



National Judicial Conference for High Court Justices on IPR

Emerging Issues on IP Regime in India and Globally

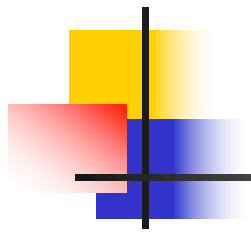
Pushpendra Rai

**National Judicial Academy, Bhopal
November 17 to 19, 2017**



Emerging Issues and Changing Landscapes

- Legislative and Treaty – with special reference to the pharma sector
- Global IP Profiles, Shifting Landscapes and Administrative Challenges
- Innovation Deficit



Legislative and Treaty



National Legislation

- Post 1970, most significant changes made between 1995 and 2005
- Triggered by the 'Triad'
- IP laws amended/new laws adopted in several areas
- Some developments have had widespread implications for stakeholders over a wide spectrum – both internal and external
- Two examples from pharma sector....



Section 3(d) Issue

THE PATENTS ACT, 1970

INVENTIONS NOT PATENTABLE

Section 3

What are not inventions

(d) the **mere discovery** of a ***new form*** of a known substance which does not result in the enhancement of the known efficacy of that substance or the **mere discovery** of any new property or ***new use*** for a known substance or of the ***mere use*** of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant



Challenged Unsuccessfully

■ Novartis case

- Contested by Novartis after the patent application on the beta crystalline form of *imatinib mesylate* (Gleevec) was rejected – decision upheld by IPAB, HC and the SC
- Novartis: “Ruling is a setback for patients that will hinder medical progress for diseases without effective treatment and companies like Novartis would invest less money in research in India as a result of the ruling”

■ Special 301 Report of the USTR:

- The US continues to have concerns that Section 3(d), as interpreted, may have the effect of limiting the patentability of potentially beneficial innovations.



Compulsory Licenses

- In March 2012, a CL was issued to Natco to make and sell an anti-cancer drug Nexavar* patented by Bayer
- First time in the history of the Patents Act (1911)
- International right holders community considered it tantamount to reneging on new obligations for providing pharma product patents
- Patient support groups and public health activists hailed the decision and said it would set a precedent for overcoming drug price barriers.

*used for the treatment of primary kidney and advanced primary liver cancer that cannot be removed by surgery



*TRIPS truly a watershed
in terms of Treaty obligations
determining National law*



Origins....

Absence of protection or inadequate protection considered trade distortive practice leading to

the inclusion of IPRs in various international arrangements at the plurilateral and bilateral levels...



TRIPS - 1994

- Comprehensive multilateral agreement setting minimum standards
- Reduces distortions and impediments to trade
- Members determine appropriate method of implementing obligations within their own legal system and practice
- Substantial provisions of the **Paris Convention** and the **Bern Convention** to be incorporated
- **National Treatment and Most-Favoured-Nation Treatment**
- Objectives and Principles specified



Obligations on Member States

- Amend provisions of existing laws/adopt laws in new areas to adhere to TRIPS
- Modernize administrative offices, streamline operations and automate procedures
- Strengthen enforcement mechanisms
- Build human resource capacities
- Internalize new international IP framework in other bilateral/plurilateral arrangements



Significant investments in the new system...

***but did the new world order actually help
developing countries...***

***perceived imbalance and lack of concern for
vulnerable sections lead to debate on
revisiting norms and also at times seeking
paradigm shifts...***

Concerns Expressed in Various Fora

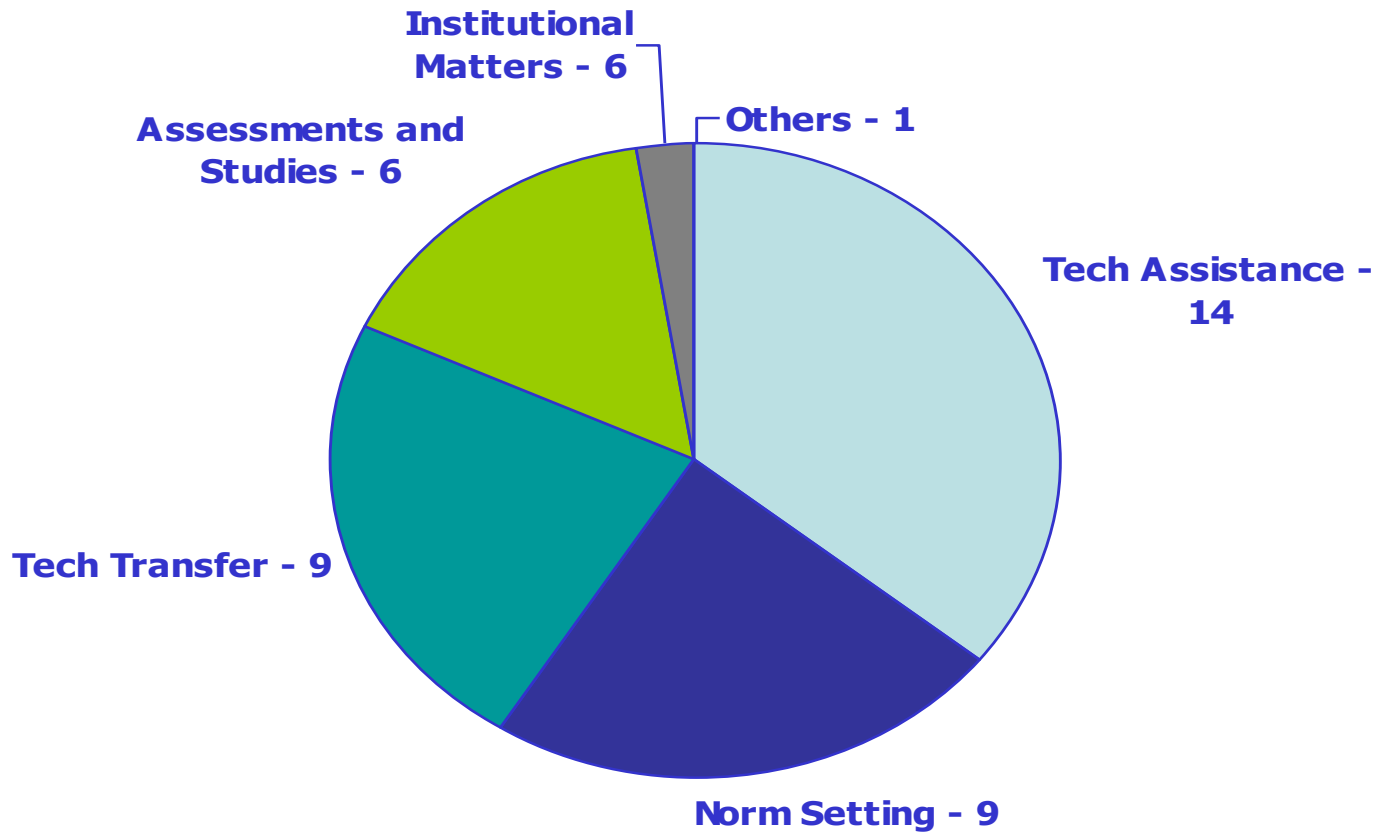
- **Doha Ministerial Declaration on TRIPS and Public Health - 2001** (<http://docsonline.wto.org/DDFDDocuments/t/WT/Min01/DEC2.doc>)
- **Commission on Intellectual Property Rights (CIPR)- 2002** (http://www.iprcommission.org/graphic/documents/final_report.htm)
- **UNCTAD XI - 2004**
(<http://www.unctad.org/Templates/meeting.asp?intItemID=1942&lang=1&m=4289&info=doc>)
- **Second South Summit - 2005**
([http://www.g77.org/southsummit2/doc/Doha%20Plan%20of%20Action%20\(English\).pdf](http://www.g77.org/southsummit2/doc/Doha%20Plan%20of%20Action%20(English).pdf))
- **Government Accountability Office (GAO) - 2007**
(<http://oversight.house.gov/documents/20071030125409.pdf>)
- **Organisation for Economic Co-operation and Development (OECD) - 2007**
(<http://www.oecd.org/dataoecd/2/31/39374789.pdf>)
- **WIPO Development Agenda – 2004 to 2007**
(<http://www.wipo.int/ip-development/en/agenda/>)



WIPO Development Agenda

- IP not end in itself - means for promoting public interest, innovation and access to S&T
- Credibility undermined by promoting **benefits of protection**, without acknowledging **public policy** concerns
- Integrating development dimension will strengthen credibility and encourage its acceptance as a tool for innovation, creativity and development
- Three-year long debate lead to adoption of 45 recommendations in 2007 - the Development Agenda

Adopted Recommendations

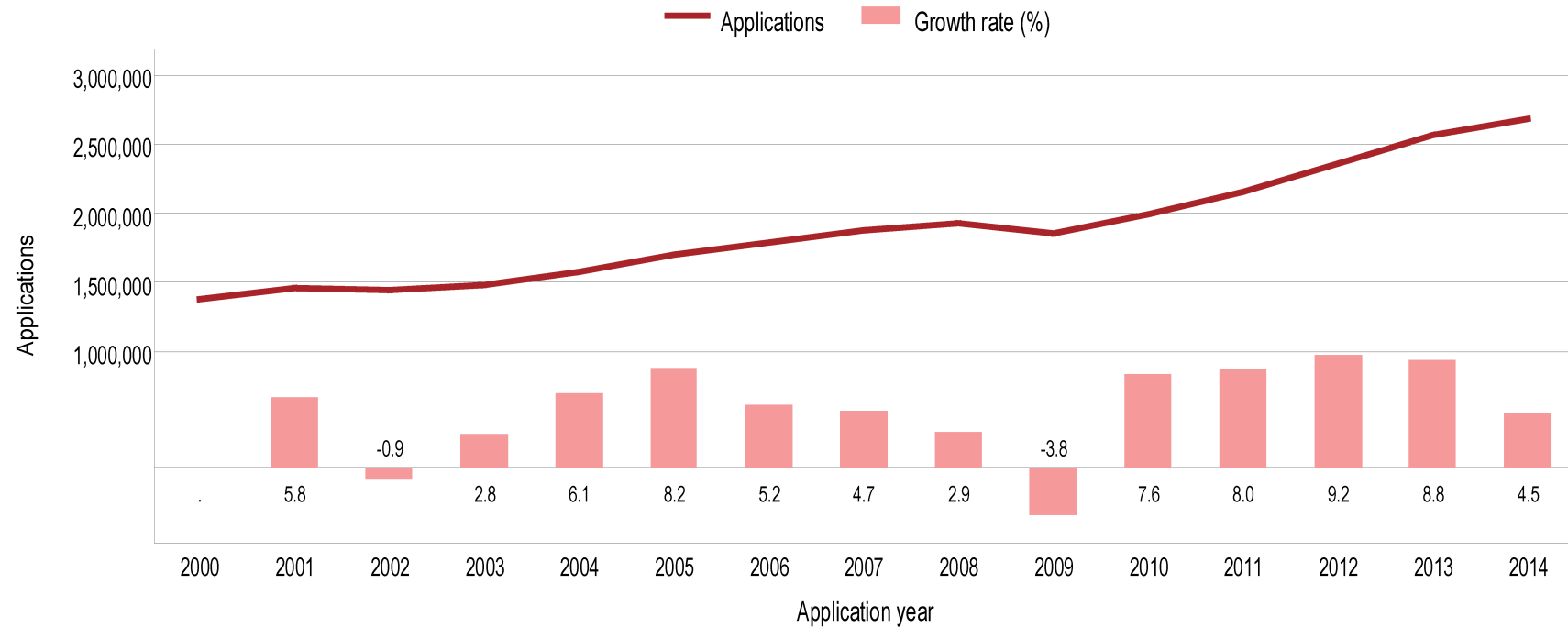




***Global IP Profiles and
Shifting Landscapes***

Patent Applications - Global

A1 Trend in patent applications worldwide



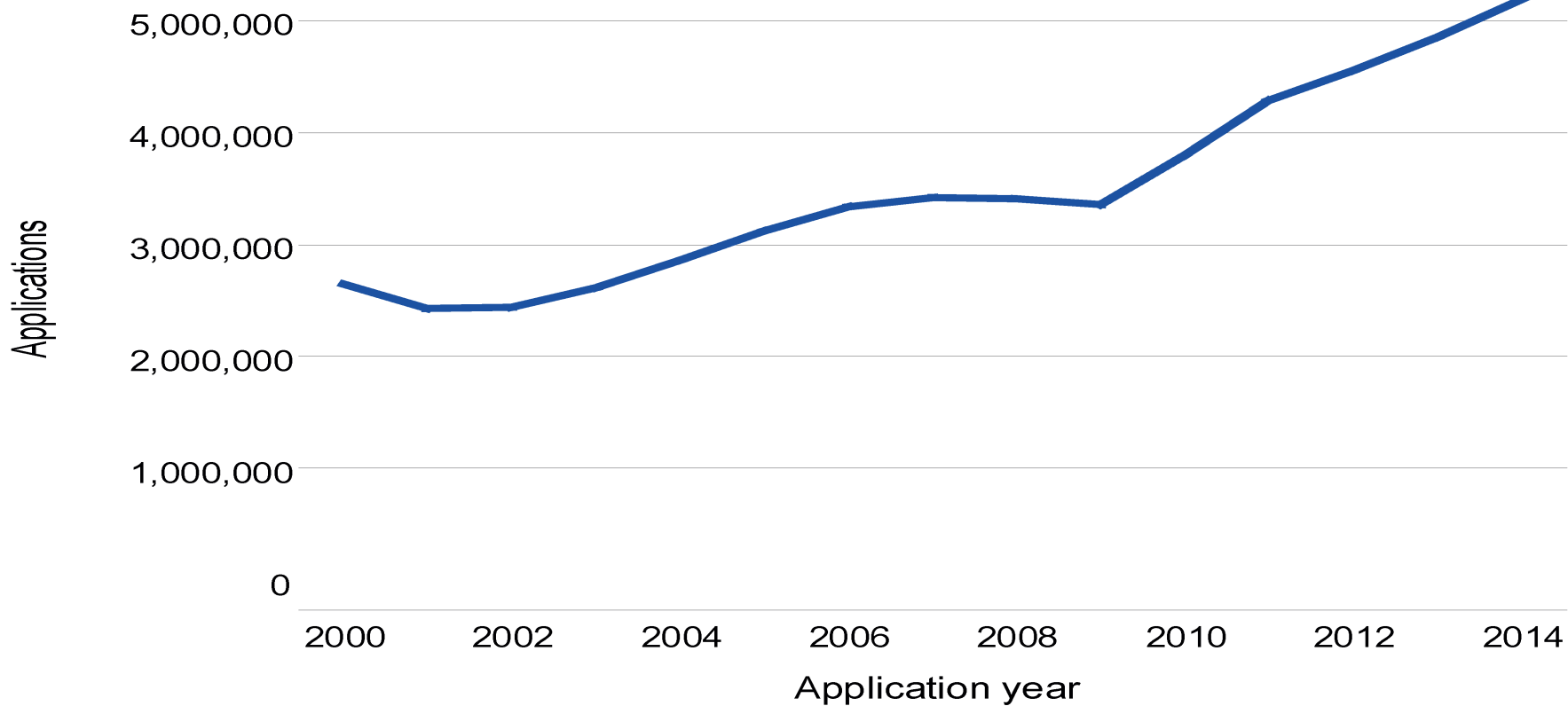
Note: WIPO estimates cover 147 patent offices and include direct applications and Patent Cooperation Treaty national phase entry data (where applicable).

Source: WIPO Statistics Database, October 2015.



Trademark Applications - Global

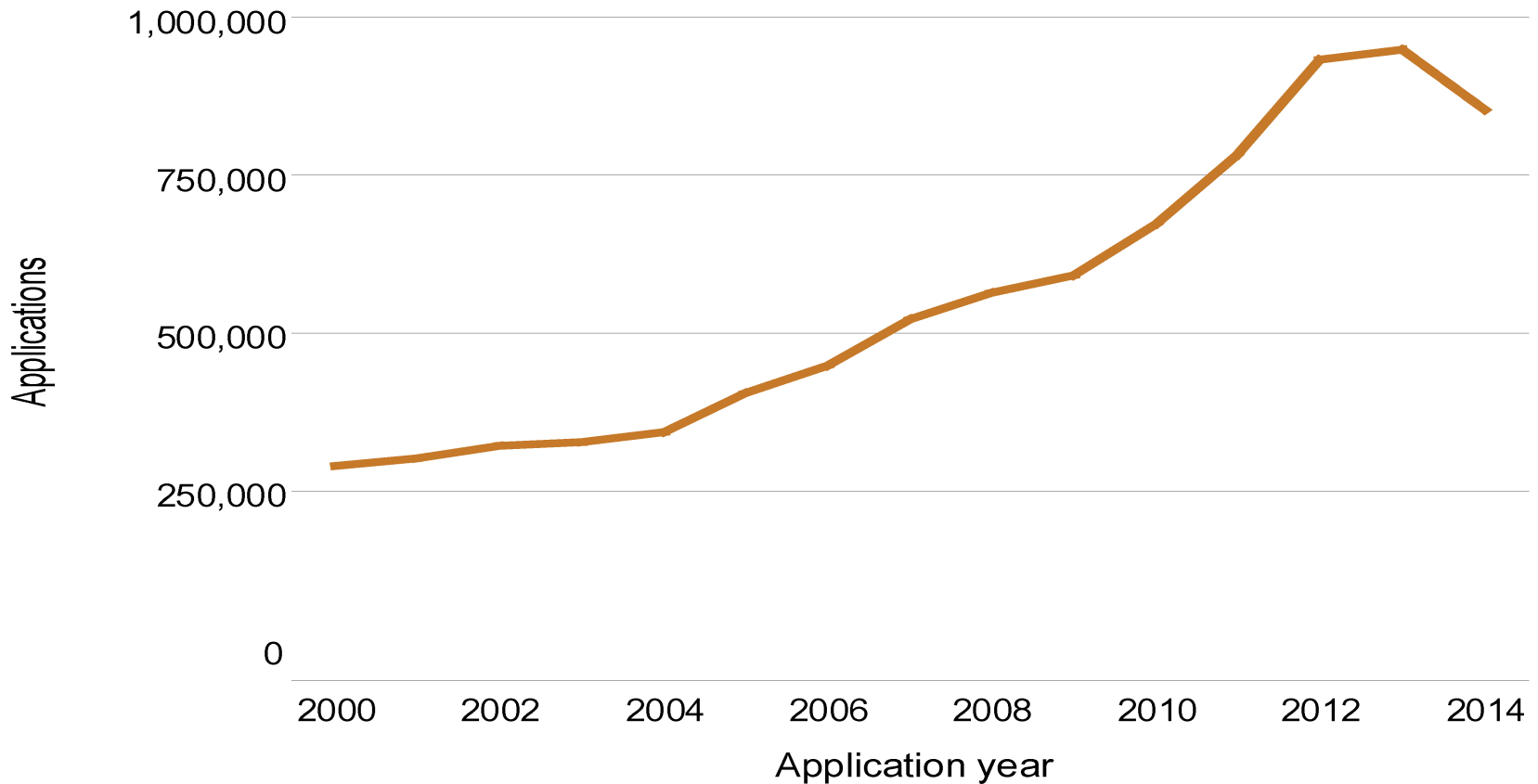
Figure 7. Trademark applications worldwide



Source: Standard figure B1.

Industrial Designs Applications - Global

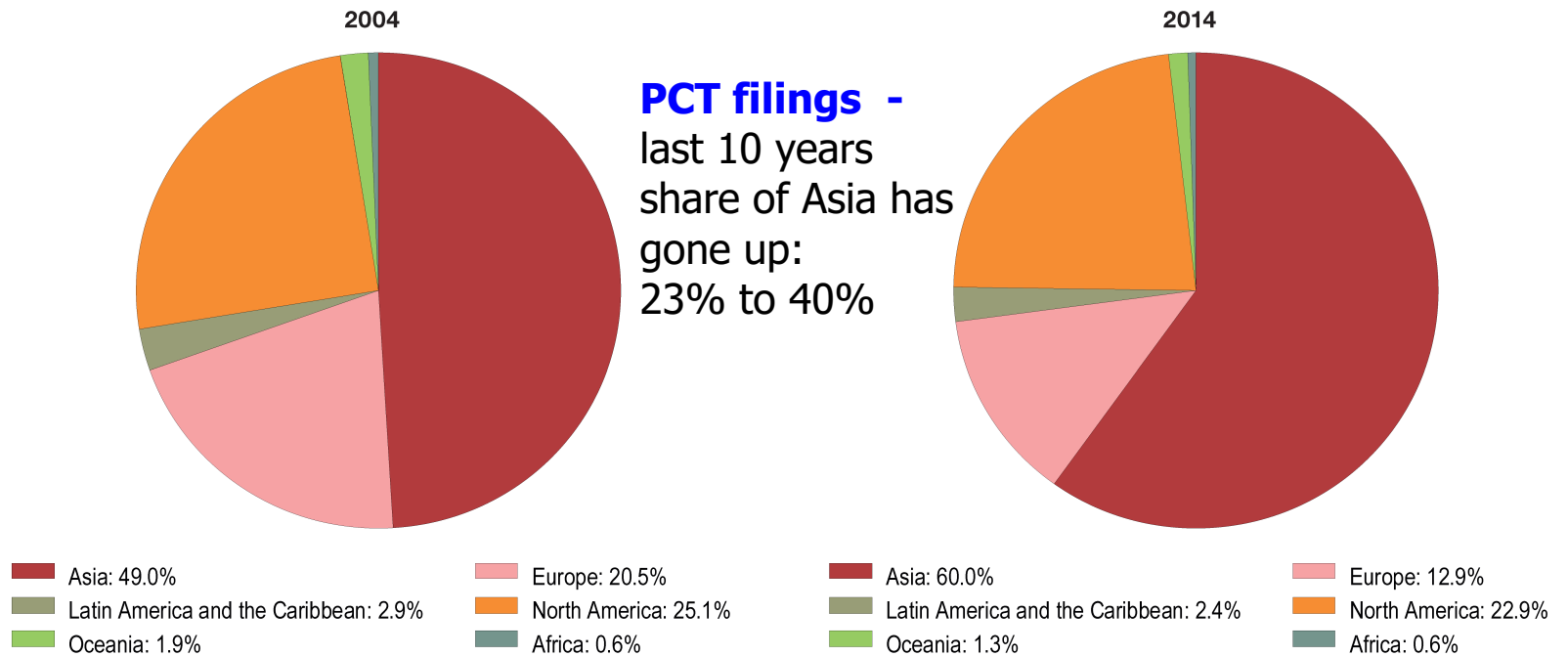
Figure 14. Industrial design applications worldwide



Source: Standard figure C1.

Recent Shifts

Figure 4. Patent applications by region



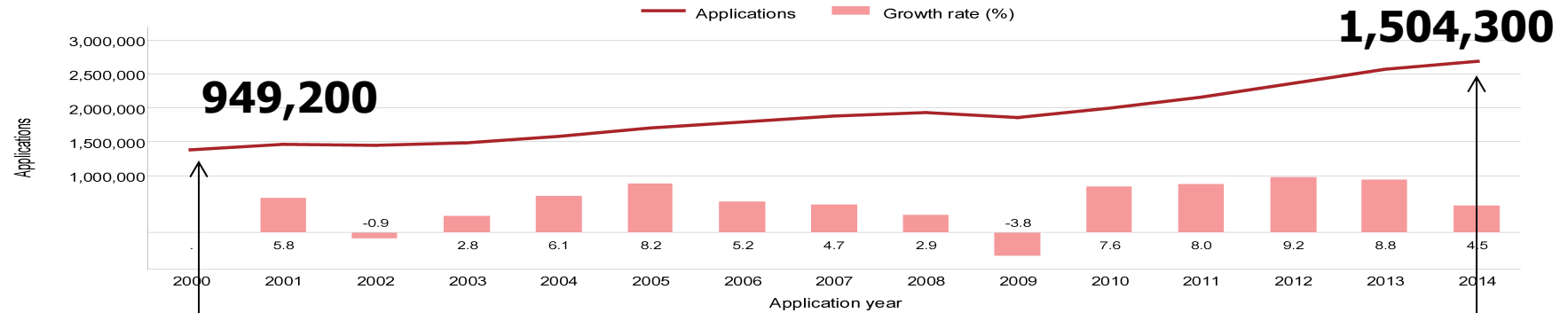
Source: Standard table A6.



Administrative Challenges

Patents – Applications and Grants

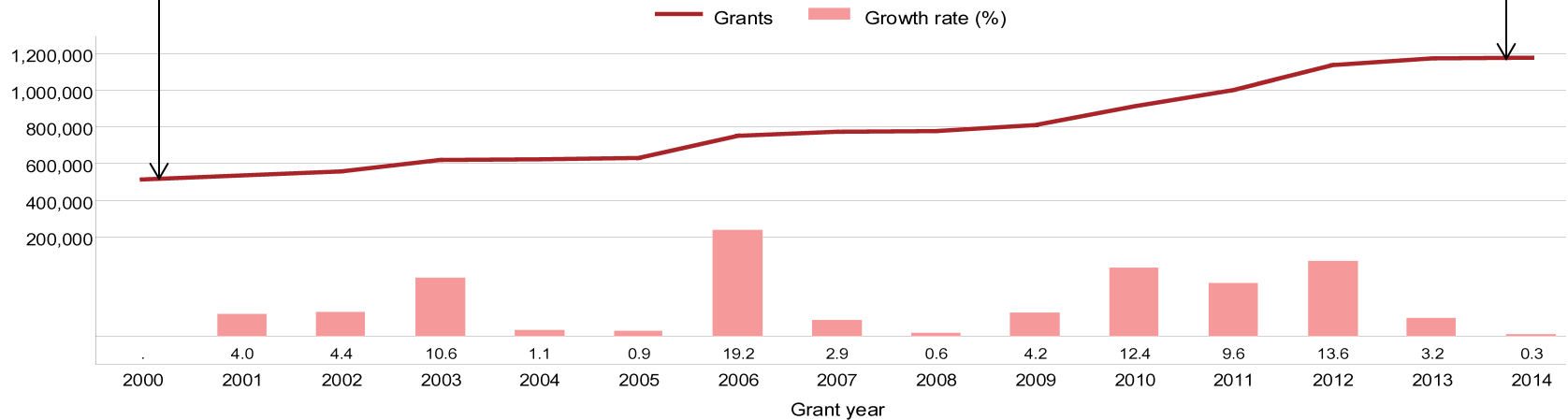
A1 Trend in patent applications worldwide



Note: WIPO estimates cover 147 patent offices and include direct applications and Patent Cooperation Treaty national phase entry data (where applicable).

Source: WIPO Statistics Database, October 2015.

Trend in patent grants worldwide



Source: WIPO estimates cover 130 patent offices and include patent grants based on direct applications and on Patent Cooperation Treaty national phase entry data (where applicable).

Source: WIPO Statistics Database, October 2015.



Backlogs - Implications

- Longer pendency time reduces the value of patents to applicants, and hence R&D motivation
- Non-grantable applications may remain unexamined, and hence gain temporary monopoly power for a longer period
- Backlogs also lead to decline in patent quality as patent offices' resources are stretched
- Uncertainty over the scope of granted patent rights may deter investment and hence slow down, or prevent, valuable innovation



Innovation Deficit



Developing Countries

- One of the measures of a country's innovative ability is the number of patent applications filed by its residents, *per million of population*
 - In 2012 - Global 245; India 8; China 396; S.Korea 2962
- PCT filings:

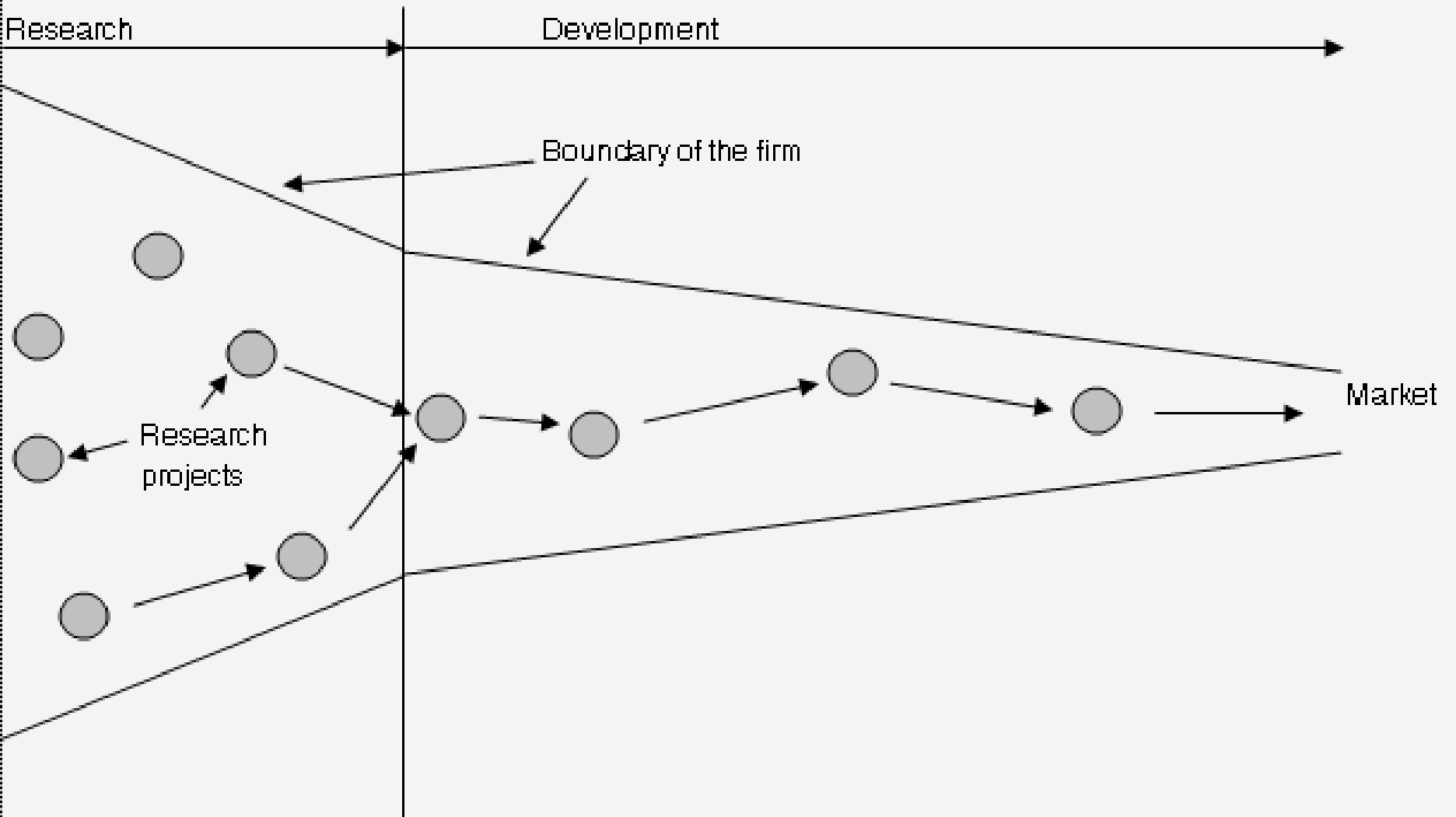
Country	2013	2002
India	882	480
China	22,942	1124
S.Korea	12,442	2552



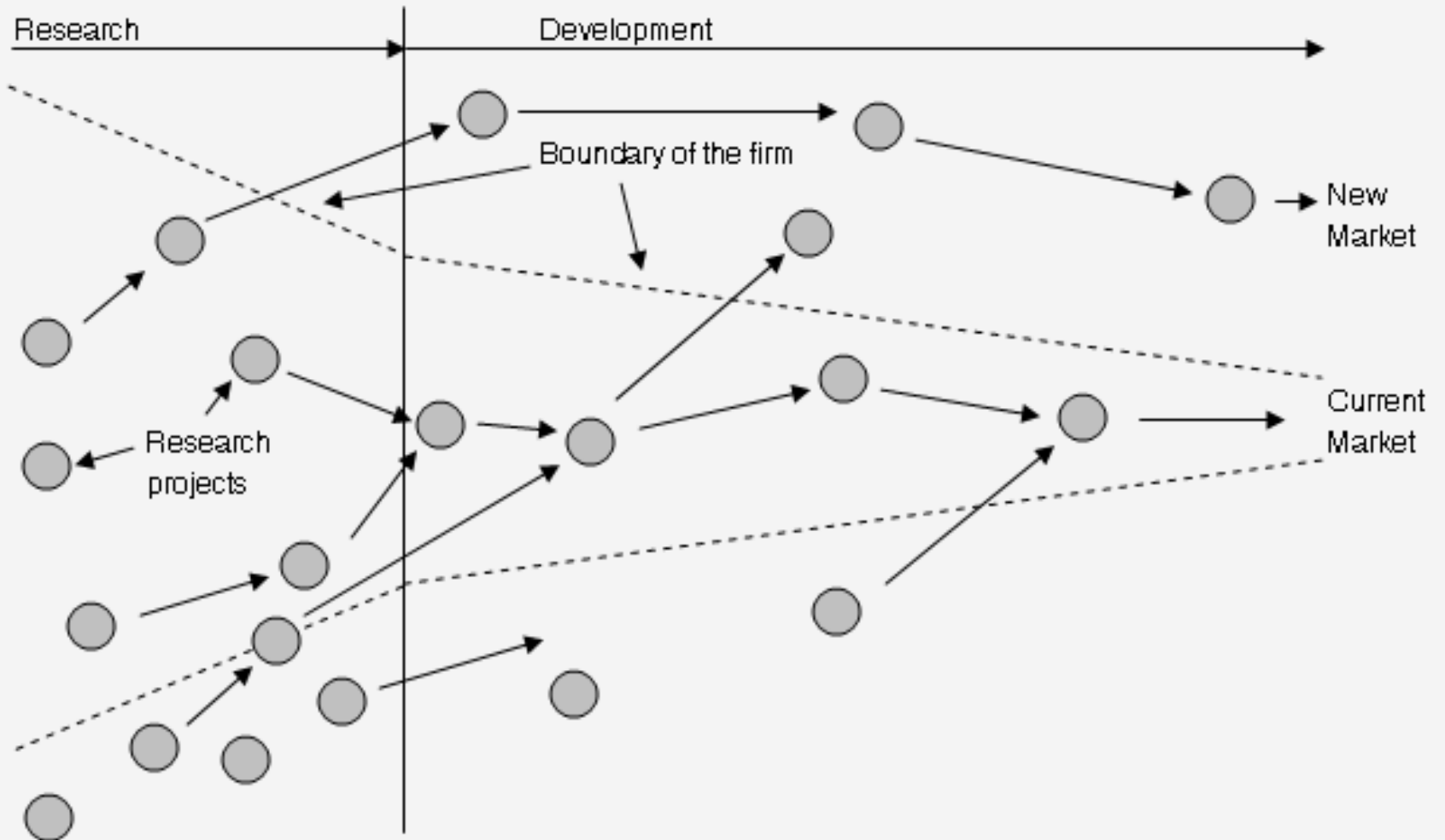
Alternative Paradigm - Open Innovation

- A combination of several factors
 - Intensification of the Knowledge Economy
 - Geographic Shifts
 - Pressure on IP systems
 - Mobility of people, products, capital
 - Internationalization of S&T
- Catalyzed businesses to be outward looking in order to sustain and further the innovation process
- Encouraged rise to the phenomenon of “**Open Innovation**” - *Henry Chesbrough*

Closed innovation



Open innovation



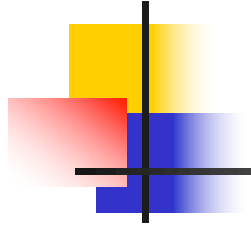
Source: Chesebrough :2003

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Some Examples

- AIDS Vaccine Discovery (Bill & Melinda Gates Foundation July 2006)
 - 600 investigators in 103 institutions across 16 countries
 - collaborators working on various aspects of AIDS vaccine, while remaining mindful of the overall goal
- Open Source Drug Discovery Project (CSIR)
 - launched to “hasten the drug discovery process”
 - contributions from over 7900 participants and 75 institutions communicating from 130 countries
 - all contributions are recognized; patents ensure quality; availability of subsequent innovations in open source; affordability through non-exclusive licenses



Thank you