Information about our Innovative Medicine patent portfolio

(Updated February 16, 2024)

Johnson & Johnson Innovative Medicine (JJIM) operates in a highly competitive environment and plays a major role in advancing health and well-being by investing billions of dollars in R&D to address unmet health and medical needs of patients around the world. We face new and increasing competition as many of our marketed products are indicated for disease areas in which other products or treatments are currently available or being pursued by our competitors. This competition could impact pricing and market share of our products.

Patents play an important role in allowing us to make the significant research and development investments required to develop new medicines, particularly given the appreciable costs of performing clinical trials and pursuing global regulatory approvals based on these clinical trials. Johnson & Johnson and its affiliates regularly seek patent protection on inventions relating to their products and processes, including for example, patents that claim pharmaceutical substances, formulations, dosing regimens, medical prophylactic or treatment methods, devices used in combination with our products, or production methods.

JJIM's patents regularly face challenges from third parties, including from generic and biosimilar manufacturers seeking to manufacture and market versions of JJIM's key pharmaceutical products prior to expiration of the applicable patents. Additional information regarding significant legal proceedings and claims involving JJIM's patents and other intellectual property are described in the "Legal Proceedings" notes in Johnson & Johnson's Annual Report on Form 10-K and Quarterly Reports on Form 10-Q.

The following tables provide expiry information with respect to certain patents related to the products listed in our Major Pharmaceutical Therapeutic Area Sales table in Johnson & Johnson's Annual Report on Form 10-K, and Quarterly Reports on Form 10-Q. Certain of the patents identified in the tables below are in-licensed from third parties.

Biologics (large molecule) table

(Updated February 16, 2024)

The table below includes information regarding the expiry year of the U.S. Composition of Matter patent owned by or licensed to JJIM with respect to each of the referenced products.

Notes to the Table:

- The use of "-" in the Composition of Matter Patent Expiry Year column reflects that the term of any Composition of Matter patent for that specific product has expired.
- The below table is not exhaustive as additional patents relevant to these products might describe additional active ingredients, formulations, dosing regimens, medical prophylactic or treatment methods, devices used in combination with our products, or production methods.

Drug	*US Composition of Matter patent expiry year*
CARVYKTI	2036
DARZALEX	2029
SIMPONI	2024
STELARA	-
TECVAYLI	2036
TREMFYA	2031

The FDA has created a searchable, online database (the Purple Book, formally known as the List of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations) that lists approved biological products with reference product exclusivity and biosimilarity or interchangeability evaluations. The Purple Book, on a product-by-product basis, may provide patents and their respective expiration dates listed in relation to such a product. https://purplebooksearch.fda.gov/. A reference product sponsor, such as JJIM, must submit initial and updated lists of patents to the Purple Book reflecting patent information that it shares with a biosimilar applicant that engages in patent infringement proceedings as to a biological product in accordance with the procedure described by section 351(l) of the Public Health Service Act. More information can be found here: https://purplebooksearch.fda.gov/faqs.

The Purple Book currently includes patents listed for Stelara. As of the date of this publication, the Purple Book does not list patents for other Biologics in JJIM's portfolio.

The table below includes the current patents listed in the Purple Book for Stelara.

Proprietary Name	*Proper Name*	*Patent Number*	*Patent Expiration Date*
Stelara	Ustekinumab	6,902,734	September 25, 2023
Stelara	Ustekinumab	8,852,889	July 6, 2032
Stelara	Ustekinumab	9,217,168	March 14, 2033
Stelara	Ustekinumab	9,475,858	July 6, 2032
Stelara	Ustekinumab	9,663,810	March 14, 2033
Stelara	Ustekinumab	10,961,307	September 24, 2039

Small molecule products table

(Updated February 16, 2024)

The table below provides information on certain products listed in in the publication of Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the Orange Book). The column "Composition of Matter patent expiry year" refers to information regarding the expiry year of the U.S. patent covering the Composition of Matter, whether owned by or licensed to JJIM. In addition, the table presents the Orange Book patent information as available on February 16, 2024. The expiration dates from the Orange Book as provided reflects the patent term under 35 U.S.C. § 154, and any granted Patent Term Extension, and also presents any added 6-month Pediatric Exclusivity (as indicated by *P).

Notes to table:

- The "Drug" column provides links to the Orange Book listing for the relevant product. Where more than one NDA exists for a product, a link is provided for each of the product's Orange Book listings. The "Orange Book Listed Patents" columns below reflect the aggregation of patents that may be listed for a particular product considering its various dosage forms in sequentially increasing order. The information below is the information as available on February 16, 2024. Please consult the Orange Book for the most accurate and updated information as to patents listed for the products.
- The use of "-" in the Composition of Matter Patent Expiry Year column reflects that the term of any Composition of Matter patent for that specific product has expired.
- The "Use" column provides information as to whether the Orange Book provides a "Patent Use Code." Additional information may be found regarding the particular patent use code through the Product Link under the "Drug" column.
- The below table is not exhaustive and additional patents relevant for these products might cover for example manufacturing process patents, packaging patents, or patents directed to process intermediates or metabolites.

Small molecule products table cont.

Drug	US Composition of Matter patent expiry year	Orange Book listed patents		Drug Substance patent	Drug Product patent	Use
		Patent number	Expiration date			
EDURANT	2025	7125879*P	10/21/2025	X	X	X
ERLEADA	2030 (2032 PTE pending)	8445507 8802689 9388159 9481663 9884054 9987261 10052314 10702508 10849888 RE49353	09/15/2030 03/27/2027 03/27/2027 06/04/2033 09/23/2033 03/27/2027 09/23/2033 04/30/2038 09/23/2033 09/23/2033	X X X 	X X X X 	X X X X X X X X
IMBRUVICA*						
INVEGA HAFYERA	-	11304951 11324751 11666697	05/07/2041 05/07/2041 11/24/2041			X X X
INVEGA SUSTENNA	-	9439906	01/26/2031			X
INVEGA TRINZA	-	10143693	04/05/2036			X
INVOKANA	2027	7943582 7943788 8222219 8513202 10617668	02/26/2029 07/14/2027 04/11/2025 12/03/2027 05/11/2031	X X X 	X X X X	X X X X
OPSUMIT	2025	7094781 8268847 8367685 9265762 10946015	12/05/2025 04/18/2029 10/04/2028 05/29/2027 09/11/2026	X 	X X X X	 X X X X

Small molecule products table cont.

Drug	US Composition of Matter patent expiry year	Orange Book listed patents		Drug Substance patent	Drug Product patent	Use
		Patent number	Expiration date			
PREZCOBIX	2029	7700645*P	06/26/2027	X	X	
		8148374	09/03/2029	X	X	X
		8518987*P	08/16/2024	X	X	
		10039718	10/06/2032		X	
PREZISTA NDA 021976 Or PREZISTA NDA 202985	-	7700645*P	06/26/2027	X	X	
		8518987*P	08/16/2024	X	X	
SPRAVATO	-	8785500	03/05/2033			X
		9592207	03/20/2027			X
		10869844	09/10/2035			X
		11173134	09/10/2035			X
		11311500	09/10/2035			X
		11446260	03/14/2034			X
SYMTUZA	2029	7390791	04/17/2025	X	X	
		7700645	12/26/2026	X	X	
		8148374	09/03/2029	X	X	X
		8518987	02/16/2024	X	X	
		8754065	08/15/2032	X	X	X
		9296769	08/15/2032	X	X	X
		10039718	10/06/2032		X	
		10786518	07/19/2038			X
UPTRAVI NDA207947 or UPTRAVI NDA214275	2026	7205302	10/31/2026	X	X	X
		8791122	08/01/2030	X	X	
		9173881	08/12/2029			X
		9284280	06/25/2030			X
		10821108	12/01/2036		X	X
		10828298	12/01/2036		X	X

Small molecule products table cont.

Drug	US Composition of Matter patent expiry year	Orange Book listed patents		Drug Substance patent	Drug Product patent	Use
		Patent number	Expiration date			
XARELTO (NDA 022406)	2025	7157456*P	02/28/2025	X	X	X
or		9415053*P	05/13/2025		X	X
XARELTO (NDA 215859)		9539218*P	08/17/2034			X
		10828310*P	07/31/2039			X

The U.S. Composition of Matter patent has expired for each of CONCERTA, RISPERDA/L CONSTA and ZYTIGA and no patents are currently listed in the Orange Book for these products.

*: IMBRUVICA is developed in collaboration and co-marketed with Pharmacyclics LLC, an AbbVie company. AbbVie disclosed in its Annual Report on Form 10-K filed with the SEC on February 20, 2024 that the United States composition of matter patent covering ibrutinib is expected to expire in 2027, with pediatric regulatory exclusivity extending until May 2028. However, no generic entry for any ibrutinib product is currently expected prior to March 30, 2032. The Orange Book contains additional patent information regarding IMBRUVICA (NDA 205552), IMBRUVICA (NDA 217003) and IMBRUVICA (NDA 210563).