




Philanthropy and IP: Access to medicines for developing countries
The Novartis Perspective


Corey Salsberg
 Head International IP Policy
 University of Geneva Philanthropy Series, March 13, 2014






Who We Are: Novartis at a Glance




Novartis is a global healthcare company whose mission is to discover, develop and successfully market innovative products to prevent and cure diseases, to ease suffering, and to enhance the quality of life for patients.

- 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

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Novartis: Innovation and Patient Health

- Our core medicines reach more than **1 billion** people annually.
- Consistent with our focus on patients, we reach **hundreds of millions more** through our special access programs.
- Our ability to continue to address patient needs depends on **innovation**.



gleevec
imatinib mesylate

"[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.

Omnitrope
somatotropin

In 2006, Sandoz launched the first-ever biosimilar in the EU Omnitrope® (somatotropin), and in March 2015 secured FDA approval for the first biosimilar in US history, Zarxio™ (filgrastim).

- At heart, we are an "innovation company."



More than 200 R&D projects are underway, with **20** compounds in development, and **5** FDA breakthrough therapy designations (2 in 2014)



* Sources: IFPMA, *The Changing Landscape on Access to Medicines* (2012); and *The Pharmaceutical Industry and Global Health* (2014); WHO and Health Action International, *Measuring Medicine Prices, Availability, Affordability & Price Components* (2008).

IP and Access to Medicine: Our Perspective

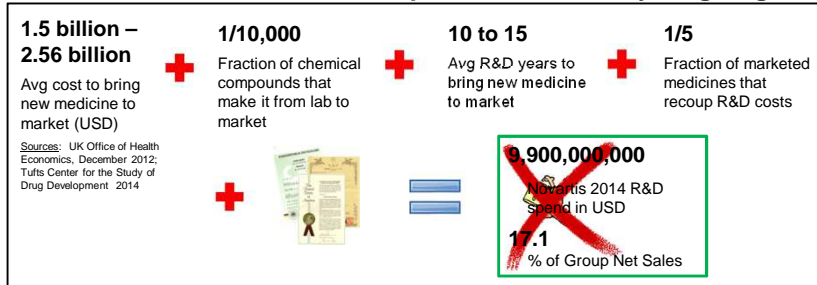
- Improving access is a **critical goal** that we share with all other stakeholders.
- But access is a **long-term and short-term** goal—both of critical importance to patients!

Today's Medicines, Today's Patients	<p>Short-Term Access <i>A complex problem with complex causes and complex solutions</i></p> <p>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.*</p> <ul style="list-style-type: none"> Affordability—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	<p>Long-Term Access <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
	<ul style="list-style-type: none"> With its important role in enabling long and short-term access, IP is part of the solution. 		



IP Enables Long-Term Access

- IP alters the economics of drug discovery to make a “bad” investment feasible, and to keep the innovation cycle going



- Our Efforts Yield Medicines and Medicines Save Lives!



- From 1998-2007, 76% of new FDA-approved medicines were discovered by industry (Pharma + Biotech).
- For remaining 24% discovered by universities patents enabled their development and commercialization.

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

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IP Enables Short-Term Access

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

Seven times the number of patients receive a needed medicine 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

- Generic medicines play an important role in lowering healthcare costs and increasing access to medicine.
- But Generics can only produce cheaper medicines by foregoing R&D and its costs and risks and copying successful innovative R&D.
- The Generics 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 FTC

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The Role of Philanthropy: 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)

- Philanthropy in various forms is an important part of our strategy and commitment to addressing access to medicine.

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



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, NITD and NVGH: Licensed compounds for TB and vaccines for typhoid for developing countries



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

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

700 million

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

Innovative 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 the 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



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Novartis, Licensing and Developing Countries

Novartis Vaccines Institute for Global Health (NVGH)

- Novartis was the first vaccine manufacturer to create a not-for-profit vaccines research institute.
- Effective and affordable vaccines for neglected infectious diseases of developing countries.
- Voluntarily license and tech transfer to Indian firm BioE for manufacture, further clinical development, approval and distribution of typhoid and paratyphi A vaccines to developing world.



Novartis Institutes for Tropical Diseases (NITD) — Tuberculosis

- Patent-pending preclinical compounds active against drug-sensitive/multidrug-resistant strains of TB
- Exclusively licensed these compounds and related R&D program to Global Alliance for TB Drug Development for further development, approval and distribution of compounds

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

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IP and Access to Medicine: The Way Forward

Access to Medicines solutions are complex, and must include

- Better prevention, diagnosis and treatment
- Appropriate facilities and personnel
- Adequate health policies and systems
- Work to alleviate poverty

Philanthropy is only part of the solution

- Our philanthropic efforts reach hundreds of millions
- But our core business reaches over *1 billion* patients each year
- Core business allows us to subsidize our philanthropy programs

FORWARD

Innovation and IP are part of the 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

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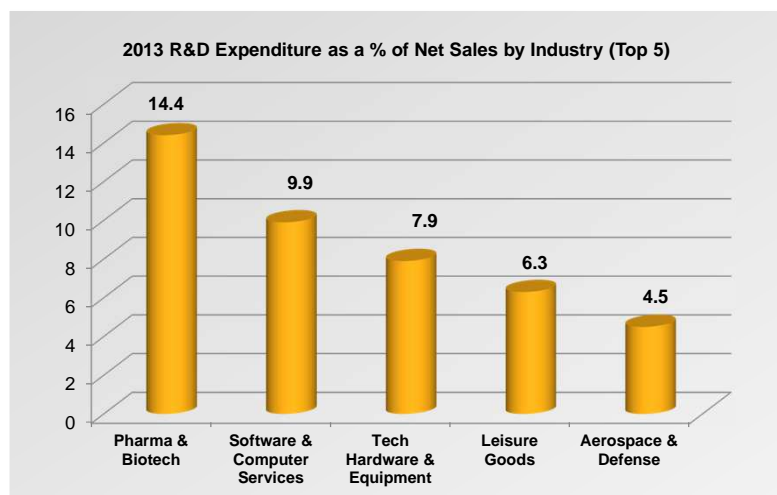
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IP Enables Long-Term Access

Our Efforts Yield Medicines and Medicines Save Lives!



Source: European Commission, 2013 EU Industrial R&D Investment Scoreboard.









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IP Enables Long-Term Access

Note: All trademarks are property of their respective owners.

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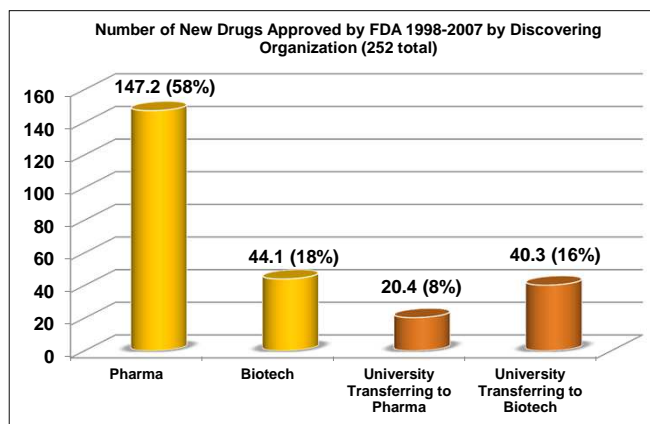
Antibiotics (1932) (Sulfonamide)	Gerhard Domagk		1939 Nobel Prize for Medicine
Chemotherapy (1940s) (antifolates)	Yellapragada Subbarao and Sydney Farber		Still used to treat cancer and other diseases
Vaccines for measles, mumps, chickenpox, rubella, Hep A, Hep B, meningitis, + 33 more (1957-1984)	Maurice Hilleman		1988 National Medal of Science (US) "Saved more lives than any other scientist of the 20th century." <small>(Source: Los Angeles Times, April 13, 2005)</small>
Ibuprofen (1961)	Stewart Adams		Order of the British Empire (OBE); Queen's Award for Tech. Achievement
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	 Burroughs Wellcome	First breakthrough in treatment of HIV
Imatinib	Nicholas Lydon, Jürg Zimmermann & Brian Druker (OHSU)		2009 Lasker Award for "converting a fatal cancer [CML] into a manageable chronic condition," 2012 Japan Prize; European Inventor of Year 2009

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WEF-WIPO Pro Bono Program: Increasing Access to the Patent System



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