# The 80's: A Decade of Transformation

**A Historical Primer on the Events that Laid the Foundations of Modern International Intellectual Property Regimes**

<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
<th>Description</th>
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<td>1980</td>
<td><strong>Diamond v. Chakrabarty</strong></td>
<td>Supreme court rules that genetically modified organisms may be patented, thereby carving out a major exception to the <em>products of nature</em> exemption for eligible subject matter.</td>
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<td>1981</td>
<td><strong>Ronald Reagan Elected</strong></td>
<td>Under Reagan, the United States Trade Representative (USTR) would exert unprecedented pressure on nations through new powers to sanction. The USTR would also allow unprecedented levels of participation in trade policy by American corporations—even to the extent that many provisions were drafted by industry itself. Under the rhetorical banner of reforms to halt an alleged decline in American competitiveness, policies of corporate welfare would take increasingly blatant precedent over the interests of the American public.</td>
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<td>1982</td>
<td><strong>Pfizer CEO Named Head of US Trade Committee</strong></td>
<td>Pfizer’s Edmund Pratt appointed as chairman of Advisory Committee on Trade Negotiations. Pratt uses position to put intellectual property at the top of US trade agenda. He was arguably the most important figure in the effort to get intellectual property rules into the WTO.</td>
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<td>1982</td>
<td><strong>National Patent Court Created</strong></td>
<td>The Court of Appeals for the Federal Circuit (CAFC) brings nationwide patent arbitration under one roof, concentrating authority that was once distributed broadly among the federal circuits. The force behind the CAFC’s creation was a small cadre of leaders from high-tech sectors, who played a crucial role in its conception and political evolution.</td>
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<td>1982</td>
<td><strong>Definition of “Useful” Expanded</strong></td>
<td>In one of its first rulings, the CAFC declares the utility requirement—one of four basic criteria for the patent eligibility of an invention—to henceforth include <em>useful for further research.</em></td>
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<td>1982</td>
<td><strong>IP Judicial Process Transformed</strong></td>
<td>Though it eliminates forum shopping between federal courts, the CAFC magnifies any bias. In the case of CAFC, that bias has been a very patent-friendly one.</td>
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BIOTECH-UNIVERSITY-INDUSTRIAL COMPLEX

ROYALTIES COLLECTED VIA BAYH-DOLE (VIA LICENSING)

Columbia University $790 M
Northwestern University $700 M
New York University $650+ M
U. California Regents $500+ M
Emory University $525+ M
Florida State University $200+ M

"Axel" Patents
Pregabalin
Remicade
HBV Vaccine
Emtricitabine
Taxol

1983

BOWSHER V. MERCK

Supreme Court rules against Government Accountability Office, who had fought a decade-long battle to access pharma’s disaggregated R&D figures. This ruling set a precedent in classifying R&D spending as proprietary information. The resulting lack of transparency has boosted pharma’s ability to distort the public’s perception of costs.

PCR INVENTED

Polymerase chain reaction would prove crucial to basic research, diagnostics, and the eventual sequencing of the human genome. The patent for PCR would be acquired by Roche.

1984

HATCH-WAXMAN ACT

A comprehensive bill that transformed the regulatory process for both new drug applicants and generic entrants. Henceforth, new drugs are granted five years of exclusivity; first generic entrant (first ANDA approval) receives six months of exclusive competition with originator, and if data for new indication presented, FDA will grant 3 years of exclusivity for the indication in question. Finally, this bill also introduces patent linkage, a key loophole for evergreening tactics.

1974 TRADE AUTHORITY EXPANDS TO INCLUDE IP

Section 301 of 1974 Trade Bill authorized the President to take unilateral appropriate action (i.e. sanctions) against nations that “burden or restrict US commerce”. In ’84, Congress extends this to include adequate and effective protection of intellectual property.

1985

POLAROID CORP V. EASTMAN KODAK

With one landmark case, the CAFC would redefine overnight the norm for patent infringement penalties. Accused of copying Polaroid’s Instant Camera, Kodak appealed to precedent in asking the court to only require it to pay past/future royalties. Instead, the court ordered a full injunction on production and sales, as well as $1 billion in damages.

KOREA THREATENED, SIGNS BILATERAL DEAL

Armed with its new authority to impose unilateral sanctions if IP laws of trade partners are deemed “unsatisfactory”, the USTR threatens Korea with trade penalties if new IP rules are not adopted. Though not in violation of any agreement, Korea folds under the pressure. Going forward, bilateral deals would be a crucial tactic in the divide-and-conquer strategy the USTR employed to overcome opposition to its IP agenda.
LEGAL ECONOMIES OF SCALE AND SCOPE

The legal costs of operating at the frontier of innovation have become increasingly prohibitive for small players. Firms entering established areas often face a simple choice: join a multinational or face slow suffocation by one in courts. The USTR, also armed with new state- or state-sticks, would present similar options: submit or exile.

PATENT WARS

Firms now have arsenals of patents for defensive and offensive purposes. As with any battle of attrition, resources matter most.

PATENT THICKETS

Lower standards for patents lead to expansion of monopolized innovation territory; routes for new exploration blocked or left idle.

PATENT TROLLS

Incentive to troll is boosted. The US, which lacks a “working requirement” on the use of a patented idea, becomes a trolls paradise.

1986

INTELLECTUAL PROPERTY COMMITTEE FORMED

The IPC—a coalition of 13 major high-tech companies—would be the driving force behind the adoption of the WTO’s agreement on trade-related aspects of intellectual property rights, or TRIPS. The IPC included: Pfizer, Dupont, Hewlett-Packard, Monsanto, General Electric, BMS, Merck, Johnson & Johnson, FMC, Warner, and General Motors.

PARALLEL IMPORT BAN

Congress passes the Prescription Drug Marketing Act, which prohibits 3rd parties from importing into the US drugs legitimately obtained abroad. Combined with US rules against international exhaustion—a principle that severely limits a 3rd party’s ability to re-sell patented goods—opportunities for arbitrage in medicines are effectively eliminated. Where such barriers are in place, drug markets may be segmented, and monopolized—a businessperson’s dream, but an economist’s nightmare.

1987

AZT APPROVED: FIRST HIV DRUG HITS THE MARKET

Despite the fact that AZT was discovered in 1964 through publicly-funded research, and despite industry’s extremely minimal role in the demonstration of AZT’s efficacy against HIV, a new-use patent for the drug is granted to Burroughs Wellcome. With a monopoly on the only HIV treatment, Burroughs price the drug at $10,000 a year.

1988

FAST TRACK AUTHORITY GRANTED BY CONGRESS

By approving fast track authority, Congress effectively abdicates to the Executive its constitutional authority on trade matters, and restricts itself to an up-or-down vote on any final deal. Under this mandate, the USTR would negotiate the terms of NAFTA and the WTO, both of which marked drastic expansions beyond the tariff/quota focus of GATT deals.

INDUSTRY MILESTONE

- Tagamet becomes the first drug to reach $1 billion in lifetime sales. By 2013, 55 drugs would reach $1 billion in ANNUAL sales alone. By 2013, Lipitor’s lifetime sales would top $140 billion.

URUGUAY ROUNDS ARE LAUNCHED, IP ON AGENDA

- Held in Punta del Este, the first round would trigger seven years of negotiations—
  that would ultimately set the terms for the WTO. USTR wins crucial battle by getting intellectual property on multilateral trade agenda for the first time.

SPECIAL 301 AUTHORITY GRANTED VIA TRADE ACT

- The Special 301 Report would formalize the system the USTR used to threaten other countries, and also provide US corporations with a direct process and litigator for pursuing complaints about foreign IP laws.

USTR SANCTIONS BRAZIL

- Due to its “unsatisfactory” laws on pharma patents, the US strips Brazil of GSP status. A decade later, the USTR’s aggression would lead President Lula to state that US-led FTAs were “not integration, but annexation”.

MLT—n.m., o.n., u.i., v.r. M.T.

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ONCO-MOUSE

AKA the Harvard mouse, the onco-mouse was genetically modified for cancer research. After filing a patent on the mouse, Harvard would issue an exclusive license for its use to DuPont. The mouse would embody the transformation of medical research in the 1980s, a period that not only saw the increasing privatization of tools for discovering future knowledge, but of entire life forms.

BAYH-DOLE + BIOTECH via recombinant DNA + COMMERCIALIZATION OF BASIC RESEARCH

"In the mid-1990s DuPont began sending out letters to better control the use of their patented Cre-lox technique to engineer mice. The company began to require academic users to give the company reach-through royalty rights. Furthermore, DuPont put restraints on informal exchange of the mice, or any other mice bred to have an oncogene, and required an annual disclosure report and claimed rights in downstream inventions. These practices broke with traditions of making research tools available for free or at reasonable prices for academic scientists." - Winickoff

1989
USTR ISSUES FIRST ANNUAL 301 REPORT

The report classified countries into a watch list and a priority watch list. The watch list included: Indonesia, Italy, Japan, Pakistan, Philippines, Portugal, Spain, Turkey, Venezuela, and Yugoslavia. The priority academic list included: Brazil, India, Mexico, China, Korea, Saudi Arabia, Taiwan, Thailand.

COLLAPSE OF BERLIN WALL

The dissolution of Soviet-led “second-world” political economies would ultimately clear the way for the adoption of the WTO. Though the WTO was paraded under the banner of the Washington Consensus principals of free-trade and competition, the terms of the trade deals often diverged sharply from the economic models leading credence to those principles. By imposing an intellectual property framework on members, the WTO radically broke from precedent. Where the previous international political economy was defined by the waning competing two ideologies, the new international system would be defined by walls around ideas themselves.

"There is a connection between the project of information feudalism and medieval feudalism as both involve a redistribution of property rights. In the case of medieval feudalism...the majority of humble folk were subject to the private power that lords exercised by virtue of their ownership of the land. The redistribution of property rights in the case of information feudalism involves a transfer of knowledge assets from the intellectual commons into private hands. These hands belong to media conglomerates and integrated life sciences corporations rather than individual scientists and authors. The effect of this is to raise levels of private monopolistic power to dangerous global heights.”

- Drahos and Braithwaite

THE 2ND ENCLOSURE MOVEMENT

“We are in the middle of a second enclosure movement. It sounds grandiloquent to call it “the enclosure of the intangible commons of the mind,” but in a very real sense that is just what it is. True, the new state created property rights may be “intellectual” rather than “real,” but once again things that were formerly thought of as either common property or uncommodifiable are being covered with new, or newly extended, property rights...We rush to enclose ever-larger stretches of the commons of the mind without convincing economic evidence that it will help our processes of innovation and with very good reason to believe it will actually hurt them.”

- Boyle

INFORMATION FEUDALISM

ACCESS TO MEDICINES

Patents are not the only barrier that the global poor face when trying to access medicines. Nevertheless, TRIPS has had an immense impact by inhibiting the development of robust markets for high-quality, low-cost generic drugs in the developing world. As the maps below show, when the WTO negotiations were launched in 1986, patents on medicines were the exception, not the rule. In fact, only 49 of the 98 signatories of the Paris Convention required patents on pharmaceutical products.
Pre-TRIPS

Countries Requiring Patents for Pharmaceutical Products

1986

Post-TRIPS

2005

TRIPS n HEALTH

Infographic by Chase Perfect

Primary Sources

Drahos and Braithwaite, Information Feudalism
Sell and Mays, Intellectual Property Rights: A Critical History
Boyle, The Public Domain
't Hoen, The Global Politics of Pharmaceutical Monopoly Power
Maps: 1988 Internal WIPO Document Written for GATT Secretariat