

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SAMSUNG BIOEPIS CO., LTD,
Petitioners,

v.

JANSSEN BIOTECH, INC.,
Patent Owner.

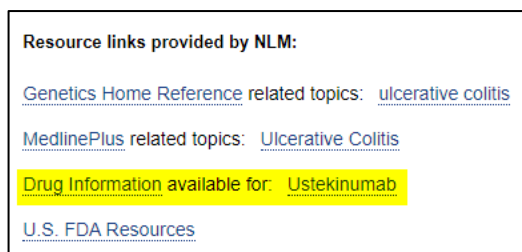
Case No. IPR2023-01103
U.S. Patent 10,961,307

**Declaration of Noah S. Frank in Support of Petition for *Inter Partes* Review of
U.S. Patent No. 10,961,307**

I, Noah S. Frank, declare as follows:

1. I am an attorney at the firm of Kirkland & Ellis LLP, counsel of record for Petitioner Samsung Bioepis Co., LTD. (“Petitioner”). I have personal knowledge of the facts set forth in this declaration and, if called as a witness, could and would testify competently under oath.

2. On June 6, 2023, I accessed <https://web.archive.org/web/20151007223045/clinicaltrials.gov/ct2/show/NCT02407236>, the same URL that was accessed to generate Ex. 1003 (NCT-236). The webpage contained the following hyperlinks (annotation added):

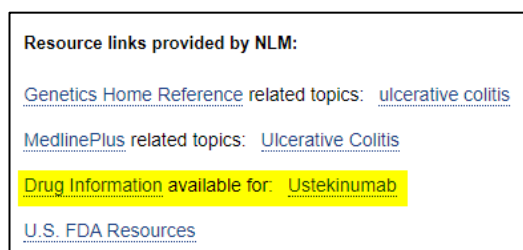


3. On June 6, 2023, when I clicked on the “Ustekinumab” hyperlink highlighted above, the following error message appeared:



Based on the error message and the redirected URL, it is my understanding that NCT-236 links to the following URL: <http://druginfo.nlm.nih.gov/drugportal/dpdirect.jsp?name=Ustekinumab>.

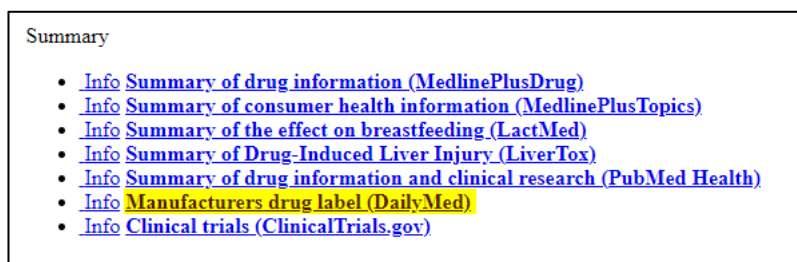
4. In order to confirm that understanding, I then navigated to the URL of Ex. 1003 (NCT-236) and selected the version of the webpage that was available on October 7, 2016: <https://web.archive.org/web/20161007165451/https://clinicaltrials.gov/ct2/show/NCT02407236>. Ex. 1064 was generated from this URL and is substantially the same as Ex. 1003. *Compare* Ex. 1003 with Ex. 1064; Ex. 1046 (showing only changes in study status, contacts/locations, and recruitment status between March 2015 and October 2016); Ex. 1047 (same). The webpage used to generate Ex. 1064 contains the same hyperlink as Ex. 1003 (annotation added):



5. When I clicked on the “Ustekinumab” hyperlink indicated above, I was directed to the following URL: <https://web.archive.org/web/20160917081227/https://druginfo.nlm.nih.gov/drugportal/name/Ustekinumab>. Ex. 1065 was generated from this URL. While Ex. 1065 was archived on September 17, 2016, it

is my understanding that Ex. 1065 is the same webpage that was hyperlinked from Ex. 1003 (NCT-236), as described in ¶3.

6. The webpage at Ex. 1065 includes the following hyperlinks (annotation added):



7. When I clicked on the “Manufacturers drug label (DailyMed)” hyperlink highlighted above, I was redirected to the following URL: <https://web.archive.org/web/20210527042114/https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=c77a9664-e3bb-4023-b400-127aa53bca2b>, which is the 2021 version of the Stelara label. Ex. 1066 was generated from this URL. While I could not locate an archive of this webpage, it is my understanding that the URL in Ex. 1003 (NCT-236) linked to a Stelara label prior to September 24, 2018.

8. In order to confirm that understanding, from the URL in Ex. 1066 I selected “View Labeling Archives,” and Ex. 1067 was generated from that link. Version 17 of the Stelara label in the labeling archives is listed as published on September 27, 2016, which corresponds to the “Revised 09/2016” date that appears in Ex. 1004 (Stelara2017-PI). However, the download link in Ex. 1067 does not provide the full label, but instead provides an xml file and images.

9. In order to confirm that the Stelara label archived on dailymed.nlm.nih.gov in September 2016 was the same as Ex. 1004 (Stelara2017-PI), I accessed <https://dailymed.nlm.nih.gov/dailymed/archives/index.cfm?query=ustekinumab&date=09%2F27%2F2016>. Ex. 1068 was generated from this URL. I then clicked the hyperlink highlighted below:

DATE POSTED	DRUG NAME	< previous
Sep 27, 2016  download	 PACKAGE IMAGE NOT AVAILABLE	STELARA (ustekinumab) injection, solution STELARA (ustekinumab) solution Packager: Janssen Biotech, Inc. Version: 17

I was then directed to <https://dailymed.nlm.nih.gov/dailymed/archives/fdaDrugInfo.cfm?archiveid=229160>. Ex. 1069 was generated from this URL. I confirmed that Ex. 1069 is substantially the same as Ex. 1004 (Stelara2017-PI).

10. I hereby declare that all statements made herein of my knowledge are true, and that all statements made on information and belief are believed to be true, and that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Executed on June 21, 2023.

Noah S. Frank

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