

## **CHO Seminar #6 Professor Peter Drahos and Dr David Graham.**

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The theme of my talk concerns the effects of the trade and intellectual property regime on drug regulation. I'll begin by saying a few words about the way in which the linkage between intellectual property, trade and drug regulation has emerged and then give an example of the way in which trade-related intellectual property rights have specifically affected the work of drug registration authorities using the example of data protection – the data that is submitted by pharmaceutical companies to drug registration authorities as part of the drug registration process.

Intellectual property and trade are linked. This linkage happened in the 1980s. Essentially, what happened was that the United States decided that it was time that intellectual property rights were introduced into the trade regime, or what was until then known as the General Agreement on Tariffs and Trade, the GATT. It wanted to pursue this agenda because it was an intellectual property exporter and from a trade point of view it made a lot of sense to do this. What we saw during the 1980s was a progressive integration of the intellectual property regime and the trade regime, and as I'll explain, that integration has had certain consequences for drug registration authorities around the world.

The US has a very clear agenda on intellectual property rights and trade. You can read it for yourself if you visit the website of the United States Trade Representative. The basic idea is that the US will continue to use the trade regime as a way of strengthening intellectual property rights standards around the world. The US wants higher standards such as longer terms of patent protection, no exceptions to patentability and so on. It also wants other states to get tougher on the enforcement of these higher standards. The way it achieves this global agenda is by getting countries to sign free trade agreements that contain chapters on intellectual property that meet US standards. In a bilateral negotiation the US will typically have much more bargaining power.

US bilateral activity on intellectual property is extensive. Picture maps of the world showing IP and they will be covered with arrows that look a bit like stealth fighters flying in over many countries, indicating that that country has signed a bilateral agreement with the US. It's either a free trade agreement or an investment agreement that's got an intellectual property component in it. There might also be a specific bilateral agreement on intellectual property.

There are many countries that have signed off on higher intellectual property standards with the US at a bilateral level. We see a lot of activity now in the former Soviet Bloc countries and in Asia. This is a pretty big agenda. The US is going around and involving all these countries in an intellectual property regime.

Australia concluded a free trade agreement with the US in 2004, as you all know. Then there's North America, and also a lot of activity in the Caribbean, and South America. There are others, such as with Thailand, that haven't been concluded yet.

Brazil is the one outstanding candidate that has not yet signed up to this US intellectual property agenda. Brazil is a big resister. For a variety of trade reasons it has not gone down this path of ever-higher intellectual property standards.

There are lots of consequences of this globalisation of stronger and stronger intellectual property rights, not just in the area of medicines, but right across the board because intellectual property rights affect pretty well every industry.

One very important consequence of this process is that there are now only three countries in the world that don't have a patent office. That is, there are only three countries in the world in which a pharmaceutical company cannot register a patent. Interestingly, Kirabati is not one. Kiribati has a patent office. It runs what's known as a re-registration system so that a company in the UK that has been granted a patent can tick a box and basically get a patent in Kiribati. Indeed, there are about 17 pharmaceutical patents registered in Kiribati. Why one would want to register a pharmaceutical patent in Kirabati I'm not clear.

It's important to note that the globalisation of pharmaceutical patenting is profound. It is very extensive. So here we have two regulatory regimes, the intellectual property rights regime and the drug registration regime. When you get a patent all you get is the right to exclude someone from copying your invention, you're not getting an authorisation from anyone to put your product on the market if authorisation is required. So in the case of medicines you're not getting a right to market - a patent is not a right to market medicines. Once you have patented a medicine you have to go to a drug registration authority and that drug registration authority will give you the authorisation to market it, provided you as the owner of the medicine have satisfied certain criteria.

This is a simplification. I'm not the expert on what drug registration authorities do in detail, but essentially an authority will look at the relevant medicine and assess it from the points of view of quality and safety. It looks at a whole bunch of clinical data that the company will have submitted with its application for registration. It will also look at efficacy - whether the drug does what is claimed for it. That is a lot of data. Pallet loads of data are submitted to drug registration authorities around the world, at least to authorities that do the job properly, like the TGA and the US FDA for example.

Now I come to the more detailed part of my talk. As I've said, a pharmaceutical company will submit a lot of data to a drug registration authority. So one very important question is, what use can a drug registration authority make of the data that is submitted to it by a pharmaceutical company? This is a very important question, because it's not just valuable to the company and it's not just valuable to the drug registration authority, it's actually valuable to the public. It is also valuable to other companies as well. For example, when the patent expires a generic company may well want to register a generic medicine and it may want to rely on the data that's already been submitted in relation to that product rather than re-run the clinical trials. That would be very expensive and very time consuming and it would also delay the entry of the generic product onto the market. Aside from that there are ethical issues about re-running trials involving human subjects the results of which have been established.

You can see why the question of what drug registration authorities can do with the data is extremely important from the point of view of ensuring that generic companies can enter the

market and that competition takes place in the off patent period. It has important implications for the price of pharmaceuticals.

Essentially what's happening as a result of the intersection of the trade and intellectual property rights regime is that a new kind of intellectual property right is evolving. I am not talking about patents here, I'm talking about a different kind of intellectual property right. This is referred to as data exclusivity or data protection. These terms mean different things.

TRIPS stands for trade-related aspects of intellectual property rights. It's an agreement that is administered by the World Trade Organisation. That agreement contains an international standard for the protection of data - the data protection standard. That's what TRIPS contains and it's very important not to confuse it with data exclusivity. They are two very different standards.

I've prepared a list of the essential criteria for the application of the data protection standard. It only applies to new chemical entities. That's very important. The data itself must be undisclosed, so if the pharmaceutical company wants the data to be protected the data must not be in the public domain. The data must also have required considerable effort to generate. That's what the TRIPS standard says. If the data is the product of routine work (bearing in mind that a lot of data is already in the public domain), and it's submitted to a drug registration authority as part of the registration process, then under the TRIPS standard that data is not entitled to protection.

The obligation under the TRIPS standard consists of two parts. The first relates to unfair commercial use. A drug registration authority is not allowed to use the data in a way that would be commercially unfair to the originator of the data. For example, a drug registration authority could not sell the data to a generic company. That would be a breach of the obligation of protecting against unfair commercial use. And of course the drug registration authority must not disclose the data to anyone else - once the obligation attaches you can't disclose the data. So the drug registration authority couldn't put it on its website.

Data exclusivity in contrast to data protection is a new kind of standard, a standard that is evolving through free trade agreements. I have talked about the multilateral standard in TRIPS (the data protection standard). The data exclusivity standard is not multilateral, but is evolving bilaterally through free trade agreements.

Cutting a long story short, both the European Union and the US want higher standards than those that were agreed to in TRIPS. They actually want a more proprietary approach to this data that would increase the number of restrictions on the data. In other words, the drug registration authority could then make less use of it than under the data protection standard.

Now cast your mind back to all those dozens of agreements on the world map. The US is going around the world signing countries up to particular standards. In each of these agreements it is inserting the higher standard in the form of the data exclusivity standard. The European Union is doing the same. The European Union has quite robust standards of data exclusivity.

In these free trade agreements we actually see set time periods for exclusivity. So, for example, the drug registration authority cannot make use of the data for at least five years.

The TRIPS standard does not have any duration of time specified. It just says “protection” and leaves it up to the country to decide the length of protection.

There are other ways in which these FTAs complicate things for drug registration authorities. Let’s take an example of, say, Honduras. A generic company in Honduras decides that it wants to register a medicine in Honduras, and decides to rely on the foreign registration of that medicine, let’s say by the FDA in the US. Under the bilateral agreements that have been negotiated, the Honduras drug registration authority could not rely on the fact that the medicine had been registered by the FDA. So the generic company could not rely on foreign registration. The data exclusivity standards in FTAs also include protection of disclosed data - information that is in the public domain in other words.

We should note that data exclusivity is independent of the patent term. So, say for one reason or another the patent becomes invalid. Data exclusivity is not affected by patent invalidity. If you have adopted the European standard of ten years of data exclusivity you have a significant barrier to entry.

And the way in which these FTA agreements are drafted is ambiguous. Whoever writes them no longer uses the language of TRIPS. Instead of referring to new chemical entities they refer to new products. What does this mean? Does it include new uses of old products? And if that’s right, where does that take us?

In the normal course of events data exclusivity is not going to operate as a barrier to entry. Imagine you have a patent period, which begins at some point, and then marketing approval is given by a drug registration authority. And let’s say you have agreed to the US standard of five years. So the period of data exclusivity runs from the date of marketing approval and goes for five years. Typically data exclusivity will expire before the patent expires. Once the patent has expired the generic company can come in and make the product.

However, data exclusivity will be a barrier to entry if a patent is unavailable for some reason. There will be situations in which countries decide not to grant patents because they may involve a method of human treatment. This is an exception that is permitted under patent law. Alternatively a patent may not be available because it fails to satisfy the criteria of patentability. The drug may not be novel, it may not be inventive, it may have no utility; there are a whole bunch of reasons. Nevertheless, data exclusivity protection is independent of patentability.

The second reason why data exclusivity might matter is if a patent has been declared invalid by a court. If the generic company takes the view that it is facing a weak patent, it may take the company that holds the patent to court. But even if the generic company wins the case it may be faced with a period of data exclusivity.

So, we’ve seen that the trade and intellectual property regimes are creating new kinds of obligations on drug regulation authorities and placing restrictions on what they may or may not do with data. That’s one impact.

A second impact is occurring in the form of a linkage between patents and the drug registration process itself. There are two views of this process at work here. The first is what I call the private rights view. This is the view that a patent is a private right and if a patent owner wants to enforce it against a company then that is a decision for the patent owner. One

implication of that view, or one consequence of the private rights view, is that the drug registration authority should not get involved in a dispute between, say, the patent owner and, say, a generic company.

For a long time drug registration authorities around the world simply took the position that their job was to decide on criteria of safety, efficacy, quality and that they would not get involved in any way in patent disputes or play the role of enforcer in some way.

However, there is a second view which is being articulated by the US but not this time by the European Union. This view says that a drug registration authority should have some procedure in place for not registering drugs that in some way may be implicated in patent infringement.

This is a very different view. It holds that a public authority should in some way get involved in the process of private rights enforcement. The linkage view, the view that drug registration authorities should get involved in patents in some way is the view that the US is pushing in FTAs. It is more than just a view. US FTAs contain standards that impose obligation on drug registration authorities to ‘police’ for patents.

It’s very important to understand that one of the standards that we find in these bilateral agreements is a standard that says drug registration authorities should provide some kind of procedure or should prevent the marketing of drugs to which a patent claim attaches in some way. If you sign one of these agreements you basically have to accept this US standard. The US does not really negotiate on intellectual property – it’s a non-negotiable issue as far as it is concerned.

It is very resource intensive for a drug registration authority to run a drug patent linkage system. I’ll use the example of Canada here, because Canada has had the longest experience, aside from the US, of running such a system. First of all, you have to have a patent register onto which all the relevant patents are put. Then you have to have people in the drug registration authority who can decide and evaluate these patents. You have to have experts in interpreting patent claims. You have to have experts who understand patent litigation. You have to have statisticians who know this stuff and can track what is happening. You need a whole branch, and in fact that’s exactly what we see in Health Canada. We see the Office of Patented Medicines and Liaison.

Another consequence of accepting a patent linkage view is that it’s very litigation intensive. I’ve taken some data, which is publicly available data, from the Office of Patented Medicines and Liaison and, as of April 2005, there were 419 medicines on the patent register and they were affected by 128 patents. I was in Canada recently talking to the Office of Patented Medicines and Liaison and they told me they’re in court every day. We had a two hour round table meeting and when we walked out they’d been served papers on a case. The Secretary came running up to the boss and said: “Look we’ve been served while you guys were having a round table.” So, you are in court almost every day, that’s just how it is.

I’d just like to end with this little quote that describes the costs of running a patent linkage system.

“When a drug patent is about to expire, one method some companies use of prolonging it is to file a brand-new patent based on a minor feature such as the colour of the pill bottle. In this

way the brand company buys time through repeated delays (because typically they'll go to court, get an injunction and so on). In the meantime the lower cost generic drug is shut out of the market.”

Who said this? George Bush, at the Rose Garden on October 21, 2002. He obviously had a very lucid moment that day describing the effect of patent linkage in the US. So it's not just in Canada. Governments around the world, particularly in Canada and the US, are realising the real costs of this system for market competition and therefore prices of drugs.