

Struggle for Access to Glivec in South Korea

Solidarity Needed Now!!!

What is Glivec?

US FDA approved Glivec, a drug for the treatment of chronic myelogenic leukemia (CML), in May 2001. In fact, Glivec is the one and only drug that is effective for refractory CML patients. But it is still 'not a drug of hope, but a drug of despair' in South Korea.

The Beginning: Struggle for Rights of Access to Glivec, Extremely High-Priced Drug

Korea is the 3rd country to which Glivec was introduced in the world in succession to Swiss. The early release of Glivec in Korea was due to the CML patients' organized efforts of pleading to the Korean Government, and of getting supports from Korean citizens. It was not until Novartis asked the Korean Government to set the price of Glivec \$2,400/month, as high as in the United States and Swiss that Glivec brought a hot issue into the Korean society.

Novartis has stated that it was its policy to have the same price for Glivec in any country in the world. CML patients should pay for Glivec at least \$720/month not to say of other treatment costs with the suggested price taking into account of 30% co-payment for outpatient visit by the National Health Insurance. This is of course from the strong assumption that all the treatment procedures would be within the range of the NHI benefits. It has been notoriously known that Korea has the lowest percentage of GDP invested in Health Care and the highest out-of-pocket payment rate for health care services among the OECD member countries. In addition, patients are sick and unable to make money from economic activities. Korean NHI is far from the social security system that plays a role as the real protection from the disease and poverty.

Accordingly, patients have no choice but to fall bankrupt, which leads to the financial crisis of the whole family and the inability of purchasing the drugs. It was out of desperate struggle that patients fought against Novartis for lower price and asked the Korean Government to cut down the co-payment rate in NHI for the CML patients.

Excluding Chronic Stage CML Patients out of NHI

At the beginning, all the CML patients including those at the chronic stages were to be covered by NHI, which was decided at the Technical Board on Pharmaceuticals meeting, one of whose main activities is to decide the price of the drugs in the NHI formulary. On the other hand, KFDA(Korea Food & Drug Administration) gave the legal permission to Novartis with listing chronic CML as appropriate indication for Glivec usage. Department of Health and Welfare, however, excluded chronic stages of CM out of the health insurance benefits on November 19, 2001 after it ordered KFDA to delete the usage of Glivec for chronic CML indication from the recommended application.

It is impossible to have the Glivec usage for chronic phase covered by the National Health Insurance when we are not sure of its efficacy for chronic stage. Our government's decision was made on the basis of the U. S. FDA lists of indication and usage, said the official in the Department of Health and Welfare. But, we cannot see any apparent reason for Korean Health Insurance to follow the United States' FDA rules.

Disapproval of Korean National Health Insurance Price and Temporal Suspension of Gilec Supply in the Market

The Korean Government set the higher price of 17,890 won(14\$) after Novartis refused to accept the price of 17,055 won. But Novartis gave disapproval to the Government's new offer and thundered a warning that it would retreat from the Korean Market, which was threatening letter to Korea itself.

Novartis suggested to the Korean Government and patients that it would take the burden of patients' co-payment (30% of the total price), but the Government declined the offer without any measure to secure patients' lives.

We interpret the Novartis' suggestion as the intention to get the same price worldwide and to rule the world with the multinational pharmaceutical company's power. It will make no difference to their total profit in the Korean market whether it accepts the Korean Government's offer of 17,862 won(14\$) or whether it wins the war to get 25,005 won(20\$) and then pays the patients' 30% co-payment of the price. The only point Novartis is targeting is to have the impression of good company in addition to getting the only one monopoly price prevailing in the global market.

In the meantime, it happened around November 27 that

Glivec supply did not meet the patients' demand and that some patients could not get the drug because of the failure to produce enough amounts. Since the vigorous protest by NGOs and patients for making steps not to have another chaos, Novartis has been providing Glivec to CML patients for nothing, which is understood as soothing measure to avoid the severer situation to the company. There is no alternative explanation because it is only patients who had been purchasing Glivec before December 2 who are eligible for the free drugs. Therefore, those who were not afford to buy Glivec due to financial problems or those who have the new disease onset can not get the Glivec although they know it will make them free of disease and fear for death.

Novartis is stick to the position that it will talk with the Korean Government again after the price in 7 other developed countries is determined, which is sure to give Novartis a stronger bargaining power. And it will continue to provide Glivec for free in Korea for the time being to make agitated patients calm down.

B. What is the problem?

Priceless Glivec Kills CML Patients

Patent threatens patients' lives by giving the powerful weapon to the pharmaceutical companies such that they have the exclusive rights to produce and sell the drugs. There is the pharmaceutical property right in the heart of the high price of Glivec. TRIPs guarantee the holder of property rights to wield the monopolistic power for 20 years. Novartis is making use of property rights entitled to them to get the good deal out of patients' lives.

Price should be determined by the purchasing power of the people in the market so that patients can afford to pay for the drug. Korean people are buying the 1.4-2.5 time more expensive Glivec among 7 countries such as U. S., Swiss, Japan, Germany, U. K., and France, considering per capita GDP, whose price are the reference to determine the price in Korea. If we consider the co-payment burden, Glivec is 1.5-21 times more expensive in Korea.

B-2

B. What is the problem?

Are you asking 30 times of production costs, Novartis?

Production costs were calculated based on the US Patent on Glivec and brochure made by Sigma Aldrich. It was revealed that production costs of 1 Kg of Glivec as raw material was \$6,499. One tablet of Glivec contains 100 mg of raw material. Thus, it costs only 65 cents to produce one tablet of Glivec in terms of raw material, which is one thirtieth of \$20 that Novartis is asking to be reimbursed. Moreover, we can produce Glivec at one third, one tenth or much lower price if we can buy the raw material at the wholesale price because our calculation is based on the retail price.

B. What is the problem?

Glivec, the Product of Public R&D

Glivec came under the sunshine with the U.S. FDA approval in May 2001, 8 years after Novartis launched the research project on the chemical STI571 that inhibits the activities of cancer cells as the collaboration with the scientists at Oregon Cancer Research Center in 1993. But, the history of research on Glivec goes 30 years back to 1960s. In general, new drug is developed after the cause of the disease is found, and in some cases, the structure of the treatment drug is chemically designed. As for Glivec, since a scientist came to find a unique chromosome anomaly in a CML patient in 1960s, many scientists have contributed to investigating the mechanism of cancer intrigued by chromosome anomaly. Without all the efforts to find a new material that inhibits the activities of cancer cells, chemical STI571 could not have been developed. And Novartis bestowed tremendous favors by the government such as tax exemption on research activities as the results of the pleas of more than 20,000 patients' to FDA, when it almost gave up the drug development due to the exorbitant R&D costs. In other words, Glivec came into the world not by Novartis' own R&D alone, but by the public efforts to avoid the fear from cancer and death.

B. What is the problem?

Exclusion of Chronic Phase CML from NHI, High Co-payment Rate; Patients are Urged to Death.

The Korean Government is not willing to take responsibility at all. It has never taken the initiative during the negotiation sessions until now. Even it set the price above the reasonable limit at Novartis' perspectives and then raised the price again with the failure of resisting Novartis' marketing policy. To our surprise, the Korean Government excluded chronic stages of CML out of the NHI benefits. Patients should pay \$720-1080 per month for Glivec because of 30% of co-payment if they were to be covered by the NHI benefit.

Chronic CML can develop into accelerating/acute phase. No treatment with Glivec would lead to acute stage and to death in the long run. If the current NHI policy holds, patients at chronic stages should wait until they become accelerating/acute phase or should pay \$2,400 per month for Glivec to secure their life. It is apparent that Novartis and the Korean Government urge patients with financial burden to choose to die. Reality tells that more and more patients are giving up treatment themselves because of money although they know that the drug of miracle is out there.

C. Significance of Struggle for Access to Glivec Struggle Stopping Murder by Patent

There have been several debates and disputes concerning health care issues till now. But most of them are related to disputes among health professionals or caused by changes in health policy. The movement for access to Glivec is the first struggle, where people have recognized the influence of intellectual property rights on rights to access of access to medicines. Glivec stimulated the debates about intellectual property rights in South Korea. Many people are now watching neo-liberal globalization destroy public services and medicines vividly, which are directly related to human lives.

C. Significance of Struggle for Access to Glivec First Struggle for Access to Medicine: Patients' Initiative

Patients have been at the heart of Glivec struggle from beginning till now. Patients have initiatives of struggles such as a petition for the early introduction of Glivec, street propaganda insisting the price cutback and insurance coverage expansion, and negotiations with the authority. So this struggle attracts attention of the public. It acts as a kind of political burden to both of government and Novartis. Health care and health policy have a great influence on the daily life of people. But they have not been able to take a part in health policy formulation. They cannot be actors, but consumers. Now, they are influencing actors who take a lead of struggles against giant pharmaceutical company and government.



C. Significance of Struggle for Access to Glivec
Struggle for Access to Glivec: Global Agenda,
not South Korean

Access to medicines such as access to AIDS drugs in Brazil, Thailand, and South Africa is global agenda. Price negotiation will be started in other countries in case of Glivec. In course of these processes, the price must be determined lest patients should not afford the drug. The prices have been decided already in several countries. But the price negotiation through struggles in South Korea will provide an opportunity for ensuring access to the drug in other countries.

*D. Solidarity Needed!!***Novartis Should Lower the Price Patients Can Afford Glivec**

Novartis asks the South Korean government to set the price of drug \$20/1cap (\$2400/month) at the compensation of R&D costs. A drug is neither effective nor safe if patients cannot afford it. It is just 'a drug of despair'. Additionally, Novartis did not develop Glivec independently. It is a result of public efforts. Therefore, rights of access to Glivec should be guaranteed.

*D. Solidarity Needed!!***Chronic Phase CML Should be Covered by NHI,
and Co-payment Rate Should be Cut Down**

It is an evasion of responsibility that exclusion of chronic phase CML patents from NHI benefits force them to fall in crisis. And, which occupies 70%, the burdensome price of more than \$2400/month will aggravate chronic phase CML into accelerating/acute phase. There is no longer any reason for such a 'National Health Insurance' to exist. Government should be responsible for people's health by withdrawing limitation of NHI benefits for chronic phase patients.

Total costs of health care including drug costs and hospital fee exceed \$2400/month per person. It is the same as one-month salary of a worker in South Korea. South Korean government made a promise that co-payment rate would be much lowered. That promise should not be broken.

D. Solidarity Needed!!

Attempt at Compulsory License after Brazilian one

It was declared that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health in 'Declaration on the TRIPS Agreement and public health' passed by WTO ministerial conference in November last year. It was a political victory that confirmed public health protection including access to medicine is more important than patent protection of pharmaceutical company. Compulsory licensing is guaranteed by TRIPS Agreement lest public rights should be disturbed. But compulsory licensing have never been granted in developing countries till now, because of trade retaliation and litigation.

Patent on medicine is the central issue that cannot be taken a long way around in this struggle. In this context, the demand for a compulsory license on Glivec casts a question upon the patent right to medicine. It is a kind of praxis that health protection, the fundamental goal of medicine, is achieved by abolition of a patent, not protection of a patent.

Compulsory licensing can lower the price of a drug by introducing alternative drugs with destruction of the monopolistic patent. Price reduction has a great impact on

treatment of patients and promotion of people's health in this situation where patient's economic status affects access to medicine. It is evident in a Brazilian case in which issuing a compulsory license on nelfinavir made it possible the reduction of price by 40%.

A demand for compulsory licensing will be a challenging struggle against a transnational pharmaceutical capital and a starting point for global anti-globalization movement. Intellectual property rights should not be placed over rights to health, and each country can decide on health policy independently. These are principles.

A

ction plan for Solidarity

We hope you are concerned about struggles for access to Glivec in South Korea. We hope for your support and solidarity.

Endorse the Petition

The petition page is at <http://glivec.jinbo.net>