



Patents and Access to Medicines for Developing Countries

A Company and Industry Perspective

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Head International IP Policy

WIPO Standing Committee on Patents, Geneva, December 2, 2015

Who We Are: Novartis at a Glance



Novartis is a global healthcare company whose mission is to discover new ways to extend and improve patients' lives.

■ Headquarters: Basel, Switzerland



- **123,000+ full-time associates from 150+ countries**
- **Operations in over 140 countries (sales in 180 countries)**

■ 3 Main Global Operating Divisions



- **Pharmaceuticals – Innovative Rx**



- **Alcon – Eyecare**

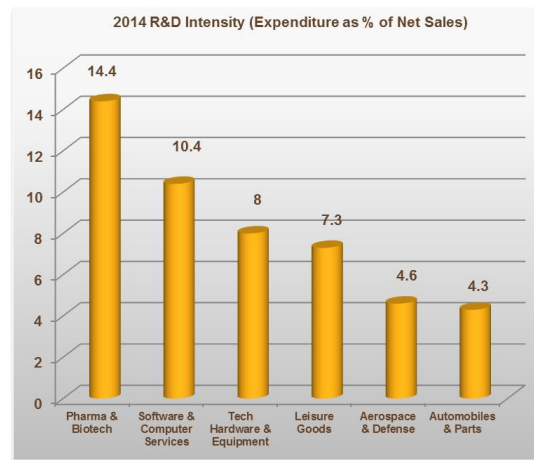


- **Sandoz – Generics + Biosimilars**

Who We Are:

A Reciprocal Business in a Reciprocal Industry

- Novartis medicines reach more than **1 billion** people globally each year.
- Our industry reinvests more of our sales back into R&D than any other.




 **NOVARTIS**

17.1%
9.9 billion USD

Source: European Commission, 2014 EU Industrial R&D Investment Scoreboard.

- And we give back **billions of dollars** annually to **100s of millions** of additional patients through our access & philanthropy programs.


5 million
leprosy patients treated free with
Novartis MDT since 2000


700 million
antimalarial treatments
without profit delivered to patients
in 60 countries since 2001

Rural health clinics for 90
million people since 2007


Arogya Parivar
a Novartis Social Venture


Cùng Sống Khỏe
a Novartis Social Venture


Familia Nawiri
a Novartis Social Venture


Keluarga Sehat
a Novartis Social Venture

**Glivec International
Patient Assistance
Program**
Donation of over USD 1 bn
of free Glivec since 2002

Quality Affordable Medicines

A Novartis Contribution

 **NOVARTIS**
ACCESS

 **NOVARTIS**

Who We Are: Innovation and Patient Health

- Our ability to continue to meet patient needs depends on innovation.



“[B]efore Gleevec, only 30% of patients with CML [chronic myelogenous leukemia] survived for even five years after being diagnosed. With Gleevec, that number rose to at least 89%.”

— Pray, L. (2008) Gleevec: the breakthrough in cancer treatment. Nature Education 1(1):37



In 2014, we teamed up with Google to develop “smart lens” technology.



In 2006, Sandoz launched the EU’s first-ever biosimilar Omnitrope® (somatropin)

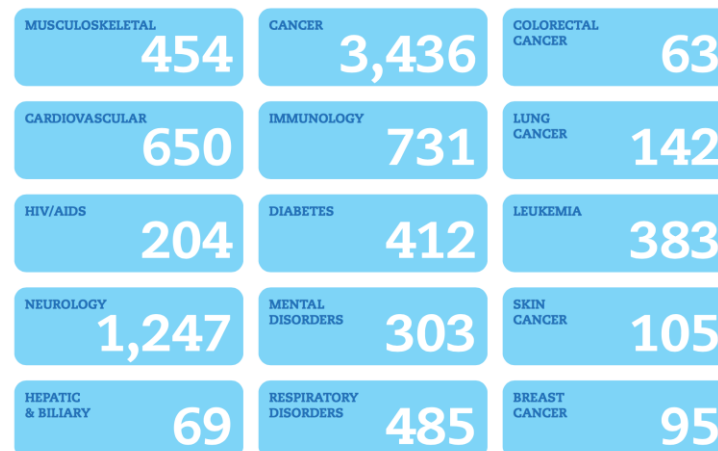
In Sept. 2015 launched the US’s first ever biosimilar Zarxio™ (filgrastim).

We are an “innovation company.”



- Over **200** R&D projects in clinical development as of July 2015
- 2014: 13** approvals in US, EU + JP
- 5** FDA breakthrough therapy designations (2 in 2014)

In an innovation-based industry



Analysis Group (2013) Innovation in the Biopharmaceutical Pipeline: A Multidimensional View.

IP and Access to Medicine: Our Perspective

- Improving access is a **critical goal** that we share with all other stakeholders.
- But access is a **long-term** as well as **short-term** goal — both equally critical to patients!

Today's Medicines, Today's Patients	<h2>Short-Term Access</h2> <p><i>A complex problem with complex causes and complex solutions</i></p>
	<p><i>95% of WHO essential medicines are off-patent, yet one-third of the world's population does not have reliable access to them, and, in parts of Africa and Asia, that is true for half the population.*</i></p>
	<ul style="list-style-type: none"> • Price — Distribution costs, taxes (import + VAT), importer and supply chain margins, IP • Weak healthcare infrastructure • Lack of health insurance/financing • Limited # of trained healthcare professionals • Poverty and a lack of general infrastructure • Limited diagnostic and prevention opportunities • Lack of health education

Tomorrow's Medicines, Tomorrow's Patients	<h2>Long-Term Access</h2> <p><i>Ensuring the future of medicine</i></p>
	<ul style="list-style-type: none"> • Innovation is the key to the future • Innovation depends on research and development (R&D) • Pharmaceutical R&D is <u>extremely</u> risky and expensive • IP is a proven tool to alter the economics of drug discovery

- As an **enabler** of both long and short-term access, IP is part of the **solution**.



How IP Enables Long-Term Access: An Economic Perspective



IP alters economics of drug discovery to make a “bad” investment feasible and create a sustainable model of biopharma innovation.

**1.5 billion –
2.56 billion**

Avg cost to bring
new medicine to
market (USD)

Sources: UK Office of Health
Economics, December 2012;
Tufts Center for the Study of Drug
Development 2014



1/10,000

Fraction of
chemical
compounds that
make it from lab to
market



10 to 15

Avg R&D years to
bring new
medicine to
market



1/5

Fraction of
marketed
medicines that
recoup R&D costs



3.3 million

Avg cost to bring
generic to market
(0.2% of brand's costs)*



*Source: Canadian Generic
Pharmaceutical Association. Incl.
product development,
bioequivalence studies, +
regulatory costs.



9,900,000,000

Novartis 2014
R&D spend in
USD

17.1

% of Group Net
Sales

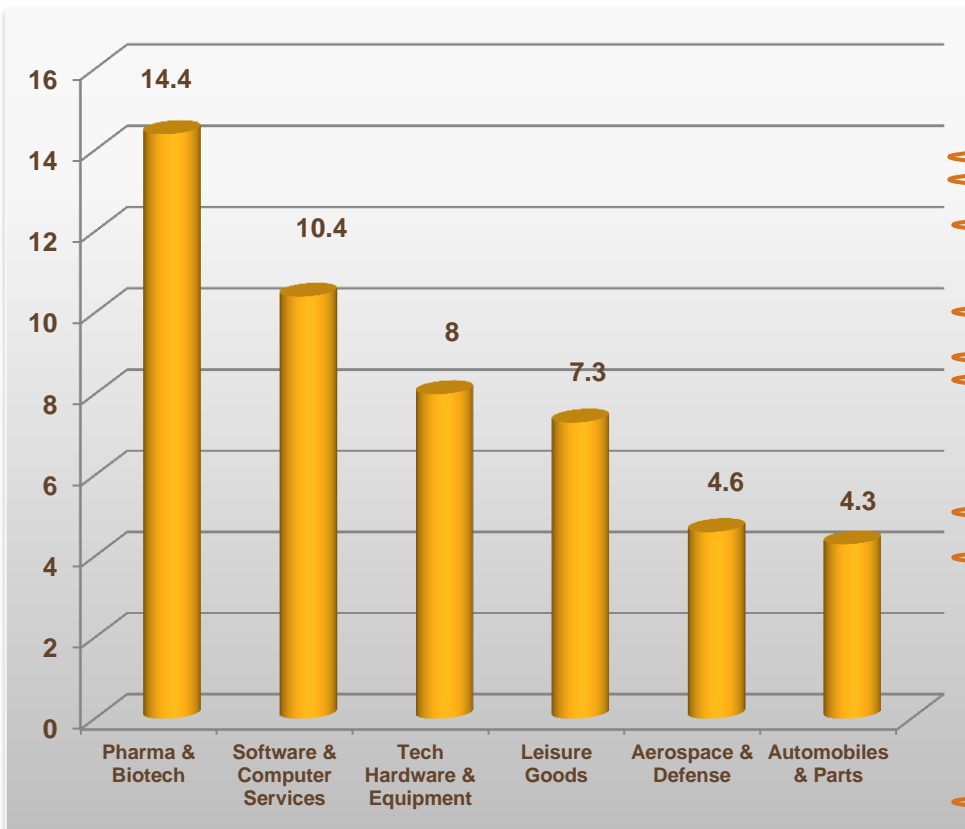
IP Enables Long-Term Access: An Economic Perspective (II)



The patent system is *effective* in incentivizing biopharma R&D.

2014 R&D Intensity

(Expenditure as a % of Net Sales by Industry (Top 7))



2014 Top Company R&D Spend

(in € millions)

Table 2.2. The top 50 companies in the 2014 Scoreboard: R&D data and rank change 2004-2014.

Rank in 2014	Company	Country	R&D in 2013 (€m)	R&D intensity (%)	Rank change 2004- 2014
1	VOLKSWAGEN	Germany	11743.0	6.0	up 7
2	SAMSUNG ELECTRONICS	South Korea	10154.9	6.5	up 31
3	MICROSOFT	US	8252.5	13.1	up 10
4	INTEL	US	7694.1	20.1	up 10
5	NOVARTIS	Switzerland	7173.5	17.1	up 15
6	ROCHE	Switzerland	7076.2	18.6	up 12
7	TOYOTA MOTOR	Japan	6269.9	3.5	down 2
8	JOHNSON & JOHNSON	US	5933.6	11.5	up 4
9	GOOGLE	US	5735.6	13.2	up 173
10	DAIMLER	Germany	5379.0	4.6	down 7
11	GENERAL MOTORS	US	5220.8	4.6	down 5
12	MERCK US	US	5165.0	16.2	up 17
13	BMW	Germany	4792.0	6.3	up 15
14	SANOFI-AVENTIS	France	4757.0	14.4	up 8
15	PFIZER	US	4750.2	12.7	down 13
16	ROBERT BOSCH	Germany	4653.0	10.1	up 10
17	FORD MOTOR	US	4640.7	4.4	down 16
18	CISCO SYSTEMS	US	4563.8	13.4	up 13
19	SIEMENS	Germany	4556.0	6.0	down 15
20	HONDA MOTOR	Japan	4366.7	5.4	down 4
21	GLAXOSMITHKLINE	UK	4154.3	13.1	down 10
22	IBM	US	4088.9	5.7	down 13
23	ELI LILLY	US	4010.8	23.9	up 18
24	ORACLE	US	3735.0	13.5	up 47
25	QUALCOMM	US	3601.6	20.0	up 112
26	HUAWEI	China	3589.3	25.6	up > 200
27	AIRBUS	The Netherlands	3581.0	6.0	up 8
28	ERICSSON	Sweden	3484.8	13.6	down 11
29	NOKIA	Finland	3456.0	14.7	down 19
30	NISSAN MOTOR	Japan	3447.2	4.8	up 4
31	GENERAL ELECTRIC	US	3444.3	3.3	up 6
32	FIAT	Italy	3362.0	3.9	up 12
33	PANASONIC	Japan	3297.2	6.2	down 26
34	BAYER	Germany	3259.0	8.1	down 2
35	APPLE	US	3244.9	2.6	up 120

Source: European Commission, 2014 EU Industrial R&D Investment Scoreboard.

IP Enables Long-Term Access: How else can we measure success? (Patient Benefit!)



Our efforts yield medicines that save and improve billions of lives.

Cancer Hypertension Heart Failure Multiple Sclerosis Macular Degeneration/Edema
 Alzheimer's COPD Psoriasis Glaucoma
 Malaria Diabetes Biosimilars Systemic Juvenile Idiopathic Arthritis (SJIA)



Fact: Between 1961 and 1990, more than 90 per cent of all new drugs were discovered and developed by pharmaceutical companies operating in countries with robust patent systems.

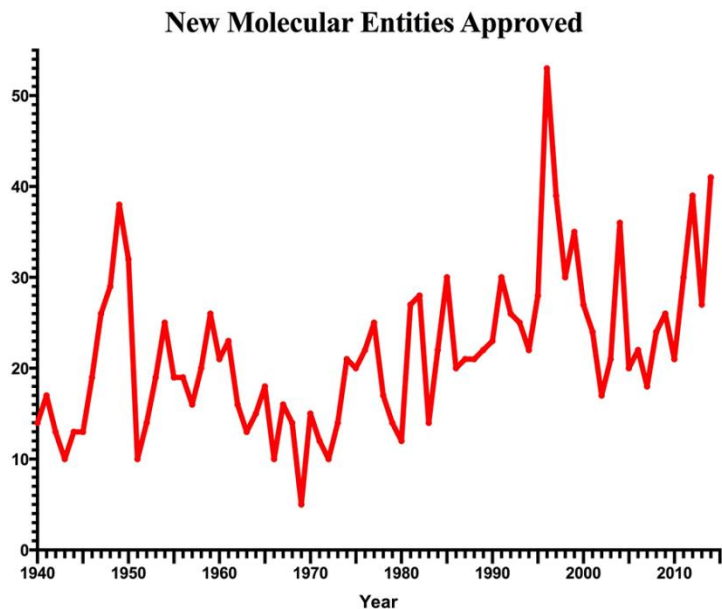
— Source: WHO, WIPO, WTO, *Promoting Access to Medical Technologies & Innovation: Intersections bet. public health, intellectual property and trade*, p. 103, 2012

Antibiotics (Sulfonamide) (1932)	Gerhard Domagk		1939 Nobel Prize for Medicine
Chemotherapy (antifolates) (1940s)	Yellapragada Subbarao and Sydney Farber		Still used for cancer and other diseases
Vaccines for measles, mumps, chickenpox, rubella, Hep A, Hep B, meningitis, + 33 more (1957-1984)	Maurice Hilleman		1988 National Medal of Science (US) "Saved more lives than any other scientist of the 20th century." (Source: LA Times, April 13, 2005)
Statins (1971)	Akira Endo		2006 Japan Prize; 2008 Lasker-DeBakey Clinical Medical Research Award
Synthetic Human Insulin; interferon; somatostatin (1977)	Herbert Boyer		1980 Lasker Award; 1990 National Medal of Science
Antiretrovirals (AZT) (1984+)	Collaboration		First breakthrough in treatment of HIV
Imatinib	Nicholas Lydon, Jürg Zimmermann & Brian Druker (OHSU)		2009 Lasker Award; 2012 Japan Prize; European Inventor of Year 2009



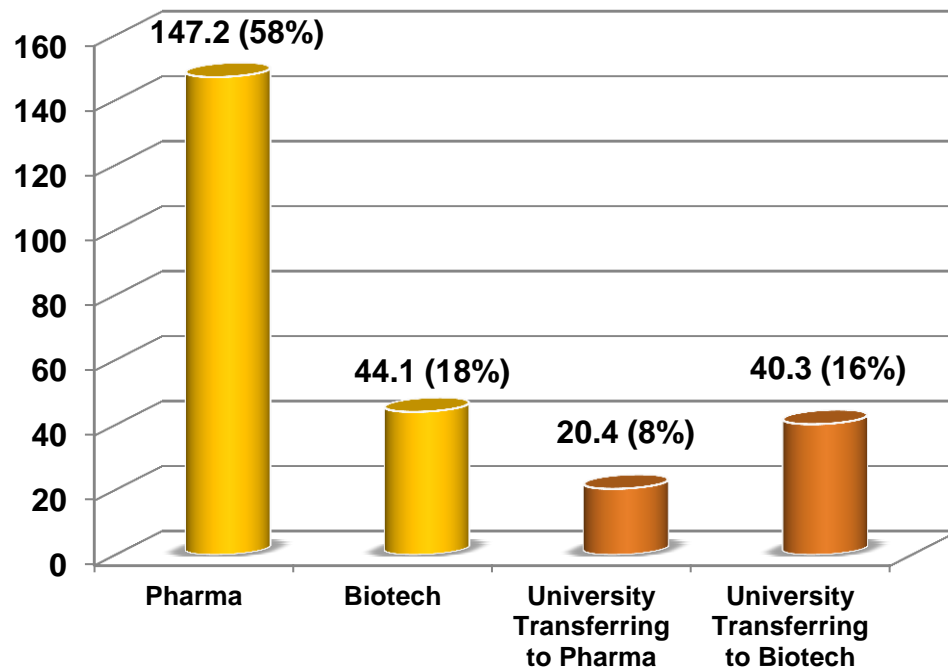
How IP Enables Long-Term Access: A Patient Benefit Perspective (II)

- 2014 saw 41 NMEs approved in the US—the second highest number in history!
- From 1998-2007, 76% of new medicines were discovered by industry (Pharma + Biotech).
 - For the remaining 24%, patents are what enabled their development and commercialization.



Source: USFDA, 2014 Novel New Drugs Summary Report

Number of New Drugs Approved by FDA 1998-2007 by Discovering Organization (252 total)



Source: Nature Reviews Drug Discovery 9, 867-882 (November 2010)

How IP Enables *Short-Term Access*

- IP incentivizes innovators to launch medicines in developing markets—which increases patient access vs. Gx launch.

Seven times the amount of a new medicine reaches patients in a developing country when an innovator launches first vs. a generic.

- Innovators spend ≈ 31% of sales to develop market vs. 18% Gx spend.
- Greater investment in infrastructure and product distribution chains
- Greater physician and patient outreach = 🏠 education and 🏠 compliance

Source: Charles River Associates, “The role of the innovative industry in ‘developing’ the market for new medicines in Emerging Markets”



- **IP and Generic Medicines**

- Gx medicines play an important role in lowering healthcare costs and increasing access to medicine.
- But Gx can only produce cheaper medicines by foregoing R&D and its costs and risks and copying successful innovative R&D.
- The Gx of today are the product of the innovative patented medicines of yesterday.



Average cost of bringing a generic medicine to market is 0.2% of brand's costs.

Source: Canadian Generic Pharmaceutical Assn.

From 1984 to 1996 to 2009, Generics soared from 19% to 43% to 74% of total US prescriptions.

Source: US Federal Trade Commission

Access Initiatives: Where are we now?

Our access programs reached more than **72 million patients** in **2014** and in 2013 were valued at **USD 2 billion**

access to
medicine
INDEX
#4 in the
Access to
Medicine
Index (2014)

- Access initiatives are an important part of our strategy and commitment to addressing access to medicine—but a holistic approach is needed!



Traditional Philanthropy

Novartis Foundation for Sustainable Development



5 million
leprosy patients treated free with Novartis MDT since 2000

We supply nearly 100% of the world's leprosy drugs, all free

Glivec International Patient Assistance Program (GIPAP)

Donation of over USD 1 billion worth of free Glivec since 2002

Alcon Eyecare Missions

Annual product donations exceed \$48MM

625 medical missions
550 000 treated patients
44 000 restored vision
80 countries

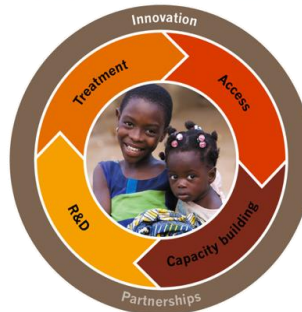


Zero Profit

Malaria Initiative

700 million

antimalarial treatments without profit delivered to patients in 60 countries since 2001



Novartis Institute for Tropical Diseases (NITD):

Collaborative research and treatments without profit to patients in developing countries

Shared Value Business

Social Ventures

Rural health education and health camps/clinics for 90 million people across 4 countries since 2007



Novartis Oncology Access (NOA):

Patient-assistance program for cancer meds.

- Cost-sharing (HC systems, charities)
- Co-pay sharing with patients
- Full donations

Voluntary Licensing

LDC Licensing Policy: Voluntary licenses to supply LDCs

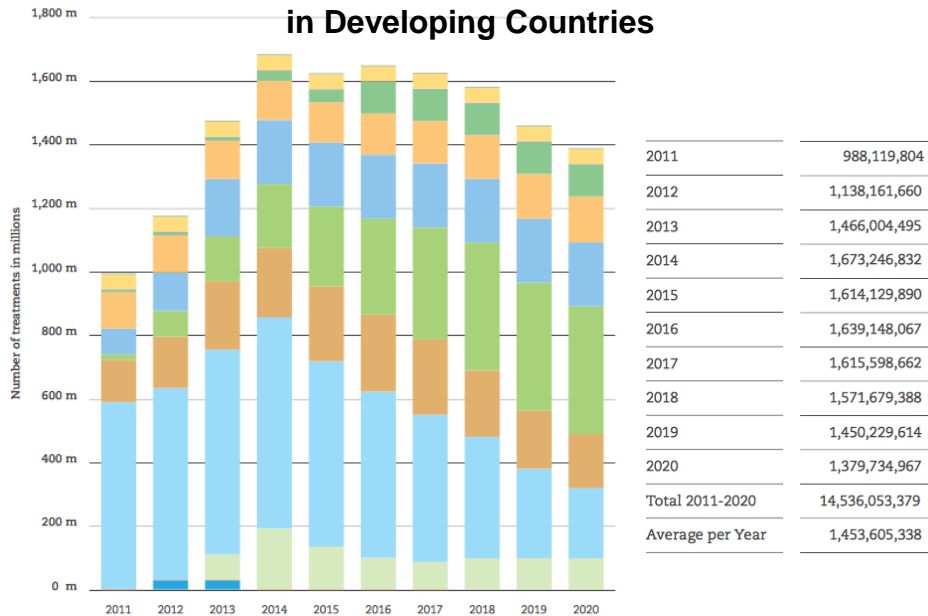
NIBR and NITD: Licensed compounds for TB for developing countries



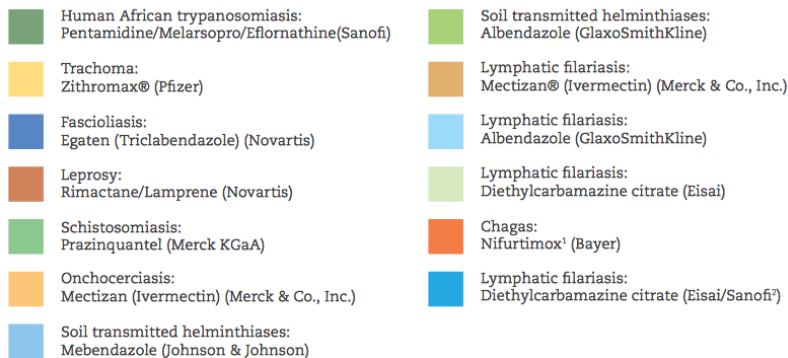
IP and expertise royalty-free; resulting products royalty-free in LDCs

Access Initiatives: An Industrywide View (Excludes malaria)

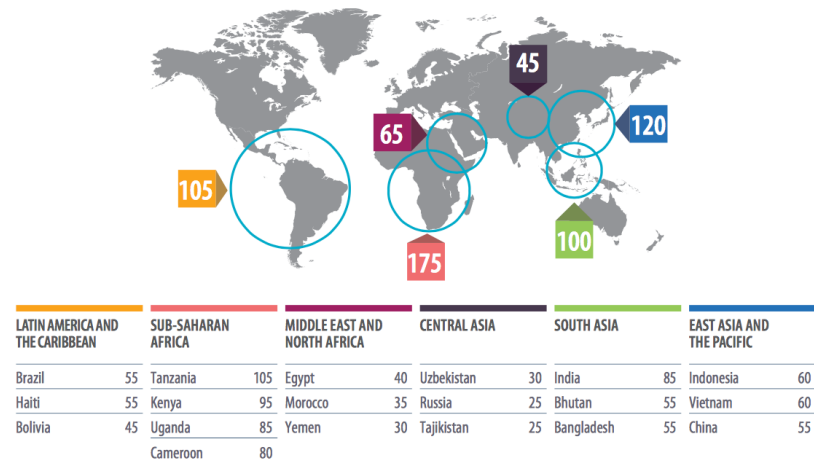
NTD Treatments Donated or Sold At-Cost in Developing Countries



¹ Nifurtimox, generally used as 2nd-line drug. ² The Bill and Melinda Gates foundation is also contributing.



Health Partnerships undertaken by R&D companies



185 
PARTNERSHIPS

to address health system infrastructure (a trained workforce, operating information systems, adequate physical infrastructure).

165 
PARTNERSHIPS

to increase availability of treatments (differential pricing, product donations, technology transfers).

150 
PARTNERSHIPS

to prevent the spread of communicable diseases and non-communicable diseases (NCDs) (vaccines, awareness raising and behavioural change).

95 
PARTNERSHIPS

to develop new treatments for diseases of the developing world (including improved research capacities, paediatric R&D).

IFPMA (2014) Developing world health partnerships directory. Geneva: International Federation of Pharmaceutical Manufacturers and Associations. http://www.ifpma.org/fileadmin/content/Publication/2014/2014_Partnership_Directory_Publication-FINAL-web.pdf

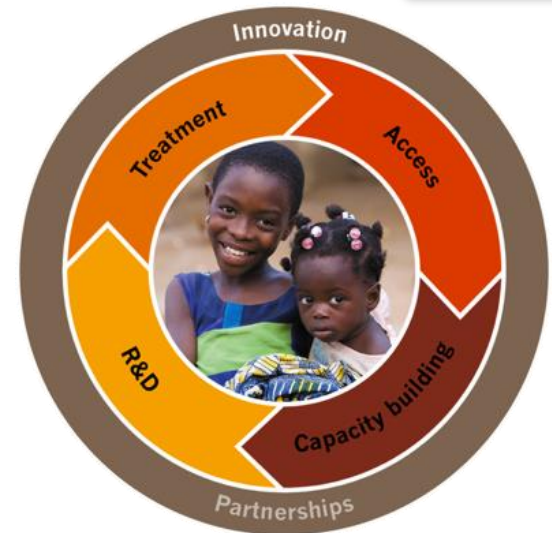
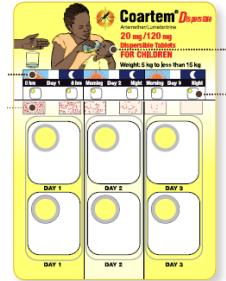
The Novartis Malaria Initiative in Focus: *Patented medicines without profit . . . and beyond*

700 million

antimalarial treatments
without profit delivered to patients
in 60 countries since 2001

- **Innovative and Patented Treatments:**
 - First fixed-dose artemisinin-based combo therapy (ACT)
 - First dispersible sweet-tasting ACT (infants /children)
 - Innovative packaging to improve compliance
- **Access:** Provided **without profit** to governments and NGOs; SMS for Life program uses **mobile technology** to help avoid stock-outs
- **Capacity building:** Practice sharing workshops for public health officials, training material, and packaging in local languages
- **Research:** Two compounds with potential to be next generation malaria treatments

 **Coartem®**
(artemether/lumefantrine) Tablets
20 mg/120 mg per tablet



PATENTS for **HUMANITY**
It's not just an invention.

2013 Honorable Mention Winner,
United States Patent No. 5,677,331

New Novartis Access Initiatives: LDC Licensing and *Novartis Access*

■ Novartis Least Developed Country (LDC) Patent Policy

We do not enforce patents in
LDCs

LDCS


We will grant non-exclusive licenses
to qualified third parties to supply our
patented products exclusively to
LDCs



First-of-its-kind social business program centered around affordable access for low and low-middle-income countries to a portfolio of Novartis non-communicable disease (NCD) medicines

- Portfolio of 15 on-and-off-patent medicines offered as a basket at USD 1 per treatment per month
- Medicines treat 4 main non-communicable disease (NCD) types—cardiovascular diseases, diabetes, respiratory illnesses and breast cancer—selected based on WHO Essential Medicines List.
- Program also includes measures to address multiple barriers to access, e.g. collaborations with government and NGOs to distribute medicines, raise disease awareness and strengthen healthcare system capabilities in key NCD areas.
- Launched in Kenya October 15, 2015 (Ethiopia and Vietnam to follow in phased approach)

IP and Access to Medicine: The Way Forward

- **Access to medicine solutions are complex, and must include**
 - Better prevention, diagnosis and treatment
 - Appropriate facilities and personnel
 - Adequate health policies and systems (including insurance/financing)
 - Work to alleviate poverty
- **Access programs can only be part of the solution**
- **Compulsory licenses are not a solution**
 - CLs impede innovation and do little to address the main barriers to short-term access
 - CLs may even *impede* short-term access if they deter innovators from launching in a country
- **Innovation and IP are part of a long-term sustainable solution**
 - IP enables short and long-term access, both of critical importance to patients
 - IP can also help spur local innovation yielding new local products and economic development
-  **Access barriers can only be overcome with coordinated efforts between private sector, governments, international agencies, foundations, NGOs**



FORWARD

Thank you.

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