Paper 55

Filed by: Trial Section Motions Panel
Box Interference
Washington, D.C. 20231
Tel: 703-308-9797
Fax: 703-305-0942

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

VICTOR BRONSHTEIN,

Junior Party,
(Patent 5,766,520),

v.

BRUCE ROSER and ENDA MARTIN GRIBBON,

Senior Party
(Application 08/923,783).

Patent Interference 104,727 (McK)

Before: McKELVEY, Senior Administrative Patent Judge, and SCHAFER and TORCZON, Administrative Patent Judges.

McKELVEY, Senior Administrative Patent Judge.

MEMORANDUM OPINION
(Opinion supporting denial of Bronshtein Preliminary Motion 1)

A. Introduction

Bronshtein Preliminary Motion 1 (Paper 22) seeks entry of judgment of no interference-in-fact. 37 CFR § 1.633(b). If a preliminary motion for judgment of no interference-in-fact is granted, then there is no need for a priority determination because the claims of both parties are patentably distinct from

the claims of the opponent regardless of which claimed invention was made first. Case v. CPC International, Inc., 730 F.2d 745, 750, 221 USPQ 196, 200 (Fed. Cir.), cert. denied, 469 U.S. 872 (1984) (no interference-in-fact means that there is no interfering subject matter and that a patentee involved patent is no impediment to granting a patent to applicant with its involved claims).

Contingent on Bronshtein Preliminary Motion 1 being granted, Roser Preliminary Motion 1 (Paper 30) seeks to present amended claims. 37 CFR § 1.633(i).

In MEMORANDUM OPINION and ORDER entered 18 December 2001 (Paper 54), we denied, with prejudice, Bronshtein Preliminary Motion 1 and we dismissed as moot Roser Preliminary Motion 1. The following is our opinion in support of our denial of Bronshtein Preliminary Motion 1.

B. Findings of fact

The record supports the following findings by at least a preponderance of the evidence.[1]

The interference

1. The interference involves a Bronshtein patent versus a Roser application.

2. The junior party is Victor Bronshtein (**Bronshtein**).

[1] To the extent these findings of fact discuss legal issues, they may be treated as conclusions of law.

3. Bronshtein is involved in the interference on the basis of its U.S. Patent 5,766,520, granted 16 June 1998, based on application 08/785,473, filed 17 January 1997.

4. Bronshtein has been accorded benefit for the purpose of priority of provisional application 06/021,796, filed 15 July 1996.[2]

5. The real party in interest is Universal Preservation Technologies, Inc.

6. The senior party is Bruce Roser and Enda Martin Gribbon (**Roser**).

7. Roser is involved in the interference on the basis of its application 08/923,783, filed 4 September 1997.

8. Roser has been accorded benefit for the purpose of priority of application 08/486,043, filed 7 June 1996.

9. The real party in interest is Quadrant Healthcare (U.K.) Limited, a wholly owned subsidiary of Quadrant Healthcare PLC (U.K.).

10. The count of the interference reads:

Count 1

A method according to claim 1 of Bronshtein patent 5,766,520,

or

a method according to any of claims 10, 12, 47, 48, 82 or 85 of Roser application 08/923,783.

[2] It is noted that the filing date, as printed in U.S. Patent 5,766,520 (item [60]]) is 18 July 1996.

11. The claims of the parties are:

Bronshtein: 1-14

Roser: 10, 12, 37-42, 46-48, 82, 85

12. The claims of the parties which correspond to Count 1, and therefore are involved in the interference, are:

Bronshtein: 1-14[3]

Roser: 10,[4] 12, 47, 48, 82, 85

13. The claims of the parties which do not correspond to Count 1, and therefore are not involved in the interference, are:

Bronshtein: None

Roser: 37-42 and 46

The Bronshtein patent[5]

14. In the summary of the invention, Bronshtein tells us that (Ex 2002, col. 1, line 65 through col. 2, line 13; **bold** added):

> the present invention is a method of preserving sensitive biological suspensions and solutions by forming stable foams from fluid materials to be dried, as an aid both to the

[3] Bronshtein claims 1 and 3 are reproduced in Findings 20 and Finding 21, respectively.

[4] Roser claim 10 is reproduced in Finding 24.

[5] The Bronshtein patent has been admitted in evidence only to establish what is described therein, not to prove the truth of any statement made therein. See (1) 37 CFR § 1.671(b), (2) Fed. R. Evid. 105 and 802 and (3) § 41 of the STANDING ORDER applicable to this interference (Paper 2). Statements in the patent are also admitted as admissions against interest as to Bronshtein. Fed. R. Evid. 801(d)(2).

drying of one or more biologically active substrates in the fluid and as an aid in preparing an easily soluble dried product suitable for further commercial use. The stable foams are formed by partially removing water in the biologically active sample to form **a viscous liquid** and by further subjecting the reduced liquid to vacuum to cause it to "boil" during further drying at temperatures substantially lower than 100 degrees C. In other words, reduced pressure is applied to viscous solutions or suspensions of biologically active materials to cause the solution or suspension to foam during boiling, and during the foaming process further water removal causes the ultimate production of a stable open-cell or closed-cell foam.

15. Following up in the detailed description of the invention, Bronshtein further tells us that the invention (Ex 2002, col. 2, lines 21-36; **bold** added):

> is a method of preserving sensitive biological dispersions, suspensions, emulsions and solutions by forming stable foams from fluid materials to be dried, as an aid both to the drying of one or more biologically active substrates in the fluid and as an aid in preparing an easily divisible dried product suitable for further commercial use. The stable foams are formed by partially removing the water to form **a viscous liquid** and by further subjecting the reduced liquid to vacuum, to cause it to "boil" during further drying at temperatures substantially lower than 100 degrees C. In other words, reduced pressure is applied to viscous solutions or suspensions of biologically active materials to cause the solutions or suspensions to foam during boiling, and during the foaming process further

solvent removal causes the ultimate production of a stable open-cell or closed-cell foam.

16. Bronshtein goes on to state (col. 3, lines 6-12):

In an important embodiment of the invention, the foam forming process includes two steps: (a) an intensive dehydration of the solution or dispersion containing the biologically active agent by boiling under vacuum, to form a stable, non-collapsing foam and (b) subsequent secondary drying of the foams, to the extent that the foams are stable and do not collapse during storage.

17. Bronshtein further goes on to state (Ex 2002, col. 3, lines 22-24):

In the method of the invention, relatively large amounts of biologically active liquids (solutions or suspensions) are dehydrated by boiling under vacuum to form stable foams. Formation of foams is a kinetic process and depends on the rate of temperature and vacuum changes during formation of the foam as well as the initial concentration and composition of the solution or dispersion containing the biologically active substance.

18. Example 1 describes the following procedure (Ex 2002, cols. 3 and 4) (material in [brackets] and **bold** added):

EXAMPLE 1

Aqueous 50% glycerol isocitrate dehydrogenase solution from Sigma Chemical Co. containing 59.4 units of activity per ml. was dialyzed for 5 hours in 0.1M TRIS HCl buffer (pH = 7.4). The activity of the isocitrate dehydrogenase in the 0.1M TRIS HCl solution after dialysis was 26 +/- 1.8 units per ml. The activity decrease was associated with

decrease in the enzyme concentration because of dilution during the dialysis.

One hundred (100) microliters of the mixture containing 50 microliters of 50% by weight sucrose solution and 50 microliters of the isocitrate dehydrogenase suspension in 0.1M TRIS HCl buffer (pH = 7.4) was placed in 1.5 ml. plastic tubes and preserved by drying at room temperature. **First, the samples were dried 4 hours under low vacuum (hydrostatic pressure P = 0.2 atm** [150 Torr]). Second, the samples were boiled during 4 hours under high vacuum of (P < 0.01 atm [7.6 Torr]). During this step a stable dry foam was formed in the tubes. Third, the samples were stored during 8 days over DRIERITE under vacuum at room temperature.

After the days of storage, the samples were rehydrated with 500 microliters water. Rehydration of the samples containing dry foams was an easy process that was completed within several seconds. Reconstituted sample was assayed for activity by assaying ability to reduce NADP, measured spectrophotometrically at 340 nm. The reaction mix included: 2 ml. 0.1M TRIS HCl buffer, pH = 7.4; 10 microliters of 0.5% by weight NADP+; 10 microliters of 10 mM solution of $MnSO_4$; 10 microliters of 50 mM 1-isocitrate; and 10 microliters of an isocitrate dehydrogenase solution. The activity was 2.6 +/- 0.2 units/ml. which means there was no loss of activity during drying and subsequent storage at room temperature.

19. Example 2, the only other example in the Bronshtein patent, describes a process similar to that described in Example 1 (material in [brackets] and **bold** added).

EXAMPLE 2

One Hundred (100) microliters of a mixture containing 50 microliters of 50% by weight sucrose solution and 50 microliters of an ice nucleating bacteria suspension supplied by Genencor International, Inc. were placed in 1.5 ml. plastic tubes and preserved by drying at room temperature. **First, the samples were dried for 4 hours under low vacuum (hydrostatic pressure P = 0.2 atm** [150 Torr]). Second, the samples were boiled during 4 hours under high vacuum (P<0.01 atm [7.6 Torr]). After boiling under vacuum, a stable dry foam was formed in the tubes. Third, the samples were stored during 8 days over DRIERITE under vacuum at room temperature. After 8 days of storage the samples were rehydrated with 500 microliters water. Rehydration of the samples containing the dry foams was an easy process that was completed within several seconds. Then the samples were assayed for ice nucleation activity in comparison with control samples. We found that there was no significant difference between the ice nucleating activity per 1,000 bacteria in the samples preserved by the present method versus the control samples.

20. Bronshtein claim 1 reads (Ex 2002, col. 4) (indentation in original):

A method of shelf preservation of biologically active materials by drying comprising the

step of subjecting a solution, dispersion or suspension containing a biologically active agent to a vacuum corresponding to the remaining hydrostatic pressure lower than 24 Torr

sufficient to cause said solution, dispersion or suspension to boil such that said boiled solution, dispersion or suspension is dried to yield a mechanically stable foam during boiling.

21. Bronshtein claim 3 reads (Ex 2002, col. 4) (indentations, matter in [brackets] and **bold** added):

> The method according to claim 1 wherein prior to the step of subjecting said solution, dispersion or suspension to a high vacuum said solution, dispersion or suspension is dehydrated or concentrated
>
> [1] **by evaporation from liquid state at a low vacuum corresponding to the remaining hydrostatic pressure higher than 7.6 Torr** or
>
> [2] by evaporation from partially frozen state or
>
> [3] by concentration by reverse osmosis or other membrane technologies
>
> to reduce the time during which said high vacuum must be applied and to increase the viscosity of said solution, dispersion or suspension before boiling under high vacuum.[6]

The Roser application[7]

22. According to the Roser application (Ex 2004) (material in [brackets] added):

> The present invention encompasses methods of producing dried foamed glass matrices (FGMs). [Page 3, lines 31-32.]
>
> * * *
>
> [O]ne aspect of the invention is methods for producing FGMs, comprising preparing a mixture comprising at least one glass matrix-forming material in at least one solvent, evaporating bulk solvent from the mixture to obtain a syrup,

[6] While it is not an issue before us, it is not apparent to us where alternatives [2] or [3] are described in the descriptive portion of the Bronshtein patent.

[7] As in the case of the Bronshtein patent, the Roser application has been admitted in evidence only to show what is described therein and not to prove the truth of statements made therein. Statements in the application are also admitted as admissions against interest as to Roser. See n.5, supra.

exposing the syrup to a pressure and temperature sufficient to cause boiling of the syrup, and optionally removing residual moisture. [Page 4, lines 3-10; see also page 7, lines 14-20.]

* * *

In the primary drying step, the solvent is evaporated to obtain a syrup. Typically, a "syrup" is defined as a solution with a viscosity in the region of 10^6 - 10^7 Pascal seconds. The syrup is not defined as a fixed concentration, but is a result of the bulk of the solvent evaporating from the mixture. Typically, a syrup is a viscous mixture containing the glass matrix-forming material and/or additives and/or substances, in a significantly higher concentration than that of the initial mixture. The evaporation step may remove 5-95% of the solvent.[8] Typically, the evaporation step is conducted under conditions sufficient to remove about 20% to 90% of the solvent to obtain a syrup. The temperature can be about 0°C to 80°C, or about 15°C to 60°C, or about 25°C to 45°C.[9] The viscosity of the syrup is preferably such that when the syrup boils, evaporation from the increased surface area, provided by extensive bubble formation, results in its vitrification. [Page 17, lines 8-23.]

* * *

The initial drying step [, i.e., the primary drying step,] can be performed under pressure less than ambient. Preferably, the pressure is 0.1 to 30 Torr/mm Hg. Even more preferably, the pressure is 5 to 20 Torr/mm Hg. Most

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[8] The sentence was added to the specification in an amendment filed 20 November 1996 (Ex 1010, page 2, Amendment entry A^1). The examiner entered the amendment. Bronshtein has not maintained that the amendment adds "new matter" (35 U.S.C. § 132).

[9] The sentence was added to the specification in an amendment filed 20 November 1996 (Ex 1010, page 2, Amendment entry A^2). The examiner entered the amendment. Bronshtein has not maintained that the amendment adds "new matter" (35 U.S.C. § 132).

preferably, the pressure is 7.5 to 12.5 Torr/mm Hg and the external temperature is 40°C. [Page 18, lines 9-14.]

* * *

The syrup obtained from the primary drying step is exposed to a reduced pressure to effect boiling of the syrup. As used *** [in the Roser application], "boiling" is defined as the point at which the vapor pressure of the mixture is equal to or exceeds the external pressure to which the sample is exposed. Boiling is evidenced visually by bubbling as the solvent and/or other volatile components rapidly vaporize. [Page 18, line 33 through page 19, line 5.]

23. Example 3a (Ex 2004, page 25) is typical of one method described in the Roser application (material in [brackets] added; underscoring in original):

[**Example 3a**]

3a. Formation from solution of glass matrix-forming material plus additive

Aliquots of 1 ml or 500 l of 25%(w/v) trehalose containing either 0.25 or 0.5 M ammonium bicarbonate, were dried in 10 ml pharmaceutical vials in the FTS drier.[10] The 1 ml samples were dried at a constant vacuum pressure of 0.03 Torr/mm Hg for 14 hrs, with shelf temperature initially 25°C, raised to 45°C after the first 2 hours (i.e., syrup formed). The 500 l samples were dried at a constant shelf temperature of 25°C and a constant vacuum pressure of 0.01 Torr/mm Hg for 14 hr. The FGMs formed (Fig. 2A) occupied larger volumes than identical samples processed by freeze-drying (Fig. 2B).

[10] FTS is described (Ex 2004, page 20, lines 4-7) as the FTS Systems Inc. (Stone Ridge, New York) Model TDS 00078-A with a VP-62P vacuum pump and a FD-00057-A condenser module.

24. Roser independent claim 1 reads (indentation in original and **bold** added):

> A method for producing foamed glass matrices (FGMs) containing a biologically active agent comprising the steps of:
>
> (a) preparing an initial mixture comprising at least one glass matrix-forming material containing a biologically active agent selected from the group consisting of a therapeutic agent, a prophylactic agent, a pharmaceutically effective substance and a diagnostic reagent, and an organic solvent(s) for the glass-matrix forming material;
>
> (b) **evaporating a portion of the solvent(s) from the mixture to obtain a syrup;**
>
> (c) boiling the syrup under less than atmospheric pressure to produce foaming of the syrup; and
>
> (d) continuing step (c) until the boiling results in the formation of a solid foam and produces a foamed glass matrix containing the biologically active agent.

Bronshtein Preliminary Motion 1

25. In Bronshtein Preliminary Motion 1, Bronshtein asserts that "[a]through numerous patentable distinctions between the Roser claims and Bronshtein claims exist, this Preliminary Motion focuses only on step (b) of Roser ***." Thus, as a matter litigation strategy, Bronshtein bottoms its no interference-in-fact position on the proposition that step (b) in Roser claim 10 means that Roser claim 10 defines an invention which is separately patentable from all Bronshtein claims, including Bronshtein claim 3. In its opposition (Paper 35, page 15), Roser notes that "Bronshtein Motion 1 only focuses on one element [sic-

limitation] of Roser's claims." We therefore have no occasion to consider other "distinctions" which Bronshtein may believe exist between Roser claim 10 and Bronshtein claim 3.

26. An interesting feature of Bronshtein Preliminary Motion 1 is that, contingent on the motion being granted, Bronshtein will disclaim Bronshtein claim 3.

Roser opposition

27. In its opposition (Paper 35), Roser makes the following observations (material in [brackets] added):

> Roser submits that evaporation is inherent in the method claimed by both parties even though Bronshtein's claims do not specifically recite evaporation. Both parties are claiming a patentably indistinct process and each set of claims-in-interference anticipates the other or, in the alternative, is [sic--would have been] obvious over the other. [Paper 35, page 1.]
>
> * * *
>
> Unfortunately for Bronshtein, the laws of physics make it impossible for Bronshtein's and Roser's claimed method to be carried out without evaporation to form a syrup. [Paper 35, page 15.]

Bronshtein's reply

28. In its reply (Paper 39), Bronshtein maintains (page 3, ¶ 11): that [t]he Bronshtein method does not necessarily evaporate to obtain a syrup at or below boiling point."

The "expert" testimony

29. Both parties called "expert" witnesses.

30. Bronshtein did not rely on any expert in filing Bronshtein Preliminary Motion 1.

31. In its opposition (Paper 35), Roser relies on the declaration testimony of Dr. Geoffrey Lee (Ex 1014). Dr. Lee was cross-examined in London, England (Ex 2022, page 1). Senior Administrative Patent Judge McKelvey presided over Dr. Lee's cross-examination via teleconference (Ex 2022, pages 5 and 126).

32. In its reply (Paper 39), Bronshtein relies on the declaration testimony of Dr. Vijay Dhir (Ex 2023). Dr. Dhir was cross-examined in Newport Beach, California (Ex 2023, page 3). Senior Administrative Patent Judge McKelvey presided over Dr. Dhir's cross-examination via teleconference.

Dr. Lee's testimony

33. Roser qualified Dr. Lee as an expert on the use of vacuum drying to produce stable biological materials embedded in glasses (Ex 1014, ¶ 3, last sentence).

34. In Dr. Lee's opinion, a solution of the type described by Bronshtein and Roser, "must pass through a 'highly viscous' state ('syrup') on vacuum drying, otherwise it would be impossible for it to become a glass" (Ex 1014, ¶ 11, page 7).

35. According to Dr. Lee (Ex 1014, ¶ 14, page 8):

> Roser describes his drying process in a way that appears to recite two distinct steps: first, formation of a syrup below the solution's boiling point, and second, boiling of the syrup under less than atmospheric pressure.

36. Further according to Dr. Lee (Ex 1014, ¶14, page 8) (material in [brackets] in original):

> Bronshtein describes his invention as a drying process in which the solution is dried by "partially removing the water to form a viscous liquid [evidently below the boiling point] and by further subjecting the reduced liquid to vacuum, to cause it to boil [evidently at the boiling point]."

37. Dr. Lee understands the Roser specification as follows (Ex 1014, ¶ 17, page 10):

> The [Roser] specification describes a continuous process of direct vacuum drying via evaporation. The solution is held under vacuum (0.1 to 30 Torr) to effect evaporation of the liquid. This [evaporation] leads to an increase in concentration of the dissolved material and a simultaneous increase in the viscosity of the solution until it has the appearance of a "syrup." Continued application of the same vacuum eventually causes the product temperature to reach its boiling point corresponding to the applied vacuum pressure and temperature. This [reaching the boiling point] occurs because "the reduced mobility of water molecules through the viscous syrup reduces the rate of evaporative cooling.

38. Dr. Lee understands the Bronshtein specification as follows (Ex 1014, ¶ 22, page 13) (underscore in original):

> In his specification, Bronshtein describes his invention of removal of water to form a foam as follows: "the stable foams are formed <u>by partially removing the water to form a viscous liquid and by further subjecting the reduced liquid to vacuum</u>, to cause it to boil during further drying at temperatures substantially lower than 100 degrees C."

* * *

> Elsewhere, the Bronshtein patent further states in identical terms how water is removed from suspensions and solutions of biologically active materials: "[t]he stable foams are formed by partially removing water in the biologically active sample to form a viscous liquid and by further subjecting the reduced liquid to vacuum to cause it to boil during further drying at temperatures substantially lower than 100 degrees C."

39. According to Dr. Lee (Ex 1014, ¶23, page 13) (citations to the Bronshtein patent omitted):

> Bronshtein does not disclose any methods lacking evaporation and syrup formation steps prior to boiling. The two illustrative examples in Bronshtein confirm that *** [i]n both, a solution is first dried for 4 hours under low vacuum (0.2 atm, equivalent to 152 Torr), after which time the vacuum pressure is lowered to 0.01 atm (equivalent to 7.6 Torr), to cause boiling. ***. Initially, under low vacuum the solution does not boil, but progressively loses solvent via evaporation "to form a viscous liquid ***. The subsequent high vacuum causes the viscous liquid "to boil" ***.

Dr. Dhir's testimony

40. Bronshtein qualified Dr. Dhir as an expert on physicochemical differences between evaporation and boiling (Ex 2023, ¶ 2, last sentence).

41. Most of Dr. Dhir's declaration testimony, and for that matter his cross-examination, deals with (1) the theoretical thermodynamics and other subtleties of evaporation and boiling

and (2) taking on Dr. Lee's qualifications to give opinions about evaporation and boiling.

42. During Dr. Lee's cross-examination a boiling curve was discussed (Ex 2022, 28:13-46:10). Its significance, if any, to the issues in this case is not entirely clear. In any event, Dr. Dhir notes (Ex 2023, ¶ 8, pages 5-6):

> Based on Dr. Lee's gross misinterpretation and obvious unfamiliarity with the boiling curve (Ex 2022, pgs. 28-43), an understanding of which is essential to a rigorous scientific appreciation of the thermodynamics of boiling, it is my opinion that Dr. Lee lacks the necessary expertise to provide any credible opinion regarding the physico-chemical properties of boiling.

43. Dr. Dhir goes on to identify "four specific examples of Dr. Lee's alleged inaccurate and alleged erroneous interpretations of the boiling curve (Ex 2023, ¶ 8, pages 6-7).

44. Dr. Dhir testified (Ex 2023, ¶ 18, page 9):

> Roser's contention that Bronshtein's method necessarily requires formation of a syrup prior to boiling is incorrect because Bronshtein's claimed method may be carried out by dissolving solutes in a solvent before boiling.[11]

45. Without stating the underlying basis therefor, Dr. Dhir further testified (Ex 2023, ¶ 21, page 10):

[11] It is not apparent, and we have not been told, where the Bronshtein describes or otherwise discusses the option mentioned by Dr. Dhir.

There are many solutions of biologically active salts and dispersions or suspension of viruses or cells that will not form a syrup during evaporation or boiling.[12]

Resolution of conflicting testimony

46. To the extent there is a conflict between the testimony of Dr. Lee and Dr. Dhir on technical factual issues in dispute which we find necessary to resolve in deciding Bronshtein Preliminary Motion 1, we credit the testimony of Dr. Lee and accord it more weight.[13]

47. Dr. Lee is familiar with the art (i.e., the field of the invention,) involved, whereas Dr. Dhir does not claim to be familiar with that art.

48. A review of their respective cross-examination transcripts will reveal that Roser's witness Dr. Lee demeanor was one of attempting to answer in a forthright manner questions

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[12] In this respect, attention is directed to § 42 of the STANDING ORDER (Paper 2) applicable to this interference:

> Affidavits expressing an opinion of an expert must disclose the underlying facts or data upon which the opinion is based. See Fed. R. Evid. 705 and 37 CFR §§ 1.639(b) and 1.671(b).
>
> Opinions expressed without disclosing the underlying facts or data may be given little, or no, weight. See Rohm and Haas Co. v. Brotech Corp., 127 F.3d 1089, 1092, 44 USPQ2d 1459, 1462 (Fed. Cir. 1997) (nothing in the Federal Rules of Evidence or Federal Circuit jurisprudence requires the fact finder to credit the unsupported assertions of an expert witness).

[13] In re Inland Steel Co., 265 F.3d 1354, 1366, 60 USPQ2d 1396, 1405-06 (Fed. Cir. 2001) (board is given broad deference in its weighing of the evidence before it). We have weighed and credited conflicting testimony in the same sense as Semiconductor Energy Laboratory Co. v. Samsung Electronics Co., 4 F.Supp.2d 477, 483 n.8, 46 USPQ2d 1874, 1879 n.8 (E.D. Va. 1998) ("In this regard, and indeed generally, the Court credits the testimony of Samsung's witnesses Dr. Fonash, Dr. Tsai, and Dr. Meyerson over SEL's witnesses Dr. Lucovsky and Dr. Yamazaki whenever there is a conflict."), aff'd, 204 F.3d 1368, 1376, 54 USPQ2d 1001, 1006 (Fed. Cir. 2000) ("As a generally matter, we first note that the district court found Dr. Yamazaki and SEL's other witnesses to be not credible. Instead, the district court credited the testimony of Samsung's witnesses over that of SEL's whenever there was a conflict.").

asked, whereas Bronshtein's witnesses Dr. Dhir often avoided straightforwardly answering cross-examination questions.

49. Moreover, in our judgment, Dr. Lee's testimony on conflicting factual issues we address and resolve in this opinion is more consistent with, and more solidly bottomed on, the Roser and Bronshtein specifications than the corresponding testimony of Dr. Dhir.[14]

C. Discussion

1. The issue

a.

An interference is not declared, unless at the time the interference is declared, the Director, through the board on recommendation of a primary examiner, is of the opinion that a pending application "would interfere" with another pending application or an unexpired patent. 35 U.S.C. § 135(a); 37 CFR § 1.610(a).

In the opinion of the board, an application interferes with an unexpired patent when both the application and patent have claims which are directed to the same patentable invention within the meaning of 37 CFR § 1.601(n). The notice declaring interference is an interlocutory order presumed to be correct. 37 CFR § 1.655(a). Accordingly, when an interference is declared, a presumption is created that there is an interference-

[14] To the extent Bronshtein believes it is an issue, we expressly reject any notion that Dr. Lee is not an objective expert, i.e, that he is biased, based on his cross-examination which revealed as he has previously served as an expert for Roser's assignee (2022, 17:4-21:4).

in-fact between at least one claim of the application and at least one claim of the patent. 37 CFR § 1.601(j).

A party in an interference seeking to overcome the presumption of the existence of an interference-in-fact may file a preliminary motion for judgment of no interference-in-fact. 37 CFR § 1.633(b), The party filing the preliminary motion has the burden of showing that it is entitled to the relief sought in the preliminary motion. 37 CFR § 1.637(a); see also Case v. CPC International, Inc., 730 F.2d 745, 750, 221 USPQ 196, 200 (Fed. Cir.), cert. denied, 469 U.S. 872 (1984) (burden is on the party who contends that there is no interference-in-fact). The burden in a case where the application and patent are "copending" is by a preponderance of the evidence. Cf. Bruning v. Hirose, 161 F.3d 681, 685, 48 USPQ2d 1934, 1937-38 (Fed. Cir. 1998) (the burden of proof on the issue of patentability of the claims of a patent in an interference where applications are copending is by a preponderance of the evidence).

One way for a party to establish that there is no interference-in-fact between any of its claims and any of its opponent's claims, is to establish that the subject matter of its claims (which, for purpose of ruling on the motion, are presumed to be prior art) do not anticipate or render obvious the subject matter of any claim of its opponent which have been designated as corresponding to the count.

b.

Based on the principles set out above, it becomes manifest that the issue before the panel is whether Bronshtein has sustained its burden of establishing by a preponderance of the evidence that there is no interference-in-fact between any Bronshtein claim corresponding to the count and any Roser claim corresponding to the count.

Specifically, the issue is whether Bronshtein has established that the subject matter of Roser claim 10 is anticipated or rendered obvious by the subject matter of Bronshtein claims 1 or 3. By virtue of Bronshtein's litigation position, the issue narrows considerably to whether step (b) in Roser claim 10 is a limitation which is not anticipated or rendered obvious by the subject matter of any Bronshtein claim, including Bronshtein 3, assuming the subject matter of the Bronshtein claims to be prior art to Roser.[15]

c.

As part of the debate between the parties, an issue has surfaced of whether the process claimed by Bronshtein inherently includes "evaporating a portion of the solvent(s) from the mixture to obtain a syrup", i.e., step (b) in Roser claim 10.

Bronstein maintains that his claimed process does not inherently include Roser's step (b) and Roser seems to maintain otherwise.

[15] The parties do not seem to question that the subject matter of Roser claim 1 would anticipate the subject matter of Bronshtein claim 1.

To the extent it is an issue in need of resolution, it was Bronshtein's burden to make out a prima facie case that its claimed method does not inherently perform Roser step (b) because Bronshtein has the burden of showing that the subject matter of its claims does not anticipate the subject matter of any Roser claim. 37 CFR § 1.637(a).

d.

In an attempt to help us understand the scope of Bronshtein claims 1 and 3 and Roser claim 10, both parties offered the testimony of expert witnesses. We have considered the testimony. Nevertheless, construction of the meaning and scope of a claim is an issue of law. See Markman v. Westview Instruments, Inc., 517 U.S. 370, 391, 116 S.Ct. 1384, 1396 (1996) (we hold that interpretation of the word "inventory" [in a patent claim] in this case is an issue for the judge, not the jury ***.") and Kraft Foods Inc. v. International Trading Co., 203 F.3d 1362, 1366, 53 USPQ2d 1814, 1817 (Fed. Cir. 2000), which notes:

> Claim construction is a question of law. In interpreting language in a claim, one should look first to the intrinsic evidence of record, i.e., the patent itself, including the claims, the specification and, if in evidence, the prosecution history. Within this intrinsic evidence, the appropriate starting point is always the language of the claim itself. A claim term should be given its ordinary meaning unless the specification or prosecution history provide a special, different meaning or definition. There is a heavy presumption in favor of the ordinary meaning of claim

language. Any special definition given to a word must be clearly defined in the specification.

We want all to know that we have considered that testimony in light of the principles announced in Markman and Kraft Foods and other post-Markman precedent of the Federal Circuit. In essence, we have given weight to the "expert" testimony only to extent it helps us understand factual issues of a technical nature. As noted earlier, to the extent there is a conflict, we credit the testimony of Dr. Lee.

2. Scope of Bronshtein claims 1 and 3

Resolution of the interference-in-fact issue turns largely on the scope and meaning of Bronshtein claims 1 and 3.

Bronshtein claim 3 is a dependent claim which sets out three alternative process steps to be incorporated into the process of Bronshtein claim 1. We believe it useful to re-write Bronshtein dependent claim 3 in independent form limited to the first of the three alternative steps[16] set out in Bronshtein claim 3 (indentation and material in [brackets] added; material in ~~strikeout~~ deleted).

Bronshtein claim 3 rewritten in independent form

A method of shelf preservation of biologically active materials by drying comprising the ~~step~~ [steps] of

[1] subjecting a solution, dispersion or suspension containing a biologically active agent to dehydration or concentration by

[16] See Finding 21, alternative [1].

evaporating from liquid state at a low vacuum corresponding to the hydrostatic pressure higher than 7.6 Torr

[i] to reduce the time during which ~~said~~ [a] high vacuum [as set out in step [2]] must be applied and

[ii] to increase the viscosity of said solution, dispersion or suspension before boiling under high vacuum [as set out in step [2] and thereafter]

[2] subjecting ~~a~~ [the] solution, dispersion or suspension [of step [1]] to a vacuum corresponding to the remaining hydrostatic pressure lower than 24 Torr sufficient to cause said solution, dispersion or suspension [of step [1]] to boil such that said boiled solution, dispersion or suspension [of step [2]] is dried to yield a mechanically stable foam during boiling.

3. Anticipation

To establish anticipation, a moving party must show that a prior art reference discloses every limitation of the claimed invention, either explicitly or inherently. Atlas Powder Co. v. IRECO Inc., 190 F.3d 1342, 1346, 51 USPQ2d 1943, 1945-46 (Fed. Cir. 1999); In re Schreiber, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997). Accordingly, for Bronshtein to establish that the subject matter of its claims 1 and 3 does not anticipate the subject matter of Roser claim 10, Bronshtein must show that

the subject matter of its claims 1 and 3 does not disclose every limitation of Roser claim 10, either explicitly or inherently.

Inherency is a question of fact. In re Schreiber, supra, In re Fracalossi, 681 F.2d 792, 794, 215 USPQ 569, 571 (CCPA 1982). To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill; inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient. See Continental Can Co. v. Monsanto Co., 948 F.2d 1264, 1268-69, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991).

Dr. Lee is of the opinion, as a matter of technical fact, that a solution of the type described by Bronshtein and Roser, "must pass through a 'highly viscous' state ('syrup') on vacuum drying, otherwise it would be impossible for it to become a glass" (Finding 34; Ex 1014, ¶ 11, page 7). There was an attempt to undermine Dr. Lee's opinion during cross-examination. According to Bronshtein (Paper 39, pages 3, ¶ 11) (underscore and bold in original; italics added):

> The Bronshtein method does not necessarily evaporate to obtain a syrup at or below the boiling point. Instead, samples *may be* subjected to "a vacuum ... sufficient to cause said solution, dispersion or suspension to immediately boil ... [i.e., **above** the boiling point]". Dr. Lee admitted that this was possible on cross-

examination (Ex. 2022, pgs 102 at 19-22 and pg. 103 at 23-25).

In our opinion, Bronshtein failed to undermine the credibility of Dr. Lee's opinion on cross-examination. The Lee cross-examination testimony to which Bronshtein directs our attention has been evaluated in its surrounding context (Ex 2022, 98:3-107:12[17]). In plain English what Dr. Lee said is that one might be able to immediately boil a solution of the type described by Bronshtein or Roser: "It could happen. I would not be surprised but I am trying to get an elegant product that has a stable foam" (Ex 2022, 103:23-25). As noted earlier in his testimony, Dr. Lee testifies (Ex 2022, 102:19 through 103:5)

> Q. [By counsel for Bronshtein]. In your opinion, it is impossible to pull a hard vacuum on a syrup immediately to bring it to a boil?
>
> A. Of course you can do that but it would start to bump and you would start to lose material which is thrown out of the solution on to the insides of the wall and that compromises what is called "pharmaceutical elegance" and also would be very detrimental to foam formation because your product is being thrown out of the solution and that needs to be avoided.

We believe Dr. Lee's testimony is properly understood to say that theoretically one could immediately boil a solution, and therefore there would be no evaporation step, but you will not

[17] The cited cross-examination is a question and answer session between Dr. Lee and the presiding judge, followed by follow-up questions by counsel for Bronshtein (Ex 2022; 101:8 et seq.).

get a stable foam. The object of the Bronshtein and Roser inventions is to get a stable foam. Hence, the fact that one might be able to "inefficiently" boil without evaporation becomes essentially irrelevant in context of the object of the invention of Bronshtein claim 3, as reproduced above. Dr. Lee's testimony is manifestly credible given the context of the inventions described in the Bronshtein and Roser specifications and Bronshtein's explicit disclosure that an evaporation steps leads to a viscous solution and all examples in the Bronshtein specification have an evaporation step ("samples were dried").[18]

Dr. Dhir disagrees (Finding 45). As noted earlier, however, Dr. Dhir has not favored us with the underlying basis for his opinion. What is plain is that his opinion has not been shown to be based on the invention described in the Bronshtein patent, including for example Bronshtein Examples 1 and 2. Dr. Dhir did not convincingly explain why the "viscous" liquid described by Bronshtein (Findings 14 and 15) is not a syrup within the meaning of a syrup as described in Roser's specification. Basically, Dr. Dhir's opinion amounts to an opinion based on the existence of a theoretical possibility not confined to the invention before us.

For the reasons given, we decline to find that Bronshtein has established that the subject matter of Bronshtein 3,

[18] Although it had every opportunity to do so, Bronshtein did not reproduce Bronshtein Examples 1 and 2 to attempt to demonstrate that a syrup, within the meaning of Roser claim 10 step (b), is not produced at some point in the process of going from a solution to a stable foam.

reproduced above in independent form, fails to anticipate by inherency Roser claim 10.

4. Obviousness

Assuming arguendo that Bronshtein had sustained its "no anticipation" burden, we hold that Bronshtein failed to sustain its burden of establishing that the subject matter of Bronshtein 3, as reproduced above, would not have rendered obvious the subject matter of Roser claim 10.

Roser claim 10 step (b), the only limitation in issue, calls for evaporation to obtain a syrup. Bronshtein claim 3, as reproduced above, calls for "dehydration or concentration by evaporating from liquid state at a low vacuum corresponding to the hydrostatic pressure higher than 7.6 Torr *** [ii] to increase the viscosity of said solution, dispersion or suspension before boiling under high vacuum ***." We are at a loss to see how Bronshtein has established that the subject matter of its claim 3 would not have rendered obvious the subject matter of Roser claim 10, including Roser step (b).

We have had considerable difficulty finding that there is in fact a difference. Accordingly, we have difficulty articulating the precise difference, if any, between the subject matter of Bronshtein claim 3 and Roser claim 10. Bronshtein claim 3, as reproduced above in alternative [1], calls for an evaporation step at a pressure higher than 7.6 Torr (Finding 21). According to Bronshtein Examples 1 and 2, evaporation occurs at room temperature. Roser's initial drying step may take place "most

preferably" at a pressure of 7.5 to 12.5 Torr at a temperature of 0°C to 80°C (Finding 22). Thus, Roser and Bronshtein describe overlapping evaporation conditions. Roser tells us that syrup "typically" is defined as having viscosity of 10^6 - 10^7 Pascal seconds. Bronshtein does not tell the viscosity of its "viscous liquid." Roser also tells us that the evaporation step may remove from 5-95% of the solvent (Finding 22). Bronshtein does not describe the amount of solvent removed during its evaporation step. But, if one uses the same temperature and pressure to partially evaporate the same solution to obtain a "viscous liquid" or a syrup, the viscous liquid and syrup start to look like the same thing. We are reminded of the adage that if it has webbed feet, a bill, feathers, wings, can swim and fly and quacks like a duck, there is an excellent chance it is a duck.

If one assumes, for purpose of discussion, that the subject matter of Roser claim 10 differs from that of Bronshtein claim 3, as reproduced above, then the difference has to be that Bronshtein's "viscous liquid" is not a syrup within the meaning of Roser claim 10. But, both Bronshtein and Roser contemplate evaporation of a solution, dispersion or suspension to obtain something more viscous than the original solution, dispersion or suspension subjected to evaporation. The viscous liquid is then boiled to obtain a stable foam--a result sought by both Bronshtein and Roser. Bronshtein has not told us, in the context of the inventions described and claimed by Bronshtein and Roser, why one skilled in the art would not have been able, and

motivated, to follow both the Bronshtein and Roser teachings to evaporate in such a manner as to obtain a suitable "viscous liquid" or syrup which would then be subjected to boiling to obtain a suitable stable foam. Dr. Lee's cross-examination discussed above makes it clear that the idea is to get a stable foam (Ex 2022, 103:23-25). Thus, given the subject matter of Bronshtein claim 3, as reproduced above, Bronshtein has failed, as was its burden, to show why the subject matter of Roser claim 10 would not have been obvious.

D. Order

We have considered all arguments made by the parties. Upon consideration of Bronshtein Preliminary Motion 1 and Roser Preliminary Motion 1, and for the reasons given, it is

ORDERED that Bronshtein Preliminary Motion 1 is denied, with prejudice.

FURTHER ORDERED that the Bronshtein offer to disclaim Bronshtein claim 3 is dismissed.

FURTHER ORDERED that the time for seeking reconsideration of our decision denying Bronshtein Preliminary Motion 1 shall be fourteen (14) days after entry of this MEMORANDUM OPINION and ORDER.

FURTHER ORDERED that Roser Preliminary Motion 1 is dismissed without prejudice as moot.

FRED E. McKELVEY, Senior Administrative Patent Judge	)
RICHARD E. SCHAFER Administrative Patent Judge	) BOARD OF PATENT APPEALS AND INTERFERENCES
RICHARD TORCZON Administrative Patent Judge	)

cc (via Federal Express):

Attorney for Bronshtein
(real party in interest
Universal Preservation Technologies, Inc.):

Daniel E. Altman, Esq.
Brenton R. Babcock, Esq.
Mark R. Benedict, Esq.
KNOBBE MARTENS OLSON & BEAR LLP

Attorney for Roser
(real party in interest
Quadrant Healthcare (U.K.) Limited,
a wholly owned subsidiary of
Quadrant Healthcare PLC (U.K.):

Debra A. Shetka, Esq.
Thomas E. Ciotti, Esq.
Madeline I. Johnston, Esq.
MORRISON & FOERSTER, LLP