Initial Response to the Korus FTA Pharmaceuticals and IP Chapters

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Today, USTR released the negotiated text of the Korea-US free trade agreement. The text can be found on their website - www.ustr.gov. Enclosed are some of our preliminary thoughts on the text.

I. Pharmaceuticals and Medical Devices Chapter Favors U.S. Firms

The Korus FTA's chapter on drugs and medical devices will force Korean health authorities to favor brand name drugs when negotiating drug reimbursement rates for the Public Health Insurance. This is the second bilateral trade agreement to include a section on the pricing and reimbursement of pharmaceuticals - the other was annex 2c of the Australia-US FTA.

Annex 2(c) was viewed by many as a direct attack on the Australian Pharmaceuticals Benefits Scheme under which reimbursement rates for medicines are set by comparing their safety, efficacy and cost effectiveness to that of existing medicines in the same therapeutic class. Annex 2c included a host of procedural requirements intended to give pharmaceutical companies opportunities to challenge listing decisions by Australian health authorities. There is some debate whether Annex 2c succeeded in this aim; some argue that Australian negotiators effectively protected the most important parts of the program and succeeded in agreeing only to relatively weak notice and procedural requirements most of which were already in Australian law.

The Korus FTA chapter on Pharmaceuticals is based on Annex 2(c) of the US-Australia FTA, yet it is more obstructive and burdensome to health officials in Korea than the Annex 2 (c) is to the Australians.

"Pharmaceuticals" v. "Pharmaceuticals and Medical Devices"

While Annex 2(c) of the US-Australia FTA applies specifically to pharmaceuticals, the scope of the corresponding chapter of the Korus FTA applies to medical devices as well. Article 5.8 defines a "pharmaceutical product or medical device" as "a pharmaceutical, biologic, medical device, or diagnostic product." These types of products can be very expensive. An example of a popular medical device is a cochlear implant for the hearing impaired, which costs over $20,000. Biologics (medicines derived from living organisms) often cost many tens of thousands of dollars as well - one example is Avastin, the $100,000 cancer treatment that saved the life of PhRMA President Billy Tauzin.

"Innovative" v. "Patented"

The US-Australia FTA included a commitment to "promote timely and affordable access to innovative pharmaceuticals." This wording is intentionally vague, allowing negotiators from both sides to claim they won a concession in the deal. The meaning of the phrase depends on the definition of "innovative," which the Australians define as conferring a clinically important improvement in patient outcome. When setting reimbursements for the Pharmaceutical Benefits Scheme, they do not count me-too drugs as

especially "innovative." The US pharmaceutical industry and American trade negotiators tend use "innovative" as a synonym for patented.

In order to avoid further confusion on this matter, the Korus FTA specifically requires greater access to "patented and generic" medicines. It specifies that when a government is determining reimbursement for a specific product, it must "appropriately recognize the value of patented pharmaceutical products and medical devices in the amount of reimbursement it provides." (Art. 5.2.B) This provision may require drug price negotiators to favor expensive brand name drugs over lower-priced generics.

Transparency

Annex 2C of the US-Australia FTA required that the system ensure decisions within a specified period of time, disclose "procedural" rules and guidelines used to assess a proposed listing, afford opportunities to companies to provide comments, provide written reasons for listing decisions, and "make available an independent review process" for the decisions.

The Korus FTA section on transparency contains the same requirements as Annex 2(c) and adds more requirements. Health care authorities are required to provide pharmaceutical companies "meaningful and detailed written information regarding the basis for recommendations or determinations of the pricing and reimbursement of pharmaceutical products or medical devices." Changes in procedures for determining formulary listings be made only if the government formally solicits comments and replies to them in writing. A confirmation letter from the Korean Minister of Trade agrees to create an "independent review body" that is composed of individuals completely outside of the health ministry. Whether this body will have the authority to overturn decisions of the health authorities is left ambiguous in the letter and text of the agreement.

II. Korus FTA Chapter on Pharmaceuticals May Not Affect the U.S.

The chapter on Pharmaceuticals and Medical Devices is designed to hamper the operations of the Korean National Health Insurance. Provisions of the chapter apply to formulary-based price negotiations conducted by the public sector. Nearly all drug prices in the US are negotiated through the use of a formulary, but the negotiations are not carried out through the federal government. Most Americans receive pharmaceuticals at discounts negotiated by private insurance companies. Elderly Americans who receive the prescription drug benefit through Medicare are actually enrolled in private plans which are contracted by the US government - the government is paying money, but the actual price negotiation is carried out by a private firm.

Both the Department of Defense and the Veterans Administration run health programs that directly purchase drugs at negotiated prices. Another chapter of the Korus FTA places rules on government procurement, and a footnote to Article 5.2 exempts these programs from the rules in the pharmaceuticals chapter based on this fact:

> Pharmaceutical formulary development and management shall be considered to be an aspect of government procurement of pharmaceutical products for healthcare agencies that engage in government procurement. Chapter Seventeen (Government Procurement) and not the provisions of this Chapter shall govern government procurement of pharmaceutical products.

This language may effectively exempt DoD and VA programs from the scope of the pharmaceuticals chapter, although there is not explicit text or letter conclusively demonstrating this fact. VA describes its program as a reimbursement formulary and VA officials have privately expressed reservations about the impact of USTR's excursions into this area.

The other major government program that negotiates drug prices in the United States is Medicaid, which provides medical insurance for 47 million poor and disabled people. Medicaid is a health program administered by state governments under federal guidelines. Most state Medicaid programs negotiate drug discounts through open formularies, called "Preferred Drug Lists." In apparent response to public opposition by states to formulary restrictions in FTAs, the Korus pharmaceuticals chapter applies only to each Party's "central level of government." Furthermore, a footnote to Article 5.8 reads:

> For greater clarity, Medicaid is a regional level of government health care program in the United States, not a central level of government program.

This language ensures that government programs that provide drugs for poor Americans are not bound by the same burdensome Korus FTA rules as government programs that provide drugs for poor Koreans.

III. TRIPS-Plus Intellectual Property Provisions

The intellectual property chapter of the Korus FTA is designed to delay generic competition in Korea and thereby keep drug prices higher for longer periods of time. Like other bilateral FTAs, its rules on IP exceed those mandated by the World Trade Organization's Agreement on trade Related Aspects of Intellectual Property Rights (TRIPS). The rules in the Korus FTA are also considerably tougher than the "New Trade Policy for America" (NTPA) framework agreed to by the US Congress and president last week for the FTAs with Panama, Colombia and Peru.

Summary of TRIPS-Plus Provisions

The agreement includes the following TRIPS-Plus provisions:

- Five years of data exclusivity for new chemical entities and three years for less innovative medicines
- Linkage requirement for health authorities to block generic registrations for patented medicines
- Mandatory extensions of patents beyond the original 20-year term in cases of delay in the granting of the patent or registration with health authorities
- Patents required for new uses of known products

Data Exclusivity

When a generic firm seeks approval from health authorities to sell its product, it does not generally repeat the human trials performed by the brand name firm to prove safety and efficacy. Repeating the trials would be unethical, prohibitively expensive, and extremely time consuming. Instead, a generic firm shows that its product is bioequivalent to the brand name drug, meaning that it is chemically identical and behaves the same way in the body.

The TRIPS Agreement requires that the data submitted to national health authorities be protected from "unfair commercial use." In the US, this is done by granting a period of data exclusivity during which time no generic competitors can apply for FDA approval of their products based on the originator's test data. It should be clear, however, that such periods of exclusivity are not required by the TRIPS agreement. Other models of data protection such as monetary payment to the originator in return for use of the data have been proposed.

Korus Article 20.9.1 requires five years of data exclusivity for new chemical entities, and three years of data exclusivity for compounds that do not include new medicinal substances. If one country allows approval based on previous approval in another, a firm may further delay generic competition by not registering the drug in the second country until exclusivity is about to expire in the first.

This is stronger protection than was agreed to the "New Trade Policy for America," which does not explicitly include exclusivity for medicines other than new chemical entities, and which requires concurrent periods of exclusivity in situations where one country bases approval on approval in another country.

Linkage

Linkage provisions in free trade agreements prevent health regulatory authorities from approving the sale of generics while the brand name drug is still under patent. In the United States, our system of linkage has led to widespread abuse since the Food and Drug Administration lacks the expertise to adjudicate intellectual property disputes. Companies are able file patents for insignificant changes to their products and win extensions of marketing exclusivity. In many cases, patents that would not survive legal challenge are filed, but the cost of challenging a pharmaceutical patent is prohibitively high.

Korus FTA Article 20.9.4 requires each country to prevent the health authorities from approving the sale of generics while the brand-name drug is still under patent. The TRIPS Agreement makes no mention of linkage, and the NTPA specifically excludes linkage provisions (though it says some sort of procedural remedy for patent holders will be necessary).

Patent Extensions

The TRIPS Agreement mandates 20 year patents. Many bilateral trade agreements require extensions of patents to make up for delays in the issuance of the patent or in the winning of marketing approval for a new drug. The NTPA makes such extensions optional for the FTAs with Peru, Panama and Colombia, but Korus FTA Article 20.8.3 requires mandatory extensions of the patent term.

Second Use Patents

Often, medicines developed for one disease are found to be effective in the treatment of another. Gleevec, for instance, was originally developed for the treatment of a rare form of leukemia, and was subsequently found to also fight another cancer called GIST. The TRIPS Agreement requires patents for new inventions, but not for new uses of existing products. The NTPA does not address the issue of so-called second use patents, but the Korus FTA confirms that new uses for existing products will be patentable.

CONCLUSION

The Korus FTA includes many provisions that ratchet up IP protection and ratchet down government regulatory and price negotiation powers compared to all previous FTAs. The intended and likely result is clear: drug prices will be much higher, particularly in Korea.