Workshop for High Court Justices on IPR

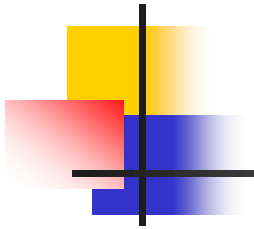
Emerging Trends in IP Regime: Indian and Global Perspective

Pushpendra Rai

National Judicial Academy, Bhopal
November 2 and 3, 2019

Road Map

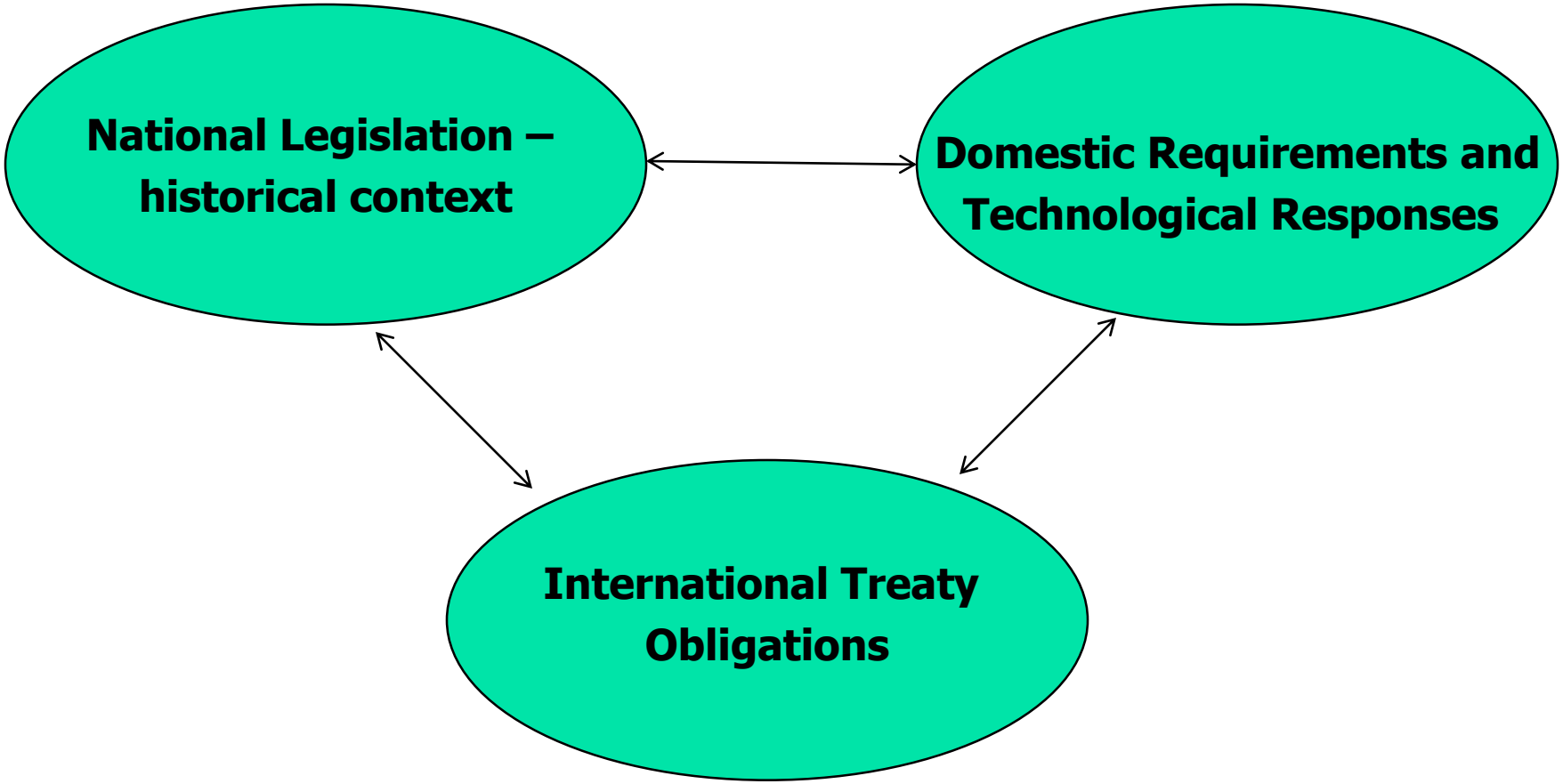
- Legislative and Treaty – with special reference to the Pharma sector
- Global IP Profiles and Challenges
- The New Frontiers



Legislative and Treaty

Pushpendra Rai

Considerations – the Triad



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

Contrary to public order or morality *Method of agri or horti frivolous*

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 c
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- 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

US Omnibus Foreign Trade and Competitiveness Act 1988

Priority Foreign Country*
Priority Watch List
Watch List

**Countries with the most onerous or egregious acts, policies and practices impacting on US goods/services*

Announced April 27, 2019

2019 Special 301 Report

★ ★ ★

OFFICE *of the* UNITED STATES TRADE REPRESENTATIVE

APRIL 2019

India

*India on the **Priority Watch List** for lack of sufficient measurable improvements to its IP framework on long-standing and new challenges that have negatively affected U.S. right holders over the past year.*

Long-standing IP challenges facing U.S. businesses:

- *insufficient **enforcement actions***
- ***copyright policies** that do not properly incentivize the creation*
- *outdated and insufficient **trade secrets legal framework***
- *application of **patentability exceptions to reject pharmaceutical patents**,*
- *unauthorized disclosure, of **undisclosed test or other data** generated to obtain marketing approval for certain agricultural chemical products.*
- ***difficult for innovators to receive and maintain patents** particularly for **pharmaceuticals***

Evergreening

- India: 72 percent of granted patents: little improvement - Office unable to guard against evergreening with 78 % qualifying as formulations*
- U.S: 74 percent of medicines associated with new patents already on the market
  - 100 best-selling drugs, 80 percent extended patent protection at least *once*, with 50 percent winning added protection *more* than once**

**Accessibsa: Innovation & Access to Medicines in India, Brazil & South Africa after reviewing 2,293 patents granted between 2009 and 2016, and analyzing 249 secondary patents granted and subject to detailed scrutiny*)

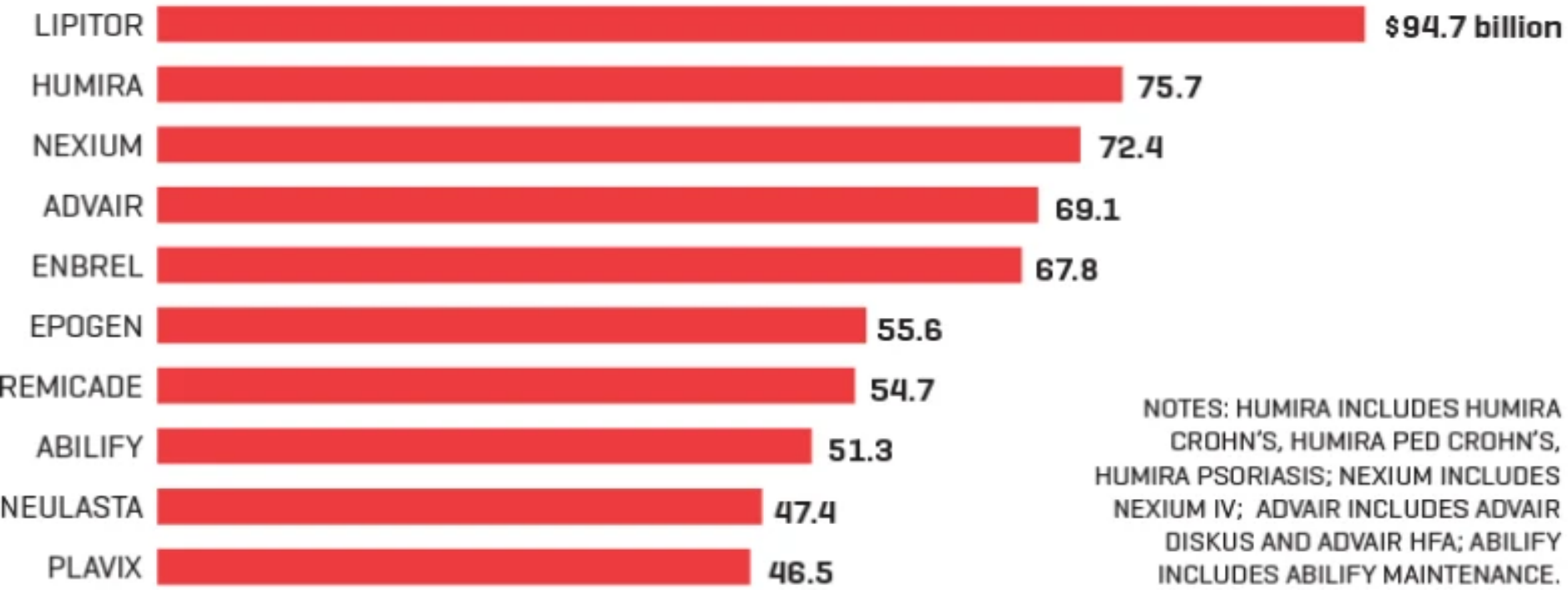
***Pharma is getting away with lots of patent 'evergreening' in India*

Ed Silverman @Pharmalot October 23, 2018

*

U.S. BESTSELLING DRUGS

CUMULATIVE SALES, 1992–2017, EXCLUDING OVER-THE-COUNTER DRUGS



NOTES: HUMIRA INCLUDES HUMIRA CROHN'S, HUMIRA PED CROHN'S, HUMIRA PSORIASIS; NEXIUM INCLUDES NEXIUM IV; ADVAIR INCLUDES ADVAIR DISKUS AND ADVAIR HFA; ABILIFY INCLUDES ABILIFY MAINTENANCE.

And that's precisely what AbbVie
U.S. Patent and Trademark Office
patents on the ways in which the
various formulations of the drug
manufacturing processes; and ab
customers use to take the medici

USPTO) has granted the company more than 30
rug is administered; more than 25 patents on
ore than 50 patents related to Humira's
t 20 patents on the delivery devices that

A European health insurer sues AstraZeneca over a patent maneuver

By ED SILVERMAN @Pharmalot / SEPTEMBER 21, 2018

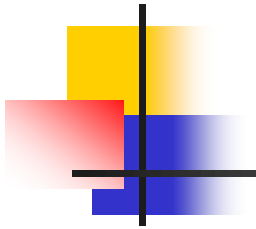
TOBY TALBOT/AP

In an unusual move, a Dutch health insurer has filed a lawsuit accusing AstraZeneca (AZN) of creating an unfair monopoly for its Seroquel antipsychotic with a series of unwarranted patents that raised the cost of the medicine.

In a statement posted earlier this week on its web site, the insurance company Menzi said the drug maker "abused its position" in the marketplace and consequently forced the insurer to pay more for Seroquel because lower-cost generic alternatives were precluded from becoming available. The insurer claims more than $4.7 million

The Multilateral Push

TRIPS (1994) truly a watershed in terms of Treaty obligations determining National law

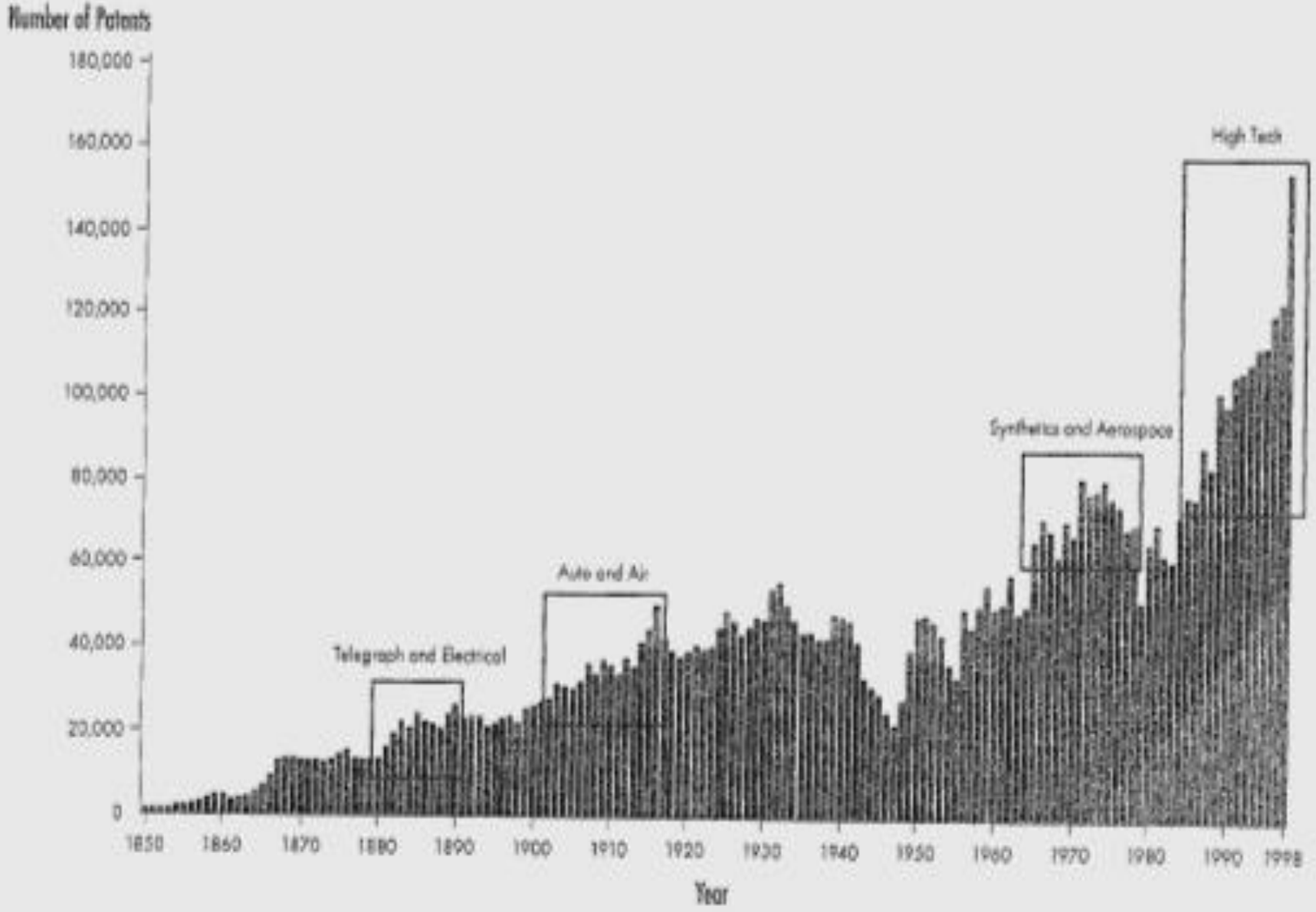


Origins….

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…

FIGURE 1-2 U.S. PATENTS ISSUED, 1850–1998

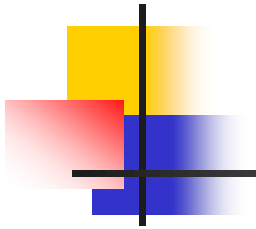


TRIPS - 1994

- 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…

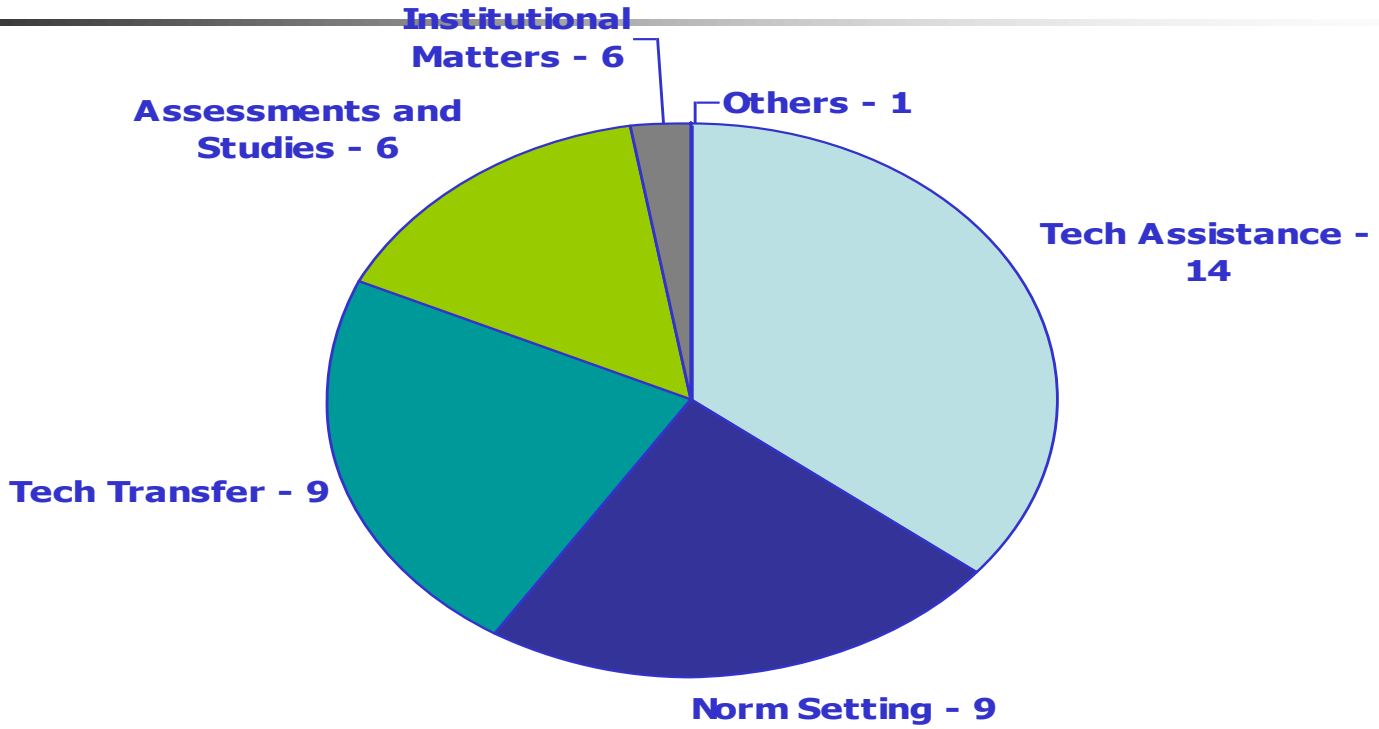
Concerns Expressed in Various Fora

- Doha Ministerial Declaration on TRIPS and Public Health - 2001 (http://docsonline.wto.org/DDFDocuments/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)
- 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/)

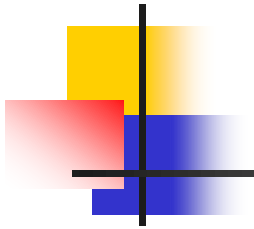
WIPO Development Agenda

- 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



As development and public interest dimensions of IP assume greater importance, ***increasing references to courts*** *to interpret discretionary space in IP Treaties and Statutes (flexibilities/exceptions/limitations)*



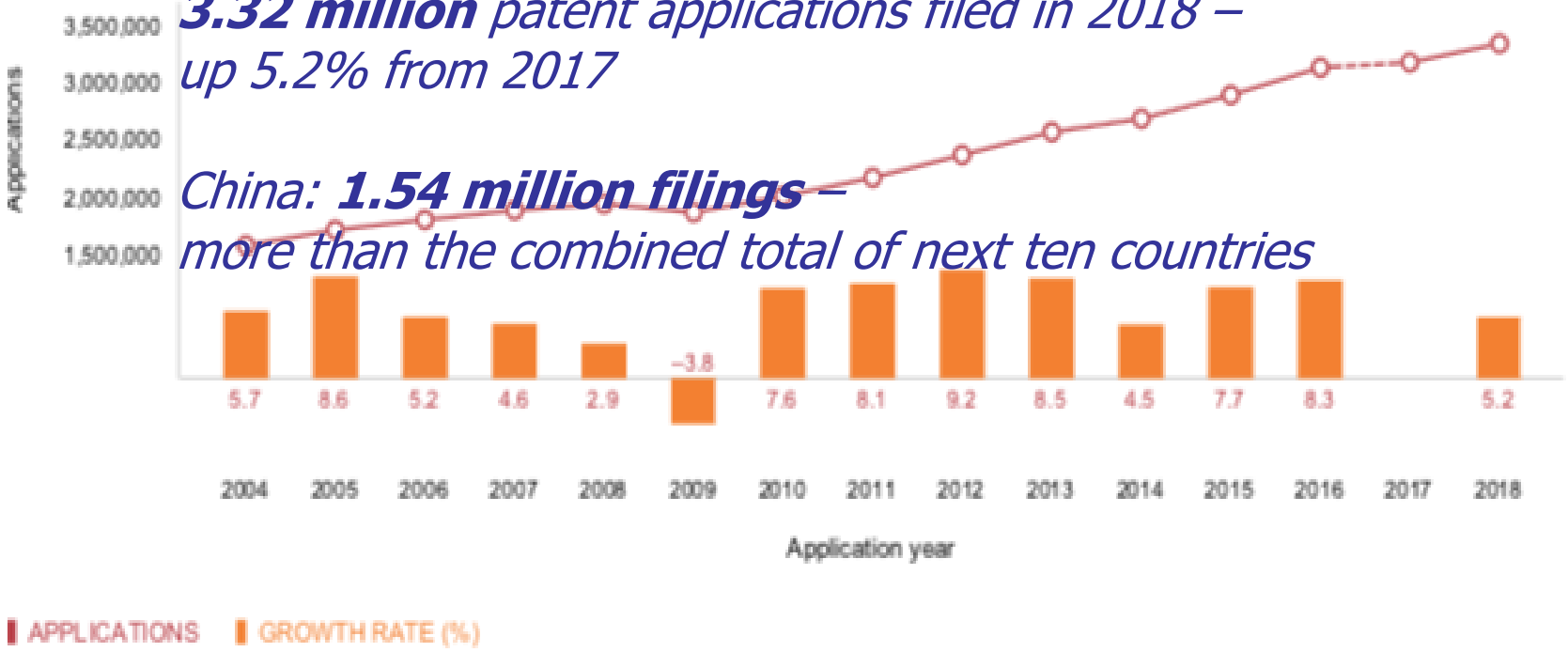
Global IP Profiles and Challenges

Patent Applications - Global

A1. Trend in patent applications worldwide, 2004–2018

3.32 million *patent applications filed in 2018 – up 5.2% from 2017*

China: ***1.54 million filings*** *– more than the combined total of next ten countries*



Trademark Applications – Global

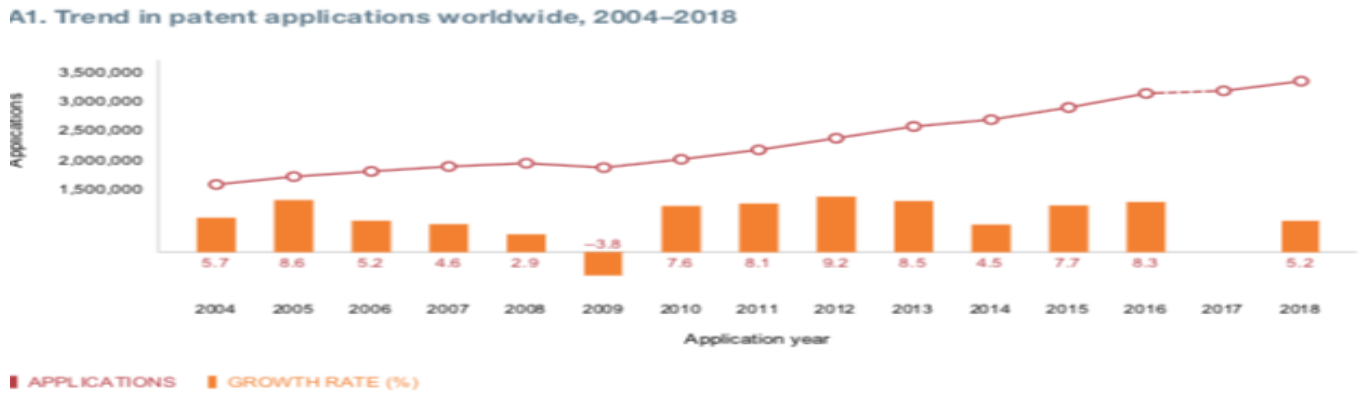
B2. Trend in trademark application class counts worldwide, 2004–2018

14.32 million *applications filed in 2018 – 16% more than 2017*

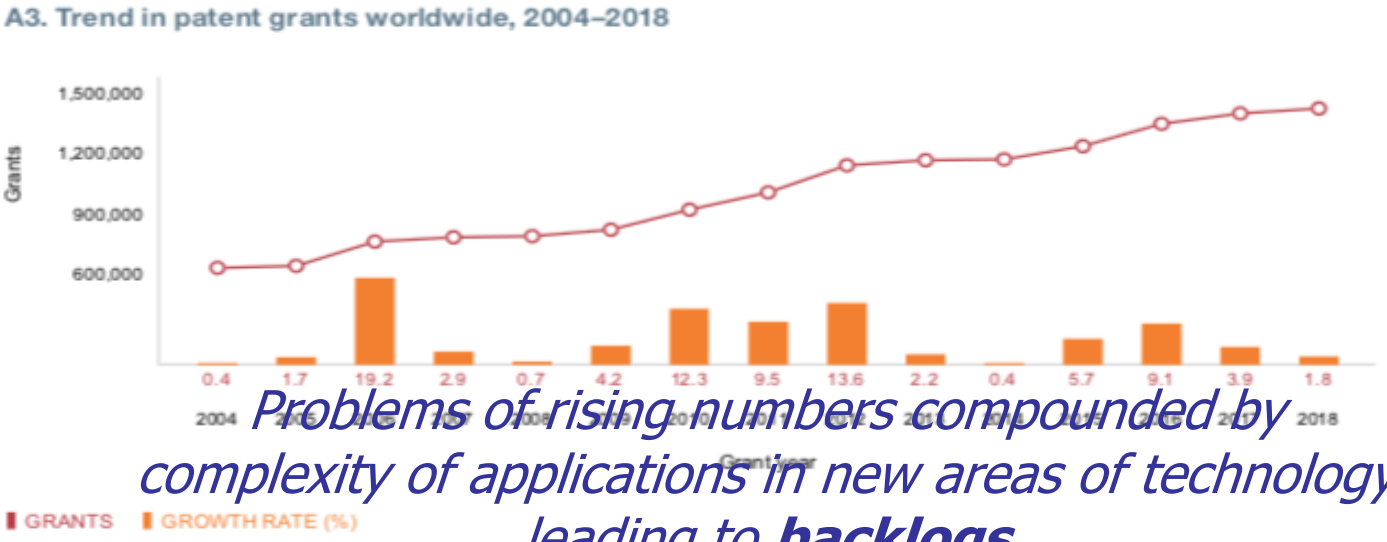
7.37 million *filed in China which is* ***double*** *the total number filed in US, India, Germany, Japan and UK*

Patents – Applications and Grants

1,893,500



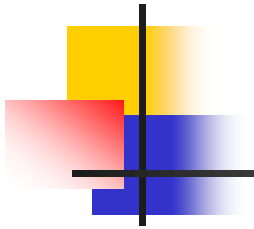
949,200



*Problems of rising numbers compounded by complexity of applications in new areas of technology leading to **backlogs***

Backlogs - Implications

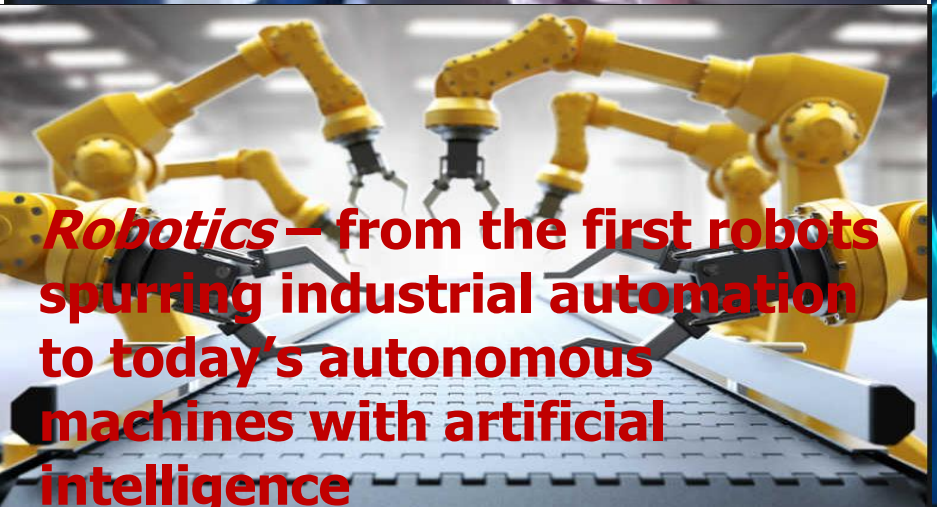
- Longer pendency time reduces the value of patents to applicants, and hence R&D motivation
- Non-grantable applications remain unexamined, gaining temporary monopoly power for longer period
- Backlogs also lead to decline in patent quality as patent offices' resources are stretched
- Poor quality patents trigger *unnecessary litigation placing greater* ***burden on courts***



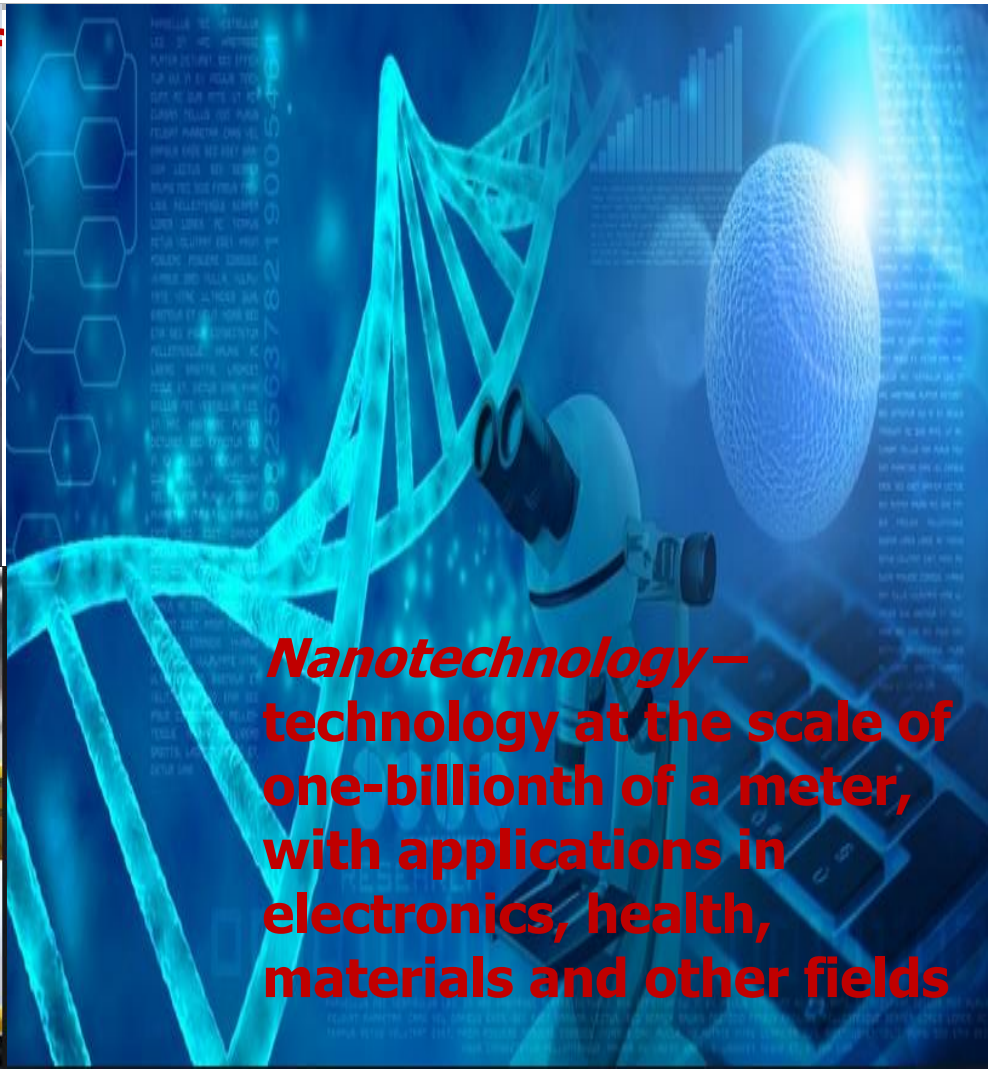
The New Frontiers

Three Cutting–edge Areas

3D printing **– the creation of 3D objects through successive layering of material, aided by digital technology**



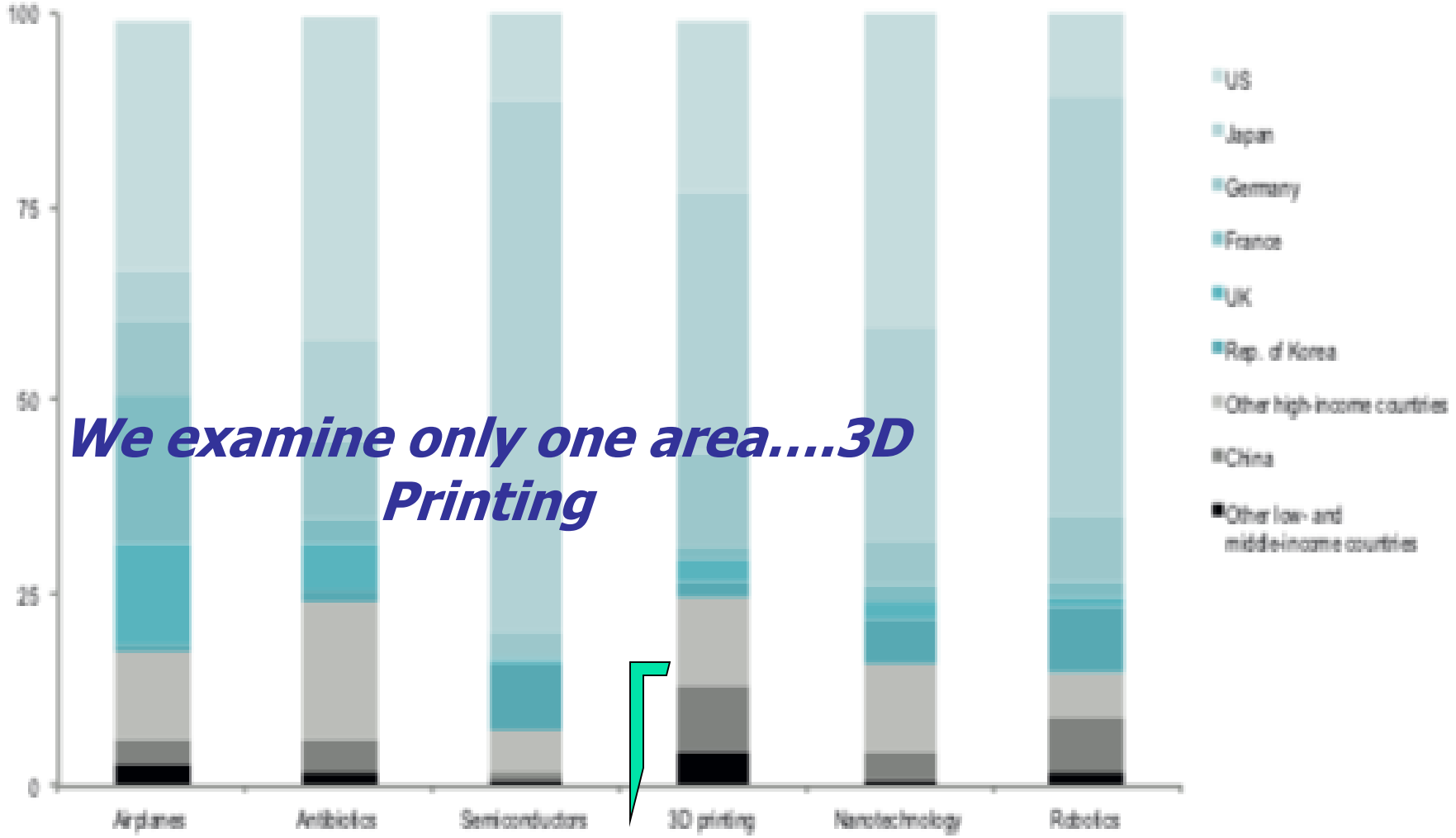
Robotics **– from the first robots spurring industrial automation to today's autonomous machines with artificial intelligence**



Nanotechnology **– technology at the scale of one-billionth of a meter, with applications in electronics, health, materials and other fields**

Figure 4: Patenting activity has been geographically concentrated

Share of first patent filings in world total



We examine only one area….3D Printing

Notes: This figure is a summary of figures 2.3, 2.5, 2.8, 3.2, 3.7 and 3.12, covering the same time periods as the ones shown in those figures. Note that the bars do not exactly sum up to 100 percent, reflecting unknown origins in less than 1 percent of first patent filings.

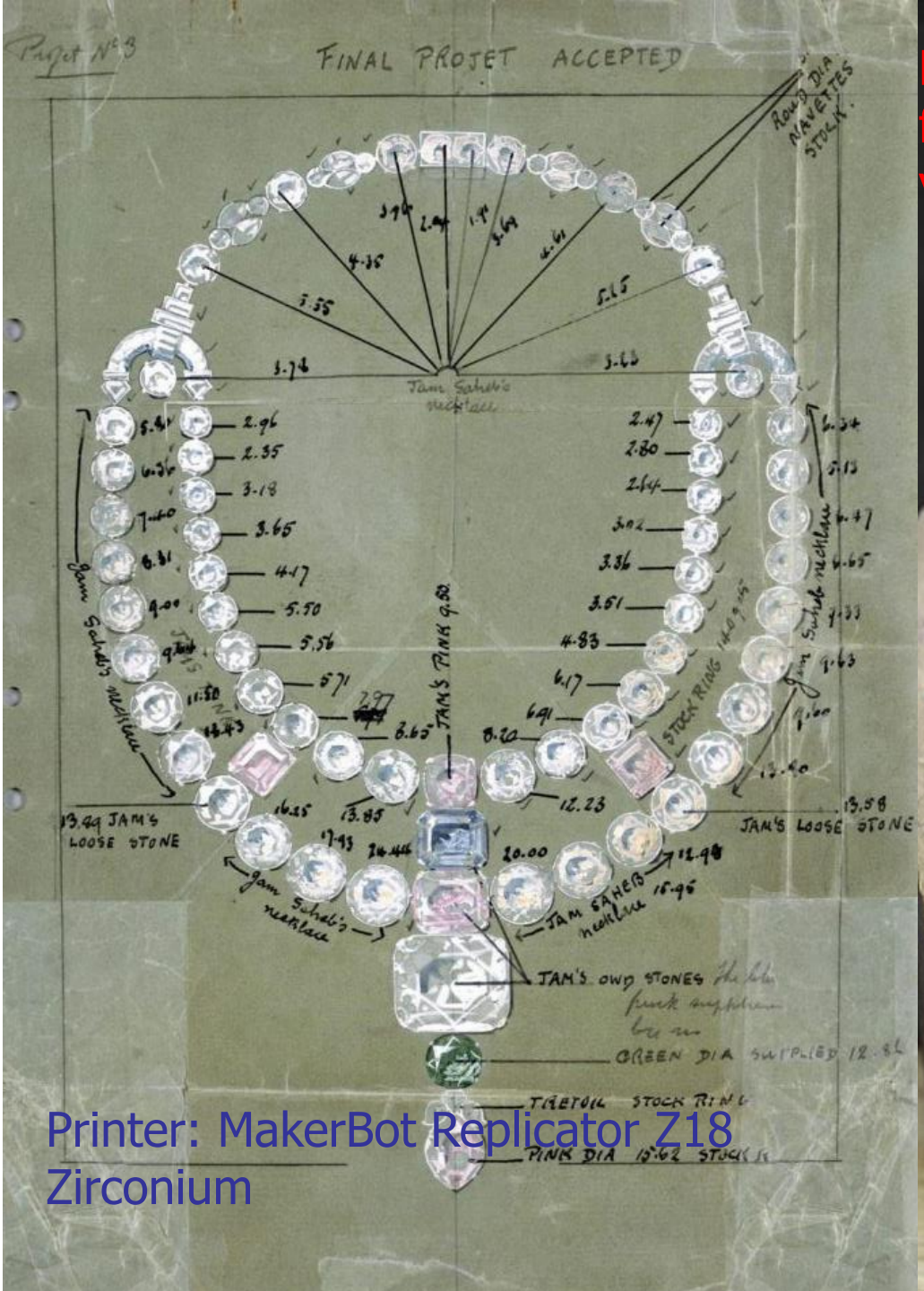
Source: WIPO based on PATSTAT database (see technical notes).

3D Printing

Generate *revenues* of USD 20 billion by 2020
Financial impact of the technology estimated between $230 and 550 bn annually by 2025

- *Additive manufacturing* – Allows production of small number of products at low cost
- **Cost savings** to produce spare parts for maintenance, repair and operation in the global aerospace market could amount to **$3.4 billion**
- Important role not only in rapid prototyping, but also in the production of product components and finished products (sockets for hip replacement, hearing aid shells)
- Will lead to decentralized manufacturing..possibilities


Cartier



Printer: MakerBot Replicator Z18
Zirconium

Lockheed Martin 3D print tech used for metal pieces for military vehicles, satellites

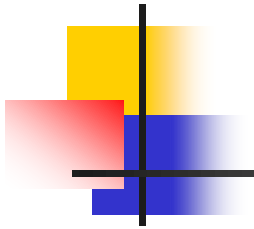
NOW:
Applied for patent for 3D printer to print **synthetic diamonds**!

So, Issues for the IP World

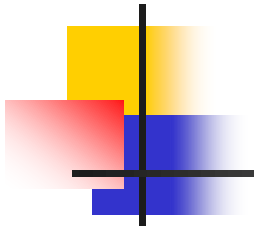
- **Patent** rights in 3D printing components, processes and raw printing material
- **Trade Secret** protection of 3D manufacturing processes
- **Copyright** protection of controlling software programs
- **Design** protection of 3D object designs
- **Trademark** protection of the 3D printer product

Challenges

- Enforcement: Anyone with access to 3D printer can print object with digital representations of that object
- Exact replicas that may be protected under industrial **design** right or **copyright** easily reproducible and sold without the right holder's permission
- ⟶ large-scale infringement of existing IP rights by 3D printing users
- *As issues surrounding these developments are uncertain,* ***legal challenges*** *to increase*



Therefore Progressive Development of IP law imperative to respond to ever evolving challenges….



Thank you