

FILED

UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF VIRGINIA  
ALEXANDRIA DIVISION

2012 AUG 15 P 2:57

TACT IP, LLC  
2300 Glades Road, Suite 305E  
Boca Raton, Florida 33431

Plaintiff,

v.

JANSSEN BIOTECH, INC.  
200 GREAT VALLEY PARKWAY  
MALVERN, PENNSYLVANIA 19355

And

NEW YORK UNIVERSITY  
550 FIRST AVENUE  
NEW YORK, NEW YORK 10016

CLERK US DISTRICT COURT  
ALEXANDRIA, VIRGINIA

CIVIL ACTION  
Docket No.

1:12 CV 909  
TSE/JFA

COMPLAINT UNDER 35 USC 146

Plaintiff TACT IP, LLC bring this action against defendants JANSSEN BIOTECH, INC. and NEW YORK UNIVERSITY, pursuant to 35 USC 146, to reverse a decision of the Board of Patent Appeals and Interferences in patent interference number 105,841.

## THE PARTIES

1. Plaintiff, TACT IP, LLC is incorporated in Delaware, with a regular place of business at 2300 Glades Road, Suite 305E, Boca Raton, Florida 33431.
2. Defendant JANSSEN BIOTECH, INC., on information and belief, is a Pennsylvania corporation, with a place of business indicated by the records of the United States Patent and Trademark office to be: 200 GREAT VALLEY PARKWAY, MALVERN, PENNSYLVANIA 19355.
3. Defendant, NEW YORK UNIVERSITY, on information and belief, is an educational corporation of the state of New York, with an address at: 550 FIRST AVENUE, NEW YORK, NY 10016; and an office of general counsel at: 70 Washington Square South, 11th floor New York, NY 10012.

## JURISDICTION AND VENUE

4. This court has jurisdiction over this action under 28 USC 1331 (arising under federal law), 28 USC 1338(a) ( "district courts shall have original jurisdiction of any civil action arising under any Act of Congress relating to patents."), and 35 USC 146 (as amended in 2011 by the America Invents Act, "District Court for the Eastern District of Virginia shall have jurisdiction" when adverse parties reside in plural districts).
5. Venue is proper in this district pursuant to 35 USC 146, 28 USC 1391(b)(2)(“ substantial part of the events or omissions giving rise to the claim occurred”) and (3)(“district in which any defendant is subject to the court’s personal jurisdiction”).

## BASIS FOR COMPLAINT

6. This action arises from the 6/21/2012 adverse judgment, paper 228, in patent interference 105,841, in which the Board of Patent Appeals and Interferences of the United States Patent and Trademark Office (herein after “Board”) entered judgment adverse to “Tobinick in regard to Patent 6,419,944 claims 1-23, 30-34, and 37 and Patent 6,537,549 claims 1-20, 23, and 25-33.” Paper 228, page 2 lines 1-3.
7. TACT IP, LLC, is the assignee of record of both of Tobinick’s patents 6,419,944 and 6,537,549.
8. TACT IP, LLC is dissatisfied with the decision of the Board. TACT IP, LLC seeks an order reversing the Board’s judgment insofar as Tobinick’s patent 6,419,944 Claims 1 –4, 7-10, 12 –21, 30 – 34; and patent 6,537,549 Claims 1-4, 7-10, 12-18 and 25-33 are concerned.

## ADVERSE PARTIES AS DEFINED IN 35 USC 146

9. Patent interference 105,841 involved junior party Tobinick on US patents 6,419,944 and 6,537,549).

10. Patent interference 105,841 involved senior party Le on US patent applications 10/227,488 and 10/665,971.

11. The USPTO assignment database records for party Le application 10665971:  
at Reel/Frame: 020997/0728 shows a first 4 inventors assigned their rights in that application to CENTOCOR, INC. in 2008;  
at Reel/Frame: 020997/0802 shows the fifth and sixth inventors assigned their rights in that application to NEW YORK UNIVERSITY in 2008;  
at Reel/Frame: 027066/0594 that Centocor, Inc subsequently assigned its rights in that application to CENTOCOR ORTHO BIOTECH INC.; and  
at Reel/Frame: 027082/0917 that CENTOCOR ORTHO BIOTECH INC. subsequently, in 2011, assigned its rights in that application to JANSSEN BIOTECH, INC.

12. The USPTO assignment database for party Le application 10665971 shows that all assignment recordings for application 10227488 occurred prior to the 6/21/2012 date of the decision complained of in this complaint.

13. The USPTO assignment records for party Le application 10/227,488:  
at Reel/Frame: 020997/0840 shows a first 4 inventors assigned their rights in that application in 2008, to CENTOCOR, INC.,;  
at Reel/Frame: 020997/0833 that the fifth and sixth inventors assigned their rights in that application in 2008, to NEW YORK UNIVERSITY;  
at Reel/Frame: 027066/0594 that Centocorr, Inc. subsequently assigned its rights in that application to CENTOCOR ORTHO BIOTECH INC.; and  
at Reel/Frame: 027082/0917 that CENTOCOR ORTHO BIOTECH INC. in 2011 assigned its rights in that application to JANSSEN BIOTECH, INC..

14. The USPTO assignment database for party Le application 10/227,488 shows that all assignment recordings for application 10227488 occurred prior to the 6/21/2012 date of the decision complained of in this complaint.

15. In Patent interference 105,841, on 12/29/2011, party Le filed a statement of real party in interest, paper 6. That statement said:

1 Senior Party Le, et al., hereby identifies the real party in interest as Janssen Biotech, Inc.

2 (one of the Janssen Pharmaceutical Companies of Johnson & Johnson, and assignee of Centocor

3 Ortho Biotech, Inc.) and New York University.

#### RELEVANT EVENTS IN PRIOR INTERFERENCE 105,621

16. In patent interference 105,841, the Board relied in part upon its decision in earlier Interference 105,621.

17. On 5/02/2008, the Board declared patent interference 105,621, titled "Tobinick v. Le v. Le", paper 1. Therein, the Board accorded benefit to Tobinick of US 09/256,388, filed 02/24/1999. Interference 105,621, Paper 1, page 5 line 5.

18. On 6/10/2008, in interference 105,621, the Board entered paper 23, titled "REDECLARATION BD.R.203(C)", that stated at page 1 lines 3-7:

3 ORDERED that the interference is redeclared to the following extent only:  
4 1. New Count 2 is substituted for Count 1.  
5 2. Count 2 is as follows:  
6 Claim 1 of Tobinick (6,015,557) or claim 4 of Le (10/227,488) or claim 1 of Le  
7 (10/665,971).

19. On 5/19/2008, in interference 105,621, paper 15, Tobinick had filed the paper "TOBINICK CLEAN COPY OF CLAIMS". Paper 15, TOBINICK CLEAN COPY OF CLAIMS" contains the following recitation for claim 1 of Tobinick 6,015,557:

1. A method for inhibiting the action of TNF for treating neurological conditions in a human by administering a TNF antagonist for reducing the inflammation of neuronal tissue of said human, or for modulating the immune response affecting neuronal tissue of said human, comprising the step of:  
a) administering a therapeutically effective dosage level to said human of said TNF antagonist selected from the group consisting of etanercept and infliximab for reducing the inflammation of neuronal tissue of said human, or for modulating the immune response affecting neuronal tissue of said human.

20. Annotated claims filings in interferences, by requirements of rule 37 CFR 41.110(b)(1) includes citations to support in the corresponding patent application or patent specification in braces "{}".

21. On 6/11/2008, in interference 105,621, paper 28, Le filed "LE ANNOTATED COPY OF CLAIMS" which contains the following recitations for claim 4 of Le (10/227,488) and claim 1 of Le (10/665,971):

4. A method of inhibiting or neutralizing TNF $\alpha$  *in vivo* {16:9-19} in a patient with neurodegenerative disease {58:15 to 59:4}, comprising:  
administering to said human patient a dosage level of at least one anti-TNF $\alpha$  antibody {60:15-18} or antigen-binding fragment {61:7} thereof, said antibody comprising a human constant region {10:8-15}, wherein said antibody or antigen binding fragment (i) competitively inhibits binding of A2 (ATCC Accession No. PTA-7045) {25:16-23} to human TNF $\alpha$  {30:5-25}, and (ii) binds to human TNF $\alpha$  with an affinity of at least  $1 \times 10^8$  liter/mole, measured as an association constant (K<sub>a</sub>) {61:3}, said dosage level effective for inhibiting TNF $\alpha$  in said human patient {60:7-24}, with the proviso that none of the neurodegenerative diseases is multiple sclerosis {58:26-27}.

1. A method of inhibiting {16:7-12} the pro-inflammatory action {1:21} of TNF $\alpha$  in a human patient {59:26} having a neurodegenerative disease {57:25 to 58:15}; comprising administering {59:13-17} to said human patient an effective TNF $\alpha$ -inhibiting amount of an anti-TNF $\alpha$  {16:13-24} monoclonal antibody or antigen-binding fragment thereof {59:26 to 60:17}, said anti-TNF $\alpha$  antibody comprising a human constant region {10:7-14}, wherein said anti-TNF $\alpha$  antibody or antigen binding fragment

thereof (i) competitively inhibits binding of A2 (ATCC Accession No. PTA-7045) {25:15-22} to human TNF $\alpha$  {30:2-22} and (ii) binds to a neutralizing epitope of human TNF $\alpha$  {39:6-8} with an affinity of at least  $1 \times 10^8$  liter/mole, measured as an association constant (K<sub>a</sub>) {60:14-15}, with the proviso that the neurodegenerative disease is not multiple sclerosis {57:26}.

22. On 12/3/2008, in interference 105,621, paper 33, the Board entered adverse judgment on priority as to count 2, the sole count of that interference, against junior party Tobinick, and ordered claims 1-3, 13, 14, 17-21, and 23-25 of Tobinick patent 6,015,557 of Tobinick be cancelled.

#### RELEVANT EVENTS IN INTERFERENCE 105,841

23. On 12/25/2011, the Board declared interference 105,841, paper 1. At page 4, lines 18-25, the Board defined count 1 as:

18 Count 1  
19 Claim 1 of Tobinick US Patent 6,419,944  
20 or  
21 Claim 1 of Tobinick US Patent 6,537,549  
22 or  
23 Claim 4 of Le 10/227,488  
24 or  
25 Claim 1 of Le application 10/665,971

24. Claim 1 of Tobinick US Patent 6,419,944 reads:

1. A method for inhibiting the action of TNF for treating neurological conditions in a human by administering a TNF antagonist for reducing the inflammation of neuronal tissue of said human, or for modulating the immune response affecting neuronal tissue of said human, comprising the steps of: a) administering a therapeutically effective dosage level to said human of said TNF antagonist selected from the group consisting of a fusion protein identified as etanercept, infliximab, CDP571 (a humanized monoclonal anti-TNF- $\alpha$  IgG4 antibody), CDP 870 (a humanized monoclonal anti-TNF- $\alpha$  antibody fragment) and D2E7 (a human anti-TNF mAb) for reducing the inflammation of neuronal tissue of said human, or for modulating the immune response affecting neuronal tissue of said human; and b) administering said dose either intralesionally or perilesionally.

25. Claim 1 of Tobinick US Patent 6,537,549 reads:

1. A method of treating neurological conditions in a human by inhibiting the action of TNF, by administering a TNF antagonist for reducing the inflammation of neuronal tissue of said human, or for modulating the immune response affecting neuronal tissue of said human, comprising the steps of: a) administering a therapeutically effective dosage level to said human of said TNF

antagonist selected from the group consisting of a fusion protein identified as etanercept, infliximab, CDP571 (a humanized monoclonal anti-TNF-alpha IgG4 antibody), CDP 870 (a humanized monoclonal anti-TNF-alpha antibody fragment), D2E7 (a human anti-TNF mAb), soluble TNF receptor Type I, and pegylated soluble TNF receptor Type I (PEGs TNF-R1) for reducing the inflammation of neuronal tissue of said human, or for modulating the immune response affecting neuronal tissue of said human; and b) administering said dose either intralesionally or perilesionally.

26. On 12/25/2011, in interference 105,841, paper 1, at pages 5 and 6, the Board accorded benefit to Tobinick of a chain of applications extending back in time to 09/256,388, filed 24 February 1999, abandoned. Paper 1, page 6, line 4.

27. On 12/15/2011, in interference 105,841, paper 3, at page 2 lines 16-24, the Board stated that:

16 Judgment on priority was entered against Tobinick as to the count in the '621  
17 Interference and the involved claims of Tobinick patent 6,015,557 were cancelled after  
18 settlement. ('621 Interference, Paper 33.) Because those claims corresponded to a  
19 count encompassing the same subject matter as the current Count, it appears that  
20 Tobinick is estopped from claiming this subject matter. See *In re Kroekel*, 803 F.2d 705  
21 (Fed. Cir. 1986) (holding that if a party never attempted to include in a prior interference  
22 subject matter that would have dominated the lost count of that interference, it may not  
23 later claim the subject matter). Accordingly, Tobinick must show why judgment should  
24 not be entered against it.

28. On 1/18/2012, in interference 105,841, paper 50, Tobinick explained why judgment should not be entered against it. Tobinick stated in part, at page 2 line 28 to page 3 line 2 that:

28 On the other hand, all other claims in the '944 and '549 patents relating to treatment of  
29 neurodegenerative disease are limited to "intralesional" or "perilesional" administration, which  
30 are species of localized administration; these methods are carefully described as such in the  
1 Tobinick specification, as are the therapeutic advantages gained by use of localized  
2 administration. EX2001 ¶¶10 - 21 (Tobinick Declaration).

and at page 4 lines 31-39 that:

31 The APJ granted the "Tact Motion" on Nov. 26, 2008, Paper 29 ("Tobinick asks that  
32 claims 22 and 26 be designated as not corresponding to Count 2, the sole Count of the  
33 interference. Le does not oppose the Tobinick motion. We GRANT the Tobinick motion."  
34 EX2002).  
35 Tobinick claims 22 and 26 are dependent claims limited to a localized mode of  
36 administration ("intrathecally") of etanercept, for treatment of neurodegenerative disorders.  
37 As shown above the Parties agreed that only four claims in the involved Tobinick '944 and '549  
38 patents should correspond to Count 2 of the '621 interference, and by implication to the Count of  
39 this interference, while all other claims in the Tobinick patents do not correspond.

and at page 6 lines 1-15 that:

1 To summarize the situation, Senior Party Le previously considered the subject matter of  
2 the involved Tobinick patents 6,419,944 (EX2009) and 6,537,549 (EX2010), and agreed to be  
3 legally bound to the position that no interference exists between Le's involved applications and  
4 any claims in US 6,537,549 and US 6,419,944 *except* for a) the four Tobinick claims which have  
5 now been disclaimed for a second time and b) two Le claims which should have been cancelled  
6 after the '621 interference. That is, Le has agreed that the only Tobinick claims which interfere  
7 with claims that Le is entitled to are: '944 patent claims 35 – 36, and '549 patent claims 21 – 22,  
8 all four of which have been disclaimed by Tobinick.

9  
10 For most of the claims still existing in Tobinick's involved patents the agreed basis of the  
11 Parties' to non-interference was a limitation related to localized administration of the active  
12 ingredient, i.e., '944 Claims 1 – 21, 24 – 36; and '549 Claims 1 – 18, 25 – 33. For the rest of  
13 Tobinick's claims, the basis for non-interference was the nature of the disease being treated, i.e.,  
14 '944 Claims 22, 23 and 37 (glaucoma); and Claim 38 (Postherpetic Neuralgia), '549 Claims 19,  
15 20, 23 (glaucoma) and Claim 24 (Postherpetic Neuralgia). EX2001¶21

29. On 02/23/2012, in interference 105,841, paper 83, at page 2 lines 19-25, the Board stated that:

19 It was agreed during the conference call that instead of redeclaring the  
20 Interference, the parties will file a Joint Motion for No Interference-in-Fact. The parties  
21 will file a schedule for this motion, by 27 February 2012, which is separate from the  
22 schedule provided in the Appendix to this Order. Accordingly, the conference call  
23 scheduled for 1 March 2012 is canceled and the parties are not required to file a list of  
24 Proposed Motions at this time. Should the parties decide to file other motions, they  
25 are reminded that none may be filed without prior authorization.

30. On 2/27/2012, in interference 105,841, page 84, titled "Joint Submission Following Conference Call Held on February 24, 2012", at page 2 lines 5-21, the parties jointly stated that:

5 The parties hereby agree to jointly file a Motion for no interference-in-fact showing the  
6 following:

7 1. Tobinick '944 Claims 1 – 21, 24 – 36; and '549 Claims 1 – 18, 25 – 33 (all Tobinick  
8 claims reciting species of localized administration).

9 The motion will show that localized administration is a separate patentable  
10 invention from the Count.

11 2. Tobinick '944 claim 38, and '549 claim 24 (treating post-herpetic neuralgia,  
12 systemically).

13 The motion will show that treatment of post-herpetic neuralgia is a separate  
14 patentable invention.

15 3. Tobinick '944 Claims 22, 23 and 37; and '549 Claims 19, 20, and 23 (treating glaucoma,  
16 systemically).

17 These claims will not be defended and will remain designated as corresponding to  
18 the Count.

19 4. Tobinick will also file a contingent Motion for Adverse Judgment against the remaining [sic; remaining]  
20 '944 Claims 22, 23 and 37; and '549 Claims 19, 20, and 23 (treating glaucoma,

21 systemically), contingent on the granting of the joint motion for no interference-in-fact.

31. On 2/27/2012, in interference 105,841, paper 85 page 2 lines 3-7, the Board stated that:

3 The Joint Submission Following Conference Call Held on February 24, 2012  
4 (Paper 84) is acknowledged and is generally consistent with what was discussed. It is  
5 understood that the parties now request to file a Joint Motion for No Interference-in-  
6 Fact. If the motion is granted, the Board may revise the count, which currently  
7 expressly includes claims said not to interfere.

32. On 4/9/2012, in interference 105,841, paper 88, titled "TOBINICK Motion to Dedesignate Claims", at page 2 lines 2-5, stated that:

2. Pursuant to the ORDER filed 27 February 2012 (Paper 85), as modified by the telephone  
3 conference on April 9, 2012, Tobinick moves to dedesignate claims 1-21, 24-34, and 38 of the  
4 Tobinick '944 patent, and claims 1-18 and 24-33 of the Tobinick '549 patent, due by 9 April  
5 2012. Party Le stated that it will not oppose. The page limit has been increased by one page.

33. On 4/9/2012, in interference 105,841, paper 89, page 2 lines 2-5, Tobinick also filed the contingent motion, stating that:

Tobinick contingently Moves for Adverse Judgment as to claims 22, 23, and 37 of its  
2 '944 patent, and claims 19, 20, and 23 of its '549 patent; contingent on the granting of  
3 Tobinick's motion to dedesignate '944 patent claims 1-21, 24-34, and 38; and Tobinick '549 4 patent claims 1-18  
and 24-33.

34. On 5/17/2012, in interference 105,841, paper 173, titled "Decision on Motion", the Board rendered a decision on Tobinick's paper 88, motion to dedesignate claims. The decision at page 14 lines 16 et seq. stated that:

Tobinick '944 patent claims 1-21 and 30-34 and '549 patent claims 1-18 and 25-  
33 interfere with the claims of the Count. The designation of these Tobinick claims as  
corresponding to the Count is not modified.

Tobinick '944 patent claims 24-29, which are drawn to inhibiting the action of  
interleukin, do not correspond to the Count.

Tobinick '944 patent claim 38 and '549 patent claim 24, directed to treating PHN,  
do not correspond to the Count.

A Redeclaration will be issued concurrently.

35. On 5/17/2012, in interference 105,841, paper 174, titled "Redeclaration", the Board redeclared the interference. At page 2 lines 8-10, it identified Tobinick's corresponding claims, stating that:

The claims of the parties which correspond to Count 1 are:

Tobinick ('944): 1-23 and 30-37

Tobinick ('549): 1-23 and 25-33

36. On 5/17/2012, in interference 105,841, paper 174, the Board issued an order to show cause against Tobinick, which stated at page 1 first line to page 2 last line that:

In the Decision on Motion the panel concluded that the Tobinick claims directed to treating neurological conditions by administering TNF antagonists "intralesionally," "perilesionally," and "subcutaneously to the area anatomically adjacent to the site of disc herniation" do not recite subject matter that is patentably distinct from the subject matter of Le's claims of the Count. (*See* Paper 173.)

The prior interference 105,621 ("the '621 interference") used the same Le claims in the Count (Le '488 application claim 4 and Le '971 application claim 1), with the same Le claims corresponding (Le '488 application claims 4, 7-10, 32, 33, 37, 53-58, 60, 61, 63, 64, 85, 87, and 88, and Le '971 application claims 1-7, 18-20, and 22-37). (*See* '621 Interference, Papers 23 and 30.) Judgment was entered against Tobinick in the '621 Interference and claims of the Tobinick's Patent 6,015,557 that corresponded to the Count were canceled. ('621 Interference, Paper 33.)

In the prior Order to Show Cause issued in the current Interference we required Tobinick to show why judgment should not be entered against it because the claims it lost in the '621 Interference corresponded to a count encompassing similar subject matter as the current Count. (Paper 3.) We continued this Interference in light of Tobinick's response that it had disclaimed claims directed to systemic administration and was presenting only claims directed to localized administration (and claims directed to specific diseases). (*See* Paper 50, pp. 1-7 and 16.)

Tobinick has now had a full opportunity to show that its present claims do not interfere with Le's involved claims and should not correspond to a count that encompasses similar subject matter to the count of the '621 Interference. As provided in our Decision on Motion (Paper 173), Tobinick persuaded the panel that certain claims did not correspond, but failed to persuade the panel that claims 1-21 and 30-34 of the Tobinick '944 patent and claims 1-18 and 25-33 of the Tobinick '549 patent do not interfere with Le's involved claims and do not correspond to the current Count. Thus, Tobinick is estopped from claiming this subject matter because judgment on priority was entered against it in the '621 Interference. ('621 Interference, Paper 33.) *See In re Kroekel*, 803 F.2d 705 (Fed. Cir. 1986) (holding that if a party never attempted to include in a prior interference subject matter that would have dominated the lost count of that interference, it may not later claim the subject matter).

37. On 6/1/2012, in interference 105,841, paper 178, Tobinick filed a response to the 5/17/2012 Order to show cause. The response cited to exhibits EX 2136 to EX 2144.

38. On 6/21/2012, in interference 105,841, paper 227, titled "Decision - Tobinick Response to Show Cause Order", the Board concluded that Tobinick had failed to show cause why

judgment should not be entered against claims 1-23, 30-34, and 37 of Tobinick patent 6,419,944, and claims 1-20, 23, and 25-33 of Tobinick patent 6,537,549. There, the Board stated, at page 6 lines 18-21, that:

18 Tobinick has failed to present sufficient evidence to show that it is entitled to the  
19 subject matter of claims 1-23, 30-34, and 37 of Tobinick patent 6,419,944, and claims 1-  
20 20, 23, and 25-33 of Tobinick patent 6,537,549 by showing that these claims are  
21 patentably distinct from the claims it lost in '621 Interference.

39. On 6/21/2012, in interference 105,841, paper 227, titled "Decision - Tobinick Response to Show Cause Order", at page 2 lines 6-7, the Board noted that:

6 Previously, in this Interference, Tobinick was required to show cause why it is not  
7 estopped from claiming the subject matter it lost in the '621 Interference. (Order to  
8 Show Cause, Paper 3.) In response, Tobinick argued that only claims directed to  
9 localized administration of a TNF antagonist remain in the currently involved patents  
10 (Tobinick Response to Show Cause Order, Paper 50, p. 6) and that these claims do not  
11 interfere with Le's involved claims, which are not limited to a route of administration (*id.*,  
12 pp. 11-16). Tobinick also argued that certain claims directed to treating glaucoma and  
13 postherpetic neuralgia do not interfere with Le's involved claims because of the nature  
14 of the disease being treated. (First Show Cause Response, Paper 50, pp. 6 and 16.)  
15 The current Interference was allowed to proceed on the preliminary showing that  
16 Tobinick had disclaimed claims that clearly encompassed systemic administration and  
17 because the remaining claims might not interfere with Le's involved claims.

40. On 6/21/2012, in interference 105,841, paper 227, titled "Decision - Tobinick Response to Show Cause Order", at page 4, lines 4-31, the Board explained that:

4 To show that it is not estopped from claiming the subject of the current claims,  
5 Tobinick must show that the currently involved claims are patentably distinct from claims  
6 it lost in a prior interference. *In re Deckler*, 977 F.2d 1449 (Fed. Cir. 1992). (See Order  
7 to Show Cause, Paper 175, p. 2: "Tobinick is estopped from claiming [the subject matter  
8 of claims 1-21 and 30-34 of the Tobinick '944 patent and claims 1-18 and 25-33 of the  
9 Tobinick '549 patent] because judgment on priority was entered against it in the '621  
10 Interference.") In the prior '621 Interference, adverse judgment was entered against  
11 claim 1 of Tobinick's Patent 6,015,557 ("the '557 Patent"), which recites:  
12 A method for inhibiting the action of TNF for treating neurological  
13 conditions in a human by administering a TNF antagonist for reducing the  
14 inflammation of neuronal tissue of said human, or for modulating the  
15 immune response affecting neuronal tissue of said human, comprising the  
16 step of:  
17 a) administering a therapeutically effective dosage level to said  
18 human of said TNF antagonist selected from the group consisting of  
19 etanercept and infliximab for reducing the inflammation of neuronal tissue  
20 of said human, or for modulating the immune response affecting neuronal  
21 tissue of said human.  
22  
23 Tobinick is entitled only to claims that are patentably distinct from claim 1 of the '557  
24 Patent. But, in its Response to the Order to Show Cause (Paper 178 ("Response"))

25 Tobinick fails to compare the currently claims to any claims of the '557 Patent.  
26 Tobinick's Response considers only the differences between Tobinick's currently  
27 involved claims and Le's currently involved claims, not the claims Tobinick lost in the  
28 '557 Patent. Tobinick does not provide support to show that any of its currently involved  
29 claims are patentably distinct from claim 1 of the '557 Patent. Tobinick has failed to  
30 present argument or evidence to persuade us that it is not estopped from claiming the  
31 subject matter of any of its currently involved claims.

41. The Board's reasoning in paper 227 lines 9-19 (*italics in the original*), indicates that Tobinick failed to present sufficient evidence. That passage reads as follows:

... The request to designate claims directed to  
10 "intralesionally or perilesionally" or "subcutaneously to the area anatomically adjacent to  
11 the site of disc herniation" routes of administration in the current Interference was  
12 denied because Tobinick failed to present sufficient evidence that *any* type of local  
13 administration would not have been obvious over systemic administration, even if it was  
14 previously held that one local route of administration, "intrathecal," would not have been  
15 obvious. (Decision on Motion, Paper 173, pp. 4-11.) The request to have claims  
16 directed to inhibiting the action of interleukin and to treating post-herpetic neuralgia  
17 designated as not corresponding to the Count was granted because Tobinick provided  
18 sufficient evidence to show that these methods would not have been obvious over the  
19 subject matter of the Count. (Decision on Motion, Paper 173, pp. 11-14.)

42. TACT IP, LLC will present additional evidence including live testimony, which shows that Tobinick's patent 6,419,944 Claims 1 -4, 7-10, 12 -21, 30 - 34; and patent 6,537,549 Claims 1-4, 7-10, 12-18 and 25-33, are (1) patentably distinct from count 2 in interference 105,621 and (2) do not interfere with the claims of Le involved in interference 105,841.

#### PRAYER FOR RELIEF

Plaintiff TACT IP, LLC prays for a judgment and order and decree that:

1. Interference estoppel based upon the judgment in interference 105,621 does not bar any of Tobinick's patent 6,419,944 Claims 1 -4, 7-10, 12 -21, 30 - 34; and patent 6,537,549 Claims 1-4, 7-10, 12-18 and 25-33.
2. Tobinick patent 6,419,944 Claims 1 -4, 7-10, 12 -21, 30 - 34; and patent 6,537,549 Claims 1-4, 7-10, 12-18 and 25-33 are patentably distinct from count 2 in interference 105,621.
3. Tobinick patent 6,419,944 Claims 1 -4, 7-10, 12 -21, 30 - 34; and patent 6,537,549 Claims 1-4, 7-10, 12-18 and 25-33 do not interfere with Claim 4 of Le 10/227,488 or Claim 1 of Le application 10/665,971.

4. The Board's adverse judgment against patent 6,419,944 Claims 1 –4, 7-10, 12 –21, 30 – 34; and patent 6,537,549 Claims 1-4, 7-10, 12-18 and 25-33 is reversed.
5. Other such relief that Court deems just and proper.

Date: 8/15/2012

By: 

RICHARD NEIFELD (VA BAR NO. 37310)  
DANIEL SACHS (VA BAR NO. 36397)  
NEIFELD IP LAW, PC  
4813-b EISENHOWER AVENUE  
ALEXANDRIA, VA 22304  
703-415-0012 – telephone  
703-415-0013 – facsimile  
RNEIFELD@NEIFELD.COM – email

OF COUNSEL

ROBERT HAHL  
NEIFELD IP LAW, PC  
4813-b EISENHOWER AVENUE  
ALEXANDRIA, VA 22304

Ran

Date: 8-9-2012

Pat: Y:\Clients\TACT Tact IP, LLC\TACT\_Int105841\_146CivilAction\Drafts

File: Complaint\_TACT\_105841\_146Action.docx