

# DNA-RELATED PATENTING IN INDIA: SOME NUMBERS, SOME SPECULATIONS

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# **POST-TRIPS PATENT LAW IN INDIA**

# TRIPS Mandated Changes in India

- Minimum patent terms of 20 years
- No field discrimination: product patent protection in pharma
  - Applies to applications filed post-1995
- Generally, an “upward” harmonization in patent law

# TRIPS Flexibilities

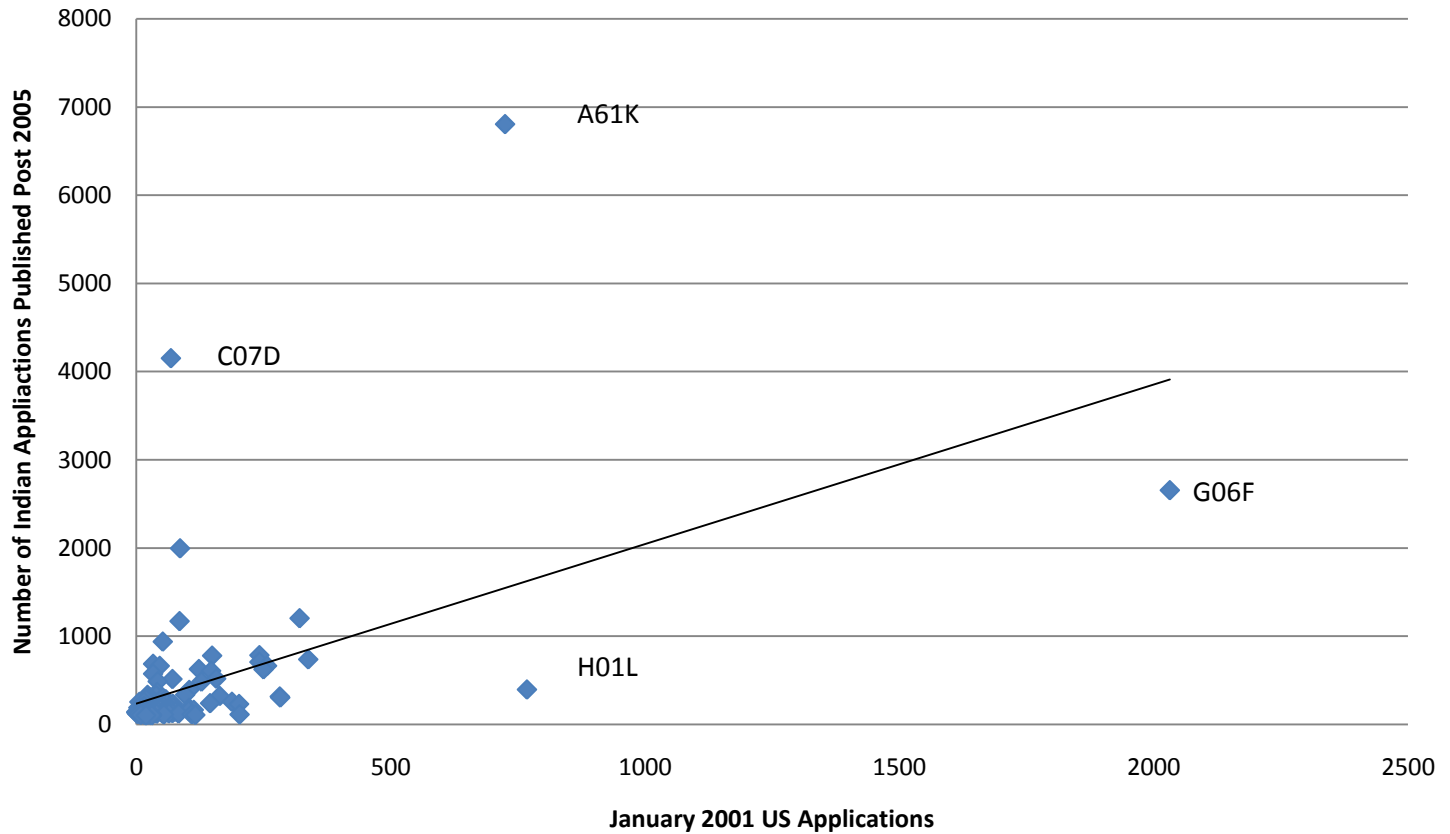
- Definition of inventive step, utility
- Research exemption
- Section 3 excludes from patentability (among other things)
  - Scientific principles and abstract theories; products of nature (3c)
  - New forms of old substances w/o increase efficacy (3d)
  - Any process for the medicinal, surgical, curative, prophylactic diagnostic treatment or other treatment of human beings ... (3i)
    - But these terms will ultimately be defined via the courts
    - *De jure* versus *de facto* patent standards
    - International political economy of TRIPS implementation

# **INDIAN PATENT ACTIVITY POST TRIPS: AN OVERVIEW**

# Indian patent applications: Top Ten IPCs by Volume

IPC	NAME	N
A61K	PREPARATIONS FOR MEDICAL, DENTAL, OR TOILET PURPOSES	6804
C07D	HETEROCYCLIC COMPOUNDS	4151
G06F	ELECTRIC DIGITAL DATA PROCESSING	2655
C07C	ACYCLIC OR CARBOCYCLIC COMPOUNDS	1996
H04L	TRANSMISSION OF DIGITAL INFORMATION, e.g. TELEGRAPHIC COMMUNICATION	1204
C12N	MICRO-ORGANISMS OR ENZYMES; COMPOSITIONS THEREOF	1171
A01N	PRESERVATION OF BODIES OF HUMANS OR ANIMALS OR PLANTS OR PARTS THEREOF; BIOCIDES	939
H04B	TRANSMISSION	785
H04Q	SELECTING	780
H04N	PICTORIAL COMMUNICATION, e.g. TELEVISION	738

# Indian vs. US Applications by IPC

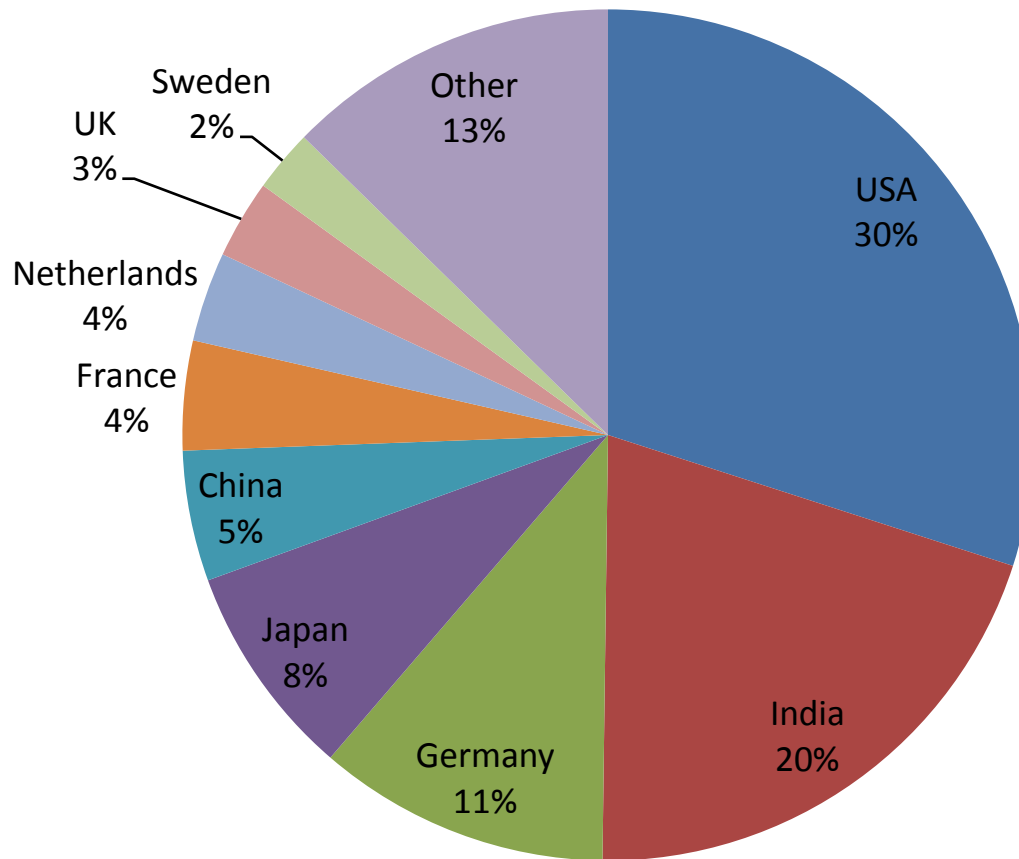


# Indian Patent Applications: Top 20 Applicants by Volume

<b>Standardized Assignee Name</b>	<b>Number of Apps</b>
Council of Scientific and Industrial Research	1,278
Hindustan Lever Ltd.	940
Bayer AG (BAYZY)	816
Koninklijke Philips Electronics N.V. (PHG)	765
Pfizer Inc. (PFE)	759
Honda Motor Company Ltd. (HMC)	751
QUALCOMM Inc. (QCOM)	727
Novartis Inc. (NVS)	704
GlaxoSmithKline plc (GSK)	695
Microsoft Corp. (MSFT)	657
AstraZeneca PLC (AZN)	600
Sanofi-Aventis	595
Samsung Electronics Company Ltd. (SEC)	560
BASF AG (BF)	527
Johnson and Johnson (JNJ)	465
Merck and Company Inc. (MRK)	376
LM Ericsson Telephone Co. (LMEB)	374
Roche Holding AG (RHHVF)	349
Matsushita Electric Industrial Co. Ltd. (MC)	342
E.I. du Pont de Nemours and Co. (DD)	338



# Distribution of Indian patent applications by country



# **DNA PATENTING IN INDIA**

# Method One: Rough IPC-Based Figures

- Empirical difficulty: cannot search claims in India
- Accordingly, used Verbeure et al. (2006) list of IPCs corresponding to DNA patents:
  - “ a group of IPC codes has been selected encompassing the various IPC codes that have been given by the patent offices to the DNA patents that we aim to retain by our search” (*European Journal of Human Genetics* **14**: 26-33).
- This will be overinclusive
  - Verbeure et al. also narrow by claims

# Method One: Rough IPC-Based Figures

- Of the ~60,000 Indian patent applications filed since 1995, 2246 or about 4 percent are in DNA-related IPCs
- The top 25 patenters in these classes account for one-third of all patents in these classes
- Who are they?

# Method One: Rough IPC Based Figures

Assignee Name	Record Count	% of 2246
NOVO NORDISK AS	70	3.12%
NOVO-NORDISK AS	54	2.40%
AVENTIS PHARMA DEUT GMBH	39	1.74%
COUNCIL SCI & IND RES INDIA	37	1.65%
HOFFMANN LA ROCHE & CO AG F	37	1.65%
NOVOZYMES AS	37	1.65%
LIFESCAN INC	26	1.16%
LILLY & CO ELI	25	1.11%
SANOFI-AVENTIS DEUT GMBH	23	1.02%
WYETH	23	1.02%
CORIXA CORP	22	0.98%
NOVARTIS AG	22	0.98%
WYETH CORP	22	0.98%
DSM IP ASSETS BV	21	0.94%
JOHNSON & JOHNSON	21	0.94%
HOECHST AG	20	0.89%
SMITHKLINE BEECHAM BIOLOGICALS	20	0.89%
UNIV CALIFORNIA	20	0.89%
ZYMOGENETICS INC	20	0.89%
AVENTIS PHARMA SA	19	0.85%
GLAXOSMITHKLINE BIOLOGICALS SA	18	0.80%
MONSANTO TECHNOLOGY LLC	18	0.80%
NOVARTIS-ERFINDUNGEN VERW GES MBH	17	0.76%
AVENTIS PHARM INC	16	0.71%
BASF AG	16	0.71%

# Method Two: Using the DDPD

- Identified all DNA patents issued in the U.S. in 2000 and 2005, using the search algorithm developed for the Duke *DNA Patent Database*
  - <http://dnapatents.georgetown.edu>
- Collected priority application data for all resulting patents
- Retrieved 6551 DNA patents:
  - 3,820 in issue year 2000
  - 2,731 in issue year 2005
- Mapped priority data from these patents to Indian patents/applications in [india.bigpatents.org](http://india.bigpatents.org)
- Note: advantages/disadvantages of this approach

# DNA patenting in India

**indianpatentorapp?**

<b>year</b>	no	yes	Total
2000	3,779	41	3,820
	98.93	1.07	100.00
2005	2,662	69	2,731
	97.47	2.53	100.00
Total	6,441	110	6,551
	98.32	1.68	100.00

# DNA patenting in India

- The 110 U.S. DNA related patents with corresponding Indian applications map to 100 distinct Indian patents/applications
- Almost all of these are applications:

status	Freq.	Percent	Cum.
granted	1	1.00	1.00
pending	42	42.00	43.00
pending PCT	57	57.00	100.00
Total	100	100.00	

- Unclear which of these are on disease-gene associations or genetic tests
  - It would be easy for an “expert” to make a quick determination, given small N



# Who is filing DNA patents in India?

## Analysis by assignee country

Assignee/Applicant Country	Freq.	Percent	Cum.
US	53	48.18	48.18
DK	12	10.91	59.09
DE	10	9.09	68.18
GB	6	5.45	73.64
JP	6	5.45	79.09
CH	5	4.55	83.64
FR	3	2.73	86.36
NL	3	2.73	89.09
AU	2	1.82	90.91
BB	2	1.82	92.73
BM	2	1.82	94.55
CN	2	1.82	96.36
BR	1	0.91	97.27
IN	1	0.91	98.18
NO	1	0.91	99.09
SG	1	0.91	100.00
Total	110	100.00	

# Who is filing DNA patents in India?

## Assignees with >1 applications

Assignee/Applicant Name	Freq.	Percent	Cum.
Novo Nordisk A/S	8	7.27	7.27
Corixa Corporation	4	3.64	10.91
Monsanto Technology LLC	3	2.73	13.64
Novartis AG	3	2.73	16.36
Ajinomoto Co., Inc.	2	1.82	18.18
BASF Aktiengesellschaft	2	1.82	20.00
Calgene LLC	2	1.82	21.82
Hoechst Aktiengesellschaft	2	1.82	23.64
Ingeneus Corporation	2	1.82	25.45
Neuralab Limited	2	1.82	27.27
Novartis Finance Corporation	2	1.82	29.09
Novo Nordisk Biotech, Inc.	2	1.82	30.91
Source Precision Medicine, Inc.	2	1.82	32.73
The Regents of the University of Califo	2	1.82	34.55
ZymoGenetics, Inc.	2	1.82	36.36

# Academic versus non-academic assignees on DNA patents, 2005

univ	indianpatentorapp?		Total
	0	1	
0	2,118	61	2,179
	97.20	2.80	100.00
	79.56	88.41	79.79
1	544	8	552
	98.55	1.45	100.00
	20.44	11.59	20.21
Total	2,662	69	2,731
	97.47	2.53	100.00
	100.00	100.00	100.00

# **PATENTING BY INDIAN PUBLIC SECTOR INSTITUTIONS**

# Academic patenting in India

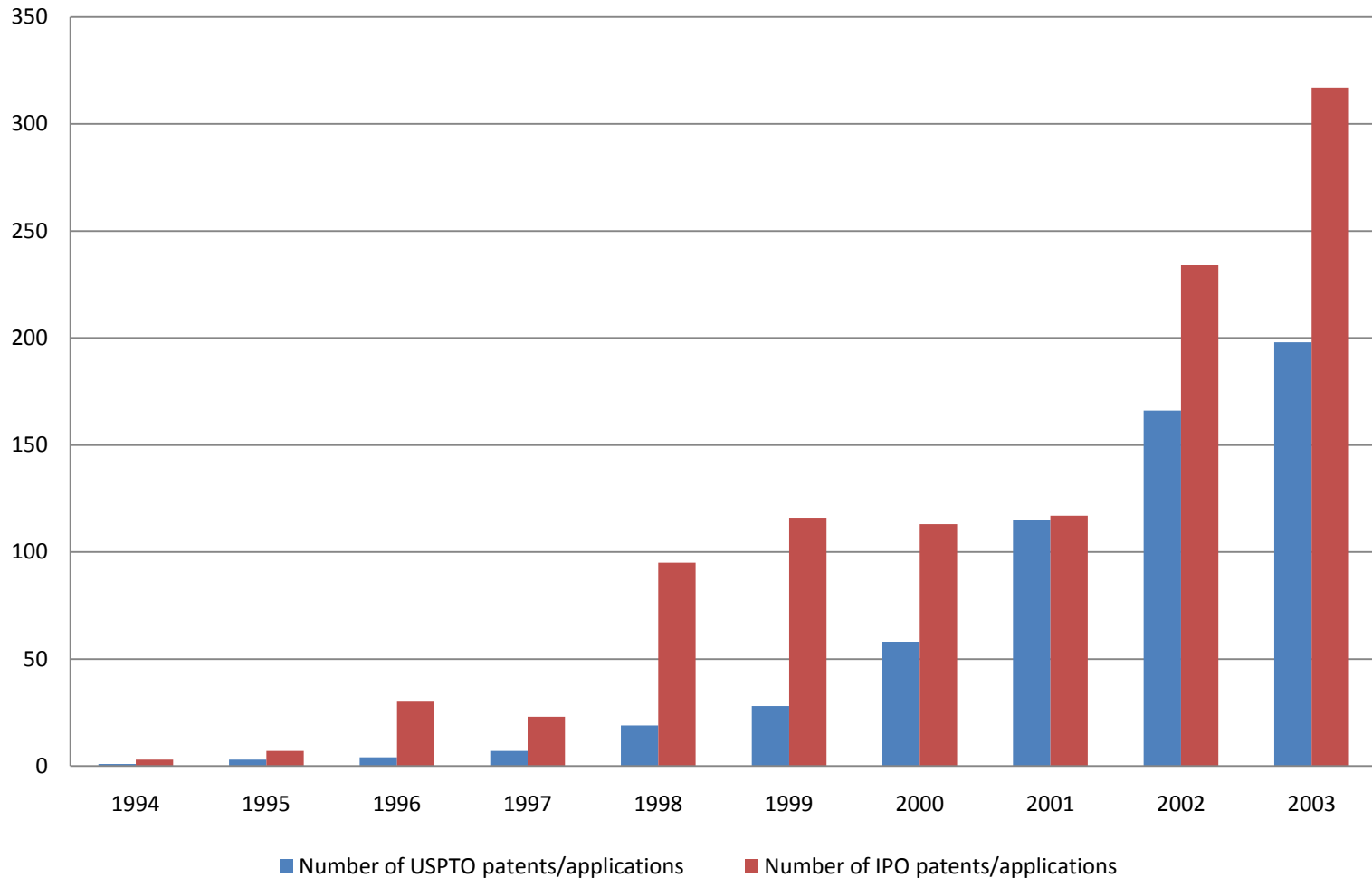
- While TRIPS is silent on this, there has been a dramatic growth of interest in academic patenting/licensing/entrepreneurship in India
- Some of the impetus coming from specific institutions
- But Bayh-Dole type legislation on the way
- To the extent that Indian academic institutions important producers of DNA related inventions—including genetic tests—this is an important development to watch

# Top 20 Indian “Universities” As Ranked by SCI Publication Volume (2004-6)

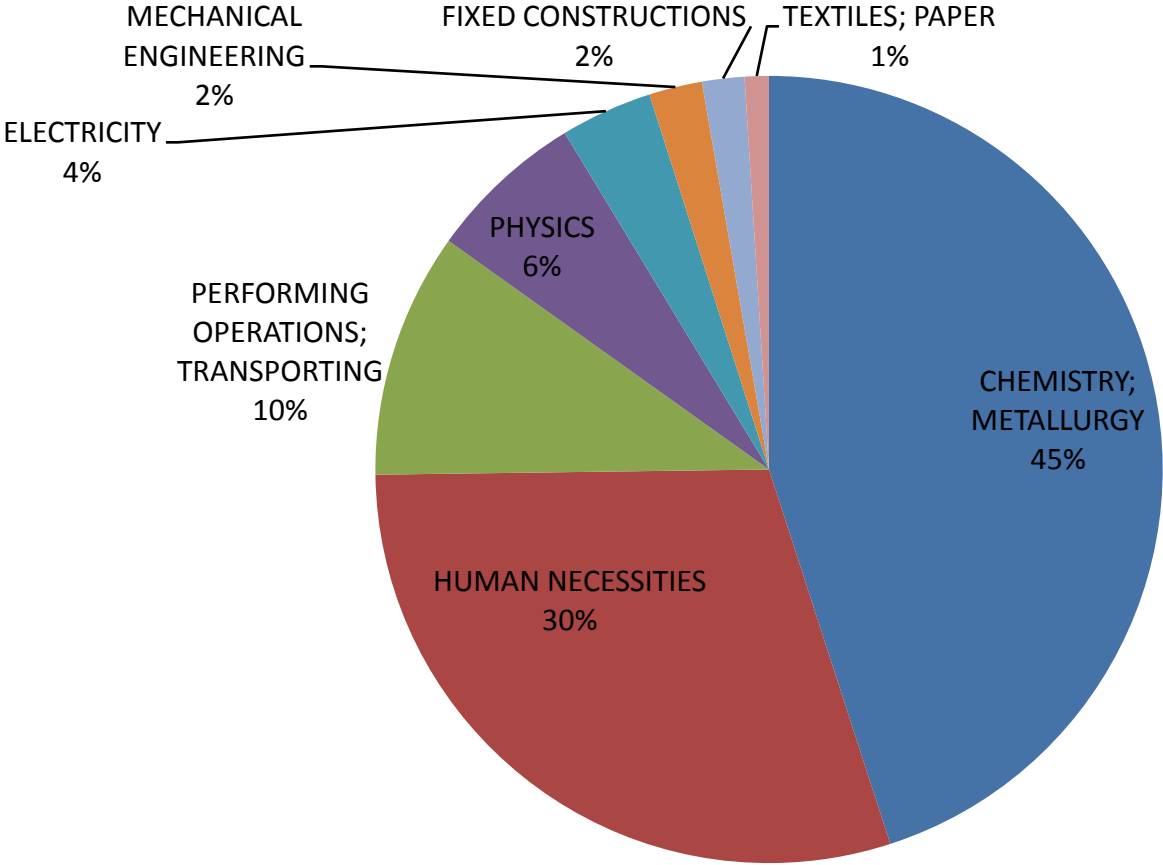
INDIAN INST TECHNOL	9696
INDIAN INST SCI	3393
BHABHA ATOM RES CTR	2050
ALL INDIA INST MED SCI	1930
UNIV DELHI	1651
INDIAN INST CHEM TECHNOL	1433
TATA INST FUNDAMENTAL RES	1367
NATL CHEM LAB	1264
BANARAS HINDU UNIV	1237
JADAVPUR UNIV	1226
POSTGRAD INST MED EDUC & RES	1040
UNIV MADRAS	988
ANNA UNIV	978
INDIAN ASSOC CULTIVAT SCI	925
PANJAB UNIV	790
CSIR	780
INDIAN STAT INST	757
ALIGARH MUSLIM UNIV	750
UNIV HYDERABAD	747
UNIV CALCUTTA	728

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# Patenting by Top 20 Indian “Universities”



# Distribution of Indian “University” Patents By Main IPC





# DNA Related Patenting By Indian Universities?

- Of the 2016 patent applications by Indian Universities, 103 are DNA-related (based on the IPC measure)
  - Of the 1261 applications filed *only in India*, 1.6 percent are DNA related
  - Of the 586 applications filed *only in the U.S.*, 10.2 percent are DNA related
  - Of the 169 applications filed *both in India and the U.S.*, 13 percent are DNA related
- The top 25 Indian “universities” account for 43 of the 2,246 DNA related patents filed in India (<2%)

# **CONCLUSIONS AND POLICY LEVERS**

# Conclusions

- Limited DNA related patenting in India thus far
- Most existing tests likely unpatented given priority years
  - Note that there are other barriers to access in India as well (medical infrastructure, poverty, etc.)
- Unlike pharmaceuticals, even if genetic tests were patented in India price discrimination likely would blunt costs
- Little evidence of a “problem” at this point
  - nevertheless, several policy options could limit future costs with little downside risk

# Policy Levers

- In many cases, including genetic testing, not patents per se that are problematic, but overly broad patents
  - TRIPS flexibilities; *de jure* versus *de facto* patent standards
  - Patent “quality control” an important issue in India
  - Pre-grant opposition can help; evidence from pharmaceuticals
- In the case of public section inventions, licensing more important than patenting per se
  - Academic biomedical patenting on the rise; likely to be codified in Bayh-Dole type legislation soon
  - India should resist temptation to mimic Bayh-Dole as is; there are other models that can facilitate technology transfer as well as protect the public interest
    - Building research exemptions into licensing contracts?
    - A rebuttable presumption of non-exclusive licensing?
    - Opening up academic patent applications to peer review?