

## It Was All So Different Before Nothing Changed

Well I was confused. The Intellectual Property protections of the Trans-Pacific Partnership had been published and these radical new agreements were going to: 1) disrupt commerce and end innovation throughout the world; and 2) strip nations of their sovereignty and deprive millions of people of access to their basic necessities. Apparently, it depends on whether you listen to Fox News or MSNBC.

And so, in one of the worst personal decisions I had made since I traded a Land Rover for a dog and a cat, I decided to actually read Chapter 18 of the TPP to see what was going on.

The short version: not much.

The longer version is provided below.

### **Administrative Process**

The parties agree to: 1) respond to requests for IP protection with written decisions that include legal justifications and reasoning for these decisions; 2) provide the applicant with the opportunity to respond to a decision; 3) provide a written response to the applicant's response that includes legal justifications and reasoning for the decisions provided in the written response; 4) provide an opportunity to appeal decisions described in point 3); and, 5) provide a written decision regarding the appeal that includes legal justifications and reasoning for the decisions provided in the appeal decision.

### **Trade Secrets**

The parties will put in place legal remedies to protect against the loss of trade secrets through fraudulent action, unauthorized access, or misappropriation.

### **Trademarks and Geographic Indications**

The parties will recognize Geographic Indications and treat them like trademarks.

### **Internet Service Providers**

Each party will establish laws that require internet service providers to cooperate with right holders to remove protected materials from the internet. Each party will also establish laws that provide internet service providers with safe harbor protections if they unknowingly or inadvertently distribute protected materials.

### **Patents**

The standards for determining the patent eligibility of an invention will follow reasonably closely to USPTO practices with the exceptions that: 1) diagnostic, surgical, and therapeutic methods do not have to be patentable; 2) plants do not have to be patentable; and, 3) biological processes do not have to be patentable.

The parties agree to make publically available information about patents and patent applications the maps fairly closely the practices of the USPTO. This is a fairly consistent practice across most countries.

### **Protection of Proprietary Data by Regulatory Agencies**

When seeking marketing approval for an Agricultural Chemical, Pharmaceutical or Biologic product, each party will not permit the use of undisclosed or proprietary data that was used for the marketing approval of a previously submitted Agricultural Chemical, Pharmaceutical or Biologic product that is the same or a similar product unless the same right holder owns both products. Each party also agrees not to use such undisclosed or proprietary data received from other countries or other entities whether or not the other country or other entity is a part of the TPP agreement.

For Agricultural Chemicals, this protection will expire ten years after the marketing approval of the Agricultural Chemical product.

For Pharmaceuticals, this protection will expire five years after the marketing approval of the Pharmaceutical product. Clinical trial data for pharmaceuticals is protected for three years.

For Biologics, this protection will expire eight years after the marketing approval of the Biologic. There is a provision within the biologics to reduce this protection to five years if the reducing party compensates the right holder in a manner that creates a comparable market outcome. I think the intent is clearly that a party can force a right holder of Biologic products to accept a buy out for the last three years. This is a pretty fuzzy section of the chapter and, unfortunately, the devil will be in the implementation details.

The definition of a pharmaceutical product is a product that does not contain a chemical entity that has been previously approved. I am assuming that the definition of an agricultural chemical product is similar. The definition of a biologic product is a protein made using biotechnology methods that is intended for use in humans. If these definitions are not met by a product seeking marketing approval, the above protections will not apply.

The above protections will be provided by a party to Agricultural Chemical products, Pharmaceutical products or Biologic products whether or not the products have patent protections from the party.

### **The Australia and Chile “Exemption” Claim**

There has been some noise made that Australia and Chile are claiming that the five year biologic rule means they do not have to change their laws. This sounds worse than it actually is because Australia and Chile have already changed their laws. Australia and Chile already have trade agreements with the US that are considered to be generally consistent with Chapter 18. In addition, the US has already reached agreements with both Chile and Australia that work out which sections of Chapter 18 will replace the existing agreements.

### **Patent Term Extension**

The parties agreed to patent term adjustment if the approval process for a patent application takes longer than five years. The parties also agreed to extend the patent term for Pharmaceutical products that faced unreasonable or unnecessary delays in the market approval process. This extension does not appear to apply to Agricultural Chemical products or Biologic products which is a little surprising to me. The language of this section is a little vague.

### **Copyrights**

The actual copyright section was fairly straight forward. It is the enforcement section where things got interesting in this area.

In general, the normal copyright protections apply. In addition, the parties agree to legally protect the use of Technology Protection Measures and Rights Management Information techniques and technologies. There will be civil and criminal legal remedies for people and entities who knowingly bypass these techniques and technologies. The parties also agreed to make it illegal to make or sell equipment to get around Technology Protection Measures, Rights Management Information, or satellite decryption technologies involving programmed content.

Libraries, museums, archives, educational institutions, and non-commercial broadcasting entities can be exempted from criminal penalties.

### **Enforcement**

Each party agrees to put in place the laws and enforcement mechanisms to enforce the agreements in this chapter. This includes judicial procedures that provide the judicial system with the authority to order injunctive relief, restitution, and damage payments. In addition, the judicial system will be given the authority to order payment of bonds or to suspend the release of counterfeit, misleadingly labeled, or pirated goods based on prima facie evidence

of an intellectual property rights violation. The chapter goes into a lot of detail about what this means and what appropriate relief measures should be. The chapter also goes into a lot of detail regarding what constitutes criminal activity and the appropriate criminal remedies.

## **Final Observations**

In interpreting all of this, I am going to avoid addressing the argument that the US could have cut a better deal because I can't speak to that point.

What I would point out is that in many respects, this section of the TPP is pretty consistent with, if somewhat less generous than, existing United States laws and procedures in most of the major intellectual property protection areas. In trademarks we got protection of geographic indicators. While the copyright section is updated to accommodate new technologies and the internet, the basic copy right protections are essentially the same as they have been since the 1950s. From what I can see, no changes in US law will be required to accommodate the patent protections and industrial design protections called for in the TPP. I was surprised to see that trade secrets were even addressed because, by definition, trade secrets are secret and will not generally be registered with a government.

Even the differences between US law and the TPP were predictable. For example, within the patent community opinions are divided regarding the appropriateness of patenting medical methods and biological processes and practices vary by country. The result that the agreement does not require patents for these sorts of innovations should not have been unexpected.

In reading the popular press, one seemingly controversial point that I hear coming from the mainstream media is the idea that the administrative process described in the TPP will infringe on the national sovereignty of the parties. This seems misguided to me. The administrative processes described in Chapter 18 seem reasonable and are consistent with the standard procedures of many, if not most, countries. Unless you hold the opinion that disagreeing with the administrative decisions of a government is an infringement of national sovereignty, I don't really see an issue here.

I would point out is that the proprietary data protections and the patent term extensions that were agreed to are unusual. These types of protections are rare especially beyond the first world countries. In my mind, these are not valueless concessions for the protection of Agricultural Chemical products, Pharmaceutical products or Biologic products. Even if these protections are flawed, if I were betting I would think these industries would rather have these weaker protections than to not have the protections at all.

At David's request, I have published an article by article summary of the intellectual property agreements that were made in Chapter 18 of the Trans-Pacific Partnership. This summary has been put up on the Agathon Associates website.

And yes – I still have the dog and the cat ☺

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