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Patent Management

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Patent Management

Intellectual property rights established by the World Trade Organization have performed a critical role in stimulating R&D. By sharing risks and rewards, this system has created the appropriate environment for delivering the greatest returns for society not just for today, but also for tomorrow.

Sanofi believes that patents are a fundamental incentive for driving innovation in the pharmaceutical sector. The development of new medicines and vaccines is a risky, costly, and lengthy process. Patents are an essential incentive for pharmaceutical companies to invest in research & development to address unmet medical needs. IP policies therefore need to be safeguarded. While patents by themselves should not be considered a barrier for access, Sanofi believes that being transparent and flexible with our patents can help address pressing health challenges in developing countries.

In order to enable access to our medicines and vaccines:

- Sanofi makes patent status of their Essential Medicines and Vaccines in developing countries publicly available (see Annex I);
- Sanofi does not file patent applications or enforce patent rights in all Least Developed Countries (LDCs) and Low-Income Countries (LICs);
- Sanofi does not file or enforce patents in several Lower-Middle-Income Countries (LMICs) and Upper-Middle-Income Countries (UMICs). See Annex II for the complete list of countries;
- Sanofi supports implementation of the 2001 WTO Doha Declaration on TRIPS and Public Health and the appropriate use of the flexibilities therein intended to protect public health;
- Sanofi supports the transition period that LDCs are exempted from obligations under the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement) regarding pharmaceutical patents until January 1, 2033. We support this exemption of LDCs and an extension of the exemption beyond 2033;
- Sanofi acknowledges the value of voluntary licensing agreements and patent pools for access to medicines in developing countries. We would consider joining patent pools and engaging in voluntary licensing if relevant to our portfolio, and aimed at accelerating access to medicines and vaccines in low- and middle- income countries;
- Sanofi respects compulsory licensing as a short-term and targeted measure where urgent access to patented medicines is critical to maintaining public health, and no appropriate alternative is available. We believe that compulsory licenses should only be used in extraordinary and very limited circumstances, such as meeting a health crisis or emergency; and
- Sanofi respects a formal exemption from patent infringement for activities which are undertaken as part of the regulatory review process: "[c]onducting the necessary studies and trials with a view to the application of paragraphs 1 to 4 [i.e. bioequivalents and biosimilars] and the consequential practical requirements shall not be regarded as contrary to patent rights or to supplementary protection certificates for medicinal products." (Bolar exemption, Directive 2004/27/EC. Article 10(6)).

Annex I - Patent Status of Sanofi's Essential Medicines and Vaccines in Developing Countries

Annex II - Developing Countries in which Sanofi does not file or enforce patents*

* For products where Sanofi solely owns and controls the patent rights

Annex I

Sanofi Products ⁽¹⁾ as of 2025 listed on the WHO Essential Medicine List (EML, 2025)

MEDICINES			DEVICES FOR LANTUS, APIDRA, ADMELOG AND TOUJEO ADMINISTRATION		
Product	Active Ingredient(s)	Patent Rights	Product		Patent Rights
ADMELOG®	Insulin lispro	No ⁽⁴⁾	ALLSTAR®	Reusable pen	No ⁽⁴⁾
AGEN®	Amlodipine	No	SOLOSTAR®	Prefilled pen	No ⁽⁴⁾
APIDRA®	Insulin glulisin	No			
APPROVEL®	Irbesartan ⁽²⁾	No			
ARSOBAL®	Melarsoprol	No			
ASAQ Winthrop®	Artesunate/ amodiaquine	No			
AZITRHOMYCIN	Azithromycin dihydrate	No			
CAPTEA	Captopril/Hydrochlorothiazide	No			
CERUBIDINE®	Daunorubicin	No			
CETAPIN®	Metformin hydrochloride	No			
CIDOMYCIN®	Gentamicin	No			
CLEXANE®/LOVENOX®	Enoxaparin	No			
DEPAKINE®	Valproate sodium	No			
EFAVIRENZ	Efavirenz	No			
ELOXATIN®	Oxaliplatin	No			
ENOXAPARIN	Enoxaparin	No			
EURELIX	Piretanide	No			
FEXINIDAZOLE Winthrop	Fexinidazole	No ⁽³⁾			
FLUDARA®	Fludarabine phosphate	No			
GLUCANTIME®	Meglumine antimoniate	No			
LANTUS®	Insulin glargine	No ⁽⁴⁾			
MALOCIDE®	Pyrimethamine	No			
PLAVIX®	Clopidogrel	No			
PRIFTIN®	Rifapentine	No			
PRIMAQUINE	Primaquine diphosphate	No			
PYRAZINAMIDE	Pyrazinamide	No			
QUINIMAX®	Quinine	No			
RIFADIN®	Rifampicin	No			
RIFATER®	Rifampicin/ isoniazid/ pyrazinamide	No			
RIFINAH®	rifampicin/ isoniazid	No			
RISORDAN®	Isosorbide dinitrate	No			
TAVANIC®	Levofloxacin	No			
TAXOTERE®	Docetaxel	No			
TENOFOVIR®	Tenofovir disoproxil	No			
TOUJEO®	Insulin glargine	No ⁽⁴⁾			
TRITAZIDE®	Ramipril/Hydrochlorothiazide	No			
TRIAPIN®	Ramipril/Felodipine	No			
VERAPAMIL	Verapamil	No			

VACCINES		
Product	Vaccine Type	Patent Rights
ACTHIB®	<i>Haemophilus influenzae</i> polysaccharide type b conjugated to tetanus protein (PRP-T)	No
ADACEL®	Diphtheria, Tetanus, Pertussis (acellular, component) Vaccine (adsorbed, reduced antigen(s) content)	No
DENGVAXIA®	Dengue live attenuated tetravalent chimeric vaccine	No ⁽⁵⁾
HEXAXIM®	Diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inactivated) and <i>Haemophilus influenzae</i> type b conjugate vaccine (adsorbed)	No ⁽⁶⁾
MENACTRA®	Meningococcal (Groups A, C, Y and W-135) Polysaccharide Diphtheria Toxoid Conjugate Vaccine	No ⁽⁶⁾
PENTAXIM®	Diphtheria, tetanus, pertussis (acellular, component), poliomyelitis (inactivated) vaccine and <i>Haemophilus</i> type b conjugate vaccine, adsorbed	No
STAMARIL	Yellow Fever Vaccine	No
TETAVAX®	Purified tetanus toxoid (PTT)	No
TETRAXIM®	Booster vaccine	No
TYPHIM VI®	Typhoid polysaccharide vaccine	No
VAXIGRIPTETRA®	Quadrivalent influenza vaccine (split virion, inactivated)	No
VAXIGRIP®	Influenza vaccine (split virion, inactivated)	No
VERORAB®	Rabies vaccine, inactivated	No
FLUBLOK QUADRIVALENT / SUPEMTEK	Quadrivalent influenza vaccine (recombinant, prepared in cell culture)	No
MENQUADFI	Meningococcal group A, C, W-135 and Y conjugate vaccine	No ⁽⁴⁾
VAXIGRIP® QIV	Influenza quadrivalent vaccine (4 strains)	No
VAXIGRIP® TIV	Influenza trivalent vaccine (3 strains)	No

(1) Sanofi products encompass the products marketed and/or distributed in 2025 by Sanofi and its affiliates. Trademarks followed with ® mean that the trademark is registered in one or some of the countries listed in Annex II. Depending on the countries, (i) some products are associated with other trademarks, not listed in Annex I and (ii) some trademarks are used under licensing by Sanofi. FLUDARA® is a registered trademark of Alcaflou. TAVANIC® is a registered trademark of Daiichi Sankyo limited. CETAPIN® and CIDOMYCIN® are registered in countries other than those listed in Annex II.

(2) Products followed with ⁽²⁾ are considered clinically equivalent medicines to a representative example within a pharmacological class listed on the 2025 WHO EML, as indicated by the square box symbol. All other products are listed on the 2025 WHO EML as core essential medicines.

(3) For countries via ARIPO, actions have been taken in June 2020 to effectively abandon patents directed to Fexinidazole. Therefore, the “no patent” statement applies to the product FEXINIDAZOLE Winthrop for countries listed in Annex II.

(4) The “no patent” statement applies to the products for countries listed in Annex II.

(5) For Lao, action has been taken in July 2021 to effectively abandon the patent covering DENG VAXIA®. Therefore, the “no patent” statement applies to the product DENG VAXIA® for countries listed in Annex II.

(6) For Syria, Tajikistan and countries via **ARIPO** or via **OAPI**, actions have been taken in November 2019 to effectively abandon patents or patent applications directed to HEXAXIM® or MENACTRA®. Therefore the “no patent” statement applies to the products HEXAXIM® and MENACTRA® for countries listed in Annex II.

For all other products listed with no patent in the present Annex I, this statement applies for countries listed in Annex II and for all other countries worldwide.

KEYS

ARIPO. ‘African Regional Intellectual Property Organization’ Countries:

Botswana; Gambia; Ghana; Kenya; Lesotho; Liberia; Malawi; Mozambique; Namibia; Rwanda; Sierra Leone; Sudan; Swaziland; Tanzania; Uganda; Zambia and Zimbabwe.

OAPI. ‘Organisation Africaine de la Propriété Intellectuelle’ Countries:

Benin; Burkina Faso; Cameroon; Central African Rep.; Chad; Comoros; Congo, Rep.; Côte d’Ivoire; Equatorial Guinea; Gabon; Guinea; Guinea-Bissau; Mali; Mauritania; Niger; Senegal and Togo.

Annex II
Developing Countries in Which Sanofi Does not File or Enforce Patent

Country	UN Classification (2025)	World Bank Classification (12/ 2025)
Afghanistan	LDC	LIC
Angola	LDC	LMIC
Bangladesh	LDC	LMIC
Belize	NO	UMIC
Benin	LDC	LMIC
Bhutan	NO	LMIC
Botswana	NO	UMIC
Burkina Faso	LDC	LIC
Burundi	LDC	LIC
Cambodia	LDC	LMIC
Cameroon	NO	LMIC
Cape Verde	NO	UMIC
Central African Rep.	LDC	LIC
Chad	LDC	LIC
Comoros	LDC	LMIC
Congo, Dem. Rep.	LDC	LIC
Congo, Rep.	NO	LMIC
Côte d'Ivoire	NO	LMIC
Djibouti	LDC	LMIC
Equatorial Guinea	NO	UMIC
Eritrea	LDC	LIC
Ethiopia	LDC	LIC
Gabon	NO	UMIC
Gambia, The	LDC	LIC
Ghana	NO	LMIC
Guinea	LDC	LMIC
Guinea-Bissau	LDC	LIC
Guyana	NO	HIC
Haiti	LDC	LMIC
Iraq	NO	UMIC
Kiribati	LDC	LMIC
Korea, Dem. Rep	NO	LIC
Lao PDR	LDC	LMIC
Lesotho	LDC	LMIC
Liberia	LDC	LIC
Madagascar	LDC	LIC
Malawi	LDC	LIC

Country	UN Classification (2025)	World Bank Classification (12/2025)
Maldives	NO	UMIC
Mali	LDC	LIC
Mauritania	LDC	LMIC
Micronesia, Fed. Sts.	NO	LMIC
Mongolia	NO	UMIC
Mozambique	LDC	LIC
Myanmar	LDC	LMIC
Namibia	NO	LMIC
Nepal	LDC	LMIC
Niger	LDC	LIC
Palestine, State of (West Bank and Gaza)	NO	LMIC
Papua New Guinea	NO	LMIC
Rwanda	LDC	LIC
Samoa	NO	UMIC
São Tomé and Príncipe	NO	LMIC
Senegal	LDC	LMIC
Sierra Leone	LDC	LIC
Solomon Islands	LDC	LMIC
Somalia	LDC	LIC
South Sudan	LDC	LIC
Sudan	LDC	LIC
Suriname	NO	UMIC
Swaziland (Eswatini)	NO	LMIC
Syrian Arab Rep.	NO	LIC
Tajikistan	NO	LMIC
Tanzania	LDC	LMIC
Timor-Leste	LDC	LMIC
Togo	LDC	LIC
Tonga	NO	UMIC
Tuvalu	LDC	UMIC
Uganda	LDC	LIC
Vanuatu	NO	LMIC
Yemen, Rep.	LDC	LIC
Zambia	LDC	LMIC
Zimbabwe	NO	LMIC

LDC: Least Developed Country, UN Human Development Index, 2025.

LIC: Low Income Country, World Bank income classifications, December 2025.

LMIC: Lower middle-income country, World Bank income classifications, December 2025.

UMIC: Upper middle-income country, World Bank income classifications, December 2025.