



Science For A Better Life



Entering the Asian Market: Challenges for Pharma Companies in Asia

June 8, 2016 / Dr. Ursula Königer



Agenda

- Bayer and Bayer Pharma
- Compulsory Licensing and India
- Challenges in China
- Patent Linkage in South Korea
- Other Challenges



Bayer and Bayer Pharma



Our Business Areas



Pharmaceuticals

- Prescription drugs



Consumer Health

- Over-the-counter medicines, dietary supplements, dermatology products, foot care and sunscreen



Crop Science

- Innovative crop protection and seeds

Employees

As of March 31, 2016, incl. Covestro



Bayer Group

116,482* (previous year: 117,987)



Regions

Europe	56,337
North America	16,190
Asia / Pacific	28,106
Latin America / Africa / Middle East	15,849

Segments

Pharmaceuticals	40,315
Consumer Health	13,297
Crop Science	23,481
Animal Health	3,853
Corporate Functions, Business Services and other	19,796
Covestro	15,740

Functions¹

Production	47,800
Marketing and Distribution	44,700
Research and Development	14,700
General Administration	9,600

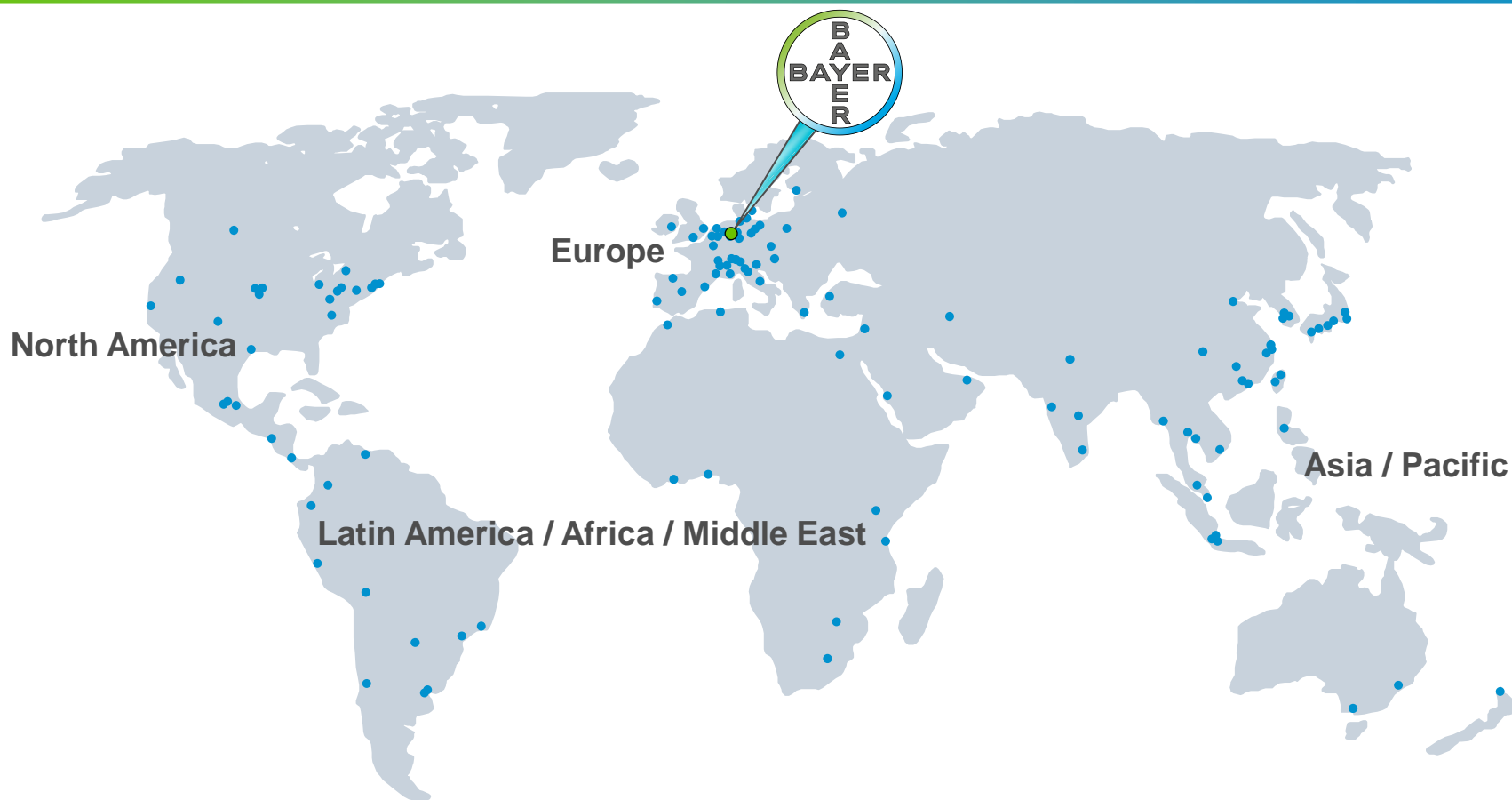
1) As of December 31, 2015

* Excluding Covestro: **100,742** (previous year: 103,393)

Employees in full-time equivalents



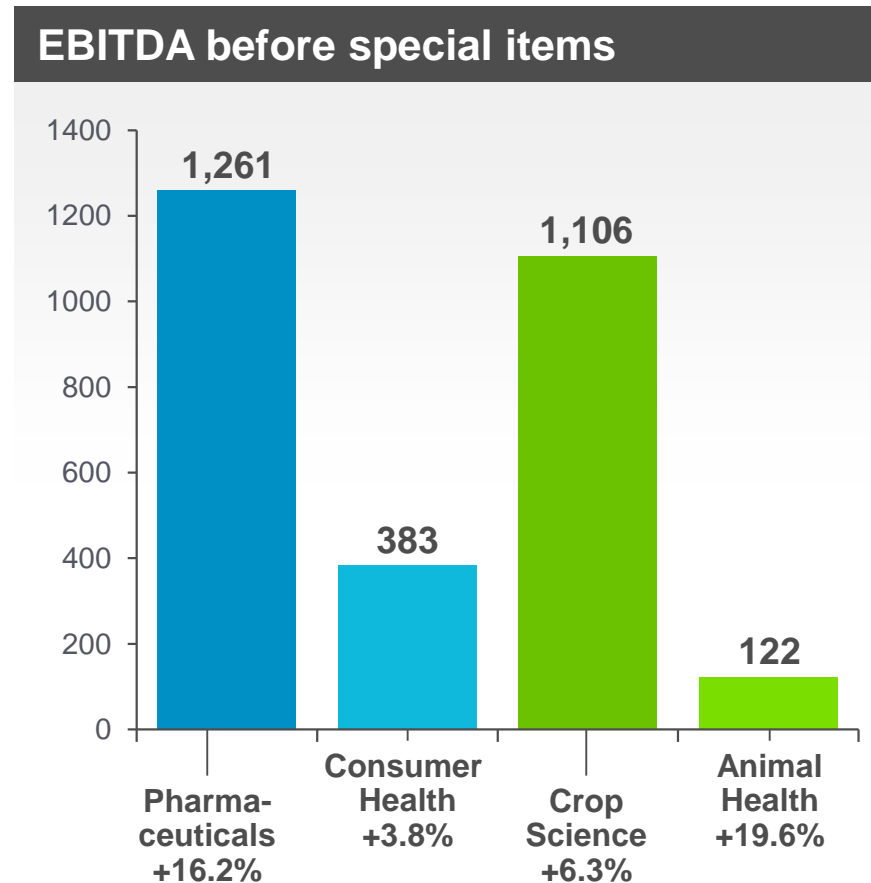
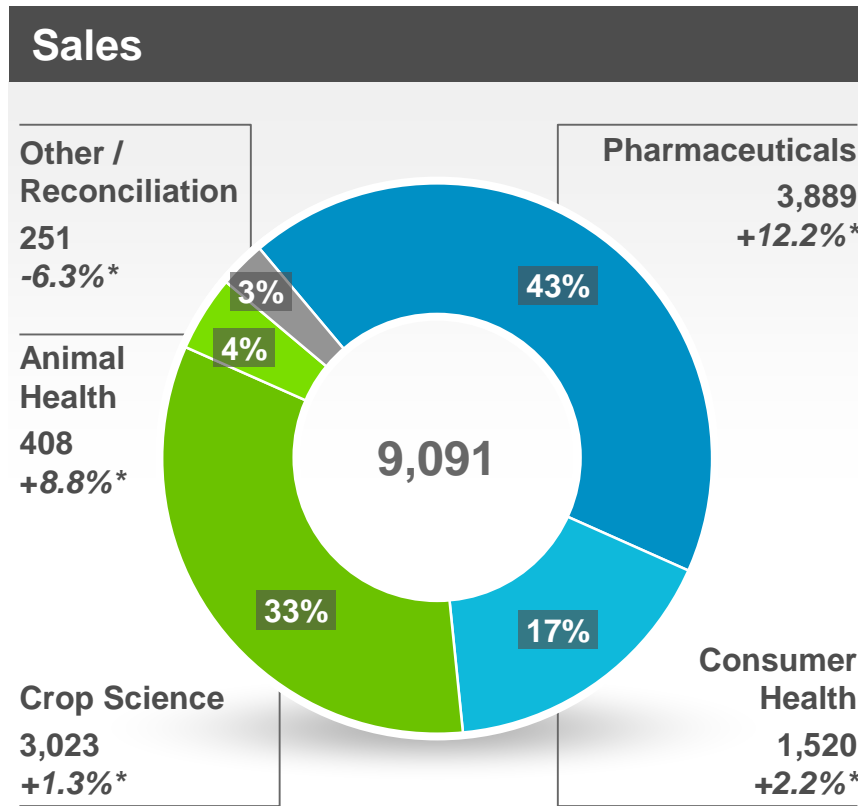
Key Locations / Regions



The Bayer Group is a global enterprise with companies in 77 countries.

Key Data, First Quarter of 2016

Life Sciences by Segments in € Million



* year-on-year change currency-adjusted

Key Data, First Quarter of 2016

By Region, € Million, incl. Covestro



Sales (by market)

Latin America / Africa / Middle East

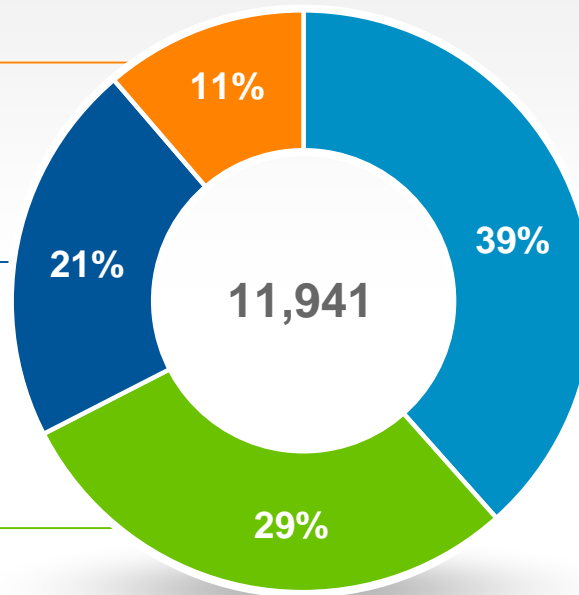
1,349
+6.0%*

Asia / Pacific

2,536
+3.0%*

North America

3,465
+2.5%*



Europe

4,591
+3.0%*

* year-on-year change currency-adjusted



Compulsory Licensing and India

Why CLs are discussed in Pharma...

...while being used more broadly



- CLs are established tool in IP protection (§24 PatG)
 - In case of public interest
 - To enable practicing of an invention
 - In case of shortages of patented products
- Some stakeholders want to use them broadly for pharmaceutical inventions, justified by characterizing patents as the main issue in
 - Access to Medicine
 - Drug Pricing

Patents on drugs raise emotions



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NEW DELHI, September 6, 2011

A victory for Novartis could spell death for millions

PRISCILLA JEBARAJ

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Health Ministry wants FDI safeguards to keep drug prices low

TOPICS

health
medicine

The Swiss pharma giant fighting in Supreme Court for patent on anti-cancer drug

A case being heard in the Supreme Court on Tuesday could signal a death sentence for Loon Gangte.

Mr. Gangte is not accused of any crime. But he — and thousands of other HIV positive people — will be avidly following the Supreme court's hearing of the Novartis vs Union of India, Cancer Patients Aid Association & others, because if the Swiss pharmaceutical giant wins its case, the drugs that keep Mr. Gangte alive could become too expensive for him.

CL in India under Sec. 84



Section 84

(1) At any time after the expiration of three years from the date of the grant of a patent, any person interested may make an application to the Controller for grant of compulsory licence on patent on any of the following grounds, namely:—

- (a) that the reasonable requirements of the public with respect to the patented invention have not been satisfied, or
- (b) that the patented invention is not available to the public at a reasonably affordable price, or
- (c) that the patented invention is not worked in the territory of India.



The first of its kind in India...



Image courtesy of Bayer Healthcare

Even courts differentiate industries...



So far as luxury articles are concerned the meeting of adequate extent test would be completely different from the meeting of adequate extent test so far as medicines are concerned. In respect of medicines the adequate extent test has to be 100% i.e. to the fullest extent. **Medicine has to be made available to every patient and this cannot be deprived/scarified at the altar of rights of patent holder.** ... This would also be in accord with Doha Declaration 2001

Pharma IP Issues in India



- Patent for Sutent (Pfizer) **revoked** as obvious
 - Patent for Pegasys (Roche) revoked because found **not** to be **an invention** under Section 3(d)
 - Patent for Tarceva (Roche) found to cover only mixture of polymorphs, not the pure polymorph and thus **not infringed** by generic
 - Compulsory License for Nexavar (Bayer) **granted**
- Overall an extremely difficult environment



Challenges in China

China IP Environment Overview



- **A 30+ years history in IP**
 - IP laws: in compliance with international standards
- **Significant interests in applications for IP rights**
 - More invention patent filings by Chinese companies since 2003
 - Busiest trademark office in the world since 2006
- **2008 National IP strategy aiming to encourage innovation**
 - Busiest patent office in the world since 2011 (1.6 million filings)
 - 3 specialized IP courts established in 2014
 - Patent law amendment draft in 2015
- **IP enforcement remains a challenge**
 - High level of counterfeiting and piracy
 - Short of experienced IP judges, examiners and attorneys



Room for Improvement

- **Legislative**
 - Everything that restricts the freedom to transfer IP cross-border is a concern for MNCs to secure IP
- **Administrative**
 - Lacking of an effective regulatory data protection for imported drugs
 - Lacking of an effective patent linkage system
- **Judicial**
 - Technically trained judges are needed
 - Court order should be more effectively enforced
 - Preservation of evidence needs to be more efficient (although no U.S. discovery system is needed)
 - Damages awarded by courts need to be commensurate with IP owners' loss



Patent Linkage in Korea



What is Patent Linkage?

- In a patent linkage system, the regulatory review for market authorization of a drug and its patent status are linked as part of an early dispute resolution.
 - Example US:
 - The originator lists relevant patents in the „Orange Book“
 - If launch before patent expiration is desired, the generic company has to argue why patents are not infringed by generic or why they are invalid
 - Situation is clarified by court litigation during regulatory review period
- Advantage for Originator: Planning security and avoidance of market erosion in case of success
- Advantage for Generic: Planning security and avoidance of damages risk after a launch-at-risk



Patent Linkage in APAC

- A similar system was recently introduced in South Korea
 - The result was a massive wave of litigation: more than 100 cases against Bayer in the first wave after the system coming into force, because the hurdle to initiate a case is too low!
 - First experiences show a highly efficient system (duration < 1 year) with so far reasonable outcomes on the merits.
 - Some room for improvement can also be identified (no access to generic material possible; only written information available).
- More countries will introduce such systems (e.g. Taiwan in 2017)
 - In general, such systems may be reasonable. However, they should be designed to avoid mass litigation!



Other Challenges



Speed, Counterfeiting, Environment

- Speed: Some APAC countries seem to be overwhelmed by the growing number of patent applications
 - Very long processing times and significant backlogs
 - In Thailand, sometimes patents are not even granted when a product is launched into the market; however:
 - China Patent Office (SIPO) recently helped to train over 70 Thai examiners which is expected to release the prosecution backlog.
 - Patents are limited in term, so adequate processing times are essential!
- Counterfeiting products
- Multi-language, multi-jurisdiction, multi-culture
- Low IP awareness



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Thank you!