

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

JANSSEN BIOTECH, INC.)	
)	
Plaintiff,)	
)	
v.)	Civil Action No. 2:17-cv-03524 (MCA)(SCM)
)	
SAMSUNG BIOEPIS, CO., LTD.)	
)	
Defendant.)	
)	

JOINT STIPULATION AND [PROPOSED] ORDER

WHEREAS, Plaintiff Janssen Biotech, Inc. (“Janssen”) asserted a claim titled “Count 1: Violation of Mandatory Procedures Under 42 U.S.C. § 262(l)(2);”

WHEREAS, in Count 1, Janssen alleged that, “[u]nder current law, the Federal Circuit has not interpreted 42 U.S.C. § 262(l)(2)(A) to be mandatory;”

WHEREAS, at the time of the Complaint, the Supreme Court had granted *certiorari* on, but had not yet decided, the question whether 42 U.S.C. § 262(l)(2)(A) is mandatory;

WHEREAS, Janssen alleged in the Complaint that “the Supreme Court may hold that biosimilar makers that make use of the BPCIA’s regulatory procedures must also follow its patent dispute resolution procedures;”

WHEREAS, in view of the Supreme Court’s decision in *Sandoz Inc. v. Amgen Inc. et al.*, 582 U.S. ___, 137 S. Ct. 1664 (2017), Count 1 is moot;

WHEREAS, Janssen asserted a claim titled “Count 2: Violation of Mandatory Procedures Under 42 U.S.C. § 262(l);”

WHEREAS, in Count 2, Janssen alleged that under Federal Circuit law at the time, the requirement to provide effective notice under 42 U.S.C. § 262(l)(8)(A) was “mandatory,” and that Bioepis’s first purported notice was “not effective” under then-controlling law;

WHEREAS, in Count 2, Janssen conditionally alleged that it would be harmed “[i]f Bioepis were to rely on an ineffective notice or not comply with the law;”

WHEREAS, in view of the Supreme Court’s decision in *Sandoz Inc. v. Amgen Inc. et al.*, 582 U.S. ___, 137 S. Ct. 1664 (2017), Count 2 is moot;

WHEREAS, in light of the above, Defendant proposed that the Court should dismiss with prejudice each of Janssen’s “Count 1: Violation of Mandatory Procedures Under 42 U.S.C. § 262(l)(2)” and “Count 2: Violation of Mandatory Procedures Under 42 U.S.C. § 262(l),” based on the June 12, 2017 Supreme Court decision in *Sandoz Inc. v. Amgen Inc. et al.*, 582 U.S. ___, 137 S. Ct. 1664 (2017);

WHEREAS, Plaintiff has consented to dismissal of Counts 1 and 2 of the Complaint as moot in light of the Supreme Court’s decision;

NOW THEREFORE, IT IS HEREBY STIPULATED AND AGREED that:

1. Janssen’s Count 1 shall be dismissed as moot;
2. Janssen’s Count 2 shall be dismissed as moot.

Date: September 22, 2017

/s/ Michelle M. Bufano

Michelle M. Bufano

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Attorneys for Defendant

Samsung Bioepis Co., Ltd.

IT IS SO ORDERED.

Dated: _____

UNITED STATES DISTRICT JUDGE

CERTIFICATE OF SERVICE

I certify that on August __, 2017 this document, filed through the ECF system, will be sent electronically to the parties or their counsel who are registered participants as identified on the Notice of Electronic Filing.

/s/ Michael E. Patunas_____