

## Patent “Evergreening” of Medicine–Device Combination Products: A Global Perspective

« Perpétuité » des brevets pour les produits mixtes de médicaments et dispositifs médicaux : un aperçu mondial

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**TABLE 1.** Proportion of product sample ( $n = 88$ ) with device versus other patents internationally

Category	Count of jurisdictions in sample	Percentage of products with one or more device patents, median percentage, $n =$ products (IQR percentage, $n =$ products)	Percentage of products with one or more formulation patents, median percentage, $n =$ products (IQR percentage, $n =$ products)	Percentage of products with one or more substance patents, median percentage, $n =$ products (IQR percentage, $n =$ products)
<b>Income</b>				
High	43	25%, $n = 22$ (IQR: 9–64%; $n = 8–57$ )	18%, $n = 16$ (IQR: 6–44%, $n = 5–39$ )	16%, $n = 14$ (IQR: 3–25%, $n = 3–22$ )
Upper middle	22	17%, $n = 15$ (IQR: 8–40%, $n = 7–35$ )	16%, $n = 14$ (IQR: 4–28%, $n = 4–25$ )	8%, $n = 7$ (IQR: 3–15%, $n = 4–12$ )
Lower middle	9	8%, $n = 7$ (IQR: 5–13%, $n = 4–12$ )	3%, $n = 3$ (IQR: 2–10%, $n = 2–9$ )	3%, $n = 3$ (IQR: 2–8%, $n = 2–7$ )
Low	0	0%, $n = 0$	0%, $n = 0$	0%, $n = 0$

Category	Count of jurisdictions in sample	Percentage of products with one or more device patents, median percentage, <i>n</i> = products (IQR percentage, <i>n</i> = products)	Percentage of products with one or more formulation patents, median percentage, <i>n</i> = products (IQR percentage, <i>n</i> = products)	Percentage of products with one or more substance patents, median percentage, <i>n</i> = products (IQR percentage, <i>n</i> = products)
<b>Key countries</b>				
Australia	1	87%, <i>n</i> = 78	60%, <i>n</i> = 53	28%, <i>n</i> = 25
Brazil	1	65%, <i>n</i> = 57	45%, <i>n</i> = 40	25%, <i>n</i> = 22
Canada	1	90%, <i>n</i> = 79	60%, <i>n</i> = 53	28%, <i>n</i> = 25
China	1	78%, <i>n</i> = 69	45%, <i>n</i> = 40	24%, <i>n</i> = 21
Japan	1	87%, <i>n</i> = 78	61%, <i>n</i> = 54	28%, <i>n</i> = 25
Korea	1	74%, <i>n</i> = 65	45%, <i>n</i> = 40	28%, <i>n</i> = 25
South Africa	1	65%, <i>n</i> = 57	40%, <i>n</i> = 35	25%, <i>n</i> = 22
United States	1	97%, <i>n</i> = 85	62%, <i>n</i> = 55	28%, <i>n</i> = 25
<b>Regional patent filings</b>				
ARIPO	1	14%, <i>n</i> = 12	7%, <i>n</i> = 6	6%, <i>n</i> = 5
EAPO	1	25%, <i>n</i> = 22	19%, <i>n</i> = 17	8%, <i>n</i> = 7
EPO	1	90%, <i>n</i> = 79	61%, <i>n</i> = 54	26%, <i>n</i> = 23
OAPI	1	10%, <i>n</i> = 9	6%, <i>n</i> = 5	3%, <i>n</i> = 3
WIPO (PCT)	1	90%, <i>n</i> = 79	60%, <i>n</i> = 53	25%, <i>n</i> = 22

Beginning with a sample of 88 products with at least one device patent located in the US medicine patent register between 2000 and 2016, patent number linkage to the INPADOC international patent collection was 97% (i.e., three patent numbers were not contained in INPADOC). Some high-income jurisdictions showed a similarly high presence of device patents above all other patent types, including Canada and Europe. This same pattern was also apparent among countries such as Brazil, China and South Africa, but at relatively smaller scales.

ARIPO = African Regional Intellectual Property Organization; EAPO = Eurasian Patent Organization; EPO = European Patent Office; IQR = interquartile range; OAPI = Organisation Africaine de la Propriété Intellectuelle; WIPO (PCT) = World Intellectual Property Organization (Patent Cooperation Treaty).

**TABLE 3.** Products with device-only patent filings found in 10 key jurisdictions internationally

Product(s) (manufacturer)	Therapeutic class	FDA-approved indication	Last-expiring device priority* patent (assignee history)	Anticipated expiry date of last-expiring device patent**	Patent title	Key jurisdictions with equivalent filings
Accuneb (Mylan)	Asthma/COPD	Relief of bronchospasm in patients 2 to 12 years of age with asthma (reversible obstructive airway disease)	US34820301 / US20030124063A1 (from Dey LP to Mylan Specialty)	2021-12-27	Albuterol inhalation solution, system, kit and method for relieving symptoms of pediatric asthma	AU, CA, CN, EP, JP, US, WO
Atrovent HFA (Boehringer Ingelheim)	Asthma/COPD	Maintenance and treatment of bronchospasm associated with COPD	DE102007045438 (Boehringer Ingelheim)	2029-09-16	Inhaler device	AU, BR, CA, CN, EP, JP, KR, US, WO, ZA
AUVI-Q (Kaleo)	Anaphylaxis	Emergency treatment of allergic reactions (Type I) including anaphylaxis	US12/180,708 (from Intelliject to Kaleo)	2029-11-02	Medicament delivery device configured to produce an audible output	AU, CA, CN, EP, JP, US, WO
EpiPen (Mylan)	Anaphylaxis	Emergency treatment of allergic reactions (Type I) including anaphylaxis	US59905404P / US20100318037A1 (from Meridian to Mylan)	2025-09-11 to 2026-05-25	Automatic injector with kickback attenuation	AU, CA, CN, EP, JP, KR, US, WO
Humalog mix 50/50 Kwikpen; 75/25 Kwikpen; Humulin 70/30, N, & R (Eli Lilly)	Diabetes	Indicated to improve glycemic control in patients with diabetes mellitus	US49449903P / US20060206057A1 (Eli Lilly)	2024-08-09	Medication dispensing apparatus with triple screw threads for mechanical advantage	AU, CA, CN, EP, JP, KR, US, WO, ZA
Lantus and Toujeo Solostar (Sanofi Aventis)	Diabetes	Indicated to improve glycemic control in patients with diabetes mellitus	GBGB0304822.0A / US20120089100A1/ US20060264839A1 (Sanofi Aventis)	2024-03-02 to 2027-09-23	Improvements in and relating to a pen-type injector	AU, BR, CA, CN, EP, JP, KR, US, WO, ZA

Product(s) (manufacturer)	Therapeutic class	FDA-approved indication	Last-expiring device priority* patent (assignee history)	Anticipated expiry date of last-expiring device patent**	Patent title	Key jurisdictions with equivalent filings
Novolog mix 70/30 Flexpen (Novo Nordisk)	Diabetes	Indicated to improve glycemic control in patients with diabetes mellitus	EP07101729/ US20100145282A1 (Novo Nordisk)	2032-09-23	Injection button	AU, BR, CA, CN, EP, JP, KR, US, WO, ZA
Otrexup (Antares)	Arthritis	Indicated for RA and PJI, and control of severe psoriasis in adults	US16211409P/ US20130030367A1 (Antares)	2030-03-19	Hazardous agent injection system	AU, BR, CA, CN, EP, JP, KR, US, WO
Twinject 0.15 (Amedra)	Anaphylaxis	Indicated in the emergency treatment of allergic reactions (Type I) including anaphylaxis	US49449903P / US20070017532A1 (Washington Biotech)	2024-08-09	Method and apparatus for delivering epinephrine	AU, BR, CA, CN, EP, JP, US, WO, ZA

\*Earliest equivalent patent filing globally.

\*\*Anticipated expiry dates were taken from Google Scholar and include patent term extensions where applicable.

COPD = chronic obstructive pulmonary disease; EP = EPO [European Patent Office]; PJI = polyarticular juvenile idiopathic arthritis; RA = rheumatoid arthritis; WO = WIPO [World Intellectual Property Organization].

AU = Australia; BR = Brazil; CA = Canada; CN = China; JP = Japan; KR = South Korea; US = United States; ZA = South Africa.