AMERICAN PHOENIX
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FORGING A NEW CONSENSUS ON TRADE.

NAFTA 2.0: Access to Medicines

One of the goals of this blog has been to facilitate an understanding of the backlash against the global trading system. That system is characterized by a very broad set of complex rules --- opaque, even -- with which few are familiar, even many of those staunchly defending the status quo. An improved understanding of these rules, how they operate, and whom they benefit sheds light on why it is dangerous to dismiss criticisms of the current regime as a paroxysm of populist ignorance. Until criticisms of the system are understood, instead of dismissed out of hand, the system cannot be repaired.

It is no accident that the first post in this blog discussed the effects of trade on inequality. Specifically, it recalled that economic theory posits that trade worsens income inequality, and that theory is borne out in reality. Even pro-trade publications such as The Economist agree that globalisation favors capital over labor. And, as Michael Ignatieff explained,

> [I]t is not the anger of globalisation's losers that ought to worry us most, but the blindness of its winners.

The intersection of intellectual property rights and access to medicine is one of the most salient representations of the extraordinary scope of these agreements; the complexity of the rules; the relative ignorance of the existence of these rules, let alone how they operate; and the conflict between the winners of globalization and the losers.

As Americans themselves struggle to contain rising health care costs, concerns about the price of pharmaceutical products have increased, and will continue to do so. Understanding how our trade agreements address access to medicines is, therefore, relevant to pressing domestic issues.

Intellectual Property Rights in U.S. Trade Agreements

Intellectual property rights (IP) in the first bilateral U.S. trade agreement, with Israel, were captured by a single paragraph. They were expanded in the U.S.-Jordan agreement and, in the original NAFTA, became the subject of an entire chapter. The NAFTA effort ran parallel to the negotiation of an agreement on intellectual property rights at the World Trade Organization.

The IP chapter in the new NAFTA runs to 63 pages. That is longer than the text of the entire U.S.-Israel trade agreement.

Who Benefits from these Provisions?

The standard argument in favor of stronger IP (typically, longer terms of exclusive use) is that pharmaceutical innovation is expensive, and companies must be able to recoup their

investments. The exclusive right to your discovery – a patent – is, after all, provided for in the U.S. Constitution (Article I, Section 8:8). As is a finite period of exclusivity, to be granted "for limited Times."

Thus, the social contract is for patents to provide temporary monopoly rights – and their associated profits. In return, society benefits from innovation, and, eventually, from market competition in the invented product. In the context of pharmaceutical products, for example, market competition comes from generics, which, once the patent expires, are allowed to market off-brand versions.

Do pharmaceutical companies need the specific provisions found in trade agreements in order to recoup their investments? There are at least two reasons to question the premise that pharmaceutical companies need more cash to fund R&D:

- Companies are reputed to spend more on marketing than on research.
- Companies like to spend their net income on share buy backs. Including windfalls from the 2018 tax cuts.

What, exactly, is the nexus to trade, such that these provisions are included in trade agreements? It isn't as though there is no other venue for addressing intellectual property at a global level. As this blog has noted before, the IP chapter applies without regard to whether there is any cross-border transaction. Claims under these provisions aren't limited to whether they affect trade or investment between the parties, as is the case with the labor and environment chapters. Does innovation create jobs? Undoubtedly. But where? Nothing in the agreement requires pharmaceutical products benefitting from the agreement's protections to be produced *in the region.* They can be produced in tax havens instead, for example.

Who are the real beneficiaries, then? Shareholders, it seems. Monopoly rents increase, inuring to the benefit of the rightholders (the companies). Those rents are in turn passed on to shareholders. And executives; CEOs now make some 271 times what the average American makes.

This structure is consistent with the view that, beginning in the 1970s, U.S. trade policy morphed from a focus on returns to manufacturing to a focus on returns to finance.

The 1970s are also the beginning of the Milton Friedman era, where "shareholder value" became the mantra used to justify corporate policies increasingly detached from the communities in which they operate.

But there isn't just a backlash against globalization; there's a backlash against Friedman's attitude *from the elites themselves*. Jack Welch, of all people, referred to the theory of shareholder value as "the dumbest idea in the world."

And of course the most urgent context for a discussion of the balance between monopolies for inventors and benefits to society is the current anxiety over health care costs. Pharmaceutical prices continue to be targeted. Other countries seem to manage these costs by having better domestic strategies in place.

The Administration is trying to follow suit in an effort to control prices in the context of Medicare. This is not surprising; health care is viewed as the Democratic message that delivered them the House in the 2018 elections.

As we will see below, the Administration's efforts seem at odds with the tack taken in the new NAFTA, where intellectual property rights are in some respects even more expansive than they were in the original Trans-Pacific Partnership, and certainly moreso than in the TPP-11.

This gets back to the fundamental issue of the modern trade agreement, which has increasingly become a vehicle for blithely maximizing returns to capital -- with comparatively little consideration for the externalities those returns may cause.

Strong IP rules may be perfectly appropriate for trade agreements. But as long as trade agreements – and trade policies -- continue outsized fealty to finance, with marginal if any regard for the consequences to others, the backlash against globalization can be expected to continue.

Summary of May 10th on Access to Medicines

The groundbreaking May 10th Agreement has been discussed here before. In addition to tackling labor and environmental issues, May 10th also tackled access to medicines. Specifically, May 10th sought to modify U.S. trade agreements to moderate some of the provisions that were viewed as unduly inhibiting access to medicine in developing countries.

There were four key issues that May 10th sought to address. This House Ways and Means Democratic Staff Report goes into the issues in more detail, but briefly, the issues are as follows:

- *Data exclusivity*. In order to obtain government approval to sell a new drug in the United States, the manufacturer must provide clinical data on the safety and efficacy of that drug. Clinical testing is expensive, so the manufacturer is typically afforded an exclusive period of time during which other manufacturers (*e.g.,* generic producers) may not piggy-back on the data in order to be able to make and market the drug themselves.

  After the original NAFTA, trade agreements began to include a provision on data exclusivity. They provided for a period of exclusivity of minimum of five years from the date the marketing approval is granted in a particular country. (*e.g.,* US-Australia FTA,

Article 17.10.1(a)). However, the concern has been that manufacturers do not necessarily rush to developing countries to market their drugs, depriving those countries of the medicines.

May 10th changed the trigger for the five-year period for developing countries. Instead of using the date of marketing approval *in that country*, the trigger is the date of marketing approval *in the United States.* (Peru FTA Article 16.10.2(b)). This incentivizes manufacturers to market their products simultaneously in the United States *and* developing countries, while preserving the manufacturer's five-year period of exclusivity.[1] (The period is "normally" five years, and thus there is room for exceptions.)

- *Biologics*. Biologics are not a May 10th issue *per* se, but TPP surfaced a number of questions about the data exclusivity period for biologics, whether for developing countries or developed countries.

  There is an ambiguity in the May 10th language as it relates to biologics. The data exclusivity provisions hinge on the marketing of a pharmaceutical product that utilizes a "new chemical entity." (Peru FTA Article 16.10.2(a)). New chemical entities are associated with drugs, rather than biologics. However, the data exclusivity provisions more broadly cover "pharmaceutical products" rather than just drugs, and thus the intent seems to have been – and logically would have been – to cover both drugs and biologics. The alternative is that none of the trade agreements concluded between the original NAFTA and TPP (*e.g.,* the agreement with Central American countries (Article 15.10(1)(c)) provides any protection for data submitted in connection with marketing approval for biologics – an outcome that biologics producers cannot be comfortable with.

  For biologics, the question is not simply about when the five-year clock begins to run. The question is whether the period of exclusivity is in fact five years. This proved to be one of the most significant issues in TPP, where pharmaceutical companies – with key Congressional support -- were pushing for a period of exclusivity of 12 years.

- *Patent term extensions*. Patent terms are set by TRIPs at 20 years from the date of filing, as opposed to the date the patent is granted. (Article 33). In the original NAFTA, parties were authorized – but not required – to extend the patent term to compensate for delays due to the regulatory approval process. (Article 1709.12). Subsequent U.S. trade agreements required governments to extend patent terms if there were "unreasonable delays" in granting the patent, or an "unreasonable curtailment" of the effective patent term because of marketing approval delays. (*e.g.* CAFTA Article 15.9.6)

[1] Technically, the five-period runs from the date of the first marketing approval in one of the parties to the trade agreements. In bilateral agreements with the United States and a developing country, that party will typically be the United States. In a multiparty agreement such a TPP, that party might be Japan.

May 10th eliminated the obligation and effectively returned to the original NAFTA standard of making patent term extension permissive. (Peru FTA Article 16.9.6)

- *Linkage*. Linkage refers to the mechanism by which the ability of a government to issue a marketing approval (will FDA let you sell it?) is tied to whether the product in question is covered by a patent (did PTO gives you exclusive rights to it?). Linkage as found in U.S. trade agreements requires no investigation of whether the patent is actually valid; rather, if a product is covered by a patent, then no marketing approval can be issued to a generic manufacturer. (*e.g.*, CAFTA Article 15.10.2) May 10th moved away from the prescriptive solution of mandating linkage and instead provided that parties should have notice and judicial or administrative remedies to adjudicate any conflict. (Peru FTA Article 16.10.3)

- *The right to protect public health*. In 2001, some six years after the entry into force of TRIPs, WTO Members agreed to a declaration that recognized that the IP agreement does not, and should not, prevent a party from taking measures to protect public health by promoting access to medicines for all. May 10th folded this language into the IP chapter. (Peru FTA Article 16.13)

  (It is worth noting that people often confuse the language in the declaration with the standard for compulsory licensing, *i.e.*, that compulsory licensing is only authorized in cases of extreme urgency or national emergency. That is not correct. Article of 31(b) of TRIPs authorizes compulsory licensing provided the WTO member has "made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time." The obligation to make these efforts is what does not apply during cases of extreme urgency of national emergency. The availability of compulsory licensing is confirmed by Article 20.F.5 of the new NAFTA.)

As noted above, May 10th was designed to be applicable to developing countries. However, there is a legitimate question about whether it is also appropriate for developed countries. Indeed, the TPP-11 seem to think so. While this blog has criticized the TPP-11 for deeming the agreement "progressive" even as it walked back some of the labor provisions applicable to Vietnam, the TPP-11 version *does*, for all parties, eliminate any obligation to provide data exclusivity (for drugs or biologics) or to extend patent terms. (TPP did not have the pre-May 10th language on linkage. (Article 18.53))

NAFTA 2.0

- *Biologics*. As noted above, biologics was not a May 10th issue *per se*, but TPP highlighted the fight over the appropriate period of data exclusivity. In prior agreements, the period of exclusivity has been five years (if you assume the language is not limited to

drugs, as discussed above). TPP-12 arguably extended it to something approaching eight (the language is ambiguous, likely intentionally so). (Article 18.51).

NAFTA 2.0[2] provides an even longer period of exclusivity than did TPP-12 – 10 years instead of what was at most eight. (Article 20.49)

From the perspective of U.S. domestic policy, anything above seven is controversial. The Obama Administration had sought to change the period of exclusivity from 12 years to seven, and Congresswoman Jan Schakowsky has introduced legislation to that effect. The relentless push in TPP to lock in 12 years was seen as a direct effort to prevent Congress from rolling back current law.

For Canadians, their government will now be required to change its laws – something not required under TPP, even before the suspension of provisions. Canada currently provides eight years of exclusivity both for drugs and biologics. Canada has a grace period to come into compliance with the new NAFTA. (Article 20.K.4(c); Article 20.90.4). Mexico had agreed to eight years under TPP, but the TPP-11 suspended the biologics provisions. Mexico has no data exclusivity provisions for biologics (or drugs).

More generally, the chapter defines pharmaceutical products as "drugs" and treats biologics as a separate category. In some places (Article 20.48); , but not others (Article 20.49). Apparently a biologic is both a pharmaceutical product, and not a pharmaceutical product, all at the same time! This kind of drafting is an offense to the Vienna Convention on the law of treaties. It was borrowed from TPP-12 (Articles 18.50 and 18.51). No wonder the 11 remaining parties suspended it the minute the United States walked away.

As a matter of sound drafting, if drugs and biologics are to be treated differently, then have two separate sections covering drugs on the one hand, and biologics on the other, instead of torturing the phrase "pharmaceutical product." When clear, consistent drafting is not in play, something is afoot. Perhaps in this case, it's an effort to paper over the semantic issues in previous agreements' treatment of data exclusivity, as noted above, so that biologics both can been seen as benefiting from the previous agreements' protection of five years, while getting an extra five years in this agreement.

It is difficult to consider this type of three-card monte a legitimate mechanism for addressing such a critical issue. It is certainly the kind of undertaking that contributes to the view that trade negotiations are a product of crony capitalism; this is particularly

[2] The link worked when this paper was first drafted; perhaps the legal scrub has been completed. Canada has posted a text with different numbering, and it does not include any disclaimers about legal review. https://www.international.gc.ca/trade-commerce/assets/pdfs/agreements-accords/cusma-aceum/cusma-20.pdf

true in light of the asymmetrical access that the beneficiaries of these provisions have to the negotiating process. Including reviewing, and commenting on, classified text.

- *Data exclusivity for drugs.* These provisions are consistent with those prior to May 10th. (Article 20.48) Mexico must comply with this provision within five years. (Article 20.K.1(3)(d)).

  May 10th did not have a "graduation" provision *per se*, although it did state that agreements "could include a provision calling for the periodic review of the implementation and operation of the IPR Chapter, and giving the Parties an opportunity to undertake further negotiations." It also noted that it might be possible for economic development to warrant amendments.

  In that context, requiring Mexico to implement this provision within five years, regardless of whether Mexico remains a developing country at that time, is not consistent with May 10th. This is all the more applicable because NAFTA 2.0, unlike prior agreements, does in fact have a review mechanism of the kind suggested by May 10th.

- *Patent term extension*. These provisions require adjustment of the patent term for pharmaceutical products (Article 20.44, Article 20.46). Mexico has a grace period of 4.5 years for curtailment. (Article 20.90(3)). It is not clear whether Mexico currently provides patent term extensions for delays, but there is no grace period otherwise.

  Canada also has a grace period, but for unreasonable delays rather than curtailment. (Article 20.90.4). While Canada would not be subject to May 10th with respect to this provision, the fact that Canada does not currently provide for extension of patent terms for delays – coupled with the TPP-11's suspension of these provisions -- suggests that such terms are not necessarily the only appropriate redress for unreasonable delays. As discussed above, this is an unusually prescriptive remedy.

- *Linkage.* This language is largely consistent with May 10th, and applies to all parties, whether developing or developed. (Article 20.51)

  However, there is a criticism of the linkage regime in U.S. trade agreements that has nothing to do with May 10th or the level of development of the parties to the agreement. Linkage is provided for in Hatch-Waxman legislation from 1984. But the only aspects of linkage that are reflected in U.S. agreements are those that favor the rightholder – that is, the blocking of approval for a generic for a product covered by a patent. Hatch-Waxman limited the duration of the stay to a maximum of 30 months; the rightholder is obliged to pursue patent infringement litigation within 45 days; and generics are incentivized to *challenge* patent validity by being granted their own period of exclusivity in the case of a successful challenge. These elements are missing from U.S.

agreements and thus reflect a one-sided approach that favors rightholders at the expense of generics (and, arguably, the public fisc).

- *Public health.* The relevant provisions of the Doha Declaration are included. (Article 20.6.)

"Evergreening." Evergreening is the practice of having patent protections extended beyond the initial 20-year term. Concerns have arisen with respect to language in U.S. trade agreements that arguably facilitates evergreening. The language, found in the new NAFTA, makes patents available for "inventions claimed as . . . new uses of a known product, new methods of using a known product, or new processes of using a known product." (Article 20.36.2.) This language is not found in TRIPs. However, it is not new to NAFTA 2.0; it was, and remains, in TPP-11, and similar languages dates back to earlier U.S. agreements, such as the U.S.-Korea trade agreement. (Article 18.8.1) Critics of this language contend that it allows companies to obtain a new patent term through something less than a genuinely new invention.