

Mail Stop Interference
P.O. Box 1450
Alexandria Va 22313-1450
Tel: 571-272-4683
Fax: 571-273-0042

Filed: 22 January 2013

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

EDWARD TOBINICK,
Junior Party
(Application 12/714,205),

v.

KJELL OLMARKER and **BJÖRN RYDEVIK**
Senior Party
(Patents 7,708,995, 7,811,990, 7,906,481, 8,057,792, and 6,649,589).

Patent Interference No. 105,866
(Technology Center 1600)

*Before Richard Torczon, Sally Gardner Lane, and Deborah Katz, Administrative
Patent Judges.*

Katz, Administrative Patent Judge.

JUDGMENT

1
2

1 Further to the Decision on Motions (Paper 615), finding all of Tobinick involved
2 claims 68, 69, and 71-80 unpatentable under 35 U.S.C. § 112, first paragraph, for lack
3 of sufficient written description, it is **ORDERED** that judgment is awarded against Junior
4 Party Tobinick.

5 **FURTHER ORDERED** that claims 68, 69, and 71-80 of Tobinick Patent
6 Application 12/714,205 are FINALLY REFUSED. 35 U.S.C. § 135(a).

7 **FURTHER ORDERED** that attention is directed to 35 U.S.C. § 135(c) Bd. R. 205
8 regarding the filing of settlement agreements.

9 **FURTHER ORDERED** that a copy of this JUDGMENT shall be placed in the files
10 of (1) Tobinick Patent Application 12/714,205, (2) Olmarker Patent 7,708,995, (3)
11 Olmarker Patent 7,811,990, (4) Olmarker Patent 7,906,481, (5) Olmarker Patent
12 8,057,792, and (6) Olmarker Patent 6,649,589.

13

cc (via e-mail):

Attorney for Tobinick:

Robert W. Hahl, Esq.
Richard A. Neifeld, Esq.
NEIFELD IP LAW, PC
Email: rhahl@neifeld.com
Email: rneifeld@neifeld.com

Attorney for Olmarker:

Todd R. Walters, Esq.
Christopher L. North, Esq.
Erin M. Dunston, Esq.
BUCHANAN INGERSOLL & ROONEY PC
Email: todd.walters@bipc.com
Email: christopher.north@bipc.com
Email: erin.dunston@bipc.com

Mail Stop Interference
P.O. Box 1450
Alexandria Va 22313-1450
Tel: 571-272-4683
Fax: 571-273-0042

Filed: 22 January 2013

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

EDWARD TOBINICK,
Junior Party
(Application 12/714,205),

v.

KJELL OLMARKER and **BJÖRN RYDEVIK**
Senior Party
(Patents 7,708,995, 7,811,990, 7,906,481, 8,057,792, and 6,649,589).

Patent Interference No. 105,866
(Technology Center 1600)

Decision on Motions – Bd. R. 125(a)

1
2 *Before* Richard Torczon, Sally Gardner Lane, and Deborah Katz, *Administrative*
3 *Patent Judges.*
4 Opinion by Katz, *Administrative Patent Judge.* Concurring opinion by Torczon,
5 *Administrative Patent Judge.*
6

1 **I. Statement of the Case**

2 The Interference is before a motions panel for consideration of the parties’
3 pending non-priority motions. An oral argument was held on 4 December 2012.
4 (Transcript at Paper 614.) Robert Hahl represented Edward Tobinick and Todd Walters
5 represented Kjell Olmarker and Björn Rydevik.

6 **A. The Parties**

7 Edward Tobinick (“Tobinick”) is involved based on his Patent Application
8 12/714,205 (“the Tobinick ‘205 application”), which was filed 26 February 2010.
9 (Declaration, Paper 1, at 3.) Claims 68, 69, and 71-80, all of the pending claims of the
10 Tobinick ‘205 application (Tobinick Clean Copy of Claims, Paper 10,at 2), were
11 designated as corresponding to the Count (Declaration, Paper 1, at 5).

12 Tobinick represents that Tact IP, LLC is the real party-in-interest. (Tobinick
13 Notice of Real Party In Interest, Paper 11, at 2.)

14 Kjell Olmarker and Björn Rydevik (“Olmarker”) are involved based on the claims
15 indicated for the following U.S. Patents:

| Patent | Involved claims |
|---------------------------------------|---------------------------------------|
| 7,708,995, issued 04 May 2010 | 12 and 13 |
| 7,811,990, issued 12 October 2010 | 13, 22, 31, 40, 45, 48, 49, and 51 |
| 7,906,481, issued 15 March 2011 | 2, 20, 22, and 32 |
| 8,057,792, issued 15 November 2011 | 10, 11, 23, and 24 |
| 6,649,589, issued 18 November 2003 | 8, 18, 27, and 34 |

16

1 (Declaration, Paper 1, at 3-5; and Redecoration, Paper 27, at 3.)

2 Olmarker represents that Sciaticon AB, BioAssets Development Corporation,
3 Cephalon, Inc., and Teva Pharmaceutical Industries, Ltd., are the real parties-in-
4 interest. (Olmarker Notice of Real Party In Interest, Paper 8, at 2.)

5 **II. Subject Matter and Count**

6 Both Tobinick and Olmarker claim methods of inhibiting the action of a molecule
7 called TNF- α to achieve therapeutic results in patients with nerve disorders. The parties
8 agree that TNF- α inhibitors are molecules that inhibit TNF- α activity by either binding
9 directly to it or preventing its release and that such molecules have been previously
10 used to treat diseases such as rheumatoid arthritis and Crohn's disease. (Andersson
11 Decl., Ex. 1060, §III, ¶ 23, p. 26, Weinberger Decl., Ex. 2097, ¶¶ 87, 88, 99.) TNF- α
12 inhibitors were previously known to include antibodies. (Andersson Decl., Ex. 1060, §
13 III, ¶ 23, p 26; Weinberger Decl., Ex. 2097, ¶ 98.)

14 The Count is claim 68 of the Tobinick '205 application, which recites:

15 A method of treating or alleviating one or more symptoms of a nerve
16 disorder mediated by nucleus pulposus in a mammal in need of such
17 treatment comprising the step of administering a therapeutically effective
18 amount of a TNF- α inhibitor to the mammal, wherein said TNF- α inhibitor
19 is an antibody that blocks TNF- α activity, wherein the antibody is
20 administered locally.

21
22 (Declaration, Paper 1, at 4; Tobinick Clean Copy of Claims, Paper 10, at 2.) Thus, the
23 subject matter of the Interference is limited to methods that relate to symptoms of a
24 nerve disorder mediated by nucleus pulposus tissue. The parties agree that the
25 nucleus pulposus is a jelly-like substance in the middle of a spinal disc, which can
26 become herniated, or displaced from its normal location in the disc. (Andersson Decl.,

1 Ex. 1060, §III, ¶¶ 6, 13, and 19, p. 14, 20, and 23; Weinberger Decl., Ex. 2097, ¶ 66.)
2 The Count is also limited to method in which the antibody is “administered locally.”

3 **III. Motions**

4 Tobinick has filed five motions, as follows.

- 5 • Motion 1 for judgment against all of Olmarker’s involved claims under
6 35 U.S.C. §135(b). (Paper 172.)
- 7 • Motion 2 that Olmarker be denied benefit of International application
8 PCT/SE99/01671. (Paper 173.)
- 9 • Motion 3 that Olmarker be denied benefit of Swedish Applications
10 9803276-6 and 9803710-4. (Paper 174.)
- 11 • Motion 4 for permission to change the priority claims in application
12 11/262,528 (now Patent 8,119,127), application 10/269,745 (now Patent 6,982,089),
13 and application 10/236,097 (now abandoned). (Paper 238.) Tobinick’s requests in
14 this motion are contingent on the granting of Olmarker Motion 3, for judgment that
15 Tobinick’s involved claims are unpatentable over the prior art (Paper 163). (Tobinick
16 Motion 4, paper 238, at 2.)
- 17 • Motion 5 to exclude evidence. (Paper 363.)

18 Olmarker has filed 11 motions:

- 19 • Motion 1 for judgment against all of Tobinick’s involved claims under
20 35 U.S.C. §135(b). (Paper 161.)
- 21 • Motion 2 for judgment that all of Tobinick’s involved claims are
22 unpatentable under 35 U.S.C. §112, first paragraph, for lack of written description and

1 enablement. (Paper 162.)

2 • Motion 3 for judgment that all of Tobinick’s involved claims are

3 unpatentable under 35 U.S.C. §102 and or §103 over WO 00/18409. (Paper 163.)

4 • Motion 4 that Tobinick be denied benefit as to any U.S. patent application.

5 (Paper 165.)

6 • Motion 5 that additional Olmarker claims of the involved Olmarker patents

7 be designated as corresponding to the Count. (Paper 166.)

8 • Motion 6 that additional claims of Olmarker involved patent 6,649,589 be

9 designated as corresponding to the Count. (Paper 167.)

10 • Motion 7 to substitute a new Count for the current Count. (Paper 168.)

11 • Motion 8 for judgment that all of Tobinick’s involved claims are

12 unpatentable under 35 U.S.C. §102 and/or §103 over the publication Olmarker and

13 Larsson, “Tumor Necrosis Factor α and Nucleus-Pulposus-Induced Nerve Root Injury,”

14 23 Spine 2538 (1998). (Paper 240.)

15 • Motion 9 to introduce an additional claim to application 13/489,830 and

16 have it designated as corresponding to the Count. (Paper 241.) Olmarker’s request in

17 this motion is contingent on the granting of Tobinick Motion 1 for judgment against

18 Olmarker’s claims under 35 U.S.C. § 135(b). (Olmarker Motion 9, Paper 241, at 1.)

19 • Motion 10, requesting reconsideration of the Order – Contingent Motion

20 (Paper 236) and authorization to file a motion to add claims in response to Tobinick

21 Motion 1. (Paper 242.)

22 • Motion 11, requesting discovery, specifically communications between

1 Edward Tobinick and his counsel on issues relating to Tobinick Contingent Motion 4.
2 (Paper 270.)

3 We take up these motions in the order that secures the most just, speedy, and
4 inexpensive determination of the proceedings. *Berman v. Housey*, 291 F.3d 1345, 1352
5 (Fed. Cir. 2002); 37 C.F.R. § 41.125(a). Olmarker argues in its Motion 2 that all of
6 Tobinick's involved application claims are unpatentable under 35 U.S.C. § 112, first
7 paragraph, for lack of adequate written description support. (Olmarker Motion 2, Paper
8 162, at 1.) Because Tobinick's claims were copied from the Olmarker 7,708,995 and
9 7,811,990 patents for the purpose of provoking this Interference (see Olmarker Motion
10 2, Paper 162, at 2; Tobinick response to Olmarker MF¹ 1; Amendment filed in the
11 Tobinick '205 application, Ex. 1081, at 5), Olmarker's Motion 2 presents a threshold
12 issue. See 37 C.F.R. § 41.201(2)(ii). We exercise our discretion under 37 C.F.R.
13 § 41.125(a) to take up Olmarker Motion 2 first.

14 As discussed below, the preponderance of the evidence leads us to find that
15 Tobinick's claims are not fully supported by a written description in the specification of
16 the Tobinick '205 application. Thus, Tobinick was not entitled to file the claims used to
17 provoke this Interference and the Interference was mistakenly declared. See *Berman*,
18 291 F.3d at 1353. In light of this decision, we do not reach Tobinick Motion 1, which is
19 directed to the alleged unpatentability of Olmarker's claims under 35 U.S.C. § 135(b).

20 We note that Tobinick Motion 1 does not present a threshold issue under
21 § 41.201 because Tobinick, as junior party applicant, has asserted that Olmarker's
22 patent claims are unpatentable over claims of uninvolved Tobinick U.S. Patent

1 6,015,557. In this interference, Olmarker, not Tobinick, is the patentee who would be
2 entitled to repose. At best, Tobinick’s motion raises a patentability issue. See *In re*
3 *Berger*, 279 F.3d 975, 982 (Fed. Cir. 2002); *Strelchenko v. Campbell*, 2002 WL
4 1300267, at *2-3 (BPAI June 10, 2002) (Interference 104,809). Thus, in light of the
5 decision that Tobinick’s application claims lack written description support, we do not
6 consider Tobinick Motion 1.

7 In addition, though we consider Tobinick Motion 5 to exclude evidence, we do not
8 reach any of Tobinick’s or Olmarker’s other motions, because the issues raised are
9 moot in light of our decision that Tobinick’s claims are unpatentable for lack of written
10 description support.

11 **IV. Analysis – Olmarker Motion 2**

12 In its Motion 2, Olmarker argues that the Tobinick specification cannot provide a
13 written description of the subject matter Tobinick claims because, in part, it does not
14 describe treating “symptoms of a nerve disorder mediated by nucleus pulposus” with
15 antibodies “administered locally.” (Olmarker Motion 2, Paper 162, at 1.) Olmarker also
16 argues that the Tobinick specification does not provide sufficient enabling disclosure to
17 support the claimed methods.

18 Witnesses

19 Olmarker relies on the testimony of Gunnar Bengt Johan Andersson, M.D.,
20 Ph.D., to support the arguments in Motion 2. (Declaration of Gunnar Bengt Johan
21 Andersson, M.D., Ph.D. (“Andersson Decl.”), Ex. 1060.) Dr. Andersson testifies that he
22 is currently a Professor and Chairman Emeritus in the Department of Orthopedic

¹ “MF” indicates Material Fact.

1 Surgery and Professor in Spinal Deformities at the Rush University Medical College in
2 Chicago, IL. (Andersson Decl., Ex. 1060, § II, ¶ 6, p. 8.) Dr. Andersson testifies that
3 since 1975 he has served in many academic and administrative positions in medical
4 schools, specifically in departments of orthopedic surgery. (Andersson Decl., Ex. 1060,
5 § II, ¶ 7, p. 9.) Dr. Andersson testifies that he obtained the degree of Candidate of
6 Medicine from the University of Zurich, Switzerland, a Medicine Licenciate Certificate
7 and a Ph.D. in Medical Science from the University of Göteborg, Sweden. (Andersson
8 Decl., Ex. 1060, § II, ¶¶ 3-5. p. 8.) Dr. Andersson also testifies that he has conducted
9 research in orthopedic medicine and has authored more than 300 original peer-
10 reviewed and invited medical and scientific publications, many of which concern causes
11 and treatments of spinal disorders and symptoms associated with such disorders.
12 (Andersson Decl., Ex. 1060, § II, ¶ 10. p. 11-12; see also Curriculum Vitae Gunnar
13 Bengt Johan Andersson, M.D., Ph.D., Ex. 1061.) Dr. Andersson testifies that he is a
14 National Institutes of Health-funded researcher and has a grant to study degenerative
15 vertebral disc disease. (*Id.*)

16 Dr. Andersson is qualified to testify on the subject matter of the Interference.

17 Tobinick raises concerns about the scientific bases Dr. Andersson relies on and
18 an asserted bias. (Tobinick Opp. 2, Paper 300, at 4; see *also* Tobinick Motion 5, Paper
19 363, at 2 and 10-11.) Tobinick argues that because Dr. Andersson included a statement
20 reserving the “right to amend, supplement, or otherwise modify [his] opinions”
21 (Second Declaration of Gunnar Bengt Johan Andersson (“Second Andersson Decl.”),
22 Ex. 1085, §IV, ¶ 1, p. 28), his testimony is unreliable. (Tobinick Opp. 2, Paper 300, at 4;

1 see *also* Tobinick Motion 5, Paper 363, at 3, 10-11, and 13.) Olmarker argues that this
2 statement is consistent with the role an expert witness plays in a trial, where they have
3 an affirmative duty under the Federal Rules of Civil Procedure 26(a)(2), 26(a)(2)(E), and
4 26(e)(2) to supplement their disclosures, including written reports. (Olmarker Reply 2,
5 Paper 343, at 9.)

6 Dr. Andersson declares that his statements are believed to be true, with the
7 knowledge that willful false statements are punishable under 18 U.S.C. § 1001.
8 (Anderson Decl., Ex. 1060, § XIV, p. 150; Second Andersson Decl., Ex. 1085, § IV, ¶ 2,
9 p. 28.) Thus, we are not persuaded that Dr. Andersson’s testimony is generally
10 unreliable merely because he expressed a wish to reserve the right to modify it. We
11 address Tobinick’s concerns about specific, substantive statements made by Dr.
12 Andersson below.

13 Tobinick also argues that Dr. Andersson’s testimony is unreliable because he has
14 a financial interest in the outcome of the Interference and therefore is biased. (Tobinick
15 Opp. 2, Paper 300, at 4, *see also* Tobinick Motion 5, Paper 363, at 2 and 11.) Tobinick
16 relies on Dr. Andersson’s cross-examination testimony that in the past he received
17 money from the sale of BioAssets to Cephalon, a real party-in-interest to Olmarker and
18 that “there is a possibility that [he] will receive additional dollars in the future based on
19 the potential approval of the product by the FDA, and sales exceeding \$500 million.”
20 (Deposition of Gunnar Andersson, M.D., Ph.D., 11 June 2012, p. 6, l. 17, through p. 7, l.
21 3; Tobinick Opp. 2, Paper 300, at 4, citing Weinberger Decl., Ex. 2097, ¶¶ 262-66.) We
22 note, that Olmarker similarly alleges that Tobinick’s witness, Dr. Alan Weinberger, M.D.,
23 has a financial interest in the outcome of the Interference because he has a royalty-free

1 license to practice Dr. Tobinick's patented methods. (See Olmarker Reply 2, Paper
2 343, at 10, citing Deposition of Alan Walter Weinberger, M.D., 20 September 2012, Ex.
3 1134, p. 10, l. 17, through p. 11, l. 17.) Because we review both witnesses' testimony in
4 light of the support they provide for their opinions in the patent specifications at issue
5 and the medical and scientific literature, we do not disqualify either Dr. Andersson or Dr.
6 Weinberger solely on the basis of a possible financial interest in the outcome of the
7 Interference.

8 We note that Tobinick has also raised concerns about the conduct of Dr.
9 Andersson. (See Orders – Inequitable Conduct, Papers 369, 371.001, and 612;
10 Tobinick Statement pursuant to the Order – Inequitable Conduct (Paper 369), Paper
11 370.) We discuss these issues below, following our analysis of Olmarker Motion 2.

12 Tobinick relies on the testimony of Dr. Alan Weinberger, M.D., to support the
13 arguments it makes in against Olmarker's Motion 2. (Tobinick First Declaration of Alan
14 Weinberger, M.D. ("Weinberger Decl."), Ex. 2097.) Dr. Weinberger testifies that he is a
15 board-certified rheumatologist in private medical practice involving the evaluation and
16 treatment of patients with rheumatologic and other medical disorders, including non-
17 surgical treatment of back and neck pain. (Weinberger Decl., Ex. 2097, ¶¶ 4-5.) Dr.
18 Weinberger testifies that he has expertise in and routinely uses biologic TNF inhibitors,
19 including for the treatment of back and neck pain. (Weinberger Decl., Ex. 2097, ¶ 6.)
20 Dr. Weinberger's curriculum vitae indicates that he holds the academic positions of
21 Associate Clinical Professor of Medicine at the Center for Health Sciences, University of
22 California, Los Angeles and is an Attending Physician in the Rheumatology Clinic and
23 Service at Cedars-Sinai Medical Center, but does not indicate that he has conducted

1 any research or published any information relating to the subject matter of this
2 Interference. (Alan Weinberger, M.D., Curriculum Vitae, Ex. 2098.)

3 Dr. Weinberger is qualified to testify on the subject matter of this Interference.

4 Tobinick also relies on the testimony of Dr. M. L. Richardson, III, M.D., to support
5 its arguments. (Deposition of Marion L. Richardson, III, M.D., 25 June 2012
6 (“Richardson Deposition”), Ex. 2105.) Dr. Richardson testifies that he is a board-
7 certified anesthesiologist with a sub-specialty in pain management and has been in
8 private practice since 1987. (First Declaration of Mel Richardson, M.D., (“Richardson
9 Decl.”) Ex. 2003, ¶ 1; see *also* Curriculum Vitae of M. L. Richardson, III, M.D., Ex.
10 2034.) Dr. Richardson testifies that he has been actively involved in the treatment of
11 spinal pain syndromes for more than two decades and is a Diplomat of both the
12 American Board of Anesthesiology and the American Academy of Pain Management.
13 (*Id.*) Dr. Richardson testifies that he was previously the Medical Director and Chief of
14 Staff at the Indian River Memorial Hospital Ambulatory Surgery Center and Chief of the
15 Department of Anesthesia at USAF Eglin Regional Hospital in Florida. (*Id.*) Dr.
16 Richardson does not indicate that he has conducted any research or published any
17 information relating to the subject matter of this Interference. (*Id.*)

18 Dr. Richardson is qualified to testify on the subject matter of this Interference.
19

1 Findings of Fact

2 The following findings of fact, as well as others relied upon in the discussion
3 above and below, are supported by a preponderance of evidence in the record.

4 1. Tobinick copied the involved claims from Olmarker patents 7,708,995 (“the
5 ‘995 patent”) and 7,811,990 (“the ‘990 patent”). (Tobinick Application 12/714,205,
6 Amendment filed 27 June 2011, Ex. 1081, at 5.)

7 2. The Olmarker ‘995 patent uses the term “locally” to describe experiments
8 on the involvement of TNF- α in nucleus pulposus-induced effects, in which

9 [t]o assess if TNF-alpha may be involved in the nucleus pulposus induced
10 nerve root injury, the presence of TNF-alpha in nucleus pulposus-cells was
11 assessed and was studied if the nucleus pulposus-induced effects could be
12 blocked by doxycycline, a soluble TNF-receptor, and a selective monoclonal
13 TNF-alpha antibody, the latter administered both locally in the nucleus
14 pulposus and systemically.

15
16 (Olmarker ‘995 patent, Ex. 1046, 19:12-18; Olmarker Motion 2, Paper 162, at 9, MF 47;
17 Olmarker Reply 2, Paper 343, at 2.)

18 3. The Olmarker ‘995 patent provides details of experiments in which “[f]our
19 pigs received 100 mg of doxycycline intravenously, 8 pigs had a blocking monoclonal
20 antibody to TNF-alpha applied locally in the nucleus pulposus, and 4 pigs remained
21 non-treated (controls).” (Olmarker ‘995 patent, Ex. 1046, 17:44-47; Olmarker Reply 2,
22 Paper 343, at 2.)

23 4. The Olmarker ‘995 patent provides for administration of anti-TNF- α
24 antibody, wherein “the nucleus pulposus was mixed with 100 ul of a 1.11 mg/mL
25 suspension of the anti-TNF-alpha antibody used in series 1, before application.”

1 (Olmarker '995 patent, Ex. 1046, at 20:27-29; Olmarker Motion 2, Paper 162, at 9, MF
2 48.)

3 5. The Olmarker '995 patent contrasts local administration with systemic
4 administration as follows:

5 Two recently developed drugs for specific TNF-alpha inhibition were also
6 included in the study. Infliximab is a chimeric monoclonal antibody
7 composed of human constant and murine variable regions. Infliximab
8 binds specifically to human TNF-alpha. As opposed to the monoclonal
9 antibody used in series-2 for the 3-day observation period, infliximab was
10 not administered locally in the autotransplanted nucleus pulposus, but
11 instead was administered systemically in a clinically recommended dose
12 (4 mg/kg).
13

14 (Olmarker '995 patent, Ex. 1046, 27:12-20; Olmarker Motion 2, Paper 162, at 9, MF 49.)

15 6. Dorland's Illustrated Medical Dictionary defines "local" as "[r]estricted to or
16 pertaining to one spot or part; not general." (Dorland's Illustrated Medical Dictionary,
17 772 (23rd Ed., 1957) ("Dorland's Dictionary") at 772, Ex. 1063; Olmarker Motion 2,
18 Paper 162, at 8.)

19 7. Dorland's Illustrated Medical Dictionary defines "general" as "[a]ffecting
20 many parts or all parts of the organism, not local." (Dorland's Dictionary, at 552, Ex.
21 1064; Olmarker Motion 2, Paper 162, at 8.)

22 8. Dorland's Illustrated Medical Dictionary defines "systemic" as "pertaining
23 to or affecting the body as a whole." (Dorland's Dictionary, at 1357, Ex. 1065; Olmarker
24 Motion 2, Paper 162, at 8.)

25 9. Stedman's Medical Dictionary defines "local" as "[h]aving reference or
26 confined to a limited part; not general or systemic." (Stedman's Medical Dictionary for

1 the Health Professions and Nursing (7th Ed. 2012) (“Stedman’s Dictionary”), at 982, Ex.
2 2082; Tobinick Opp. 2, Paper 300, at 18.)

3 10. Olmarker’s witness, Dr. Andersson, testifies that based on dictionary
4 definitions “local” administration means administration directly to the site where the
5 medicine is intended to act, while “systemic” or “general” administration is administration
6 in which the medicine is broadly distributed before reaching the site of action, such as
7 being carried to the site of action by the vascular system. (Andersson Decl., Ex. 1060,
8 § VI, ¶ 21, p. 57.)

9 11. Dr. Andersson testifies that “locally” in the specification of Olmarker’s ‘995
10 patent is consistent with the dictionary definition of the term “locally” because it is
11 exemplified in Olmarker’s specification by applying anti-TNF- α antibodies to the affected
12 nerve roots in the nucleus pulposus and by contrasting it with “systemic” administration.
13 (Andersson Decl., Ex. 1060, § VI, ¶ 22, p. 57.)

14 12. The specification of the Tobinick ‘205 application provides that
15 Perispinal administration is a novel new concept for a delivery method for
16 cytokine antagonists for treating neurological or neuropsychiatric
17 diseases.
18 (Tobinick ‘205 application, Ex. 1008, at 8:7-8.)

19 13. The specification of the Tobinick ‘205 application provides that
20 [f]or the purposes of this discussion, “perispinal” means in the anatomic
21 vicinity of the spine. For this discussion “anatomic vicinity” is generally
22 defined as within 10 centimeters, or functionally defined as in close
23 enough anatomic proximity to allow the therapeutic molecules of
24 consideration herein to reach the spine and/or the subarachnoid space
25 surrounding the spinal cord in therapeutic concentration when
26 administered directly to this area.
27 (Tobinick ‘205 application, Ex. 1008, at 8:10-14; Olmarker Motion 2, Paper 162, at 9.)
28
29

- 1 14. The specification of the Tobinick '205 application provides:
- 2 Perispinal administration includes, but is not limited to the subcutaneous,
3 intramuscular, interspinous, epidural, peridural, parenteral, or intrathecal
4 routes, and may be perilesional or alternatively, particularly when treating
5 diseases of the brain, remote from the ultimate site of pathology.
6
- 7 (Tobinick '205 application, Ex. 1008, at 2:8-11; Olmarker Motion 2, Paper 162, at 10.)
- 8 15. The specification of the Tobinick '205 application provides that
9
- 10 [a]natomically localized administration involving perispinal use includes,
11 but is not limited to the subcutaneous, intramuscular, interspinous,
12 epidural, peridural, parenteral or intrathecal routes.
13
- 14 (Tobinick '205 application, Ex. 1008, at 8:3-5; Olmarker Motion 2, Paper 162, at 9.)
- 15 16. The specification of the Tobinick '205 application provides that
- 16 [a]n example of one preferred embodiment for treatment of lumbar
17 radiculopathy due to disc herniation at the L 3-4 interspace is the
18 perispinal administration of etanercept 25mg by injecting through the skin
19 of the back, between the L3 and L4 spinous processes, to deliver
20 etanercept in anatomic proximity to the site of disc herniation.
21
- 22 (Tobinick '205 application, Ex. 1008, at 11:21-24; Olmarker Motion 2, Paper 162, at 9.)
- 23 17. The specification of the Tobinick '205 application provides:
- 24 Direct injection of these specific cytokine antagonists into the CSF
25 (intrathecal administration) is also a form of localized anatomic
26 administration and can be accomplished by the perispinal route.
27
- 28 (Tobinick '205 application, Ex. 1008, at 8:19-21 Tobinick Opp. 2, Paper 300, at 12.)
- 29 18. The specification of the Tobinick '205 application provides:
- 30 Epidural administration, for the purposes of this patent, is also a form of
31 perispinal administration, and, in certain clinical circumstances may be the
32 delivery method of choice, despite its greater difficulty and greater risk.
33
- 34 (Tobinick '205 application, Ex. 1008, at 9:3-6; Tobinick Opp. 2, Paper 300, at 12.)
- 35 19. The specification of the Tobinick '205 application provides:

1 In another preferred embodiment injection of the therapeutic molecule to
2 the anatomic area adjacent to the disc herniation is accomplished by
3 epidural injection.
4

5 (Tobinick '205 application, Ex. 1008, at 12:3-4; Olmarker Motion 2, Paper 162, at 10;
6 Tobinick Opp. 2, Paper 300, at 12.)

7 20. Olmarker's witness, Dr. Andersson, testifies that Tobinick's definition
8 effectively removes any functional distinction between local and systemic
9 administration. (Andersson Decl., Ex. 1060, §VI, ¶ 29, pp. 60-61.)

10 21. Tobinick's witness, Dr. Richardson, testified that "transspinal
11 administration" is a "subcutaneous type injection where the medication is delivered via
12 the venous system called Batson's plexus." (Tobinick Opp. 2, Paper 300, at 20, citing
13 Richardson Deposition, Ex. 2105, at 11:12-16.)

14 22. Tobinick's witness, Dr. Richardson, testified that in his clinical experience,
15 injection of steroid in the caudal region, that is at the bottom of the spine, is useful for
16 treating a disc herniation at a disc that may be four to six inches away at L3-4.
17 (Richardson Deposition, Ex. 2105, 48:3-17.)
18

19 Discussion

20 To determine if the Tobinick '205 specification provides sufficient support for
21 Tobinick's copied claims, we first construe the claim terms, focusing on "administered
22 locally." As the parties agree, "when a party challenges written description support for
23 an interference count or the copied claim in an interference, the originating disclosure
24 provides the meaning of the pertinent claim language." *Agilent Tech., Inc. v. Affymetrix,*
25 *Inc.*, 567 F.3d 1366, 1375 (Fed. Cir. 2009). (See Olmarker Reply 2, Paper 343, at 2;

1 Amendment in Tobinick application 12/714,205, filed 27 June 2011, at 6-8.) Tobinick
2 copied claims from Olmarker '995 and '990 patents (FF² 1; Tobinick Application
3 12/714,205, Amendment filed 27 June 2011, Ex. 1081, at 5.) Thus, we look to
4 Olmarker's specification to construe the claim terms. We focus on the specification of
5 the '995 patent, noting that Tobinick does not raise, and we do not find, conflicting
6 disclosures in the '990 patent specification.

7 As Tobinick notes, the Olmarker specification describes experiments (called
8 "series-2") in which some nucleus pulposus tissue is removed from a vertebral disc and
9 is immersed in a solution containing anti-TNF- α antibodies. The mixture is then applied
10 to surgically exposed, but otherwise healthy, nerve roots. (Tobinick Opp. 2, Paper 300,
11 at 17; see Olmarker '995 spec., Ex. 1046, at 17:41-48.) Thus, the Olmarker
12 specifications describe experiments in which antibody is administered directly to the
13 nucleus pulposus tissue and the nerve root.

14 The Olmarker specification uses the term "locally" to describe these experiments.
15 (FFs 2-4; Olmarker '995 specification, Ex. 1046, at 19:12-18, 17:44-47, and 20:27-29.)
16 This local administration is contrasted with "systemic" administration, such as
17 intravenous, in other experiments (called "series-3"). (FF 5; Olmarker '995 specification,
18 Ex. 1046, at 27:12-20; Olmarker Motion 2, Paper 162, at 9, and Olmarker Reply 2,
19 Paper 343, at 2.)

20 Tobinick argues that because these references to local administration are not
21 directed to therapeutic methods they do not limit the claim scope. (Tobinick Opp. 2,
22 Paper 300, at 17.) We are not persuaded that even if the methods used in the

²"FF" indicates Finding of Fact.

1 experiments provided in the Olmarker specification are inappropriate for therapy, the
2 discussion is not at least somewhat useful for construing the claim terms. Tobinick's
3 argument is not that Olmarker's specifications do not support therapeutic methods in
4 general, only that the experimental conditions are not relevant to the claimed
5 therapeutic methods. If, though, the experiments demonstrate some of the
6 characteristics of the claimed methods they are relevant. Because the experiments
7 described in the '995 specification use anti-TNF- α antibody to investigate effects on the
8 nucleus pulposus and nerves these experiments are relevant to the claimed methods of
9 treatment and we do not ignore the use of the term "locally" in Olmarker's specification.

10 Olmarker also cites to a medical dictionary definition of the term "local" as
11 meaning "restricted or pertaining to one spot or part; not general" to construe the claims.
12 (Olmarker Motion 2, Paper 162, at 8; FF 6.) According to Dr. Andersson, this definition
13 is consistent with the usage of "local" in the Olmarker specification because the
14 antibodies are applied to the nerve roots in the nucleus pulposus. (Olmarker Motion 2,
15 Paper 162, at 9; FFs 10 and 11; Andersson Decl., Ex. 1060, § VI, ¶¶ 21 and 22, p. 57.)
16

17 Tobinick relies on a different medical dictionary to define "local," arguing that the
18 dictionary used by Olmarker is 50 years old. (Tobinick Opp. 2, Paper 300, at 17-18.)
19 The dictionary definition Tobinick relies on is not very different from the dictionary
20 definition on which Olmarker relies. Instead of reciting "one spot," Tobinick's dictionary
21 definition recites "confined to a limited part" and both definitions contrast "local" with
22 "general" or "systemic." (Compare FF6, Dorland's Dictionary at 772, Ex. 1063, with
23 FF9, Stedman's Dictionary, at 982, Ex. 2082; see *also* FF 7, Dorland's Dictionary, at

1 552, Ex. 1064, defining “local”, and FF 8, Dorland’s Dictionary, at 1357, Ex. 1065,
2 defining “systemic.”) Tobinick’s dictionary definition is not in conflict with the dictionary
3 definition put forth by Olmarker and we are not persuaded that it conflicts with Dr.
4 Andersson’s understanding of the claim term “administered locally” as being
5 administered directly to the site where the medicine is intended to act.

6 In light of these definitions and the use of the term “local” in Olmarker’s
7 specification, we construe Tobinick’s claims as being directed to administering TNF- α
8 inhibitor directly to the site where it is intended to act, that is, to the location where the
9 nucleus pulposus is causing the symptoms of the nerve disorder. The limitation
10 “administered locally” excludes systemic administration away from the site where the
11 TNF- α inhibitor is intended to act.

12 Olmarker argues that the concept of administering a drug locally, as described in
13 the Olmarker ‘995 patent specification, is contrary to the description of administering
14 treatments in the Tobinick ‘205 application. (Olmarker Motion 2, Paper 162, at 9.) The
15 Tobinick specification is directed to “perispinal” administration of cytokine antagonists.
16 (FF 12, Tobinick ‘205 application, Ex. 1008, at 8:7-8.) “Perispinal” is defined as being in
17 the “anatomic vicinity” of the spine, which is in turn defined as being within 10
18 centimeters or close enough to allow therapeutic molecules to reach the spine or
19 subarachnoid space. (FF 13; Tobinick ‘205 spec., Ex. 1008, at 8:10-14; see Olmarker
20 Motion 2, Paper 162, at 9.) Olmarker cites to portions of Tobinick’s specification that
21 define “perispinal” administration as including subcutaneous, intramuscular,
22 interspinous, epidural, peridural, parenteral, or intrathecal routes (FFs 14-16; Tobinick
23 spec., Ex. 1008, at 2:8-11, 8:3-5, and 11:21-24), which according to Olmarker does not

1 limit the route of administration at all. (Olmarker Motion 2, paper 162, at 9-10.)
2 Olmarker relies on Dr. Andersson’s testimony to argue that this definition does not
3 exclude systemic routes of administration, and, thus, does not describe local
4 administration. (Olmarker Motion 2, Paper 162, at 9, FF 18; Andersson Decl. Ex. 1060,
5 § VI, ¶ 26-28.)

6 Tobinick opposes Olmarker’s arguments by pointing to the anatomic structure
7 called the “Batson’s plexus,” which, according to Drs. Richardson and Weinberger,
8 allows for molecules delivered by perispinal injection to be delivered directly to the
9 central nervous system. (Tobinick Opp. 2, Paper 300, at 19-20; FF 21, Richardson
10 Deposition, Ex. 2105, at 11:12-16, and Weinberger Decl., Ex. 2097, ¶¶ 110-123.)

11 We are not persuaded by the evidence provided by Tobinick that the ‘205
12 specification refers to administration through the Batson’s plexus. Even if, as Tobinick
13 appears to argue, such administration is “local,” Tobinick does not direct us to use of the
14 term “Batson’s plexus” in the specification of the ‘205 application. None of the evidence
15 that Tobinick cites indicates that one of skill in the art would consider “perispinal”
16 administration, or any of the other modes of administration referred to in the
17 specification of the ‘205 application, to be through the Batson’s plexus. Dr. Weinberger
18 testifies that the Batson’s plexus provides an explanation for the methods of delivery
19 provided in the ‘205 specification, but he does not testify that those of skill in the art
20 would have read the ‘205 specification and would have understood it to refer to
21 administration into the Batson’s plexus. (See Weinberger Decl., Ex. 2097, ¶¶ 110-123.)
22 Thus, without a specific disclosure of the Batson’s plexus in the ‘205 specification, we

1 are not persuaded that one of skill in the art would consider the specification to be
2 directed to administration to it.

3 Furthermore, even if those of skill in the art would have read the '205
4 specification to mean administration to the Batson's plexus, Tobinick has not persuaded
5 us that it would result in a drug being "administered locally," as this term is construed
6 from Olmarker's specification. As noted in an exhibit relied upon by Dr. Weinberger, the
7 volume of the Batson's plexus can be up to 1000 mL. (Olmarker Reply 2, Paper 343, at
8 3, citing Tobinick & Vega, "The Cerebrospinal Venous System: Anatomy, Physiology,
9 and Clinical Implications," Medscape General Medicine (2006), Ex. 2158, at 6.)
10 Tobinick has not directed us to sufficient evidence to show that administration of a
11 molecule perispinally into any portion of the Batson's plexus would result in
12 administration directly to the location where the nucleus pulposus is causing the nerve
13 disorder. (Olmarker Reply 2, Paper 343, at 3, Andersson; Fourth Declaration of Gunnar
14 Bengt Johan Andersson, M.D., Ph.D. ("Fourth Andersson Decl."), Ex. 1135, at §III, ¶ 4,
15 p. 4.)

16 In addition, Tobinick's arguments and evidence about the efficacy of perispinal
17 administration do not persuade us that Tobinick's route of administration is the same as
18 the "local" administration provided in Olmarker's specification. (Tobinick Opp. 2, Paper
19 300, at 20-21.) Whether or not the methods disclosed in Tobinick's '205 specification
20 and those Dr. Tobinick performs are effective does not reveal if the disclosure supports
21 treatments "administered locally" as construed from Olmarker's specification.

22 Tobinick argues that intrathecal and epidural routes of administration are
23 localized forms of administration disclosed in the specification of the '205 application.

1 (Tobinick Opp. 2, Paper 300, at 12; FFs 17 and 18, Tobinick '205 application, Ex. 1008,
2 at 8:19-21 and 9:3-6.) According to Olmarker, though, such injections are not described
3 as being administered directly to the site where the medicine is intended to act. For
4 example, epidural administration is described as being administered “to the anatomic
5 area adjacent to the disc herniation” (FF 19, Tobinick '205 application, Ex. 1008, at
6 12:3-4), instead of to the site of disc herniation. (Olmarker Motion 2, Paper 162, at 10-
7 11.) Olmarker relies on Dr. Andersson’s testimony to argue that when administration is
8 at an anatomic area adjacent to the site of disc herniation, any functional distinction
9 between local and systemic administration is removed. (*Id.*, FF 20, Andersson Decl.,
10 Ex. 1060, §VI, ¶ 29, pp. 60-61.)

11 Tobinick opposes Olmarker’s argument by arguing that Dr. Andersson’s
12 testimony about the efficacy of intrathecal injection is wrong. (Tobinick Opp. 2, Paper
13 300, at 21.) Tobinick also cites Dr. Richardson’s testimony to assert that caudal
14 epidural injections (near the base of the spine) of steroids can allow the drug to diffuse
15 upwards through the epidural space to the site of disc herniation and that this is
16 considered to be a form of local administration. (Tobinick Opp. 2, Paper 300, at 23,
17 citing Richardson Deposition, Ex. 2105, at 48:3-17, FF 22.) Dr. Richardson’s testimony
18 does not indicate that such caudal epidural administration is local or at the site where it
19 is intended to act. Dr. Richardson does not refer to local administration, but only to the
20 efficacy of injecting steroids caudally. In fact, Dr. Richardson contrasts such caudal
21 injections with those that are administered at the site of disc herniation. (Richardson
22 Deposition, Ex. 2105, at 48:8-17: “And that’s been my clinical experience many times
23 over thousands and thousands of patients where a caudal injection, which is way down

1 at the bottom of the spine where the epidural space starts, you inject the steroid there
2 and even though the patient has a disc at L3-4, which would probably be, I'd say, in
3 most patients, may be four to six inches away from the injection, you can still get a
4 clinical effect or pain relief from injecting it caudally *as opposed to where the disc may*
5 *be herniated.*" (emphasis added)). We are not persuaded by the evidence that Tobinick
6 presents that the disclosures of intrathecal and epidural administration in the '205
7 specification are disclosures of molecules "administered locally" as construed from the
8 Olmarker specification.

9 The balance of the evidence on this record persuades us that the specification of
10 the Tobinick '205 application does not describe a method of treatment wherein anti-
11 TNF- α antibody is "administered locally" to treat or alleviate symptoms of a nerve
12 disorder mediated by nucleus pulposus. Olmarker has shown that the specification of
13 the '205 application is directed to administering TNF inhibitor near or adjacent to a
14 nerve disorder, but not directly to the site where the medicine is intended to act.
15 Because we are constrained under *Agilent* to use the Olmarker '995 patent specification
16 to construe Tobinick's claims, we cannot find, based on this record, that the
17 specification of the '205 application provides written description for the methods claimed
18 by Tobinick.

19 Because the lack of sufficient written description in junior party Tobinick's
20 application is a threshold issue, we do not reach the issue of whether the '205
21 application enables the methods claimed.

1 **V. Additional Matters**

2 In addition to the arguments discussed above, Tobinick requests that Dr.
3 Andersson’s testimony be excluded in Motion 5 to exclude evidence. (Paper 363.) In
4 general, Tobinick argues that the First Andersson Declaration should be excluded
5 entirely because “[e]ssentially all of the evidence supporting Olmarker’s assertion that
6 Tobinick’s disclosures would have been and still are unbelievable to one of ordinary skill
7 in the art are based on biased and unreliable testimony by Dr. Andersson.” (Tobinick
8 Motion 5, Paper 363, at 2.) As explained above, we do not rely on Dr. Andersson’s
9 testimony about the effectiveness or belief of effectiveness of Tobinick’s disclosures to
10 reach our decision that Tobinick’s involved claims are not supported by the specification
11 of the ‘205 application. We do not exclude Dr. Andersson’s testimony on these
12 grounds, as Tobinick requests.

13 Tobinick also points to specific testimony by Dr. Andersson, which it considers to
14 be factually incorrect and irrelevant. Tobinick cites to Dr. Andersson’s interpretation of
15 the term “epidural,” which Olmarker relied on in its Motion 2. (Tobinick Motion 5, paper
16 363, at 7.) As Tobinick notes, Olmarker relies on Dr. Andersson’s testimony to support
17 its Material Fact 70, which states: “The ‘205 Application does not limit the location of
18 epidural administration to the site of the herniation in reciting ‘injection of the therapeutic
19 molecule to the anatomic area adjacent to [a] disc herniation . . . by epidural injection.’
20 Ex. 1060, pp. 60-61, § VI ¶ 29.” (Olmarker Motion 2, Paper 162, at MF 70.) Tobinick
21 cites to Dr. Weinberger’s Declaration, apparently in support of its argument. (Tobinick
22 Motion 5, Paper 363, at 7, citing Weinberger Decl., Ex. 2097, at ¶ 104.) Dr.
23 Weinberger’s testimony provides:

1 Both the spinal nerve roots and the spinal cord are located in the
2 intrathecal (subarachnoid) space. This is because both the spinal nerve
3 roots and the spinal cord are contained within the thecal membranes. The
4 thecal membranes consist of the dura (dura mater) and the arachnoid
5 membranes. Both the spinal nerve roots and the spinal cord are
6 surrounded by the cerebrospinal fluid.
7

8 (Weinberger Decl., Ex. 2097, ¶ 104.) Dr. Weinberger’s testimony also cites to a
9 publication authored by Dr. Olmarker and provides a diagram of the major neural
10 structures in the intrathecal space. Tobinick does not provide other explanation of why
11 Dr. Andersson’s testimony is factually incorrect and irrelevant.

12 It is not apparent to us how this testimony of Dr. Andersson is in conflict with Dr.
13 Weinberger’s testimony. The statement that Tobinick objects to does not discuss
14 epidural administration in general, but only epidural administration as provided in the
15 ‘205 application. Dr. Weinberger’s testimony, though, refers only to the anatomy of the
16 spinal nerve roots and spinal cord in the intrathecal space. Tobinick has not provided
17 sufficient explanation of how Dr. Weinberger’s testimony demonstrates that Dr.
18 Andersson’s testimony is factually incorrect or irrelevant.

19 We note that the testimony of Dr. Andersson cited by Tobinick also states that
20 “Tobinick’s description of localized administration is poorly conceived and would not
21 guarantee that any medicine will reach the site of a disorder.” (Andersson, Decl., Ex.
22 1060, pp. 60-61, § VI ¶ 29.) We do not rely on this statement in our opinion and do not
23 offer any opinion of it.

24 Tobinick also cites to the Fourth Andersson Declaration and Olmarker’s reliance
25 on it in Tobinick’s motion to exclude evidence. (Tobinick Motion 5, paper 363, at 12-13.)
26 Tobinick does not provide specific arguments against particular statements made by

1 Dr. Andersson in his fourth declaration. Instead, Tobinick argues that “the scientific
2 errors made by Dr. Andersson were so numerous, and so significant, that his scientific
3 testimony is entirely unreliable,” citing to almost 70 paragraphs of testimony by Dr.
4 Weinberger. (Tobinick Motion 5, Paper 363, at 13.) Review of this testimony by Dr.
5 Weinberger does not persuade us that the testimony in Dr. Andersson’s fourth
6 declaration we relied on regarding local administration and the Batson’s plexus was
7 incorrect. (See Andersson Fourth Declaration, Ex. 1135, at §III, ¶ 4, p. 4.) Tobinick has
8 not provided sufficient argument or citation in its motion to persuade us otherwise.
9 *Halliburton Energy Servs., Inc. v. M-I LLC*, 514 F.3d 1244, 1250, n.2 (Fed. Cir. 2008)
10 (quoting *United States v. Dunkel*, 927 F.2d 955, 956 (7th Cir. 1991) (“Judges are not like
11 pigs, hunting for truffles buried in briefs.”)).

12 We do not rely on any of the other evidence that Tobinick cites to in its Motion 5,
13 and thus do not review Tobinick’s arguments regarding this evidence.

14 We also note that Tobinick has raised issues of inequitable conduct in this
15 Interference and prior Interference 105,842. (See Tobinick Statement pursuant to the
16 Order – Inequitable Conduct (Paper 369) (“Tobinick Statement”), Paper 370.)
17 Tobinick’s allegations relate to whether nucleus pulposus causes central nervous
18 system disorders and the prior art status of “the Le ‘488 application.” (Tobinick
19 Statement, Paper 370, at 6.) Because our opinion in this Interference does not hinge on
20 whether nucleus pulposus causes central nervous system disorders and the prior art
21 status of “the Le ‘488 application” was not raised in this Interference, we do not consider
22 Tobinick’s allegations. Furthermore, to the extent that Tobinick argues that that certain
23 Olmarker patent claims involved in this Interference should have been found

1 unpatentable in another interference, we decline to address these concerns in light of
2 our decision on the threshold issue of the lack of written description support for
3 Tobinick's involved claims.

4 **VI. Conclusion**

5 We enter judgment against Tobinick '205 application claims 68, 69, and 71-80,
6 separately.

7

1 Torczon, *Administrative Patent Judge*, concurring.

2 This case underscores the peril in claim copying.

3 For more than a generation, claim copying has not been necessary to suggest an
4 interference. *E.g.*, *Aelony v. Arni*, 547 F.2d 566, 570 (CCPA 1977) (claimed subject
5 matter need not even overlap). Nevertheless, patent practitioners persisted in copying
6 claims. Claim copying is a nuisance (inevitably leading to a mismatch between the
7 language of the claim and the disclosure with resulting confusion or otherwise unneeded
8 analysis), but it was essentially harmless.

9 Now claim copying is destructive to applicants and their counsel. Without any
10 basis in a statute or any justification in interference practice, a court opinion created a
11 surprising exception in written description law for copied claims, albeit only at the United
12 States Patent and Trademark Office. *In re Spina*, 975 F.2d 854, 856 (Fed. Cir. 1992);
13 *Agilent Techs., Inc. v. Affymetrix, Inc.*, 567 F.3d 1366 (Fed. Cir. 2009); *Koninklijke*
14 *Philips Elecs. N.V. v. Cardiac Sci. Operating Co.*, 590 F.3d 1326, 1332 (Fed. Cir. 2010);
15 *but see Cultor Corp. v. A.E. Staley Mfg. Co.*, 224 F.3d 1328, 1332 (Fed. Cir. 2000)
16 (wisely declining to extend *Spina* to the district courts).³

17 Whether a doctrine, not compelled by statute or logic, messy to administer and
18 catastrophic to unwary applicants and patent practitioners should persist is a question
19 only the courts can resolve. Resolution is urgently needed.

20

³ For a catalogue of some of the difficulties that *Agilent* has created, see, *e.g.*, *Lazaridis v. Eggleston*, 2011 WL 1676301 (BPAI 2011) (dubitante opinion); *Rilo v. Benedict*, 2011 WL 729494 n.55 (BPAI 2011).

1 cc (via e-mail):

2
3

4 Attorney for Tobinick:

5

6 Robert W. Hahl, Esq.

7 Richard A. Neifeld, Esq.

8 NEIFELD IP LAW, PC

9 Email: rhahl@neifeld.com

10 Email: rneifeld@neifeld.com

11

12

13 Attorney for Olmarker:

14

15 Todd R. Walters, Esq.

16 Christopher L. North, Esq.

17 Erin M. Dunston, Esq.

18 BUCHANAN INGERSOLL & ROONEY PC

19 Email: todd.walters@bipc.com

20 Email: christopher.north@bipc.com

21 Email: erin.dunston@bipc.com