Public Health and Compulsory Licensing: Korea's Experience with Glivec

HeeSeob Nam

Access and Incentives: Negotiating Health Care and Intellectual Property Rights
HPAIR (Harvard Project for Asian and International Relations)
Seoul, Korea
24 August 2003

What Problem and Why in Korea?

- Glivec is not Essential Drug and Leukemia is not Epidemic or Neglected Disease
- But Non-Accessibility to Glivec is the same in HIV/AIDS
- Accessibility = Affordability + Availability
- Glivec became available from April 2001 or December 2000

Price of Glivec (Per 100mg capsule)	**Patients' Share**	
	Early CML	Other Patients
KRW 25,000 (Argued by Novartis, 2001)	100%	30%
KRW 17,862 (Set by SKG, Nov. 2001)	100%	30%
KRW 24,050 (Argued by Novartis, 2002)	100%	30%
KRW 23,045 (Re-set by SKG, Feb. 2003) = USD 1220 to 3,050 per month*	20% = USD 415 to 1,037 per month*	

* At 4 to 8 capsules a day

Three Factors related to the Glivec Accessibility

- High Price: Argued by Novartis under Single World-Wide Price Policy
- Pharmaceutical Pricing System (A7 Average Pricing)
  - Adopted in 1999 by the pressures of the US and the EU (Letter of Ministry of Foreign Affairs and Trade to Richard Fisher, Deputy USTR dated April 22, 1999).
  - http://www.ustr.gov/reports/nte/2002/korea.PDF "The Korean Government reached agreement with the United States in 1999 to price new, innovative drugs at the average ex-factory price of A-7 countries (United States, United Kingdom, Germany, France, Italy, Switzerland, and Japan).
  - *Even though the USA doesn't regulate the prices of drugs in the United States, it regulates the prices in Korea. In this case, it regulates the prices to be higher.* [James Love at Cptech.org]
- National Health Insurance System in Korea

- NGOs and CML patients requested to lower the price and broaden the benefits of the National Health Insurance System to Novartis and the Ministry of Health & Welfare

- It dis not take long until the Glivec Coalition recognized that access to Glivec is mainly a problem of monopolistic high price and the monopoly is institutionally and systematically guaranteed by worldwide patent rights granted to Glivec. Thus, the problem is a result of institutional or systematic mechanism.

- Glivec is covered by 43 patents world wide. Basic Patent: FI 9301458 (March 31, 1993, Patent Assignee: Ciba Geigy AG; Entitled “Pyrimidinerivat Oct Forfarande Foer Deras Framstaelling (Swedish); Inventor: Zimmermann Juerg)

- If patients were not organized to voice their position and NGOs in public health and IPRs did not join the patients group, this systematic problems of Glivec would not have been heard in Korea

Patients/NGOs *versus* SKG/Novartis

- At least regarding the price, SKG did not side with leukemai patients unlike other cases like HIV/AIDS, Anthrax and ddI.
- SKG (Ministry of Health & Welfare)
  - Unwillingness of SK Government to lower the price: Even under the A7 pricing system, the maximum price of a drug can be determined independently, when the Minster of Health and Welfare deems it necessary for the management of the health insurance budget, policy or pharmaceutical budget or other reasons [so called, ‘Separate Pricing for the Upper Limit of Cost’]
  - SKG refused to allow patients and NGOs to participate in price negotiation with Glivec.
  - Failed to recognize the link between the high price and the patent right.
  - SKG finally raised the price by about 30% by accepting Novartis’ argument.

- SKG (Korea Intellectual Property Office)
  - Undue delay at KIPO: Allowing about 5 months for Novartis to prepare the first response; Waiting for MoHW's decision with regard to the price of Glivec; and Long but superficial discussion in the Industrial Property Dispute Resolution Committee.
- Novartis
  - Novartis did not accept the price (KRW 17,862) initially set by SKG
  - Novartis avoided official meeting with the patients, while it approached Mr. Kang (former secretary of the CML Patients Group) to have him persuade patients to accept its proposed price level.
  - Novartis warned of trade pressures from advanced countries.
  - Suspicion that Novartis tried to lobby officials in KIPO and members in the Industrial Property Dispute Resolution Committee

Obstacles in Legal Aspects

Text of Patent Law and Interpretation (I)

- Paragraph1(iii) of Article 107 of Korean Patent Law
  - Where a patented invention falls under any of the following subparagraphs, a person who intends to work a patented invention may request the Commissioner of the Korean Intellectual Property Office (KIPO) to adjudicate for the grant of non-exclusive license. ··· (iii) where non-commercial working of a patented invention is necessary for public interest.
- Translation by the KIPO
  - (iii) where the working of the patented invention is necessary for public non-commercial use.
- Japanese Patent Law (Article 93)
  - Where the working of a patented invention is particularly necessary in the public interest, a person who intends to work the invention may request the patentee or the exclusive licensee to hold consultations on the grant of a non-exclusive license.

Text of Patent Law and Interpretation (II)

- Non-commercial Working : Working
- Public Interest : Public Non-commercial Use
- Without ‘Particular Necessity’ Requirement
- No Restriction on a Party Who Can Request a Compulsory License

Procedural Obstacles

- No Formal Document Format
- Identifying Patent Right Sought to be Compulsory-Licensed
  - Prior-negotiation with patent owner and waiting for three years before the request for a compulsory license (Article 31 of TRIPs Agreement) are widely recognized hindrances in obtaining a compulsory license.
  - I spent about three months in identifying the domestic patent related to Glivec even with the helps of pharmacists and experts in patent searching.
  - When patent number is erroneously identified, the request for a compulsory license is dismissed without further reviewing the substantial requirements.

Necessity in Public Interest (Substantial Requirement (I)

- No precedents in finding this requirement.
- As put by German Court, “there can be no universally valid definition of public interest. On the contrary, this term, like any general term, is subject to change. The assessment of the balancing of the interests of the patent holder and of the general public is subject to varying points of view. The decision depends entirely on the circumstances of the individual case [*1996 GRUR 190, 192, 28 IIC 242 (1997)*].

Non-Commercial Working (Substantial Requirement (II)

- A Patentee has an exclusive right to work the patented invention both commercially and industrially (Article 97)
- Definition of Working: In case of an invention of a product, acts of manufacturing, using, assigning, leasing, importing, or offering for assigning or leasing the product (Article 2 of the Patent Law)
- “Commercially and Industrially” means to exclude individual and domestic working of patented invention.
- As a patent right relates to commercial and industrial use, it would follow that a “non-commercial working” falls outside such right. Thus, this requirement becomes absurd and illogical and it is not appropriate to view that the compulsory licensing system under the Korean patent law aims to exclude all the commercial working of the patented invention.

Ability to Work (Substantial Requirement (III)

- NGOs had an intention to work the patented invention, Glivec.
- But NGOs had no resources to produce Glivec
- Domestic pharmaceutical companies had ability to produce Glivec, but no intention to do so. Further, when the domestic companies are the petitioner, the requirement for non-commercial working is probably not met.
- When combining the two requirements of ‘non-commercial working’ and ‘ability to work’, no party can domestically work the patented invention, excepting the government.
- This was the direct reason why NGOs visited India.

Visiting India for Seeking Generic Companies

- Hetero International
- Cipla
- Natco Pharma

Controversies between NGOs and Novartis

Eligibility of the Petitioner

- **Novartis**: Some petitioners are unincorporated organizations and all the petitioners have no human or material resources for working the patented invention.

- **NGOs**: There is no limitations on a person who is able to request the compulsory license. In view of legislative history, any party can be the petitioner under Article 107 of the current Patent Law so long as he/she has an intension to work a patented invention.

Public Interest (I)

- **Novartis**:
  - Novartis supplies and will keep supplying Glivec to meet the demands of patients and thus CML patient access to Glivec is not restricted.
  - The number of CML patients is not so great that the public health will become at risk or that a compulsory license will be required for pubic interest.
  - In testing the public interest, balance between the social interest served by protecting patentees' interests and maintaining the patent system and the public interest served by granting a compulsory license.
  - Grant of a compulsory license for public interest under the TRIPS Agreement is based on the premise that there is an urgent necessity to grant the compulsory license without previous agreement with the right holder in circumstances of extreme urgency.

Public Interest (II)

- **NGOs**:
  - The use of a patent right may trigger the public interest exception when a patent right is regarded to be abusive with respect to all of the individuals in a given area or in a specific conditions (rather to a specific individual having a relationship to the patent right).
  - If the public would derive more benefit by ensuring that Glivec is stably supplied at an affordable price as a result of the grant of a compulsory license than by protecting the exclusive patent right, the working of Glivec patent is necessary in public interest.
  - The public interest must not be denied simply because the patients are not a large constituent. Rather, how serious CML is, how essential Glivec is to CML, how serious consequences would result and how the public interest would fail to be served if the compulsory license for Glivec is not granted, should be equally taken into account in balancing the public interest against the exclusive protection of patent rights of Glivec.

Non-Commercial Working

- **Novartis**:
  - the Petitioners, who have the burden of proof, did not persuasively argue or prove that their working will be a non-commercial working. It cannot be concluded that the working by the Petitioners will be a non-commercial, only because the Petitioners are civil organizations.
- **NGOs**:
  - “Non-commercial working of a patented invention" of the Patent Law would exclude "profit-making" activities from the "commercial and industrial" working. Moreover, taking into account the legislative history of Article 31 of the TRIPs Agreement, the requirement of non-commercial working of patented invention should be regarded as a wide and comprehensive concept that excludes the working of the patented invention for highly profit-making activities.

Novartis Arguments on General Issues

- Compulsory license can be granted for public interest when the government determines that it is practically necessary for a third person to urgently work a patented invention in consideration of the public interest in an urgent and serious crisis.
- Grant of a compulsory license for public interest under the TRIPS Agreement is based on the premise that there is an urgent necessity to grant the compulsory license without previous agreement with the right holder in circumstances of extreme urgency
- If the Petitioners' request is accepted, pharmaceutical companies will be demotivated to develop new drugs.
- Korea, as a member country to WTO, is obliged to observe the TRIPS Agreement. If the request is accepted to grant a compulsory license, there may be a contention that Korea violates the TRIPS Agreement.

Decision of the KIPO

- If Glivec is imported at a lower price, it will be possible to reduce the financial burden of patients who desperately require Glivec to treat leukemia. However, CML is not a disease that is infectious or may cause an extremely dangerous situation in our nation or society. If nevertheless a compulsory non-exclusive license is granted for Glivec merely due to its high price, the basic purport of the patent system, which is to grant an exclusive right and interest to an inventor, thereby inspiring the public with inventive mind and striving for the development of technology and industry, will then become meaningless. Accordingly, the two conflicting interests above should be considered to determine whether a compulsory non-exclusive license should be granted for Glivec.

- All of the CML patients (including those who in chronic phase) are currently covered by health insurance. The patients actually bear about 10% of the price fixed and announced by the Ministry of Health & Welfare. The supply of Glivec is now stable. Also, it is possible to import pharmaceutical products for self-care purposes according to Article 14 of the Foreign Trade Act and Article 7 of the Foreign Trade Management Regulations. In consideration of such present situations relating to the supply of Glivec, a compulsory license for the patented invention (Glivec) is not considered to be necessary for the public interest as prescribed in Article 107, Paragraph 1(3) of the Patent Act.

Implications of and Lessons from the Experiences

Compulsory Licensing as Inherent Limitations on Patent (I)

- Patent right is a government-granted monopoly to exclude others from ‘working’ a patented invention without authorization of the right holder. In effect, patent law makes an inventor to be an owner of the incorporeal or immaterial object, i.e., the invention and the technological information into capitalistic goods
- However, the exclusive nature of patent right is not necessarily because this is logically reasonable or inevitable. For instance, it is also possible to form a patent law with priority with given to the relationships among people to technological information rather than the traditional monopolistic reward conception.
- Recognition of patents as property does not provide the patentee with unrestricted rights to use his/her property in any manner. Most property is subject to limited restrictions that are necessary for the benefit of the public. Likewise, patents may be subject to limitations as both real property and tangible personal property.

Compulsory Licensing as Inherent Limitations on Patent (II)

- Therefore, two fundamental elements that define the nature of patent are: contents of right to be conferred; and limitation or exception of the right.
- Contents of Right: For instance, without any provision in a patent law, it is unclear that if an act of putting a patented article on display infringes a patent right or not. Under TRIPS Article 28, a patentee is conferred an exclusive right to prevent third parties from the act of offering for sale, and hence if the purpose of display is for sale, such an action constitutes an infringement of patent right.
- Exceptional Nature of Patent: This takes on great significance because the patent right is not an absolute approval of unchangeable dominion on an object. Rather, the patent right is variable and relative in its nature depending on economical and social circumstances. Particularly, patent right is an artificially devised monopoly for the purpose of promoting domestic industry by rewarding an inventor to his/her contributions to society, and the patent right, by its exclusivity, can define the social relationships to technological information. In this regard, the variable and relative nature of patent right must be emphasized.

Compulsory Licensing as Inherent Limitations on Patent (III)

- The inherent nature of limitation of patent tells us that a compulsory license of patent is not the case that would only be invoked in ‘exceptionally limited conditions’ such as national emergencies or circumstances of extreme urgency.
- Comparing with other limitations (e.g., non-infringing area or cancellation or forfeiture of the right), the compulsory licensing is relatively passive and partial limitation.
- Therefore, compulsory license can be a tool transforms the monopoly benefit to reasonable remuneration.
- *Maximizing an inventor’s economic benefit is neither the goal nor purpose of the patent system. The economic reward is merely a necessary method of getting new technology into the public storehouse of knowledge. As long as any limitations on patent right does not substantially limit the development and public disclosure of new technology such restrictions are consistent with both with the underlying purpose of patent law and the fact that patents are property.* [Jerome H. Reichman & Caterine Hasenzahl, Non-voluntary Licensing of Patented Invention, UNCTAD/ICTSD, September 2002]

Compulsory Licensing as Inherent Limitations on Patent (IV)

- Global Sales of Glivec

Total	First Half of 2003	2002	2001
USD 1,283 million	USD 515 m	USD 615 m	USD 153 m

- Number of CML Patients in Korea : About 480 (Source: Korea Orphan Drug Center, January 2003) or About 800 (Source: Korea Leukemia Patients Group)
- Suggested Remuneration for Compulsory License of Glivec Patent: 0.9 sFR per 100mg capsule (= USD 0.64)
- Price of Generic Medicine
  - Veenat (by Natco Pharma): USD 2.00
  - Imatinib (by Cipla): USD 1.00

Compulsory Licensing in respect of Human Rights (I)

- The Universal Declaration on Human Rights (UDHR) and the International Covenant on Economic, Social and Cultural Rights (ICESCR) recognized that patent right is one form of human rights: the right of everyone to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he or she is the author.
- At the same time, the international human right frameworks also recognized public right to enjoy the benefits of scientific progress and its application.
- Then, it becomes important to design a patent system that strikes a balance between promoting general public interests in accessing inventive drugs and in protecting the interests of inventors in developing such drugs.

Compulsory Licensing in respect of Human Rights (II)

- Where is the right balance to strike?
- The public/private balance should be accomplished with the primary objective of promoting and protecting human right as was recognized by the Doha Declaration on 'TRIPS Agreement and Public Health.
- From the drafting history of UDHR and ICESCR, it should be noted that: *the rights of inventors are not just good in themselves but were understood as essential preconditions for cultural freedom and participation and access to the benefits of scientific progress; and the rights of creators should facilitate rather than constrain cultural participation on the one side and broad access to the benefits of scientific progress on the other* [Audrey R. Chapman, "Appoaching Intellectual Property as a Human Rights].