

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AlphaVax, Inc.)	
)	
)	
Plaintiff,)	
)	
v.)	CIVIL ACTION No. 09-11176
)	
Novartis Vaccines and Diagnostics, Inc.)	
)	
)	
Defendant.)	

COMPLAINT

Plaintiff AlphaVax, Inc. (hereinafter “AlphaVax”) for its Complaint under 35 U.S.C. §146 against Novartis Vaccines and Diagnostics, Inc. (hereinafter “Novartis”) states as follows:

I. THE PARTIES

1. Plaintiff AlphaVax is a corporation organized and existing under the laws of the State of North Carolina, with a principal place of business at 2 Triangle Drive, Research Triangle Park, North Carolina 27709.

2. Defendant Novartis is, on information and belief, a Swiss corporation with offices throughout the United States. Its headquarters in the United States, on information and belief, is in Cambridge, Massachusetts.

II. THE NATURE OF THE ACTION

3. This is an action pursuant to 35 U.S.C. §146, to review and remedy the Decision and Final Judgment of the Board of Patent Appeals and Interferences (hereinafter “Board”) in Interference 105,456, declared on August 2, 2006 and entitled Robert E. Johnston et al, Junior

Party (AlphaVax) v. Thomas W. Dubensky Jr. et al Senior Party (Novartis) (hereinafter “Interference” or “Interference 105,456”).

III. JURISDICTION AND VENUE

4. This Court has subject matter jurisdiction pursuant to 35 U.S.C. §146, as well as 28 U.S.C. §1338(a). Venue is proper in this judicial district under 35 U.S.C. §146, as well as 28 U.S.C. §1391(b).

IV. FACTS GIVING RISE TO THE COMPLAINT

5. AlphaVax is the exclusive licensee of U.S. Patent Application Serial No. 10/683,781 (hereinafter “’781 application”) involved in Interference 105,456. AlphaVax enjoys the power and right to prosecute the ‘781 patent application, including contesting interferences.

6. Novartis is the assignee of U.S. Patent 6,015,694 (hereinafter “’694 patent”) involved in Interference 105,456.

7. The Board declared Interference 105,456 on August 2, 2006. Claims 9 - 11 of the ‘694 patent were designated as corresponding to the single Count of the Interference. The only claim of the ‘781 application, Claim 38, was designated as corresponding to the Count.

8. Count 1 of the Interference is comprised of Claim 38 of the ‘781 application or Claim 9 of the ‘694 patent.

9. On August 2, 2006, the Board, in Paper 4, issued an Order to Show Cause, explaining that it found the showing earlier made by Johnston during prosecution of the ‘781 application was insufficient to establish priority, *prima facie*, in the Interference. Specifically, it found that the corroborating testimony of Ian Caley, Cathleen Lind and Loreen Loft was insufficient to “corroborate the inventors’ testimony.” See, Paper 4, page 2. The Order to Show Cause set a date

of September 5, 2006 as the time to file a suitable response, showing good cause why judgment should not be entered against AlphaVax.

10. On August 21, a conference call was held between lead counsel for the parties and the Administrative Patent Judge then responsible for Interference 105,456, Judge Sally Gardner Lane. In response to the Order to Show Cause, Johnston and AlphaVax requested permission to file two Motions – one attacking the priority date accorded the ‘694 patent, such that Dubensky/Novartis would no longer be Senior Party, and one, contingent on denial of this first Motion, to substitute a different Count as to which Dubensky/Novartis would not be entitled to benefit, and thus not Senior Party. Johnston was given express permission to file these Motions on or before September 19, 2006.

11. The two Motions expressly approved were filed on September 19, 2006, together with evidence in the form of Declarations and supportive documents. As provided for in the rules applicable to interferences (“Rules”), the Motions included Statements of Fact based on the evidence provided and referencing that evidence, and an Index of Evidence Relied On.

12. Also on September 19, 2006, Johnston/AlphaVax filed a Response to the Order to Show Cause, noting that the inventive work was conducted in a Biosafety Level 3-4 laboratory, where materials and personnel are isolated due to the dangerous nature of the materials used (in particular, viruses that can induce morbidity and even death in humans), and the type of “in person” corroboration the Board complained was lacking was not possible. It was argued instead that the laboratory record, including laboratory notebooks that were the subject of the inventors’ declarations previously submitted, and laboratory diaries, also the subject of previous declarations, all provided the necessary corroboration, as provided for in case law.

13. On September 26, 2006 there was another conference call. The results of that call are reflected in Paper 24. Among other Orders issued, APJ Lane expressly authorized AlphaVax to file three motions for Judgment – (1) a Motion seeking Judgment that the ‘694 patent Claims 9 – 11 were not patentable for lack of enablement; (2) a Motion seeking judgment that Claims 9 – 11 were unpatentable over prior art, and (3) a Motion for Judgment that Claims 9 – 11 of the ‘694 patent are unpatentable as indefinite. Time periods in which to serve and file Motions, Oppositions, Replies, Evidence and other procedural matters were established in the same paper.

14. On October 26, 2006, the Board issued an Order finding that AlphaVax’s Motions (1 and 2) attacking the benefit date accorded the ‘694 patent, and the Response to the Order to Show Cause, were sufficient to require the filing of oppositions thereto. If the Motions and Response were not sufficient to establish a *prima facie* showing, on the record as it existed, then the Board would have issued judgment in the Interference. Specifically, the showing, to extend the interference, must be sufficient such that – unrebutted, it supports a determination of priority in favor of the party making the submission. 37 C.F.R. §41.202(e). The Board’s practices are set forth in *Basmadjian v. Landry*, 54 USPQ2d 1616-17, 1622 (PBAI 2000). (*If summary judgment is deemed appropriate by a merits panel, a final decision is entered against the applicant.... On the other hand, if the APJ or the merits panel determines that summary judgment is not appropriate, an order is entered allowing the interference to proceed in the normal manner.*) The paper of October 26, 2006, Paper 26, found that the papers filed by AlphaVax were sufficiently compelling, if not rebutted, to support a determination of priority in favor of AlphaVax, as it ordered Interference 105,456 to proceed in a normal fashion.

15. The Interference did indeed proceed in normal fashion – Motions were filed and served, Oppositions and Replies were filed and served, and supporting evidence was served by

both parties. Novartis filed a Motion to Suppress certain evidence obtained in cross-examination or redirect examination, and an Opposition and Reply was filed to same. Ultimately, the evidence relied on by both parties was timely filed with the Board, in the form of the Record.

16. On June 19, 2007, the Board held an Oral Hearing before merits Panel Judges Schafer, Nagumo and the Judge in Charge of the interference, Judge Lane. Subsequently, Judge Schafer was made the Judge in Charge in place of Judge Lane.

17. It was not until May 20, 2009, more than two years after the final Replies and evidence was filed by the parties, that the Board ruled on the Response to the Order to Show Cause. Reversing its earlier decision without discussing it, the Board found that AlphaVax's Response to the Order to Show cause was **not** sufficient, but nowhere in the Decision did the Board point to rebuttal evidence of any type in so deciding. Similarly, the Board now found that while, previously, AlphaVax's showing on the issue of the benefit date to which the '694 patent was entitled was sufficient to continue the Interference in the normal manner (and therefore, sufficient to support an award of priority if un rebutted), the Board now found that the Motion attacking Benefit was insufficient, again without referring to any rebuttal evidence. In the same way, Johnston's Motion to change the Count, which previously was found sufficient to continue the Interference in a normal manner, was found in the May 20, 2009 Decision to be inadequate, without the citation of rebuttal evidence.

18. The decision on Motions also declined to decide any of the three Substantive Motions AlphaVax was previously expressly authorized to file, without explaining why these previously authorized Motions should not be decided. If any one of those Motions was decided in favor of AlphaVax, Novartis would not be entitled to Claims 9 – 11 of the '694 patent, and

those Claims would have been cancelled, removing the only obstacle to issuance of Claim 38 of the '781 application.

V. SUMMARY OF CHARGEABLE ERRORS

19. Judge Lane found that the Response to the Order to Show Cause, together with Substantive Motion 1 to deny priority, and Substantive Motion 2 to redefine the Count, demonstrated that, in the absence of rebuttal evidence, AlphaVax was entitled to judgment based on priority. Accordingly, she Ordered that the Interference continue in normal fashion. Subsequently, a different judge, Judge Schafer, writing for a panel that did not include Judge Nagumo, who heard the case, concluded that the same papers were insufficient to justify an award of priority, without identifying any rebuttal evidence. This is error as to which plaintiff AlphaVax seeks review.

20. The Board rejected the evidence offered by AlphaVax to corroborate the invention of the subject matter by the AlphaVax inventors, requiring actual eyewitnessing of the events involved, notwithstanding the conditions of the research which prevented such witnessing. The Board ignored the corroborative effect of the unchallenged and continuous evidence of invention contained in the laboratory notebooks and diaries of the AlphaVax inventors and corroborators, even though the notebooks were the subject of extensive Declarations of those inventors. This is error as to which plaintiff AlphaVax seeks review.

21. The Board denied AlphaVax's Substantive Motion 1, concluding that AlphaVax had not demonstrated where the evidence it relied on could be found, when, pursuant to the Rules, the evidence relied upon was contained in separate Statements of Material Fact, each referring to the source of evidence relied on by page and column number. This is error as to which plaintiff AlphaVax seeks review.

22. The Board denied AlphaVax's Substantive Motion 2, concluding that AlphaVax had not demonstrated where the evidence it relied on could be found, when, pursuant to the Rules, the evidence relied on was contained in separate Statements of Material Fact, each referring to the source of evidence relied on by page and column number. This is error as to which plaintiff AlphaVax seeks review.

23. The Board expressly granted AlphaVax permission to advance Substantive Motion 3 seeking a judgment that Claims 9 – 11 of the '694 patent were invalid. The Motion was filed, evidence submitted, depositions taken, an Opposition filed with supporting evidence and further deposition, a Reply with evidence was filed and a hearing held. The parties to Interference 105,456 expended a significant amount of resources contesting the issues raised by this Motion. The Board declined to decide AlphaVax Substantive Motion 3, without indicating why. This is error as to which plaintiff AlphaVax seeks review.

24. The Board expressly granted AlphaVax permission to advance Substantive Motion 4 seeking a judgment that Claims 9 – 11 of the '694 patent were invalid. The Motion was filed, evidence submitted, depositions taken, an Opposition filed with evidence and further deposition and a Reply was filed with supporting evidence, and a hearing held. The parties to Interference 105,456 expended a significant amount of resources contesting the issues raised by this Motion. The Board declined to decide AlphaVax Substantive Motion 4, without indicating why. This is error as to which plaintiff AlphaVax seeks review.

25. The Board expressly granted AlphaVax permission to advance Substantive Motion 5 seeking a judgment that Claims 9 – 11 of the '694 patent were invalid. The Motion was filed, evidence submitted, depositions taken, an Opposition with evidence was submitted with an additional deposition and a Reply filed with supporting evidence, and a hearing held. The parties

to Interference 105,456 expended a significant amount of resources contesting the issues raised by this Motion. The Board declined to decide AlphaVax Substantive Motion 5, without indicating why. This is error as to which plaintiff AlphaVax seeks review.

VI. PRAYER FOR RELIEF

WHEREFORE, plaintiff AlphaVax prays for a judgment:

A. Reversing the Board's entry of Summary Judgment on the grounds that the evidence relied upon by AlphaVax of date of invention was not corroborated;

B Reversing the Board's decision denying AlphaVax Substantive Motion 1;

C. Reversing the Board's decision denying AlphaVax Substantive Motion 2;

D. Reversing the Board's decision refusing to decide AlphaVax Substantive Motion 3, and granting said motion, which will remove the basis for rejecting Claim 38 of the '791 application;

E. Reversing the Board's decision refusing to decide AlphaVax Substantive Motion 4, and granting said motion, which will remove the basis for rejecting Claim 38 of the '791 application;

F. Reversing the Board's decision refusing to decide AlphaVax Substantive Motion 5, and granting said motion, which will remove the basis for rejecting Claim 38 of the '791 application;

G. Directing the United States Patent and Trademark Office to cancel Claims 9 – 11 of the '694 patent as unpatentable to Novartis, and issue the '791 application as a United States Patent;

H. Awarding AlphaVax its costs and attorneys' fees in this action, and such other and further relief as this Court may deem just.

AlphaVax, Inc.,

By its attorneys,

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