

UNITED STATES PATENT AND TRADEMARK OFFICE

---

BEFORE THE PATENT TRIAL AND APPEAL BOARD

---

MAIA PHARMACEUTICALS, INC.,  
Petitioner,

v.

BRACCO DIAGNOSTICS INC.,

Patent Owner.

---

Case IPR2019-00345

Patent 6,803,046

---

**Patent Owner's Preliminary Response**

## Table of Contents

|      |   |    |
|------|---|----|
| I.   | <b>INTRODUCTION .....</b>   | 1  |
| II.  | <b>BACKGROUND.....</b>  | 4  |
| A.   | <i>Sincalide (CCK-8), KINEVAC, and the '046 Patent .....</i>  | 4  |
| B.   | <i>The Person of Ordinary Skill in the Art ("POSITA").....</i>  | 7  |
| C.   | <i>The Related District Court Litigation.....</i>   | 8  |
| D.   | <i>37 C.F.R. § 1.56.....</i>  | 9  |
| E.   | <i>Petitioner's Sincalide Patent Application .....</i>  | 9  |
| III. | <b>CLAIM CONSTRUCTION.....</b>  | 12 |
| IV.  | <b>PETITIONER FAILS TO ADEQUATELY ADDRESS THE SCOPE<br/>AND CONTENT OF THE PRIOR ART AS REQUIRED BY<br/>GRAHAM.....</b> | 12 |
| A.   | <i>Legal Standards.....</i>   | 12 |
| B.   | <i>"surfactant".....</i>  | 14 |
| C.   | <i>"a stabilizer".....</i>  | 20 |
| D.   | <i>"a phosphate buffer".....</i>  | 24 |
| V.   | <b>THERE IS NO MOTIVATION TO USE THE TEACHINGS OF<br/>SATO WITH THE PDR .....</b>                                       | 25 |
| A.   | <i>Petitioner's Combination .....</i>   | 26 |
| B.   | <i>There is no motivation to use Sato to modify KINEVAC-1976.....</i>   | 29 |
| VI.  | <b>THERE IS NO REASONABLE EXPECTATION OF</b>  |    |

|  |           |
|--|-----------|
| <b>SUCCESSFULLY ACHIEVING A STABLE SINCALIDE FORMULATION BASED ON THE PDR AND SATO .....</b> | <b>33</b> |
| <b>VII. PETITIONER'S ARGUMENT IS ALSO AN UNSUPPORTED "OBVIOUS TO TRY" ARGUMENT .....</b>     | <b>43</b> |
| <b>VIII. CONCLUSION .....</b>  | <b>45</b> |

**TABLE OF AUTHORITIES**

|  | Page(s)       |
|--|---------------|
| <b>Cases</b>   |               |
| <i>Apple Inc. v. Samsung Electronics Co., Ltd.</i> ,<br>839 F.3d 1034 (Fed. Cir. 2016) .....   | 13            |
| <i>Interbulk USA LLC v. Global Strategies, Inc.</i> ,<br>IPR2018-01197, Paper 7 (PTAB Jan. 11, 2019) .....                               | 3, 19         |
| <i>Bausch &amp; Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc.</i> ,<br>796 F.2d 443 (Fed. Cir. 1986) .....                                  | 13            |
| <i>Bayer Schering Pharma AG v. Barr Laboratories</i> ,<br>575 F.3d 1341 (Fed. Cir. 2009) .....   | 44            |
| <i>Bracco Diagnostics Inc. v. Maia Pharmaceuticals, Inc.</i> ,<br>3:17-cv-13151-PGS-TJB (D. N.J. Dec. 15, 2017).....                     | 8, 9, 41      |
| <i>Daiichi Sankyo Co., Ltd. v. Matrix Labs.</i> ,<br>619 F.3d 1346 (Fed. Cir. 2011) .....  | 32            |
| <i>Graham v. John Deere Co. of Kansas City</i> ,<br>383 U.S. 1 (1996)..... <i>passim</i>   |               |
| <i>KSR v. Teleflex Inc.</i> ,<br>550 US 398 (2007).....  | 3, 7, 13      |
| <i>In re Magnum Oil Tools</i> ,<br>829 F.3d 1364 (Fed. Cir. 2016) .....  | 4, 12, 13, 21 |
| <i>Oxford Nanopore Techs. Ltd. v. Univ. of Washington and UAB Research Found.</i> ,<br>IPR2014-00513, Paper 51 (PTAB Feb. 26, 2016)..... | 33, 40        |
| <i>Panduit Corp. v. Dennison Mfg. Co.</i> ,<br>810 F.2d 1561 (Fed. Cir. 1987) .....  | 14            |
| <i>Phillips v. AWH Corp.</i> ,<br>415 F.3d 1303 (Fed. Cir. 2005) ( <i>en banc</i> ) .....  | 12            |

|  |        |
|--|--------|
| <i>Procter &amp; Gamble Co. v. Teva Pharmaceuticals USA,</i><br>566 F.3d 989 (Fed. Cir. 2009) .....                  | 26, 40 |
| <i>Seabed Geosolutions (US), Inc. v. Fairfield Indus. Inc.,</i><br>IPR2018-01269, Paper 11 (PTAB Jan. 7, 2019) ..... | 19     |
| <i>Simpson Strong-Tie Co. Inc. v. Oz-Post Int'l, LLC,</i><br>IPR2018-01379, Paper 8 (PTAB Jan. 28, 2019) .....       | 19, 23 |
| <i>Travelocity.com L.P. v. Cronos Tech. LLC,</i><br>CBM2014-00082, Paper 12 (PTAB Oct. 16, 2014) .....               | 13     |
| <i>In re Wesslau,</i><br>353 F.2d 238 (CCPA 1965) .....  | 13     |
| <b>Statutes</b>  |        |
| 35 U.S.C. § 103 .....  | 8, 13  |
| <b>Other Authorities</b>   |        |
| 37 C.F.R. § 1.56 .....   | 9      |
| 37 C.F.R. § 42.100(b) .....  | 12     |

# 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.