# United States Court of Appeals for the Federal Circuit

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**KING PHARMACEUTICALS, INC.,**
**AND KING PHARMACEUTICALS RESEARCH AND DEVELOPMENT, INC,**
*Plaintiffs-Appellants,*

**v.**

**EON LABS, INC.,**
*Defendant-Appellee,*

**v.**

**ELAN PHARMACEUTICALS, INC.,**
*Counterclaim Defendant-Appellant.*

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2009-1437, -1438

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Appeal from the United States District Court for the Eastern District of New York in 04-CV-5540, Senior Judge David G. Trager.

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Decided: August 2, 2010

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GREGORY A. CASTANIAS, Jones Day, of Washington, DC, argued for plaintiffs-appellants. With him on the brief were F. DOMINIC CERRITO, DANIEL L. MALONE and ERIC C. STOPS, of New York, New York. Of counsel was EVANGELINE SHIH.

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Before BRYSON, GAJARSA, and PROST, *Circuit Judges*.

GAJARSA, *Circuit Judge*.

King Pharmaceuticals, Inc. and King Pharmaceuticals Research and Development, Inc. ("King") appeal the U.S. District Court for the Eastern District of New York's grant of Eon Labs, Inc.'s ("Eon") motion for summary judgment that all claims of U.S. Patent Nos. 6,407,128 (the "'128 patent") and 6,683,102 (the "'102 patent") are invalid. *See King Pharms., Inc. v. Eon Labs, Inc.*, 593 F. Supp. 2d 501 (E.D.N.Y. 2009). In granting Eon's motion, the district court held four claims invalid under 35 U.S.C. § 101, three claims invalid under 35 U.S.C. § 103, and the remaining claims invalid under 35 U.S.C. § 102. *See id.* at 506-15.

Following the summary judgment order, the district court entered a final judgment against both King and Elan Pharmaceuticals, Inc. ("Elan"), a prior owner of one of the asserted patents and a third-party, counterclaim defendant. Elan filed a "cautionary" notice of appeal on July 2, 2009 contending that the district court lacked jurisdiction to enter a final judgment against it. Elan

then moved to be dismissed as a party from this appeal for lack of subject matter jurisdiction and to vacate the district court's judgment as to Elan. A Federal Circuit motions panel denied the motion because the jurisdictional facts went to the merits of the case. Elan reasserts its jurisdictional arguments in the present appeal.

For the reasons stated below, we affirm the district court's grant of summary judgment of invalidity. We vacate the district court's invalidity order against Elan because the district court lacked subject matter jurisdiction to adjudicate the invalidity counterclaim.

## BACKGROUND

King markets and sells a name brand version of metaxalone called Skelaxin. Metaxalone is a muscle relaxant that is used to treat "discomforts associated with acute, painful musculosketal conditions." '128 patent col.1 ll.21-23. Metaxalone was first discovered in the 1960s, and the first patent claiming the method of producing the compound, U.S. Patent No. 3,062,827, issued in 1962 to A.H. Robins Company, Inc. A.H. Robins began selling metaxalone under the brand name Skelaxin in 1962. Elan eventually acquired the rights to Skelaxin and sold those rights in 2003 to King, which now markets and sells Skelaxin.

On August 31, 2004, Eon filed an Abbreviated New Drug Application ("ANDA") for a generic 800 mg metaxalone tablet. Eon filed with the ANDA a patent certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification"), which alleged that none of the claims of the '128 patent would be infringed by the manufacture, use, or sale of Eon's generic 800 mg metaxalone tablet, and that all the claims of the '128 patent are invalid. In response to the ANDA and Paragraph IV Certification, King filed suit against Eon under the

Hatch-Waxman Act (the "800 mg Action"). The complaint accused Eon of infringing the '128 and '102 patents. King's action was consolidated with an earlier, related action, *Elan Pharmaceuticals, Inc. v. Eon Labs, Inc.*, No. 03-0006 (E.D.N.Y.) (the "400 mg Action"), that Elan filed in 2001 against Eon after Eon filed an ANDA for a generic 400 mg metaxalone tablet. Elan asserted the '128 patent in the 400 mg Action, but the case was dismissed after Eon withdrew its 400 mg ANDA. The district court then severed Eon's claims for attorneys fees against King and Elan and consolidated those claims with the 800 mg Action.

The '128 patent, titled "Method for Increasing the Bioavailability of Metaxalone," issued on June 18, 2002 and was initially assigned to Elan. Elan subsequently assigned the '128 patent to King in 2003. The patent discloses a method of "increasing the bioavailability of metaxalone by administration of an oral dosage form with food." '128 patent [Abstract]. The claimed invention is the result of "the unexpected finding that administration of metaxalone with food increases both the rate and extent of absorption via the oral dosage form in human subjects." *Id.* at col.2 ll.6-9.

The '128 patent has three independent claims, claims 1, 9, and 17. Claim 1 claims "a method of increasing the oral bioavailability of metaxalone" by "administering to the patient a therapeutically effective amount of metaxalone in a pharmaceutical composition with food." Claim 9 claims a method for increasing "the rate and extent of absorption . . . of metaxalone . . . in the blood stream" by "administering to the patient a therapeutically effective amount of metaxalone in a pharmaceutical composition with food." Claim 17 claims a method similar to claim 1, but limits the effective amount of metaxalone to between 400 and 800 mg and defines an increase in bioavailability

as "an increase in the maximal plasma concentration (Cmax) and extent of absorption (AUC(last)) of metaxalone compared to administration without food."

Dependent claims 2, 3, 10, and 11 specify that the "therapeutically effective amount" of metaxalone is "200 mg to 900 mg" (claims 2 and 10) or "400 mg to 800 mg" (claims 3 and 11). Dependent claims 4-6, 12-14, and 18-20 specify specific times for administering the metaxalone relative to the consumption of food, either thirty minutes prior to two hours after consumption of food (claims 4, 12 and 18), "substantially at the same time" as consumption of food (claims 5, 13 and 19), or up to one hour after consumption of food (claims 6, 14 and 20). Dependent claims 7 and 15 limit the dosage to a tablet form, and dependent claims 8 and 16 limit the dosage to a "unit dosage form." Dependent claim 21 claims the method of claim 1 with the additional limitation of "informing" the patient that taking metaxalone with food will increase the drug's bioavailability, and dependent claim 22 claims the method of claim 1 with the additional limitation that "the metaxalone is from a container with printed labeling advising" that taking metaxalone with food will increase the drug's bioavailability.

The '102 patent issued on January 27, 2004 and is titled "Methods of Using Metaxalone in the Treatment of Musculoskeletal Conditions." Elan assigned the application that resulted in the '102 patent to King in 2003. Like the '128 patent, the '102 patent discloses a method of "increasing the bioavailability of metaxalone by administration of an oral dosage form with food." '102 patent [Abstract]. Independent claim 1 claims a method for using metaxalone in the treatment of musculosketal conditions comprising both "providing" a patient with a "therapeutically effective amount of metaxalone" and "informing" the patient that taking metaxalone with food

increases the bioavailability of the drug. Claims 2 through 5 depend from claim 1 and either specify the "therapeutically effective amount" as 200 mg to 900 mg (claim 2) or 400 mg to 800 mg (claim 3), or limit the dosage to a tablet form (claim 4) or a "unit dosage form" (claim 5).

Independent claim 6 claims a "method of using metaxalone in the treatment of musculosketal conditions" consisting of "informing a patient" that taking metaxalone with food increases the bioavailability of the drug compared to taking metaxalone without food. Independent claim 7 claims a "method of using metaxalone in the treatment of musculosketal conditions" by "obtaining metaxalone from a container providing information that administration of metaxalone with food" increases the drug's bioavailability and "ingesting the metaxalone with food."

Independent claim 8 claims a "method of using metaxalone in the treatment of musculosketal conditions" comprising both administering metaxalone with food and informing the patient that such administration increases the bioavailability of the drug. Dependent claims 9 through 11 limit claim 8 to metaxalone from a container with printed information concerning the increased bioavailability of the drug (claim 9), metaxalone in a tablet form (claim 10), and 400 mg of metaxalone (claim 11). Claims 12, 13, and 14 depend from claim 9 and limit the printed label to stating certain percentage increases in the bioavailability of metaxalone. Finally, claim 15 depends from claim 8 and limits the metaxalone to a 400 mg tablet with a printed label that states certain percentage increases in the bioavailability of the metaxalone.

Before the district court, Eon presented six prior art references it contended invalidated the '128 and '102

patents. *See King Pharms., Inc.*, 593 F. Supp. 2d at 504-06. In granting Eon's motion for summary judgment, the district court relied only upon three references: KAZEM FATHIE, *Musculoskeletal Disorders and Their Management with a New Relaxant*, CLINICAL MEDICINE 678 (April 1965) ("Fathie II"); JOSEPH A. ALBANESE, NURSES' DRUG REFERENCE 427 (2 ed. 1982) ("Albanese"); and ANNE C. ABRAMS, CLINICAL DRUG THERAPY 145 (1995) ("Abrams"). *See id.* at 506-15.

Fathie II describes a clinical study in which patients were given 800 mg of metaxalone to be taken three to five times a day. The article notes that several patients complained of nausea and that "[n]ausea might have been less prominent if the medication had been taken with food." J.A.3054.

Albanese is a reference guide for registered nurses. The guide discloses that metaxalone is available in 400 mg tablets and recommends a dosage range of 800 mg three to four times daily. The guide also notes that "[a]dministration with meals will help reduce gastric upset." J.A.3065.

Abrams is another reference guide for registered nurses. The reference guide discloses providing patients with 800 mg of metaxalone three or four times daily for not more than ten consecutive days. The reference guide also instructs nurses to give metaxalone "with milk or food" in order to "decrease gastrointestinal distress." J.A.3072.

Eon moved for summary judgment of invalidity. Eon's motion asserted that all claims of the '128 and '102 patents were either anticipated by or obvious in light of the prior art. The district court granted Eon's motion. *See King Pharms., Inc.*, 593 F. Supp. 2d 501.

Starting with independent claim 1 of the '128 patent, the district court found the claim's preamble – "[a] method of increasing the oral bioavailability of metaxalone to a patient receiving metaxalone therapy" – inherently anticipated because "an increase in the bioavailability of metaxalone is inherent when the drug is taken with food." *Id.* at 508. The district court then concluded that "because the '128 patent teaches nothing more than administering metaxalone with food to increase its bioavailability and because Fathie II, Albanese and Abrams all teach administering metaxalone with food – which inherently increases metaxalone's bioavailability – claim 1 is anticipated." *Id.* at 509.

Turning to the '128 patent's dependent claims, the district court found claims 2 and 3 anticipated because the prior art references disclosed dosage amounts within the claimed "therapeutically effective" range. *See id.* at 510. Claims 4 through 7 were also found anticipated because the prior art disclosed taking metaxalone with food within the various time frames claimed. *See id.* As for claim 8, the district court found that no reference disclosed taking a single tablet of metaxalone with food, but held the claim obvious in light of a prior art reference, 18 R.W. DENT, JR. AND DOROTHY K. ERVIN, *A Study of Metaxalone (Skelaxin) vs. Placebo in Acute Musculoskeletal Disorders: A Cooperative Study*, CURRENT THERAPEUTIC RESEARCH (1975) ("Dent"), which discloses a single tablet dosage and Albanese, which discloses taking dosages with food. *See id.* at 510-11.

The district court then found claims 9 through 16 mirrored claims 1 through 7, and found the claims anticipated for the earlier stated reasons. *See id.* at 512. Claim 17 was also found anticipated because the claim's "wherein the administration [of metaxalone] results in an increase in [bioavailability]" language, like claim 1's

preamble, is an inherent property of the prior art. *See id.* Claims 18 through 20, which depend from claim 17, include the same timing limitations as claims 4 through 6, and were anticipated for the same reasons. *See id.* The district court then found claim 21 invalid under 35 U.S.C. § 101 because the claim's "informing" limitation did not "transform the metaxalone into a different state or thing." *Id.* at 513 (citing *In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008), *aff'd sub nom*, *Bilski v. Kappos*, 130 S. Ct. 3218 (2010)). Finally, the district court held claim 22 anticipated because the inclusion of an instruction sheet with a known compound did not make the claim patentably distinct from the prior art. *See id.* (citing *In re Nagi*, 367 F.3d 1336 (Fed. Cir. 2004) (per curiam)).

The district court next addressed the '102 patent, reading claim 1 to "require[] giving a patient metaxalone and informing the patient about an inherent property of the drug." *Id.* at 514 (alteration added). In analyzing claim 1, the district court held that administering metaxalone to a patient was disclosed in the prior art, the "informing" limitation was not patentable for the same reasons as claim 21 of the '128 patent, and the entire claim was invalid under § 101. *See id.* Claims 2 through 4 contained dosage limitations similar to the limitations disclosed in anticipated claims 2, 3, and 7 of the '128 patent, and the district court found the claims to be similarly anticipated under § 102. *See id.* Claim 5 was similar to claim 8 of the '128 patent and was obvious for the same reasons. *See id.*

The district court found claim 6 claimed solely the "informing" limitation and invalidated it under § 101.[1] *See id.* The district court then found claims 7 and 9 invalid

[1] King does not appeal this finding of invalidity of claim 6.

for the same reasons as claim 22 of the '128 patent, and claim 8 invalid for the same reasons as claim 21 of the '128 patent. *See id.* at 514-15. Claims 10 and 11 were found invalid for the same reasons as claim 7 of the '128 patent. *See id.* at 515. Finally, claims 12 through 15, which "differ from the prior art only in the content of the written material that accompanies the metaxalone," were, like claim 22 of the '128 patent, anticipated because "a variation in written material that is not functionally related to the invention does not render a known product patentable." *Id.*

In light of its invalidity determination, the district court granted King's motion to dismiss Eon's counterclaims for fraud and unclean hands as moot. *See id.* at 516. The district court, however, permitted Eon to brief its argument that the case was exceptional under 35 U.S.C. § 285. *See id.* at 515. The district court then entered its invalidity judgment against not only King, but also Elan, which had not participated in the summary judgment proceeding.

## DISCUSSION

### A. Legal Standards

We review the district court's grant of summary judgment de novo. *See ICU Med., Inc. v. Alaris Med. Sys., Inc.*, 558 F.3d 1368, 1374 (Fed. Cir. 2009). Summary judgment is appropriate when, drawing all justifiable inferences in the non-movant's favor, there exists no genuine issue of material fact and the movant is entitled to judgment as a matter of law. *See* Fed. R. Civ. P. 56(c); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986).

Under 35 U.S.C. § 102 a claim is anticipated "if each and every limitation is found either expressly or inherently in a single prior art reference." *Celeritas Techs. Ltd.*

*v. Rockwell Int'l Corp.*, 150 F.3d 1354, 1360 (Fed. Cir. 1998). "[A]nticipation by inherent disclosure is appropriate only when the reference discloses prior art that must *necessarily* include the unstated limitation. . . ." *Transclean Corp. v. Bridgewood Servs., Inc.*, 290 F.3d 1364, 1373 (Fed. Cir. 2002) (emphasis in original). A claim is obvious when "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. § 103.

Moreover, "[t]he laws of nature, physical phenomena, and abstract ideas have been held not patentable." *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980). While a process may be patentable if "(1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing," *In re Bilski*, 545 F.3d at 954, there is no exclusive test for determining patentability under § 101, *Bilski*, 130 S. Ct. at 3226-27.

B. Analysis

The district court considered and invalidated all thirty-seven claims of the '128 and '102 patents, and King appeals thirty-six of those findings. We begin, as the district court did, with the '128 patent and then turn to the '102 patent.

I. The '128 Patent

a. Claim 1

Claim 1 is an independent claim requiring the administration of "a therapeutically effective amount of metaxalone in a pharmaceutical composition with food." Claim 1 contains a preamble, which King argues is the claim's source of novelty. The preamble reads, "[a]

method of increasing the bioavailability of metaxalone to a patient receiving metaxalone therapy." According to King, while the prior art may disclose taking metaxalone with food, it does not disclose increasing the bioavailability of the drug.

In its summary judgment opinion, the district court rejected King's argument and found claim 1's preamble inherently anticipated. *See King Pharms., Inc.*, 593 F. Supp. 2d at 507-09. According to the district court, an increase in the bioavailability of metaxalone is an inherent property of taking metaxalone with food, which is disclosed in each of Fathie II, Albanese, and Abrams. *See id.*

On appeal, King argues the district court erred because Eon did not provide any evidence or expert testimony that the prior art would *necessarily* result in an increase in metaxalone's bioavailability. King argues that the prior art's disclosure (taking metaxalone with food to reduce gastric discomfort) is vague as to the conditions under which the food was administered such that it was improper for the district court to assume that an increase in bioavailability was necessarily disclosed. Specifically, King contrasts the precise conditions on food consumption disclosed in the '128 patent with the vague conditions disclosed in Fathie II, Albanese, and Abrams.[2] For further support, King cites its own expert reports which conclude that "even a disclosure of taking metaxalone with food would not inherently disclose increasing the bioavailability of metaxalone."

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[2] Participants in the study were given fifteen minutes to eat the following before administration of the metaxalone: two eggs (fried in butter), two strips of bacon, two slices of toast with butter, four ounces of hash brown potatoes, and one glass whole milk (eight ounces). *See* '128 patent col.3 ll.14-25.

As an initial matter, King's attempt to link an increase in metaxalone's bioavailability to specific food conditions is untenable. While the '128 patent's written description discloses specific conditions for food consumption, its claims only recite taking metaxalone "with food." It would be improper to limit the broad terms used in the '128 patent's claims to the specific food conditions disclosed in the written description. *See Kara Tech. Inc. v. Stamps.com Inc.*, 582 F.3d 1341, 1348 (Fed. Cir. 2009) ("The claims, not specification embodiments, define the scope of patent protection. The patentee is entitled to the full scope of his claims, and we will not limit him to his preferred embodiment or import a limitation from the specification into the claims."). Moreover, the written description in no way suggests that the specific food conditions disclosed were necessary for increasing metaxalone's bioavailability. Rather, the written description teaches that the claimed increase in metaxalone's bioavailability can be achieved through the consumption of "a meal, such as breakfast, lunch or dinner." '128 patent col.2 ll.37-38. The district court was therefore correct in finding that "the '128 patent does not identify any additional conditions that must be present for the food effect to occur. Rather, it occurs naturally in most people when they take metaxalone with food." *King Pharms., Inc.*, 593 F. Supp. 2d at 508; *see also Verdegaal Bros., Inc. v. Union Oil Co. of California*, 814 F.2d 628, 632 (Fed. Cir. 1987) (holding reliance on non-claimed distinction between prior art method and claimed method "inappropriate" and insufficient to save the claim from inherent anticipation).

As for the merits of King's argument, we first note that Fathie II, Albanese, and Abrams each disclose administering metaxalone "with food" or "with meals" to treat musculosketal conditions. Fathie II, published

thirty-six years prior to the filing of the '128 patent, teaches administering metaxalone "with food" to reduce nausea. J.A.3054. Albanese, published nineteen years prior to the filing of the '128 patent, teaches administering metaxalone "with meals" to "reduce gastric upset." J.A.3065. And, Abrams, published six years prior to the filing of the '128 patent, teaches administering metaxalone "with milk or food" to "decrease gastrointestinal distress." J.A.3072.

We have held that "[i]t is a general rule that merely discovering and claiming a new benefit of an old process cannot render the process again patentable." *In re Woodruff*, 919 F.2d 1575, 1578 (Fed. Cir. 1990). Such newly discovered benefits are not patentable because they are inherent in the prior art. *See Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1376 (Fed. Cir. 2001). While inherent anticipation "may not be established by probabilities or possibilities," *In re Oelrich*, 666 F.2d 578, 581 (CCPA 1981), if "the [prior art's] disclosure is sufficient to show that the natural result flowing from the operation as taught would result in the performance of the questioned function, it seems to be well-settled that the disclosure should be regarded as sufficient," *id.* (alterations added).

According to the '128 patent, the natural result of taking metaxalone with food is an increase in the bioavailability of the drug. The prior art discloses taking metaxalone with food, but not the natural result of this process. However, because the prior art methods in their "normal and usual operation . . . perform the function which [King] claims in [the '128 patent], then such [patent] will be considered, to have been anticipated by the [prior art]." *In re Ackenbach*, 45 F.2d 437, 439 (CCPA 1930) (alterations added). As taught by the '128 patent, the only steps required to increase metaxalone's bioavail-

ability are (1) ingesting metaxalone (2) with food. These steps are undeniably disclosed by the prior art. An increase in metaxalone's bioavailability is, therefore, an inherent aspect of the prior art. In other words, the increase in metaxalone's bioavailability is the "'natural result' flowing from the [prior art's] explicitly explicated limitations." *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 970 (Fed. Cir. 2001) (alterations added); *see also MEHL/Biophile Int'l Corp. v. Milgraum*, 192 F.3d 1331, 1336 (Fed. Cir. 1999) ("[T]o the extent the embodiment in the patent achieves [the limitation], so does the [prior art]."") (alterations added). Accordingly, claim 1's preamble is inherently anticipated.

King's experts' opinions that "even a disclosure of taking metaxalone with food would not inherently disclose increasing the bioavailability of metaxalone," do not undermine our analysis. To anticipate, the prior art need only meet the inherently disclosed limitation to the extent the patented method does. *See Hewlett-Packard Co. v. Mustek Systems, Inc.*, 340 F.3d 1314, 1326 (Fed. Cir. 2003) ("[A] prior art product that sometimes, but not always, embodies a claimed method nonetheless teaches that aspect of the invention."). Because the '128 patent discloses no more than taking metaxalone with food, to the extent such a method increases the bioavailability of metaxalone, the identical prior art method does as well. As the district court aptly stated, "to inherently anticipate, the prior art need only give the same results as the patent, not better." *King Pharms., Inc.*, 593 F. Supp. 2d at 509.

For the foregoing reasons, the district court's inherent anticipation analysis was proper. The preamble to claim 1 is inherently anticipated. To hold otherwise would remove from the public a method of treating muscle pain that has been performed for decades. *See Atlas Powder*

*Co. v. Ireco, Inc.*, 190 F.3d 1342, 1348 (Fed. Cir. 1999) ("The public remains free to make, use, or sell prior art compositions or processes, regardless of whether or not they understand their complete makeup or the underlying scientific principles which allow them to operate. The doctrine of anticipation by inherency, among other doctrines, enforces that basic principle."). Accordingly, the district court's finding that claim 1 is anticipated is affirmed.

Because we reject King's argument that claim 1's preamble is novel, we also affirm the district court's findings of invalidity as to claims 2, 3, 8-11, and 15-17. For these claims, King's sole argument on appeal was that their incorporation of claim 1's preamble (claims 2, 3, 7, and 8) or their recitation of a similar preamble (claims 9-11 and 15-17) made the claims novel. Like claim 1, these claims are anticipated because their sole source of novelty is inherently disclosed by the prior art.

b. Claims 4-6, 12-14, and 18-20.

Claims 4-6 depend from claim 1. The claims limit the time frame in which the patient must ingest the metaxalone in relation to consuming food. Claim 4 limits the time frame to "30 minutes prior to 2 hours after consumption of the food," claim 5 limits it to "substantially at the same time," and claim 6 limits it to "immediately after the consumption of food up to 1 hour after." Fathie II, Albanese, and Abrams respectively disclose administering metaxalone "with food," "with meals," and "with food or milk." J.A.3054, 3065, 3072.

On appeal, King argues that none of the claims' specific timeframe requirements is disclosed in Fathie II, Albanese, or Abrams. Yet, according to King's own experts, "with food" could mean taking metaxalone "1 hour prior to up to about 2 hours after eating." J.A.3221 (Decl.

of Dr. Elia). Under this common-sense definition of "with food," the prior art discloses a timeframe for ingesting metaxalone in relation to consuming food that falls within the timeframes claimed by claims 4-6. The district court's finding that claims 4-6 are anticipated is therefore affirmed. *See Titanium Metals Corp. of America v. Banner*, 778 F.2d 775, 782 (Fed. Cir. 1985) ("[It is] an elementary principle of patent law that when, as by a recitation of ranges or otherwise, a claim covers several compositions, the claim is 'anticipated' if one of them is in the prior art."); *Fresenius USA, Inc. v. Baxter Int'l, Inc.*, 582 F.3d 1288, 1298 (Fed. Cir. 2009).

Claims 12-14 and 18-20 contain identical timeframe requirements. The district court invalidated these claims for the same reasons it invalidated claims 4-6. We therefore affirm the district court's invalidation of these claims for the same reasons we affirmed its invalidation of claims 4-6.

c. Claim 21

Claim 21 depends from claim 1 and adds the limitation "informing the patient that administration of a therapeutically effective amount of metaxalone in a pharmaceutical composition with food results in an increase in the maximal plasma concentration (Cmax) and extent of absorption (AUC(last)) of metaxalone compared to administration without food." The district court invalidated claim 21 pursuant to 35 U.S.C. § 101. In invalidating claim 21, the district court cited this court's opinion in *In re Bilski* and held that "the act of informing another person of the food effect of metaxalone does not transform metaxalone into a different state or thing." *King Pharms., Inc.*, 593 F. Supp. 2d at 513.

On appeal, King contends it was legal error for the district court to focus solely on the "informing" limitation

in invalidating the claim. Instead, according to King, the district court should have examined the claim as a whole to determine whether it recited patent eligible subject matter. King is correct.

The Supreme Court has stated that a § 101 patentability analysis is directed to the claim as a whole, not individual limitations. *See Parker v. Flook*, 437 U.S. 584, 590 (1978) ("[A] process is not unpatentable simply because it contains a law of nature or a mathematical algorithm." (alterations added)); *see also In re Bilski*, 545 F.3d at 958 ("[T]he [Supreme] Court has made clear that it is inappropriate to determine the patent-eligibility of a claim as a whole based on whether selected limitations constitute patent-eligible subject matter." (alterations added)). Contrary to the Supreme Court's instructions, the district court ignored the claim as a whole and improperly focused on one limitation, the "informing" limitation, in invalidating the claim under § 101. Such an analysis is improper.

Reviewed as a whole, claim 21 teaches a method of treating patients with metaxalone, whereby the patient is administered metaxalone with food and informed that such treatment increases the bioavailability of the drug. Prior to the Supreme Court's decision in *Bilski*, this court held that such medical treatment methods were patentable processes under § 101 because they fell squarely within the machine-or-transformation test applied in *In re Bilski*. Specifically, we held that methods of treatment "are always transformative when a defined group of drugs is administered to the body to ameliorate the effects of an undesired condition," because such methods transform the human body. *Prometheus Labs., Inc. v. Mayo Collaborative Serv.*, 581 F.3d 1336, 1346 (Fed. Cir. 2009), *cert. granted and vacated*, No. 09-490, 78 U.S.L.W. 3254 (U.S. June 29, 2010). While the Supreme Court in *Bilski* made

clear that our machine-or-transformation test is not the exclusive test for patentability, *Bilski*, 130 S. Ct. 3226-27, it also made clear that the test "is a useful and important clue, an investigative tool, for determining whether some claimed inventions are processes under § 101," *id.* at 3227. We therefore understand the Supreme Court to have rejected the exclusive nature of our test, but not necessarily the wisdom behind it.

The present case, however, does not present the proper vehicle for determining whether claims covering medical treatment methods are eligible for patenting under § 101 because even if claim 21 recites patent eligible subject matter, that subject matter is anticipated for the reasons discussed below. As an appellate court, we are not limited to a district court's stated reasons for invalidating claims and can affirm a grant of summary judgment on any ground supported by the record and adequately raised below. *See Glaxo, Inc. v. Torpharm, Inc.*,153 F.3d 1366, 1371 (Fed. Cir. 1998); *Jaffke v. Dunham*, 352 U.S. 280, 281 (1957) (per curiam). In moving for summary judgment, Eon argued that claim 21, as well as the other claims the district court invalidated under § 101, was invalid under § 102, not § 101. Accordingly, the novelty of claim 21 was an issue presented to the district court and an alternative ground upon which the district court's invalidation of the claim can be affirmed. *See Hester Indus., Inc. v. Stein, Inc.*, 142 F.3d 1472, 1480 (Fed. Cir. 1998) (affirming summary judgment of invalidity on ground advanced by defendant in summary judgment motion but not adopted by district court).

Because we have already determined that independent claim 1 is anticipated, dependent claim 21's sole potential source of novelty is the "informing" limitation. King argues that the district court committed legal error

because it never found the "informing" limitation disclosed in the prior art, which it was required to do. *See Atofina v. Great Lakes Chem. Corp.*, 441 F.3d 991, 999 (Fed. Cir. 2006) ("Anticipation requires a showing that each limitation of a claim is found in a single reference, either expressly or inherently."). Eon tacitly concedes that the district court never expressly found the "informing" limitation disclosed in the prior art, but contends such a finding was unnecessary because the non-patentable "informing" limitation cannot breathe novelty into an otherwise anticipated method.

The specific question before us is whether an otherwise anticipated method claim becomes patentable because it includes a step of "informing" someone about the existence of an inherent property of that method. We hold it does not. The "informing" limitation adds no novelty to the method, which is otherwise anticipated by the prior art. In other words, in light of our holding that the method of taking metaxalone with food to increase the drug's bioavailability, as recited in claim 1, is not patentable, it readily follows that claim 21, which recites the same method with the sole additional step of informing the patient about this increase in bioavailability, is not patentable.

In an analogous context, we have held that "[w]here the printed matter is not functionally related to the substrate, the printed matter will not distinguish the invention from the prior art in terms of patentability." *In re Gulack*, 703 F.2d 1381, 1385 (Fed. Cir. 1983) (alterations added). In such cases, we have recognized that the printed matter is not independently patentable, but have cautioned that the limitation must not be excised from the claim. *See id.* at 1385 ("[T]he board cannot dissect a claim, excise the printed matter from it, and declare the remaining portion of the mutilated claim to be unpat-

entable. The claim must be read as a whole.") (alterations added). Instead, the relevant question is whether "there exists any new and unobvious functional relationship between the printed matter and the substrate." *Id.* at 1386 (citing *In re Miller*, 418 F.2d 1392, 1396 (CCPA 1969)). The rationale behind this line of cases is preventing the indefinite patenting of known products by the simple inclusion of novel, yet functionally unrelated limitations. *See In re Nagi*, 367 F.3d at 1339.

Although these "printed matter" cases involved the addition of printed matter, such as written instructions, to a known product, we see no principled reason for limiting their reasoning to that specific factual context. *See In re Ngai*, 367 F.3d at 1338-39; *In re Gulack*, 703 F.2d at 1385-87. Rather, we believe that the rationale underlying these cases extends to the situation presented in this case, wherein an instructional limitation is added to a method, as opposed to a product, known in the art. Thus, the relevant inquiry here is whether the additional instructional limitation of claim 21 has a "new and unobvious functional relationship" with the known method of administering metaxalone with food. *See In re Ngai*, 367 F.3d at 1338 (quoting *In re Gulack*, 703 F.2d at 1386).

King contends that there is a functional relationship between the "informing" limitation and the method. Specifically, at oral argument, King's counsel argued that the "informing" limitation increases the likelihood that the patient will take metaxalone with food, thereby increasing the efficiency of the method. *See* Oral Arg. at 7:30-8:26. This relationship, however, is not functional. Informing a patient about the benefits of a drug in no way transforms the process of taking the drug with food. Irrespective of whether the patient is informed about the benefits, the actual method, taking metaxalone with food, is the same. In other words, the "informing" limitation "in

no way depends on the [method], and the [method] does not depend on the ['informing' limitation]." *In re Nagi*, 367 F.3d at 1339 (alterations added). "It is not invention to perceive that the product which others had discovered had qualities they failed to detect." *Gen. Elec. Co. v. Jewel Incandescent Lamp Co.*, 326 U.S. 242, 249 (1945). Accordingly, we affirm the district court's finding that claim 21 is invalid, but on the alternative ground that the claim is anticipated by the prior art.

d. Claim 22

Claim 22 is closely related to claim 21. Claim 22 depends from claim 1 and limits claim 1's method to situations "wherein the metaxalone is from a container with printed labeling advising that administration with food results in an increase in the maximal plasma concentration (Cmax) and extent of absorption (AUC(last)) of metaxalone compared to administration without food." The district court, relying on this court's printed matter precedent as articulated in *In re Nagi*, found the claim anticipated by Fathie II, Albanese, and Abrams. *See King Pharms., Inc.*, 593 F. Supp. 2d at 513.

Because it depends from claim 1, the printed label limitation is claim 22's only potential source of novelty. However, as the district court correctly found, the printed label limitation falls squarely within our printed matter cases discussed above with respect to claim 21. While ostensibly a method claim, the potentially novel aspect of claim 22 concerns a printed label on a product. Like claim 21's "informing" limitation, the printed label is not functionally related to either the product within the method claim or the method claim as a whole. Therefore, the district court was correct in finding the claim anticipated. *See In re Nagi*, 367 F.3d at 1339.

King attempts to avoid *In re Nagi* by limiting that case to product claims. According to King, because claim 22 is a method claim, *In re Nagi*, which addressed a product claim, is not applicable. During our discussion of claim 21, we rejected the notion that *In re Nagi*'s holding should be limited solely to product claims. Accordingly, we reject King's argument and affirm the district court's finding that claim 22 is anticipated.

We also affirm the district court's invalidation of claims 7, 9, and 12-15 of the '102 patent, which are nearly identical to claim 22 of the '128 patent. The district court invalidated these claims for the same reasons it invalidated claim 22. On appeal, King argues claims 7, 9, and 12-15 of '102 patent are novel for the same reasons claim 22 was allegedly novel, i.e., their incorporation of a printed label limitation. For the reasons discussed above, we reject this argument and affirm the district court's invalidation of claims 7, 9, and 12-15 of '102 patent.

## II. The '102 Patent

### a. Claim 1

Claim 1 of the '102 patent is an independent claim, which claims a "method of using metaxalone in the treatment of musculoskeletal conditions" comprising both "providing the patient with a therapeutically effective amount of metaxalone" and "informing the patient that administration with food results in an increase in the maximal plasma concentration (Cmax) and extent of absorption (AUC(last)) of metaxalone compared to administration without food." The district court held the claim was invalid under § 101 for the same reasons it invalidated claim 21 of the '128 patent. *See King Pharms., Inc.*, 593 F. Supp. 2d at 514. King contends the district court erred because it failed to consider the claim as a whole.

As we discussed with respect to claim 21 of the '128 patent, we agree with King that the district court's invalidation of claim 1 under § 101 is improper because it ignored the claim as a whole and focused on one limitation. Yet, also like claim 21, claim 1's sole source of novelty is the "informing" limitation. Because this limitation is not functionally related to the otherwise anticipated method, the claim is anticipated. Accordingly, we affirm the district court's finding that claim 1 is invalid, but on the alternative ground that the claim is anticipated by the prior art.

Because we reject King's argument that claim 1's "informing" limitation is novel, we also affirm the district court's finding of invalidity as to dependent claims 2 through 4 and independent claim 8 and its dependent claims 10 and 11. For these claims, King argued on appeal that their incorporation of the "informing" limitation (claims 2-4) or their recitation of a similar limitation (claims 8, 10, and 11) made the claims novel. For the reasons discussed above, we reject King's argument and find the claims anticipated by the prior art.

b. Claim 5

Claim 5 depends from claim 1 and limits the metaxalone to a "unit dosage form." Like claim 8 of the '128 patent, the district court found claim 5 obvious over Albanese in light of Dent. *See King Pharms., Inc.*, 593 F. Supp. 2d at 514.

In addition to arguing that the "informing" limit provides the claim with novelty, King argues that the district court improperly disregarded King's evidence of secondary indicia of non-obviousness. King's secondary-considerations evidence consisted primarily of an expert report concerning sales of Skelaxin from 1998 to 2003. As the district court found, however, a significant portion of

the increase in Skelaxin sales occurred prior to the determination that ingesting metaxalone with food increases the drug's bioavailability and well before the patents issued. Moreover, King has not shown any nexus between the drug's alleged commercial success and the specific invention claimed in claim 5. *Brown & Williamson Tobacco Corp. v. Philip Morris Inc.*, 229 F.3d 1120, 1130 (Fed. Cir. 2000) ("A nexus between commercial success and the claimed features is required."). With respect to claim 5, the claimed invention is the administration of metaxalone in a tablet that constitutes a "unit dosage form." King has not shown any connection between administering metaxalone in a "unit dosage form" and the alleged commercial success.

Turning to the district court's obviousness analysis, the district court held that a prior art reference, Dent, disclosed taking metaxalone in a single 400 mg tablet four times a day. *King Pharms., Inc.*, 593 F. Supp. 2d at 511. Dent does make such a disclosure. It would be obvious to a person of ordinary skill in the art to combine Dent's teaching of taking a tablet dosage of metaxalone four times a day with Albanese's teaching of administering metaxalone with food. *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2008) ("A person of ordinary skill is also a person of ordinary creativity, not an automaton."). Accordingly, the district court's determination that claim 5 is obvious is affirmed.

## III. Jurisdiction Over Elan

In January 2003, after Eon filed an ANDA with the Food and Drug Administration ("FDA") for a generic 400 mg metaxalone tablet, it was sued by Elan for infringement of the '128 patent, the 400 mg Action. While that suit was pending, Elan entered into a sale agreement with King in which Elan transferred to King all of Elan's

rights to Skelaxin, including the '128 patent and the application that would yield the '102 patent. The sale occurred on June 12, 2003, and a month later Elan recorded a patent assignment agreement with the Patent and Trademark Office assigning both the '128 patent and the application that would lead to the '102 patent to King.

Following the sale, Elan attempted to extricate itself from the 400 mg Action by moving to (1) substitute King as a plaintiff and (2) dismiss itself from the suit. In addition to its motion, Elan represented to the district court in several letters that it no longer possessed any rights in the '128 and '102 patents and that it was willing to enter into a stipulation to that effect. While Elan's motion to substitute King as the plaintiff in the 400 mg Action was pending, King filed suit against Eon when Eon filed an ANDA with the FDA for a generic 800 mg metaxalone tablet, the 800 mg Action. In this second action, Eon filed several declaratory counterclaims against Elan, including a counterclaim of invalidity. The district court initially consolidated the 400 and 800 mg Actions, but eventually dismissed the 400 mg Action when Eon withdrew its 400 mg metaxalone ANDA. However, despite the dismissal of the 400 mg Action, the district court denied Elan's motion to substitute King as a plaintiff and dismiss Elan from the consolidated litigation. Instead, the district court dismissed various anticompetitive counterclaims Eon had asserted against Elan, but maintained Eon's various invalidity counterclaims against Elan.

Despite not being formally removed from the litigation, Elan did not participate in the merits proceedings of the litigation. Indeed, Elan did not submit briefing in conjunction with Eon's motion for summary judgment of invalidity, and Eon stated in a letter to the district court that its motion was "directed at King, not Elan." J.A.9700. Nonetheless, when issuing its final order

declaring the '128 and '102 patents invalid, the district court entered the order against both King and Elan.

On appeal, Elan argues that the district court lacked jurisdiction to enter an invalidity order against it. According to Elan, it sold all its rights to the '128 and '102 patents prior to King filing suit, and therefore the district court lacked jurisdiction to adjudicate the counterclaim.

In granting summary judgment of invalidity, the district court did not address whether it had jurisdiction over Elan. This court, however, must address the issue. *See Jenkins v. McKeithen*, 395 U.S. 411, 421 (1969) ("[S]ince the question of standing goes to this Court's jurisdiction, we must decide the issue even though the court below passed over it without comment." (citation omitted)).

Whether an actual case or controversy exists is reviewed de novo. *See Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, 540 F.3d 1353, 1359 (Fed. Cir. 2008). A case or controversy exists when "the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *MedImmune, Inc. v. Genetech, Inc.*, 549 U.S. 118, 127 (2007) (quoting *Maryland Casualty Co. v. Pacific Coal & Oil Co.*, 312 U.S. 270, 273 (1941)). Eon has the burden of demonstrating an actual case or controversy. *See Benitec Australia, Ltd. v. Nucleonics, Inc.*, 495 F.3d 1340, 1344 (Fed. Cir. 2007) ("The burden is on the party claiming declaratory judgment jurisdiction to establish that such jurisdiction existed at the time the claim for declaratory relief was filed and that it has continued since.").

Eon has not met its burden of demonstrating the existence of an actual case or controversy between it and Elan. The acquisition documents between Elan and King

demonstrate quite clearly that Elan sold all its interests in the asserted patents to King. For example, the Asset Purchase Agreement transferred "all Skelaxin Patent Rights" from Elan to King. Elan also produced the Patent Assignment agreement which unambiguously assigns "an undivided right, title, and interest in and to the Patent Rights" to King. J.A.9653-54. The "Patent Rights" include both the '128 patent and the application (U.S. Patent Application No. 10/104,044) that issued as the '102 patent.

Moreover, in a letter to the district court, Elan stated it "will waive any rights it may have, if any, separate and apart from any rights it has transferred to the new patent owners, to pursue any damages or relief from Eon . . . based on Elan's past ownership of the '128 patent." J.A.7408. Once the '102 patent issued, Elan wrote Eon's counsel and made a similar proposal concerning that patent. Elan reiterated its proposals in several pleadings before the district court and made a similar representation during oral argument, which Eon's counsel found sufficient. *See* Oral Arg. at 24:32-25:30 (representation), 25:43-25:48 (acceptance by Eon's counsel).

Elan's broad and unrestricted covenants not to sue Eon for infringement of the '102 or '128 patents, remove any case or controversy that may have existed between the parties at one point. *See Microchip Technology Inc. v. Chamberlain Group, Inc.*, 441 F.3d 936, 943 (Fed. Cir. 2006) (vacating district court's summary judgment of invalidity because the declaratory judgment plaintiff could "not identif[y] a single legal claim that it believes [the defendant] could have brought against it in the absence of [the] declaratory judgment action"); *Benitec Australia, Ltd.*, 495 F.3d at 1347-48 (finding no case or controversy where patentee withdrew its infringement claims and covenanted not to sue the defendant for future

acts). Had Elan retained the right to sue Eon in some instances, then an actual case or controversy may exist. *See Revolution Eyewear, Inc. v. Aspex Eyewear, Inc.*, 556 F.3d 1294, 1298 (Fed. Cir. 2009) (holding that covenant not to sue did not divest district court of declaratory judgment jurisdiction because the covenant did not cover future products). Elan, however, did not retain any such rights, and its covenants not to sue confirm that there is no case or controversy between it and Eon. Accordingly, we vacate the district court's order of invalidity as entered against Elan.

In summary, while the district court erred in invalidating several of the claims as unpatentable under § 101, all the claims of the '128 and '102 patents are ultimately anticipated under 35 U.S.C. § 102 or obvious under 35 U.S.C. § 103 in light of the prior art. Additionally, the district court erred in entering a judgment of invalidity against Elan because no case or controversy currently exists between Elan and Eon.[3]

**AFFIRMED and VACATED-IN-PART**

COSTS

No costs.

[3] We take no position as to whether the district court possesses jurisdiction to hear any claim by Eon against Elan for attorneys fees under 35 U.S.C. § 285.