

Module 203

[The following is a transcript of the recorded lecture for Module 203 of the PatentX course. The recording of the lecture itself is available through <https://ipxcourses.org>. Stripped of the accompanying slides and other visual materials, the transcript will likely be hard to follow. It is not intended to be a free-standing document. Rather, its purpose is to assist students, who have already watched the lecture, when reviewing the material.]

Part A: Developing Countries

Hello, I'm Terry Fisher. This is the third in a series of four lectures that examine the relationship between the legal system and the global health crisis.

In the first lecture in the series, I described the global health crisis and the potential roles of vaccines and medicines in alleviating it.

In the second, I examined some ways of improving the markets for pharmaceutical products that would help all parties: innovator firms, generic manufacturers, distributors, the governments of developing countries, and above all the residents of developing countries who would have more ready access to affordable medicines.

In this, the third in the series, I'll be discussing ways in which intellectual property laws could be adjusted -- both to improve access to existing medicines and to improve incentives for the creation of new ones.

In the first half of the lecture, I'll discuss ways in which developing countries could modify their legal systems. In the second half, I'll turn to analogous reforms that developed countries could pursue.

The premise of my analysis of the options available to developing countries is that the availability of intellectual property protection for pharmaceutical products in those countries currently has little impact on the incentives of pharmaceutical firms to develop new medicines. This is not to say that intellectual property protection is unimportant as a source of incentives; quite the contrary. Patent rights and data-exclusivity rights in developed countries are extremely important in stimulating and directing research and development. Much of the second half of this lecture will be focused on refining the pattern of incentives they create.

But IP rights in developing countries have much less impact on incentives to engage in research and development. Why? Well, simply because the revenues that the pharmaceutical firms can earn from the patients in developing countries are much more modest than those they can and do earn in the United States, Europe, Japan, Australia, and a few other jurisdictions.

One manifestation of the relative unimportance of developing countries in terms of incentives is that, in a surprisingly large subset of cases, even when patent protection for medicines and

vaccines is available in those countries, pharmaceutical firms do not bother to apply for such patents.

The implication of this generalization is that the governments of developing countries should, to the extent possible, curtail patent protection and data-exclusivity protection for pharmaceutical products. By doing so, they would reduce impediments to access to those products without undermining incentives to create them.

This is a controversial assertion. My hope is that it will become less controversial when, at the completion of this lecture series, I'll show how a combination of the legal reforms we're considering could fit together – and thereby, in the aggregate, enhance (not just preserve) incentives for new drug development and the revenues of the key innovators.

So, to repeat, governments of developing countries should, to the extent possible, curtail patent protection and data-exclusivity protection for pharmaceutical products. The qualifying phrase, “to the extent possible,” is very important. As you know from previous lectures in this course, the power of developing countries to modify their IP regimes is limited by multilateral treaties, the most important of which is the TRIPS Agreement. Some developing countries are also bound by the terms of bilateral or regional agreements. They can go no further than those agreements permit. To determine the options available to them, we must catalogue and interpret the constraints.

The most important of the relevant provisions of the TRIPS Agreement is Article 27.1, set forth on your screen. It provides, in pertinent part, that patents shall be available -- and patent rights enjoyable -- without discrimination as to the field of technology. This language is not crystal clear, but, in historical context, there's little doubt that the objective of this provision of Article 27 was to require all member countries of the World Trade Organization to extend patent protection to pharmaceutical products.

In just a minute, we'll consider some offsetting provisions elsewhere in the TRIPS Agreement, but first we need to consider some other constraints.

Articles 42 through 49 of TRIPS, now set forth on your screen, require member countries of the World Trade Organization to make effective remedies for violations of intellectual property rights available to the holders of those rights. The most important of the provisions within this set is 44.1, which provides that the judicial authorities in a member country shall have the authority to order a party to desist from an infringement -- in other words, to grant injunctions.

Finally, article 39.3 requires member countries to protect pharmaceutical firms that submit data in support of applications for marketing approval, against “unfair commercial use” of that data by others. This is the residue of efforts by the United States and some other countries to include in the TRIPS Agreement an obligation to provide pharmaceutical firms data-exclusivity

protections. For the most part, those efforts failed. The vague language of 39.3 is all that they were able to secure.

OK, those are the main fences erected by the TRIPS Agreement, As I mentioned, a second source of limitations on the zones of discretion enjoyed by some developing countries are so-called free-trade-agreements that those countries have entered into – for example, with either the United States or the European Union.

Some of these so-called FTAs contain provisions that impose upon the parties obligations stricter than TRIPS to respect intellectual property rights in general -- and patent rights in pharmaceutical products in particular. There are four main types of such provisions.

- Some limit the availability of compulsory licenses more sharply than does Article 31 of the TRIPS Agreement.
- Others restrict the freedom of countries to mandate international exhaustion and thus to permit parallel importation of patented goods
- Others pertain to the duration of patents
- And still others mandate data exclusivity protections more effectively than does TRIPS 39.3.

I'll provide examples of each in due course.

The FTAs are important – but not as important as is generally supposed. The reason is that, although there are currently over 200 such agreements in force, only a modest number of developing countries, are subject to them. As you can see from this map, if we focus on the FTAs to which the United States is a party, it's a surprisingly small number, and most them consist of agreements between the US and upper-middle-income or high-income countries.

The sparse geographic coverage of these agreements may not last. The United States continues to try to negotiate agreements with additional countries. For example, it is currently in the late stages of negotiating with Ecuador an agreement that would complement those already in place with Peru and Colombia. The European Union pushes for such deals at least as hard as the US. Finally, as Peter Yu has shown, a growing group of other countries are now participating. But, for the time being, relatively few LMICs are bound by them.

We now turn to the zones of latitude left by these constraints. The first of them is a byproduct of the fact that TRIPS only binds members of the World Trade Organization. The countries indicated in red in this map are not members of the World Trade Organization and thus are not bound by TRIPS. As you can see, several of them are developing countries.

The countries marked in yellow on the map are members of the World Trade Organization -- but are classified as “least-developed countries.” Article 66 permits them to delay compliance with the relevant aspects of TRIPS until a date that several times has been extended by the TRIPS Council. Currently, that date is July 1, 2034, more than a decade down the road.

The net effect is that the red and yellow-colored countries shown on the map may, if they wish, deny patent protection to pharmaceutical products altogether. Arguably they should.

The countries that are subject to the TRIPS constraints cannot go that far, but they retain some important options. They have come to be known as the TRIPS flexibilities. As indicated on the screen, there are four general types of such flexibilities. By far the best known are flexibilities pertaining to limiting the rights enjoyed by patentees. The other categories -- tightening patentability requirements, limiting duration, and limiting remedies -- are less well-known and less often exercised. But as I'm going to try to show you, they may actually be more effective in opening up opportunities for increased access to medicines.

Let's start with the familiar category. The TRIPS Agreement, as amended and construed, contains two mechanisms for allowing developing countries faced with health emergencies to limit the rights enjoyed by patentees. The first and most general is the right of parallel importation. The relevant provision is Article 6 of the TRIPS Agreement. As usual, the language is not lucid, but its effect is to free member countries to permit the importation of patented products from other countries. That makes it possible for poor countries, if they're able to identify any other jurisdiction of the world that has drugs available for sale at low prices, to buy them and import them.

As I mentioned a minute ago, a few FTAs limit the discretion that countries enjoy under Article 6. Here's an example – implicitly compelling renunciation of international exhaustion. But very few developing countries are subject to such constraints.

Even better known is the freedom of developing countries to exercise their power to impose compulsory licenses upon drugs when necessary to meet health emergencies. Two provisions in the original version of TRIPS create opportunities to issue such compulsory licenses. Article 30 provides broadly:

Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

Article 31, as you can see, is vastly more detailed.

All of these provisions contain important ambiguities – some of them unintentional, others deliberate. Article 30 is perhaps the most ambiguous. It contains a version of the so-called “three-step test,” which sets a general limit on countries’ freedom to recognize “exceptions and limitations” to patent rights. The crucial terms it employs -- “unreasonably”; “normal”; and “legitimate” – are notoriously vague.

Article 31 at first appears more precise than Article 30, but turns out to be leavened with similarly undefined terms: “national emergency”; “extreme urgency”; “adequate remuneration”; “anti-competitive”; and so forth.

These ambiguities help explain why the initial invocations of these flexibilities were so fraught. The first major step was taken by Brazil. In 1996, facing the early waves of the AIDS epidemic, the legislature amended Brazil’s patent statute to impose compulsory licenses on patents if they were not “worked” in the country – specifically, if the patentees did not manufacture products governed by their patents in the territory of Brazil within three years of the patent grants. Pharmaceutical firms denounced the initiative and spurred the U.S. government to initiate a WTO dispute settlement proceeding against Brazil, contending that the amendment violated Articles 27 and 28. Brazil responded aggressively, contending that the compulsory licensing options in Article 31 qualified the non-discrimination provision in Article 27 – and moreover, that if Brazil’s law violated TRIPS, then so did some provisions of the U.S. patent statute, which required that products embodying specific inventions be “manufactured substantially in the United States.”

The attractiveness of the U.S. position was further corroded by the obvious effectiveness of Brazil’s campaign to fight AIDS – a campaign sustained in part by low prices on patented ARVs. In 2001, increasingly worried about both the feasibility and the wisdom of pressing the issue, the U.S. retreated, withdrawing its complaint. The practical result was that ARVs remained affordable and widely available in Brazil and the curve of the AIDS epidemic there was flattened.

Meanwhile, the government of South Africa, facing an even more serious threat from AIDS, began considering bills that asserted the government’s right to import patented drugs from countries where they were being sold more cheaply – and, even more radically, would have compelled the patentees to license generic manufacturers to produce the drugs at issue in return for modest license fees. These bills were denounced by major drug manufacturers as “abrogations” or “expropriations” of their patent rights. The manufacturers brought suit in the High Court of South Africa, contending that they ran afoul of the South African Constitution. In addition, at the manufacturers’ behest, the government of the United States threatened South Africa with various trade sanctions.

Three related developments eventually prompted the firms and the U.S. government to back down. First, AIDS activists, both in South Africa and in the United States, vocally supported the South African government’s initiatives and accused the pharmaceutical firms and the United States of killing poor patients. Second, Al Gore, who, in his capacity as co-chair of the U.S./South Africa Binational Commission, had lent support to the drug manufacturers, became a candidate for President of the United States and became concerned that the activists’ sharp criticisms of his stance threatened his candidacy. Third, the controversy attracted growing attention from the media throughout the world. In combination, these developments prompted Gore and President Clinton to signal a willingness to reconsider the position of the US government and prompted the firms to look for ways of escaping what they had come to see as a public-relations nightmare.

Refinement and formalization of the outcomes of these high-profile battles occurred in three stages. First, the scope of the power retained by developing countries to temper intellectual-property rights to respond to health emergencies was one of the main topics of the Fourth Ministerial Conference of the WTO, held in Doha, Qatar in November of 2001. The discussions gave rise to the so-called “Doha Declaration,” which adopted most of the positions advocated by a united group of developing countries. Second, in the wake of the Doha meeting, a prolonged and multi-cornered negotiation concerning the use of compulsory licenses to enable developing countries that lacked domestic drug-manufacturing capacity to import drugs made by generic firms in other countries eventually led to the WTO Decision of August 30, 2003, which ostensibly endorsed this option but burdened it with an extensive set of procedural requirements. Finally, in 2017, the 2003 Decision was embraced by two thirds of the WTO member countries and thus was cemented into a new provision of the TRIPS Agreement itself: Article 31bis.

This prolonged and unconventional process by which the meaning of TRIPS was clarified has not eliminated all disagreement concerning the scope of Articles 6, 30, and 31. But at least two important points are now reasonably settled. First, all countries are free to set their own policies pertaining to “exhaustion” of patent rights – and thus may, if they wish, permit importation into their own jurisdictions of drugs sold at low prices in other countries with the authority of the patentees. Second, developing countries have considerable latitude under Article 31 to decide what constitutes a “health emergency” and to compel patentees to give generic firms and/or procurement authorities permission to manufacture, distribute, and import drugs that would alleviate those emergencies, provided that the licensees pay modest license fees.

The most important practical question that remains is whether Article 31bis is adequate to enable compulsory licenses to be used to authorize production of drugs in one country for export to another. Critics contend that its intricate requirements make it virtually unworkable. As you can see, the provision itself is complex. But that’s not all. It incorporates by reference the requirements of paragraph 2 of the Annex, which is comparably detailed. And paragraph 2, in turn, has several footnotes, which refine the requirements further. Whether its practicable to overcome these various hurdles is a topic that is likely to come up in the seminars that accompany this lecture.

For the most part, this first set of flexibilities remains unaffected by the Free Trade Agreements, discussed above. A few of the FTAs that the United States has negotiated with other *developed* countries – for example, those with Singapore and Australia -- do set limits on compulsory licenses. But not those with low and lower-middle income countries.

Flexibilities of the second type – opportunities to constrict the set of innovations that may be patented – have been invoked less often by developing countries. Partly as a result, their scope remains more contested. However, because they have the effect of eliminating patent protection for some drugs altogether, they are potentially more powerful than flexibilities of the first type.

The best known option in this group derives from the ambiguity of the term, “inventive step.” As I mentioned, Article 27 requires that patents “be available for any inventions ... in all fields of technology, provided that they are new, *involve an inventive step* and are capable of industrial application.” An accompanying footnote permits countries to treat “inventive step” as synonymous with “non-obviousness.” But TRIPS does not define either “inventive step” or “nonobviousness.” This has prompted some commentators to argue that WTO members are free to define them in ways that would prevent the patenting of modest improvements on existing drugs.

The only country that, to date, has invoked this option is India. When the government of India was finally obliged to recognize patent protection for pharmaceutical products, it tempered that recognition by adding to its patent statute section 3(d), which excludes from patentability “the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance.” In a series of cases involving the patentability of a recently developed variant of Novartis’ cancer drug, Glivec, the courts in India construed this provision to require patent applicants to demonstrate that a “new form” of an existing drug has greater therapeutic efficacy than the original.

Thus far, no country has initiated a WTO dispute resolution proceeding to challenge section 3(d) of India’s statute. Perhaps mindful of the fate of the U.S. actions against Brazil and South Africa, the government of Switzerland, where Novartis is based, has indicated that it will not do so. However, there remains considerable disagreement concerning whether the Indian provision is compatible with TRIPS. Commentators who think not make two main arguments. First, they assert that, when the TRIPS Agreement was adopted, the terms, “inventive step” and “nonobvious,” had stable, well-recognized meanings, which the drafters of TRIPS meant to invoke. Far from being free now to adopt their own definitions of those terms, developing countries are obliged to extend patent protection to all inventions that satisfy the definitions in place *circa* 1994. Second, commentators contend that India’s statute, by subjecting pharmaceutical product patents to an inventive-step requirement more stringent than that imposed on other types of inventions, violates the requirement of Article 27 that “patents shall be available and patent rights enjoyable without discrimination as to ... the field of technology.”

In my view, the first of these arguments is unpersuasive. The terms, “inventive step” and “nonobvious” have meant very different things at different times and in different countries. As you know from the Module 104, even within the United States, the degree of inventiveness required for patentability has fluctuated dramatically. In sum, to suggest that the meaning of “inventive step” was clear and stable as of 1994 (and thus now binds developing countries) is historically naïve.

The second of the two arguments advanced by the critics of section 3(d) is more colorable. India does seem to hold applicants for patents on pharmaceutical products to a higher standard of

inventiveness than it does applicants for patents on innovations in other fields – something that TRIPS seems to forbid. However, the United States is not free of criticism on this score.

Here again, the Module 104 lecture is relevant. As I showed there, although U.S. patent law purports to be “technology neutral,” in practice U.S. courts have applied different meanings of nonobviousness in different technological contexts. Were the U.S. to accuse India of discriminating among fields of technology, it would likely be met (as it was in the proceeding it brought against Brazil) by an accusation of hypocrisy.

Suppose, then, that a developing country less populous and powerful than India adopted a provision resembling Section 3(d) and that the United States challenged it in a WTO dispute resolution proceeding. Would the developing country prevail? The answer would depend in part on the strength of the arguments just summarized. But one of the lessons of the struggles over compulsory licensing in Brazil and South Africa is that the outcomes of such proceedings are likely to depend at least as much on the larger political environment, one aspect of which would be whether the provision could be characterized persuasively as necessary to save lives. In short, whether a developing country could win a fight with the U.S. would likely depend heavily on the political context and on the manner in which its initiative was depicted in the media – factors over which it would have only partial control.

A second patentability requirement that could be tightened by a developing country without running afoul of the TRIPS Agreement is enablement. To my knowledge, no country has yet done this, and commentators seem not to have noticed this flexibility. But it is potentially even more useful than inventive-step. As the Module 103 lecture explained, all developed countries currently require patent applicants to provide in their applications sufficient information to enable a person having ordinary skill in the relevant art to practice the invention at issue.

The interpretation of this requirement by courts has varied considerably, but it is certainly not currently taken literally. As you know by now, the holders of patents on complex pharmaceutical products routinely withhold proprietary know-how which is essential to manufacturing the products in question – and do not thereby forfeit patent protection. Nothing in the TRIPS Agreement – or in the FTAs – would prevent a developing country from interpreting the enablement requirement more strictly. Particularly if their courts defined the famous PHOSITA as a person within the country in question having ordinary skill in the art, the result would be either to compel disclosure of much more information than the patentees conventionally provide – or to narrow their claims sharply – or simply not to apply for patent protection in the developing country in question. Any one of these outcomes would increase access to medicine in that country.

One type of product to which an initiative of this sort would be especially powerful would be monoclonal antibodies. As we have seen, patents on those drugs often include broad genus claims. By requiring the patentees to provide enough information to enable a person having ordinary skill to produce every species within the genus, courts or legislatures in developing

countries could sharply narrow the patent protection available to new antibodies. To be sure, this by itself would not induce the innovator to make available the proprietary know-how related to the production on monoclonal antibodies. Thus, the practical benefit would be limited to countries in which pharmaceutical firms have the skills to produce such things unaided. But the set of developing countries that have that capacity is growing.

Flexibilities of the third type are simpler and clearer. Article 33 of the TRIPS Agreement requires that the term of patents not be shorter than “twenty years counted from the filing date.” However, TRIPS neither requires that patent applications be processed within a specific period of time nor compels countries to extend patents to compensate applicants for the amounts of time they expend prosecuting their applications or securing regulatory approval. This means that developing countries are free to squeeze patents at both ends.

At the front end, they could drag their feet processing applications. Many developing countries have long done this semi-intentionally, simply by not allocating significant resources to the offices charged with evaluating applications. TRIPS creates no impediment to adopting this strategy more deliberately.

Similarly, TRIPS does not require countries to extend patents on pharmaceutical patents beyond the 20-year line, regardless of how long it takes to process applications or secure regulatory approval. As we have seen, the U.S. patent system contains provisions enabling the holders of pharmaceutical-product patents to obtain term extensions sufficient to give them, on average, 12 years of commercial life. But developing countries are not obliged by TRIPS to follow suit.

This is one zone where the Free Trade Agreements, discussed above, potentially have bite. As I mentioned, a few of the existing agreements do contain requirements that the member countries either process patents reasonably expeditiously or extend their duration. For example, the agreement between the US and Colombia contains the provision shown on your screen. The Central American Free Trade Agreement, which binds Costa Rica, the Dominican Republic, El Salvador, Guatemala, Honduras, and Nicaragua, contains a similar obligation.

What about the large majority of developing countries that are not subject to commitments of this sort? Should they avail themselves of these options? Deliberately slowing down the processing of patent applications is probably a bad idea. Few generic firms are likely to take advantage of the temporary gap in patent protection, uncertain whether or when it will close. By contrast, refusing to extend the duration of patents beyond 20 years from the date of application is probably a good idea. It would accelerate the moment when generics could enter the field and thereby significantly increase access to medicines.

To date, flexibilities of the last type – opportunities to limit the *remedies* available to patentees whose rights have been infringed – have received almost no usage or attention. However, recent developments in U.S. patent law ironically have revealed a substantial zone of discretion that developing countries might use to increase the availability of drugs.

To remind you, the relevant provisions of the TRIPS Agreement are Articles 42 to 49, which collectively require all WTO-member countries to make available to the holders of intellectual-property rights effective “civil and administrative procedures and remedies.” At the time the TRIPS Agreement was drafted, these provisions were widely regarded as onerous. But lurking in these provisions are opportunities for curtailing, rather than expanding the availability of remedies for patent infringement. Note, in particular, that all of these provisions require countries to give their courts the power to issue injunctions, award compensatory damages, and so forth -- but do not specify the criteria that must govern the exercise of that authority. Silence in this respect is thus analogous to TRIPS’ silence with respect to the meaning of “inventive step.” Arguably, it leaves countries free to adopt provisions limiting the circumstances in which remedies must be available.

To this interpretation there is an obvious retort: As indicated above, the overarching purpose of the Agreement – and of Articles 41-49 in particular – was to provide patentees *effective* remedies for violation of their rights. Any interpretation of the pertinent clauses that would undermine that central objective cannot be right.

Until recently, that retort would have been powerful. It has been significantly undermined, however, by the history of the portions of the U.S. patent regime pertaining to remedies. As I explained in the lecture for Module 107, the decision by the Supreme Court in the 2006 eBay case has prompted federal courts in the US to limit sharply the circumstances in which they will grant injunctions to prevailing patentees. Today, grants of injunctions are considered the exception, not the rule.

To be sure, denial of an injunction ordinarily does not mean that the defendant is free thereafter to engage in the activity in question with impunity. Instead, the judge will ordinarily, at the patentee’s request, determine an “ongoing royalty” – an amount of money that the defendant has to pay the patentee if it wishes to continue. The amounts of such royalties vary substantially – in part because neither the Supreme Court nor the Federal Circuit has thus far given the trial judges guidance concerning how to calculate them. The crucial point for our purposes is that the amount is under the control of the judge – and is almost always less than the license fee that the patentee, given its druthers, would demand.

Assuming, plausibly, that U.S. law governing patent remedies would not be deemed to violate the TRIPS Agreement, the recent history of injunctive relief has two implications for developing countries. First, they are free to instruct their judges to deny injunctions in circumstances in which such injunctions would threaten “the public interest” – and, specifically, would endanger public health. Second, they are free to empower judges to determine the amounts of the “ongoing royalties” that generic firms must pay the patentees if they wish to manufacture and distribute products covered by their patents.

What criteria should be used to calculate those ongoing royalties? On this issue, the practice of U.S. courts provides less guidance. Recurring to the language of the TRIPS Agreement itself, a

plausible answer would be: judges should select an amount “adequate to compensate for the injury the right holder would suffer” as a result of the generic firm’s conduct. As we have seen, in many developing countries, the revenues that patent owners are able to extract by enforcing their patents are modest. Consequently, the royalty that judges could order in lieu of injunctive relief should be comparably modest.

The fruit of this inquiry is that, hidden in the structure of the TRIPS Agreement is an alternative mechanism by which developing countries can free up generic firms to make patented drugs. They need not rely upon compulsory licenses issued by statute or administrative decree – a process that, as we have seen, is fraught with controversy. Instead, they could follow the lead of the United States in limiting the availability of injunctive relief for patent violations – and then allow generic firms to use declaratory-judgment suits to determine the amounts of the license fees they have to pay.

To review, there are four ways in which developing countries can limit patent protection for pharmaceutical products without violating their treaty obligations: (a) limit patentees’ exclusive rights (for example, by permitting parallel importation of patented drugs lawfully sold elsewhere or imposing compulsory licenses on the relevant patents); (b) require patent applications to meet high inventive-step and enablement requirements; (c) limit the duration of patents by renouncing term extensions; and (d) limit the remedies available to patentees in ways suggested by the recent history in the United States.

Of these options, the only one that developing countries have thus far used with any frequency is compulsory licensing – and recently even that device has been used less and less often. I’m going to place on the screen a list compiled by the Medicines Patent Pool of all 168 instances in which, since 2001, countries have initiated an exercise of one of the TRIPS flexibilities. Take a minute to peruse the list. Then I’ll distill from it some generalizations.

Here are some things that can be gleaned from the list:

Until 2014, the large majority of the invocations involved drugs aimed at HIV/AIDS. Since 2020, by contrast, all have involved drugs aimed at COVID-19.

Putting aside the invocations that are still pending, 82% were finally executed and 18% were not.

Of the 168 invocations, 27% were by least developed countries, invoking their exemption (confirmed by paragraph 7 of the Doha Declaration) from the relevant provisions of TRIPS. At the opposite end of the spectrum, 13% of the invocation were by high-income countries

71% involved actual or threatened invocations of Articles 31 or 30 – the provisions that, as you now know, identifies the circumstances in which compulsory licenses are available.

Only one of the 168 involved the special sort of compulsory license governed by paragraph 6 of the Doha Declaration, later cemented into Article 31bis of TRIPS – namely deals in which drugs would be produced in one country and exported to another. That one instance involved an export of products from Canada to Rwanda in 2007. As I mentioned, the lessons that can be drawn from that single instance will be discussed in the seminars that accompany this lecture.

Last but not least, the frequency of actual or threatened issuance of compulsory licenses by developing countries (including LDCs) has been declining over time. As you can see, it peaked in 2005. Except for a brief surge during the COVID pandemic, it's been low ever since.

The numbers shown on your screen I derived from the TRIPS Flexibilities database. The numbers provided by a group of scholars led by Ellen t'Hoen are slightly different, but show the same overall trend.

Let's return to the finding that, in 18% of the cases in which invocation of one of the flexibilities was initiated, it was not executed. Here's a list of those cases. There are 28 of them. As you can see, in most of the instances in which the invocations did not go forward, the country in question secured a concession of some sort from the patentee, typically a price reduction or a voluntary license.

An important general issue lurks in this observation. Effective use of a TRIPS Flexibility does not necessarily require that it actually be exercised. A credible threat can be employed to induce an innovator to increase access to affordable medicines in some other way. Arguably, the TRIPS flexibilities should be used as leverage in this fashion more often and more strategically.

For example, instead of securing a price reduction, a country might use a promise to forego compulsory licensing -- not in general, but rather with respect to a particular drug -- as part of a package that persuades the patentee to agree to the kind of voluntary licensing system we discussed last week.

Another example of leverage: As we have seen, most developing countries currently enjoy substantial discretion in determining whether to extend data exclusivity to registered innovative products. A few middle-income countries have given up that discretion as part of FTAs – Peru would be an example – but most have not. Agreeing to extend data exclusivity to a particular drug could be one of the inducements that triggers a voluntary license.

OK. Let's return to the overall picture. 168 invocations over a 20-years period is a remarkably small number.

A natural question is why have the flexibilities been used so infrequently by developing countries, especially recently. One possible explanation is that the governments of developing countries discovered that their use was ineffective in reducing the prices or increasing the availability of drugs.

That hypothesis quickly collapses. Several recent empirical studies have examined the impacts of compulsory licenses in specific countries; all have concluded that they resulted in sharp price reductions, which in turn increased the set of patients who had access to the drugs in question, reduced the financial burdens borne by public health systems, or both.

An alternative possible explanation for the declining usage of TRIPS flexibilities supposes that the strategic and high-profile initiatives that I described a minute ago by Brazil, South Africa and some other large developing countries convinced pharmaceutical firms of the willingness of all developing countries to use their powers. Since then, the firms may have taken that willingness into account when negotiating the prices they charge either the developing countries themselves or the international organizations that are providing them drugs. As a result, countries may no longer feel the need to use compulsory licenses; the threat – explicit or tacit – to use them is enough. However, the ability of pharmaceutical firms to maintain high prices in developing countries on many other patented drugs strongly suggests that this is not a complete explanation.

Three other factors seem to be at work. The simplest is that the relevant officials in some developing countries are simply unaware of the powers they enjoy. This is the most likely explanation of the fact that some of the poorest countries, who until 2033 have no duty to extend patent protection for drugs, currently do so.

Second, it is difficult, controversial, and time-consuming to use these powers on an ad-hoc basis. A country's ability to respond to threats to public health – some of which, as we have seen, arise suddenly – is maximized if, when they emerge, the administrative apparatus necessary to invoke these powers is already in place. Although the large majority of countries now have statutes (or adhere to regional agreements) that authorize the issuance of compulsory licenses, few of those provisions establish machinery sufficiently detailed to enable expeditious issuance of such a license.

The third factor is that government officials in some developing countries have been deterred from using these tools by the prospect of retaliation, either by developed countries or by adversely affected pharmaceutical firms. As we have seen, the early exercises of these powers provoked fierce reactions. The persistence and notoriety of these retaliations may have prompted most small developing countries – many of whom depend on the United States and the European Union for foreign aid – to refrain from poking the bears.

If developing countries are to employ the flexibilities more actively, these obstacles must be dismantled. With respect to the first of the three factors, the principal reason why I have devoted so much attention to the arcane issues involving the interpretation of the TRIPS Agreement is to clarify, for officials in developing countries, the options currently available to them.

With respect to the second factor, lawmakers in developing countries can and should act now to create the administrative machinery to enable them to respond most effectively to the threats on the horizon. For example, countries (such as Bangladesh) that have not yet adopted the

necessary statutory authority to impose compulsory licenses on pharmaceutical patents, should do so. The countries that do have such provisions can and should amend them to facilitate their efficient invocation. A sensible statute would have at least the features that appear on the screen. Less important than the details of such a statutory regime is that a country have one. That way, when a health crisis looms, they do not need to start from scratch.

Of the three factors, the most troubling – and perhaps the most powerful – is the threat of retaliation. There is little that the governments of developing countries can do to mitigate this hazard; that can only be achieved by the governments of the countries from which the threats emanate. We thus postpone our discussion of it until the second half of this lecture, which deals with possible modifications of the IP systems of developed countries.

Part B: Developed Countries

Hello, I'm Terry Fisher. This is the second half of a lecture examining potential modifications of intellectual property systems that might help alleviate the global health crisis. In the first half, I examined possible reforms of the laws of developing countries. In this half, I turn to possible modifications of the laws of developed countries.

This shift in focus has an important implication: The laws of developed countries, unlike those of developing countries, do have a major impact on the creation of new drugs. Consequently, from this point forward, we must keep in mind not only the value of increasing access to crucial medicines, but also the need to preserve or, better yet, to augment incentives for research and development on new medicines.

As we have seen, the country whose laws have the greatest impact on the creation and availability of vaccines and drugs is the United States. Consequently, the bulk of my analysis will concentrate on possible reforms of U.S. patent law. However, most of the proposals I'll discuss are equally applicable to other developed countries.

As I did with developing countries, I'll start by examining the constraints that set limits on the potential scope of law reform. There are three of them. The first is obvious. Developed countries, including the US, are of course bound by the terms of the pertinent multilateral treaties, the most important of which is the TRIPS Agreement. In the first half of this lecture, we examined the complex combination of limitations and "flexibilities" produced by TRIPS. That combination binds the United States just as much as it binds developing countries.

The second of the three constraints is peculiar to the United States. When adjusting the patent regime, US lawmakers are bound by the so-called "takings" provision of the Fifth Amendment to the federal Constitution. That provision provides: "Nor shall private property be taken for public use without just compensation." Judicial interpretations of that provision are both intricate and unstable. Mapping them would take us far afield. The readings that accompany this lecture

explore this territory at a medium level of detail. But, for the purposes of this lecture, I'll ask you to take, more or less on faith, a few illustrative conclusions of the analysis:

An outright expropriation of an existing patent (or a group of patents) would surely be declared unconstitutional. So, for example, the federal government could not simply declare that the patent held by a private pharmaceutical firm on a newly developed COVID vaccine henceforth would belong to the government, which would assume responsibility for manufacturing and distributing the vaccine.

To be sure, the government could expropriate such a patent if it paid the firm the value of the patent. Indeed, a federal statute implicitly confirms that power by specifying a mechanism for determining the appropriate amount of the compensation. But an uncompensated expropriation would be unconstitutional.

Second, prospective modifications of patent laws – in other words, changes that would not affect existing patents or perhaps patent applications – would not be unconstitutional.

Whether a particular retroactive modification of the patent laws would pass muster would depend on the circumstances. Some examples:

Suppose that Congress shortened the commercial life of pharmaceutical patents by eliminating the term extension designed to offset the time spent doing clinical trials and securing regulatory approval. . There is a good chance that the courts would strike this down, reasoning that the term extension thereby eliminated is “discrete” and that many patentees had made substantial investments relying on its availability.

By contrast, the adoption of a comprehensive set of price controls on sales of pharmaceutical products – analogous to the regimes already in place in many other countries – would probably not be deemed unconstitutional. The effect would not be an “economic wipeout” of the affected patents, and the multi-factor test that is conventionally applied to reductions in value would tilt in the government’s favor.

Finally, suppose that the government imposed a compulsory license on the patent on a particular drug – say, a patent held by Regeneron on a particular monoclonal antibody cocktail that promises to reduce COVID fatality rates. (Ignore for the moment the limits that TRIPS imposes on the use of this strategy.) This too would be likely to pass constitutional muster, at least if the compulsory license fee were adequate to permit Regeneron to recover its costs.

The last of the three constraints is political, rather than legal. In the United States, pharmaceutical firms spend more on lobbying (directed at legislators of both political parties) than do the firms in any other industry. Here are some diagrams showing how contributions flow from the major companies to the members of Congress.

Partly as a result of such donations, and partly because of the importance of the firms to the national economy, the firms enjoy substantial political power. The prospects for any change in intellectual-property law that substantially disadvantages them are not good.

Although this barrier is formidable, two things make it less than insurmountable. First, popular hostility to the pricing practices of the firms has been rising in recent years, and the current pandemic has augmented it.

Second, although the firms would oppose any individual adjustment of the patent system that reduced their revenues, they might acquiesce in – or even support – a package of adjustments, some of which disadvantaged them, so long as the net impact of the combination left them at least equally well off. This has already occurred at least twice. Portions of both the Hatch-Waxman Act and of the Affordable Care Act hurt the pharmaceutical firms, but in each instance the overall package left them, roughly speaking, equally well off. That the firms did not oppose either initiative was crucial to their passage. When considering how to alleviate the health crisis in the developing world, we should look for similar combinations.

With these three constraints in mind, we can now turn to the reforms of patent law that developed countries might employ to help alleviate the health crisis in the developing world.

As we have seen, the intellectual-property systems currently used by the United States and other developed countries create biases against research and development on three overlapping types of pharmaceutical products. The first is the bias against drugs aimed at the subset of infectious diseases that have disproportionate impact on developing countries. The second disfavored category consists of vaccines, regardless of the type of disease they are designed to prevent – partly for the reasons discussed by Martin Friede in his interview. The third consists of “breakthrough” drugs of all sorts.

The relationships among these categories might be depicted using the venn diagram shown on your screen. To reduce these biases, we might either augment incentives for innovations that fall into one or more of the three zones or reduce incentives for innovations outside of them.

Before addressing what dials might be turned to achieve these effects, we pause to consider how the three categories might be defined. The green circle is the easiest to draw. The meaning of the term, “vaccine,” is clear: “a product that stimulates a person’s immune system to produce immunity to a specific disease, protecting the person from that disease.”

The red zone can and should be defined by using an administrative process to make (and periodically revise) a list of the diseases in question. The FDA has already developed such a list to implement its “priority review voucher” program, which we’ll discuss in due course. That list appears on your screen. It’s not perfect, but should suffice for illustrative purposes.

The blue zone would be the most difficult to define. One imperfect but simple way of doing so would be to use the criteria that the FDA already employs when designating particular drugs as “breakthrough.” Unfortunately, the way in which the agency defines “breakthrough” does not align well with how we have been using the term. More administratively burdensome but better would be to create a new metric, which estimated the health benefits that would be associated with a particular drug (over and above the benefits of drugs already available) and treated all drugs above a particular number as “breakthrough.” In the next lecture, when discussing prize systems, I’ll say a bit about how such a metric might be constructed. For the time being, that it would be feasible.

Having defined the three zones, at least provisionally, we turn to the crucial question: how, without running afoul of the limitations discussed in the preceding section, could the IP rights associated with a drug falling into one or more of these categories be enhanced -- or could the IP rights associated with a drug outside them be reduced?

With respect to enhancements, four options seem most promising. First, the duration of the IP rights at issue might be extended. This, in turn, might be achieved either by increasing the duration of the patent(s) on such an invention or by increasing the duration of the data-exclusivity protections given to the innovator. The first technique, as we saw in Chapter 2, was employed as one component of the Hatch-Waxman Act. The second, however, would be simpler and more effective. Some years ago, I was one of a group of scholars advocating an extension of data-exclusivity protections to enhance incentives for breakthrough drugs focused on disorders of the central nervous system. That reform has not yet been adopted, but I continue to support it. The same technique could be employed to buttress inventions falling into any of the three zones we have identified here.

The significance of the venn diagram now becomes apparent. As it suggests, the biases are cumulative. Adjustments to the duration of IP rights thus ought to be cumulative as well. Suppose, for example, that the bonus associated with each category were three years. A breakthrough vaccine for a neglected infectious disease would then receive a bonus of nine years.

The second of the four ways of enhancing incentives for the currently disfavored categories would be to modify the guidelines for claim construction with respect to patents on products or processes falling within any one of these zones. As I discussed in Module 105, in recent years, US courts have largely repudiated the traditional principle that claims pertaining to pioneering inventions should be construed more broadly than claims pertaining to incremental inventions.

How, traditionally, was the term “pioneering” defined? A few of the definitions crafted by the courts appear on your screen. These terms align reasonably well with what I’ve been describing as “breakthrough” inventions. The implication should be obvious: Even without authorization from Congress, US courts could reinstate the traditional principle of claim construction – and extend it from pioneers to patents on vaccines -- and on medicines aimed at neglected diseases.

Even when competitors' products are found not to encroach upon the literal claims, they should more often be found to infringe under the doctrine of "equivalents." One context in which such a reform would make a difference concerns so-called "after-arising technology." Courts have long struggled with the degree to which products or processes incorporating technologies that did not exist when the application for a patent was filed but that resemble the invention at issue should be deemed to infringe. Adoption of this proposal would make that more likely if the patent fell into one of the preferred zones than if it did not.

The fourth and last of the possible techniques for enhancement concerns the remedies for patent infringement. For the reasons we discussed in Module 107 and in the first half of this lecture, the holders of U.S. patents now have a much harder time obtaining injunctions against infringers than was true at the turn of the century. The result has been to diminish significantly the magnitude of the royalties that they can extract from competitors. Like the flood and ebb of the extra latitude given pioneers, this doctrinal adjustment was made by the courts, not by Congress. Thus, it could be undone – in whole or in part – by the courts. Specifically, the courts revive the availability of injunctive relief for patents falling into any of the three zones.

The tool by which they could make this adjustment is readily at hand. As we have seen, since the decision by the Supreme Court in the *eBay* case, courts have been paying greater attention to whether a grant of injunctive relief would advance or impair "the public interest." For reasons that should now be apparent, augmenting the production of breakthrough vaccines, particularly those aimed at neglected infectious diseases, would advance the public interest.

To summarize, in three ways incentives to produce innovations involving breakthrough drugs, vaccines, and neglected diseases could be increased: (i) by extending the duration of the data-exclusivity rights associated with drugs of the three sorts; (ii) by expanding the set of similar products and processes that would be deemed to infringe the patents on such innovations; and (iii) by awarding injunctions more often to the holders of such patents when infringement has been found. The first of these changes would require legislation, but the second and third could be implemented by the courts.

Note that I'm suggesting such reforms only with respect to the laws of the United States and other developed countries. For the reasons discussed in the first half of this lecture, developing countries need not and should not adjust their laws in this way. Doing so would do little or nothing to increase incentives for the creation of new medicines and vaccines and would seriously impair the availability of such drugs to their residents.

An alternative way of reducing the current biases against the three zones would be to curtail the rights associated with innovations that fall outside them. The ways in which this might be achieved are probably already apparent.

The most obvious is that the duration of the rights associated with so-called "me-too" drugs could be reduced. This is where the constraints upon U.S. lawmakers' discretion become relevant.

Retroactive reduction of patent terms – in other words, shortening the duration of existing patents on me-too drugs – would not run afoul the TRIPS Agreement unless the surviving term were shorter than 20 years from the date of the patent application. However, for the reasons we have discussed, in the United States such a change would likely be deemed unconstitutional. Whether retroactive reduction of the duration of data-exclusivity rights would violate the Constitution is much less clear, but it would undoubtedly provoke the ire of the pharmaceutical firms that hold such rights. Their opposition would doom any initiative of this sort. *Prospective* adjustments of the duration of these rights would not implicate the Constitution, but the resistance of the firms would be almost as adamant. The probability of prevailing against such opposition seems low enough that I'll put this option to one side.

The second approach would be to reduce the availability of injunctive relief in cases where the patents on me-too drugs have been found to be infringed. As noted above, securing an injunction in such a case is more difficult than it used to be, but not impossible. Patentees' access to injunctions could be reduced further. The courts could do so by invoking the same criterion mentioned above: the "public interest." In his concurring opinion in the *eBay* case, Justice Kennedy (joined by three colleagues) already identified three types of patents whose violation should be especially unlikely to trigger injunctions: those held by nonpracticing entities; business-method patents; and patents in fields susceptible to royalty stacking. Kennedy's list has proven remarkably influential. To his set of disfavored types could be added a fourth: patents on me-too drugs.

The final option would apply to the laws of developed countries the modification of the nonobviousness doctrine that I discussed at length when considering modifications of the laws of developing countries. Specifically, the bar could be raised to exclude from patentability "a new form of a known substance which does not result in the enhancement of the known efficacy of that substance."

The Fifth Amendment would likely not prevent such a reform in the United States. As we saw in Module 104, the U.S. nonobviousness standard has been raised and lowered several times. Against this background, even a retroactive adjustment of the sort we have proposed would likely pass constitutional muster.

However, the pharmaceutical firms would almost certainly oppose such a change – even if it were only prospective. As a result, its prospects would hinge upon whether it could be packaged with reforms that the firms would support, such as the expansion of the rights associated with patents on breakthrough drugs.

The final way in which the legal systems of developed countries could be reformed is simple but important. As we have seen, one of the reasons that low and middle income countries have exercised their TRIPS flexibilities infrequently is that they fear retaliation by the adversely affected pharmaceutical firms or by the United States Trade Representative. That fear is justified by the manner in which the firms and the USTR have frequently acted in the past.

A simple way in which the government of the United States could come to the aid of developing countries would be to forbid such retaliation. Specifically, all executive officers, including the USTR, could be instructed to cease imposing sanctions on countries that adjust or apply their IP regimes in ways that are permitted by the multilateral treaties to which those countries have agreed. In addition, pharmaceutical firms could be forbidden to retaliate against countries that make such adjustments.

This suggestion is not radical. After all, in many other contexts, we forbid private parties to retaliate against others for exercising their legal rights. For example, employees who seek to organize unions, persons who file civil-rights claims, and tenants who complain about the poor condition of their apartments are all shielded from retaliation from the parties disadvantaged by their actions. Countries that exercise their legal authority to curtail IP rights to address health emergencies could and should be afforded similar protection.

Less obvious but equally important, the governments of developed countries, when they negotiate “free-trade agreements” with developing countries, should cease hobbling their exercise of the TRIPS flexibilities. For the reasons we have discussed, the powers retained by developing countries by the terms of TRIPS and by its subsequent interpretations and amendments are socially beneficial. Developing countries should not seek to limit them.

If U.S. lawmakers wanted to maximize the freedom of developing countries to use the TRIPS flexibilities, they could go even further. In addition to forbidding the USTR to discourage or penalize exercises of those options, Congress (or the President) might require the USTR to provide developing countries advice that would assist them in using these tools. Several U.S. government agencies already routinely and conscientiously provide private parties with guidance concerning the permissibility of proposed courses of conduct. For example, the Internal Revenue Service issues “private revenue rulings” to individuals or firms who want assurance concerning the tax implications of business plans, and the Federal Trade Commission indicates in advance whether specific mergers would be permissible. U.S. law could be amended to require the USTR to do something analogous when asked by a developing country.

Suppose, for example, that the government of Ghana were considering following the lead of Israel in imposing a compulsory license on a drug designed to alleviate COVID-19. Prior to doing so, the Ghanaian government could submit to the USTR an application describing the proposed license, royalty rate, etc. in detail -- and request a ruling concerning the permissibility of the initiative in question. The ideal response would consist of a published, reasoned analysis of the compatibility of the proposed initiative with TRIPS and other multilateral agreements. A more modest and practicable response, in light of the limited resources and authority of the USTR, would consist of a simple statement that the agency would or would not initiate proceedings to challenge the initiative. The United States would be bound by the USTR’s response, much as the IRS is bound by its “revenue rulings.”

To be sure, the creation of such a mechanism would entail a significant adjustment of the USTR's responsibilities. For many years, the agency has staunchly defended the interests of the pharmaceutical firms based in the United States whenever they have objected to initiatives by developing countries to promote access to medicine. The reform I've suggested would reorient the agency's mission sharply.

In the book I'm currently writing on the topic, I explore the legal and policy considerations relevant to this proposed reorientation of the USTR's responsibilities. I have to admit that it's unlikely in the near future that the Trade Representative would, as I've suggested, begin providing guidance to the governments of developing countries in the way that other federal agencies provide guidance to private parties. But global social welfare would be enhanced if the USTR took the more modest step of ceasing to discourage developing countries from exercising the flexibilities that they enjoy under the terms of the multilateral treaties to which the US is a subscriber.

This concludes my analysis of possible reforms of the IP laws – first in developing countries and then in developed countries – to alleviate the global health crisis. Next week, I'll step outside the frame of intellectual property and consider alternative incentives for the creation and distribution of life-saving drugs.