Lecture # 20 – IP in Developing Countries

I. Intellectual Property Protection in Developing Countries: Theory

- Most technological development in LDCs starts with and builds on transfers of technology.
    - Starting an industry from scratch, without the use of foreign knowledge, is very costly.
    - Similarly, FDI without exchange of technology does little than provide short term employment.
    - Thus, policies to help encourage transfer of technology are needed.
- However, intellectual property rights policies should be set up to encourage domestic invention as well.
- The "stages" approach to intellectual property argues that a country's IPP system should evolve as a country grows.
    - The benefits of intellectual property are likely to increase as a country grows. Thus, so should the level of protection.
    - We considered four types of countries:
        1. *IP exporters*: net producers and sellers of intellectual property. Favor strong international IP rights.
        2. *High-income IP importers*: net purchasers of intellectual property. However, their industries require access to sophisticated technology. Thus, favor strong protection with some limits.
        3. *IP followers*: industrializing countries that need access to modern technology but prefer that such access be inexpensive and readily diffused. Have mixed interests between strong protection to encourage incoming investment and weak protection to promote imitation and learning.
        4. *Low-income IP importers*: produce little intellectual property. Instead, they depend on foreign technology, so favor weak IP.
- Note that many developed countries went through these same stages themselves.
    - For instance, IP laws in the U.S. were much weaker in the 19th century.
    - Developing countries claim they are being denied the same opportunities that developed countries had when they were growing.
- Links between IPR and FDI
    - Evidence is mixed
        - Some studies find no relationship between level of IPR and FDI or licensing
        - Others show positive effect of IPR on licensing
            - IPR leads firms to invest in production, rather than distribution
            - Appears less likely to lead to increased FDI for lower income countries
        - IPR seems more important for promoting FDI for high-tech goods

        - However, not necessary when the nature of the good itself makes copying difficult

II. Intellectual Property Rights Agreements

- International patent agreements go back to the nineteenth century.
- Paris Convention of 1863
    - Signed by 98 nations, including many developing countries.
    - Covers patents and trademarks
    - Two major provisions:
        1. Each country's patent system would provide equal treatment of nationals and non-nationals.
        2. Applicants would have priority rights dating from one year after then initial filing.
    - Other than these two provisions, countries could have varying patent laws (e.g. deciding what things are and aren't covered).
    - Analysis
        - Countries that export technology benefit. Technology importers could no longer refuse patent or trademark protection.
        - Of course, countries were free to offer no protection, or no protection for certain goods.
- Berne Convention of 1886
    - Covers copyright law
    - Similar to the Paris Convention, but it goes further in setting minimum standards.
    - Key provisions:
        - Copyright protection is extended without formal applications or examinations.
        - Minimum protection period is the lifetime of the author plus 50 years.
- International Convention for the Protection of New Varieties of Plants (UPOV)
    - Signed in 1961
    - No developing countries signed then, but some have since joined (list of members).
    - Provides plant breeders' rights (PBR) protection to new plant varieties.
        - In addition, the US offers patent protection for new plant varieties.
- Patent Cooperation Treaty (PCT) of 1970
    - Patent applicants can file a single application through the PCT for all of 40+ member countries.
    - A single literature search is done through the PCT.
    - Applications are examined through the PCT office.
    - Actual patent protection is granted through national patent offices, so the applicant needs to decide if he or she wants to transfer the application to various national offices.
        - However, this is costly, as fees must be paid at each office.

    - The advantage of the PCT is that the applicant has up to 18 months to make this transfer. In addition to the 12-month priority after filing at the home patent office, this gives an applicant 30 months (2.5 years) to decide whether to make the costly decision to file abroad.
        - The tradeoff is that the PCT application itself is expensive.
- Most international agreements are carried out by the World Intellectual Property Organization (WIPO).
    - Headquartered in Geneva
    - It is a specialized agency of the United Nations
- Regional offices
    - European Patent Convention of 1973
        - Allows a single patent application to be granted in EPO member states (currently 20)
    - African Regional Property Organization (ARIPO)
        - Established in 1976.
        - Headquartered in Zimbabwe
        - Serves English-speaking countries of East Africa.
        - Established to pool the resources of its member countries in industrial property matters together in order to avoid duplication of financial and human resources.
        - Laws are uniform across member states.
        - Protection is weak.
    - Organisation Africaine de la Propriété Intellectualle (OAPI)
        - Formed in 1962
        - Headquartered in Cameroon
        - Serves French-speaking nations
        - Laws are uniform across member states.
        - Protection is weak.
- The WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)
    - Signed as part of the Uruguay Round of GATT in 1994
    - The agreement covers five basic principles:
        - How basic principles of the trading system and other international IP agreements should be applied.
            - Equal treatment among nations
        - Common ground rules for giving adequate protection to IPR.
            - Follows Paris and Berne Conventions, but adds new features:
                - Copyrights:
                    - Computer programs will be protected as copyrightable literary works.
                    - Producers of computer programmers and sound and film recordings retain the rental rights to their works.

- Patents:
    - Patent protection must extend for at least 20 years.
    - Protection must be available for products and processes in almost all fields.
        - biggest impact was in pharmaceuticals.
        - Prior to TRIPS, about 50 developing countries did not grant pharmaceutical patents.
    - What can be excluded from patent protection:
        - Governments can refuse to issue a patent if commercial exploitation prohibited for reasons of public order or morality.
        - “Diagnostic, therapeutic, and surgical methods”
        - Plants and animals (other than microbiological organisms).
            - However, if plants are excluded, PBR must be available.
    - Governments can issue compulsory licenses
        - The government gives licenses to use the technology without the inventor’s consent.
- Enforcement
    - Governments must ensure IPR are enforced under their laws.
- How to settle disputes between WTO members
    - As in other WTO agreements, initial rulings are made by a panel, and can be appealed.
- Transition
    - Developed countries were given 1 year to comply with TRIPs
    - Developing countries have from 5-11 years (more for LDCs)
    - Developing countries that did not offer protection for certain products have 10 years to introduce the protection.
    - For pharmaceuticals and agricultural products, countries must begin accepting applications immediately, although the patent doesn't need to be granted until the transition period is over.

- Trends in patent protection levels
  - Higher income groups have higher patent protection indices.
    - Ginarte/Park's results suggest a threshold effect. The motivation for strong IPR increases once the R&D/GDP ratio reaches a critical size.
    - Note that these results fit the theoretical suggestions for different intellectual property standards discussed in the previous lecture.
  - Patent rights in African countries are surprisingly high, because former colonies follow the UK or French systems.
- There is currently much variation in patent policy across countries. Thus, substantial changes will be needed to comply with TRIPs.
  - Ginarte/Park discusses an index of patent protection. The index uses a 0-5 scale, and is based on several features:
    0. Extent of coverage
       - Are their exceptions for some items, such as drugs, chemicals, plants?
    1. Membership in international agreements
       - Is the country a member of the Paris Convention, the PCT, and/or UPOV (plant protection)?
    2. Loss of protection
       - Can the patent holder lose rights because of:
         - "Working" requirements
           - Some countries require that a good based on the patent be manufactured or imported into the country.
           - Useful if the inventor cannot afford to make the product yet, or if the product is not yet economically viable in that country.
         - Compulsory licensing
           - Can the government require the inventor to share exploitation with third parties.
           - Compulsory licensing has been used in the case of drug patents in South Africa and Brazil.
    3. Enforcement
       - Are preliminary injunctions (pre-trial actions requiring cessation of potentially infringing activities) allowed?
       - Are contributory infringement pleadings allowed?
         - Contributory infringement is when actions themselves do not infringe but might cause infringement by others. An example would be supplying parts essential to the operation of patented inventions.
       - Is the burden of proof on the inventor or accused infringer?
    4. Duration of protection
       - The standard is 20 years from the application date, as in the TRIPS.

            - Of course, the length of processing time for an application varies across countries.
- Note also that creating a patent system is expensive.
    - One economist estimates it will cost between $1.5-$2 million to build a "bare-bones" infrastructure to comply with TRIPS.
- Impact of TRIPS on developing countries
    - Although developing countries not all the same, and although theory suggests different patent systems for different countries, TRIPS treats all countries other than LDCs the same
    - Whether developing countries benefit from TRIPS depends on whether gains from innovation outweigh additional rent extraction made possible by TRIPS
        - Countries can influence this both by enhancing innovation and making use of flexibility in TRIPS to limit rent extraction
            - For example, countries with little innovative capacity could threaten use of compulsory licenses without fear of losing patent protection for their own firms
            - Countries must keep in mind, however, that firms may decide to leave the market rather than comply
        - Policies should aim to promote spillovers, as spillovers are important for promoting growth
            - Four main methods:
                - Licensed tech transfer
                - Unauthorized imitation (“piracy”)
                - Patent disclosure
                - Reverse engineering
        - Related to TRIPS, developing countries can take advantage of stronger patents by making disclosure of applications easily available to local firms
    - Gervais notes that it is more than IPR that matter
        - If the goal for developing countries is to attract foreign investment, must pay attention to other policies that encourage FDI
    - Differences among industries
        - Many of the reforms in TRIPS were pushed for by the pharmaceutical industry
        - Are they beneficial to other industries?
            - Gervais argues it would be better to allow different standards for different industries, using examples we’ve already discussed earlier in the class, such as software patents
        - Note, for example, that countries without domestic pharmaceutical innovation have more bargaining power over compulsory licenses

- What can we expect the effect of TRIPs to be?
  - Potential winners
    - Calculations suggest US will be main beneficiaries of TRIPs ($5.76 billion).
      - US has to make only minor changes to its own system, but will be the main beneficiary of changes abroad.
    - Other big winners include Germany, France, Italy, Sweden, and Switzerland.
    - Note that the countries gaining from TRIPs have well-established research systems.
  - Countries hurt:
    - Although the UK and Japan gain rents on inward flows, they are net losers of rents, due to changes in patent policy.
    - Canada is the biggest loser ($1.04 billion).
      - Most of its patents go to US, which makes few changes, so gains little. Lose do to changes in their patent law.
    - Most developing countries see rents transferred to developed countries.
      - They have many changes to make.
      - Also, as noted above, strong IP protection may not be suitable for their level of development.
        - Even today's developed countries had weaker IP when growing.
          - For example, the US had very weak enforcement of copyright laws in the 19th century.
- These results suggest that, unless there are positive long run effects, developing countries will be hurt by harmonization. However, they have agreed to TRIPS. Why?
  - Seen as necessary for entry into WTO.
    - Other benefits of free trade may dominate
  - Signaling effect: makes markets more attractive to inventing countries
- Other issues raised by TRIPS:
  - Drugs
    - At Doha in 2001, developing countries declared that they should have until 2016 to come into compliance with IPR and pharmaceuticals.
    - They argue public health is more important that IPR
  - Compulsory licensing
    - Once IPRs are in place, and India is no longer a source for cheap generics, where will countries that do not have their own drug industries get the drugs from?
    - Compulsory licensing doesn’t help if there is no one to use the license.
    - Developed countries complain that compulsory licensing has been used too freely by developing countries.

- Education and research
  - Fair use is a big concern: will copyright laws inhibit access to texts & research?
  - Should developing countries have free access?
- Traditional knowledge
  - Traditional knowledge often makes its way into high-priced uses in developed countries. The best example is herbal medicines.
  - The source countries are rarely compensated
  - Furthermore, the drug companies may receive patents for traditional knowledge, because examiners are unaware of these traditional uses.
  - Even if traditional users wanted patent protection, they would have a hard time affording it.
  - One suggestion is a database of traditional knowledge, so that patent examiners are aware of its existence.

III. Pharmaceutical Markets in Developing Countries

- In recent years, a major policy concern has been access to medicines in developing countries. There are two main issues:
  1. Incentives for research and development
     - For developing country diseases, such as malaria, there is a lack of interest in developing new treatments.
  2. Access to existing medicines
     - Most drugs are produced by developed country pharmaceuticals, and many are under patent. As such, they can be expensive.
- Before the 20th century, most advances in life expectancy occurred due to increases in income, rather than technological change. That is no longer the case.
  - Of this, pharmaceuticals have played a key role.
  - For example, vaccines provided by the World Health Organization (WHO) save 3 million lives per year.
- What discouraged R&D towards neglected diseases? Were patent rights a concern?
  - Historically, for-profit firms have paid less attention to developing country diseases.
    - Examples of neglected diseases include malaria and tuberculosis.
  - Between 1975 & 1997, only 13 new drugs (out of 1,233 licensed worldwide) were for 10 “neglected diseases”.
- Possible reasons
  - Weak intellectual property rights
    - However, the article in *JAMA* finds that pharmaceuticals take out few patents in Africa.
      - It is not because pharmaceutical patents aren’t allowed. The members of the Organisation Africaine de la Properiété have offered pharmaceutical patents since 1977, and African Regional Industrial Property Organization members have offered them since 1984.

            - This suggests that stronger IPR will not, by itself, stimulate more research.
        - Profits from AIDS drugs are driven by the North American and European markets.
            - The entire African pharmaceutical market is just 1.1% of the global market.
        - Indeed, US companies often sell drugs at lower prices in developing countries.
            - For example, Bristol-Myers Squibb (BMS), an American firm, sells stavudine treatments for $3,400/year in the U.S., and for $55/year in Africa. Cipla, an Indian firm, can sell the same drug for $40/year.
            - In addition, competition from generics forces American companies to sell drugs at lower prices in India. In the U.S., Pfizer sells the antibiotic Zithromax for $2.70 for each 250 mg capsule. In India, Pfizer sells the same drug for $0.84. This is in part due to competition from Indian generics, which are available at prices ranging from $0.39 to $0.54 per pill.
                - Will this change after TRIPS? Note that competition from Indian generics is important here. Will TRIPS cut off this competition?
    - Low income
        - Drug companies focus on treatments where there are large potential markets. Even in developed countries, there is less incentive to do research for diseases affecting few people, which is why the US has the Orphan Drug Act.
        - Because developing countries have lower incomes, diseases that only affect these populations will get less attention from for-profit researchers.
        - Even with lower prices, drug prices may be too high.
            - A 2001 study found that countries such as Ghana, Nigeria, and Tanzania have annual health budgets of $8 or less per capita.
    - Weak institutions make it difficult to get drugs to patients in need.
        - Both political will and medical infrastructure matter here.
        - Also, tariffs and taxes may be high.
- What can be done to encourage research and development relevant for developing countries?
    - In recent years, increased public/private partnerships have played an important role.
        - These partnerships do ¾ of the projects
            - Co-ordinate contributions
            - Manage research portfolios
            - Raise money

- Companies focus on early stage research, and shift the risk of clinical trials to the partnership.
    - Firms may not expect big profits, but this helps them limit costs.
- Where does the funding come from?
    - Only 20% from governments.
    - Foundations play a big role.
        - Gates Foundation
            - Has a $28 billion endowment.
            - In 2005, gave $750 million to the Global Alliance for Vaccines and Immunisation (GAVI).
                - The foundation's contributions have nearly doubled global spending on malaria research.
            - Are there risks to having so much funding come from a foundation?
                - Will the Gates Foundation control the research agenda?
                    - To avoid this, money is awarded to projects via competitive processes.
                    - The goal is to stimulate the research agenda, not create it.
                - Will the donation crowd out other sources of funding?
                    - To help avoid this, priority is given to projects that leverage additional support.
        - GAVI
            - Sources of funding
                - In its early years, about half of GAVI's income came from the Gates Foundation.
                - In recent years, developed countries such as Norway and Britain have provided substantial contributions.
            - What they have done
                - GAVI created a purchasing fund to purchase vaccines for use in developing countries.
                - Monopsony power helps it to purchase vaccines at lower costs.
                - The Foundation's Global HIV/AIDS Vaccine Enterprise promotes collaboration between funding agencies

and scientists, with the goal of developing an AIDS vaccine.
        - The foundation has also helped developing countries set up anti-AIDS programs.
        - Additional work supported by the foundation has proposed an Advance Market Commitment for financing new vaccines.
- The effect of TRIPS on pharmaceuticals in India
    - Until TRIPS, allowed process patents but not product patents for drugs.
        - Thus, Indian firms developed new processes to produce generic copies of drugs from developed countries.
    - Costs in India are 20-40% those of Western companies.
    - The effect of TRIPS
        - New law allowing pharmaceutical patents passed in March 2005.
            - All generic drugs already approved in India can still be sold, although those selling the drugs must now pay licensing fees.
            - Provisions are in place to allow these firms to copy drugs in the future, but at higher costs.
                - Copies cannot be made until a drug has been marketed for three years, and the patent holder is allowed to object to the copies.
                - In addition, the generic manufacturer must pay a "reasonable" royalty.
            - Allowed to waive patents on drugs for a national emergency.
        - One concern is what will happen to drugs supplied by India to other developing countries.
            - Because of the historically weak patent protection, generic manufacturers from India have successfully produced inexpensive generic drugs.
                - For example, Bristol-Myers Squibb (BMS), an American firm, sells stavudine treatments for $3,400/year in the U.S., and for $55/year in Africa. Cipla, an Indian firm, can sell the same drug for $40/year.
                - Patent protection for medicine will make it difficult for companies such as Cipla to continue their work producing generic drugs.
        - At the same time, some of the larger Indian pharmaceuticals may benefit from stronger patent protection.
            - They have expanded their own research efforts and be competitive in global markets.

        - For example, Ranbaxy, the largest Indian pharmaceutical firm, generates nearly one-half of its business in America.
        - These successful companies pushed for increased protection, as they hope to do more original research, rather than simply copying products developed elsewhere.
- Nonetheless, most pending patent applications for new drugs are from foreign companies, rather than Indian firms.
    - In 2003, India allowed firms to “deposit” applications for new drugs in anticipation of changing the law.
    - 7,000 of the 8,500 applications deposited prior to passage of the new patent law are from foreign firms.