

[BoxInterferences@uspto.gov](mailto:BoxInterferences@uspto.gov)

Tel: 571-272-9797

Filed: 2 December 2019

UNITED STATES PATENT AND TRADEMARK OFFICE

---

BEFORE THE PATENT TRIAL AND APPEAL BOARD

---

**Mirexus Biotechnologies, Inc.**

(Inventors: Anton Korenevski, Erzsebet Papp-Szabo,  
John Robert Dutcher, and Oleg Stukalov)

Junior Party  
(Patent 9,737,608),

v.

**Purdue Research Foundation**

(Inventor: Yuan Yao)

Senior Party  
(Patent Application 14/130,412).

---

Patent Interference No. 106,101 (DK)

---

**Decision on Motions**  
**37 C.F.R. § 41.125(a)**

Before SALLY GARDNER LANE, JAMES T. MOORE, and DEBORAH KATZ,  
*Administrative Patent Judges.*

KATZ, *Administrative Patent Judge.*

1 *Introduction*

2 Junior Party Mirexus Biotechnologies, Inc. (“Mirexus”) is involved in this  
3 interference based on its patent 9,737,608 (“the ’608 patent”), which issued from  
4 an application filed 26 October 2015. (*See* Declaration, Paper 1, 3.) Claims 17–29  
5 of the ’608 patent were designated as corresponding to Count 1 of the interference,  
6 whereas claims 1–16 and 30 were not. (*See id.* at 4.) Mirexus was accorded  
7 benefit of the filing date, 25 April 2014, of its prior international application when  
8 the interference was declared. (*See id.* at 5.)

9 Senior Party Purdue Research Foundation (“PRF”) is involved based on its  
10 application 14/130,412 (“the ’412 application”), which was filed 3 March 2014.  
11 (*See id.* at 3.) Claims 1–3, 46, and 48–50, all of the pending claims, of the  
12 ’412 application were designated as corresponding to Count 1 of the interference.  
13 (*See id.* at 4.) PRF was accorded benefit of the filing date, 2 August 2012, of its  
14 prior international application when the interference was declared. (*See id.* at 5.)

15 Both parties’ claims, and thus Count 1, are directed to methods of preparing  
16 phytoglycogen – a plant polysaccharide. Like glycogen, a similar polysaccharide  
17 found in animals, phytoglycogen is an energy storage molecule. (*See* ’608 patent,  
18 Ex. 2009, 1:18–27; ’412 appl.<sup>1</sup>, Ex. 1002, 1:9.) The parties report that various  
19 methods of isolating glycogen from plant material were known in the art before  
20 their inventions. (*See* ’608 patent, Ex. 2009, 1:43–47; ’412 appl., Ex. 1002, 1:19–

---

<sup>1</sup> PRF presents International Patent Application Publication WO 2013/019977, Exhibit 1002, for the ’412 application, asserting that the international application is identical to the ’412 application. (*See* PRF Exhibit List, Paper 197, description of Exhibit 1002.)

Interference 106,101

1 24.) In general, the parties' currently involved claims recite methods wherein plant  
2 material is contacted with water, the aqueous phase is separated from the solids  
3 and subjected to filtration to obtain particles that are 300 kDa or larger. (*See*  
4 Mirexus Clean Copy of Claims, Paper 7; PRF's Clean Copy of Claims, Paper 6.)

5 The parties are before us in the preliminary motions phase of the  
6 interference. Mirexus filed three motions.<sup>2</sup> In two of these motions, Mirexus  
7 argues that the interference should be terminated. One motion argues that the  
8 Office does not have jurisdiction over the '608 patent in an interference because  
9 the '608 patent is subject to the provisions of the Leahy-Smith America Invents  
10 Act ("AIA"). (*See* Mirexus Motion 2, Paper 174.) The other argues that the  
11 subject matter of the parties' claims do not interfere, as defined in 37 C.F.R.  
12 § 41.203(a). (*See* Mirexus Motion 3, Paper 175.) In addition to these motions,  
13 Mirexus filed a motion arguing that PRF's claims are not patentable under  
14 35 U.S.C. § 112, first paragraph, for lack of a sufficient written description. (*See*  
15 Mirexus Motion 4, Paper 176.)

16 PRF filed two motions.<sup>3</sup> In Motion 1, PRF argues that Mirexus claims 1–16  
17 and 30 should be designated as corresponding to the count. (PRF Motion 1,

---

<sup>2</sup> Mirexus was authorized, but chose not to file a motion arguing that it should be accorded the benefit of priority of the filing date of its provisional application 61/816,686 as a constructive reduction to practice of the count. (Mirexus Notice Regarding Motion 5, Paper 177.)

<sup>3</sup> PRF was authorized to file a motion to add one claim, copied from Mirexus's involved '608 patent claims 1–16 and 30, to its involved '412 application and to include one additional count in the interference. (*See* Order Authorizing Motions and Setting Times, Paper 18, 6:3–6.) PRF did not file this motion.

Interference 106,101

1 Paper 147.) PRF also filed a motion to be accorded benefit of the filing date  
2 (2 August 2011) of its provisional application 61/514,399 as a constructive  
3 reduction to practice of the count. (*See* PRF Motion 3, Paper 146.)

4 To support its arguments about the subject matter of the interference,  
5 Mirexus presents the declaration of Dr. Rickey Yada (Ex. 2001). Dr. Yada testifies  
6 that he is Professor and Dean, Faculty of Land and Food Systems at the University  
7 of British Columbia and has been engaged in food science research for 35 years.  
8 (*See* Declaration of Dr. Rickey Yada (“Yada Decl.”), Ex. 2001, ¶ 9.) Dr. Yada  
9 testifies further that he has conducted research in food science relating to the  
10 postharvest quality of fruits and vegetables and has authored more than 50 original  
11 peer-reviewed publications in that field, as well as reviews, books and book  
12 chapters on these and related subjects. (*See id.* at ¶ 15.) PRF does not dispute  
13 Dr. Yada’s qualifications. We find Dr. Yada to be qualified to provide opinion  
14 testimony on the subject matter of this interference.

15 PRF does not present the testimony of a witness who can provide opinions  
16 on the subject matter of the interference.

17 We first turn to Mirexus’s motion to terminate the proceeding because the  
18 parties’ claims do not interfere.<sup>4</sup> *See* 37 C.F.R. § 41.125(a) (“The Board may take  
19 up motions for decisions in any order, may grant, deny, or dismiss any motion, and  
20 may take such other action appropriate to secure the just, speedy, and inexpensive

---

<sup>4</sup> Both parties requested oral argument. (*See* Papers 208 and 209.) After review of the parties’ briefs and evidence, oral argument was not considered to be necessary. Accordingly, as is our discretion, no oral argument was held. *See* 37 C.F.R. § 41.124(c) (“If a request for oral argument is granted . . .”).

Interference 106,101

1 determination of the proceeding.”) After reviewing Mirexus’s arguments, PRF’s  
2 arguments, and the evidence each presents in support, we grant Mirexus Motion 3.  
3 Because a determination of no interference-in-fact deprives the parties of standing  
4 in the proceeding, we terminate the proceeding without deciding the parties’ other  
5 motions. *See* 37 C.F.R. § 41.201 (including no interference-in-fact as a threshold  
6 issue, wherein “[t]hreshold issue means an issue that, if resolved in favor of the  
7 movant, would deprive the opponent of standing in the interference.”).

8 *Mirexus Motion 3*

9 Under 37 C.F.R. § 41.203(a), “[a]n interference exists if the subject matter  
10 of a claim of one party would, if prior art, have anticipated or rendered obvious the  
11 subject matter of a claim of the opposing party and vice versa.” Thus, we look to  
12 the elements of the parties’ claims to determine if there is interference-in-fact  
13 between them. Mirexus argues that there is no interference because elements  
14 recited in Mirexus’s claim 17 are not anticipated or rendered obvious by PRF’s  
15 claims. (*See* Mirexus Motion 3, Paper 175.) PRF opposes this motion (*see* PRF  
16 Opp. 3, Paper 190) and Mirexus replied (*see* Mirexus Reply 3, Paper 201).

17 Mirexus claim 17 is representative and recites:

18 A method of producing monodisperse phytoglycogen nanoparticles  
19 comprising:

20 a. immersing disintegrated a phytoglycogen-containing plant material  
21 in water at a temperature between about 0 and about 50°C;

22 b. subjecting the product of step (a.) to a solid-liquid separation to  
23 obtain an aqueous extract;

24 c. passing the aqueous extract of step (b.) through a microfiltration  
25 material having a maximum average pore size of between about 0.05 and  
26 0.15 µm; and

1           d. subjecting the filtrate from step c. to ultrafiltration to remove  
2           impurities having a molecular weight of less than 300 kDa to obtain an  
3           aqueous composition comprising monodisperse phytoglycogen nanoparticle,  
4           having a polydispersity index of less than 0.3 as measured by dynamic light  
5           scattering (DLS).

6  
7 (Mirexus Clean Copy of Claims, Paper 7.)

8           PRF claim 1 is representative and recites:

9           A method for extracting soluble phytoglycogen from kernels or  
10          fractions of kernels of a maize mutant sugary-1 (su1) comprises:

- 11           (1) contacting the kernels or fractions of kernels with water;  
12           (2) separating and removing solids from the combination of kernels or  
13          fractions of kernels and water to generate a water extract containing soluble  
14          phytoglycogen;  
15           (3) subjecting the water extract containing soluble phytoglycogen to  
16          tangential flow ultrafiltration to reduce saccharide impurities having  
17          molecular weight of 300,000 Daltons (Da) or less; and  
18           (4) collecting aqueous retentate fraction of ultrafiltration that  
19          comprises at least 90% purity (dry weight base) of soluble phytoglycogen  
20          components of molecular weight above 300,000 Da.

21  
22 (PRF's Clean Copy of Claims, Paper 6 (indentations and spacing added).)

23          Mirexus argues that PRF's claims fail to teach or suggest a method for  
24          extracting phytoglycogen by, among other elements, passing an aqueous extract  
25          “through a microfiltration material having a maximum 3 average pore size of  
26          between about 0.05 and 0.15  $\mu\text{m}$ .” (Mirexus Motion 3, Paper 175, 12:1–4.)

27          Mirexus argues further that the method recited in PRF's claims fails to obtain a  
28          “monodisperse phytoglycogen nanoparticle” that has “a polydispersity index of  
29          less than 0.3 as measured by dynamic light scattering (DLS).” (*Id.* at 12:4–6.)

1 A.

2 To evaluate Mirexus's arguments, we turn to the meaning of specific terms  
3 in its claim 17. In regard to the term "monodisperse," Dr. Yada testifies that a  
4 suspension of nanoparticles is considered to be "monodisperse when it contains  
5 particles of nearly the same size forming a narrow distribution about an average  
6 value." (Yada Decl., Ex. 2001, ¶ 45, citing to Ex. 2035.) Dr. Yada testifies further  
7 that "[a] polydisperse suspension of nanoparticles contains particles of different  
8 sizes, forming a broad distribution." (Yada Decl., Ex. 2001, ¶ 45.) Dr. Yada  
9 testifies that size distribution is important because it affects bulk properties,  
10 product performance, stability, and appearance. (*See id.*, citing Ex. 2060 (abstract:  
11 "These include average particle size/diameter and the polydispersity index (PDI),  
12 which is an indication of their quality with respect to the size distribution.")  
13 According to Dr. Yada, a person of ordinary skill in the art would consider many  
14 factors in evaluating the monodispersity of a sample, including: the component(s)  
15 of the particles, whether the sample is heterogeneous or homogeneous, the  
16 molecular weight range, the particle size range, the molecular weight or particle  
17 size histograms, and the standard deviation in the particle size or molecular weight.  
18 (Yada Decl., Ex. 2001, ¶ 46.)

19 The phrase, "polydispersity index" or "PDI," highlighted by Mirexus in its  
20 claim 17, characterizes phytyglycogen preparations. (*See* '608 patent, Ex. 2009,  
21 5:20–27.) According to the '608 patent, there are two ways of calculating  
22 polydispersity. The first technique uses diameters of particles determined by  
23 dynamic light scattering ("DLS"). A PDI using DLS-determined particle  
24 diameters is defined as the square of the ratio of standard deviation (" $\sigma$ ") to mean

Interference 106,101

1 diameter (“d”), that is,  $PDI=(\sigma/d)^2$ . (*See id.* at 5:20–22.) The ’608 patent explains  
2 that a monodisperse material has a PDI close to zero. (*See id.* at 5:27–29.)

3 Mirexus claim 17 recites polydispersity using this technique, wherein the  
4 method is “to obtain an aqueous composition comprising monodisperse  
5 phytoglycogen nanoparticle, having a polydispersity index of less than 0.3 as  
6 measured by dynamic light scattering (DLS).” (*See Mirexus Clean Copy of*  
7 *Claims, Paper 7.*)

8 The ’608 patent provides another way of calculating polydispersity through  
9 distribution of the molecular weight of polymer. (*See ’608 patent, Ex. 2009, 5:23–*  
10 *27.*) This calculation is defined as the ratio of weight average molar mass (“Mw”)   
11 to the number average molar mass (“Mn”) and is referred to as the PDI\*. (*See id.*)  
12 In contrast to the evaluation of PDI measured by DLS, the ’608 patent explains that  
13 a monodisperse material evaluated by this technique has a PDI\* close to one (1.0).  
14 (*See id.* at 5:27–29.)

15 Mirexus argues that PRF’s claims do not expressly recite limitations to  
16 “monodisperse” nanoparticles or to nanoparticles “having a polydispersity index of  
17 less than 0.3 as measured by dynamic light scattering (DLS).” (*See Mirexus*  
18 *Motion 3, Paper 175, 16:15-20*) .Because the plain language of claim 17 supports  
19 this argument, we agree.

20 In opposition, though, PRF argues that these claim terms do not limit  
21 Mirexus claim 17. First, PRF argues that the term “monodisperse” and “having a  
22 polydispersity index of less than 0.3 as measured by . . . DLS” mean the same  
23 thing within the context of Mirexus claim 17. (*See PRF Opp. 3, Paper 190, 3:8–*  
24 *5:16.*) PRF cites to Table 1 of the ’608 patent, which purports to provide DLS



Interference 106,101

1 determinations for phytoglycogen nanoparticles prepared according to Example 2,  
2 a method within the scope of Mirexus claim 17. The PDI determinations of  
3 15 samples reported in Table 1 are all less than 0.3, but range from 0.053 to 0.129.  
4 None of the PDI determinations reported in Table 1 are 0.0, the value noted in the  
5 '68 patent regarding monodispersity. (*See* '608 patent, Ex. 2009, 5:27–28 (“In the  
6 first case [using DLS measurement], monodisperse material has PDI close to zero  
7 (0.0) . . . .”).) PRF notes further that the '608 patent allows for PDI values of “less  
8 than about 0.3, less than about 0.2, less than about 0.15, less than about 0.10, less  
9 than 0.07 or less than 0.05 as measured by DLS,” as being embodiments of the  
10 invention of “a composition of monodisperse nanoparticles.” (*Id.* at 5:15–33; *See*  
11 PRF Opp. 3, Paper 190, 3:13–18.)

12 According to PRF, the term “monodisperse” in Mirexus claim 17 does not  
13 mean having a PDI of 0.0, but rather allows for higher PDIs. PRF concludes that  
14 “consistent with its specification, and since the particles are not uniform . . .  
15 ‘monodisperse’ must mean a particle population with ‘a PDI of less than 0.3 as  
16 measured by DLS.’” (PRF Opp. 3, Paper 190, 3:18–20 (citations omitted).)

17 Mirexus argues that PRF is wrong because of the grammatical construction  
18 of claim 17. (*See* Mirexus Reply 3, Paper 201, 2:11–21.) According to Mirexus,  
19 the term “monodisperse” modifies the term “nanoparticle” in claim 17, whereas the  
20 term PDI modifies the term “aqueous composition.” (*See id.*) Mirexus argues that  
21 the term “monodisperse” describes other attributes of composition, including the  
22 components, or particles of interest, the homogeneity of the composition, the  
23 molecular or particle size range, and the molecular weight or size distribution  
24 histograms, but Mirexus presents no argument or evidence that the method of

Interference 106,101

1 claim 17 is limited to any of these characteristics other than PDI as measured by  
2 DLS. (*See* Mirexus Reply 3, Paper 201, 3:9–16, citing Yada Decl., Ex. 2001,  
3 ¶¶ 43–47.)

4 Even if Mirexus is correct, this argument does not explain why the terms  
5 “monodisperse” and “[PDI] less than 0.3” do not limit claim 17 to the same degree  
6 and therefore, in the context of claim 17, are not the same. Mirexus does not argue  
7 that the method of claim 17 produces phyto glycogen nanoparticles that are limited  
8 by any characteristic other than a PDI of less than 0.3. Thus, neither Mirexus’s  
9 argument nor claim 17 indicate other characteristics that define a method within  
10 the scope of the claim.

11 After considering both parties’ positions, we are persuaded that claim 17 is  
12 limited to a method of obtaining an aqueous composition comprising monodisperse  
13 nanoparticles, which in the context of claim 17 means that the nanoparticles have a  
14 PDI of less than 0.3 as determined by DLS. That is, we find that in claim 17 the  
15 term “monodisperse” is limited to nanoparticles that have a PDI of less than 0.3 as  
16 measured by DLS and not to any other determinations of polydispersity or  
17 monodispersity.

18 PRF argues further that the term limiting the PDI to less than 0.3 is not  
19 limiting because it is merely the result of the claimed method. (*See* PRF Opp. 3,  
20 Paper 190, 5:17–6:12.) PRF argues, citing *In re Woodruff*, 919 F.2d 1575, 1578  
21 (Fed. Cir. 1990), and other cases, that new benefits of old methods and the claims  
22 to a natural result that flows from a prior art method are not patentable. (*See id.* at  
23 5:18–6:5.) We agree with PRF that if the prior art discloses the very same  
24 methods, then the particular benefits must naturally flow from those methods even

Interference 106,101

1 if not recognized as benefits at the time of the patent disclosure. *See Perricone v.*  
2 *Medicis Pharm. Corp.*, 432 F.3d 1368, 1378 (Fed. Cir. 2005); *see also Bristol–*  
3 *Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1376 (Fed.Cir.2001)  
4 (explaining that newly discovered results of known processes are not patentable  
5 because those results are inherent in the known processes).

6 In the current inquiry, though, the issue presented by Mirexus Motion 3 is  
7 whether the parties' claims interfere. To make that determination, we look, in part,  
8 to whether Mirexus claim 17 would be anticipated or rendered obvious by PRF  
9 claim 1, if PRF claim 1 were prior art to it. *See* 37C.F.R. § 41.203(a). Thus, the  
10 prior art context in which we evaluate the terms of Mirexus claim 17 is PRF  
11 claim 1. Mirexus claim 17 includes a step not recited in PRF claim 1: “passing the  
12 aqueous extract of step (b.) through a microfiltration material having a maximum  
13 average pore size of between about 0.05 and 0.15  $\mu\text{m}$ .” (*See* Mirexus Clean Copy  
14 of Claims, Paper 7.) Thus, Mirexus claim 17 does not necessarily recite an “old”  
15 process within the context of an interference-in-fact inquiry. In the context of no  
16 interference-in-fact, PRF has not persuaded us that the term “having a  
17 polydispersity index of less than 0.3 as measured by dynamic light scattering  
18 (DLS)” carries no weight for our inquiry.

19 In summary, we conclude that Mirexus claim 17 is limited to a method of  
20 preparing phytoglycogen by the recited steps to produce a composition “having a  
21 polydispersity index of less than 0.3 as measured by dynamic light scattering  
22 (DLS).” We turn to the question of whether the method of PRF claim 1 is also  
23 limited by this element.

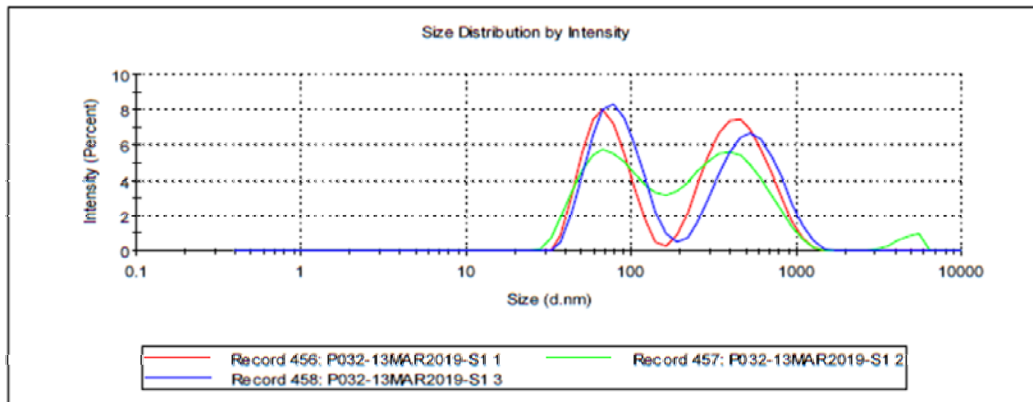
24

Interference 106,101

1 B.

2 “[A] prior art reference may anticipate without disclosing a feature of the  
3 claimed invention if that missing characteristic is necessarily present, or inherent,  
4 in the single anticipating reference.” *Schering Corp. v. Geneva Pharm.*, 339 F.3d  
5 1373, 1377 (Fed. Cir. 2003). Mirexus relies on the testimony of Dr. Yada to argue  
6 that PRF claim 1 does not produce the same composition of phytoglycogen  
7 nanoparticles as Mirexus claim 17 and, therefore, does not inherently recite the  
8 same method as Mirexus claim 17. (See Mirexus Motion 3, Paper 175, 13:5–12.)

9 Dr. Yada testifies that he performed the experiment disclosed in Example 1  
10 of PRF’s ’412 application and did not obtain a phytoglycogen nanoparticle with a  
11 PDI of less than 0.3. (See Yada Decl., Ex. 2001, ¶¶ 138–44.) Specifically,  
12 Dr. Yada refers to Exhibit 2018 for results of the procedure he used to repeat  
13 Examples 1 and 2 of PRF’s ’412 application. The graph in Exhibit 2018 is  
14 reproduced below.



15  
16 The graph is entitled “Size Distribution by Intensity,” with an x-axis labeled “Size  
17 (d.nm) and a y-axis labeled “Intensity (Percent).” The graph contains three plots,  
18 which Dr. Yada explains are three separate measurements of the final product

Interference 106,101

1 obtained from the reproduction of PRF's '412 application Examples 1 and 2. (*See*  
2 *id.* at ¶ 142.)

3 Dr. Yada testifies that the graph shows the final product “produces at least a  
4 bimodal size distribution,” with a third peak detected in one of the measurement  
5 runs. (*Id.* at ¶ 141.) Dr. Yada reports that the mean PDI from the measurements  
6 provided in Exhibit 2018 is 0.490 and the standard deviation is  $\pm 0.010$ . (*Id.* at  
7 ¶ 142.) According to Dr. Yada, one of ordinary skill in the art would have rounded  
8 the PDI measured in his experiments to 0.5 in order to consider them with one  
9 significant figure, as the claimed PDI value of “less than 0.3” is expressed. (*See*  
10 *id.*)

11 Dr. Yada concludes from his reproduction of Examples 1 and 2 of the  
12 '412 application that the final product of PRF claim 1 does not meet the limitation  
13 of “having a PDI of less than 0.3” as required in claim 17 of the Mirexus  
14 '608 patent. (*See id.*) Dr. Yada testifies that one of ordinary skill in the art would  
15 have understood that the final product of claim 1 of the '412 application is not  
16 monodisperse. (*See id.* at ¶ 143.)

17 PRF does not dispute that Dr. Yada followed the protocols provided in  
18 Examples 1 and 2 of its '412 application or that these protocols are an embodiment  
19 of its involved claim 1. Instead, PRF argues that Dr. Yada's analysis is faulty  
20 because the distribution of phytyglycogen should be “monomodal,” with a single  
21 peak, unlike the distribution of glycogen, which PRF asserts is “bimodal.” (*See*  
22 PRF Opp. 3, Paper 190:9:14–16.) PRF argues that because a phytyglycogen  
23 distribution has a single peak, and the size of phytyglycogen particles ranges from

Interference 106,101

1 50–200 nm, the “right peak” in the data presented by Dr. Yada must be starch. (*See*  
2 *id.* at 9:17–10:2.)

3 PRF argues further that even if the “right peak” in Exhibit 2018 is material  
4 other than phytoglycogen, the final product produced by Dr. Yada is encompassed  
5 by Mirexus claim 17 because the claim recites a composition “comprising”  
6 monodisperse phytoglycogen nanoparticles and therefore allows other components  
7 in the composition. (*Id.* at 10:3–4.)

8 PRF continues its argument with an analysis of PDI for the “left peak” alone.  
9 Specifically, PRF argues

10 [u]sing a left-peak average of 75 nm and a PDI of 0.3 in Mirexus’ PDI  
11 equation yields a standard deviation of just over 41 nm. That is, if at least  
12 68 percent . . . of the particle sizes are between 34 and 116 nm, then the PDI  
13 is less than 0.3. From visual observation, the left peak appears to meet that  
14 condition, and Mirexus has not suggested otherwise. It is likely that  
15 Ex. 2018 shows a composition comprising “monodisperse”/“PDI less than  
16 0.3” phytoglycogen, plus whatever the right peak is.

17  
18 (PRF Opp. 2, Paper 190, 10:5–10 (referring to page 5 of PRF Opposition 2 for the  
19 reference to 68 percent of the particle sizes in the omitted text).)

20 The references cited by Dr. Yada support PRF’s argument that a  
21 phytoglycogen distribution is a single peak. For example, Exhibit 2107 states that  
22 “[t]he molecular size distribution of liver glycogen is bimodal, with distinct  $\alpha$  and  
23  $\beta$  components, while that of phytoglycogen is monomodal.” (*See* Ex. 2107,  
24 abstract; *see* PRF Opp. 3, Paper 190, 9:14–16.) Furthermore, Dr. Yada testifies  
25 that glycogen particles have a size ranging from 50–200 nm, whereas the second  
26 (“right”) peak in the data reported by Dr. Yada is outside of that range. (*See* Yada

Interference 106,101

1 Decl., Ex. 2001, ¶ 114; *see* PRF Opp. 3, Paper 190, 9:17–10:2.) Nevertheless, PRF  
2 has not provided sufficient support for its argument about the specific data  
3 resulting from Examples 1 and 2 of the '412 application as performed by Dr. Yada.

4 Without an analysis of Dr. Yada's specific data by a witness who can testify  
5 about the understandings of those having ordinary skill in the art, we are not  
6 persuaded that Dr. Yada's analysis is incorrect. We have insufficient basis to find  
7 that one of ordinary skill in the art would have related the generalized reports cited  
8 by PRF to the specific data presented by Dr. Yada to determine that only the first  
9 ("left") peak in the figure of Exhibit 2018 is phytoglycogen. PRF fails to provide  
10 sufficient evidence, such as contrary cross-examination testimony of Dr. Yada or  
11 the testimony of another casting doubt on Dr. Yada's conclusions. PRF's  
12 arguments about how one of ordinary skill in the art would have determined the  
13 PDI of the "left peak" alone is similarly unsupported. Thus, we are not persuaded  
14 by credible evidence that Dr. Yada's conclusions about the PDI from the data  
15 reported in Exhibit 2018 are incorrect. (*See* PRF Opp. 3, Paper 190, 10:3–10.)

16 We are persuaded by Dr. Yada's testimony that the method of PRF's claim 1  
17 does not necessarily produce phytoglycogen nanoparticles with a PDI of less than  
18 0.3 as determined by DLS. We are persuaded that the method recited in PRF  
19 claim 1 is not identical to the method recited in Mirexus claim 17. Thus, whether  
20 or not the limitation to nanoparticles with a PDI less than 0.3 as determined by  
21 DLS is the natural result of the method recited in Mirexus claim 17, it highlights  
22 the difference between the parties' claims. Said another way, we are persuaded  
23 that PRF claim 1 does not anticipate Mirexus claim 17 due to the limitations

Interference 106,101

1 recited in claim 17 not recited in claim 1, for example as microfiltration through  
2 material having a maximum average pore size of between about 0.05 and 0.15  $\mu\text{m}$ .

3 C.

4 Given our finding that the method recited in PRF claim 1 does not produce  
5 phytoglycogen nanoparticles as recited in Mirexus claim 17, we turn to whether it  
6 would have been obvious to one of ordinary skill in the art to use the method of  
7 Mirexus claim 17, if the method of PRF claim 1 were prior art. *See* 37 C.F.R.  
8 § 41.203(a).

9 As discussed above, Mirexus claim 17 requires “passing the aqueous extract  
10 of step (b.) through a microfiltration material having a maximum average pore size  
11 of between about 0.05 and 0.15  $\mu\text{m}$  . . . .” (*See* Mirexus Clean Copy of Claims,  
12 Paper 7, 2.) Mirexus argues that this step would not have been obvious if PRF  
13 claim 17 were prior art. (*See* Mirexus Motion 3, Paper 175, 21:9–22:11.)  
14 Specifically, Mirexus argues that there would not have been a motivation to use a  
15 two-step filtration method and that it would not have been reasonable to expect that  
16 such a method would produce monodisperse phytoglycogen nanoparticles. (*See id.*  
17 at 21:14–20.)

18 According to Mirexus, although phytoglycogen nanoparticles had been  
19 reported in the literature before the parties’ filing dates, they were known to be  
20 polydisperse, not monodisperse. (*See id.* at 14:16–15:19, citing, e.g., Putaux,  
21 Ex. 2056; *see also* Yada Decl., Ex. 2001, ¶¶ 102-111.) Mirexus cites to  
22 publications such as Powell et al., published in 2013, which refers to the wide size  
23 distribution of particles obtained by purifying phytoglycogen. (*See* Powell,  
24 Ex. 2108, 430; *see* Mirexus Motion 3, Paper 175, 15:15–19.)



1 Mirexus argues that before 2011 there was no market demand for  
2 monodisperse phytyglycogen nanoparticles because the methods known to prepare  
3 phytyglycogen then were known to make polydisperse nanoparticles. (*See*  
4 Mirexus Motion 3, Paper 175, 16:20–17:6, citing Yada Decl., Ex. 2001, ¶¶ 54–60.)  
5 Mirexus argues that the art, and even PRF’s ’412 application, failed to recognize  
6 that monodisperse phytyglycogen particles could be produced. (*See* Mirexus  
7 Motion 3, Paper 175, 17:23–20:20.) Mirexus argues further that the art relating to  
8 production of glycogen, a similar particle, would not have motivated an ordinarily  
9 skilled artisan to develop a method to produce monodisperse phytyglycogen  
10 nanoparticles because it was known that glycogen was polydisperse. (*See* Mirexus  
11 Motion 3, Paper 175, 20:23–21:8, citing Yada Decl., Ex. 2001, ¶¶ 130-132.)

12 Mirexus argues that beyond the lack of motivation to make monodisperse  
13 phytyglycogen nanoparticles, there would have been no motivation for one of  
14 ordinary skill in the art to use a two-step filtration method. (*See* Mirexus Motion 3,  
15 Paper 175, 21:11–22:11, citing Yada Decl., Ex. 2001, ¶¶ 133–137.) Dr. Yada  
16 explains that the microfiltration step recited in Mirexus claim 17 imposes an upper  
17 boundary, removing compounds greater than the pore size of the filter (between  
18 about 0.05 and 0.15  $\mu\text{m}$ ), whereas the ultrafiltration step imposes a lower boundary  
19 and removes compounds smaller than 300 kDa. (*See* Yada Decl., Ex. 2001, ¶ 134.)  
20 According to Dr. Yada, those of ordinary skill in the art were generally aware of  
21 different techniques to separate and purify products, including chromatography,  
22 precipitation, and filtration. (*See id.* at ¶ 135.) But Dr. Yada testifies that it was  
23 also known to use other methods, such as solvents, heat adjustment, pH  
24 adjustment, or enzymatic treatment, to cause precipitation of different components.

Interference 106,101

1 (*See id.*) In Dr. Yada's opinion, there was no suggestion in the art that the method  
2 of Mirexus claim 17 would produce monodisperse phyto glycogen nanoparticles.

3 (*See id.*) Relying on this testimony, Mirexus argues that there was no indication in  
4 the art to suggest that the filtration steps of Mirexus claim 17 would provide a  
5 useful way to produce monodisperse phyto glycogen nanoparticles. (*See* Mirexus  
6 Motion 3, Paper 175, 21:23–22:2.)

7 Mirexus's argument is mostly an argument that one of ordinary skill in the  
8 art would not have had a motivation or a reasonable expectation of success in  
9 making monodisperse phyto glycogen nanoparticles. Specifically, Mirexus argues  
10 that there was no indication in the art that the use of a microfiltration step with an  
11 average pore size between about 0.05 and 0.15  $\mu\text{m}$  would produce a monodisperse  
12 product. (Mirexus Motion 3, Paper 175, 22:2–5.) In support, Dr. Yada testifies  
13 that there would not have been a reasonable expectation that a two-step filtration  
14 method would produce monodisperse phyto glycogen nanoparticles with a PDI of  
15 less than 0.3 because it was known that microfiltration eliminates molecules based  
16 only on the particle size, not the other characteristics that are uniform in a  
17 monodisperse product. (*See* Yada Decl., Ex. 2001, ¶ 136.) Dr. Yada testifies  
18 further that because the molecular weight of phyto glycogen overlaps other  
19 particles, such as amylopectin, one of ordinary skill in the art would have  
20 understood that filtration would not be able to produce monodisperse  
21 phyto glycogen nanoparticles. (*See id.* at ¶ 137.) According to Dr. Yada, one of  
22 ordinary skill would use a more refined technique, such as chromatography, to  
23 remove molecules based on the physicochemical characteristics of the molecule,  
24 rather than just size. (*See id.*) Dr. Yada testifies that one of ordinary skill in the

Interference 106,101

1 art would not have expected to be able to produce monodisperse phyto­glycogen  
2 nanoparticles using filtration. (*See id.*)

3 PRF opposes Mirexus’s argument regarding the nonobviousness of Mirexus  
4 claim 17 over PRF claim 1 on several grounds. In general, PRF argues that the  
5 filtration pore size recited in Mirexus claim 17 is not critical to preparing  
6 phyto­glycogen nanoparticles with a PDI of less than 0.3 and that the difference in  
7 the parties’ claims is merely an obvious difference in size. (*See* PRF Opp. 3,  
8 Paper 190, 12:15–18.) PRF’s argument is based, in part on the assertion that  
9 “[o]ne of ordinary skill would expect successful production of phyto­glycogen  
10 having a PDI less than 0.3 using the pore sizes recited in Mirexus’ Claim 17.  
11 Putaux [the prior art reference cited by Mirexus] demonstrated production of such  
12 phyto­glycogen using microfiltration with 46µm and 0.2 µm pores.” (*Id.* at 13:5–  
13 12; *see also id.* at 12:17–18.)

14 According to PRF, Putaux published a report of phyto­glycogen  
15 nanoparticles with a PDI less than 0.3 in 2009. (*See id.* at 6:13–7:14, citing  
16 Putaux, Ex. 2110.) Specifically, PRF relies on the report in Putaux of particles  
17 having an average diameter of 46.9 nm, with a standard deviation of 11.7, in the  
18 column entitled “Negative Staining” of Table 1. (*See* PRF Opp. 3, Paper 190, 7:3–  
19 9, citing Putaux, Ex. 2110, at 148, Table 1.) Using the definition of PDI provided  
20 in the ’608 patent, wherein  $PDI = (\sigma/d)^2$ , with  $\sigma$  being the standard deviation and  $d$   
21 being the average diameter, counsel for PRF calculates that the PDI of the particles  
22 reported in Putaux is 0.0622. (PRF Opp. 3, Paper 190, 7:5–7.) PRF performs the  
23 same calculation on the data in the column entitled “Cryo-TEM” in Table 1 of

Interference 106,101

1 Putaux, which reports an average diameter of 55.8 nm and a standard deviation of  
2 13.4 nm, to obtain a PDI of 0.0577. (*See* PRF Opp. 3, Paper 190, 7:7–9.)

3 PRF concludes from these calculations that both sets of data in Table 1 show  
4 nanoparticles with a PDI approximating 0.06, which PRF notes is well within the  
5 scope of the PDI recited in Mirexus claim 1. (*See* PRF Opp. 3, Paper 190, 7:12–  
6 14.) PRF argues further that the results in Putaux show that the concept of low  
7 PDI phytoglycogen nanoparticles was known in the prior art. (*See id.*)

8 Mirexus disputes PRF’s characterization of the data reported in Putaux,  
9 arguing that PRF uses the wrong calculations. (*See* Mirexus Reply 3, Paper 201,  
10 6:11–7:4.) Specifically, Mirexus argues that PRF’s counsel uses a DLS-based  
11 calculation with data that was not collected by DLS. (*See id.* at 6:15–16.) Mirexus  
12 argues that Putaux provides molecular weight data that would be used to determine  
13 a PDI\* value instead of the DLS-based PDI values calculated by PRF. Mirexus  
14 argues further that when the proper calculation is used, a PDI\* value of 1.64 is  
15 obtained – not the lower PDI values of approximately 0.06 asserted by PRF. (*See*  
16 *id.* at 6:18–7:3, citing Yada Decl., Ex. 2001, ¶¶ 107–108.)

17 Mirexus relies on Dr. Yada’s testimony to support its argument. (*See*  
18 Mirexus Reply 3, Paper 201, 6:18–7:3.) Dr. Yada testifies:

19 Putaux *et al.* calculated a diameter-polydispersity index by computing the  
20 mean diameters, in number,  $D_n$ , and weight,  $D_w$ . ([Putaux, Ex. 2110] at  
21 148.) The diameter polydispersity index  $D_w/D_n$  values were calculated by the  
22 authors, based on measurements of the diameters of about 1000 particles  
23 (both stained using TEM or embedded in ice using cryo-TEM), as provided  
24 by the authors in Table I. (Ex. 2110 at 148.) For the cryo-TEM results, the  
25 diameter polydispersity index is  $D_w/D_n = 65.7 \text{ nm}/55.8 \text{ nm} = 1.18$ . (*Id.*)  
26

1           However, a POSA would understand that the PDI as expressed in Putaux *et*  
2           *al.* is not directly proportional to the molecular weight distribution of the  
3           particle. In order to convert the PDI to be a reflection of the molecular  
4           weight, a POSA would convert the diameter into a volume ratio—*i.e.*,  
5            $(D_w/D_n)^3$ . The resulting PDI based on molecular weight called PDI\* in the  
6           '608 patent would be about 1.64. A POSA would thus understand that this  
7           PDI is greater than a PDI of 0.3 as measured by DLS taking into account the  
8           differing scales in the tests.

9  
10  
11           (Yada Decl., Ex. 2001, ¶¶ 107–108.) Thus, Dr. Yada testifies that the PDI\* of the  
12           phytoglycogen nanoparticles reported in Putaux would be 1.64. This PDI is higher  
13           than that determined by PRF and is not within the scope of Mirexus claim 1.

14           PRF does not cite to any support, such as the testimony of a qualified  
15           witness, for its calculations from the data in Putaux. Nor does PRF present cross-  
16           examination testimony of Dr. Yada that casts doubt on his declaration testimony.  
17           Because we find Dr. Yada qualified to testify to the knowledge of a person of  
18           ordinary skill in the art at the time when the parties' relevant applications were  
19           filed and PRF has not presented contradictory evidence, we are persuaded by  
20           Dr. Yada's testimony that Putaux does not report phytoglycogen particles within  
21           the scope of Mirexus claim 1. PRF's argument that phytoglycogen nanoparticles  
22           having a polydispersity index of less than 0.3 as measured by DLS was known in  
23           the prior art is unsupported and we are not persuaded by it. Accordingly, we are  
24           not persuaded that an ordinarily skilled artisan would have expected producing a  
25           composition of phytoglycogen of PDI less than 0.3 would be successful with  
26           microfiltration on the basis of Putaux.

Interference 106,101

1 PRF argues further that a difference in size is obvious unless it is shown to  
2 be critical, citing *In re Woodruff*, 919 F.2d 1575, 1578 (Fed. Cir. 1990). (*See* PRF  
3 Opp. 3, Paper 190, 12:7–15.) PRF asserts that “[t]he [microfiltration] pore size  
4 cited in Claim 17 is not critical to a composition comprising phytoglycogen  
5 nanoparticles, nor to preparing such particles having a PDI less than 0.3.” (*Id.* at  
6 12:15–17 and 16:13–19.)

7 PRF argues further that Putaux and its ’412 application demonstrate that  
8 particulates could be removed by several different methods, including filtration  
9 through a sieve or other microfiltration device, or by centrifugation, or both. (*See*  
10 *id.* at 12:19–23.) According to PRF, the methods used in Putaux and its  
11 ’412 application are known alternatives used for their usual purpose. Putaux  
12 argues that, thus, under *KSR Int’l Inc. v. Teleflex Inc.*, 550 U.S. 398, 416–17  
13 (2007), the microfiltration recited in Mirexus claim 17 would have been obvious.  
14 (*See* PRF Opp. 3, Paper 190, 12:23–13:2.)

15 Relying on an admission made by Mirexus, PRF argues that those of  
16 ordinary skill in the art knew that microfiltration eliminates particles larger than  
17 the size of the particles retained by the specific pore size. (*See id.* at 11:6–8, citing  
18 Yada Decl., Ex. 2001, ¶ 170.) PRF cites to Dr. Yada’s testimony that one of  
19 ordinary skill in the art would have understood that to produce a monodisperse  
20 product with a PDI of less than 0.3, one would need a product that has high purity  
21 and a narrow size distribution. (*See* PRF Opp. 3, Paper 190, 11:8–10, citing Yada  
22 Decl, Ex. 2001, ¶ 136.) PRF argues further that microfiltration was known for  
23 preparation of phytoglycogen nanoparticles, citing several exhibits. (*See* PRF Opp.  
24 3, Paper 190, 11:15–17.) For example, Putaux provides a method for preparing a

Interference 106,101

1 maize phytoglycogen suspension that includes filtering through a 0.2- $\mu\text{m}$  mesh  
2 filter. (See PRF Opp. 3, Paper 190, 11:15–19, citing Putaux, Ex. 2110, at 146,  
3 ¶ 2.1) PRF concludes that “[t]he person of skill in this art had reason to use  
4 microfiltration with a 0.15  $\mu\text{m}$  filter (or finer) for a purpose for which  
5 microfiltration at similar pore sizes has been previously used, and would expect  
6 that he or she could use it successfully.” (See PRF Opp. 3, Paper 190, 11:19–22.)

7 PRF does not cite to support for its assertion of the reasons one of ordinary  
8 skill would use microfiltration. According to PRF, “mere determination of optimal  
9 size, or change of size, is obvious” (*Id.* at 11:22–23), but there must still be a  
10 reason the skilled artisan would make such a change. As explained in *KSR Int'l*  
11 *Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007),

12 [o]ften, it will be necessary for a court to look to interrelated teachings of  
13 multiple patents; the effects of demands known to the design community or  
14 present in the marketplace; and the background knowledge possessed by a  
15 person having ordinary skill in the art, all in order to determine whether  
16 there was an apparent reason to combine the known elements in the fashion  
17 claimed by the patent at issue. To facilitate review, this analysis should be  
18 made explicit.

19  
20 PRF fails to cite a reason, supported by testimony or other evidence, why one of  
21 ordinary skill in the art would have considered it obvious to use microfiltration  
22 through a material having a maximum average pore size of between about 0.05 and  
23 0.15  $\mu\text{m}$  with the method of PRF claim 1.

24 In contrast, Mirexus offers Dr. Yada’s testimony that the techniques being  
25 used to isolate phyto-glycogen at the time maximized yield, but did not produce a  
26 monodisperse product. (See Mirexus Motion 3, Paper 175, 17:9–20, citing Yada

Interference 106,101

1 Decl., Ex. 2001, ¶¶ 54–60 and 116–118.) Mirexus argues further that it was known  
2 that conventional techniques, such as heat, pH, and enzymatic treatment degraded  
3 phytoglycogen and produced a polydisperse product and that those of ordinary skill  
4 in the art would not have been motivated to stop using these techniques, which  
5 enhance purity. (*See id.*)

6 PRF does not offer contradictory testimony or cross-examination testimony  
7 of Dr. Yada that casts doubt on testimony cited by Mirexus. Accordingly, we have  
8 no evidentiary basis on which to determine that Mirexus is wrong and PRF is right  
9 about the reason why one of ordinary skill in the art would or would not have  
10 considered it obvious to use microfiltration through a 0.05 to 0.15  $\mu\text{m}$  in the  
11 method of PRF claim 1.

12 PRF also argues that

13 [s]ince smaller-pore microfiltration would remove the same particles and  
14 others larger than phytoglycogen (Ex. 2001, e.g. ¶170) the same or better  
15 PDI result as Putaux obtained would be expected. Smaller-pore  
16 microfiltration will not generate a wider standard deviation of  
17 phytoglycogen particles. There is no basis to suggest a lack of an expectation  
18 of success using microfiltration with smaller pores than are explicitly noted  
19 in Putaux and the '412 Application.

20  
21 (PRF Opp. 3, Paper 190, 13:7–12.) PRF concludes that “a microfiltration step for  
22 the purpose of preparing phytoglycogen particles is prior art to Mirexus’ claims,  
23 and the specific pore size range in Claim 17 is not distinguishing.” (*Id.* at 13:13–  
24 16.) According to PRF, the smaller pore size recited in claim 17 would be used for  
25 the same purpose as the microfiltration step of Putaux and another prior art



Interference 106,101

1 reference, Inouchi (Ex. 1020), and would achieve the same results. (*See* PRF  
2 Opp. 3, Paper 190, 13:13–16.)

3 Even if it would be obvious that using a smaller pore-size microfiltration  
4 would generate a smaller narrower standard deviation of phytoglycogen particles,  
5 PRF fails to support its argument that one of ordinary skill in the art would have  
6 had a reason to make this modification of the method recited in Mirexus claim 17.

7 Instead, we are persuaded by the testimony of Dr. Yada that  
8 [a]s of the critical date, scientists in art were not focused on developing  
9 particular size distribution patterns of phytoglycogen. This is at least in part  
10 due to the fact that commercial applications used phytoglycogen as a food  
11 additive or in cosmetic products—neither of which would have required  
12 phytoglycogen to be produced as monodisperse nanoparticles. . . . Based  
13 up[on] my review, the prior art appears to have been more concerned with  
14 the common food industry concepts of creating phytoglycogen extracts or  
15 preparations—not on producing monodisperse nanomaterials.

16  
17 (Yada Decl., Ex. 2001, ¶ 59.) PRF does not direct us to evidence contradicting  
18 Dr. Yada’s testimony or evidence of other considerations those of ordinary skill in  
19 the art would have made. Therefore, we are not persuaded that even if the  
20 technology existed to generate a narrower standard deviation of nanoparticles, one  
21 of ordinary skill in the art would have disregarded the known methods of  
22 purification that increase polydispersity (altering temperature or pH or adding  
23 enzymes, etc.) to obtain a more monodisperse preparation.

24 After weighing the parties’ arguments and evidence in support, we conclude  
25 that Mirexus claim 17 would not have been obvious over PRF claim 1 because  
26 Dr. Yada testifies that there would not have been a reason to use microfiltration as  
27 recited in Mirexus claim 17 in the method of claim 1.

Interference 106,101

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14

*Conclusion*

Mirexus has presented evidence to meet its burden of showing that PRF claim 1 does not anticipate or render obvious Mirexus claim 17. PRF fails to present sufficient evidence to the contrary. Because none of PRF's other involved claims recite the limitation to microfiltration identified by Mirexus, we are persuaded that none of PRF's claims anticipate or render obvious any of the involved Mirexus claims. Accordingly, we grant Mirexus Motion 3.

*Order*

It is

ORDERED that Mirexus Motion 3 is GRANTED;  
FURTHER ORDERED that Mirexus Motions 2 and 4 and PRF  
Motions 1 and 3 are DISMISSED as moot; and  
FURTHER ORDERED that judgment terminating the interference  
will be entered in a separate paper to follow.

Interference 106,101

cc (via e-mail):

Attorney for Junior Party Mirexus

Steven R. Trybus  
Locke Lord LLP  
Steven.Trybus@lockelord.com  
patent@lockelord.com

Ren-How H. Harn  
JENNER & BLOCK LLP  
rharn@jenner.com

Lorelei G. Graham  
NORTON ROSE FULBRIGHT CANADA LLP  
lorelei.graham@nortonrosefulbright.com

Attorney for Senior Party PURDUE

Christopher A. Brown  
William A. McKenna  
WOODARD, EMHARDT, HENRY, REEVES & WAGNER, LLP  
cbrown@uspatent.com  
wmckenna@uspatent.com

Yonghao Hou  
PURDUE RESEARCH FOUNDATION  
yhou@prf.org