclose a reason to exclude sucralfate, so there was no need for the court to decide whether Section 112 required such a reason. Judge Newman expressed concern that the panel majority had unexpectedly created new and potentially far-reaching grounds for invalidity without considering the implications. *See id.* at 1359.

## DISCLOSING TWO CONCURRENT SOLUTIONS FOR SOLVING RELATED PROBLEMS, BUT CLAIMING JUST ONE SOLUTION

A patent may disclose multiple solutions for addressing problems in the art without claiming every solution as the invention. However, written description issues may arise when claims cover just one solution if that solution is not disclosed independently from the others. It may be argued that claims covering solution A with or without solution B are broader than, and not described by, disclosures of solution A only together with solution B.

Following the trajectory of *Revolution Eyewear, Inc. v. Aspex Eyewear, Inc.* 563 F.3d 1358 (Fed. Cir. 2009), the Federal Circuit’s decision in *Crown Packaging Tech., Inc. v. Ball Metal Beverage Container Corp.*, 635 F.3d 1373 (Fed. Cir. 2011) highlights the difficulties of challenging a claim’s validity on these grounds.

The patents at issue in *Crown Packaging* shared a common specification and related to an improved beverage can lid and method for attaching it to the cylindrical can body. Compared to the prior art (shown in Figure 2 below), the patents disclosed two improvements (shown in Figure 5 below): (1) reducing the size of the reinforcing groove, or ‘bead’, included in the lid for structural support (compare Figure 2, no. 15, with Figure 5, no. 25); and (2) created a more gradual slope in the lid between the bead and the lid edge (compare Figure 2, no. 14, with Figure 5, around no. 24). *See id.* at 1375–77.

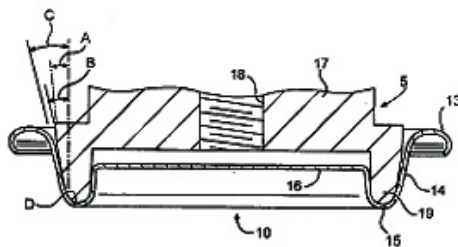


Fig. 2  
Prior Art

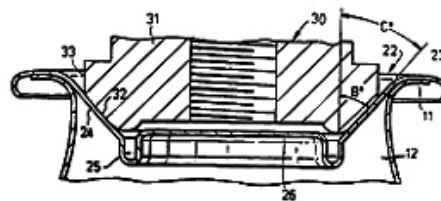
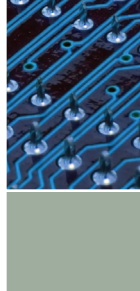


Fig. 5  
The Invention

Each of these improvements had the benefit of reducing the amount of metal needed to form the lid. *See id.* However, a narrower bead had the drawback of being more prone to damage during the process of attaching the lid. This process involved holding the lid in place with a chuck (hashed elements 17 and 30 above) and deforming it to form a tight seam with the can body. To address this concern, the specification disclosed using a chuck that held the lid without driving deeply into the bead. *Id.* at 1377.



However, certain claims were broad enough to cover adjusting the lid slope whether or not the chuck was driven inside or outside the bead. *Id.* at 1377, 1379. The defendant asserted that the specification only disclosed adjusting the lid slope while driving the chuck outside the bead; accordingly, claims that covered driving the chuck inside the bead were invalid for lack of written description. The district court agreed and granted summary judgment of invalidity. *See id.* at 1378–79.

In an opinion authored by Judge Whyte of the Northern District of California, sitting by designation, a panel of the Federal Circuit reversed. According to the panel, “the critical question is whether the specification, including the original claim language, demonstrates that the applicants had possession of an embodiment that improved metal usage by increasing the slope of the chuck wall [which determined the slope of the lid] without also limiting the width of the reinforcing bead.” *Id.* at 1380. The panel viewed the specification as teaching “two independent ways to save metal,” and that limiting the chuck to driving outside the bead came into play only when the bead was narrowed. *Id.* at 1381. Citing its decision in *Revolution Eyewear*, the panel noted: “[I]t is ‘a false premise that if the problems addressed by the invention are related, then a claim addressing only one of the problems is invalid for lack of sufficient written description.’” *Id.* (quoting 563 F.3d 1358 (Fed. Cir. 2009)).

While allowing that there may be instances in which a patent discloses that two problems must be solved simultaneously, the panel rejected the plaintiff’s argument that the problems of metal usage and risk of damaging the narrow bead must necessarily be solved together. Notably, the specification taught that metal savings could be achieved simply by adjusting the chuck wall angle, and the limitations that there be no driving contact between the chuck and the bead surface was added only to certain claims during prosecution. *Id.* Thus, the specification did not teach that adjusting the chuck wall angle and driving the chuck outside the bead must always occur together. *Id.*

Judge Dyk dissented from this holding. According to Judge Dyk, the written description requirement was not satisfied for claims that covered gradually sloping chuck sides in combination with a prior-art bead because the specification did not disclose this precise combination. *Id.* at 1385 (Dyke, J., concurring in part and dissenting in part).

### **Cases Referenced**

*Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336 (Fed. Cir. 2010) (en banc)

*Boston Scientific Corp. v. Johnson & Johnson*, 647 F.3d 1353 (Fed. Cir. 2011)

*Crown Packaging Tech., Inc. v. Ball Metal Beverage Container Corp.*, 635 F.3d 1373 (Fed. Cir. 2011)

*Revolution Eyewear, Inc. v. Aspex Eyewear, Inc.*, 563 F.3d 1358 (Fed. Cir. 2009)

*Santarus, Inc. v. Par Pharma., Inc.*, 694 F.3d 1344 (Fed. Cir. 2012) (per curiam)

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## ENABLING THE FULL SCOPE OF CLAIMS RECITING AN OPEN-ENDED RANGE

In addition to describing the invention, the specification must enable one of ordinary skill to make and use the full scope of the claimed invention without undue experimentation. The enablement requirement “prevents both inadequate disclosure of an invention and overbroad claiming that might otherwise attempt to cover more than was actually invented.” *Magsil Corp. v. Hitachi Global Storage Techs., Inc.*, 687 F.3d 1377, 1381 (Fed. Cir. 2012).

The patent at issue in *Magsil* was directed to a tunnel junction employed in a sensor for a computer hard drive. The claims included a limitation that “applying a small magnitude of electromagnetic energy to the junction . . . causes a change in the resistance by at least 10% at room temperature.” *Id.* at 1379, 1381. The plaintiff in the court below advocated a broad construction of this limitation covering changes in resistance of 100% or even 1,000%. Indeed, changes of this magnitude were eventually achieved by researchers years after the patent was filed. However, the specification disclosed that at the time, the inventors achieved only an 11.8% change. *Id.* at 1381–82. The defendant presented evidence that one skilled in the art could not have taken this disclosure and achieved changes of 100% or 1,000% without undue experimentation. On this basis, the district court granted summary judgment of invalidity for lack of enablement. *Id.*

The Federal Circuit affirmed, reiterating that “[t]he specification must contain sufficient disclosure to enable an ordinarily skilled artisan to make and use the entire scope of the claimed invention at the time of filing.” *Id.* While the “field of art has advanced vastly after the filing of the claimed invention . . . [t]he specification containing these broad claims . . . does not contain sufficient disclosure to present even a remote possibility that an ordinarily skilled artisan could have achieved the modern dimensions of this art.” *Id.* As to the policy underlying the enablement requirement, the Federal Circuit noted that the “doctrine’s prevention of over broad claims ensures that the patent system preserves necessary incentives for follow-on or improvement inventions. . . . Enablement operates to ensure fulsome protection and thus ‘enable’ these upcoming advances.” *Id.* at 1384.

### Cases Referenced

*Magsil Corp. v. Hitachi Global Storage Techs., Inc.*, 687 F.3d 1377 (Fed. Cir. 2012)

## SPECIAL PURPOSE COMPUTER-IMPLEMENTED MEANS-PLUS-FUNCTION LIMITATIONS REQUIRE DISCLOSURE OF AN ALGORITHM

Section 112 requires that the specification “conclude with one or more claims particularly pointing out and distinctly claiming the subject matter” of the invention—the so-called ‘definiteness’ requirement. The recent case of *Noah Systems, Inc. v. Intuit Inc.*, 675 F.3d 1302 (Fed. Cir. 2012), highlights the boundaries of this requirement as to means-plus-function claim limitation implemented by a computer.



The patent-in-suit was directed to an accounting system and method. Among other limitations, the asserted system claims required:

means for providing access to [a] file of [a] financial accounting computer for [a] first entity and/or agents of said first entity so that said first entity and/or said agent can perform one or more activities selected from the group consisting of entering, deleting, reviewing, adjusting and processing . . . data inputs.

*Id.* at 1305–07 (emphasis added). There was no dispute that this constituted a means-plus-function limitation, and therefore should “be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.” § 112 ¶6. Nonetheless, the parties did not agree on what structure the specification disclosed for performing the function. *Noah*, 675 F.3d at 1307. The plaintiff asserted that the corresponding structure was a financial accounting computer programmed to allow access to files upon entry of a passcode. However, the defendant argued that the specification did not disclose an algorithm by which the computer was programmed to perform this function, and thus did not disclose sufficient structure. The district court agreed that the specification was required to, but did not, disclose an algorithm, and entered summary judgment of invalidity. *Id.* at 1309.

The Federal Circuit affirmed, albeit on more nuanced grounds than did the district court. The Federal Circuit began its analysis by addressing the interplay between the definiteness requirement and means-plus-function provisions of Section 112:

Even if the specification discloses a ‘corresponding structure’ [to the function recited in the claims], the disclosure must be adequate; the patent’s specification must provide ‘an adequate disclosure showing what is meant by that [claim language]. If an applicant fails to set forth an adequate disclosure, the applicant has in effect failed to particularly point out and distinctly claim the invention as required by the second paragraph of section 112.

*Id.* at 1311–12 (quoting *In re Donaldson Co.*, 16 F.3d 1189, 1195 (Fed. Cir. 1994) (en banc)). When the function is something that any general purpose computer can perform—e.g., “processing,” “receiving,” or “storing”—disclosure of a general purpose computer may suffice. See *In re Katz*, 639 F.3d 1303, 1316 (Fed. Cir. 2011). But if a function entails particular programming, the specification must “disclose an algorithm for performing the claimed function.” *Id.* at 1312 (citing *Aristocrat Techs. Austl. Pty Ltd. v. Int’l Game Tech.*, 521 F.3d 1328, 1333 (Fed. Cir. 2008) and *Net MoneyIn, Inc. v. VeriSign, Inc.*, 542 F.3d 1359, 1367 (Fed. Cir. 2008)). “When the specification discloses some algorithm . . . the question is whether the disclosed algorithm, from the viewpoint of a person of ordinary skill, is sufficient to define the structure and make the bounds of the claim understandable.” *Id.* at 1313.

According to the Federal Circuit, the specification did disclose an algorithm for the claimed function of “providing access,” namely, providing authorized agents with passcodes and verifying a passcode before permitting an agent to enter, delete, review, adjust, or process data inputs. *Id.* at 1313. An algorithm may be expressed “in any understandable terms including as a mathematical formula, in prose, or as a flow chart, or in any other manner that provides sufficient structure.” *Id.* at 1312 (quoting *Finisar Corp. v. DirecTV Grp., Inc.*, 523 F.3d 1323, 1340 (Fed. Cir. 2008)). The procedure disclosed in the patent was sufficient to provide structure for at least the function of providing access to a file. *Id.* at 1314.

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However, this did not end the analysis. The claims also required that once access was provided, the system had to enable the performance of the “one or more activities” also recited in the claim. *Id.* The specification did not provide an algorithm for accomplishing these “specialized functions.” The specification did suggest employing “off-the-shelf accounting software” known to persons of skill in the art, but this non-specific disclosure failed to place meaningful limits on the scope of the invention. “[T]he disclosure must identify the method for performing the function, whether or not a skilled artisan might otherwise be able to glean such a method from other sources or form his own understanding.” *Id.* at 1314–15 (emphasis in original).

The Federal Circuit treated the disclosure of an algorithm supporting some, but not all, of the functions associated with the means-plus-function limitation “as if no algorithm has been disclosed at all.” According to the Court, to do otherwise would permit purely functional claiming with no perceivable bounds. *Id.* at 1318.

### Cases Referenced

*Aristocrat Techs. Austl. Pty Ltd. v. Int’l Game Tech.*, 521 F.3d 1328 (Fed. Cir. 2008)

*Finisar Corp. v. DirecTV Grp., Inc.*, 523 F.3d 1323 (Fed. Cir. 2008)

*In re Donaldson Co.*, 16 F.3d 1189 (Fed. Cir. 1994) (en banc)

*In re Katz*, 639 F.3d 1303 (Fed. Cir. 2011)

*Net MoneyIn, Inc. v. VeriSign, Inc.*, 542 F.3d 1359 (Fed. Cir. 2008)

*Noah Systems, Inc. v. Intuit Inc.*, 675 F.3d 1302 (Fed. Cir. 2012)

## AMENDMENTS TO SECTION 112 UNDER THE AMERICA INVENTS ACT

On September 16, 2011, the Leahy-Smith America Invents Act was enacted into law. The Act impacts nearly every aspect of the patent laws, including Section 112.

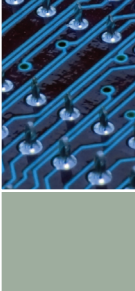
### SECTION 112’S NEW FORMAT

The Leahy-Smith America Invents Act of 2011 made minor amendments to Section 112 that apply to all patent applications filed on or after September 16, 2012. These amendments to Section 112 are shown below:

(a) In General.— The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.

(b) Conclusion.— The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention inventor or a joint inventor regards as the invention.





(c) Form.— A claim may be written in independent or, if the nature of the case admits, in dependent or multiple dependent form.

(d) Reference in Dependent Forms.— Subject to the following paragraph subsection (e), a claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed. A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers.

(e) Reference in Multiple Dependent Form.— A claim in multiple dependent form shall contain a reference, in the alternative only, to more than one claim previously set forth and then specify a further limitation of the subject matter claimed. A multiple dependent claim shall not serve as a basis for any other multiple dependent claim. A multiple dependent claim shall be construed to incorporate by reference all the limitations of the particular claim in relation to which it is being considered.

(f) Element in Claim for a Combination.— An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

The addition of subsection headings in particular will likely put an end to the common practice of referring to Section 112 requirements by paragraph number—for example, 112 ¶1 for written description and enablement, and 112 ¶6 for means-plus-function limitations.

#### ELIMINATION OF BEST MODE AS GROUNDS FOR INVALIDITY

The America Invents Act also eliminates best mode as a requirement outside of prosecution. Section 112 continues to require that a patent specification “set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.” However, a failure to disclose a best mode may no longer be raised as an invalidity claim or defense. Effective September 16, 2011, Section 282 of the Patent Act as amended provides that in an action involving validity or infringement of a patent, “the failure to disclose the best mode shall not be a basis on which any claim of a patent may be canceled or held invalid or otherwise unenforceable.”

Disclosure of a best mode remains a formal requirement for patent applications, and thus may serve as grounds for rejection by the Patent Office. However, post-grant review may not be obtained on grounds that a best mode was not disclosed.

#### References

Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011)





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