

Is Compulsory Licensing a Viable Approach to Combat Monopolization by Patents?

Corporate Influence

- National corporations and MNCs have had undue influence on national legislation and regulation, on determining what gets researched, how it gets researched.
- Corporations devise and influence trade agreements to help institutionalize the current regime of neoliberalism internationally.

Noah Zerbe, Agricultural Biotechnology Reconsidered, Africa world Press, 2005.

Steven P. McGiffen, Biotechnology, Corporate Power versus the Public Interest (Pluto Press, 2005).

International Intellectual Property Instruments

- Such international instruments include Trade agreements such as TRIPS and TPP; and other inventions such as the Convention on Biological Diversity (CBD).
- Trade Related International Property Rights Agreement (TRIPS) and the Trans Pacific Partnership (TPP) – international instruments guaranteeing intellectual property protection for products and methods worldwide, ensuring monopoly returns to biotech industry worldwide. This forces intellectual property/patenting paradigms onto other countries. (Locke's unlimited property rights).

Convention on Biological Diversity

- Convention on Biological Diversity – Attempts to commodify biodiversity to protect it.
- Corporations want indigenous knowledge and biodiversity from third world countries.
(shorter product development times, reduction in research costs).

Convention on Biological Diversity

- Corporate profits estimated in 2005 at \$32 billion annual market for drugs based on traditional medicines.
- CBD tries to reconcile private property with community needs.
- Egalitarian way to privatize control over genetic resources, encouraging commercialization and privatization of intellectual biological and genetic commons, but with mandated sharing.
- Is considered as legalized theft of the third world. Colonial practice of buying off individuals (rent seeking bureaucrats, local elites, government officials and brokers of natural resources).

Material Transfer Agreements

- Costa Rica and Merck (\$1 million and undisclosed royalty, est. 5% for all products derived from plants and insects)
- Monsanto and Peru
- Bristol Myers Squibb and Surinam
- Diversa Corp and Yellowstone Nat'l Park, selling off our microorganisms from hotspots.

Corporate influence in erosion of safety and labeling standards

- FDA, USDA, EPA – fragmented patchwork with no teeth.
- Providers for safety data. FDA conducts no tests of its own, but relies on review of studies paid for by industry.
- Bovine Somatotropin (rBGH or BST) FDA approved without any evidence that it's safe. Humans consume it. Cows fed BGH to bolster milk production. Associated with elevated levels of bacteria in milk. Pus and residue from high conc of antibiotics fed to cows to combat disease. Increases chances of mastitis.

Conversion of Science from Public to Private

- Tax credits for R & D;
- Reduction in capital gains taxes,
- erosion in anti-trust law enforcement.
- Flood of speculative investment in the 1990's, generating a biotech bubble.
- Venture capital investments were \$10 million in 1975, then were \$4.5 billion by 1983. (increase of 25,000 % !!!).
- Federal funding was being drastically cut, also driving academics to commercial sources of funding.
- So modern biology as an academic field was replaced by biotech as a commercial enterprise.

Conversion from public to private funding

- Reagan repealed protections for labor and environment, weakened regulatory infrastructure and research through funding cuts, awarding key appointments to supervisory positions that reinterpreted legislation resulting in non enforcement.
- Commercial interest in biotechnology sparked by Supreme Court decision, *Diamond v. Chakrabarty* (1980), gave monopoly rents to patent holder for recombinant bacteria.
- This allowed for strong intellectual property regime rewarding corporate research interests. E.g. Recombinant insulin allowed founders of small biotech firms to become instant millionaires (Genentech).
- Biotech firms were founded on hope of future returns and aggressive venture capital.
- ***Bayh-Dole Act*** in 1980 granted universities and small businesses the right to patent products/methods arising from federally funded research.
- Bayh-Dole Act and *Chakrabarty* lead the way to use results of publicly funded research for private commercial profit. Laid foundation for commercial development of biotech industry.

What is the main focus of biotech research and marketing of GMO's?

- Biotech products generally are not aimed at helping those in need, they are profit driven, then use altruistic rhetoric to legitimate them in the public's eye. Technology development tends to favor capital at expense of labor. Agricultural biotechnology involves input and capital intensive farming and makes farmers increasingly dependent on purchasing monopoly owned products.
- e.g. herbicide resistance and accompanying mandatory use of herbicide (Roundup) \$2.5 billion sales for Roundup. Farmers are contractually req'd to use Roundup with the herbicide resistance crops.
- Most GMOs are not suited for Africa. They are geared to Midwestern, large scale farming. The crops are not those most readily used in Africa.

PATENTS FRAGMENT THINGS

- Patents drive up the prices of pharmaceutical, and resulting fragmentation stifles access to research and diagnostic materials. Frances Collins, former head of the Human Genome Project, warned of this.
- Myriad Law Suit – Gene fragments prevent access to breast cancer tests.

Academic Independence is Suppressed by Corporations

- **Chapela and Quist**
- Chapela was tenure track at Berkeley. Berkeley had \$25 million grant from Novartis.
- Quist and Chapela study showing risk of contamination by GMO maize to wild strains (criollo) maize. Showed gene flow from GMO corn to genome of contaminated wild plants. Published in Nature. Industry scrutinized paper to discredit it.
- Industry orchestrated a backlash, Chapela was vilified by peers and anonymous critics from Monsanto. Mountain of letters to Nature orchestrated by industry. Including from persons at Berkeley who benefitted from Novartis grant. Nature retracted publication.

Research Suppression by Corporations

- **Dr. Losey and the Monarch Butterfly**
- Dr. Losey found that the monarch caterpillar grew more slowly, died more often after eating leaves that had been dusted with GM maize which had recombinant toxin to kill a pest (Euro. corn borer).
- Generated backlash by industry. Six different research studies performed to try to refute Losey's findings. Could not refute, but sought to shroud results in language that minimized the toxic findings.

Research and Industry Love Affairs

- One third of (789) biomedical papers in 1992 were by people who stood to financially gain from conclusions, but did not reveal that in the paper.
- 2002 study found industry funded research results in higher proportion of studies showing positive results for new drugs compared to publicly funded research.
- HPV debacle.
- IL-2 debacle.

Knowledge versus Patents

- Knowledge is a fundamentally different type of property. It doesn't fit neatly into Locke's private property theory. Knowledge for the public good is not for exclusivity, or scarcity.
- Sharing knowledge doesn't reduce total knowledge available.
- Intellectual property (IP) creates artificial scarcity of knowledge, generates a commodity fiction.

Bayh-Dole Act

- Following Bayh-Dole Act, universities expanded their technology transfer offices to provide the infrastructure and personnel to scour university labs for commercially profitable discoveries.
- In fy 2000, US universities filed 8534 patent applications, and from 1980 – 1990, patent applications by NIH funded **inventions increased by almost 300%**.
- New patent applications increased by 238% between 1991-2000, licensing agreements increased by 161%, and royalties increased by more than 520%.
- In 2005, about half of life sciences faculty members acted as consultants for industry.
- Since the mid 1980s, 21-28% consistently received research support from industry and 7-8% reported that they held equity in a company related to their research.

* Lieberwitz, 12 Ind. J. Global Legal Stud. 120, 2005

Expansive Biological Patent Claims

Patent claims circumscribe the biologicals that others are excluded from using or making. Here are two examples of expansive biological patent claims. Their breadth is amazing.

US 20080214412:

Claim 73. A method for synthesizing polymers, comprising synthesizing a multiplicity of oligomeric building blocks on a carrier in parallel steps, removing said oligomeric building blocks from said carrier and bringing said oligomeric building blocks into contact with each other to synthesize the polymers.

Claim 74. The method of claim 73, wherein said polymers are double-stranded nucleic acid polymers of at least 300 bp.

Claim 76. The method of claim 74, wherein said polymers are nucleic acid polymers selected from the group consisting of genes, gene clusters, chromosomes, viral genomes, bacterial genomes and sections thereof.

Expansive Patent Claims

US 2008/0260763

Claim 68. A composition comprising a plurality of distinct, individually addressable, and non-pure recombinant proteins of at least one vertebrate pathogen, wherein the plurality of recombinant proteins represents at least 10% of a totality of all immunogenic proteins of the pathogen with respect to an immune response of a vertebrate;

Claim 69. The composition of claim 68, wherein the plurality of proteins represents at least 70% of a totality of all proteins of the pathogen.

What is Compulsory Licensing?

- Compulsory licensing authorizes a 3rd party to make, use or sell a patented invention without the patentee's consent.
- States have the power to take real and intellectual property for a public use, as long as due process occurs and a reasonable compensation is offered.

Compulsory Licensing

Statutory exceptions include:

- Plant Variety Protection Act – to ensure an adequate supply of food.
- The Clean Air Act – to license technology that is vital to preventing and controlling air pollution...
- Lmtn on Medical Practitioner's Performance of Medical Activity
- Atomic Energy Act – nat'l defense and security of nuclear materials.

Historical basis for compulsory licensing in the US

- Sludge case (1934)
- Vitamin technologists
- Antibiotic price fixing schemes (remedy for anti-trust violations)
- Articulated possibility of Cipro licensing for combating anthrax scare...

Compulsory Lic. In Trade Agreements

- Article 31 of TRIPS permits any WTO member country to issue compulsory licenses of patents to address national emergencies,
- enabling governments to license patents to domestic businesses to manufacture low cost generic drugs in the face of national health crises or other national emergencies.
- Now able to export pharmaceutical products manufactured under a compulsory license to WTO member countries lacking manufacturing capacity.

US Role in Stifling Compulsory Licensing

- The US has filed more WTO TRIPS complaints than all other member countries combined. Developing countries have also faced pressure from governments attempting to discourage their use of compulsory licensing and generic drug manufacturing.
- The US has used economic power to threaten trade sanctions or WTO complaints against Thailand, Brazil, South Africa for manufacturing generic AIDS drugs.

DC Compulsory licensing statute invalidated by Federal Circuit

- DC passed a compulsory licensing statute that was challenged in the courts by *pharma* (2005-6).
- The Federal Circuit determined DC's attempt to license to be unconstitutional.
- No compulsory licenses have been issued domestically for affordable pharmaceuticals following this DC model.

NAFTA

- NAFTA's first eleven years, 42 cases and claims have emerged under Chapter 11, giving private enforcement mechanisms for corporations trumping national and state laws.
- Foreign investors get a second chance to litigate the same claim if unsuccessful in a federal court

Metalclad v. Mexico Toxic Waste Facility

- Mexico authorized a Mexican company to operate a hazardous waste transfer station in Mexico
- Bought by a California company, which sought to expand to a toxic waste processing plant and landfill
- Site was contaminated with 55,000 drums (20,000 tons) of toxic & potentially explosive waste.
- Region has complex hydrology, unstable soils, allows toxic waste to infiltrate subsoil and enter water sources.
- There was a community uproar, and the town denied the municipal permit.
- Corporation sued under NAFTA Chapter 11, claiming expropriation.
- **The NAFTA panel awarded \$16 million to the corporation.**