



Issues and Innovations in Intellectual Property for Crop Biotechnology: Intellectual Property Issues in Developing Countries

**The Second Decade of Crop Biotechnology:
Opportunities and Challenges for the Food System**

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MIHR
PIPRA

IP Handbook of Best Practices

IP concerns in developing countries, circa 1990s

1. CALLS for greater PROTECTION

- To induce innovation
- To promote technology transfer
- To foster economic growth

2. CALLS for greater ACCESS

- To promote national interests (domestic research agendas, industries, farmers, consumer prices)
- To prevent South-to-North transfer of economic rents/royalties
- To foster economic growth

IP trends in developing countries 1997 thru 2007 - specific to agbiotech

1. IP issues have been overshadowed by research capacity, regulatory, and consumer issues
2. Selective strengthening of IP PROTECTIONS
3. Stronger ag IP inducing public sector technology transfer
4. Working out of IP ACCESS issues

1. Overshadowing of IP

- IP is only one plank in the policy platform of biotech in agriculture:
 - Public research investments
 - IP rights
 - Environmental/Biosafety
 - Food safety/consumer choice
- National stance of support/opposition based on positions of constituent economic sectors:
 - Consumers
 - Environmentalists
 - Farmers
 - Ag input suppliers
- In Europe, and some developing countries, **more constituent sectors stand to lose than to gain**
 - Other planks in national policy platforms are currently more effective, more binding against biotech
- Hybrid strategies: such as regulatory ban while pushing research

2. Strengthening of IP protections: IPRs relevant to agriculture



- Trade Secrets
- Patents
 - Utility patents
 - Plant patents
- Trademarks
- Plant Variety Protections/Plant Breeders' Rights*
- Geographical Designations of Origin*

* Industry specific or *sui generis* forms of protection

2. Strengthening of IP protections: guided by external forces

- Over ten multilateral agreements since 1989
 - Four relate directly to crop genetics:
 - UPOV, 1991
 - CBD, 1992
 - TRIPS, 1995
 - ITPGR, 2001
- IP tie-ins of bilateral trade agreements
- Foreign/global business investors/exporters
- Tend to be overestimated.

Real strengthening of IP protections driven by internal forces

- Rise of an innovative sector:
 - Innovators emerge within/from existing economic sectors
 - Become domestic advocates of stronger IP policies
 - Shift domestic political-economic calculus relative to IP
- Sea-change in economic development philosophies:
 - De-emphasizing policies based on natural resources, traditional manufacturing, infrastructure development
 - Emphasizing *intangibles*: human capital, social capital, intellectual capital development; “Science for Development”
 - Emulating technology based productivity growth of US economy

Selectivity of IP strengthening

- 1st Law of IP POLITICAL-ECONOMY: Maximize protection of what you've got; minimize protection of what you don't.
- Historic case studies:
 - US Copyright in 19th century
 - European biotech patenting since 1970s
 - Developing countries: TRIPS vs. CBD
- Taking full advantage of TRIPS flexibilities
 - Exercise of subject matter exemptions
 - Interpretations/implementation of “effective *sui generis* system” of plant breeders rights
- Advancing CBD
- RESULT: great heterogeneity among “developing countries”

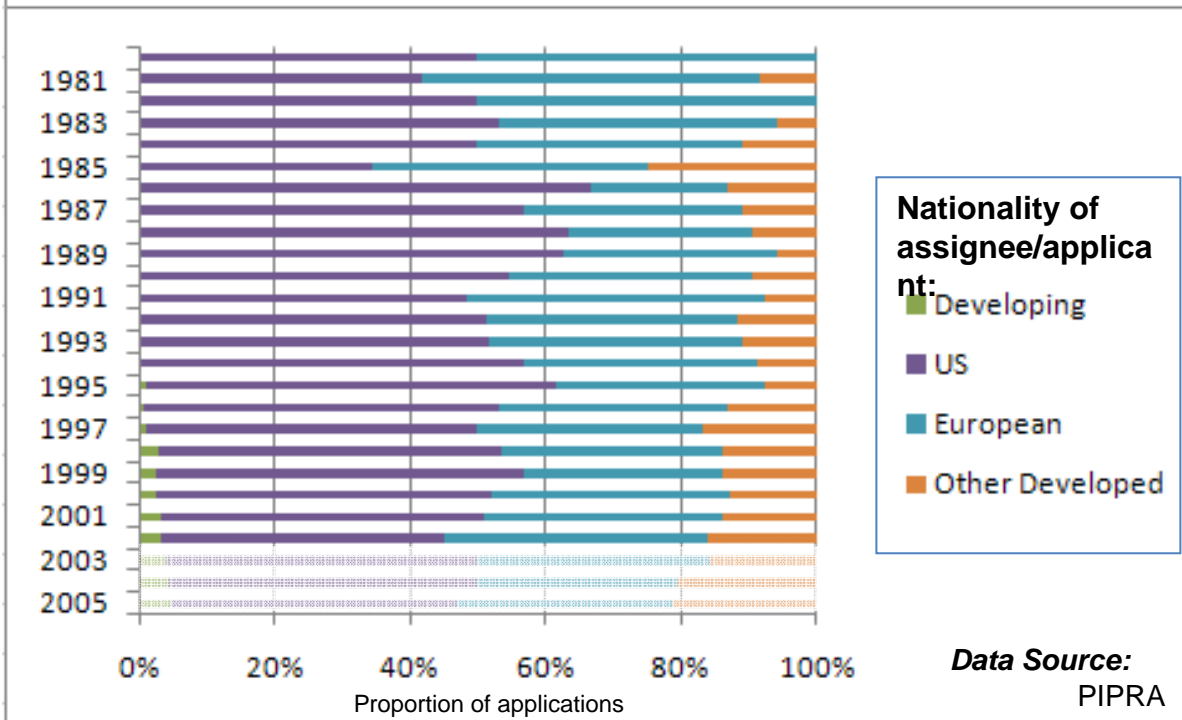
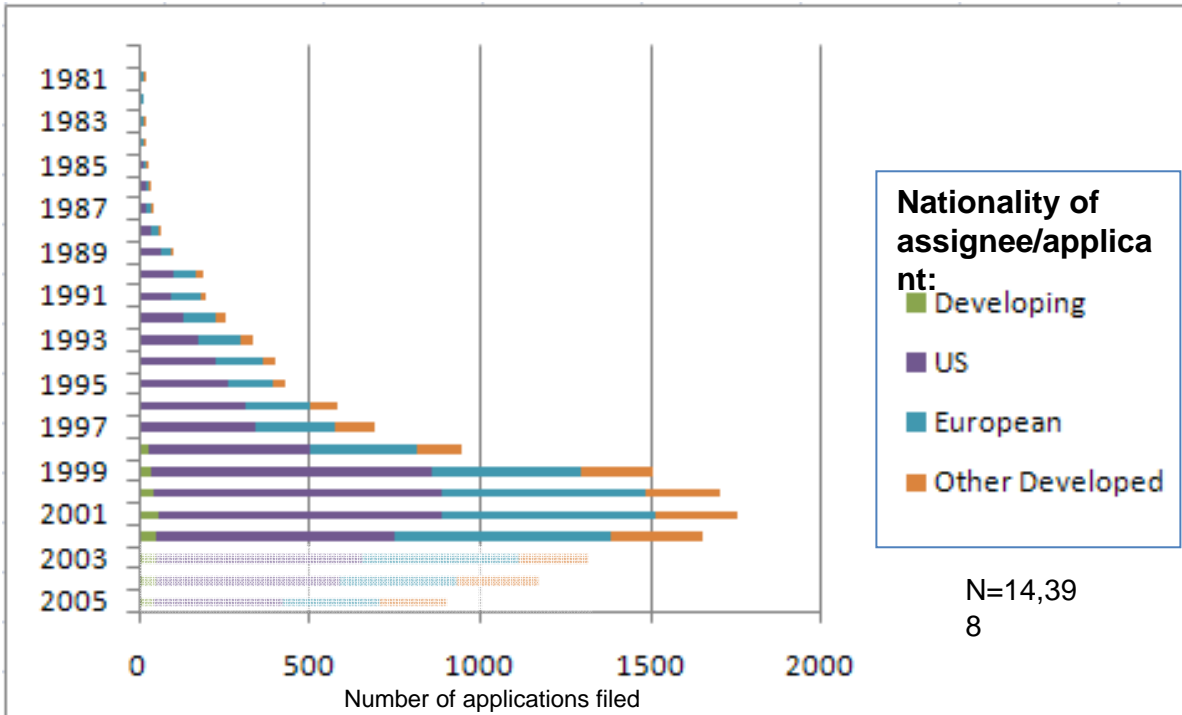
TABLE 1: DETERMINANTS AND INDICATORS OF THE STATUS OF NATIONAL IP SYSTEMS

COUNTRY	PER CAPITA GDP BY PPP, 2005 ¹⁰²	NUMBER OF SCIENCE & ENGINEERING ARTICLES, 2003 ¹⁰³	NUMBER OF GLOBALLY TOP-RANKED UNIVERSITIES ¹⁰⁴	DATE OF FIRST PATENT LAW	DATE JOINED TRIPS	DATE(S) PATENT LAW AMENDED FOR TRIPS COMPLIANCE	DATE OF PVP LAW	DATE JOINED UPOV	PATENTS TO RESIDENTS / PATENTS TO FOREIGNERS (YR)	RATIO OF RESIDENT TO FOREIGN
United States	41,399	211,233	168	1789	1995	-	1930	1981	84,271/80,020 (2004)	1.05
TIER 1										
Russia	11,041	15,782	2	1812	-	2003	1992	1998	19,447/3,943 (2005)	4.93
China	7,198	29,186	8	1984	2001	1992,2001	1997	1999	18,241/31,119 (2004)	0.59
South Africa	12,161	2,364	4	>1925	1995	2002	1976	1977	5549*/5501* (1995)	1.01
Poland	12,994	6,770	3	>1925	1995	2000	1995	1989	778/1,016 (2004)	0.77
India	3,320	12,774	3	1856	1995	1999,2002	2001	-	851/1,466 (2004)	0.58
Brazil	8,560	8,684	4	1809	1995	1996-1997	1997	1999	666/1,366 (2002)	0.49
TIER 2										
Argentina	14,108	3,088	1	>1875	1995	1996-2001	1973	1994	145/1,442 (2000)	0.10
Mexico	10,186	3,747	1	>1850	1995	1997,1999	1997	1997	162/6,677 (2004)	0.02
Chile	11,936	1,500	1	>1850	1995	2005	1997	1996	32/569 (2000)	0.06
Indonesia	4,459	178	0	1989	1995	1997	2001	-	16/615 (1996)	0.03
Malaysia	11,201	520	2	1983	1995	2000	2004	-	31/1,542 (2003)	0.02
Jordan	5,095	263	0	1999	1999	1999,2001	2000	2004	4/56 (2004)	0.07
Vietnam	3,025	216	0	1995	2006	2005	2004	2006	17/756 (2005)	0.02
Philippines	4,923	179	0	1947	1995	1998	2002	-	16/1,437 (2004)	0.01
TIER 3										
Ethiopia	823	99	0	1995	-	-	2006	-	0/1 (2006)	0.00
Kenya	1,445	258	0	1914	1995	2001	1972	1999	0/33 (2001)	0.00
Tanzania	723	86	0	1931	1995	-	2002	-	0/23 (1989)	0.00
Uganda	1,501	90	0	>1950	1995	-	1994	-	0/34 (2001)	0.00

* Patent applications filed.

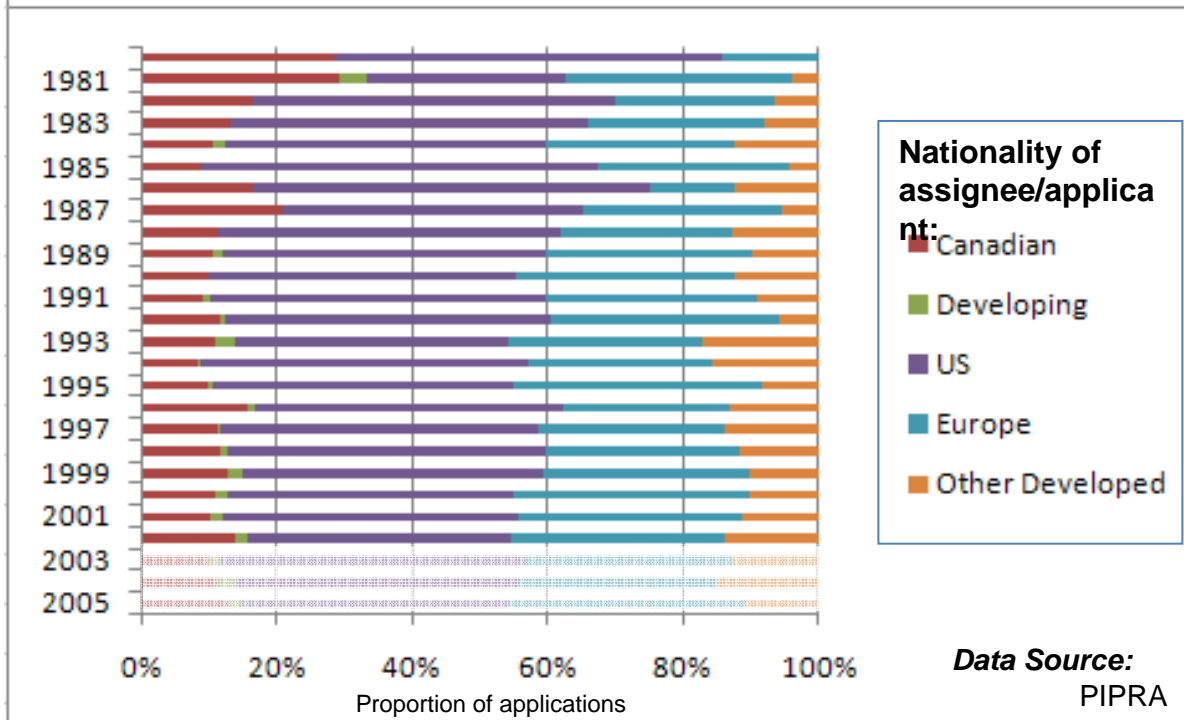
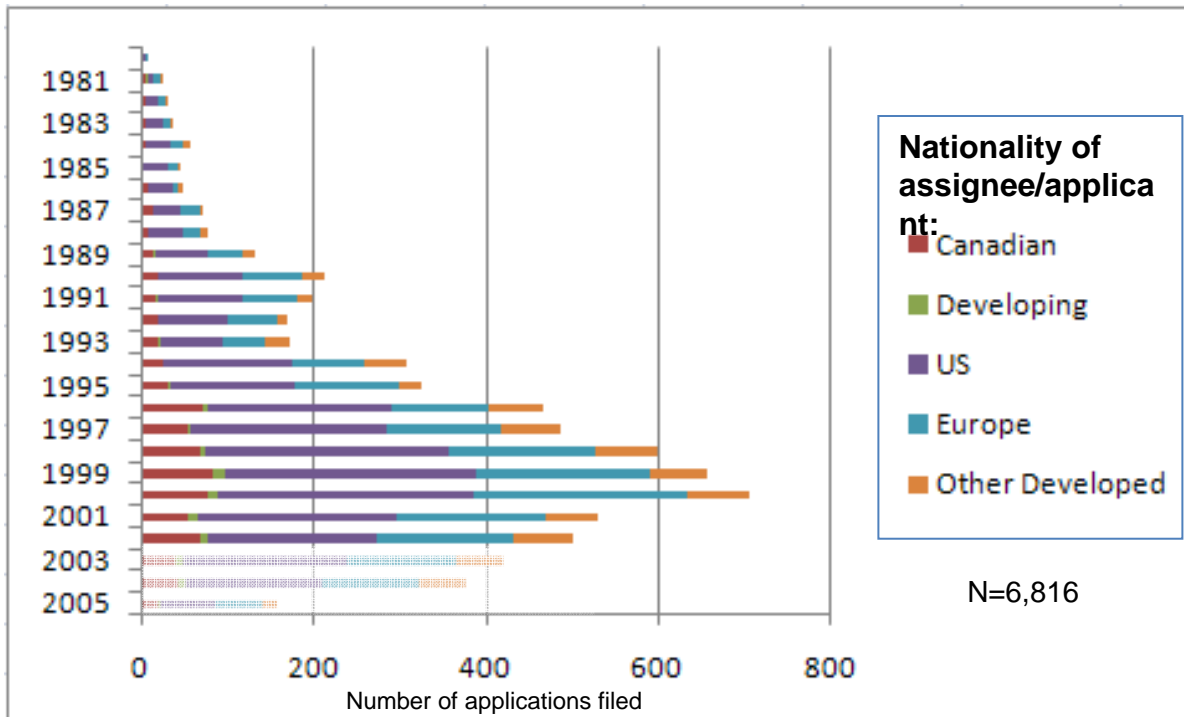
Source: Graff, "Echoes of Bayh-Dole", Chapter 3.3, *IP Handbook*, MIHR & PIPRA, 2007

WO patent applications related to agbio, 1980-2005



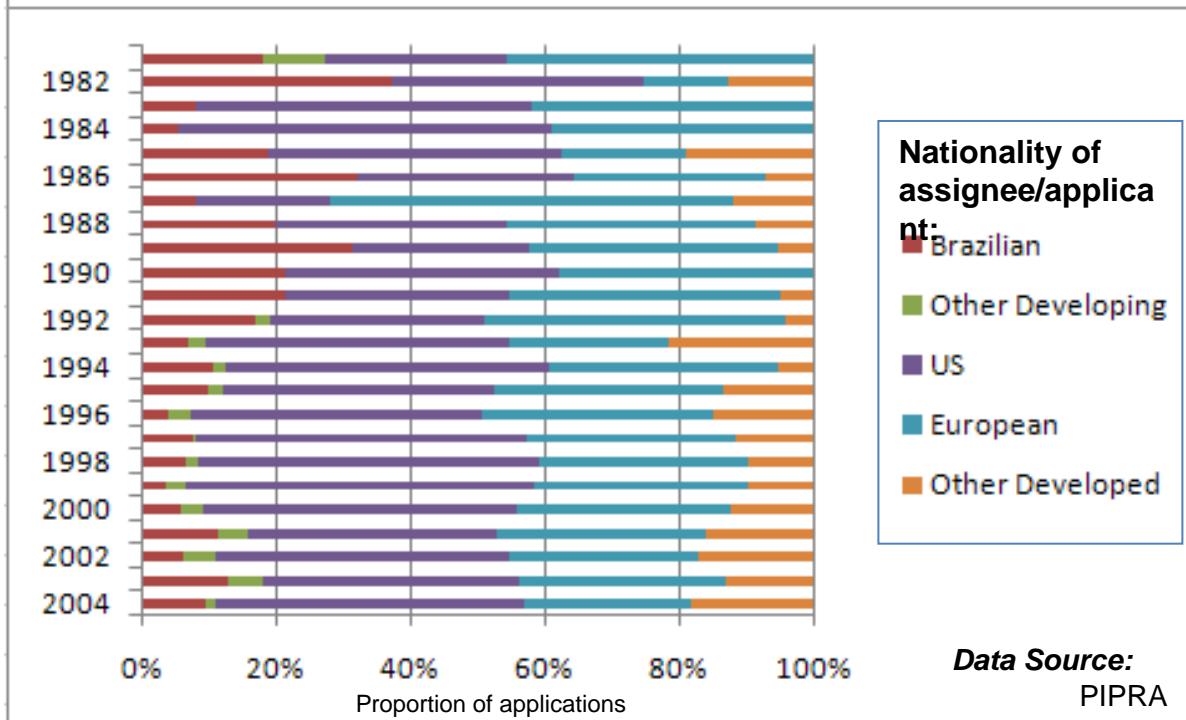
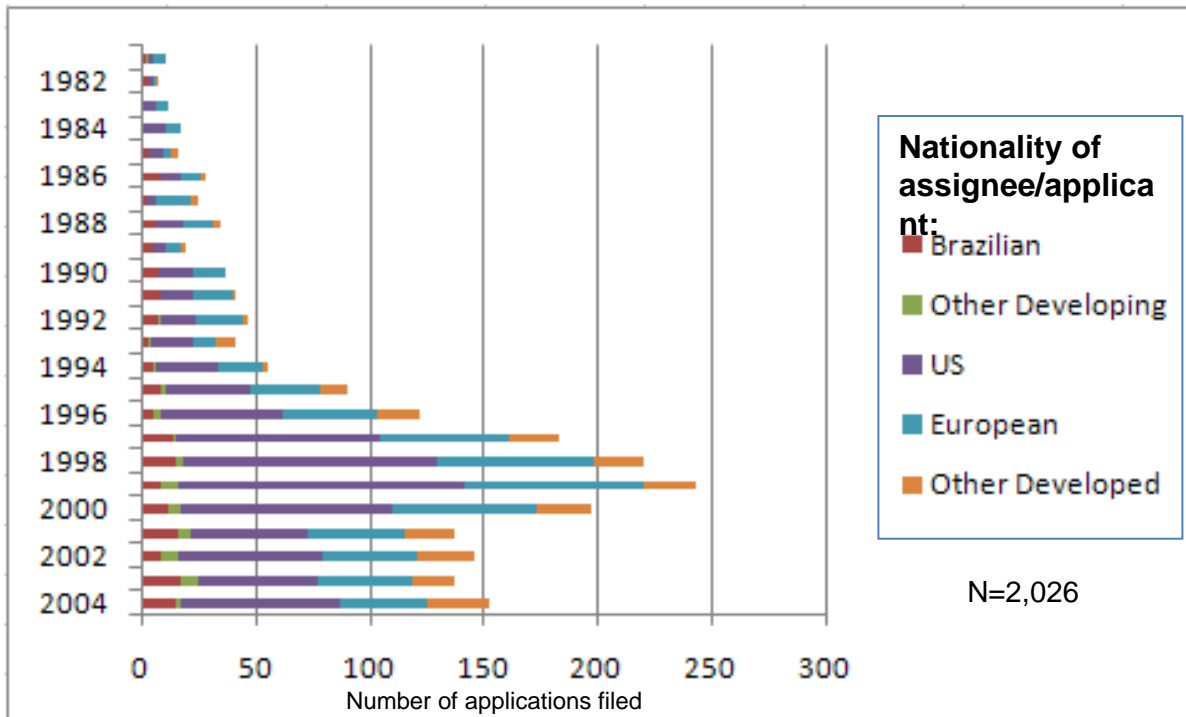
- Developing countries contributing patented technologies only last 10 years
- Developing countries account for <5%
- US ~50%
- Europe ~30-35%
- Other OECD ~10-15%
- Shares of others stable for almost 3 decades

Canadian utility patent filings related to agbio, 1980-2005



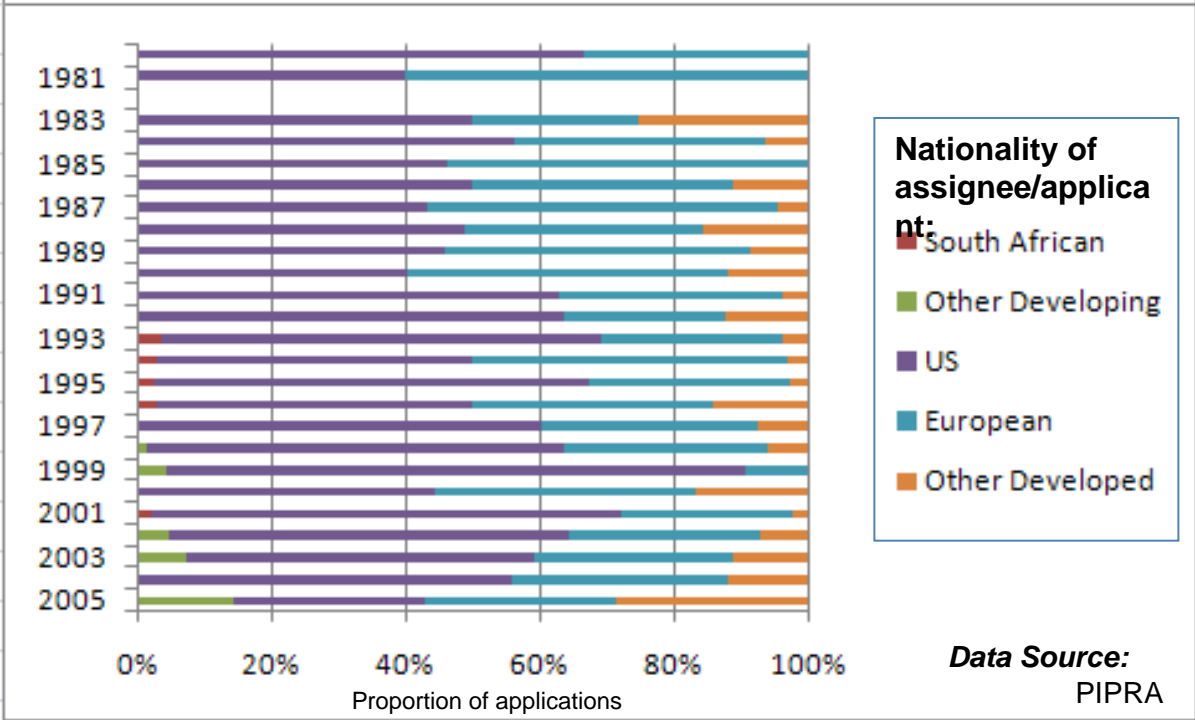
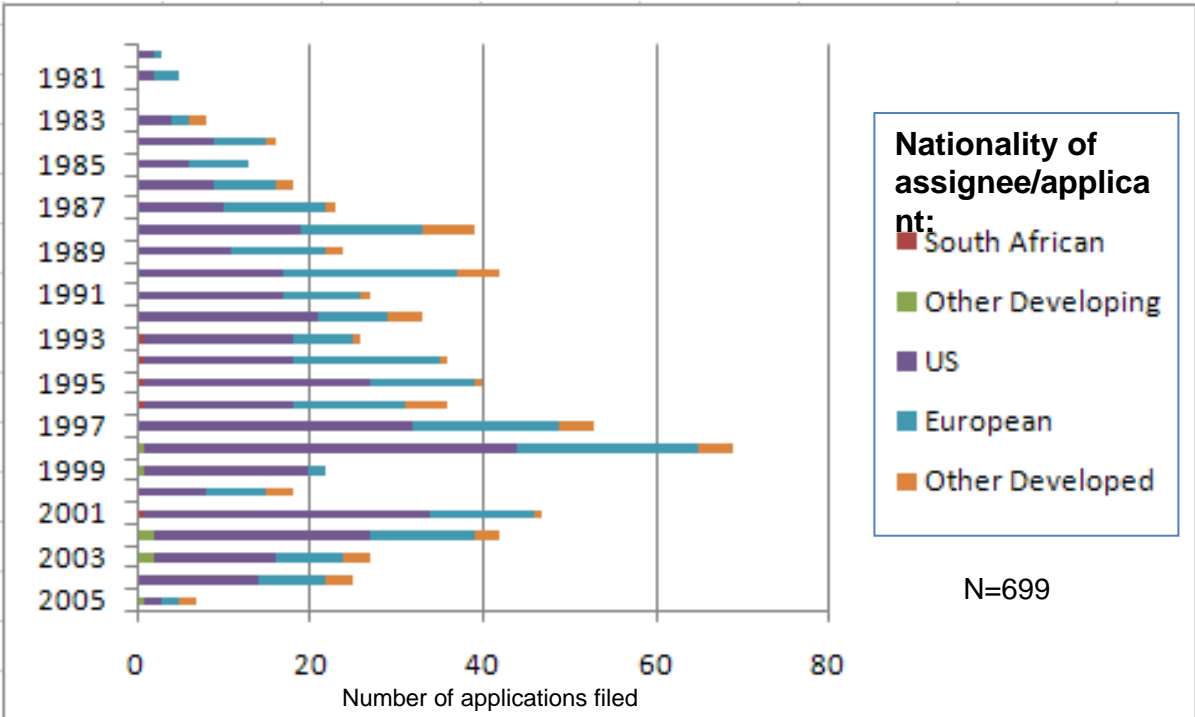
- Canada receives about ~50% of rate of WO filings in agbio
- Domestic Canadian inventions ~10-15%,
- Proportions of filings from other countries very similar to patterns in WO

Brazilian utility patent filings related to agbio, 1981-2004



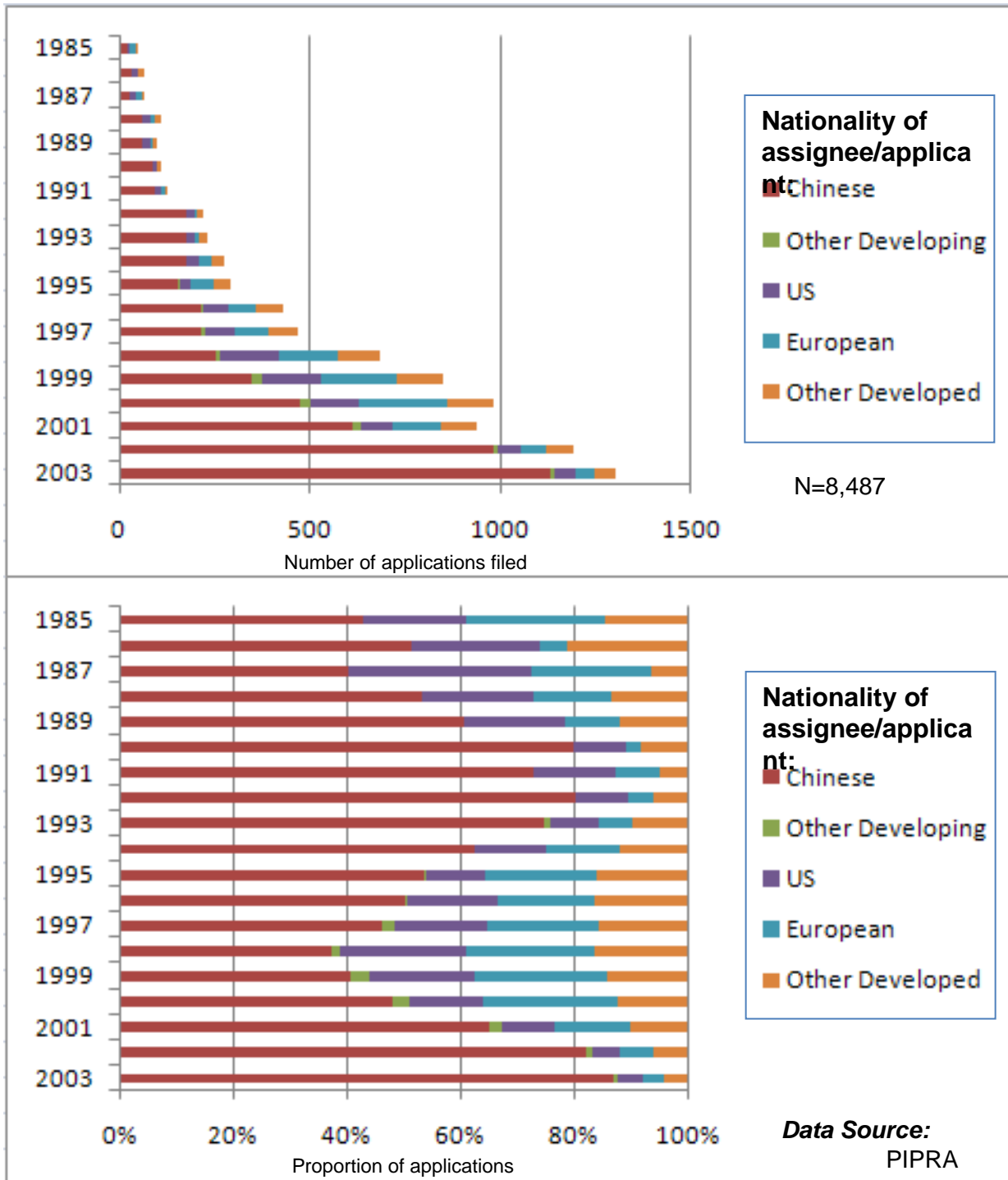
- Brazil sees only about 15% of the rate of WO filings in agbio
- Otherwise, proportions of filing nationalities similar to Canada
- Domestic Brazilian inventions ~10%, makes it a Tier I “Innovative” developing country
- Some domestic political constituency to drive agbio patent protections

South African utility patent filings related to crop biology, 1982-2005



- Again, typical developing country pattern
- <5% of the rate of WO filings
- Negligible (~0%) domestic filings
- Implications about domestic political support for IP policy?

Chinese utility patent filings related to crop biology, 1985-2003



- An exception to the rule
- Very high rate (~60%) of filing by domestic Chinese inventors
 - Lots of domestic 'junk' patents?
 - Incentives for academics to patent?
- Implications about domestic political support for IP protection?

3. Stronger ag IP necessitates public sector IP management

Table 5—Estimated global public and private agricultural R&D investments, circa 2000

Region/country	Expenditures (million 2000 international dollars)			Share (percent)	
	Public	Private	Total	Public	Private
Asia-Pacific	7,523	663	8,186	91.9	8.1
Latin America and the Caribbean	2,454	124	2,578	95.2	4.8
Sub-Saharan Africa	1,461	26	1,486	98.3	1.7
Middle East and North Africa	1,382	50	1,432	96.5	3.5
Developing-country subtotal	12,819	862	13,682	93.7	6.3
High-income country subtotal	10,191	12,086	22,277	45.7	54.3
Total	23,010	12,948	35,958	64.0	36.0

SOURCE: Calculated by authors based on Agricultural Science and Technology Indicators (ASTI) initiative data and data presented in OECD (2005).

Source: Pardey et al, “Agricultural Research”, IFPRI, 2006

- Globally, public sector spends twice as much as private sector
- In developing countries, public sector spends < 90%
- **As IP strengthens, public research institutions & universities most affected**

TABLE 2: SPECIFIC POLICIES ON OWNERSHIP OF INTELLECTUAL PROPERTY ARISING FROM RESEARCH FUNDED BY THE GOVERNMENT

	COUNTRY	YEAR	POLICY SPECIFIC TO OWNERSHIP OF INTELLECTUAL PROPERTY	
	United States	1980	Patent law: ownership of inventions made under federal government funding (Bayh-Dole Act)	
TIER 1	Russia	2003	Patent law: ownership of inventions made under government contract	
	China	1985 2002	State Council on Technology Transfer regulations Ministry of Education and Ministry of Science & Technology joint ruling: university ownership and transfer of intellectual property	
	Poland	-	-	
	South Africa	In process	Legislation on national research system: ownership of inventions made under government funding	
	Brazil	1996	Patent law: ownership of inventions by employer, with terms of revenue sharing for public-sector employers	
	India	2000	Ministry of Science & Technology ruling: ownership under ministry funding	
TIER 2	Argentina	1990 1995	Law on national research system: universities and institutes establish TTOs Patent law: ownership of inventions by employer	
	Mexico	1998 2002	Labor law: ownership of inventions by employers Law on national research system: ownership of inventions to be determined by policy of the institution	
	Chile	1991	Patent law: section on university ownership and transfer of inventions	
	Indonesia	2002	Law on national research system: universities and institutes to establish TTOs	
	Malaysia	In process	Ministry review of incentive system for scientists, including ownership of intellectual property	
	Jordan	In process	High-level commission review of all relevant legislation and regulations for technology transfer	
	Vietnam	-	-	
	Philippines	-	-	
	TIER 3	Ethiopia	-	-
		Kenya	-	-
Tanzania		-	-	
Uganda		-	-	

Source: Graff, "Echoes of Bayh-Dole", Chapter 3.3, *IP Handbook*, MIHR & PIPRA, 2007

Intellectual Property Management in Health and Agricultural Innovation

a handbook of best practices
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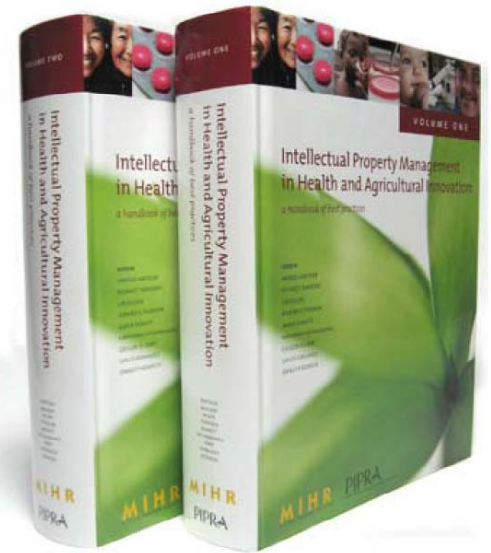
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4. Working out IP access issues

1. In many countries: no IP = no issue
 - legally: no protection available
 - practically: no filing
 - **caveat: exports into stronger IP regimes**
2. In other countries with some IP, for major crops often cheaper/easier to pay royalties than to make home grown versions
3. For “orphan crops”: IP access arrangements
 - Donations: GoldenRice, AATF
 - Open source: CAMBIA/BiOS
 - Public sector work arounds: PIPRA

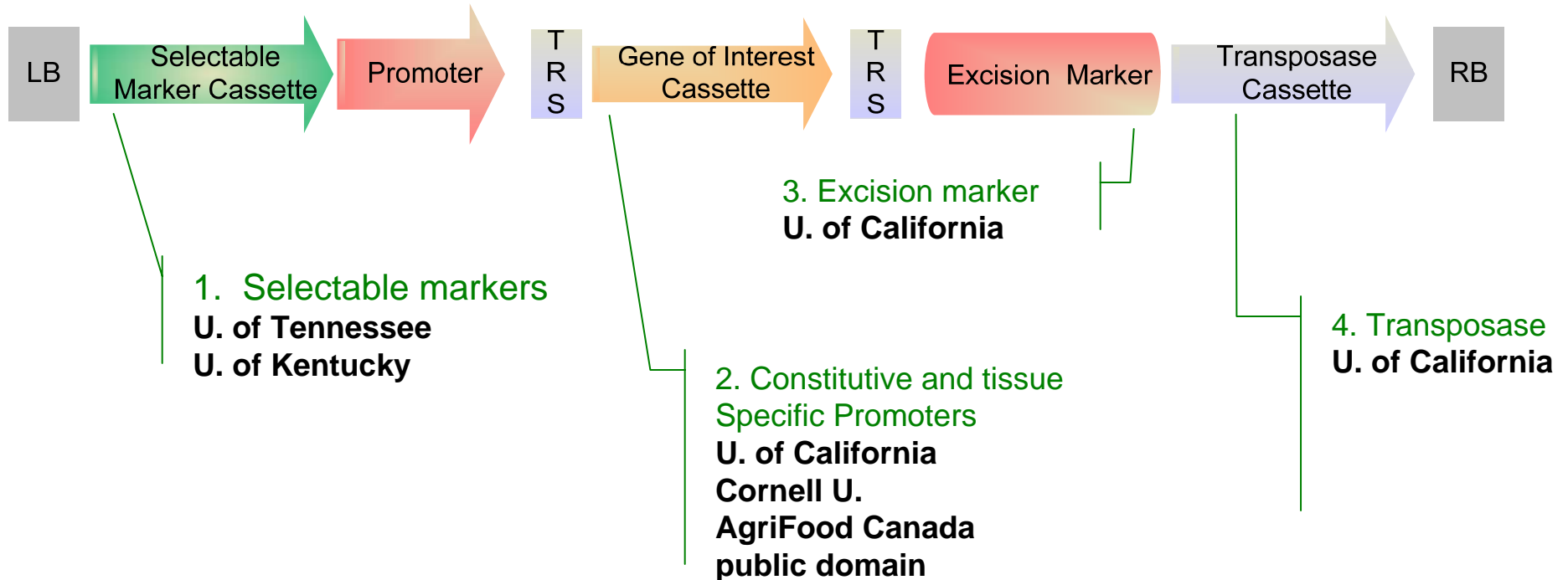
PIPRA patent pool project

**PIPRA Vector Workshop
Danforth Center, St Louis
October 2004**



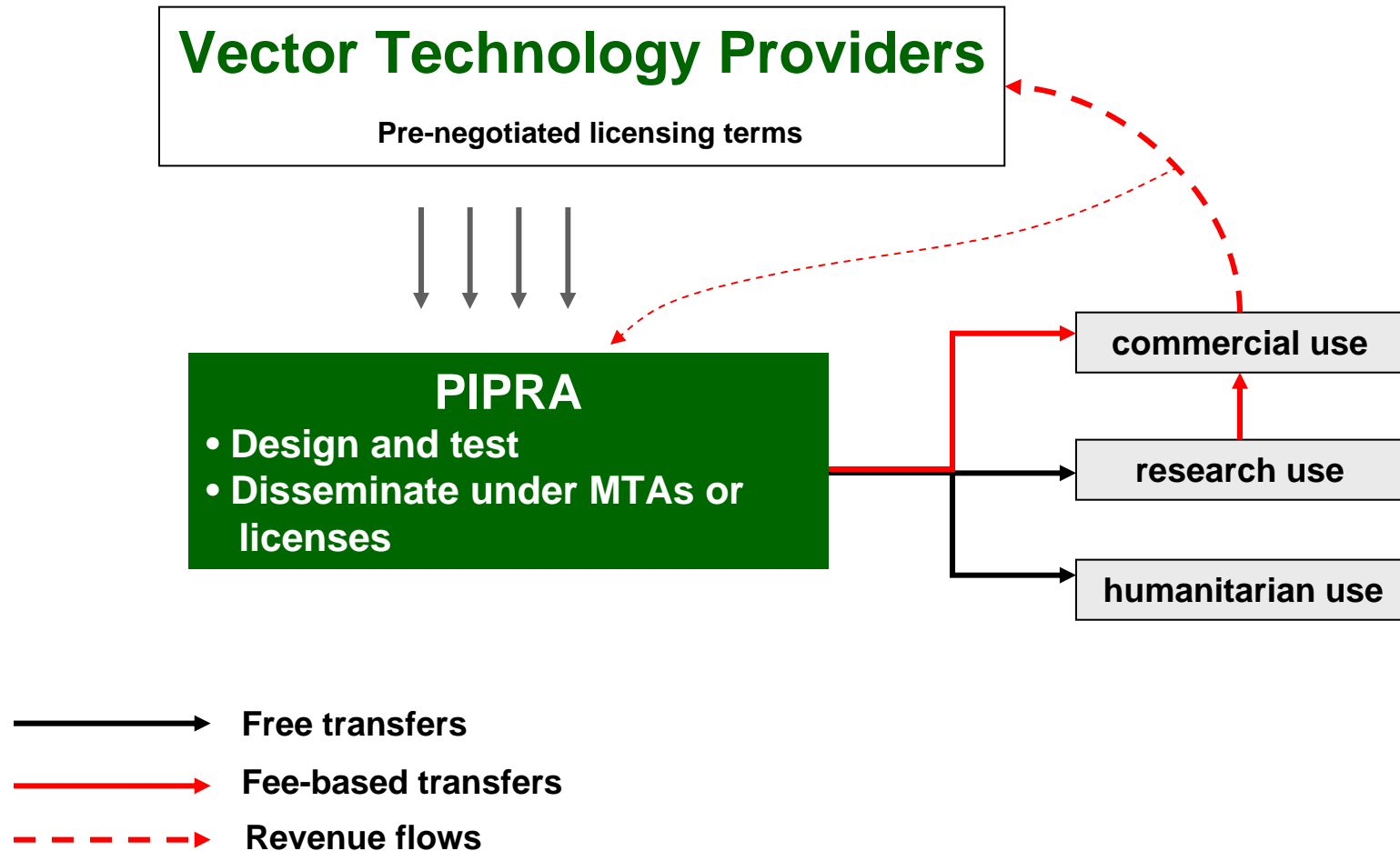
- **Identified technical, legal, and regulatory design parameters for vector**
- **Characterized the FTO landscape around vector components**
- **Identified PIPRA-owned or public domain technologies that would work around FTO 'road blocks'**

Technologies in PIPRA's plant transformation vector



- Comprised of multiple patented components (owned by PIPRA members)
- Incorporates technical, legal, and regulatory design features
- Compatible with:
 - Agrobacteria and Non-Agrobacteria strains (Transbacter/CAMBIA)
 - T-DNA transfer borders from Agrobacteria or plant derived

PIPRA vector pool licensing model



Initial licensees' comments

- US-based commercial licensee:
 - “Lowers financial barriers to entry”
 - “Promotes entrepreneurship among smaller companies”
 - “Provides otherwise non-existent opportunities”
 - “Absence would result in entrepreneurial disincentive and a virtual monopoly by the biotechnology ‘Titans’ ”
 - “Can play a critical role ‘leveling the playing field’ ”
- Africa-based humanitarian-use licensee:
 - “Clarifies IP rights for Sub-Saharan Africa, even if there is no IP enforced in target countries”
 - “Humanitarian basis allows us access to a license royalty-free, with no fee and no royalty payments needed”
 - “Clarifies ownership of improvements”
 - “Allows Africans to export products for food and feed purposes outside Africa.”

IP conclusions in developing countries

1. IP overshadowed by regulatory and capacity issues. It will re-emerge.
2. Strength of IP protection is driven by political-economic calculus of who benefits and who loses.
3. Stronger ag IP necessitates public sector IP management
4. Working out of IP ACCESS issues