

UNITED STATES PATENT AND TRADEMARK OFFICE

---

**BEFORE THE PATENT TRIAL AND APPEAL BOARD**

---

FRESENIUS KABI USA, LLC and FRESENIUS KABI SWISSBIOSIM GmbH  
Petitioners,

v.

AMGEN, INC. and AMGEN MANUFACTURING LIMITED  
Patent Owner

---

Case IPR2019-00971  
Patent 9,856,287 B1

Title: REFOLDING PROTEINS USING A CHEMICALLY CONTROLLED  
REDOX STATE

---

**PETITIONERS' REPLY TO PATENT OWNER'S  
PRELIMINARY RESPONSE**

## TABLE OF CONTENTS

	<b>Page</b>
I. The Petition Is Timely .....	1
II. Discretionary Denial Is Unwarranted Under §§ 314(a) and 325(d).....	3

**TABLE OF AUTHORITIES**

**Page(s)**

**Cases**

*Antonious v. Spalding & Evenflo Cos., Inc.*,  
10 F. App'x 801 (Fed. Cir. 2001) .....2

*Bailey v. Sharp*,  
782 F.2d 1366 (7th Cir. 1986) .....2

*Hospira, Inc. v. Genentech, Inc.*,  
IPR2017-00739, Paper 16 (July 27, 2017) .....4

*Intex Recreation Corp. v. Team Worldwide Corp.*,  
IPR2019-00245, Paper 7 (May 15, 2019).....1, 2

*King Pharm., Inc. v. Eon Labs, Inc.*,  
616 F.3d 1267 (Fed. Cir. 2010) .....4

*Moderna Therapeutics, Inc. v. Arbutus Biopharma Corp.*,  
IPR2019-00554, Paper 8 (July 24, 2019) .....5

*Niantic, Inc. v. Blackbird Tech.*,  
IPR2019-00489, Paper 8 (July 11, 2019) .....5

*Nickel v. Bank of Am. Nat. Tr. & Sav. Ass'n*,  
119 F.3d 6 (9th Cir. 1997) .....2

*Samsung Elec. Am., Inc. v. Uniloc Luxembourg S.A.*,  
IPR2017-01801, Paper 8 (Feb. 6, 2018).....3

*Valve Corp. v. Elec. Scripting Prods. Inc.*,  
IPR2019-00062, Paper 13 (April 2, 2019) .....3

**Statutes**

35 U.S.C. § 311(c) .....1, 2

35 U.S.C. § 314(a) .....1, 3

35 U.S.C. § 325(d) .....1, 4

**Other Authorities**

37 C.F.R. § 42.102(a).....1

The Board’s institution of post-grant review on Adello’s petition (PGR2019-000001) neither requires nor warrants denial of this Petition for inter partes review. The Petition was timely filed, and the parallel proceedings do not raise the core concerns supporting discretionary denial of institution under §§ 314(a) and 325(d).

### **I. The Petition Is Timely**

35 U.S.C. § 311(c) and 37 C.F.R. § 42.102(a) provide that a petition for IPR may be filed after the later of “the date that is **9 months after the grant of the patent**” or “*if a post-grant review is instituted* ... , the date of the termination of such post-grant review.” The Petition was filed on April 14, 2019. There is no dispute that on that day, no PGR had been instituted, so the PGR bar did not apply. The Petition was thus timely because it was filed more than nine months after the ’287 patent issued on February 1, 2017, and no other time bar was applicable.

Against this plain application of text to facts, Amgen asserts that the subsequent institution of Adello’s PGR has rendered the Petition untimely. In support, Amgen relies on the Board’s denial of institution in *Intex Recreation Corp., v. Team Worldwide Corp.*, IPR2019-00245, Paper 7 (May 15, 2019). But Intex’s petition was *untimely when filed* “**because it was filed less than nine months** from the issue date” of the challenged patent. *Id.* at 10. Although the Board noted that an IPR “may not be filed until ... [the pending PGR] is completed,” the Board did not rely on the PGR as a basis for finding a previously

# 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.