IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

INO THERAPEUTICS LLC and IKARIA, INC.)
Plaintiffs,))
V.))
PRAXAIR DISTRIBUTION, INC. and)
PRAXAIR, INC.,)
Defendants)

C. A. No.: 15-170-GMS

DEFENDANTS' INITIAL INVALIDITY CONTENTIONS

Defendants Praxair Distribution, Inc. and Praxair, Inc. ("Praxair" or "Defendants") serve their Initial Invalidity Contentions ("Invalidity Contentions") and accompanying document production on Plaintiffs INO Therapeutics LLC and Ikaria, Inc. ("Ikaria" or "Plaintiffs"). Defendants contend that each of the asserted claims of U.S. Patent Nos. 8,282,966 (the "966 Patent"); 8,293,284 (the "284 Patent"); 8,431,163 (the "163 Patent"); 8,795,741 (the "741 Patent"); 8,846,112 (the "112 Patent") (collectively, "Label Patents") and U.S. Patent No. 8,291,904 (the "904 Patent"); 8,573,209 (the "209 Patent"); 8,573,210 (the "210 Patent"); 8,776,794 (the "794 Patent"); and 8,776,795 (the "795 Patent") (collectively, "Device Patents") (Label Patents and Device Patents collectively referred to as the "Patents-in-Suit") is invalid under at least pre-America Invents Act (AIA) 35 U.S.C. §§ 101, 102, 103, and/or 112.

INTRODUCTION

Ikaria filed this action seeking a judgment that the claims of the Patents-in-Suit are infringed. Defendants separately counterclaimed seeking judgments that the claims of the Patents-in-Suit are invalid and not infringed. As indicated in its Disclosure of Asserted Claims and Infringement Contentions ("Infringement Contentions"), Ikaria asserts the following claims against Praxair:

01:18076737.1

Mallinckrodt Hosp. Prods. IP Ltd. Exhibit 2021 Praxair Distrib., Inc. et al., v. Mallinckrodt Hosp. Prods. IP Ltd. Case IPR2016-00781

- '904 Patent Claims 1, 3, 5, 7.
- '209 Patent Claims 1-3, 6, 7.
- '210 Patent Claims 1-4, 6, 8, 12-16.
- '794 Patent Claims 1-4, 6-20.
- '795 Patent Claims 1-4, 6-20.
- '966 Patent Claims 1-29.
- '284 Patent Claims 1-30.
- '163 Patent Claims 1-25.
- '741 Patent Claims 1-44.
- '112 Patent Claims 1-11.

These Invalidity Contentions are based in whole or in part on Defendants' present understanding of the asserted claims and Ikaria's apparent construction of the asserted claims in its Infringement Contentions. Accordingly, the Invalidity Contentions, including the attached invalidity claim charts, may reflect alternative positions as to claim construction and scope. Further, by including prior art that would anticipate or render obvious those claims based on Ikaria's apparent claim construction or on any other particular claim construction, Defendants are not adopting Ikaria's claim construction, nor admitting to the accuracy of any particular claim construction.

Ikaria's Infringement Contentions, which were only recently received, lack proper and complete disclosure as to each accused product, and thus do not provide adequate information to permit Defendants to prepare their Invalidity Contentions. Accordingly, Defendants reserve the right to further supplement or modify these contentions, including the prior art disclosed and the stated grounds of invalidity.

Defendants reserve the right to revise their Invalidity Contentions, which may change depending upon the Court's construction of the claims, additional information obtained during discovery, any findings as to the priority date of the asserted claims, and/or positions that Ikaria or expert witness(es) may take concerning claim construction, infringement, and/or invalidity issues. The Invalidity Contentions pertain only to the asserted claims as identified by Ikaria's Infringement Contentions. Defendants reserve the right to modify, amend, or supplement the Invalidity Contentions to show the invalidity of any additional claims that the Court may later allow Ikaria to assert. Defendants further reserve the right to supplement their accompanying document production should it later find additional relevant documents, software and/or source code.

Defendants further may rely on inventor admissions concerning the scope or state of the prior art relevant to the asserted claims; the patent prosecution history for the asserted patents, and related patents and/or patent applications; any deposition or trial testimony of the named inventors on the asserted patents; and the papers filed and any evidence produced or submitted by Ikaria in connection with this or related litigation. In particular, Defendants reserve the right to contend that the asserted claims are invalid under pre-AIA 35 U.S.C. § 102(f) in the event Defendants obtain evidence that the named inventors did not invent the subject matter in the asserted claims. Defendants also reserve the right to contend that the asserted claims are invalid under pre-AIA 35 U.S.C. § 102(g)(2) if the Defendants obtain evidence that the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it.

Prior art not included in these contentions, whether known or not known to Defendants, may become relevant. In particular, Defendants are currently unaware of the extent, if any, to which Ikaria will contend that limitations of the asserted claims are not disclosed in the prior art identified in the Invalidity Contentions. Accordingly, Defendants reserve the right to identify other references that would render obvious the allegedly missing limitation(s) of the disclosed device or method.

01:18076737.1

- 7 -

Discovery has recently begun and Defendants anticipate that additional prior art may be found. Thus, Defendants reserve the right to revise, amend, and/or supplement the information provided herein, including identifying, charting, and relying on additional references, should such art be found.

Additionally, because third-party discovery is ongoing, Defendants reserve the right to present additional items of prior art under pre-AIA 35 U.S.C. §§ 102(a), (b), (e), and/or (g), and/or § 103 located during discovery or further investigation, and to assert contentions of invalidity under 35 U.S.C. §§ 102(c), (d), or (f). For example, Defendants expect to issue subpoenas to third parties believed to have knowledge, documentation and/or corroborating evidence concerning the validity of the asserted claims.

In addition to the prior art identified below and the accompanying invalidity claim charts, Defendants also incorporate by reference any additional invalidity contentions, such as supplemental contentions, identified prior art, or invalidity claim charts disclosed at any time by parties in the present litigation or by any party to any other litigation or U.S. Patent and Trademark Office proceeding involving the '904, '209, '210, '794, '795, '966, '284, '163, '741, or '112 Patents.

Defendants reserve the right to supplement or otherwise amend these Invalidity Contentions in response to any original or rebuttal expert report, or in response to the Court's claim construction order. Defendants also reserve the right to supplement or otherwise amend these Invalidity Contentions in response to any rebuttal evidence by Ikaria or as otherwise may be necessary or appropriate under the circumstances.

I. THE LABEL PATENTS

A. Prior Art

Defendants list below prior art that anticipates or renders obvious the asserted claims of the Label Patents under 35 U.S.C. § 102 and/or § 103. A complete listing of these references is also 01:18076737.1

provided in Appendix A. Invalidity claim charts for these references with respect to the asserted claims of the Patents-in-Suit are attached in Appendix B.

Defendants have identified relevant portions and/or features of the prior art. However, the identified prior art may contain additional descriptions of or alternative support for the claim limitations. Defendants may rely on uncited portions or features of the identified prior art, other documents, and expert testimony, to provide context or to aid in understanding the identified prior art and the state of the art. Citations to a particular figure in a reference include the caption and description of the figure and any text relating to the figure. Similarly, citations to particular text referring to a figure include the figure and caption as well.

B. Anticipation

In Tables 1A-1B, Defendants identify prior art that anticipates certain asserted claims of the Label Patents under at least 35 U.S.C. §§ 102(a), (b), (e), (f) and/or (g), either expressly or inherently, as understood by a person having ordinary skill in the art at the time of the invention. In some instances, Defendants have treated certain prior art as anticipatory where certain elements are inherently present based on Ikaria's apparent claim construction in its Infringement Contentions. To the extent that any of the prior art identified below in Tables 1A-1B is found not to anticipate particular claims of the Label Patents, that prior art may render those claims obvious, either alone or in combination with other prior art disclosed herein, including with those patents, publications, or systems referenced in Tables 1A-1B.

01:18076737.1



DOCKET A L A R M



Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.