

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

OTERRA A/S and OTERRA, LLC,)	
)	
Plaintiffs,)	
)	C. A. NO. _____
v.)	
)	
WILD FLAVORS, INC. and ARCHER- DANIELS-MIDLAND CO.,)	JURY TRIAL DEMANDED
)	
Defendants.)	
)	

COMPLAINT FOR DECLARATORY JUDGMENT

Plaintiffs Oterra A/S and Oterra, LLC (collectively “Oterra”) seek a declaratory judgment against Defendants Wild Flavors, Inc. and Archer-Daniels-Midland Co. (collectively “Wild”) of non-infringement and invalidity of U.S. Patent No. RE46,695 (“the Patent-in-Suit” or “RE’695”). Oterra alleges as follows.

NATURE OF THE ACTION

1. This is an action for declaratory judgement arising under the patent laws of the United States, Title 35 of the United States Code, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201–2202. Oterra seeks a declaratory judgment of non-infringement and invalidity of claims 45-62 of the Patent-in-Suit.

2. Oterra A/S is a global leader in the area of natural, plant-based colorants for the food and beverage industry.

3. Today more than ever, consumers seek products that contain natural ingredients from renewable sources. In view of a growing desire for foodstuffs containing alternatives to artificial chemicals, Oterra is continuously seeking new natural colorant ingredients. In its ongoing

efforts in this regard, Oterra has sought partners around the world for natural, renewable materials and colorant products.

4. One such partner is Ecoflora, SAS (“Ecoflora”), based in Sabaneta, Antioquia, Colombia. Like Oterra, Ecoflora offers natural, plant-based colorants. Ecoflora produces a blue colorant derived from juice of *Genipa americana* fruit, also known as jagua fruit. Ecoflora’s jagua blue colorant is made in Colombia.

5. On July 31, 2020, Ecoflora submitted a Petition to the U.S. Food and Drug Administration (“FDA”) (Docket No. FDA–2020–C–2131) proposing that the FDA’s color additive regulations be amended to provide for the safe use of jagua (genipin-glycine) blue in various food categories.

6. The FDA recently published notice in the Federal Register announcing that, in response to Ecoflora’s Petition, the color additive regulations are being amended to permit use of jagua (genipin-glycine) blue as a color additive in various food categories in the U.S. 88 Fed. Reg. 75,490 (Nov. 3, 2023). The FDA notice states that the rule will be effective as of December 4, 2023.

7. In connection with its ongoing efforts to provide consumers with new natural colorant ingredients, Oterra has made significant investments in resources to ensure that it can provide Ecoflora’s jagua blue colorant to its customers. At this time, Oterra is ready to begin importing Ecoflora’s jagua blue colorant, and offering for sale and selling it to customers, immediately once the FDA rule goes into effect.

8. As described in detail below, Wild has communicated to Oterra and Ecoflora on multiple occasions over an extended period of time that it believes that at least claim 45 of RE’695 may be relevant to Ecoflora’s jagua blue colorant, and that Wild intends to enforce its patent rights.

9. Through its actions and statements, Wild has created a substantial controversy of sufficient immediacy and reality to warrant the issuance of a declaratory judgment as to whether Oterra's actions will infringe any valid claim of RE'695.

10. Therefore, there is a controversy between Oterra and Wild of sufficient immediacy and reality to warrant the issuance of a declaratory judgment of noninfringement of any of claims 45-62 of RE'695 that may be found valid.

PARTIES

11. Oterra A/S is a private company organized and existing under the laws of Denmark, with its principle place of business at Agern Allé 24, 2970 Hoersholm, Denmark.

12. Oterra, LLC is a private company organized and existing under the laws of the State of Wisconsin, with its principal place of business at 9015 West Maple Street, Milwaukee, WI 53214.

13. On information and belief, Defendant Wild Flavors, Inc. is a privately held corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 1261 Pacific Avenue, Erlanger, KY 41018.

14. On information and belief, Defendant Archer-Daniels-Midland Co. is a public company organized and existing under the laws of the State of Delaware, with its principal place of business at 77 West Wacker Drive, Suite 4600, Chicago, IL 60601.

15. On information and belief, Defendant Wild Flavors, Inc. is a wholly owned subsidiary of Defendant Archer-Daniels-Midland Co.

JURISDICTION AND VENUE

16. This Court has exclusive subject matter jurisdiction over this action pursuant to federal question jurisdiction, 28 U.S.C. §§ 1331 and 1338(a), the Declaratory Judgment Act, 28 U.S.C. §§ 2201–2202, and the Patent Laws of the United States, 35 U.S.C. § 1 et seq.

17. An actual and justiciable controversy exists between Oterra and Wild as to infringement and validity of at least claims 45-62 of RE'695.

18. This Court has subject matter jurisdiction over this action based on a real and immediate controversy between Oterra and Wild regarding whether Oterra's actions importing Ecoflora's jagua blue colorant for sale in the U.S. will infringe any valid claim of RE'695.

19. This Court has personal jurisdiction over Wild because both Wild Flavors, Inc. and Archer-Daniels-Midland Co. are incorporated in and operate under the laws of Delaware.

20. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400. Venue in declaratory judgment actions for noninfringement of patents is determined under the general venue statute, 28 U.S.C. § 1391. Under 28 U.S.C. § 1391(b)(1), venue is proper in any judicial district where a defendant resides, and an entity with the capacity to sue and be sued is deemed to reside in any judicial district in which such defendant is subject to the court's personal jurisdiction with respect to the civil action in question under 28 U.S.C. § 1391(c).

STATEMENT OF FACTS

The Patent-in-Suit

21. U.S. Patent No. RE46,695, entitled "Stable Natural Color Process, Products and Use Thereof," bears an issue date of February 6, 2018. RE'695 bears a filing date of October 13, 2015, and lists Shaowen Wu, Chad Ford, and Gregory Horn as inventors. On information and

belief, RE'695 is currently assigned to Wild Flavors, Inc. A true and correct copy of RE'695 is attached hereto as Exhibit 1.

22. RE'695 is a reissue of U.S. Patent No. 8,557,319 (“the ‘319 patent”). The ‘319 patent, entitled “Stable Natural Color Process, Products and Use Thereof,” bears an issue date of October 15, 2013, and a filing date of March 6, 2009. The ‘319 patent lists Shaowen Wu, Chad Ford, and Gregory Horn as inventors. The ‘319 patent asserts a priority date of March 28, 2008. A true and correct copy of the ‘319 patent is attached hereto as Exhibit 2.

23. The ‘319 patent issued with 21 claims, of which only claim 1 was independent. Claims 1-4 of the ‘319 patent were amended during the reissue proceeding, and claims 22-64 were newly added. RE'695 issued with 3 independent claims, claims 1, 22, and 45.

24. Independent claims 1, 22, and 45 of RE'695 each recite methods “of preparing stable, natural colors,” including a step of (a) forming a mixture comprising (i) fruit or fruit juice of a plant of the Rubiaceae family, and (ii) a second component “from a suitable food-grade source.”

25. During prosecution of the ‘319 patent, in order to overcome a rejection of the method of claim 1 as unpatentable over several prior art references, the patentee amended the claim and clarified that the claimed process was different than the prior art process because the claimed process does not use “pure chemicals (including amino acids).” *See, e.g.*, Amendment dated October 19, 2011. Further emphasizing this point, the patentee explained that a “very important” distinction between the prior art and component (ii) of step (a) of the claimed methods is that “the claims of the present application do not use extract/purified materials, but rather utilize fruit juices or liquified versions of the defined food-grade sources.” A true and correct copy of the Amendment dated October 19, 2011, is attached hereto as Exhibit 3.

26. Having failed to convince the Patent Office that the prior art's use of pure amino acids as component (ii) of step (a) sufficiently distinguished the claimed methods, the patentee was forced to add a further limitation to claim 1 to require that component (ii) of step (a) is limited to "juice or liquified material made by the chemical or mechanical liquification of a solid material." *See* Amendment dated August 31, 2012. In the accompanying remarks, the patentee again emphasized that the differences between the "purified material" of the prior art and the "simple 'juice' or 'liquified material'" as claimed was "critical and very clear." A true and correct copy of the Amendment dated August 31, 2012, is attached hereto as Exhibit 4.

27. The patentee's narrowing amendment and explanation of this "critical" distinction between the prior art's use of "purified" materials, such as pure amino acids, and the claimed "simple" juices, convinced the Patent Office that the claimed methods were not the same as the prior art methods, which used pure amino acids. Thus, the patentee's arguments regarding the scope and meaning of the language defining components (i) and (ii) of step (a) in the recited method amount to prosecution disclaimer which serves to prevent the patentee from "recapturing through claim interpretation specific meanings disclaimed during prosecution." *See Omega Engr., Inc. v. Raytek Corp.*, 334 F.3d 1314, 1323 (Fed. Cir. 2003).

28. Although claim 1 of the '319 patent was amended during the reissue proceeding, the amendments to at least component (ii) of step (a) in claim 1 of RE'695 do not broaden or materially change the language of claim 1 as issued in the '319 patent.

29. The patentee did not disavow any of the amendments or arguments relied on to achieve issuance of claim 1 of the '319 patent at any time during the prosecution of the '319 patent or the subsequent reissue proceeding.

30. Claim 45 of RE'695 recites language in component (ii) of step (a) that is similar to, but broader than, that of claim 1 of the '319 patent prior to the Amendment dated August 31, 2012.

The Parties' Actions Regarding the Patent-in-Suit

31. On February 5, 2020, Archer-Daniels-Midland Co. sent a letter to David Anderson of Chr. Hansen Natural Colors A/S (the previous name of Oterra A/S), informing Mr. Anderson of, *inter alia*, RE'695. The letter stated that the patents identified “appear relevant to Ecoflora’s natural color technology” and that “Wild Flavors desires to protect its patent rights.” A true and correct copy of this letter is attached hereto as Exhibit 5.

32. On December 3, 2020, Archer-Daniels-Midland Co. sent a letter to Niels Fischer of Chr. Hansen Natural Colors A/S (the previous name of Oterra A/S), copying Ecoflora, reiterating its position that RE'695 covers a process that is relevant to Ecoflora’s FDA Petition, and stating “we plan to vigorously pursue protection of our patent claims in the US” A true and correct copy of this letter is attached hereto as Exhibit 6.

33. On February 2, 2021, Mr. Fischer responded to the December 2020 letter, explaining in a letter that the claims of RE'695 “[do] not cover what we will be doing with Ecoflora’s huito technology.” A true and correct copy of this letter is attached hereto as Exhibit 7.

34. On February 21, 2023, the law firm of Banner & Witcoff sent a letter to Ecoflora, explaining that it “represents Archer-Daniels-Midland Company (“ADM”) and its wholly owned subsidiary WILD Flavors, Inc.,” and asking Ecoflora to provide information regarding its process for making its blue colorant “to allow us to determine if Ecoflora’s activities infringe upon WILD Flavors’ patent rights, as WILD Flavors will enforce its patent rights.” A true and correct copy of this letter is attached hereto as Exhibit 8.

35. Wild's continuing assertions that RE'695 is relevant to Ecoflora's process for making its jagua blue colorant despite Oterra's assurances otherwise, and its implicit threats to file a patent infringement lawsuit, create an actual case or controversy regarding the validity and alleged infringement of RE'695. Wild's actions threaten actual and imminent injury to Oterra that can be redressed by judicial relief, and that injury is of sufficient immediacy and reality in view of the December 4, 2023, effective date of the FDA rule permitting Ecoflora's jagua blue colorant in the U.S. to warrant the issuance of a declaratory judgment. Absent a declaration of non-infringement and invalidity, Wild's continued wrongful assertions related to the alleged infringement caused by the manufacture, use, sale, offer for sale and/or importation of Ecoflora's jagua blue colorant will harm Oterra and its customers.

COUNT I

(Declaratory Judgment of Non-Infringement of Claims 45-62 of US RE46,695)

36. Oterra incorporates by reference the allegations in Paragraphs 1-35 above as though fully set forth herein.

37. An actual and justiciable controversy exists between Oterra and Wild concerning the non-infringement of claims 45-62 of RE'695.

38. Independent claim 45 of RE'695 recites a method of making "stable, natural colors" by, *inter alia*, "(a) forming a mixture comprising: (i) *Genipa americana* fruit juice . . . [and] (ii) other juice or material from a suitable food-grade source" Claims 46-62 all depend directly or indirectly from claim 45.

39. By way of example and without limiting the grounds of non-infringement that will be asserted in this action, Ecoflora's process of preparing its blue colorant, which occurs outside the U.S., does not involve a step of "(a) forming a mixture comprising: (i) *Genipa americana* fruit

juice . . . [and] (ii) other juice or material from a suitable food-grade source . . .,” as the patentee clearly and unambiguously defined those components of step (a) during prosecution of the ‘319 patent, i.e. as “simple juices” rather than “pure chemicals.” Rather, as Ecoflora’s July 31, 2020, Petition to the FDA (Docket No. FDA–2020–C–2131), which is incorporated by reference herein, confirms, Ecoflora’s jagua blue colorant uses pure glycine.

40. Therefore, Oterra seeks a declaratory judgment that its importation, offers for sale, or sales of Ecoflora’s jagua blue colorant or any product containing such colorant does not infringe claims 45-62 of RE’695 under 35 U.S.C. § 271.

41. Oterra expressly reserves the right to assert non-infringement of one or more additional claims of RE’695.

42. Oterra further expressly reserves the right to assert additional grounds of non-infringement after having the ability to conduct discovery.

COUNT II

(Declaratory Judgment of Invalidity of Claims 45-62 of US RE46,695)

43. Oterra incorporates by reference the allegations in Paragraphs 1-42 above as though fully set forth herein.

44. An actual and justiciable controversy exists between Oterra and Wild concerning the validity of claims 45-62 of RE’695.

45. Under a proper claim construction in view of the patentee’s clear and unambiguous prosecution disclaimer, Oterra’s importation, offers for sale, and/or sales of Ecoflora’s jagua blue colorant or any product containing such colorant do not infringe claims 45-62 of RE’695. However, if the patentee’s amendments and arguments during prosecution regarding the scope and meaning of the claim language defining components (i) and (ii) of step (a) were not found to be a

prosecution disclaimer limiting those components to “simple juices” rather than “pure chemicals” such as pure glycine, the prior art references the Patent Office Examiner relied on to reject then-pending claim 1 of the ‘319 patent would similarly render at least claim 45 of RE’659 invalid.

46. Therefore, by way of example and without limiting the grounds of invalidity that will be asserted in this action, if components (i) and (ii) of step (a) in claim 45 are not limited to “simple juices” but rather include “pure chemicals,” then each of claims 45-62 of RE’659 is invalid under 35 U.S.C. §§ 102 and/or 103 based on at least U.S. Patent No. 4,247,698; WO2006/082922; Butler et al., “Mechanism and Kinetics of the Crosslinking Reaction between Biopolymers Containing Primary Amine Groups and Genipin,” *Journal of Polymer Science: Part A: Polymer Chemistry*, Vol. 41, 3941-3953 (2003); and/or the knowledge of those skilled in the art.

47. By way of further example and without limiting the grounds of invalidity that will be asserted in this action, each of claims 45-62 of RE’659 is invalid under 35 U.S.C. § 112 because at least the terms “stable,” “natural colors,” “component capable of providing the desired color,” “stabilized color intensity,” “predetermined,” “blue,” and “stable natural juice-based colorant” are indefinite. The claims therefore fail to provide those skilled in the art with reasonable certainty as to their scope. *See Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 901 (2014).

48. By way of further example and without limiting the grounds of invalidity that will be asserted in this action, each of claims 45-62 of RE’659 is invalid under 35 U.S.C. § 112 because the specification fails to provide written description support for and/or enable the full scope of the claims, at least with respect to “increased -b value,” “other juice or material from a suitable food-grade source” and “amino acid.” *See Juno Therapeutics, Inc. v. Kite Pharma, Inc.*, 10 F.4th 1330, 1337 (Fed. Cir. 2021); *see also Amgen v. Sanofi*, 143 S. Ct. 1243, 1254 (2023).

49. By way of further example and without limiting the grounds of invalidity that will be asserted in this action, each of claims 45-62 of RE'659 is invalid under 35 U.S.C. § 101, because the claimed process encompasses production of “natural colors” that inherently occur in nature.

50. Therefore, Oterra seeks a declaratory judgment that claims 45-62 of RE'695 are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112.

51. Oterra expressly reserves the right to assert invalidity and/or unenforceability of one or more additional claims of RE'695.

52. Oterra further expressly reserves the right to assert additional grounds of invalidity and/or unenforceability after having the ability to conduct discovery.

JURY DEMAND

53. Pursuant to Federal Rule of Civil Procedure 38(b), Oterra demands a trial by jury of all issues so triable.

PRAYER FOR RELIEF

WHEREFORE, Oterra prays for the following judgment and relief:

A. A declaration that Oterra has not infringed, and will not infringe, either directly or indirectly, any of claims 45-62 of RE'695.

B. A declaration that claims 45-62 of RE'695 are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112.

C. An injunction against Wild and its officers, agents, servants, employees, and those persons in active concert or participation with them who receive actual notice of this judgment from directly or indirectly asserting infringement or instituting any action for infringement of the Patent-in-Suit against Oterra or any of its customers or suppliers.

D. An order declaring that Oterra is the prevailing party and that this case is an exceptional case under 35 U.S.C. § 285, and awarding Oterra its costs, expenses, and reasonable attorneys' fees under 35 U.S.C. § 285 and all other applicable statutes, rules, and common law, including the Court's inherent authority; and

E. Any other equitable and/or legal relief that the Court may deem just and proper.

Dated: December 1, 2023

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