Outline

- Plurality & Culture
  - Intergovernmental Committee on Intellectual Property, Genetic Resources, Traditional Knowledge, and Traditional Cultural Expressions Negotiations

- National Interest & International Harmonization
  - US, China, Namibia
  - USPTO Proposed Attributable Ownership Rules
  - EU Nagoya Protocol Implementation
  - EPO Patent Validation Program
- Reports (with Arti Rai) on the Nagoya Protocol and Synthetic Biology
- Consultant to Namibian IP Office
- Expert Advisor to Mozambique at WIPO IGC
National Interest & International Harmonization
International Patent Harmonization

- No global patent
- Rules vary by country

“Taken to its extreme, full harmonization would entail the following:
  - Textually identical legislation.
  - Identical interpretation of claims by granting offices made possible by sharing of search and examination reports.
  - National courts that reliably come to the same decisions on any given patent concerning validity, scope, infringement, limitations and defences.

The absolute highest stage of patent law harmonization would be a unitary global system that operates: (i) to the greatest possible extent as if the whole world were a single patent law jurisdiction; and (ii) on the basis of the principles, rules and practices of the United States, Europe or Japan (or a mixture of the three). It follows that total global patent law harmonization would mean that a patent granted somewhere would be in force everywhere else too.” (Dutfield 2014)

- Patents have different effects in different countries (national interest)
Strategic Goal III: *Provide Domestic and Global Leadership to Improve Intellectual Property Policy, Protection and Enforcement Worldwide*

**United States Patent and Trademark Office**
**2010-2015 Strategic Plan**

**Initiatives to Achieve Strategic Goal III, Objective 2**

- Lead Efforts at the World Intellectual Property Organization (WIPO) and Other International Fora to Improve IP Protection and Enforcement
- Prioritize Countries of Interest for Purposes of Improved IP Protection and Enforcement, Capacity Building, Legislative Reform, Including Creation of Country/Region Strategic Plans and Specific Action Plans
- Improve Efficiency and Cooperation in Global IP System
- Provide International IP Policy Advice and Expertise to Other U.S. Government Agencies
- Provide Technical Expertise in the Negotiation and Implementation of Bilateral and Multilateral Agreements that Improve IP Rights Protection and Enforcement
- Create USPTO and Attaché Integrated Action Plans that Focus on Country-Specific Needs and Interagency Cooperation

Historically, the United States has been at the forefront of creating the infrastructure—including public research funding, appropriate laws, and robust capital markets—that generates groundbreaking research, supports the transformation of research into innovation, and then translates innovation into economic growth and jobs. Growing international competition, however, makes continued leadership far from certain.
# WTO TRIPS Disputes

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From Edward Lee, “Measuring TRIPs Compliance and Defiance”
### Time Taken by Member to Comply with WTO Decision

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From Edward Lee, “Measuring TRIPs Compliance and Defiance”

- [China's IP rights infringement]: “cost the US economy approximately $48 billion in 2009 alone. Of that total, more than $26 billion came from the information and service sector and more than $18 billion came from the high-tech and heavy manufacturing sector, in addition to billions more from other sectors. . . . if China complied with their current international obligations to protect and enforce IPR, 2.1 million jobs could be created in the US,” . . .“The most direct jobs impact would come in high-tech, innovative industries.” May 2011
“By 2020, China will become a country with a comparatively high level in terms of the creation, utilization, protection and administration of patents. . . . The quantity of patents for inventions for every one million people and the quantity of patent applications in foreign countries will quadruple. . . . The proportion of patent applications in industrial enterprises above designated size will reach 10%. . . . The patent system will be able to effectively support the effort to make China an innovative country and the role of the patent system in promoting economic and social development in China will become very apparent.”

By 2015: China will rank in top two countries in patents granted to domestic applicants, will file 2 million patent applications worldwide.
Majority of Patent Applications in Poorer Countries filed by Foreigners
Application Trends by Country

Figure A.2.1.2 Trend in patent applications for the top five offices

Note: The top five offices were selected based on their 2012 totals.
Source: WIPO Statistics Database, October 2013
Namibian Patent applications

Source: WIPO statistics database; last updated: 03/2014
Namibia Patent Applications


- Pharmaceuticals
- Biotechnology
- Medical technology
- IT methods for management
- Civil engineering
- Others
- Organic fine chemistry
- Chemical engineering
- Materials, metallurgy
- Furniture, games
- Digital communication

Source: WIPO statistics database; last updated: 03/2014
Innovation Incentive?

“Practically all the patents in the Third World are foreign-owned. As such, the monopoly privileges granted through patents have, . . . an international, rather than simply a domestic, income distribution effect. . . Furthermore, patent protection in developing countries amounts to a policy instrument which almost totally covers innovations realized elsewhere, namely in the industrialized countries. The [R&D] allocations in the latter countries are [not] influenced by patent protection in the developing nations. Hence, there exists an effective divorce between patent protection in the Third World and incentives on the innovations concerned.” (Vaitsos 1976)

*no local working
Harmonization (or not!)
- EU Nagoya Protocol Implementation
Convention on Biological Diversity (CBD)

- 193 Parties, in effect since 1993. Key Principles:
  - States have sovereign control over biological resources within their borders and shall ensure conservation of same
  - But states shall endeavor to create conditions to facilitate access on mutually agreed terms and subject to prior informed consent
  - There should be fair and equitable sharing of benefits of use of genetic resources with providing party

Three Objectives:
1. The conservation of biological diversity;
2. the sustainable use of its components; and
3. the fair and equitable sharing of the benefits arising from the use of biological and genetic resources.
Ethnobiological Research and “Biopiracy”

“[t]he patenting of plants, genes, and other biological products that are indigenous to a foreign country without compensating the keepers of those resources and the holders of knowledge appropriated during ethnobiological research processes.”

Varying approaches

H. Schmidt, mobot.org
“For an invention or creation completed based on genetic resources, the applicant shall give an account in the patent application documents of the direct origin and ultimate origin of the genetic resources. If the applicant is unable to give an account of the ultimate origin, it/he/she shall give the reason therefor.” (Art. 26)

“... If genetic resources are obtained or used in violation of laws or administrative regulations and an invention or creation is completed on the basis of such genetic resources, the patent shall not be granted therefor.” (Art. 5)
Brazilian Provisional Law of 1999

- Penalties for obtaining patent on invention created in violation of (genetic resource acquisition) law include:
  - payment to the Federal Government of at least twenty percent of the gross income or royalties from commercializing or licensing the resulting product (benefit sharing);
  - **suspension** or **cancellation** of the resulting patent
Indian Biodiversity Act (2002)

- **Access**: “No person shall, without previous approval of the National Biodiversity Authority, obtain any biological resource occurring in India or knowledge associated thereto for research or for commercial utilization or for bio-survey and bio-utilization.”

- **Patents**: No person shall apply for any intellectual property right by whatever name called in or outside India for any invention based on any research or information on a biological resource obtained from India without obtaining the previous approval of the National Biodiversity Authority before making such application.”

- **Penalties**: “Whoever contravenes or attempts to contravene or abets the contravention [of the provision] shall be punishable with imprisonment for a term which may extend to five years, or with fine which may extend to ten lakh rupees and where the damage caused exceeds ten lakhs such fine may be commensurate with the damage caused, or with both”
Need for Nagoya Protocol

- CBD provides for ABS/PIC but does not specify methodology
- Parties implemented widely varying legislation (or none at all) to address
- Need for uniform framework, enforceable obligations on users, reasonable access provisions by providers
Nagoya Protocol (NP)

- Adopted October 2010, **coming into effect October 2014**

- **Framework** for **access** to genetic resources and traditional knowledge with **prior informed consent** and on mutually agreed terms, including terms on fair and equitable benefit sharing from **utilization** of genetic resources and associated traditional knowledge.

- NP is “**the** instrument for implementation of the access and benefit sharing provisions of the [CBD]” (Art.4)

- Two prongs: **Access** and **user compliance**
Nagoya Protocol (NP)

Some provisions:

• PIC not mandated, but if adopted, NP provisions control;

• designation of national ABS/PIC focal points;

• designation of compliance checkpoints;

• provides for “internationally recognized certificates of compliance”;

• requires GR utilization benefits be shared in a fair and equitable way on mutually agreed terms (MAT);

• obligates Parties to cooperate in cases of alleged violations of ABS/PIC/MAT.
NP Implementation Issues

- Breadth of Coverage
- Temporal Scope Disagreement
Certainty Issue: IGC Treaty Temporal Scope (Retroactivity)

- Would DOO and other obligations apply:
  - only to GR/TK/TCEs **accessed** (i.e. crossed a border) after treaty comes into force; or
  - To GR/TK/TCEs accessed at anytime but **utilized** after treaty comes into force
NP Temporal Scope (Retroactivity)

- Does NP apply:
  - only to GRs **accessed** after NP comes into force (EU, Switzerland, etc.);
  - To GRs **utilized** after NP comes into force, but **accessed** anytime after CBD in force (some provider countries, NGOs),
  - To GRs accessed at anytime but utilized after NP in force (domestic legislation could cover, e.g., Andean Community Decision)

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<th>When Genetic Resources “Accessed”</th>
<th>CBD in Effect</th>
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Article 2: Scope

“This Regulation applies to genetic resources over which States exercise sovereign rights and to traditional knowledge associated with genetic resources that are accessed after the entry into force of the Nagoya Protocol for the Union. It also applies to the benefits arising from the utilisation of such genetic resources and traditional knowledge associated with genetic resources.”

Access = crossed a border/physically obtained
Temporal Scope (Retroactivity)

- Vienna Convention Article 28:
  “Unless a different intention appears from the treaty or is otherwise established, its provisions do not bind a party in relation to any act or fact which took place or any situation which ceased to exist before the date of the entry into force of the treaty with respect to that party.”

Vienna Convention on the law of Treaties (1969)
Temporal Scope (Retroactivity)

NP Article 3: Scope

“This Protocol shall apply to genetic resources within the scope of Article 15 of the [CBD] and to the benefits arising from the utilization of such resources. . . .”
Temporal Scope (Retroactivity)

Andean Community Decision 391:

Art. 1: **Access**: the obtaining and **use** of genetic resources conserved in situ and ex situ, of their by-products and, if applicable, of their intangible components, for purposes of research, biological prospecting, conservation, industrial application and commercial use, among other things.
Nagoya Protocol

- Article 5(1) Fair and Equitable Benefit Sharing
  - “In accordance with Article 15, paragraphs 3 and 7 of the Convention, benefits arising from the utilization of genetic resources as well as subsequent applications and commercialization shall be shared in a fair and equitable way with the Party providing such resources that is the country of origin of such resources or a Party that has acquired the genetic resources in accordance with the Convention. Such sharing shall be upon mutually agreed terms.”
Nagoya Protocol

Article 2:

“Utilization of genetic resources” means to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology as defined in Article 2 of the Convention;

(d) “Biotechnology” as defined in Article 2 of the Convention means any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use.”
Temporal Scope (Retroactivity)

Problems with EU temporal scope approach:

“A significant share of GRs and associated TK used in the EU will not be covered by the Regulations, thereby undermining the spirit of the Nagoya Protocol.

Second, individual users of GRs and TK will not be able to receive what they always wanted: legal certainty. In many cases, the utilisation of GR and TK will be legal under EU law, but illegal under the law of the provider country. Although the user has received an approval from European authorities, he or she could be prosecuted in a provider country upon setting foot in that country. Nobody is interested in such a scenario.” Natural Justice/Berne Declaration (2013)
Penalties

- Violations of country ABS/PIC laws can result in
  - denial/loss of patent protection,
  - loss of contracts,
  - fines,
  - criminal penalties,
  - and more,
  - possibly even in a different country (e.g., Denmark draft legislation penalizing extraterritorial GR ABS violations)
Enforcement of ABS/PIC Laws

- 2012: Monsanto being sued by National Biodiversity Authority of India for accessing and modifying 10 varieties of Indian eggplant in development of Bt Brinjal without ABS/PIC (first such suit (criminal) under India’s Biological Diversity Act of 2002)

http://blog.izilwane.org/monsanto-sued-for-biopiracy/

Arne HÄckelheim/Wikicommons
Enforcement of ABS/PIC Laws

July 2012: Brazilian agency fined 35 companies ~$44M for violations of ABS/PIC

International Harmonization

EPO Patent Validation Program
“Validating” European Patents (EPO)

“Encouraging European and non-European countries that are not member states of the European Patent Organisation to allow international applicants to validate the effects of their European patent applications and patents on their national territory as national rights.

Known as "validation on request", this system, once introduced, “will reduce national office examination workload by up to 90% and allow the offices to focus on developing their examination capacity for national filings.”
Table A.3.3.1 Number of patent applications by origin and office: selected origins and offices, 2010

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<td>14,576</td>
<td>42,500</td>
<td>9,773</td>
<td>490,226</td>
</tr>
</tbody>
</table>

Note: The actual numbers of patent application and grant data by country of origin might be higher than the data reported above, due to incomplete data and/or because a breakdown by country of origin is not supplied by some offices. Patent office codes: AU (Australia), BR (Brazil), CA (Canada), CN (China), DE (Germany), EP (European Patent Office), FR (France), GB (United Kingdom), HK (China, Hong Kong (SAR)), JP (Japan), KR (Republic of Korea), MX (Mexico), RU (Russian Federation), SG (Singapore) and US (United States of America).

Source: WIPO Statistics Database, October 2011
Colonialism Déjà vu . . .

No bad intent but:

“[I]nternational patent structures that were created during colonization have been recreated under the EPC. . . . [I]n the first half of the twentieth century some developing countries were quietly integrated into an emerging system of international patent governance. Probably the largest scale example of this integration was the development of the re-registration system that was adopted by colonies of the British Empire. . . . [T]he re-registration system that was created in [the UK’s] Empire days seems to have been recreated under the EPO. In a number of UK territories . . . the owner of the UK European patent has three years within which to apply for the re-registration of that patent in those territories and countries.” (Drahos 2010)

“Global ownership of intellectual property rights became one of a number of ways that the sovereignty of former colonies was directed away from an obligation to promote the domestic welfare of citizens, to a duty to subordinate that welfare to the vicissitudes of the market ideology.” (Okediji, 2003)
EPO Patent Validation Program

- Laws of developing countries may be different to EPC (TRIPS flexibilities)
- Fact that another country/region has similar patent law does not mean its patent office is properly applying the law to claims it receives
- Potentially easier for foreigner to get patent than domestic applicant
Dangers of Relying on Outside Examination

- 66% of challenged EPO patents revoked or narrowed (Steven Seidenberg, Patent Lawyers Ponder the Changed Post-Grant Process, ABA J., Feb. 2013)

- ~50% patent nullifications in Germany (anecdotal)

- claims invalidated in 86% of U.S. cases (where validity challenged between 2007-2011) (Smyth 2012)

- U.S. Supreme Court decisions effectively invalidating thousands of patents
  - (e.g., AMP v. Myriad Genetics: isolated genomic DNA, Mayo v. Prometheus (some diagnostic methods), Bilski v. Kappos (some business methods), CLS Bank v. Alice (many software patents))

- 40% of patents challenged at JPO cancelled or modified (2013 JPO Annual Report)
Caution

- Using other office examination results as a floor, not a ceiling
- Might consider joining WIPO CASE to enhance search and examination, **not to replace independent** search and examination
International Harmonization
Issues

- “Certain relatively advanced catch-up country firms can take advantage of the differences between their domestic patent regimes and those in their foreign markets. Thus, it is not just domestic patent policy that counts: the patent regimes of foreign countries may matter a great deal too, if not more, especially countries seeking to grow by exporting high value products, as did Germany in the late 19th century and Japan and South Korea from the late 20th. Having patent laws that were stronger in foreign markets was at least as important as having weak laws at home if not more so. Thus, any harmonization scheme would, if implemented, be an obstacle to such industrial development.” (Dutfield 2014)
International Harmonization Issues

“Recent economic studies suggest that the realization of substantive patent law [harmonization] . . . could potentially harm the economic development interests of some if not many countries. Empirical research by Kim on the experience of South Korea, a highly successful rapid developer, led him to find that ‘‘strong IPR protection will hinder rather than facilitate technology transfer to and indigenous learning activities in the early stage of industrialisation when learning takes place through reverse engineering and duplicative imitation of mature foreign products.’” He also concluded that ‘‘only after countries have accumulated sufficient indigenous capabilities with extensive science and technology infrastructure to undertake creative imitation in the later stage that IPR protection becomes an important element in technology transfer and industrial activities.’’ Essentially, harmonization based on the regimes existing in leader countries will mostly benefit medium-sized and large firms based in these nations rather than those in follower countries. . . . wealthy countries’ attempts to impose patent harmonization could be construed as trying to ‘‘kick away the ladder’’ that they used to climb out of poverty and into developed nation country status.” (Dutfield 2014)
Conclusions

- Substantive patent harmonization still not in best interests of many developing countries

- National interest and culture drive both developed and developing countries

- Plurilateral engagement may be best option for developed and developing countries on some issues (e.g., disclosure of origin)
Strong patent protection not always needed for FDI/Tech transfer

- Malta: small country (316 km$^2$, <500k people)
- Strong patent protection, but few foreign companies registered patents there
- Strategic decision by government to woo generic drug manufacturers (worked with universities to offer special courses, train workers in pharma manufacturing, pharmacology to create skilled workforce), passed business friendly laws (low taxes, worker training, loan guarantees)
- It worked! In 2008, 15+ generics with manufacturing facilities, 1000 employees, exported +$250 million in product (tech transfer)
- FDI not due to strong patent protection