UNITED STATES DISTRICT COURT DISTRICT OF MINNESOTA

ecoNugenics, Inc.,

Plaintiff.

v.

Case No. 17-cv-5378 (JNE/DTS) ORDER

Bioenergy Life Science, Inc., Chengzhi Life Sciences Company, Ltd., and Zhejiang Gold Kropn Biotechnology Co., Ltd.,

Defendants.

Steven B. Kelber, The Kelber Law Group, and Taylor D. Sztainer, Moss & Barnett, PA, appeared for ecoNugenics, Inc.

David P. Swenson and John A. Cotter, Larkin Hoffman Daly & Lindgren Ltd., appeared for Bioenergy Life Science, Inc.

This is an action for patent infringement brought by ecoNugenics, Inc., against Bioenergy Life Science, Inc. ("Bioenergy"), Chengzhi Life Sciences Company, Ltd. ("Chengzhi"), and Zhejiang Gold Kropn Biotechnology Co., Ltd. ("Gold Kropn"). ecoNugenics alleged that Bioenergy, Chengzhi, and Gold Kropn infringe U.S. Patent No. 6,462,029; U.S. Patent No. 7,026,302; U.S. Patent No. 7,452,871; U.S. Patent No. 8,426,567; U.S. Patent No. 9,427,449; and U.S. Patent No. 9,649,329. Bioenergy moved to dismiss ecoNugenics's claims against it for failure to state a claim upon which relief can be granted. *See* Fed. R. Civ. P. 12(b)(6). It argued that the asserted patents are invalid because they do not claim patent-eligible subject matter, *see* 35 U.S.C. § 101 (2012), and that ecoNugenics failed to plausibly plead infringement. ecoNugenics

opposed Bioenergy's motion. ecoNugenics also filed a motion for partial summary judgment, requesting a finding that the claims of the asserted patents are directed to patent-eligible subject matter. For the reasons set forth below, the Court grants Bioenergy's motion and denies ecoNugenics's motion.

I. BACKGROUND

A. ecoNugenics's complaint

A summary of ecoNugenics's complaint follows. ecoNugenics is "engaged in the manufacture, importation and sale of products for support of health and nutrition comprising, inter alia, Modified Citrus Pectin (or MCP)." (Compl. ¶ 2.) It owns the asserted patents. (*Id.* ¶¶ 2, 7-12.) "Modified Citrus Pectin . . . has been in use for many years. ecoNugenics' patents disclose its discoveries that the MCP product, typically made from citrus peels and subjected to enzymatic degradation to reduce its molecular weight, may be used to address various ailments." (*Id.* ¶ 14.) "ecoNugenics has engaged in the marketing and sale of its own MCP products. This MCP is made to exacting standards, and is sold only by ecoNugenics to customers inside and outside of the United States of America." (*Id.* ¶ 15.)

Gold Kropn manufactures MCP. (*Id.* ¶ 5.) Chengzhi buys MCP in China from Gold Kropn and imports it into the United States for sale by Bioenergy, which is wholly owned by Chengzhi. (*Id.* ¶ 3-5.) "Sales by [Bioenergy] of MCP to customers of ecoNugenics inside the United States impact not only ecoNugenics['s] sales volume and market share, but also the company's reputation." (*Id.* ¶ 16.) Bioenergy's "MCP product is of an inferior quality relative to that of ecoNugenics, but customers are often unable to

tell why the product is inferior, and so regard the products generally as inferior." (*Id.*) ecoNugenics elaborated:

Specifically, while the MCP offered by ecoNugenics, often under the mark Pecta-Sol® or Pecta-SolC®, is of a high quality offering a very narrow molecular weight distribution at about 10 kDa, the MCP offered by Gold Kropn/Chengzhi/ [Bioenergy] is not similarly refined. On comparative analysis using the same testing protocol as that used for Pecta-Sol®, results for the MCP offered by the Defendants showed their product to have a molecular weight of 24.1 kDa. The MCP product produced by Gold Kropn and advertised and sold by Chengzhi and [Bioenergy] is described on Gold Kropn's website as having a molecular weight in the range of 5000 – 22000 Da. Comparative testing by qualified laboratories confirmed that, in fact, while the sample from the Defendants might be partially de-esterified citrus pectin it is "certainly not MCP with the ability to enter mammalian circulation and bind heavy metals and galectin-3 in the blood."

 $(Id. \ \ 17.)$

"Throughout 2015, Gold Kropn indicated through public advertisement and by presentation at trade shows that it would begin to sell its MCP for the purposes recited in the claims of the ecoNugenics Patents." (*Id.* ¶ 18.) After discussions with ecoNugenics, Gold Kropn agreed not to market MCP in the United States in a manner "that would suggest the methods of use claimed in the ecoNugenics Patents. (*Id.*)

In 2016, Bioenergy's sales manager asked ecoNugenics about acquiring ecoNugenics's patent portfolio. (*Id.* ¶ 19.) At that time, Bioenergy "did not make, import, or offer for sale any MCP or any product comprising MCP." (*Id.*)

Later, Bioenergy contacted customers of ecoNugenics that had purchased MCP products. (*Id.* ¶ 20.) It advertised its MCP product, sold under the name "ZyPect," as

capable of being "administered to humans to detoxify toxins and heavy metals, provide immune support, reduce inflammation, [and] reduce fibroses." (Id. ¶ 21.) In general, Bioenergy promoted administration of its MCP product "to humans for the purposes recited in the ecoNugenics patents." (Id.)

In September 2017, Bioenergy displayed an advertisement for ZyPect at a trade show in the United States. (Id. ¶ 26.) Bioenergy promoted the product "for the therapeutic treatments claimed in the ecoNugenics[] patents." (Id.)

"MCP does not require a prescription or a Doctor's support." (Id. ¶ 27.) Individuals who have read Bioenergy's promotional material "have purchased the inferior MCP made available by [Bioenergy] and administered it to themselves for the reasons set forth: detoxification of toxins and heavy metals, enhancing immune support, reducing inflammation in patients in need of same, reducing fibrosis in patients in need of same, and the like." (Id.) The "individuals infringe the claims of the ecoNugenics[] patents with the inducement and contribution of [Bioenergy], Chengzhi, and Gold Kropn." (Id.)

Bioenergy, Chengzhi, and Gold Kropn import, offer for sale, and sell "compositions comprising MCP" with recommendations that the product be administered to individuals "to treat diseases and conditions associated with toxic metals, environmental toxins and the like," (*Id.* ¶ 28); "to treat diseases and conditions associated with poisonous metals, environmental toxins, supporting weight management to prevent obesity, and the like," (*Id.* ¶ 30); "to treat diseases and conditions associated with poisonous metals, environmental toxins, and the like," (*Id.* ¶ 32); "to treat diseases and conditions associated with an immune system in need of support, and the like," (*Id.* ¶ 34);

"for Galectin-3 modulation and to reduce inflammation in those requiring such inhibition of inflammation, and the like," (*Id.* ¶ 36); and "to modulate Galectin-3 and to inhibit formation of fibroses and reduce fibrosis in those individuals requiring inhibition or reduction of fibrosis," (*Id.* ¶ 38). Bioenergy, Chengzhi, and Gold Kropn "were made aware of their ongoing inducement to infringe, contributory infringement, and infringement" of the asserted patents and were offered the opportunity to resolve the issues of infringement "on a reasonable basis." (*Id.* ¶¶ 29, 31, 33, 35, 37, 39.)

Bioenergy, Chengzhi, and Gold Kropn declined the offer and advertised their MCP product for purposes recited in the asserted patents' claims. (*Id.*) Bioenergy, Chengzhi, and Gold Kropn "have infringed and induced infringement of the [asserted patents,] and that ongoing infringement is willful." (*Id.*)

B. The patents in suit

1. The '029 Patent, the '302 Patent, and the '871 Patent

The '302 Patent was issued from a continuation of the application that was issued as the '029 Patent. The '871 Patent was issued from a continuation of the application that was issued as the '302 Patent.

The '029 Patent, the '302 Patent, and the '871 Patent are titled "Compositions and methods for treating mammals with modified alginates and modified pectins." The abstract of the '029 Patent states:

A modified alginate and/or modified pectin composition for preventing and/or treating diseases and/or conditions caused by circulating agents such as poisonous heavy metals, environmental toxins, calcium and cholesterol, is provided. The composition includes a modified alginate having a molecular weight of no more than 40,000 daltons and/or a modified pectin having a molecular weight of no more than 40,000 daltons. The method involves orally or intravenously administering the modified alginate and/or modified pectin composition, alone or with excipients.

The abstracts of the '302 Patent and the '871 Patent add "and method" after "modified pectin composition" and are otherwise essentially the same as the '029 Patent's abstract.

The '029 Patent contains 17 claims. Claim 8 is representative of the claims that require modified pectin:

8. A method of treating or preventing poisoning in a mammal which is caused by circulation in the blood of said mammal of a poison selected from the group consisting of toxic metals, environmental toxins and mixtures thereof, comprising administering to a mammal in need of same an effective amount of modified pectin having a molecular weight of no more than 40,000 daltons, and obtained by hydrolysis or enzymatic degradation of pectin, in an amount to effectively bind said poison.

The '302 Patent contains five claims. Claim 1 is the only independent claim:

1. A method of treating a condition or disease mediated by an agent selected from the group consisting of a poisonous metal, an environmental toxin and calcium circulating in the blood, the disease or condition being selected from the group consisting of blood poisoning, arteriosclerosis, atherosclerosis, calcinosis, dermatomytosis, obesity, hypercholesterolima, and diabetes, the method comprising administering to a mammal in need of same an effective amount of alginate comprised of a mixture of polymannuronic acid with galactic linkages at the 1e-4e-diequatorial position and polyguluronic acid with glycosidic linkages at the 1e-4e-di-axial position having a molecular weight of no more than 40,000 daltons, in an amount to effectively bind said agent.

Claim 2, which depends from claim 1, recites that "said condition is metal poisoning, and said agent is a poisonous heavy metal." Claim 3, which depends from claim 2, recites a list from which "said heavy metal" is selected. Claim 4, which depends from claim 3, recites that "administration of said alginate is accompanied by administration of pectin comprised of partially esterified polymers of galacturonic acid having a molecular weight of no more than 40,000 daltons."

The '871 Patent contains four claims. Claim 1 is the sole independent claim:

1. A method of treating a condition or disease mediated by an agent selected from the group consisting of a poisonous metal, an environmental toxin and calcium circulating in the blood, the disease or condition being selected from the group consisting of blood poisoning, calcinosis, and dermatomyositis, the method comprising administering to a mammal in need of same an effective amount of pectin comprised of partially esterified polymers of galacturonic acid having a molecular weight of no more than 40,000 daltons, in an amount to effectively bind said agent.

2. The '567 Patent

The '567 Patent is titled "Method for enhancing mammalian immunological function." Its abstract states:

Low molecular weight modified pectin, particularly modified citrus pectin (MCP), and/or low molecular weight modified alginate is useful in a composition for stimulating the immune response of a mammal, particularly a human. Modified pectin and/or modified alginate is administered in a composition in an amount sufficient to modulate, support, enhance or extend an immune response, particularly to an individual having an inadequate or reduced immune function. Stimulation of an immune response is evidenced by stimulation of cell-mediated immune function, humoral immune function, phagocytic function of mononuclear macrophages, and NK cell activity. The composition also

may comprise well known pharmacologically acceptable agents, such as sulfured amino acids, cilantro, garlic, minerals, and herbs.

The '567 Patent contains 28 claims. Claim 1 is the only independent claim:

1. A method of stimulating an immune response in a mammal, comprising selecting a mammal exhibiting an inadequate or reduced immune function characterized by at least one of a cell-mediated immunity below average in said mammal, a humoral immunity below average in said mammal, phagocyte mononuclear macrophage function below average in said mammal or NK cell activity below average in said mammal, and administering to said mammal a composition comprising an agent effective to stimulate an immune response in said mammal, wherein said agent consists of a modified pectin, a modified alginate, or a combination of a modified pectin and a modified alginate, where the modified alginate or modified pectin has an average molecular weight of 40,000 daltons or less, where the modified alginate or modified pectin is present in an amount effective to stimulate an immune response in said mammal.

3. The '449 Patent and the '329 Patent

The '449 Patent was issued from a continuation-in-part of the application that was issued as the '567 Patent. The '329 Patent was issued from a continuation-in-part of the application that was issued as the '449 Patent. The '449 Patent and the '329 Patent are titled "Binding of galectin-3 by low molecular weight pectin." Each contains two claims. The claims of the '449 Patent are:

- **1.** A method of treating a mammal which benefits from a reduction in available circulating galectin-3, comprising the steps of:
- a) Selecting a mammal in need of at least one of inhibition or reduction of inflammation, and
- b) Administering to said mammal an amount of modified citrus pectin of molecular weight of 3,000-13,000 Daltons, in

an amount of 10-750 mg/kg/day, for a period of time sufficient such that said mammal exhibits a reduction in active galectin-3 levels in said mammal and thereby inhibit in said mammal said inflammation or thereby reduce it.

- **2.** A method of treating a mammal which benefits from a reduction in available galectin-3, comprising the steps of:
- a) Selecting a mammal in need of at least one of inhibition and reduction of inflammation, and
- b) administering to said mammal an amount of modified citrus pectin of low molecular weight of 10,000-20,000 Daltons, in an amount of 5-1,500 mg/kg/day, for a period of time sufficient for said mammal to exhibit a reduction in active galectin-3 levels in said mammal and thereby inhibit in said mammal said inflammation or thereby reduce it.

The claims of the '329 Patent are:

- **1.** A method of treating a mammal which benefits from a reduction in available circulating galectin-3, comprising the steps of:
- a) Selecting a mammal in need of at least one of inhibition or reduction of formation of fibroses, and
- b) Administering to said mammal an amount of modified citrus pectin of molecular weight of 3,000-13,000 Daltons, in an amount of 10-750 mg/kg/day, for a period of time sufficient such that said mammal exhibits a reduction in active galectin-3 levels in said mammal and thereby inhibit in said mammal formation of fibroses or thereby reduce formation of fibroses in said mammal.
- **2.** A method of treating a mammal which benefits from a reduction in available galectin-3, comprising the steps of:
- a) Selecting a mammal in need of at least one of inhibition or reduction of the formation of fibroses, and
- b) Administering to said mammal an amount of modified citrus pectin of low molecular weight of 10,000-20,000 Daltons, in an amount of 5-1,500 mg/kg/day, for a period of time sufficient for said mammal to exhibit a reduction in

active galectin-3 levels in said mammal and thereby inhibit in said mammal formation of fibroses or thereby reduce formation of fibroses in said mammal.

II. DISCUSSION

A. Bioenergy's motion

"To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" Ashcroft v. Igbal, 556 U.S. 662, 678 (2009) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007)). A plaintiff satisfies this requirement by "plead[ing] factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Id. "[T]he tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions. Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." Id. "When there are well-pleaded factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement to relief." *Id.* at 679. "The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Id.* at 678. "The court may consider the pleadings themselves, materials embraced by the pleadings, exhibits attached to the pleadings, and matters of public record." Mills v. City of Grand Forks, 614 F.3d 495, 498 (8th Cir. 2010). "Documents necessarily embraced by the pleadings include 'documents whose contents are alleged in a complaint and whose authenticity no party questions, but which are not physically

attached to the pleading." *Ashanti v. City of Golden Valley*, 666 F.3d 1148, 1151 (8th Cir. 2012) (quoting *Kushner v. Beverly Enters., Inc.*, 317 F.3d 820, 831 (8th Cir. 2003)).

ecoNugenics filed a single memorandum in support of its motion for partial summary judgment and its opposition to Bioenergy's motion to dismiss. Insofar as matters outside the pleadings were presented by ecoNugenics to oppose Bioenergy's motion, the Court excludes the matters outside the pleadings and considers Bioenergy's motion under Rule 12(b)(6). *See* Fed. R. Civ. P. 12(d).

1. Infringement

Bioenergy asserted that ecoNugenics failed to state a plausible claim of patent infringement. It maintained that ecoNugenics admitted that Bioenergy's MCP does not infringe and that ecoNugenics set forth no plausible claims of direct, induced, or contributory infringement.

Direct infringement

"Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent." 35 U.S.C. § 271(a) (2012). "Direct infringement under § 271(a) occurs where all steps of a claimed method are performed by or attributable to a single entity." *Nalco Co. v. Chem-Mod, LLC*, 883 F.3d 1337, 1351 (Fed. Cir. 2018) (quoting *Akamai Techs., Inc. v. Limelight Networks, Inc.*, 797 F.3d 1020, 1022 (Fed. Cir. 2015) (en banc)).

ecoNugenics failed to state a claim of direct infringement against Bioenergy.

Claim 8 of the '029 Patent, a representative claim, claims "[a] method of treating or

preventing poisoning in a mammal which is caused by circulation in the blood of said mammal of a poison . . . comprising administering to a mammal in need of same an effective amount of modified pectin . . . in an amount to effectively bind said poison." Claim 4 of the '302 Patent claims a method of treating metal poisoning mediated by a poisonous heavy metal circulating in the blood. Claim 1 of the '871 Patent claims "[a] method of treating a condition or disease mediated by an agent selected from the group consisting of a poisonous metal, an environmental toxin and calcium circulating in the blood." The method "compris[es] administering to a mammal in need of same an effective amount of pectin comprised of partially esterified polymers of galacturonic acid having a molecular weight of no more than 40,000 daltons, in an amount to effectively bind said agent." Claim 1 of the '567 Patent claims a method of stimulating an immune response in a mammal. The claims of the '449 Patent and of the '329 Patent are addressed to administering modified citrus pectin to a mammal to reduce active galectin-3 levels. As noted above, ecoNugenics alleged that "[c]omparative testing by qualified laboratories confirmed that, in fact, while the sample from the Defendants might be partially de-esterified citrus pectin it is 'certainly not MCP with the ability to enter mammalian circulation and bind heavy metals and galectin-3 in the blood." (Compl. ¶ 17.) The allegation that the sample of Bioenergy's product that was tested is not MCP with the ability to enter mammalian circulation and bind heavy metals and galectin-3 in the blood renders ecoNugenics's infringement claims implausible.

In addition, the asserted patents recite administration of modified pectin.

ecoNugenics alleged that the purchasers of Bioenergy's product administer the product to themselves:

MCP does not require a prescription or a Doctor's support. Accordingly, there is no restriction on those who have read the promotional material circulated by [Bioenergy], Chengzhi, and Gold Kropn from doing exactly as suggested. Such individuals have purchased the inferior MCP made available by [Bioenergy] and administered it to themselves for the reasons set forth: detoxification of toxins and heavy metals, enhancing immune support, reducing inflammation in patients in need of same, reducing fibrosis in patients in need of same, and the like. These individuals infringe the claims of the ecoNugenics' patents with the inducement and contribution of [Bioenergy], Chengzhi, and Gold Kropn.

The Court grants Bioenergy's motion to dismiss insofar as Bioenergy moved to dismiss ecoNugenics's claims of direct infringement against Bioenergy.

Induced infringement

"Whoever actively induces infringement of a patent shall be liable as an infringer." 35 U.S.C. § 271(b). "[D]irect infringement is a necessary predicate for a finding of induced infringement in the usual patent infringement case. It also 'must be established that the defendant possessed specific intent to encourage another's infringement and not merely that the defendant had knowledge of the acts alleged to constitute inducement.' Circumstantial evidence can support a finding of specific intent to induce infringement." *Vanda Pharm. Inc. v. W.-Ward Pharm. Int'l Ltd.*, 887 F.3d 1117, 1129 (Fed. Cir. 2018) (citations omitted). "Section 271(b), on inducement, does

not contain the 'substantial noninfringing use' restriction of section 271(c), on contributory infringement." *Sanofi v. Watson Labs. Inc.*, 875 F.3d 636, 646 (Fed. Cir. 2017).

ecoNugenics's allegation that the sample of Bioenergy's product that was tested is not MCP with the ability to enter mammalian circulation and bind heavy metals and galectin-3 in the blood renders ecoNugenics's claims of direct infringement implausible. Having failed to plausibly allege induced infringement's necessary predicate, ecoNugenics failed to plausibly allege its claims of induced infringement against Bioenergy. The Court grants Bioenergy's motion to dismiss insofar as Bioenergy moved to dismiss ecoNugenics's claims of induced infringement against Bioenergy.

Contributory infringement

"Whoever offers to sell or sells within the United States or imports into the United States a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer." 35 U.S.C. § 271(c). There can be no contributory infringement without an underlying act of direct infringement. *Nalco*, 883 F.3d at 1355. "[C]ontributory infringement requires knowledge of the patent in suit and knowledge of patent infringement.' "[C]ontributory infringement requires "only proof of a defendant's *knowledge*, not *intent*, that his activity cause[s] infringement."" *Id.* at 1356-57 (alterations in original) (citation omitted). "A

substantial noninfringing use is any use that is 'not unusual, far-fetched, illusory, impractical, occasional, aberrant, or experimental.' 'For purposes of contributory infringement, the inquiry focuses on whether the accused products can be used for purposes *other than* infringement.'" *Id.* at 1357 (citation omitted).

ecoNugenics's allegation that the sample of Bioenergy's product that was tested is not MCP with the ability to enter mammalian circulation and bind heavy metals and galectin-3 in the blood renders ecoNugenics's claims of direct infringement implausible. Having failed to plausibly allege direct infringement, ecoNugenics failed to plausibly allege its claims of contributory infringement against Bioenergy. In addition, ecoNugenics failed to plausibly allege that there are no substantial noninfringing uses of Bioenergy's product. *Cf. id.* (concluding plaintiff adequately alleged no substantial noninfringing use). ecoNugenics alleged that MCP "has been in use for many years," (Compl. ¶ 14), and Bioenergy promoted ZyPect for many uses beyond those addressed in the asserted patents. The Court grants Bioenergy's motion to dismiss insofar as Bioenergy moved to dismiss ecoNugenics's claims of contributory infringement against Bioenergy.

2. Patent-eligible subject matter

Bioenergy moved to dismiss, arguing that the asserted patents do not claim patenteligible subject matter. Having concluded that ecoNugenics failed to plausibly plead infringement claims against Bioenergy, the Court declines to address Bioenergy's assertion that the patents do not claim patent-eligible subject matter.

B. ecoNugenics's motion

ecoNugenics moved for partial summary judgment, requesting a finding that the claims of the asserted patents are directed to patent-eligible subject matter. The Court denies the motion. *See Toben v. Bridgestone Retail Operations, LLC*, 751 F.3d 888, 894 (8th Cir. 2014) ("As a general rule, summary judgment is proper 'only after the nonmovant has had adequate time for discovery."").

III. CONCLUSION

Because ecoNugenics failed to plead plausible claims of patent infringement, the Court grants Bioenergy's motion. The Court dismisses ecoNugenics's claims against Bioenergy without prejudice. *See Orr v. Clements*, 688 F.3d 463, 465 (8th Cir. 2012) ("Although there is a presumption that a dismissal under Rule 12(b)(6) is a judgment on the merits made with prejudice, such a dismissal can be rendered without prejudice if the court so specifies." (citation omitted)). The Court denies ecoNugenics's motion.

Based on the files, records, and proceedings herein, and for the reasons stated above, IT IS ORDERED THAT:

- 1. Bioenergy's motion to dismiss [Docket No. 27] is GRANTED.
- 2. ecoNugenics's motion for partial summary judgment [Docket No. 33] is DENIED.
- 3. ecoNugenics's claims against Bioenergy are DISMISSED WITHOUT PREJUDICE.

Dated: September 4, 2018

s/ Joan N. EricksenJOAN N. ERICKSENUnited States District Judge