| UNITED STATES PATENT AND TRADEMARK OFFICE           |
|---|
| BEFORE THE PATENT TRIAL AND APPEAL BOARD            |
| MYLAN PHARMACEUTICALS INC., Petitioner,             |
| v.  |
| SANOFI-AVENTIS DEUTSCHLAND GMBH, Patent Owner       |
| Case No. IPR2018-01675<br>U.S. Patent No. 8,603,044 |
|   |





### **TABLE OF CONTENTS**

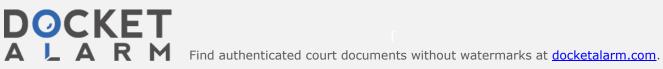
|     |      |       |  | Page |
|-----|------|-------|--|------|
| I.  | INTI | RODU  | CTION  | 1    |
| II. |      |       | RD SHOULD EXERCISE ITS DISCRETION TO DENY ION PURSUANT TO §§ 314(A) AND 324(A)   | 4    |
|     | A.   | Proce | edural Background  | 6    |
|     | В.   |       | Board Has Discretion to Deny Institution Under 35 U.S.C. 14(a) and 324(a)  | 8    |
|     | C.   |       | Spring Co. v. Intri-Plex Technologies, Inc., IPR2018-  | 9    |
|     |      | 1.    | The parties are engaged in District Court litigation on the same patent  | 10   |
|     |      | 2.    | The Petitioner relies on the same prior art in the Petition as in the District Court case  | 11   |
|     |      | 3.    | The District Court trial will conclude before the IPR  | 12   |
|     |      | 4.    | Instituting the IPR permits the Petitioner a tactical advantage  |      |
|     | D.   |       | eral Plastic Industrial Co. v. Canon Kabushiki Kaisha, 016-01357   | 14   |
|     |      | 1.    | General Plastics Factors 1, 2, 4, and 5: whether the same petitioner previously filed a petition directed to the same claims of the same patent; whether at the time of filing of the first petition the petitioner knew of the prior art asserted in the second petition or should have known of it; the length of time that elapsed between the time the petitioner learned of the prior art asserted in the second petition and the filing of the second petition; whether the petitioner provides adequate explanation for the time elapsed between the filings of multiple petitions directed to the same claims of the same patent |      |



|      |     | 2.     | General Plastics Factor 3: whether at the time of filing of<br>the second petition the petitioner already received the<br>patent owner's preliminary response to the first petition or<br>received the Board's decision on whether to institute<br>review in the first petition | 17               |
|------|-----|--------|---|------------------|
|      |     | 3.     | General Plastics Factors 6 and 7: the finite resources of the Board; and the requirement under 35 U.S.C. § 316(a)(11) to issue a final determination not later than 1 year after the date on which the Director notices institution of review                                   | 17               |
| III. | THE | 044 P. | ATENT   | 19               |
| IV.  | CLA | IM CC  | ONSTRUCTION   | 24               |
|      | A.  | "heli  | cal groove" (claim 11)  | 24               |
|      | B.  | "tubu  | ular clutch" (claim 11) and "clicker" (claim 14)  | 28               |
| V.   | THE | PRIO   | R ART   | 29               |
|      | A.  | Burro  | oughs   | 29               |
| VI.  | REA | SONS   | WHY THE PETITION SHOULD BE DENIED   | 36               |
|      | A.  | Discl  | nd 1 Should Be Denied Because Burroughs Does Not<br>lose Or Render Obvious A Helical Groove Provided Along<br>Outer Surface Of Said Dose Dial Sleeve  | 36               |
|      |     | 1.     | Burroughs Does Not Disclose A Helical Groove Provided Along An Outer Surface Of Said Dose Dial Sleeve   | 36               |
|      |     | 2.     | Burroughs In View Of The Knowledge Of A POSA Does<br>Not Render Obvious A Helical Groove Provided Along<br>An Outer Surface Of Said Dose Dial Sleeve  | 36               |
|      |     | 3.     | Petitioner Does Not Establish A Motivation To Modify<br>Burroughs' Threads To Include A Groove  | 41 <del>39</del> |



|      | В.  | Ground 1 Should Be Denied Because Burroughs Does Not Disclose Or Render Obvious That The Helical Groove Of The Dose Dial Sleeve Has A Different Lead Than The Internal |              |
|------|-----|--|--------------|
|      |     | Threading Of The Drive Sleeve  | <u>43</u> 41 |
|      |     | 1. Burroughs Does Not Disclose Or Render Obvious Helical Groove Of The Dose Dial Sleeve  |              |
|      |     | 2. Burroughs Does Not Disclose That The First Lead Ar Second Lead Are Different  |              |
|      |     | 3. Burroughs Does Not Render Obvious That The First Lea<br>And Second Lead Are Different   |              |
|      | C.  | The Petition Fails To Put Patent Owner On Notice Of How To Claims Are To Be Construed In The Grounds As Required Ed. C.F.R. § 42.104(b)                                | Зу           |
| VII. | CON | LUSION   | 5048         |



### **TABLE OF AUTHORITIES**

Page(s)

| Cases   |
|---|
| Compass Bank, Commerce Bankshares, Inc. v. Intellectual Ventures II, LLC, IPR2014-00786, Paper 46 (P.T.A.B. Sept. 23, 2015) |
| Corning Inc. v. DSM IP Assets,<br>IPR2013-00050, Paper 77 (P.T.A.B. May 1, 2014)  |
| Cutsforth, Inc. v. MotivePower, Inc., 636 F. App'x 575 (Fed. Cir. 2016)   |
| Gen. Electric Co. v. Vestas Wind Systems A/S,<br>IPR2018-00928, Paper 9 (P.T.A.B. Nov. 5, 2018)                             |
| Gen. Plastic Indus. Co. v. Canon Kabushiki Kaisha,<br>IPR2016-01357, Paper 19 (P.T.A.B. Sept. 6, 2017)                      |
| Kinetic Concepts, Inc. v. Smith & Nephew, Inc.,<br>688 F.3d 1342 (Fed. Cir. 2012)   |
| Microsoft Corp. v. Koninklijke Philips N.V., IPR2018-00277, Paper 10 (P.T.A.B. June 8, 2018)                                |
| NetApp, Inc. v. Realtime Data LLC,<br>PR2017-01195, Paper 9 (P.T.A.B. Oct. 12, 2017)  |
| NHK Spring Co. v. Intri-Plex Techs., Inc., IPR2018-00752, Paper 8 (P.T.A.B. Sept. 12, 2018)                                 |
| Polaris Indus., Inc. v. Arctic Cat, Inc.,<br>882 F.3d 1056 (Fed. Cir. 2018)   |
| Williamson v. Citrix Online, LLC,<br>792 F.3d 1339 (Fed. Cir. 2015)29   |
| Statutes and Rules  |
| 21 C.F.R. § 314.50, et seq  |
| 21 CEP \$ 214.52  |



# 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.

