17 FTA policy- Making in the EU and its Effects : Policies on Geographic Indicators and Medicines/Medical Equipment (*)

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Recently, the European Union has shifted external trade policy priority from multilateral negotiations to bilateral talks, growing aggressive about concluding bilateral or regional free trade or economic partnership agreements. The EU's recent FTAs concluded amid the shift have growingly included new protection provisions on intellectual property rights that are tougher than TRIPs (Trade-Related Aspects of Intellectual Property Rights) Agreement standards, attracting attention along with U.S. FTAs. Generally, the EU's policy shift has been discussed only from the viewpoint of stalled trade liberalization talks at the World Trade Organization. In contrast, this study discerns how political relations within the EU have influenced the EU's FTA policy including the IPR protection policy. Specifically, it focuses on two topics: access to drugs and geographical indications -- and analyzes how EU healthcare and agricultural policy changes over the past more than 10 years have led to new IPR protection provisions in EU FTAs.

I Introduction

In response to stagnant multilateral trade negotiations at the WTO over recent years, industrial countries including the United States and EU nations have growingly attempted to realize IPR protection tougher than the TRIPs Agreement through regional trade agreements, particularly FTAs, instead of WTO talks. Among such attempts to enhance the TRIPs Agreement through FTAs, this paper takes up the moves of the EU. While the United States and Asian countries including Japan had begun to emphasize bilateral and regional FTA negotiations rather than WTO talks, the EU had long retained a trade policy pillar of promoting multilateral WTO talks. Recently, however, the EU has reversed the policy and made clear its attitude of giving priority to concluding FTAs with other countries. Reversing the EU policy was a trade strategy titled "Global Europe: Competing in the World" released by the European Commission in October 2006. Actually, the EU struck the Canada-EU Comprehensive Economic and Trade Agreement, known as CETA, in October 2014, after signing FTAs with South Korea and Singapore. In 2013, it launched FTA negotiations with Japan and the United States.

This paper focuses on the problems of access to drugs and geographical indications in the recent EU FTAs. Drug and agriculture industries have long been mainstay industries for the EU and have grown even more important as exporters. Nevertheless, the EU's recent FTA negotiations indicate that EU countries have been more aggressive than other industrial countries in terms of geographical indications while being less enthusiastic than the United States about drug access. Why has the EU taken such different approaches on the two problems? The EU is now a large union of as many as 28 countries so that its decision-making process reflects various EU organizations' positions, member countries' national interests and various interest groups' opinions. This paper's objective is to ascertain how the EU's FTA policy regarding the two IPR-related problems of drug access and geographical indications is linked to its healthcare and agriculture policies under such situation, by analyzing interviews with EU experts and primary materials.

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Ⅱ EU Trade Policy and IPRs

Generally, all EU external economic policies including trade policies are first drafted and considered by the European Commission before being submitted to the EU Council. In response, the Council authorizes the Commission to conduct external negotiations. The most central actor in this process is the Commission that drafts trade negotiation policies and serves as the only EU trade negotiator. Particularly important is its policy drafting. Trade policies are drafted by the Trade Directorate-General and subjected to its consultations with other directorates-general before being presented to the Council. Internal market matters are referred to the Internal Market and Services Directorate-General and agricultural matters to the Agriculture and Rural Development Directorate-General. The Trade Directorate-General usually consults with the two other departments on trade policies. Since trade problems have recently been related to the environment, development and other matters, however, it has growingly consulted with the International Cooperation and Development Directorate-General and the Environment Directorate-General as well. Based on such inter-department consultations, the European Commission analyzes roadmaps and policy effects regarding the policies. After these consultations, a group of relevant commissioners considers draft policies. Trade policies are considered at the Trade Policy Committee. The TPC informs other EU organizations of the Commission's trade policies and notifies EU member countries of the Commission's policy implementation. Finally, the draft policies are submitted to a college meeting of European Commissioners and then to the EU Council.

Unlike European Parliament members, European Commissioners are not elected through a direct election. Unlike EU Council members, the Commissioners are not given any credentials from member countries' parliaments. Therefore, each directorate-general of the Commission positively contacts non-state actors through regular or ad hoc civil society dialogue and public consultations. Non-state actors participating in many of these meetings include both non-profit organizations like rights and social groups, and profit-making institutions such as enterprises and business groups. Over recent years, enterprises and business groups have rapidly expanded their lobbying of EU organizations instead of their respective governments. In response, the EU created a lobbyist registration system in 2011 to help secure the transparency of lobbying in political processes.

In this way, various opportunities are given for various non-state actors to participate in the process for making trade policies while the European Commission nominally plays a central role in the policy-making process with which the EU Council and Parliament as well engage. Essentially, however, the European Commission's roles in making EU trade policies have greatly changed through the history of European integration. Particularly, these changes have grown more remarkable sine the EU became proactive about concluding new FTAs in the mid-2000s. While the EU has shifted trade policy priority from the WTO to FTAs, effective authorities to make trade policies have concentrated in the European Commission more and more. There are three factors behind the concentration. The first factor is the diversification or complication of trade problems. In recent years, the scope of problems discussed in the trade area has expanded to cover not only tariff and nontariff trade barriers but also intellectual property rights, the environment and investment. Human resources who are well versed in both trade and each of these problems are limited. Therefore, officials in the European Commission's Directorate-General for Trade, including the IPR Unit, have decisive influences on the trade policy-making process. Second, details of recent FTA negotiations have mostly been kept confidential. A general trend for today's FTA negotiations is that progress in negotiations is sequentially and briefly reported with details kept confidential. This is the same case with the EU's FTA negotiations. EU member governments are given opportunities to raise opposition to details of negotiations only when FTA negotiations enter the final stage with FTA provisions mostly fixed. Third, FTA negotiations on IPRs have recently tended to specialize in issues given priority by negotiating countries. In negotiations on traditional IPR treaties, participating countries had generally begun with discussions on basic matters such as definitions and scopes of all IPRs including patents, trademarks and copyrights in a bid to set international standards that all these countries could implement. In most recent FTA negotiations between industrial countries, however, participating countries have concentrated discussions and made consensus only on specific IPRs that they want to protect.

Therefore, European Commission negotiators can concentrate their knowledge and information on a limited range of areas, making it more difficult for others to raise objection to agreements drafted by these negotiators.

Ⅲ International Discussions on Drug Access and Geographical Indications

Issues cited as IPR problems related to drug access include the protection of drug patents and conditions for compulsory licenses. In response to international opinions sympathetic to poor countries over drug access, however, the U.S. government has eased its once tough attitude on these problems. Some developing countries like India are now attempting to develop drug patent systems to the advantage of its drug industry's international competitiveness. While many operational problems are left unsolved, countries with extreme opinions seeking to exempt drugs from patent protection or exceptionally admit compulsory licensing now belong to a minority. Therefore, these problems are not discussed frequently at trade negotiations among industrial and emerging countries.

Rather, international discussions on drugs are making progress in response to drug technology development and drug distribution expansion. Major issues at present include (1) extending drug patent protection periods, (2) protecting drug approval application data, (3) generic drug promotion systems, (4) protecting medical technology patents and (5) protecting biotechnology-related drug patents. No consensus exists on these issues both between industrial and developing countries and between industrial countries. At a time when multilateral negotiations at the WTO remain stagnant with developing countries' opinions growing dominant at other international organizations, how these issues would be solved through other frameworks such as regional and bilateral talks is attracting attention. Particularly, the U.S. government gives priority to the first, second and third issues in FTA negotiations.

As for geographical indications, the TRIPs Agreement, though providing definitions, falls short of specifying how any goods should be protected. It only provides for protection to avoid consumers' misperception or confusion about geographical indications. But the agreement calls for protection for geographical indications for wines and spirits irrespective of consumers' misperception or confusion. The European Community had given top priority to the protection for wines and spirits at the Uruguay Round. After the creation of the WTO, the EU strongly urged other countries to expand the range of products for the "additional protection" to cover not only wines and spirits but also others. But the United States, Australia, Canada, New Zealand and Chile raised strong opposition to the EU proposal, leading the whole of WTO negotiations to stagnate with no consensus formed on the matter. Meanwhile, the World Intellectual Property Organization has set up a working group to revise the Lisbon Agreement, the only international system for the international registration of appellations of origin. Despite vigorous discussions at the group, the number of participating countries is limited.

At present, no international treaty requires countries to take specific measures to protect appellations of origin or geographical indications, leaving protection measures to differ from country to country. The United States and Australia protect them under trademark systems including certification and collective trademarks, while the EU and India have identified geographical indications as an independent IPR for their respective protection systems. Some other countries adopt both protection systems.

Ⅳ Drug Access in EU and FTA Policy

The drug industry has traditionally been a mainstay industry in European countries. Europe has the second largest share of the global drug market after the United States. In 2013, the U.S. share stood at about 41% against around 27.4% for Europe. Research and development spending at large companies in Europe, though less than in the United States, grew smoothly from 1990 to 2010.

Since the early 2010s, however, the European drug industry has faced a difficult situation. R&D spending has stagnated since 2011. While R&D costs for new drugs in Europe have grown greatly as in other industrial countries, European drug makers are required to develop new leading products with patents for their present leading products planned to expire in a few years. As seen in other industrial countries, generic drugs' penetration rate has increased in Europe. In addition to the problems seen in other industrial countries, the EU drug industry has unique problems. First, each EU member country's drug market share is very small, with the European drug

market saturated. Since the principle of free movement of goods works in the EU, goods with prices differing from country to country are imported from countries with lower prices to those with higher ones. Particularly, such parallel imports of drugs can expand due to lower transportation costs, discouraging drug makers from stepping up R&D operations.

As explained above, the European drug industry has reached regional and international turning points. Policy harmonization in the drug area started only in 2006, giving priority to correcting healthcare inequality. Moves to harmonize policies to raise healthcare technology levels throughout Europe have yet to gain momentum. EU member countries strongly resist harmonizing their drug IPR systems. The EU's recent IPR policy has given priority to making a balance between old and new drug market players. Within the EU, conflicts exist between old industry players and between old and new players. EU member countries also have disputes over drug price gaps. Relevant EU policies thus give priority to balancing between different interests. Therefore, the EU is not as proactive as the United States about promoting old drug market players' R&D operations or making it easier for generic drug makers to enter the market through IPR policies.

This is the same case with the EU's FTA policy. Drug IPR provisions in the EU's recent FTAs with others indicate that the EU has asked FTA negotiation partners to adopt provisions similar to U.S.-requested ones for extending patent protection periods and protecting drug approval application data, while being less proactive about taking up in FTAs other problems such as regulating third-party licensing before patent period expiration and protecting healthcare technology patents. Rather than setting new international rules on patent systems, the European Commission wants to expand cooperation in procedures for inspection regarding the code of conduct for drug production and in drug regulation procedures such as the simplification of generic drug approval systems. The Commission's Trade Directorate-General still emphasizes improvement of the IPR protection levels in developing countries and vows to enhance efforts to provide developing countries with legitimate drugs through appropriate routes by enhancing regulations to block the fast-expanding market for counterfeit drugs and by improving the efficiency of the tiered pricing system. Such FTA policy of the European Commission still remains under fire among citizen and rights groups but is popular among European drug makers and industry groups.

Ⅴ Geographical Indications in EU and FTA Policy

Agriculture as well is the EU's mainstay industry. The Common Agricultural Policy, known as CAP, transformed European countries plagued with serious food shortages during and after World War II into big agricultural countries. The CAP initially gave priority to stable food supply. As overproduction grew chronic in the 1980s, surplus products were exported with export subsidies provided. Then, CAP spending expanded. As new European Community members had less production capacity and output than original members, growing gaps between EC members emerged as a serious problem. In response, the MacSharry reform was decided on in 1992 to shift the CAP model from price support to direct payments to farmers. The MacSharry reform was designed to address regional problems. But the eventual bold model reform responded primarily to external relations, particularly U.S. pressure. In the 1990s, EC grain exports began to exceed imports, prompting the United States, exporting grains to the EC, to take advantage of the Uruguay Round launched in 1986 under the General Agreement on Tariffs and Trade to demand the abolition of EU price support and export protection. As a result of the Uruguay Round, a farm trade agreement came for the tariffication of quantitative import restrictions and other nontariff trade barriers, the reduction of domestic support and export subsidies, and other measures. The CAP was later reformed several times. CAP spending has expanded in line with an increase in the number of member countries. But CAP spending's share of total EC/EU spending has declined since a peak in 1985.

In this way, the EU's agriculture grew smoothly based on the CAP that was maintained with priority shifting from productivity to competitiveness and to sustainability. But the global financial crisis in 2008 and a subsequent slump of the real economy greatly affected the EU's agriculture. The EU's agricultural income plunged substantially in line with an agricultural output fall. EU agricultural exports declined sharply in 2009 after expanding smoothly from 2003. Later, however, agricultural exports recovered fast while the EU's economic slump was prolonged with agricultural output leveling off. The EU achieved an agricultural trade surplus in 2010 after a deficit and has expanded its surplus year by year. Driving agricultural export growth since 2010 have been final products including spirits, liquors, wines,

vermouth and processed food products.

In response to the 2009 agriculture slump and later agricultural export growth, the European Commission's Directorate-General for Agriculture and Rural Development has growingly emphasized influences of the protection of geographical indications on the EU's external trade in its agriculture policy. It has concluded that as the enhanced protection of geographical indications grows more and more important in future international economic negotiations, appropriate provisions on geographical indications are a prerequisite for FTAs. The directorate-general has paid attention particularly to growth in final product exports including wines and spirits. At present, most wine and spirit geographical indications protected within the EU are subjected to protection in foreign countries through the TRIPs Agreement, FTAs and agreements specialized in wines and spirits. The European Commission seeks to further boost exports by expanding geographical indication protection in foreign countries to cover final agricultural products including cheese and processed meat.

Such strategy of the European Commission has been remarkably indicated in its FTA policy over recent years. A working paper of the Agriculture and Rural Development Directorate-General calls for giving priority to preparing a list of EU geographical indications to be protected in third countries, to expanding the scope of additional protection in the TRIPs Agreement to cover not only wines and spirits but also other food products and to attempting to have geographical indications coexist with existing trademarks. The EU's recent FTA policy has attracted attention by calling for EU-registered geographical indications to be protected in FTA partner countries, rather than maintaining the EU's past attitude of seeking to create a new multilateral system similar to the EU system. Such EU attitude had been seen at WTO negotiations. The policy seeks to use value-added such as quality and brands for enhancing products having less international competitiveness to promote exports.

The EU and the private sector have established consensus on the FTA policy of the European Commission. EU agricultural groups have consented to the advantage that foreign countries' protection of EU-registered geographical indications for products will add value to the products. Few conflicts of interest have emerged between EU member countries over the protection of geographical indications registered in the EU. No EU member country has raised an objection to providing a list of geographical indications for protection to FTA partner countries. As EU members differ over reforming the present geographical indication system or expanding the scope of geographical indication protection to cover non-agricultural products as well, some members are cautious about allowing the geographical indication protection system itself to be considered at FTA negotiations. But such cautious countries' opinions are now seen as unlikely to block the European Commission from promoting FTA negotiations.