Our Commitment to Expanding Access to Healthcare through Intellectual Property

MedImmune AstraZeneca

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Intellectual Property as a Driver for Innovation

Intellectual property (IP) rights provide the incentives our industry needs to do research and development (R&D) that leads to new medicines.

Developing a drug is a long process. Bringing a new drug to market typically takes 10 to 15 years and costs more than $2 billion, taking into account the cost of failures – thousands and sometimes millions of compounds that are screened and assessed early in the R&D process to get the few that will ultimately receive approval.

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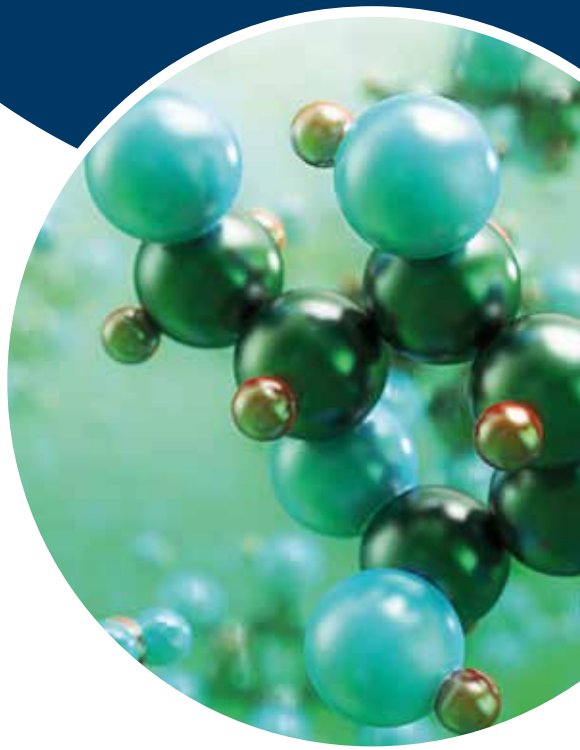

Our Commitment to Flexible Intellectual Property Strategies that Improve Access to our Medicines

AstraZeneca recognises our role in helping to make our products accessible and affordable to patients in need. Our Commitment to Deliver our Science to Patients and our Sustainability Report detail our efforts to address barriers our patients face—financial or otherwise—in developing and developed markets.

Those efforts include our approach to intellectual property. AstraZeneca seeks to protect innovations worldwide, and we prioritise the countries where we seek patent protection. AstraZeneca does not file patent applications in any low-income countries (LICs) or least developed countries (LDCs). AstraZeneca also does not file in a number of low-middle-income countries (LMICs) and medium human development countries (MHDCs). (The Index countries where AstraZeneca does not file patent applications are listed in Table 1.)

AstraZeneca abandons all patent property that could cover a medicine but does not support a product, or an actual or potential AstraZeneca pipeline asset, unless constrained by contract, such that these patent rights can be freely practised and used, without licence.

To provide greater certainty to manufacturers when planning to license our products, AstraZeneca is committed to providing transparency about where our patents are filed and enforced. Where AstraZeneca maintains patent protection for assets which may have relevance to Index Diseases, AstraZeneca provides patent expiry information for Index Countries. (This patent expiry information is listed in Table 2.) For key products across the pipeline, AstraZeneca also provides patent expiry information for China, EU, Japan, and US in our Annual Report.

AstraZeneca supports the Bolar research (or safe harbour) exemption allowing a third party to seek regulatory approval so that a generic product can be available when a patent expires. AstraZeneca does not interpret the exemption to extend to commercial manufacture, importation, or stockpiling during the life of a patent.

> “AstraZeneca is committed to providing transparency about where our patents are filed and enforced. ”

Our Commitment to Granting Voluntary Licensing in Developing Countries

Licensing is an important way of allowing access to patent-protected inventions. Through licencing, we seek to balance the societal objectives to address unmet health needs in the developing world with the incentives needed for future R&D. We are flexible and will consider any proposal for a Non-Exclusive Voluntary Licence (NEVL) agreement to support the needs of the most disadvantaged.

The geographic scope is often reserved for LIC, LDC, LMIC, or MHDCs, particularly in instances where access to medicines for patients is a priority and otherwise not available, but there are exceptions and AstraZeneca will consider proposals. With respect to disease scope, AstraZeneca will license its patent rights in the neglected tropical disease space regardless of country. AstraZeneca is also open to licensing options in all disease areas, including NCDs. Through our Open Innovation initiative, AstraZeneca makes available patient-ready compounds for novel, clinical, and translational research into diseases with significant unmet medical need. AstraZeneca will consider proposals to grant licences for intellectual property covering Open Innovation compounds.

While AstraZeneca commits to being flexible towards licensing proposals, the following conditions and policies for granting a NEVL agreement would need to be met:

- A NEVL does not conflict with AstraZeneca's existing obligations;
- The medicine meets AstraZeneca's quality assurance standards; and
- The licensee works to increase access to that medicine by offering it at a greatly reduced price or making it available to patient groups that do not already have access (for example, to new hospitals or clinics).

> "Through licencing, we seek to balance the societal objectives to address unmet health needs in the developing world with the incentives needed for future R&D."

Our Commitment to Respecting International Trade Agreements and Compulsory Licensing

The World Trade Organisation (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) provides a mechanism for any WTO Member State to issue a compulsory licence to secure access to medicines under specific, exceptional circumstances, while upholding international intellectual property rights.

Article 31f of TRIPS allows the export of products under compulsory licence to developing or least-developed countries without domestic manufacturing capacity in a "national emergency or other circumstances of extreme urgency".

AstraZeneca believes that the best way to address the healthcare challenges faced by developing countries, including in cases of national emergency or other extreme urgency, is through engagement of our industry with other stakeholders to find constructive ways to improve access to medicines and delivery of healthcare. AstraZeneca recognises the right of countries to use the flexibilities in TRIPS, and supports the principles outlined in the Doha Declaration, including compulsory licensing, while maintaining consideration of the principles below:

- Other approaches, including good-faith negotiation and voluntary licensing, should be the first means of obtaining supplies of patented medicines, and compulsory licensing used only if these approaches fail to deliver the needed products.
- Compulsory licensing should only be considered where urgent access to patented medicines is critical to maintaining public health, and no appropriate alternative is available.
- Compulsory licensing arrangements should be linked to mechanisms to prevent diversion of medicines from the intended market to any other market.

We do not view TRIPS as a barrier to access to medicines in developing countries. AstraZeneca believes that the intellectual property rights addressed in TRIPS are essential if pharmaceutical companies are to continue to invest heavily in research and development.

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Our Commitment to Sustainable Access to Healthcare

While our intellectual property strategies are critically important, they are only one piece of the equation as there is no single action that will increase access to healthcare. Among many key enablers, we aim to support improvements in healthcare infrastructure, train healthcare professionals in areas with limited availability, and provide effective supply and distribution of our medicines. Improving outcomes for our patients requires systems-thinking and effective partnership that help more people gain access to our medicines at more affordable prices.

Links to Additional Resources:

WTO TRIPS fact sheet

More information on Least Developed Countries

October 2018

MedImmune AstraZeneca

Table 1: Countries where AstraZeneca does not file Patent Applications

East Asia & Pacific	
Cambodia	LMIC
Kiribati	LMIC
Korea, Dem. Rep.	LIC
Lao PDR	LMIC
Micronesia, Fed. Sts.	LMIC
Mongolia	LMIC
Myanmar	LMIC
Papua New Guinea	LMIC
Samoa	LMIC
Solomon Islands	LMIC
Timor-Leste	LMIC
Tonga	LMIC
Tuvalu	LDC
Vanuatu	LMIC

Europe & Central Asia	
Armenia	LMIC
Georgia	LMIC
Kosovo	LMIC
Kyrgyz Rep.	LMIC
Moldova	LMIC
Tajikistan	LMIC
Turkmenistan	MHDC
Uzbekistan	LMIC

Latin America & Caribbean	
Belize	HiHDI
Bolivia	LMIC
Guyana	MHDC
Haiti	LIC
Paraguay	MHDC
Suriname	HiHDI

Middle East & North Africa	
Djibouti	LMIC
Iraq	MHDC
Palestine, State of/West Bank Gaza	LMIC
Syrian Arab Rep.	LMIC
Yemen, Rep.	LMIC

South Asia	
Afghanistan	LIC
Bangladesh	LMIC
Bhutan	LMIC
Maldives	HiHDI
Nepal	LIC
Sri Lanka	LMIC

Sub-Saharan Africa	
Angola	LHDC
Benin	LIC
Botswana	MHDC
Burkina Faso	LIC
Burundi	LIC
Cabo Verde	LMIC
Cameroon	LMIC
Central African Rep.	LIC
Chad	LIC
Comoros	LIC
Congo, Dem. Rep.	LIC
Congo, Rep.	LMIC
Côte d'Ivoire	LMIC
Equatorial Guinea	MHDC
Eritrea	LIC
Ethiopia	LIC
Gabon	MHDC
Gambia, The	LIC
Guinea	LIC
Guinea-Bissau	LIC
Lesotho	LMIC
Liberia	LIC
Madagascar	LIC
Malawi	LIC
Mali	LIC
Mauritania	LMIC
Mozambique	LIC
Namibia	MHDC
Niger	LIC
Rwanda	LIC
São Tomé and Principe	LMIC
Senegal	LIC
Sierra Leone	LIC
Somalia	LIC
South Sudan	LIC
Sudan	LMIC
Swaziland	LMIC
Tanzania, United Rep.	LIC
Togo	LIC
Uganda	LIC
Zambia	LMIC
Zimbabwe	LIC

LIC Low-Income Country

LMIC Low-Middle-Income Country

LHDC Low Human Development Country

MHDC Medium Human Development Country

HiHDI High Human Development Country with high inequality

LDC Least Developed Country

Table 2: Patent rights, in Index Countries, for medicines used to treat Index Diseases, and an indication of the expiry of those rights

Medicine	Compound	Process	Formulation	Indication	Combination	Technology
Accolate	No	No	No	No	No	No
Alvesco	No	No	No	No	No	No
Arimidex	No	No	No	CN, ID, MX, PH Dec 2022	No	No
Atacand/Atacand Plus	PH Dec 2024	No	No	No	No	No
Bambec	No	No	No	No	No	No
Bricanyl	No	No	No	No	No	No
Brilinta	Genus: BR Oct 2020; UA Jul 2023. Species: CN, EG, ID, IN, MX, ZA Dec 2019; BR Aug 2025; PH, TH Nov 2019. Polymorph: CN, ID, IN, MX, PH, TH, ZA May 2021; PK Jun 2020; UA May 2026.	BR, CN, MX May 2032; CO May 2021; IN Sep 2030	CN Apr 2037; CO, EG, ID, IN, MX, PH, TH, UA, ZA Aug 2027; PK Aug 2026	BR, CN Jan 2036; ID, MX, PH, VN, ZA Dec 2028	No	No
Bydureon	No	CN, MX Apr 2021	CN, IN, MX Apr 2025	MX Aug 2026	No	No
Byetta	No	No	BR Jan 2026; CN Jan 2020	CN Jan 2020	No	No
Capecitabine	No	No	No	No	No	No
Casodex	No	No	No	No	No	No
Crestor	VU Jun 2021 HT Jul 2022	BR Jan 2023 & Feb 2026; CN, MX, ZA Feb 2020 & Aug 2023 & Jun 2024; CO Aug 2023 & Jun 2024	BR, CN, CO, GH, GM, GY, ID, IN, KE, KS, MX, MW, PH, TH, TZ, UA, UG, VN, ZA, ZW Aug 2020	CN Nov 2021	CN, Feb 2020	No
Daxas	No	AM, CN, IN, KG, MD, MX, PH, TJ, TM, ZA Mar 2024	CN, ID, IN, KG, MX, PH, PK, TJ, TM, TN, VN, ZA Feb 2023; MD Dec 2026; AM Feb 2028	No	No	No
Duaklir/Eklira	BO, CN, CO, EG, ID, IN, MX, NG, PE, PH, TH, UA, ZA Jul 2020; PK Jul 2019; BR Mar 2026	BO, BR, CO, CN, MX, ZA Jul 2027	BO, BR, CN, CO, EG, ID, MX, PE, PH, TH, UA, VN, ZA Mar 2029; PK Mar 2028	CN, ID, MX, PH, UA, ZA Jan 2028; CN Apr 2032; CN Dec 2033	BO, BR, CN, CO, EG, ID, IN, MX, NG, PE, PH, TH, UA, VN, ZA May 2025; PK May 2024	BR, CN, CO, IN, MX, VN, ZA Jul 2025; CN, IN, MX, UA, ZA Jun 2022; BR Apr 2028
Flumist / Fluenz	No	CN 2020-2021	CN, IN 2025	No	No	BR, CN, MX, ZA 2020-2021
Forxiga	BR, CN, CO, EC, EG, ID, IN, KS, MX, PE, PH, PK, TH, UA, VN, ZA May 2023	No	BR, CN, IN, MX March 2028	No	No	No
Imdur	No	No	No	No	No	No
Inderal	No	No	No	No	No	No
Kombiglyze	BR, CN, CO, EC, EG, ID, IN, MX, PH, PK, TH, ZA March 2021	CN, IN Apr 2025	BR, CN, CO, ID, IN, MX, PE, PH, TH, UA, VN, ZA May 2025	No	BR, CN, CO, ID, IN, MX, PE, PH, TH, UA, VN, ZA May 2025	No
Logimax & Plendil	No	No	No	No	No	No

Table 2: Patent rights, in Index Countries, for medicines used to treat Index Diseases, and an indication of the expiry of those rights

Medicine	Compound	Process	Formulation	Indication	Combination	Technology
Metformin	No	CN, IN Nov 2030	No	No	No	No
Nolvadex	No	No	No	No	No	No
Oxis	No	No	No	No	No	No
Onglyza	BR, 2025; CN, CO, EC, EG, ID, IN, MX, PH, TH, ZA March 2021; PK 2020	No	BR, CN, CO, ID, IN, MX, PE, PH, TH, VN, ZA May 2025	No	No	No
Pulmicort	No	CN, IN, MX, ZA Nov 2018	No	No	No	No
Q-LAIC flu vac	No	CN, IN 2025	CN, IN 2025	No	No	BR, CN, IN, MX, ZA 2020-2021
QTERN	BR, CN, CO, EC, EG, ID, IN, KS, MX, PE, PH, PK, TH, UA, VN, ZA May 2023	No	BR, CN, CO, ID, IN, MX, PE, PH, TH, VN, ZA May 2025; BR, CN, IN, MX March 2028	No	No	No
Ramace	No	No	No	No	No	No
Seloken, Betaloc & Treloc	No	No	No	No	No	No
Seroquel	No	No	PH Mar 2021	No	No	No
Symbicort Turbuhaler	No	No	PH Sept 2018	COPD: CN, IN, ID, MX, PH, ZA, Sept 2018; SMART: CN, ID, MX, ZA, Jun 2019		
Symbicort pMDI	No	No	CN, ID, MX, PH, ZA, UA Jan 2023	COPD: CN, IN, ID, MX, PH, ZA, Sept 2018	No	No
Tenormin/ Tenoretic/ Tenif	No	No	No	No	No	No
Vimovo	No	No	AM, MX May 2022	BR June 2030	No	No
Xigduo	BR, CN, CO, EC, EG, ID, IN, KS, MX, PE, PH, PK, TH, UA, VN, ZA May 2023	No	BR, CN, IN, MX Nov 2030	No	BR, CN, IN, MX Nov 2030	No
Zestoretic/ Zestril	No	No	No	No	No	No
Zinforo	CN Dec 2018	No	BR, BZ, DO, EC, EG, GT, HN, ID, IN, MX, NI, PE, PH, SV, TH, UA, UZ, VN, ZA Sept 2030	No	BR, CN, IN, MX Aug 2029	No

October 2018