

The new offensive on enforcement of IPRs

- Domestic and international actions
- Pressures on developing countries
- Critical areas: definition of counterfeiting and piracy; permanent injunctions; preliminary injunctions; border measures

European Union: internal market

- Customs Regulation (Council Regulation (EC) No 1383/2003 of 22 July 2003
- Enforcement Directive 2004/48/EC
- Draft European Directive on ‘Criminal measures aimed at ensuring the enforcement of intellectual property rights’

European Union: actions in foreign countries

- Strategy for the Enforcement of Intellectual Property Rights (IPR) in Third Countries' (2005)
- Provide a long-term line of action for the Commission with the goal of achieving a significant reduction of the level of IPR violations in third countries

USA: domestic measures

- The Stop Counterfeiting in Manufactured Goods Act (March 2006)
- The Intellectual Property Protection Act of 2007 ([H.R. 2391](#))

USA-enforcement strategies

- Strategy Targeting Organized Piracy (“STOP!”) Initiative
- National Intellectual Property Law Enforcement Coordination Council’ (NIPLECC)



REPORT TO THE PRESIDENT AND CONGRESS ON COORDINATION OF INTELLECTUAL PROPERTY ENFORCEMENT AND PROTECTION

JANUARY 2008

The National Intellectual Property Law
Enforcement Coordination Council

US agencies involved in the enforcement strategy

- Department of Commerce-International Trade Administration (ITA)
- US State Department
- US Customs and Border Protection (CBP)
- USTR
- US Patent and Trademark Office

Bilateral/regional actions

- Free trade agreements
- Economic Partnerships Agreements

Global action

- WTO: submissions to the TRIPS Council by USA, Japan, EU
- Group of 8:
 - Statement on “Combating IPR Piracy and Counterfeiting”
 - G8 Intellectual Property Experts’ Group

Anti-Counterfeiting Trade Agreement' (ACTA)

- United States, Canada, the European Union, Japan, Korea, Mexico, New Zealand y Switzerland (October 2007)

Developing countries under pressure to...

- Harmonize or 'approximate' laws and procedures
- Create special units/task forces in national administrations

Developing countries under pressure to...

- Criminalize any commercial scale IP violation and consumers for purchasing or possession of counterfeit or pirated products
- Act ex-officio and bear the costs and liability of enforcement of *private rights*

Critical areas

- Definition of counterfeiting and piracy
- Permanent injunctions
- Preliminary injunctions
- Border measures

Counterfeiting and piracy

- Expansion of these concepts to *any* infringement of IPRs
- Linkage to criminal activities and terrorism
- Counterfeit medicines: confusion between IP and public health issues

Counterfeiting in medicines

- WHO definition: fraud in labelling with respect to identity and source; not generics or 'copies'
- Global problem: Switzerland, India and United Arab Emirates top the list of sources of counterfeit medicines.
- Drug regulations, not IP regulations are the main mechanisms to fight against counterfeiting

Permanent injunctions

- *eBAY INC. et al v. MERCEXCHANGE*
- US Supreme Court “the decision whether to grant or deny injunctive relief rests within the equitable discretion of the district courts.”

Permanent injunctions (2)

- *Innogenetics NV v. Abbott Laboratories*
(January 2008)
- U.S. Court of Appeals for the Federal Circuit reversed a permanent injunction against Abbott and ordered the judge to determine the terms of a compulsory license on a patent owner by Innogenetics

Permanent injunctions (3)

- Amgen v. Roche (March 2008)
- Validity and violation of three Amgen patents relating to Roche's 'Mircera' established by District Court
- District judge William Young denied permanent injunction and order a compulsory license in favor of Roche: reduced drug price that would result from competition


Amado v. Microsoft

(Febrero 26, 2008)

- U.S. Patent 5,293,615 (Carlos Armando Amado, Guatemala) "point and shoot interface for linking database records to spreadsheets"

Microsoft requests to Federal court of California a compulsory license, which is accorded with a royalty of US\$ 0.12 per copy (Amado requested US\$ 2 per copy)

The Court of Appeals for the Federal Circuit confirms the license and requests the district court to review royalty payment



EMBASSY OF THE
UNITED STATES OF AMERICA
BANGKOK

THE AMBASSADOR

July 20, 2007

Your Excellency:

When we spoke in late March, before my trip to the United States, I welcomed your assurance that no new compulsory licenses on pharmaceuticals would be issued. I reported this news to my Government and to U.S. industry on my subsequent travels back to Washington, which greatly eased the tension. I now fear that the compulsory licensing issue will soon reemerge.

My Government thinks it is important for all countries, including Thailand, to play a role in, and benefit fully from, the development of new and more advanced medical treatments. Strong protection of intellectual property rights, including through patents, remains a vital part of that process. While all WTO members have the ability to make appropriate use of flexibilities to address urgent situations, these decisions should not be made lightly and only as a last resort.

Preliminary injunctions in patent litigation: France 1984-2004

- 6000 requests filed
- 19 provisional measures granted

Source: Institut National de la Propriété Industrielle

Provisional injunctions in the USA

- Reasonable likelihood of prevailing if the validity of the patent were challenged;
- Irreparable harm (it is not irreparable if an economic compensation may be obtained)
- Proportionality (harm caused to right holder higher than harm caused to alleged infringer if measure were wrongly granted)
- Reasonable likelihood that infringement exists
- Impact on the public interest

Abuses in enforcement: Bristol Myers Squibb

- Bristol Myers Squibb filed baseless patent infringement lawsuits to deter entry by generics

US Federal Trade Commission (2003)

Expanded border measures

- **TRIPS: importation of trademark counterfeiting and copyright piracy**
- **Current demands: *all* IP violations, exportation and goods in transit, ex-officio intervention by customs**

Abuses of border measures: Monsanto and the RR soybean meal

- EP 0546090 et EP 0218571: gene constructs
- Article 9 Biotechnology Directive: genetic information must perform its function in the biological material

World Customs Organizations

- Provisional Standards Employed by Customs for Uniform Rights Enforcement (SECURE)
- Models provisions on border measures

Conclusions (1)

- IPRs are private rights: the burden of their defense should lie primarily with right-holders
- Not all infringements of IPRs are ‘counterfeiting and piracy’
- No evidence that TRIPS-plus commitments are necessary and promote development

Conclusions (2)

- Enforcement measures should contain elements to protect against abuses by right-holders
- Enforcement measures should introduce balances to protect the public interest and avoid abuses