Introduction to Compulsory licences

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Regional Consultation and Planning Workshop
"Use of TRIPS Flexibilities to Access Affordable ARVs in Asia"
Bangkok
29-31 May 2012

Outline

- Compulsory licences and government use
- Overview of post-Doha licences
- Review of recent CLs in Asia
- Lessons learnt

Compulsory licences

- Where does the term "compulsory licence" appear? In the Doha Declaration, in TRIPS Agreement – non-voluntary licences
- Compulsory licences permit 3rd parties to use patented inventions without consent of the patent holder
  - E.g., under a compulsory licence, generic versions of medicines patented in the country may be *locally produced* or *imported* from generic producers abroad
- WTO Members have the right to determine grounds for compulsory licences; i.e., not limited to emergencies
- Compulsory or government use licences are permitted under TRIPS, provided conditions set out are met.
  - What are these conditions?

Conditions for grant

Article 31 of TRIPS does not limit the grounds for grant of compulsory licences but sets out conditions for their grant:

- **case-by-case authorization: 31(a)**
- **prior negotiations: 31(b)**
  - waiver in emergency and public non-commercial use cases: 31(b)
- **scope and duration of licences: 31(c)**
- **limitation on exports: 31(f)**
- **termination of licence: 31(g)**
- **adequate remuneration: 31(h)**
  - waiver in anti-competition cases: 31(k)

Government use

- Government's right to use patent in the public interest, for public non-commercial purposes (Article 31)
  - E.g., under a government use licence, *local production* of generic versions of patented medicines or *import* of generics, may take place for public, non-profit use
- Typically expressed in broadly-defined provisions, with less administrative hurdles. E.g. of state practice: US and UK legislation
- Government use of patents can enable public sector production of generic medicines, or importation of generics for use in, and distribution by, public hospitals

Government use

Although government use is a form of compulsory licensing, there are important distinctions between compulsory licences for private sector vs. public non-commercial use:

- **Government right to use patents**
- **use by or for the government**
- **public purpose**
- **not-for-profit vs. commercial**
- **"*fast-tracking*" – waiver of specific conditions under Article 31**
- **no requirement for prior negotiations with patent holder**

Model Provisions:
Learning from the developed countries

Compulsory licences on public interest ground

Section 47 Danish, Consolidated Patents Act, 1998:

When required by important public interests, any person who wishes to exploit and invention commercially for which another person holds a patent may obtain a compulsory licence to do so.

Government use of patents

United States, 28 USC 1498 (1997):

Whenever an invention described in and covered by a patent of the U.S. is used or manufactured by or for the U.S. without license of the owner …, the owner's remedy shall be by action against the U.S. … for the recovery of his reasonable and entire compensation.

… use or manufacture of an invention … by a contractor, subcontractor or any person … for the Government and with the authorization or consent of the Govt shall be construed as use or manufacture for the U.S.

Interpreting Article 31

Paragraph 4: ***… TRIPS Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and in particular, to promote access to medicines for all***

Paragraph 5:

- ***Each member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted***
- ***Each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency …***

Compulsory licences post-Doha

Country	Type of licence	Reason	Adequate Remuneration
Zimbabwe (2002)	CL to Varichem for local production of ARVs	National emergency	No information
Malaysia (2003)	CL for import of ARVs from India	Government use	Offer of 4% was not taken up
Indonesia (2003)	CL to Kimia Farma for local production of ARVs	Government use	0.5% compensation fee of generic net sales value
Mozambique (2004)	CL to Pharco Mocambique Lda for local production of ARVs	National emergency	Not exceeding 2% of generic sales
Zambia (2004)	CL to Pharco Ltd. For local production of ARVs	National emergency	Not exceeding 2.5% of generic sales

Compulsory licences post-Doha

Country	Type of License	Reason	Adequate Remuneration
Ghana (2005)	CL for importation of ARVs from India	Government use	Not exceeding 1% of retail prices of generics
Thailand (2006-7)	CLs to Govt Pharmaceutical Org. to import or manufacture 7 generic medicines	Government use	0.5% of generic sale price of EFV, LPV/r and clopidogrel; 3% and 5% for anti-cancer drugs
Brazil (2007)	CL for import of ARV from India	Government use	No information
Ecuador (2009)	CL for import of ARV from India	Compulsory licence (non-exclusive)	Tiered Royalty Method: US$0.041 for each capsule of ritonavir 100 mg, US$0.02 for lopinuine (ritonavir and lopinavir combination)
India (2012)	CL for manufacture of generic version of cancer drug	Compulsory licence	6% royalty

Some lessons learnt

Changes to, or clarity in, national laws

- Use the full flexibility available in TRIPS and affirmed by Doha Declaration, including 2016 extension for LDCs

Determining patent status

- Cooperation with Patent Offices to obtain up-to-date and accurate relevant patent information

Effective cooperation between agencies

- Use of TRIPS flexibilities require cooperation between government agencies with different mandates; e.g., public health, trade and commerce, foreign affairs

Procedural and administrative issues

- Procedures for decision-making should be straightforward, transparent and speedy
- Clear, easy-to-apply and transparent guidelines for remuneration or royalty rates

Patent status of key ARVs

			Expected(o) patent expiry date (patent number) in		
INN(1)	**Originator's Trade mark**	**Patent holder(2) (manufacturer)**	**Basic patent priority date**	**International patent application**	**Representative European corresponding patent**
Abacavir (racemic mixture)		Wellcome (GSK)	27.06.1988 (GB8815265)	No	EP0349242
Abacavir (enantiomer)	Ziagen	Wellcome (GSK)	22.12.1989 (US455201)	No	EP0434450
Didanosine - ddI		USA Gov (BMS)	26.08.1985 (US769016)	WO87/01284	EP0216510
improved oral formulation	Videx	BMS	22.07.1991 (US733547)	No	EP0524579
Efavirenz	Stocrin/Sustiva	Merck (MSD, BMS)	07.08.1992 (US926607)	WO94/03440	EP0582455
Indinavir (including sulfate)	Crixivan	Merck (MSD)	08.11.1991 (US789508)	WO93/09096	EP0541168
(related) Indinavir		Merck	07.05.1993 (US059038)	WO94/26717	EP0696277 (withdrawn)
Lamivudine - 3TC (including enantiomer)	Epivir	IAF Biochem (GSK)	08.02.1989 (US308101)	No	EP0382526
enantiomer	Epivir	IAF Biochem	02.05.1990 (GB9009861)	WO91/17159	EP0625150 (rejected)
cristalline form	Epivir	Glaxo	03.06.1991 (GB9111902)	WO92/21676	EP0517145
Nelfinavir mesylate	Viracept	Agouron (Roche)	07.10.1993 (US133543)	WO95/09843	EP0722439
Nevirapine	Viramune	Boehringer	17.11.1989 (US438923)	No	EP0429987
Syrup formulation	Viramune	Boehringer	25.08.1997 (US60/056803)	?	?
Ritonavir	Norvir	Abbott	29.12.1992 (US998114)	WO94/14436	EP0674513
Combination w/ lopinavir	Kaletra	Abbott	13.12.1995 (US572226)	WO97/21685	EP0882024
Saquinavir	Fortovase	Hoffmann-La Roche	11.12.1989 (GB8927913)	No	EP0432695
Stavudine - D4T	Zerit	Yale Univ. (BMS)	17.12.1986 (US942666)	No	EP0273277
Pro-drug		BMS	06.05.1988 (US190809)	No	EP0340778 (withdrawn)
Zidovudine - AZT	Retrovir	Glaxo Wellcome	16.03.1985 (GB8506869)	No	EP0196185
AZT - 3TC combination		Glaxo Wellcome	16.05.1991 (GB9110624)	WO92/20344	EP0513917
Tablet formulation	Combivir	Glaxo Wellcome	31.10.1996 (GB9622681)	WO98/18477	EP0941100 (expected grant 28.05.03)
AZT + 3TC + abacavir	Trizivir	Glaxo Wellcome	30.03.1995 (GB9506490)	WO96/30025	EP0817637
Tablet formulation	Trizivir	Glaxo Wellcome	29.04.1998 (GB9809213)	WO99/55372	EP1083932 (under examination)