Groundhog Day: Health-related provisions in FTAs and TRIPS

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Session on the TRIPS Agreement in the light of preferential trade and investment agreements

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Text of remarks

When I was asked to address the subject of the impact of preferential trading agreements, and particularly free trade agreements (FTAs), on public health within the context of the TRIPS Agreement, the movie "Groundhog Day", with Bill Murray and Andie McDowell, came to mind. I am sure you will all recall this film in which the flawed protagonist, Bill Murray, wakes up at the same time day after day to find that it is the beginning of the same day. That is the general sense I have about the subject of public health and FTAs. In the movie, while repeating the same day, Bill Murray learns, adapts, and improves himself in order to win the affections of his romantic interest, Andie McDowell, and he eventually succeeds. In the movies, not surprisingly, there is a happy ending. It is not so clear in the real world of public health and FTAs what will be the result. We may be learning and adapting, or we may be repeatedly beating our heads against the same wall.

One comment before I start in earnest on the subject of public health and FTAs. In this morning's discussions it was observed that not very much is going on at the WTO in the area of TRIPS, including in dispute settlement. Perhaps the tobacco cases were mentioned briefly once. Yet to my mind, the tobacco disputes are the second most significant TRIPS case to arise at the WTO, and carry large implications for public health, and for the WTO as an institution. It is clear to me that Australia's plain packaging laws and regulations are consistent with the TRIPS Agreement, and frankly I am doubtful that the Appellate Body will think differently. But, should this somehow go wrong and the tobacco companies succeed (and yes, I understand that only states are members of the WTO), I believe it will more or less signal an end to the brief era of cooperation involving WHO and WTO. It will largely put an end to the idea that the WTO operates consistently with the protection of public health. The environment may revert to the days before the Doha Declaration on the TRIPS Agreement and Public Health. It is imperative to emphasize what is at stake in these cases.

In terms of things that were discussed this morning, I would add my voice to those who have suggested that the knowledge gap about intellectual property, public health and the TRIPS Agreement, such as it may have existed a decade ago, is very substantially closed. If you look at the texts submitted by the developing countries participating in the Transpacific Partnership (TPP) negotiations, you will see that their negotiating positions in the IP chapter evidence a depth of understanding. The counterproposals to the US and Japan (and sometime other friends on the high income country side) are very well done. And this has been the case for a number of years now. To the extent that FTAs are concluded by developing

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countries with provisions that are not supportive of public health, this is not because the negotiators do not understand the subject. I will revert to this when I discuss the political economy later on.

I am speaking to a group of experts, so I am not going to explain each of the points I am making in technical detail. Over the years, I have written about these issues fairly extensively, and refer to previous writing.

Public health and IP issues in free trade agreements for most intents and purposes began as a subject of concern during the NAFTA negotiations in the early 1990s, when the United States was seeking to foreclose Canada's use of its licensing of right/automatic compulsory licensing system with respect to pharmaceuticals, and succeeded. The NAFTA also introduced regulatory data protection with respect to pharmaceutical-related submissions, though in a somewhat softer form than later US-negotiated FTAs. The NAFTA pharmaceutical patent pipeline provision played a role in assuring that the WTO TRIPS Agreement included an MFN provision for TRIPS.

There have been a significant number of US-negotiated FTAs since the NAFTA, and the results of each negotiation are somewhat different, though generally along the same theme. US proposals for the TPP IP chapter contain some significant new and troublesome elements.

First, the United States is proposing to foreclose the introduction in patent law of standards of invention modeled on India's Section 3(d) and the requirement of demonstrating a significant enhancement in efficacy as a condition of obtaining a patent. Of course, a foreclosure of Section 3(d) in the TPP will not directly override India's patent law, but it will foreclose the use of such a standard or test in the law of the TPP countries, and I expect the US views this as moving towards a new international standard that will isolate India and put pressure on it to change its regime.

If you look at the US proposal on codifying a harmonized utility standard in the TPP drafts, it appears to be directed towards eliminating Canada's doctrine of sound prediction which is at issue in the Eli Lilly arbitration claim against the government of Canada under NAFTA. I will not further comment on this here as one of my colleagues is addressing investment chapters and disputes specifically (as is another colleague addressing enforcement matters), but note that I organized a panel session on this at the joint ASIL-ILA Annual Meeting in Washington DC earlier this year, in which Professor Reichman participated, and I can provide a link to that.

The US proposals for the TPP include provisions regarding trademark packaging and labeling that are similar to those included in the ACTA. As I have noted regarding the ACTA, these trademark packaging and labeling provisions present a potential threat to parallel trade in pharmaceutical products, and I presume were inserted precisely for that reason. There is jurisprudence in the United States that replicating a trademark on product packaging constitutes an act of counterfeiting. If this jurisprudence is applied with respect to products as to which trademark rights otherwise have been exhausted, this might present a barrier to parallel trade in these products. While this is a fairly technical matter, I do not think that these provisions have been inserted or proposed for these agreements by accident.

From a public health standpoint, probably the most significant new approach by the US in the TPP is to demand a 12-year period of regulatory exclusivity (following approval for commercial marketing) for biological pharmaceutical products (or biologics). Such a provision would have a major impact on the potential introduction of biological generic products, whether biosimilar or bioidentical. For those not

well acquainted with the field of pharmaceutical regulation, it may be somewhat puzzling why the originator biologics industry demands regulatory exclusivity if the term of patents on particular biological products may (though may not) run as long as the regulatory protection. The reason is that patents are vulnerable to challenge, and the originator biologics industry is worried about this. The US Supreme Court's decision in the *Myriad* case illustrates the cause for concern. Inventions concerning replication of biological phenomenon may be vulnerable to patent challenge on one ground or another, and the industry is worried about this. Regulatory exclusivity is not vulnerable to the same type of challenge as patent. While it may be possible to proceed with some types of challenges to the grant of regulatory marketing exclusivity (such as by demonstrating that the data on which approval was granted was incomplete or misleading), this is not a common type of claim as is the patent validity challenge. The originator industry much prefers to have both patent *and* regulatory exclusivity protection to raise the barrier against the introduction of biogenerics.

If you look at the models of the Australia-US FTA and the Korea-US FTA, you will see that some of the most important provisions with potential impact on access to pharmaceutical products are those that give the originator pharmaceutical industry the ability to challenge decisions by national regulatory authorities regarding whether or not drugs should be included on national formularies, be subject to insurance reimbursement, and so forth. Drug regulatory authorities and expert bodies in countries other than the United States make decisions about whether particular "new" drugs represent genuine improvements over older drugs, and whether the cost of the new drugs can be justified. Giving foreign enterprises the ability to legally intervene in this decision-making naturally will make things more difficult for national regulatory authorities, and may well create financial burdens for national health systems.

In fact, among the main objectives of the US Pharma industry in trade negotiations with the European Union for the Transatlantic Trade and Investment Partnership (TTIP), based on PowerPoint presentations of PhRMA posted online, are to remove market access barriers in the European Union. These include challenging European price controls and decisions by national health regulatory authorities regarding reimbursable products. You will be aware from reading the newspaper that several European health regulatory authorities have recently declined to provide coverage for extremely expensive new treatments that extend life for short periods of time. The US originator industry does not like these decisions, and would like more extensive authority to challenge them.

It is interesting to see the draft European Union proposal for an FTA with Thailand of 2013. The EU proposed that the EU and Thailand be limited to national or regional exhaustion of intellectual property rights; excluding the possibility of international exhaustion. I mention this because to my surprise and astonishment, the EU Commission has lately begun to assert the position that international exhaustion of patent rights is -- or at least may be -- prohibited by the Paris Convention. I would have thought that this issue was completely laid to rest by the Doha Declaration in 2001, which the EU approved, and really even before that in 1994 when the EU approved the Uruguay Round agreements. To what possible end can the EU be reintroducing this issue, the legal answer to which is absolutely clear? Have the EU authorities not suffered enough embarrassment?

This leads to the very fundamental question of why country authorities, including developing country authorities, agree to provisions in FTAs that limit their ability to regulate their own public health systems, and their ability to establish their own intellectual property rules compatible with the TRIPS

Agreement? As I mentioned at the outset, I am not sympathetic to the argument that developing country authorities do not understand the issues sufficiently well. While there may be isolated exceptions, I believe that there is a very good stock of knowledge and expertise among the developing country negotiators, and lack of information and understanding is not the issue.

This is more specifically a political economy problem, and based on factors outside public health. The way the United States typically operates its FTA negotiations is to acknowledge fairly early on that provisions in IP chapters, and other provisions with potential impact on public health, are very controversial. The US negotiators will say, "Given the level of controversy, let's put these issues aside until the end of the negotiations when we will have the other chapters more or less wrapped up, then we can tackle these very difficult remaining issues." Toward the end of the negotiations, the matter will be moved above the level of the usual negotiators, and to the level of heads of state. The US side will approach the president(s) of the other country(ies) and say "We have reached agreement on everything else. There is no room for compromise from the United States side in terms of protection of our pharmaceutical patent owners. There are broad relations between the United States and your country(ies), including military cooperation, finance cooperation, and so forth, and this FTA will cement our relations. But, this requires that you accept our proposals with respect to pharmaceutical patents and related matters." This puts the heads of state in a difficult position, and there is a tendency to accept the US provisions (although in some cases with minor adjustment).

If this is the negotiating model or paradigm, how can those interested in public health resist or change the outcome? Recall that the Health Ministry is usually not among the most powerful in the government. It is the Finance Ministry and the Trade Ministry which tend to "call the shots" in trade negotiations. Is there something that Health Ministries, like Bill Murray in Groundhog Day, can learn from repeated experience and improve the public health outcome in the FTAs under negotiation, or to be negotiated in the future?

I do not have some magic answer or formula. I expect that health-oriented negotiators must better prepare and plan for the endgame. I could suggest they try to inform the president or head of state substantially before the endgame arises, and seek to better influence the concluding discussions. The health-oriented negotiators must be active in helping to rally public support for their position, and to the extent there is a local generics industry make sure that the public and the local industry are on the same page.

As reminded by my colleagues here in the room, national and regional legislatures are playing a bigger role, and it is not a forgone conclusion that the legislative branch will approve the agreement concluded by the executive. So, another key element of pushback can be through involvement of legislators.

This is not a movie, and I am not certain whether there will be a happy ending. The FTAs may continue to restrict access to medicines for the public, and raise prices for public health systems. Or, they may not. We may or may not learn and adapt from repeating the same day.