

[Antares Pharma, Inc. v. Medac Pharma Inc.](#)

United States Court of Appeals for the Federal Circuit

November 17, 2014, Decided

2014-1648

Reporter

771 F.3d 1354 *; 2014 U.S. App. LEXIS 21737 **; 112 U.S.P.Q.2D (BNA) 1865 ***

ANTARES PHARMA, INC., Plaintiff-Appellant, v.
MEDAC PHARMA INC. AND MEDAC GMBH,
Defendants-Appellees.

Prior History: [****1**] Appeal from the United States District Court for the District of Delaware in No. 1:14-cv-00270-SLR, Judge Sue L. Robinson.

Patent Law > US Patent & Trademark Office Proceedings > **Reissue** Proceedings > Broadening Reissues & Recapture

[Antares Pharma, Inc. v. Medac Pharma, Inc., 2014 U.S. Dist. LEXIS 93526 \(D. Del., July 10, 2014\)](#)

Disposition: AFFIRMED.

[HN1](#) Broadening Reissues & Recapture

[35 U.S.C.S. § 251](#) allows a patent holder to correct an existing, issued patent by broadening or narrowing the originally issued claims. If the claims sought on **reissue** are broader than the original claims, the patentee must apply for the **reissue** within two years of the patent issuing.

Core Terms

reissue, invention, patent, original patent, specification, Chemicals, jet, injectors, injection, patentee, invalid, recapture, disclose, original specification, safety feature, applicants, needle, cases, preliminary injunction, original claim, Medac, infringement, broadening, written description, asserted claim, embodiment, overlooked, medicant, pads

Patent Law > US Patent & Trademark Office Proceedings > **Reissue** Proceedings > Requirements

[HN2](#) Requirements

The recapture rule generally prohibits applicants from claiming, on **reissue**, patent claim scope surrendered during the course of the original prosecution. The original patent requirement requires that the original specification expressly disclose the particular invention claimed on **reissue**.

Case Summary


Overview

HOLDINGS: [1]-Claims for **reissue** of a patent for automatic injection devices used to self-administer pharmaceuticals were invalid since the original claims which focused on jet injection were significantly different in scope and coverage than the particular safety features claimed on **reissue** which were not described separately from the jet injectors in the original patent.

Patent Law > US Patent & Trademark Office Proceedings > Continuation Applications > General Overview

Outcome

Order affirmed.

[HN3](#)  Typically, if an applicant files a patent application disclosing and claiming one invention and later realizes that the specification discloses a second or broader invention, he may seek coverage of those additional claims pursuant to [35 U.S.C.S. § 120](#), which

LexisNexis® Headnotes

allows for continuing applications to claim the priority date of earlier applications. One type of continuing application is a continuation application. A continuation application is a second application for the same invention claimed in a prior non-provisional application and filed before the original prior application becomes abandoned or patented. Manual Pat. Examining P. § 201.07. A divisional application is another type of continuing application and is intended for distinct inventions, carved out of a pending application and disclosing and claiming only subject matter disclosed in the earlier or parent application. Manual Pat. Examining P. § 201.06. When an applicant seeks to add new claims pursuant to a continuation or divisional application, the statute explicitly states that the original specification provides adequate support for the new claims if the original specification satisfies the [35 U.S.C.S. § 112\(a\)](#) written description requirement for the new claims. [§ 120](#).

Patent Law > US Patent & Trademark Office
Proceedings > Continuation
Applications > Copendency & Disclosure

Patent Law > US Patent & Trademark Office
Proceedings > **Reissue**
Proceedings > Requirements

[HN4](#) Copendency & Disclosure

The filing of patent continuations and divisionals is limited by the co-pendency requirement of [35 U.S.C.S. § 120](#): a continuing application cannot be filed after the original parent application issues. In such circumstances, an applicant can only seek to add claims by filing a **reissue** application. [35 U.S.C.S. § 251](#). The delay in seeking to broaden the claims is not without cost. By waiting until after the patent is issued, the applicant becomes subject to additional requirements: first, the claims must not violate the recapture rule; second, the claims must satisfy the statutory original patent requirement of [§ 251](#).

Patent Law > US Patent & Trademark Office
Proceedings > **Reissue** Proceedings > General
Overview

[HN5](#)  See [35 U.S.C.S. § 251\(a\)](#).

Patent Law > US Patent & Trademark Office
Proceedings > **Reissue**
Proceedings > Requirements

[HN6](#) Requirements

For **reissue** under [35 U.S.C.S. § 251](#), it is not enough that an invention might have been claimed in the original patent because it was suggested or indicated in the specification. Rather, the specification must clearly and unequivocally disclose the newly claimed invention as a separate invention.

Counsel: IMRON T. ALY, Schiff Hardin LLP, of Chicago, Illinois, argued for plaintiff-appellant. With him on the brief were RICHARD J. HOSKINS and SAILESH K. PATEL. Of counsel was JOEL M. WALLACE.

CHRISTOPHER J. HARNETT, Ropes & Gray LLP, of New York, New York, argued for defendants-appellees. With him on the brief were JAMES F. HALEY, JR., CHING-LEE FUKUDA and HASSEN A. SAYEED.

Judges: Before DYK, REYNA, and TARANTO, Circuit Judges.

Opinion by: DYK

Opinion

[*1355] [***1865] DYK, *Circuit Judge*.

Plaintiff-Appellant Antares Pharma, Inc. ("Antares") appeals from a decision of the United States District Court for the District of Delaware denying Antares' motion for preliminary injunction. Antares seeks to enjoin alleged infringement of claims 31, 34, 35, and 37 of a **reissue** patent, RE44,846 ("the '846 patent"). Because we hold that these **reissue** claims are invalid for failure to comply with the "original patent" requirement of [35 U.S.C. § 251](#), we affirm.

BACKGROUND

I

Antares is a developer of automatic injection devices used to self-administer [*1356] pharmaceuticals. It is the assignee of U.S. Patent No. 7,776,015 ("the '015 patent"), which issued on August 17, 2010. That patent, entitled "NEEDLE [**2] ASSISTED JET INJECTOR," discloses [***1866] a system for injecting medicant in

which a needle punctures the skin before forcefully expelling the medicant, thereby minimizing some of the downsides of typical jet injectors (in which the medicant itself ruptures the outer layers of skin), while still maintaining some of the advantages of typical jet injectors. During prosecution, the applicants repeatedly distinguished their invention from the prior art by focusing on the "jet injector" limitation present in their claims but not the prior art. The originally issued claims all contained the "jet injection" limitation.

On June 22, 2012, roughly 22 months after the '015 patent issued, Antares sought a reissue for the patent pursuant to [35 U.S.C. § 251](#), stating that there was an error in the original '015 patent insofar as the patentee claimed "more or less than he had a right to claim in the patent." See [35 U.S.C. § 251](#). [HN1](#) [Section 251](#) allows a patent holder to correct an existing, issued patent by broadening or narrowing the originally issued claims. If the claims sought on reissue are broader than the original claims, the patentee must apply for the reissue within two years of the patent issuing. *Id.* Here, the applicants complied with the two-year requirement.

[**3] The '846 reissue patent was granted on April 15, 2014. The specification and claims 1-22 were left unaltered; claims 23-37 were added. The originally allowed claims recite various embodiments of a jet injection device and specify, for example, the exact depth the needle assist plunges to, the force at which the medicant is expelled, and the gauge of the needle. The reissue claims (claims 23-37) cover embodiments of injection devices (not restricted to jet-injection devices) with particular combinations of safety features. Claim 31, for example, covers certain injectors containing at least a latch, pushbutton, and needle guard. By Antares' own admission, the reissue claims recite a different invention from what was originally claimed. See Appellant Br. 14-15 ("These are two different inventions [Original c]laim 1 is directed to 'jet injection device' *performance* [Reissue c]laim 31, on the other hand, is directed to *safety features* for any 'injection device.'") (emphasis in original).

II

Defendants medac Pharma, Inc. and medac GmbH (collectively, "Medac") manufacture and sell pre-filled, hand-powered methotrexate syringes. On September 10, 2013, Medac submitted a [505\(b\)\(2\)](#) new drug application ("NDA") with the FDA for their pre-filled methotrexate syringes, which they intend to sell under the trade name RASUVO. Antares does not accuse the methotrexate medication [****4**] itself of infringing any

patents; rather, Antares accuses the injection device housing the methotrexate of infringing various claims. Because the product prospectively sold under the application would allegedly infringe claims of the '846 patent, the filing of the application constitutes an act of artificial infringement under [35 U.S.C. § 271\(e\)\(2\)\(A\)](#) (assuming infringement is established).

Antares filed suit against Medac in the District of Delaware on February 28, 2014, initially alleging infringement of certain patents not involved in the present appeal based on Medac's filing of the [505\(b\)\(2\)](#) NDA. On March 14, 2014, Antares filed a motion for preliminary injunction. On April 18, 2014, Antares filed an amended complaint, adding the '846 patent to the list of patents it was asserting against Medac, and amended the motion for preliminary injunction accordingly, asserting [****1357**] claims 31, 34, 35, and 37 of the '846 patent. Since only the asserted claims in the '846 patent are at issue on appeal, we limit our discussion to those claims.

On May 5, 2014, Medac counterclaimed for invalidity and non-infringement of the patents-in-suit. On May 28, 2014, Medac filed its opposition to the motion for preliminary injunction, arguing that the asserted reissue claims [****5**] of the '846 patent were invalid for violating the recapture rule and failing the original patent requirement of [§ 251](#). [HN2](#) The recapture rule generally prohibits applicants from claiming, on reissue, claim scope surrendered during the course of the original prosecution. See [In re Mostafazadeh, 643 F.3d 1353, 1358 \(Fed. Cir. 2011\)](#). As discussed below, the original patent requirement requires that the original specification expressly disclose the particular invention claimed on reissue.

On July 10, 2014, the district court denied the motion for preliminary injunction, finding that Antares failed to carry its burden of showing a likelihood of success on the merits with respect to the '846 patent because claims 31, 34, 35, and 37, added during reissue, are likely invalid for violating the recapture rule. The court found that, during the original prosecution, [****1867**] the applicants repeatedly distinguished the prior art by focusing on the fact that the claims were limited to jet injectors. During reissue, when the applicants sought to claim safety features not limited to jet injectors, they were broadening their claims to cover non-jet injectors. Because the court held that the recapture rule was violated, it did not consider the question of whether the original patent requirement [****6**] was satisfied. The court held that Antares would likely suffer irreparable

harm and that the balance of interests was in equipoise.

Antares appealed the denial of the preliminary injunction with respect to the asserted claims of the '846 patent. We have jurisdiction pursuant to 28 U.S.C. §§ 1292 & 1295. We review the district court's denial of the preliminary injunction for abuse of discretion, but we review errors of law relating to that denial de novo. *Globetrotter Software, Inc. v. Elan Computer Grp., Inc.*, 236 F.3d 1363, 1367 (Fed. Cir. 2001). We review the applicability of the recapture rule and the original patent requirement of 35 U.S.C. § 251 de novo. *Medtronic, Inc. v. Guidant Corp.*, 465 F.3d 1360, 1373 (Fed. Cir. 2006).

DISCUSSION

I

Antares argues that the district court incorrectly applied the recapture rule and that, under the "overlooked aspects" cases, the recapture rule is inapplicable. In this respect, Antares relies on *Mostafazadeh*, 643 F.3d at 1360. Antares argues that, while the recapture rule generally prohibits a patentee from "regain[ing] through **reissue** the subject matter that he surrendered in an effort to obtain allowance of the original claims," the recapture rule is entirely inapplicable if the **reissue** claims recite "overlooked aspects" of the invention. *Mostafazadeh*, 643 F.3d at 1358 (quoting *In re Clement*, 131 F.3d 1464, 1468 (Fed. Cir. 1997)); see also *In re Youman*, 679 F.3d 1335, 1347 (Fed. Cir. 2012). Antares argues that overlooked aspects are "patentably distinct (1) inventions; (2) embodiments; or (3) species not originally claimed[,] [****7**] not mere incidental features of the originally-claimed invention." *Mostafazadeh*, 643 F.3d at 1360 (citation omitted).¹ Because we hold that the asserted claims of the '846 patent fail the original patent requirement of 35 U.S.C. § 251, we [***1358**] do not reach the question of whether the recapture rule applies and, if it does, whether it was violated here.

II

HN3 [↑] Typically, if an applicant files a patent application disclosing and claiming one invention and later realizes that the specification discloses a second or broader invention, he may seek coverage of those

¹Antares acknowledges that the "overlooked aspects" cases cannot save separate inventions claimed on **reissue** but expressly disclaimed during prosecution, because "what was expressly surrendered cannot have been overlooked." Appellant Rep. Br. at 6.

additional claims pursuant to 35 U.S.C. § 120, which allows for continuing applications to claim the priority date of earlier applications. One type of continuing application is a continuation application. A continuation application is "a second application for the same invention claimed in a prior nonprovisional application and filed before the original prior application becomes abandoned or patented." MPEP § 201.07 (9th ed. Mar. 2014); see also 37 C.F.R. § 1.53(b). A divisional application is another [****8**] type of continuing application and is intended for "distinct invention[s], carved out of a pending application and disclosing and claiming only subject matter disclosed in the earlier or parent application." MPEP § 201.06; see also 37 C.F.R. § 1.53(b). When an applicant seeks to add new claims pursuant to a continuation or divisional application, the statute explicitly states that the original specification provides adequate support for the new claims if the original specification satisfies the § 112(a) written description requirement for the new claims. 35 U.S.C. § 120.²

HN4 [↑] The filing of continuations and divisionals is limited by the co-pendency requirement of § 120: a continuing application cannot be filed after the original parent application issues. In such circumstances, an applicant can only seek to add claims by filing a **reissue** application. 35 U.S.C. § 251. The delay in seeking to broaden the claims is not without cost. By waiting until after the patent is issued, the applicant becomes subject to two additional requirements [*****1868**] relevant here: first, the claims must not violate the recapture [****9**] rule; second, the claims must satisfy the statutory original patent requirement of 35 U.S.C. § 251.³

III

The original patent requirement is well-established, being recognized in the **reissue** statute and longstanding Supreme Court jurisprudence. The current statute governing reissues provides in relevant part:

HN5 [↑] Whenever any patent is, through error . . . ,

²These are in contrast to continuations-in-part, which, because they introduce new subject matter, cannot gain the benefit of the earlier filing date for the additional material. MPEP § 201.08.

³A third requirement, the prohibition on the introduction of "new matter," restricts applicants' abilities to modify the specification, rather than the claims, and is not relevant here. 35 U.S.C. § 251 (1952); 35 U.S.C. § 64 (1870); *Gill v. Wells*, 89 U.S. 1, 19, 22 L. Ed. 699 (1874); MPEP § 2163.06-07.

deemed wholly or partly inoperative or invalid . . . by reason of the patentee claiming more or less than he had a right to claim in the patent, the Director shall . . . **reissue** the patent for the invention disclosed in the original patent

[35 U.S.C. § 251\(a\)](#) (emphasis added).

Supreme Court cases have recognized this requirement for more than 150 years.⁴ [*1359] See, e.g., [Battin v. Taggart, 58 U.S. 74, 85, 15 L. Ed. 37 \(1854\)](#) (noting that reissued patents must be "for the same invention as the original patent"); [Klein v. Russell, 86 U.S. 433, 466, 22 L. Ed. 116 \(1873\)](#) (same). The requirement became even more important when the Supreme Court first held that broadening **reissue** applications were permissible. See [Miller v. Bridgeport Brass Co., 104 U.S. 350, 351, 354-55, 26 L. Ed. 783, 1882 Dec. Comm'r Pat. 49 \(1881\)](#) (holding that broadening reissues were permissible under certain [*10] circumstances, but that a patentee seeking on **reissue** to claim a particular configuration of domes relating to lamp technology violated the "same invention" requirement of the **reissue** statute because the original patent disclosed only a different configuration); see also [In re Staats, 671 F.3d 1350, 1353-54 \(Fed. Cir. 2012\)](#) ("Despite the language of the statute referring only to narrowing reissues, the [Supreme] Court . . . held that the statute allowed for broadening reissues."⁵ Thereafter, the Supreme Court continued to rigorously enforce the original patent requirement. See, e.g., [Topliff v. Topliff, 145 U.S. 156, 169-70, 12 S. Ct. 825, 36 L. Ed. 658, 1892 Dec. Comm'r Pat. 402 \(1892\)](#) (collecting and summarizing cases and noting that reissues "shall be for the same invention as the original patent, as such invention appears from the specification and claims of such original"); [Corbin Cabinet Lock Co. v. Eagle Lock Co., 150 U.S. 38, 42-43, 14 S. Ct. 28, 37 L. Ed. 989, 1893 Dec. Comm'r Pat. 612 \(1893\)](#) (rejecting **reissue** claims because they were "merely suggested or indicated in the original specification," and it was not sufficiently clear that they "constitute[d] parts or portions of the invention"); [Sontag Chain Stores Co. v. Nat'l Nut Co. of Cal., 310 U.S. 281, 288, 60 S. Ct. 961, 84 L. Ed. 1204, 1941 Dec. Comm'r Pat. 781 \(1940\)](#) ("The reissued patent must be for the same invention").

⁴As discussed below, prior to the 1952 Amendments, the original patent requirement was referred to as the "same invention" requirement.

⁵This change was codified in the 1952 Amendments. See [35 U.S.C. § 251 \(1952\)](#).

The Supreme [*11] Court's definitive explanation of the original patent requirement appears in [U. S. Industrial Chemicals, Inc. v. Carbide & Carbon Chemicals Corp., 315 U.S. 668, 62 S. Ct. 839, 86 L. Ed. 1105, 1942 Dec. Comm'r Pat. 751 \(1942\)](#). There, the Court analyzed a **reissue** patent relating to a process for the production of a chemical compound. The original claims required the presence of water as a catalyst. After the patent was issued, it became clear that water was not required as a catalyst. The patentee asserted that the original claim was in error because it required the presence of water, and the patentee sought and obtained a **reissue** that omitted that "erroneous" requirement. The patentee subsequently brought suit for infringement of the newly added claims, which omitted the water limitation. [Id. at 670-75](#). The Court held the **reissue** claims invalid for failing to satisfy the "same invention" requirement. [Id. at 680-81](#). It explained that a **reissue** claim is for the "same invention" if the original patent specification fully describes the claimed inventions, but not if the broader claims "are [] merely suggested or indicated in the original specification." [Id. at 676](#). "[I]t is not enough that an invention might have been claimed in the original patent because it was suggested or indicated in the specification." [Id.](#) The **reissue** claims were invalid because, although the [*12] original specification hinted at the fact that water might be optional (see [id. at 672](#) ("Water . . . can be admitted in the reaction vessel")), it was nonetheless clear that the invention disclosed in the original patent required the presence of water. [Id. at 676-78](#). That hint, suggestion, or indication that water was optional was not enough to save the **reissue** claims. [Id.](#) Circuit cases [*1869] immediately following [Industrial Chemicals](#) adopted the same test.⁶

[*1360] The Supreme Court's articulation of the "same invention" test in [Industrial Chemicals](#) was in the context of [35 U.S.C. § 64](#), which had slightly different language from the current **reissue** statute, [35 U.S.C. § 251](#). Prior to the 1952 Amendments, the statute [*13] provided:

⁶ See, e.g., [Freeman v. Altvater, 138 F.2d 854, 859 \(8th Cir. 1943\)](#) (citing to [Industrial Chemicals](#) and explaining that "[f]ailing to disclose in the original patent matters claimed in the **reissue** will not enable the patentee to cover such new matter by the **reissue**, as least when the matter was within his knowledge when he applied for the original patent[; i]t is not enough that the invention might have been claimed in the original patent or that it was suggested in the specification"); [Monogram Mfg. Co. v. Glemby Co., 136 F.2d 961, 963 \(2d Cir. 1943\)](#) (interpreting [Industrial Chemicals](#) as asking whether the **reissue** claims were "fairly disclosed as essential" in the original specification).

Whenever any patent is wholly or partly inoperative or invalid . . . the commissioner shall . . . cause a patent *for the same invention* . . . to be reissued to the patentee

[35 U.S.C. § 64 \(1946\)](#) (emphasis added). The 1952 Amendments changed the language from "the same invention" to "the original patent," so that the provision reads: "[w]henever any patent is, through error . . . , deemed wholly or partly inoperative or invalid . . . the Director shall . . . **reissue** the patent for the invention disclosed in the original patent" *Id.* [§ 251](#) (1952).

Despite the change in language relating to the "same invention" requirement, it appears that no change in substance was intended. There is nothing in the statutory language or legislative history suggesting that Congress intended to overturn the long line of Supreme Court cases culminating in *Industrial Chemicals* by this change in language. As explained in P.J. Federico, *Commentary on the New Patent Act*, reprinted in 75 J. Pat. & Trademark Off. Soc'y 161, 205 (1993):

While the old statute stated that the patent is reissued "for the same invention," the new statute states that the patent is reissued "for the invention disclosed in the original patent." Here, again, there is no indication in the printed record that **[**14]** any change was intended, although a slight broadening effect has been argued.⁷

So too, in [Warner-Jenkinson Co. v. Hilton Davis Chemical, 520 U.S. 17, 117 S. Ct. 1040, 137 L. Ed. 2d 146 \(1997\)](#), although not directly addressing the "same invention" requirement, the Supreme Court explained that "[t]he 1952 Patent Act is not materially different from the 1870 Act with regard to claiming, **reissue**, and the role of the PTO," and that "[s]uch minor differences as exist between those provisions in the 1870 and the 1952 Acts have no bearing on [our precedent] and thus provide no basis for our overruling it." *Id.* [at 26](#).

After the 1952 Amendments, the circuit courts and our predecessor court continued to view *Industrial Chemicals* as articulating the applicable test, irrespective of the passage of the 1952 Amendments. See, e.g., [Bolkcom v. Carborundum Co., 523 F.2d 492, 502 \(6th Cir. 1975\)](#); [McCullough Tool Co. v. Well](#)

[Surveys, Inc., 343 F.2d 381, 389 \(10th Cir. 1965\)](#); [Riley v. Broadway-Hale Stores, Inc., 217 F.2d 530, 531 \(9th Cir. 1954\)](#); [In re Rowand, 526 F.2d 558, 559-60 \(C.C.P.A. 1975\)](#).

Thus, for example, in *McCullough*, the Tenth Circuit held a **reissue** patent valid over an invalidity challenge. Referencing *Industrial Chemicals*, the court stated that "[t]he original and **reissue** patents are for the same invention where the latter **[**1361]** fully describes and claims the very invention intended to be secured by the original patent and describes and claims only those things which were embraced in that invention and where **[**15]** it is not merely suggested in the original but constitutes a part or portion of that invention." [McCullough, 343 F.2d at 389](#). The court considered that "[i]t is not enough that an invention might have been claimed in the original patent because it was suggested or indicated in the specification," but must be "explicitly disclosed and taught" in the specification. *Id.* (internal quotation marks omitted).

Similarly, in [Riley v. Broadway-Hale Stores, Inc., 217 F.2d 530, 531 \(9th Cir. 1954\)](#), the court held that a single, vague reference in the original specification to shoulder pads without gaps in the **[***1870]** padding did not adequately support the **reissue** claims, which claimed shoulder pads without gaps, when the original claims only claimed shoulder pads with gaps, and the specification described the gapped shoulder pads as an "essential feature" of the invention. [Riley, 217 F.2d at 532](#). As the court explained, "[t]he broader claims of the **reissue** must be more than merely suggested or indicated in the original patent." *Id.* "[I]t is not enough that an invention might have been claimed in the original invention because it was suggested or indicated in the specification." *Id.* (quoting [Indus. Chems., 315 U.S. at 675-76](#)).

Finally, in *In re Rowand*, our predecessor court rejected a **reissue** claim seeking coverage of a particular method for making Teflon tubing when **[**16]** the specification focused on describing the product itself. [526 F.2d at 560](#). The court held that a single, vague statement in the specification broadly summarizing the general method for making Teflon tubing did not adequately disclose the particular method claimed on **reissue**. *Id.* Citing to *Industrial Chemicals*, the court held that the invention claimed on **reissue** was not sufficiently disclosed and failed under [§ 251. Id. at 559](#).

Since the creation of this court in 1982, we have addressed *Industrial Chemicals* and the original patent

⁷Federico's commentary is an invaluable insight into the intentions of the drafters of the Act." [Symbol Techs., Inc. v. Lemelson Med., 277 F.3d 1361, 1366 \(Fed. Cir. 2002\)](#).

requirement on four occasions: *In re Hounsfeld*, 699 F.2d 1320 (Fed. Cir. 1983); *In re Weiler*, 790 F.2d 1576 (Fed. Cir. 1986); *In re Amos*, 953 F.2d 613 (Fed. Cir. 1991); and *Hester Industries, Inc. v. Stein, Inc.*, 142 F.3d 1472 (Fed. Cir. 1998). Significantly, none of those cases suggested that the 1952 change in language worked a substantive change in the "same invention" requirement or that the standard of *Industrial Chemicals* has in any way been altered by the legislative changes. *Hester Industries* simply noted there was a change in the statutory language and that "the essential inquiry under the 'original patent' clause of § 251 . . . is whether one skilled in the art, reading the specification, would identify the subject matter of the new claims as invented and disclosed by the patentees." *Hester Indus.*, 142 F.3d at 1484 (quoting *Amos*, 953 F.2d at 618) (ellipsis in original). Similarly, *Amos* noted that *Industrial Chemicals* was decided [**17] under the predecessor statute, but nonetheless described the "same invention" requirement as "time-honored." *Amos*, 953 F.2d at 617, 619 n.2. It dismissed any perceived differences between the two requirements, explaining that the "'original patent' clause of § 251" has "historically [been] styled as [the] 'same invention'" requirement. *Id.*

Our cases shed light on *Industrial Chemicals* in two respects. First, they rejected a gloss put on *Industrial Chemicals* by the Board in later cases, which had interpreted *Industrial Chemical*, *Rowand*, and *In re Mead*, 581 F.2d 251 (C.C.P.A. 1978) as creating an "intent to claim" test for the original patent requirement. In *Hounsfeld*, we reversed the [*1362] Board, holding that the Board's interpretation put an "erroneous" "gloss" on those decisions. 699 F.2d at 1322-23. The court explained that *Industrial Chemicals*, *Rowand*, and *Mead* merely indicated that "intent to claim" was "only one factor that sheds light upon whether the claims of the *reissue* application are directed to the same invention as the original patent and the *reissue* would correct an inadvertent error in the original patent." *Id.* at 1323; see also *Weiler*, 790 F.2d at 1581 ("Language appearing first in [*Industrial Chemicals*] has been picked up and has metamorphosed into a requirement that an applicant show his original 'intent to claim' the subject matter [**18] of the *reissue* claim sought."). Second, our cases explained that the *Industrial Chemicals* standard is analogous to the written description requirement, which, as our en banc decision in *Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.*, 598 F.3d 1336 (Fed. Cir. 2010) made clear, requires that the patent description "clearly allow persons of ordinary skill in the art to recognize that the inventor invented what is claimed." *Id.* at 1351 (citation and alterations omitted).

See *Hester Indus.*, 142 F.3d at 1484; *Amos*, 953 F.2d at 618; see also *Revolution Eyewear, Inc. v. Aspex Eyewear, Inc.*, 563 F.3d 1358, 1367 (Fed. Cir. 2009) (describing the original patent requirement as "analogous" to the written description requirement).⁸ Whether or not the [***1871] written description requirement of § 112 was satisfied here, *Industrial Chemicals* made clear that, *HNO*[↑] for § 251, "it is not enough that an invention might have been claimed in the original patent because it was suggested or indicated in the specification." 315 U.S. at 676. Rather, the specification must clearly and unequivocally disclose the newly claimed invention as a separate invention. *Id.*

IV

Applying the *Industrial Chemicals* standard, asserted *reissue* claims 31, 34, 35, and 37 are invalid. The original claims are significantly different in scope and coverage than the asserted claims. Claims 1-22 are focused on jet injectors, and every one of those claims contains the "jet injection" limitation. The asserted claims are focused on particular safety features and do not contain the jet injection limitation. Indeed, appellants themselves argue that the asserted *reissue* claims cover a different invention than that originally claimed. To be sure, the original patent requirement focuses on the original specification rather than the original claims. While the claims may be used to determine whether the written description requirement has been satisfied outside of the *reissue* context, *Ariad*, 598 F.3d at 1347, by definition in *reissue* the original claims do not disclose the invention claimed on *reissue*. Thus, we must look to the specification. The original specification here does not adequately disclose the later-claimed [**20] safety features to meet the *Industrial Chemicals* standard. The specification discussed only one invention: a particular class of jet injectors. This is clear from the title of the patent ("Needle Assisted Jet Injector"), the abstract ("A jet injection device. . ."), the

⁸The court in *Revolution Eyewear* rejected the "original patent" challenge in a single paragraph, ending with the statement that it was doing so "[b]ecause [it had just] held that the written description requirement [was] satisfied." 563 F.3d at 1367. That statement cannot be taken to establish as precedent that the standards are the same, [**19] but merely reflects the way the parties presented the issue, neither of whom made any reference to *Industrial Chemicals* or argued for a standard different than § 112. See Opening Brief of Counterclaim-Defendant/Appellant *Revolution Eyewear*, *Revolution Eyewear*, 2008 WL 4307403, at *29-30 (filed Aug. 18, 2008).

summary of the invention **[*1363]** ("The present invention relates to a needle assisted jet injector."), the repetitive descriptions of the "present invention" as being for a jet injector (e.g., "[t]he present invention relates to a needle assisted jet injector," '846 patent col. 2 ll. 54-55, and repetitions of "the needle assisted jet injector according to the present invention," *id.* col. 5 ll 6-7, col. 5 ll 34-35, col. 8 ll. 21-22, col. 12 ll. 34-35, col. 13 ll. 26-27), and the entirety of the specification ("jet" is mentioned 48 times in the 7-page specification).

Although safety features were mentioned in the specification, they were never described separately from the jet injector, nor were the particular combinations of safety features claimed on reissue ever disclosed in the specification. Rather, the safety features were serially mentioned as part of the broader conversation: how to build the patented jet injection device. For example, **[**21]** Antares, in its briefing, emphasizes the "push button" safety feature claimed in the reissue. But, a "push button" is mentioned in only one passage in the specification: "Alternatively, a push button could be located at the proximal end of the device and be locked in an idle position. The movement of the needle guard could unlock the push button and allow the user to depress it and consequently fire the device." *Id.* col. 12 ll. 9-13. These "suggest[ions]" or "indicat[ions]" of alternative inventions are not sufficient to satisfy the original patent requirement of [§ 251](#). [Indus. Chems., 315 U.S. at 676](#). Nowhere does the specification disclose, in an explicit and unequivocal manner, the particular combinations of safety features claimed on reissue, separate from the jet injection invention. This does not meet the original patent requirement under [§ 251](#).⁹

The situation here is quite unlike *Amos*, in which we held that the original patent requirement was satisfied. In *Amos*, the patentee sought to broaden his claims on **[**22]** an invention relating to the use of rollers to hold down work-pieces on a moving table. The specification expressly disclosed that rollers, as they approached the end of the table, could be "raised either mechanically by the roller cams or electronically by the computer controlling the router." *Amos*, 953 F.2d at 614.

⁹Although the appeal before us is from the denial of a preliminary injunction, whether the claims at issue satisfy the original patent requirement of [§ 251](#) does not depend on any not-yet-resolved factual issues, so a remand is not required. See [LifeScan Scotland, Ltd. v. Shasta Techs., LLC, 734 F.3d 1361, 1368-69 \(Fed. Cir. 2013\)](#).

The original claims only covered the manual embodiment. On reissue, the applicant sought to add the computer-controlled embodiment. *Id.* The Board denied the reissue because there was no objective intent to claim. *Id.* at 615. This court reversed the Board because the exact embodiment claimed on reissue was expressly disclosed **[***1872]** in the specification. *Id.* at 617-19. Such an express disclosure is exactly what was missing here.

CONCLUSION

The claims on appeal are invalid for failure to satisfy the original patent requirement of [35 U.S.C. § 251](#). Because Antares cannot show likelihood of success on the merits with respect to these claims, the district court properly denied Antares' motion for preliminary injunction.

AFFIRMED

Costs to appellees.

End of Document