Patents and Access to Medicines for Developing Countries

A Company and Industry Perspective

Corey Salsberg
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.

![Graph showing R&D intensity (Expenditure as % of Net Sales)](image)


- 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
- Glivec International Patient Assistance Program
  Donation of over USD 1 bn of free Glivec since 2002
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%.”

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).

• 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)

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!

<table>
<thead>
<tr>
<th>Short-Term Access</th>
<th>Long-Term Access</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>A complex problem with complex causes and complex solutions</strong></td>
<td><strong>Ensuring the future of medicine</strong></td>
</tr>
<tr>
<td>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.*</td>
<td></td>
</tr>
</tbody>
</table>

- **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**

- **Innovation is the key to the future**
- **Innovation depends on research and development (R&D)**
- **Pharmaceutical R&D is extremely 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

Canadians spend 17.1% of Group Net Sales on R&D.
The patent system is effective in incentivizing biopharma R&D.

### 2014 R&D Intensity
(Expenditure as a % of Net Sales by Industry (Top 7))

<table>
<thead>
<tr>
<th>Industry</th>
<th>2014 R&amp;D Intensity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharma &amp; Biotech</td>
<td>14.4</td>
</tr>
<tr>
<td>Software &amp; Computer Services</td>
<td>10.4</td>
</tr>
<tr>
<td>Tech Hardware &amp; Equipment</td>
<td>8</td>
</tr>
<tr>
<td>Leisure Goods</td>
<td>7.3</td>
</tr>
<tr>
<td>Aerospace &amp; Defense</td>
<td>4.6</td>
</tr>
<tr>
<td>Automobiles &amp; Parts</td>
<td>4.3</td>
</tr>
</tbody>
</table>

### 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.**

<table>
<thead>
<tr>
<th>Rank in 2014</th>
<th>Company</th>
<th>Country</th>
<th>R&amp;D in 2013 (€m)</th>
<th>R&amp;D intensity (%)</th>
<th>Rank change 2004-2014</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>VOLKSWAGEN</td>
<td>Germany</td>
<td>11743.0</td>
<td>6.0</td>
<td>up 7</td>
</tr>
<tr>
<td>2</td>
<td>SAMSUNG ELECTRONICS</td>
<td>South Korea</td>
<td>10154.9</td>
<td>6.5</td>
<td>up 31</td>
</tr>
<tr>
<td>3</td>
<td>MICROSOFT</td>
<td>US</td>
<td>8252.5</td>
<td>11.1</td>
<td>up 10</td>
</tr>
<tr>
<td>4</td>
<td>INTEL</td>
<td>US</td>
<td>7869.1</td>
<td>20.1</td>
<td>up 10</td>
</tr>
<tr>
<td>5</td>
<td>NOVARTIS</td>
<td>Switzerland</td>
<td>3127.5</td>
<td>17.1</td>
<td>up 15</td>
</tr>
<tr>
<td>6</td>
<td>ROCHE</td>
<td>Switzerland</td>
<td>7076.2</td>
<td>18.6</td>
<td>up 12</td>
</tr>
<tr>
<td>7</td>
<td>TOYOTA MOTOR</td>
<td>Japan</td>
<td>6265.9</td>
<td>3.5</td>
<td>down 2</td>
</tr>
<tr>
<td>8</td>
<td>JOHNSON &amp; JOHNSON</td>
<td>US</td>
<td>5933.6</td>
<td>11.5</td>
<td>up 2</td>
</tr>
<tr>
<td>9</td>
<td>GOOGLE</td>
<td>US</td>
<td>5755.6</td>
<td>13.2</td>
<td>up 12</td>
</tr>
<tr>
<td>10</td>
<td>DAIMLER</td>
<td>Germany</td>
<td>5317.0</td>
<td>4.6</td>
<td>down 7</td>
</tr>
<tr>
<td>11</td>
<td>GENERAL MOTORS</td>
<td>US</td>
<td>5228.8</td>
<td>4.6</td>
<td>down 5</td>
</tr>
<tr>
<td>12</td>
<td>MERCK</td>
<td>US</td>
<td>5165.0</td>
<td>16.2</td>
<td>up 17</td>
</tr>
<tr>
<td>13</td>
<td>BMW</td>
<td>Germany</td>
<td>4792.0</td>
<td>6.3</td>
<td>up 15</td>
</tr>
<tr>
<td>14</td>
<td>SANDOR-AGENTIS</td>
<td>France</td>
<td>4570.0</td>
<td>14.4</td>
<td>up 10</td>
</tr>
<tr>
<td>15</td>
<td>IBM</td>
<td>US</td>
<td>4750.2</td>
<td>12.7</td>
<td>down 13</td>
</tr>
<tr>
<td>16</td>
<td>ROBERT BOSCH</td>
<td>Germany</td>
<td>4633.0</td>
<td>10.1</td>
<td>up 10</td>
</tr>
<tr>
<td>17</td>
<td>FORD MOTOR</td>
<td>US</td>
<td>4640.7</td>
<td>4.4</td>
<td>down 16</td>
</tr>
<tr>
<td>18</td>
<td>CISCO SYSTEMS</td>
<td>US</td>
<td>4563.8</td>
<td>15.4</td>
<td>up 13</td>
</tr>
<tr>
<td>19</td>
<td>SIEMENS</td>
<td>Germany</td>
<td>4558.0</td>
<td>8.0</td>
<td>down 15</td>
</tr>
<tr>
<td>20</td>
<td>HONDA MOTOR</td>
<td>Japan</td>
<td>4366.7</td>
<td>5.4</td>
<td>down 4</td>
</tr>
<tr>
<td>21</td>
<td>PLAYSTATION</td>
<td>UK</td>
<td>4156.3</td>
<td>13.1</td>
<td>down 10</td>
</tr>
<tr>
<td>22</td>
<td>IBM</td>
<td>US</td>
<td>4066.0</td>
<td>5.7</td>
<td>down 13</td>
</tr>
<tr>
<td>23</td>
<td>ROLLS-ROYCE</td>
<td>US</td>
<td>4010.8</td>
<td>25.9</td>
<td>up 18</td>
</tr>
<tr>
<td>24</td>
<td>ORACLE</td>
<td>US</td>
<td>3735.0</td>
<td>13.5</td>
<td>up 47</td>
</tr>
<tr>
<td>25</td>
<td>QUALCOMM</td>
<td>US</td>
<td>3601.6</td>
<td>20.0</td>
<td>up 112</td>
</tr>
<tr>
<td>26</td>
<td>HUAWEI</td>
<td>China</td>
<td>3588.3</td>
<td>25.6</td>
<td>up &gt; 200</td>
</tr>
<tr>
<td>27</td>
<td>ARREUS</td>
<td>The Netherlands</td>
<td>3581.0</td>
<td>6.0</td>
<td>up 8</td>
</tr>
<tr>
<td>28</td>
<td>ERICSSON</td>
<td>Sweden</td>
<td>3484.8</td>
<td>13.6</td>
<td>down 11</td>
</tr>
<tr>
<td>29</td>
<td>NOKIA</td>
<td>Finland</td>
<td>3456.0</td>
<td>14.7</td>
<td>down 19</td>
</tr>
<tr>
<td>30</td>
<td>NISSAN MOTOR</td>
<td>Japan</td>
<td>3447.2</td>
<td>4.8</td>
<td>up 4</td>
</tr>
<tr>
<td>31</td>
<td>GENERAL ELECTRIC</td>
<td>US</td>
<td>3444.3</td>
<td>3.3</td>
<td>up 6</td>
</tr>
<tr>
<td>32</td>
<td>FIAT</td>
<td>Italy</td>
<td>3362.0</td>
<td>3.9</td>
<td>up 12</td>
</tr>
<tr>
<td>33</td>
<td>PANASONIC</td>
<td>Japan</td>
<td>3287.2</td>
<td>6.2</td>
<td>down 26</td>
</tr>
<tr>
<td>34</td>
<td>RAYNER</td>
<td>Germany</td>
<td>3259.0</td>
<td>8.1</td>
<td>down 2</td>
</tr>
<tr>
<td>35</td>
<td>APPLE</td>
<td>US</td>
<td>3244.9</td>
<td>2.6</td>
<td>up 120</td>
</tr>
</tbody>
</table>

*Source: European Commission, 2014 EU Industrial R&D Investment Scoreboard.*
Our efforts yield medicines that save and improve billions of lives.

**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.


<table>
<thead>
<tr>
<th>Medicines/Inventions</th>
<th>Scientists/Inventors</th>
<th>Awards/Recognition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antibiotics (Sulfonamide) (1932)</td>
<td>Gerhard Domagk</td>
<td>1939 Nobel Prize for Medicine</td>
</tr>
<tr>
<td>Chemotherapy (antifolates) (1940s)</td>
<td>Yellapragada Subbarao and Sydney Farber</td>
<td>Still used for cancer and other diseases</td>
</tr>
<tr>
<td>Statins (1971)</td>
<td>Akira Endo</td>
<td>2006 Japan Prize; 2008 Lasker-DeBakey Clinical Medical Research Award</td>
</tr>
<tr>
<td>Synthetic Human Insulin; interferon; somatostatin (1977)</td>
<td>Herbert Boyer</td>
<td>1980 Lasker Award; 1990 National Medal of Science</td>
</tr>
<tr>
<td>Imatinib</td>
<td>Nicholas Lydon, Jürg Zimmermann &amp; Brian Druker (OHSU)</td>
<td>2009 Lasker Award; 2012 Japan Prize; European Inventor of Year 2009</td>
</tr>
</tbody>
</table>
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.

![Graph showing New Molecular Entities Approved over years with peaks in 1998 and 2004.](image)

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

- **Pharma**: 147.2 (58%)
- **Biotech**: 44.1 (18%)
- **University Transferring to Pharma**: 20.4 (8%)
- **University Transferring to Biotech**: 40.3 (16%)

**Source:** USFDA, 2014 Novel New Drugs Summary Report

**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 forgoing 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?

- 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

- 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

- 625 medical missions
- 550,000 treated patients
- 44,000 medical vision
- 80 countries

### Zero Profit

Malaria Initiative

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

### 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

Our access programs reached more than 72 million patients in 2014 and in 2013 were valued at USD 2 billion
Access Initiatives: An Industrywide View (Excludes malaria)

### NTD Treatments Donated or Sold At-Cost in Developing Countries

<table>
<thead>
<tr>
<th>Year</th>
<th>Number of Treatments in millions</th>
</tr>
</thead>
<tbody>
<tr>
<td>2011</td>
<td>988,119,804</td>
</tr>
<tr>
<td>2012</td>
<td>1,138,161,660</td>
</tr>
<tr>
<td>2013</td>
<td>1,466,004,495</td>
</tr>
<tr>
<td>2014</td>
<td>1,673,246,832</td>
</tr>
<tr>
<td>2015</td>
<td>1,614,129,890</td>
</tr>
<tr>
<td>2016</td>
<td>1,639,148,067</td>
</tr>
<tr>
<td>2017</td>
<td>1,615,598,662</td>
</tr>
<tr>
<td>2018</td>
<td>1,571,679,388</td>
</tr>
<tr>
<td>2019</td>
<td>1,450,229,614</td>
</tr>
<tr>
<td>2020</td>
<td>1,379,734,967</td>
</tr>
<tr>
<td>Total 2011-2020</td>
<td>14,536,053,379</td>
</tr>
<tr>
<td>Average per Year</td>
<td>1,453,605,338</td>
</tr>
</tbody>
</table>

* Nifurtimox, generally used as 2nd-line drug.

**The NTD and Malaria Cures 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 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 capacity, paediatric R&D).

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

**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

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

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

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

**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
Thank you.

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Novartis International AG

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