On February 27, 2006, the governments of the United States and Colombia announced that they had reached agreement on the text of a free trade agreement (FTA). As in other recent bilateral trade accords negotiated by the United States, standards for protecting intellectual property rights (IPRs) were controversial in the negotiation of the agreement. Indeed, as one publication noted, particular IPR demands made by the United States regarding protection of confidential test data and extension of patent protection had been "largely responsible" for the stalled broader negotiations between the United States and Colombia, Ecuador, and Peru. Negotiators from the three Andean countries were concerned that such requirements would significantly restrain their governments’ ability to manage health costs and public health crises. As discussed below, there were and are numerous other sources of controversy, including, inter alia, the scope of exclusive rights for plant varieties, the exhaustion of exclusive rights, and rules for preventing the circumvention of technological devices protecting digital copyrights.

Keith E. Maskus is professor and chair of economics at the University of Colorado, Boulder.

1. This agreement is virtually identical to an earlier one announced by the United States and Peru and, in fact, these agreements jointly establish a three-way accord among the nations involved.

2. See “Intellectual Property Protection Dogs Regional Trade Deals,” Bridges, January 2005. By other accounts, agriculture was also an area in which negotiations were significantly delayed (see chapter 5).
In the negotiating text, released on May 8, 2006, by the US Trade Representative (USTR), Colombia committed itself to strengthening several areas of intellectual property protection, some of which mirror US practices. The pressure to impose strong standards comes from a sharply articulated US negotiating agenda for bilateral FTAs. A central objective of US trade policy is to strengthen IPR regimes in partner countries to levels that are at least similar to, if not more protective than, the systems already in place in the United States. Through the bilateral route, the United States is capable of pushing international standards well beyond those required in the World Trade Organization’s Agreement on Trade-Related Aspects of Intellectual Property Rights (WTO TRIPS). US negotiators have had considerable success in this regard in reaching agreements with Chile, Morocco, Bahrain, Jordan, Singapore, and Vietnam, as well as with signatories to the Central American Free Trade Agreement–Dominican Republic (CAFTA-DR). The objective is also paramount in draft language covering the prospective Free Trade Area of the Americas (FTAA). Each of these agreements embodies various examples of so-called TRIPS-plus protection for intellectual property.

For its part, Colombia faced a delicate task during the IPR negotiations. Its negotiators seemed aware that some aspects of the TRIPS-plus agenda could be problematic in terms of their country’s own development policy, even as they hoped for more certain access for Colombian products into the US market. On an institutional level, some of Colombia’s sovereignty over intellectual property rights had been ceded to the Commission of the Andean Community (Bolivia, Colombia, Ecuador, Peru, and Venezuela). Thus, in some dimensions, the country could only agree to provisions that it believed it could persuade the commission to adopt.

This chapter examines various aspects of these complex problems in the context of the negotiated draft of the US-Colombia FTA, starting with a description of the main points in the agreement’s chapter 16 covering IPRs. The agreement reflects instances in which the US negotiators achieved substantial increases in Colombia’s (and Peru’s) standards, but also cases in which those nations’ diplomats were able to resist even stronger demands. The chapter then recasts this discussion in terms of the TRIPS-plus IPR agenda of the United States in bilateral trade agreements, before turning to a tentative evaluation of the stronger standards based on their potential economic implications for Colombia’s development. Some aspects of these rules may provide long-term benefits, but they could be costly in the short to medium term. Presumably, the Colombian authorities believe that their nation is gaining sufficiently greater access to US markets and technology to justify bearing this cost. Regardless, there remain policy areas where Colombia may wish to complement these new intellectual property standards in order to maximize the scope for longer-term gains.
Negotiated Changes in Intellectual Property Rights

This section compares the preexisting situation of key aspects of intellectual property rights in Colombia with the significant changes required by the FTA. Intellectual property rights are rules governing competition (exclusivity, entry, investment, and unfair activities) in knowledge goods. These rules are qualified by limitations on the scope of exclusive rights arising from economic and social objectives. IPRs cover patents, utility models, industrial designs, trademarks, geographical indications, integrated circuit designs, copyrights and related rights, and rules governing unfair competition and the protection of trade secrets. Plant varieties are protected through a sui generis system discussed below. The use of traditional knowledge in a request for a patent typically requires prior informed consent. Each of these areas is covered by legal regimes that vary widely in their mechanisms and approaches.

As a member of the Andean Community, Colombia’s industrial property rules are determined largely by joint decisions of the Commission of the Andean Community. The current harmonized regime was adopted in 2000 in Decision 486, which was designed to make the laws of member states compliant with TRIPS requirements and other conventions, while also recognizing the need for consistency with the Convention on Biodiversity. Individual countries were given control over some procedures, including unfair competition, trade name protection, and applicable procedures in national legislation. The main features of Decision 486, their implementation into existing Colombian policy and the changes in them required by the US-Colombia FTA, are discussed in the sections that follow.3

Patents

Decision 486 limits patentable subject matter to the minimum required by TRIPS. Thus, in addition to standard exemptions from patentability, it excludes discoveries (e.g., genetic sequences); any living things found in nature, including natural biological processes, genomes, and germplasm; business methods; and computer programs and software. In contrast, the United States makes all of these items patentable (subject to novelty, inventiveness, and applicability requirements) and is anxious to encourage the Andean countries to follow suit. The Andean Community regime’s general exceptions also exclude “second-use patents” from eligibility in

---

Colombia. These are patents issued on a new use of a chemical entity (e.g., pharmaceuticals) that had been patented for a prior use.

The decision also states that patent rights in materials derived from any country’s “biological heritage and traditional knowledge” must safeguard and respect that biological and genetic heritage, together with the traditional knowledge of local communities. In effect, this means that individuals seeking patents must meet laws or treaties (such as the Convention on Biodiversity) regarding informed consent, disclosure of the source of genetic materials, and removal and payment formalities. For its part, the United States has not ratified the biodiversity convention, nor does its patent law recognize formalities of this kind. This is a significant difference between the United States and Colombia, and one that raised thorny issues for the FTA negotiations.

Colombia, through Decision 486, places limits on the scope of patent rights that depart considerably from US practice. Colombia recognizes that prior use before patent filing is not infringing activity, nor is experimental use or use for teaching, academic, or scientific research or non-commercial activity. Patents are subject to international exhaustion, meaning that Colombia is open to parallel imports of goods placed legitimately on markets in other countries. Decision 486 imposes an obligation on patent holders to exploit their invention in member countries, but this obligation may be satisfied by imports, which is consistent with TRIPS.

Under the law, it is permissible for the government to issue compulsory licenses, which force transfer of patented technologies to local firms, subject to the provisions of Article 31 of TRIPS. An interesting feature is that such licenses cannot be compelled by an individual Andean Community member if the invention is sufficiently exploited in another member. In this context, the licensing regime anticipates that the Andean Community is effectively a regional grouping with free parallel trade among members. Compulsory licensing may also be ordered in the event that a later patent (or “dependent patent”) involving substantial technological progress must have access to rights under a prior patent and the later patentee has not been able to secure a voluntary license.

Under terms of the FTA, Colombia will be required to make a number of important changes in this structure of patent rules, though the country was able to sustain some important limitations on patent scope. In terms of strengthening the regime, Colombia committed to acceding to the Patent

---

4. They are not expressly excluded in the law, but an Andean Community court ruling confirmed that second-use patents are ineligible.

5. This is true as well of goods protected by copyrights and other forms of intellectual property.

6. There remains considerable controversy over the interpretation that TRIPS permits importation to satisfy exploitation requirements, as opposed to domestic production or “working” (International Centre for Trade and Sustainable Development [ITCSD] 2005).
Cooperation Treaty by 2008 and to “make all reasonable efforts” to ratify or accede to the Patent Law Treaty at some point. The Patent Cooperation Treaty is an international agreement under which a potential patent holder can register in multiple countries upon payment of a single fee and can enjoy certain grace periods in exclusivity from the time of initial registration. Use of the Patent Cooperation Treaty tends to reduce administrative costs for patent registration offices and encourage more patenting in member countries. The Patent Law Treaty is more prescriptive regarding examination standards for issuing patents and effectively commits patent offices to recognize a presumption of validity on the part of internationally issued patents. While both agreements should reduce Colombia’s administrative costs for patenting, membership in the Patent Law Treaty could diminish the government’s discretion in approving international patent applications.

The FTA permits Colombia to retain an exemption for research use of patented information in pharmaceutical products and agricultural chemicals, but only for purposes of meeting marketing approval requirements for generic products, which cannot be sold prior to patent expiration. Nor can such generic products be exported during the patent term except to satisfy marketing approval requirements. In essence, this provision would prevent Colombia from permitting domestic generic pharmaceutical producers to supply the needs of poor countries issuing compulsory import licenses under the TRIPS waiver of August 2003. The main objective for the patent-intensive pharmaceutical companies, however, is to prevent early generic competition in Colombia.

More significantly, the FTA commits Colombia to compensate patent holders by extending the duration of patent rights when there are “unreasonable delays” (defined as a period more than five years from patent application or three years after a request for patent examination) in approving an application. This provision is extended for pharmaceutical products, wherein patent length may be attenuated by delays in marketing approval. For such goods a restoration of patent term is required. This principle is designed to limit the discretion (or abuse) of regulatory authorities in encouraging rapid entry of generic competitors on the Colombian market in favor of full-term patent rights.

While these changes signal benefits for patent holders, Colombian negotiators did successfully resist inclusion of a number of policy objectives sought by the intellectual property industries of the United States. Colombia is not required to extend patent eligibility to new areas, with the

---

7. A side letter to the agreement clarifies that Colombia may, in the event of a declared national emergency, take advantage of this waiver as an importer.

exception noted in the following section on confidential test data. Thus, patents need not be required on higher-order (or multicellular) animals, discoveries in genetic sciences, software, and business methods. Next, the agreement does not require so-called second-use patents, under which a new use for an existing patented chemical entity (e.g., a pharmaceutical product) must be patented. The FTA does not change the essentials of the compulsory licensing regulations, leaving them keyed to the conditions required in TRIPS. In addition, the agreement says nothing about Colombia’s rules permitting pre-grant opposition to patents, despite US industry’s clear preference for eliminating this provision. Finally, no change in the exhaustion regime is required, permitting Colombia to remain open to parallel imports.

Confidential Test Data

Among the most controversial issues in the negotiation of bilateral FTAs has been US insistence on a lengthy period of protection for confidential data, typically developed in expensive clinical trials, submitted to achieve marketing approval or patents in particular countries. Health authorities require such data in order to understand the safety and efficacy of particular drugs and agricultural chemicals. However, it has been the practice in many countries to release these data quickly to potential generic producers in order to permit them to establish bioequivalence of their formulations without going through costly clinical trials. Patent laws do not necessarily prevent such release, and pharmaceutical companies are keen to have a period of exclusive data use rights without facing the generic competition facilitated by it.

While the TRIPS agreement mentions the need for protecting test data from unfair commercial use (Article 39), it does not set out a minimum period during which the data may not be used. For its part, Colombia enacted Decree 2085 in 2002 that phased in data exclusivity and provides five years for pharmaceuticals registered in 2003 or later. In 2003, similar protection was provided in Decree 505 for agricultural chemicals. In this regard, Colombia already met basic US expectations for data protection in pharmaceuticals and agrochemicals.

However, the standard practice for the United States in its bilateral FTAs has been to demand protection periods of ten years for agrochemicals and five years for pharmaceuticals. The FTA adopts exactly this provision, thereby extending the protection period for new agricultural chemical entities. These periods extend also to test information issued for approvals in other countries, meaning that even if such data are publicly available in those countries, the Colombian authorities cannot approve marketing by a rival company on the basis of such data. Moreover, if a patent expires before the end of these periods of exclusive data use, the government cannot
approve competitive entry of generic versions. This principle can effectively extend exclusive marketing rights well beyond patent periods.

**Plant and Animal Varieties**

Colombia currently is a member of the 1978 Union for the Protection of New Plant Varieties (UPOV) and regulates plant varieties through Decision 345 of the Andean Community. As such, it provides sui generis protection for new plant varieties. This protection provides exclusive rights for registrants to sell seeds but preserves a research exemption for the development of competing varieties and also sustains a farmer’s privilege under which harvested seeds may be used and exchanged among farmers. Unlike the United States, Colombia does not offer patent protection for new plant varieties.

Under the FTA, Colombia must ratify or accede to the 1991 revision of UPOV, which is considerably more restrictive in its usage rights. Specifically, UPOV 1991 sharply restricts the ability of competing horticultural companies to use protected varieties in their research programs and also limits farmers to keeping harvested seeds for their own use, making it difficult to share or exchange them. Further, the FTA requires Colombia to “undertake all reasonable efforts to make . . . patent protection available” for new plant varieties. This provision is aimed primarily at ensuring that transgenic plants, especially those arising from biotechnological research, will be eligible for patents in Colombia.

Comments by US industry officials clearly anticipate that such patents will become available for new plants, while expressing disappointment that they were not extended to transgenic animals. Overall, these new provisions, especially in conjunction with the strong protection for confidential test data, represent significant victories for international pharmaceutical and life science companies operating in Colombia.

**Trademarks and Geographical Indications**

By updating protection in these areas to the standards required by TRIPS, Decision 486 established regimes that were largely consistent with the preferences of US negotiators. The rules broaden the definition and protection of well-known trademarks and remove the requirement that, to be eligible, such trademarks must be formally registered and in use. This is a

---

9. UPOV is the acronym for the French name of this international treaty. Colombia’s existing law is based on the 1978 Act of UPOV.

significant departure from prior rules, based on European traditions of civil law, that registration formalities and local use were necessary for protection. Decision 486 also permits objection to the registration and use of a domain name that might cause confusion as regards well-known names, though in general there are registration formalities in Colombia for domain names to be protected as industrial property. There is also an expanded definition of trademark dilution through exploitation of confusingly similar trademarks in closely related goods and services.

Decision 486 established further that misleading use of names or trademarks that contain an indication of origin for alcoholic beverages is not permitted. This provision extends to geographical indications, which are terms signifying that some quality characteristic of a good is related to the physical location of production. In Colombia, geographical indications may be registered as trademarks, which is essentially consistent with US practice and less restrictive than the special forms of protection advocated by the European Union.

Provisions of the FTA essentially extend trademark protection to certification marks, recognize that geographical indications and indications of origin may be registered as certification or collective marks, and further strengthen the rights afforded without formalities to owners of well-known trademarks. These changes were relatively noncontroversial as regards the preferences of both Colombian and US negotiators. Beyond those elements, the agreement clarifies that the registration of geographical indications may be blocked if the logos or images chosen for them are confusingly similar to established trademarks.

As might be expected, the main US objective in this regard was a significant improvement in Colombia’s enforcement of trademarks against counterfeiting and trade in counterfeit goods (USTR 2004a). In this regard, Decision 486 implemented expanded enforcement procedures, including preventive injunctions, suspension of infringing acts, removal of goods from circulation, temporary closure of infringing establishments, seizure of assets, fines tied to damages, the prospect of criminal prosecution, and the ability of judicial and administrative authorities to undertake enforcement actions on their own initiative. These procedures were further strengthened in the FTA, which, inter alia, will require changes in Colombian law to establish minimum fines for infringement that may be invoked at the discretion of rights holders. In general terms, the FTA enforcement provisions are more prescriptive than the broader language of TRIPS but are otherwise standard.

Copyrights and Related Rights

The current copyright laws of Colombia are based on Law 44 of 1993 and Andean Community Decision 351 of 1994. Colombia is also a member
of the Berne Convention and several other copyright treaties relating to the rights of performers and broadcasters. These are modern copyright regimes, anticipating the standards of TRIPS, which largely incorporate the requirements of the Berne Convention. Thus, Colombia offers copyright protection for literary and artistic works lasting the life of the author plus 50 years. It also recognizes the rights of performers, broadcasting organizations, and producers of recorded media to exclusive distribution of their works. Given the civil law background of Andean nations, Colombia also recognizes moral rights for authors and creators, such as the right to benefit from a share of future sales of paintings after the first sale. This is an issue with respect to the United States, which does not provide such rights. Colombia also protects copyrights in computer programs, though its law does not classify software as a literary work.

In terms of these issues, Colombia has agreed in the FTA to offer copyright protection for the life of the author plus 70 years or, in the case of copyrights owned by corporations or other entities (as opposed to individuals), for 70 years. Both standards accord with US law, which recently extended these terms from 50 to 70 years essentially in order to prevent older Disney copyrights from lapsing into the public domain. The FTA also clarifies that there can be no legal hierarchy of copyrights between authors and performers (such as musicians, actors, and directors), providing all groups equal protection under the law. As noted earlier, Colombia did not agree to extend patents to computer programs. Finally, the agreement is silent on moral rights, permitting them to continue.

Most significantly, Colombia earlier had ratified both of the World Intellectual Property Organization’s (WIPO) so-called Internet treaties. These include the WIPO Copyright Treaty (WCT) and the WIPO Performances and Phonograms Treaty (WPPT), both of which came into force in Colombia in 2000. These treaties are designed to provide a legal framework within which countries may permit copyright owners to control copies and gain compensation for their use in cyberspace. The main issue relates to the legality of actions that avoid or circumvent the technological protection mechanisms embodied in digital products. The Colombian Penal Code of 2001 establishes that such actions may carry both civil and criminal liability, as may also efforts to alter or eliminate essential copyright information on digital products. These provisions already go some way toward satisfying the US “digital agenda” in trade policy, discussed in the next section, though significant questions remain about the scope of what is permissible fair use of digital goods.

Three other structural copyright issues existed prior to the negotiations. First, Colombia was not a member of the Brussels Convention relating to the distribution of satellite transmissions, and the agreement calls for it to ratify or accede to the convention upon entry into force of the FTA. Second, according to USTR (2004b), the Colombian authorities had not taken effective actions to reduce the unauthorized use of television programs through
a strong licensing program. The FTA has extensive language regarding new protection to be provided to satellite transmissions, wireless transmission, and television broadcasts. In particular, Colombia has committed not to issue compulsory licenses for permitting unauthorized reception of such transmissions, a provision that actually goes beyond American law and practice.

Finally, as with trademarks, the most pressing issue from the US standpoint was the high rate of copyright piracy in Colombia. This refers most readily to copying of printed media, digital entertainment products, and software, but applies equally to unauthorized downloading and distribution of digital goods on the Internet. Regarding the former, the enforcement provisions highlighted above regarding trademarks apply equally to copyrighted goods. In terms of the latter, protection of electronic materials on the Internet commanded extensive language in the FTA. In particular, US negotiators were successful in extending rights that closely mirror those in the United States. For example, the temporary downloading of virtual (electronic) copies of products without authorization is made illegal. Other rights, explained further in the following section, establish civil and criminal liability for willfully downloading electronic materials without authorization, distributing such materials in a commercial volume (even if no commercial advantages were gained), and developing or using technologies to circumvent legal or technical copyright protection mechanisms. Further, while libraries, archives, and other noncommercial public entities retain some rights to download such materials, the scope of fair use for such entities is significantly limited under the FTA. These provisions are a significant victory for copyright interests in the United States.11

The US TRIPS-Plus Agenda

In popular parlance, the expression “TRIPS-plus” refers to demands made by the United States and other developed economies that trading partners agree to IPR standards that exceed those required in the WTO rules. In the area of pharmaceuticals, the Doha Declaration built on and clarified TRIPS by permitting the least developed countries to delay implementation and enforcement of patent rules until 2016, stating that governments could accord priority to public health needs over intellectual property requirements and asserting that developing nations could take full advantage of

---

the flexibility in TRIPS. In its negotiations of bilateral FTAs, the United States has systematically ignored these provisions in favor of strong protection in pharmaceuticals, in particular, and in IPRs more generally.\footnote{12 The United States is not alone in this regard. For example, the members of the European Free Trade Association have joined the United States in pressing the South African Customs Union to introduce five- to ten-year data exclusivity, even where a medicine is not patented or is subject to compulsory license (“Intellectual Property Protection Dogs Regional Trade Deals,” Bridges, January 2005). See Fink and Reichenmiller (2005) for a full discussion of negotiated standards that go beyond TRIPS.}

In operational terms, TRIPS-plus means the following. First, for items that are not negotiated within an FTA, the relevant TRIPS standards pertain, since virtually all countries are WTO members or preparing to become members. Second, the FTA might negotiate standards that exceed those of TRIPS. Third, newer areas of intellectual property rights that were not covered by TRIPS may be subject to negotiations in FTAs, a phenomenon especially prevalent in the digital age.

It should be noted that the United States has negotiated intellectual property rights in FTAs with a requirement of nondiscrimination, implying that most favored nation treatment applies. This is only practical because IPRs are competition rules rather than taxes, and it would be difficult and unwieldy to administer different sets of rules for applicants from different countries. Moreover, the TRIPS agreement itself does not have language permitting regionally differentiated standards. Accordingly, stronger IPRs that are reached in bilateral agreements must extend unconditionally to registrants of intellectual property from third countries. Thus, while particular standards vary across agreements, the trading partner involved must offer those terms to third parties. In terms of US strategy, this is an important means of ratcheting up global standards of protection.

**Negotiating Objectives in Intellectual Property Rights**

In granting trade promotion authority, the US Congress set out in the Trade Act of 2002 an extensive list of negotiating priorities, several of which pertain to intellectual property rights. One calls for the “accelerated and full implementation” of the TRIPS agreement, particularly with respect to its enforcement obligations. Another is to ensure that the intellectual property rights provisions of FTAs “...reflect a standard of protection similar to that found in U.S. law.” A third is to provide strong protection for new and emerging technologies and products embodying intellectual property. A fourth is to ensure that standards keep pace with technological developments, especially in the area of digital copyrights, providing rights holders have the “...legal and technological means to
control the use of their works through the Internet . . . and to prevent the unauthorized use of their works.”

These four objectives encapsulate precisely the nature of recent and current US negotiations on IPRs on a bilateral and multilateral basis. The priorities are enforcement, exporting US laws, upgrading standards, and technological protection of digital content. These objectives have been central to the negotiations with Colombia and Peru, building on prior agreements with, especially, Jordan, Morocco, Singapore, and the members of CAFTA-DR. Effective intellectual property protection is also expected of developing countries hoping to benefit from trade preferences in the US market. For example, Colombia is a beneficiary country of the generalized system of preferences and the Andean Trade Preference Act (ATPA), which was recently replaced by the Andean Trade Promotion and Drug Eradication Act, all of which impose high standards for intellectual property rights (Ferrero 2004).

Main Elements of TRIPS-Plus

What might be called the “TRIPS-plus agenda” has evolved over time, reflecting both stronger US interests in expanding protection and the perceived need to upgrade and develop standards as technologies change. For example, the chapter on intellectual property rights in the North American Free Trade Agreement (NAFTA) anticipated TRIPS, the language of which in many cases came from the former agreement. Accordingly, NAFTA embodies similar standards and flexibility, leaving much to national discretion. The US-Chile FTA has stronger requirements, particularly in the areas of patents and trade secrets, but generally relies on TRIPS as its model. However, in succeeding FTAs with Morocco, Singapore, Australia, and Jordan, the United States has pushed for increasingly protective standards. Indeed, in the language of US trade diplomats, the US-Jordan FTA is the “gold standard” for introducing strong intellectual property protection. That agreement appeared to be the model under which US negotiators with Colombia operated.

Therefore, it is important to understand the major elements of this approach. The primary items, none of them required by TRIPS, are described below.


14. Author’s conversation with officials at the US Department of Commerce, February 2005. Other observers noted that the initial US negotiating text was more similar to the agreement with Bahrain.
**Patents**

The United States prefers that countries provide extensions to the coverage and scope of patents in a number of ways. One way is to narrow the exclusions from patentability and, in particular, to make life forms, including genetic sequences, eligible. Other areas in which patents could be provided are plant varieties, software, and business methods (typically as embodied in computer programs). As noted earlier, patents in plant varieties would restrict research use and reduce the scope of the farmer’s privilege.

A second issue is to provide patent-term extensions for drugs in cases where health authorities issued patents with undue delay. Another is to issue second-use patents, as defined above, which effectively extend patent protection for chemical entities beyond original terms. Yet another is to limit experimental use of patented materials and also to restrict their use by potential generic firms in preparation for entry as patents expire. Perhaps most significant is the demand that health authorities ban the registration of any generic drugs during the lifetime of a patent, effectively ending access to compulsory licensing except in rare circumstances. This last plank was successfully introduced into CAFTA-DR and the FTAs with Chile, Morocco, and Singapore.

Considering this agenda, US negotiators had mixed success in the FTA with Colombia. There is little expansion in patent eligibility, though the promised extension of patents to plant varieties and transgenic plants is significant. Patent-term extensions in response to delays in approvals are now required, a victory for pharmaceutical companies, but second-use patents do not appear. Perhaps most frustrating for US interests, there are no significant limitations in the FTA on compulsory licensing beyond the difficult formalities of TRIPS.

**Test Data**

As mentioned earlier, a central demand of the United States is that there be exclusive usage rights for test data on behalf of original applicants for a period of at least five years for pharmaceutical products and agricultural chemicals. Some FTAs go beyond this and effectively permit 10-year exclusivity (by giving firms up to five years to apply for marketing approval in the country and then adding data rights) before data may be used. This is a strong restriction on competition, even in medicines where no patent is issued.

In this area, the FTA fully reflects US preferences. There are lengthy periods of confidentiality, and generic companies cannot access international data for marketing approval. Expiration of patents cannot be used to accelerate the release of confidential data. In effect, these provisions
provide strong exclusive rights for research-based pharmaceutical companies in Colombia.

**Digital Copyright Protection**

The demands put forward by the USTR in this area involve several items, as described in Wunsch-Vincent (2003). First is that countries ratify and implement the WIPO Internet treaties mentioned earlier. The significance is that both the WCT and WPPT enjoin countries to recognize copyrights in digital products, including those distributed electronically, while taking steps to penalize efforts to circumvent technical protection measures. However, those treaties are not very prescriptive when it comes to methods for accomplishing these goals, while they are largely silent on the issue of permissible fair use. Thus, for example, many countries do not consider temporary (virtual) copies to be copyrighted, while they provide leeway for making personal copies and copies for educational and scientific purposes. Countries also have latitude in defining areas within which compulsory licenses may be issued to ensure that access to digital content is available in remote areas, schools, and libraries.

In contrast, the United States has adopted extremely strong copyright protection for digital products under the Digital Millennium Copyright Act (DMCA), which is highly controversial among legal scholars. Under the DMCA, even inadvertent copying and circumvention can be subject to civil and criminal penalties, while the scope of fair use is heavily curtailed. The US negotiating strategy in recent FTAs, such as those with Morocco and Jordan, has been to export DMCA-like protection to trading partners. Interestingly, among all the TRIPS-plus agenda items, enhanced protection for digital copyrights has the full and unwavering support of the US Congress. Recorded music, software, video games, and movies form a potent lobby for international trade policy.

Here again, the United States achieved its objectives in the FTA. The rules to which Colombia agreed closely mirror those of the DMCA, including provisions for criminal penalties for circumvention and the limited liability of Internet service providers tied to their willingness to monitor the legality of content available on their systems. In brief, FTA provisions sharply restrict the scope of fair use in copyrights and could raise roadblocks to the access of scientists, educators, and students to technical information and data.

**Exhaustion of Rights**

The exhaustion doctrine governs the point of distribution at which an IPR holder loses the ability to control additional movement and sale of goods. Under international exhaustion, these rights disappear upon first sale by
the rights holder anywhere in the world. In consequence, countries follow-
ing this approach are open to parallel imports, though this may vary as regards patented, copyrighted, and trademarked goods. Under na-
tional exhaustion, the rights to exclude imports are not ended upon sale outside the country, meaning that parallel imports are not permitted.

The United States bars parallel imports in patented and copyrighted goods, though it is relatively open to products protected by trademarks (Maskus 2000b). In contrast, Colombia and the other Andean economies generally follow a doctrine of international exhaustion. The global research-based pharmaceutical companies and copyright industries would prefer that this doctrine be changed and that parallel imports be restricted. US negotiators have expanded the use of national exhaustion in a number of bilateral FTAs. For example, in both the Jordan and Morocco agreements, copyright holders are given the rights to block parallel imports. As discussed earlier, however, the US-Colombia FTA is silent on the issue of parallel trade, preserving autonomy in this regard on behalf of Colombian trade policy.

**Trademarks and Geographical Indications**

The United States protects geographical indications through collective and certification marks. During negotiations, US officials pushed for the Colombian system of geographical indications to protect American collective and certification marks. Further, the United States requested that preexisting trademarks block any registration of new marks for geographical indications that would be confusingly similar. Regarding trademarks, the major American interest, like that in copyrights, is an improved enforcement system and more resources devoted to punishing counterfeiting and piracy in the region. It is evident from the earlier discussion that the United States achieved the bulk of this negotiating agenda.

**Enforcement Commitments**

A final central plank of the TRIPS-plus agenda is to commit trading partners to considerably stronger efforts to establish effective enforcement mechanisms to deal with infringement. The TRIPS agreement has extensive language on the nature of enforcement expected of member countries, ranging from border measures to civil penalties. However, it does not require any allocation of resources to the task, nor does it require the establishment of specific means related to intellectual property rights, such as specialized courts.

Several of the US bilateral FTAs go beyond these general statements to specific obligations. For example, in the US agreements with Chile and Morocco, those countries are not permitted to invoke resource constraints...
(such as limits on administrative budgets) as justifications for failing to comply with enforcement obligations. In several FTAs there is now an obligation to apply criminal procedures in cases of willful infringements, with stronger commitments in the case of counterfeit labels attached to copyrighted works.

Similar to CAFTA-DR and agreements with Jordan and Morocco, the principles struck in the US-Colombia FTA offer extensive commitments on enforcement, though no formal pledge to minimum expenditures or special courts is made. In general, the rules for enforcement, penalties, administrative actions, and judicial oversight closely track those of US law and establish wide-ranging obligations for preliminary injunctions, alternative fines, criminal penalties, and border controls. Perhaps most significant is the injection of DMCA-like rules into copyright infringement on the Internet. Whether Colombia has the resources and the will to carry out these commitments remains to be seen, but on paper the enforcement rules are on a par with those in the most advanced industrial nations.

A Tentative Evaluation

The sections that follow evaluate the nature of US-Colombian technology trade and the existing situation regarding intellectual property rights in Colombia. As might be expected, Colombia has a significant comparative disadvantage relative to the United States in developing and trading new goods and advanced technologies, implying that its underlying interests are for rather weaker intellectual property rights. The terms of the FTA raise some problematic issues in this context.

Comparative Advantage in Technology Trade

The pursuit of stronger intellectual property protection through bilateral FTAs is understandable from the US perspective. The United States remains the largest developer of new technologies, medicines, and plant varieties, while its cultural industries generate the bulk of new content, especially in digital formats. Commercial interests in the United States would achieve considerable gains from stronger international copyright rules and patent protection. Moreover, the nondiscrimination aspects of IPR standards have the effect of ratcheting up global standards over time.

The more fundamental question is whether acceptance of TRIPS-plus requirements makes sense for developing countries such as Colombia that reach trading agreements with the United States. It is impossible to answer this question with certainty, because the nature of intellectual property rights, like other regulatory standards, is to deal with market failures in inherently second-best ways. The essential balance in IPRs is to absorb
short-run increases in market power on behalf of rights holders in return for the promise of long-run gains in greater innovation and technology transfer; that is, to sacrifice static competition in return for greater dynamic competition and growth.

A Question of Technology Balance

To gain some perspective, consider the relative positions of the two nations regarding the development and use of new technologies. It is no surprise to learn that, like other lower- to middle-income developing economies, Colombia lags far behind the United States in generating patentable new inventions. As shown in table 7.1, Colombian inventors in recent years have averaged around nine US-issued patents per year, ranking well behind Argentina and Venezuela (which are much larger economies) and approximately the same as Chile. In contrast, the Colombian authorities have granted 15 to 20 patents a year to domestic residents, but an average of 260 a year to US residents. US inventors accounted for more than 50 percent of Colombian patent grants in the early part of this decade.

As such figures might suggest, the United States has a strong bilateral comparative advantage in innovation, underscoring its interests in establishing strong IPRs in as many trading partners as possible. This situation is also evidenced by the fact that, in 2000, the US-sourced foreign direct investment stock in Colombia was around $5.3 billion, while the Colombian-

| Table 7.1 Utility patents granted, 2000–2003 |
|-------------------------------|---|---|---|---|
|                               | 2000 | 2001 | 2002 | 2003 |
| Granted by United States     |      |      |      |      |
| to residents of:             |      |      |      |      |
| Argentina                    | 54   | 54   | 51   | 63   |
| Bolivia                      | 2    | 0    | 0    | 0    |
| Chile                        | 15   | 12   | 11   | 11   |
| Colombia                     | 8    | 12   | 6    | 10   |
| Ecuador                      | 0    | 4    | 0    | 3    |
| Peru                         | 2    | 4    | 1    | 4    |
| Venezuela                    | 27   | 26   | 30   | 19   |
| Granted by Colombia         |      |      |      |      |
| to residents of:             |      |      |      |      |
| Colombia                     | 21   | 13   | 12   | n.a. |
| United States                | 329  | 189  | n.a. | n.a. |
| Other                        | 245  | 161  | 360  | n.a. |
| n.a. = not available         |      |      |      |      |

sourced foreign direct investment stock in the United States was approximately 10 percent of that total, at $585 million. The United States also sustains a bilateral trade surplus with Colombia in medicines, machinery, equipment, and high-technology goods. All of these items are channels of net technology flows to Colombia.

Economic Development Potential

Multinational enterprises headquartered in the United States naturally wish to enjoy exclusive rights to exploit the technologies they transfer to Colombia. Exclusive rights can be established both through natural lead-time advantages and technological sophistication that makes imitation difficult and costly and through legal means involving intellectual property rights. Advocates of strong intellectual property protection claim that it encourages more inward technology transfer by raising certainty and reducing the costs of transferring information and know-how (Sherwood 1997). At the same time, even if technology flows were to increase, strong protection of intellectual property rights could permit patent holders to reduce access, raise licensing fees, segment markets, and limit competition (Correa 2005).

Empirical studies of this trade-off bear mixed messages. According to one extensive study, nations that have adopted stronger patent rights have not seen increases in domestic inventive activity for a lengthy period of time. Rather, the medium-term economic gains accrued to foreign inventors who registered more intellectual property in those countries (Lerner 2002). These results have been supplemented by recent microeconomic studies of changes in the Japanese patent system (Sakakibara and Branstetter 2001) that led to no detectable increase in innovation within Japan for at least five years. On this evidence, Colombia, a developing economy with relatively small science and technology sectors, is unlikely to see much gain in domestic innovation. At the same time, these same studies suggest that greater foreign patenting in countries that improve their IPRs reflects an intention to transfer more technology through protected channels, a finding that is consistent with the majority of macro-level investigations of foreign direct investment and licensing.16

None of these studies considered the question of innovation and technology flows in the context of a free trade agreement, which raises a number of complications. First, the TRIPS-plus agenda is focused on pharmaceuticals and digital products more than on general technological


16. Maskus (2000a) reviews such studies extensively, while they are updated in several papers in Fink and Maskus (2004).
development. As such, it seems unlikely that adoption of these higher standards can do much to expand innovation and technology flows beyond the incentives established in TRIPS. Second, an FTA itself, even in terms of standard trade liberalization, is discriminatory and not necessarily beneficial because of the possibility of trade diversion. When added to the second-best aspects of IPRs, the potential welfare implications become complex and economists cannot make general predictions.

Consider, for example, the fact that Colombia would be making permanent and highly protective changes in its IPR system, offered to inventors and creators from everywhere in the world, in return for preferential market access in the United States. This preferential access presumably would exist largely in agriculture and a few labor-intensive goods, given that US most favored nation barriers in other goods are low. These preferences are likely only to be temporary, given the US mandate to negotiate additional FTAs and the potential outcomes of the Doha Round of multilateral trade negotiations. Indeed, they would be effectively eliminated upon the successful conclusion of the FTAA.

There may be other reasons for Colombia to reach an agreement. As has often been claimed, FTAs have the potential to lock in trade reforms so credibly that they cannot later be rescinded due to changes in government. While locking in the TRIPS-plus reforms of IPRs may be of questionable value when considered in the context of larger domestic reforms in services, infrastructure, and trade barriers, the Colombian economy may see net efficiency gains. In that sense, stronger IPRs are a necessary cost of achieving the credibility that an FTA with the United States would provide and a useful signal to domestic and foreign investors.

Wider Concerns for Colombia

The broader concerns over intellectual property rights reflect more than their potential impact on innovation, technology transfer, and information diffusion. IPRs also affect fundamental social and development objectives in health, agriculture and nutrition, biodiversity, education, and science (Maskus and Reichman 2005). Thus, standards for protecting intellectual property, negotiated in the context of a trade policy initiative, have far-reaching implications for the preservation and provision of public goods in the Colombian and Andean economies. It is this feature that explains why IPRs are intensely controversial in the region.

Significantly more protective IPRs have effects on social objectives that, while perhaps difficult for economists to quantify, should be accounted for in any reckoning of the potential gains and losses from the FTA. Most prominently, the requirements for patent-term extensions and test data protection are designed explicitly to delay the onset of generic competition in medicines. An extensive body of statistical evidence documents that the
presence, or threat, of generic competition places strong downward pressure on pharmaceutical prices and increases access to medicines. Colombian authorities need to think carefully about the potential implications of these restrictions.\textsuperscript{17}

One can make similar claims about other aspects of the TRIPS-plus agenda that emerged in the US-Colombia FTA. Awarding patents to plant varieties may have some positive impact on the willingness of life science firms to locate innovative activities in Colombia. However, there would be costs for farmers and researchers in the medium run. Similarly, strong anticircumvention rules in digital copyrights can result in serious constraints for students, libraries, and researchers trying to gain access to scientific and literary information available on the Internet. In both of these areas, and others, Colombian policymakers should consider the scope of fair use that makes sense for their economy.

Taking a more balanced view, the potential for net gains depends on particular circumstances and may vary over the time horizon considered (Maskus 2004). What really matters is that intellectual property standards be selected in a way that increases certainty while encouraging effective dynamic competition (World Bank 2001). Such standards also need to be complemented by appropriate regulatory and development policies, as noted below.

A Broader Strategy

The discussion in this chapter has at times been critical of the wisdom of Colombia’s decision to adopt considerably stronger intellectual property rights under its free trade agreement with the United States. This pessimism may be misplaced, for extended protection bears the prospect of longer-term advantages for innovative and creative industries in Colombia. In that context, it is useful to conclude by discussing briefly what Colombia might do in incorporate the new intellectual property obligations into a broader development strategy in order to maximize the potential for long-term gains.

Authorities should retain as much flexibility as possible in terms of policies to deal with access to public health. The FTA establishes strong protection of private rights to confidential data, marketing privileges, and patent terms, all of which will delay generic competition, with, it would seem, relatively little prospect for domestic innovation in medicines. Thus,\footnote{Again, in recent FTAs, including the US-Colombia pact, the United States has agreed to side letters that affirm the priority of public health over commercial rents from IPRs. These side letters satisfy the negotiating objective of the trade promotion authority to respect the spirit of the Doha declaration on public health. However, the legal obstacles countries must surmount to actually avail themselves of such flexibility as compulsory licensing, in the presence of TRIPS-plus standards, would be daunting.}
ensuring access to medicines through purchasing programs, insurance systems, and price regulations will be important.

In a similar vein, it may be sensible for members of the Andean Community to establish a policy of regional exhaustion in patents and copyrights in order to benefit from access to the lowest-cost medicines, agricultural technologies, and other products in the area. Using that approach, member nations would be open to parallel trade among themselves. These countries might also consider means of supporting regional production capacity for generic producers of pharmaceuticals, agricultural chemicals, and seed varieties.

Colombian officials could look at copyright laws around the world for an understanding of the potential scope of fair use that remains consistent with the general provisions of the World Intellectual Property Organization’s Copyright Treaty and Performances and Phonograms Treaty, while not violating the new FTA provisions. Colombia did retain some room for fair-use access by libraries, universities, and other public, noncommercial enterprises, and it will be important to retain such flexibility. However, the wholesale adoption within the FTA of many provisions of the US Digital Millennium Copyright Act is not likely to work in Colombia’s favor.

It is important for Colombian authorities to coordinate views among the nation’s ministries and interested citizens and businesses on how to move forward with the new system of IPRs as it is implemented. It makes little sense for a commercially driven trade ministry to undertake regulatory commitments that affect health, education, science, and technology without extensive consultation. But that effectively is what happened in this instance. The new rules, whenever implemented, will need to be complemented by broader support systems within the economy, and early consultation on these needs is essential. For example, an effective competition policy can help blunt the monopoly powers inherent in stronger IPRs. Also important are steps to encourage the development of human capital and innovation capacity within the domestic economy (Maskus and Reichman 2005).