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**The Existing Legal Infrastructure of BRICs:
Where Have We Been and Where Are We Going?**

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¶1 MR. FRANCIS: We're about to continue with Panel No. 2. I welcome you all. I'm Clint Francis on the faculty, and it is my pleasure to operate as the moderator for this panel. The focus of this panel is incrementally shifting from the previous panel. Whereas the previous was looking at public/private issues and issues relating to incentivizing innovation in the subject countries, we're going to take a focus more on, I think it's safe to say, from an external perspective looking at these countries and issues that are confronted by businesses who our either planning to deal with the four subject countries or are concerned about their technologies being used in their four subject countries.

¶2 We have four panelists, and each of them is going to speak to one of the four countries. We're going to start with Julie Lee from Foley & Lardner, and she's going to be looking at special issues relating to China. And following that we're going to be hearing from Robert Ahdieh, who is at Emory Law School. His focus is going to be in particular on Russia. We're then going to turn to Srividhya Ragavan, and she's with the University of Oklahoma College of Law. She's going to be addressing in particular India. And we're going to end by having Kevin talk to us, and his focus is going to be nominally on Brazil, though his experience has been fairly far-reaching so he will no doubt address some of the issues that apply to all four of the subject countries.

¶3 So if I can turn the floor over to Julie. Thank you very much.

¶4 (Applause.)

¶5 MS. LEE: Thank you, Professor Francis. It's a great pleasure to be hear today. I've given many presentations about doing business in China before, but this one is very special to me because I was a Northwestern Law graduate in 1998 and I learned many, many things in this wonderful institution. So it's great to be here, to be back today, and talking with you about some of the things I learned outside the classroom.

¶6 I grew up in China and finished my college education in China, and after graduating from law school in 1998 I have been a practicing attorney at Foley & Lardner for the past eight-plus years.

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*** Panel speaker. Ms. Ragavan is an associate professor of law at University of Oklahoma College of Law.

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***** Panel moderator. Mr. Francis is a professor of law at Northwestern University School of Law.

¶7 Foley & Lardner is a large international law firm providing comprehensive legal services to our clients, and we're especially recognized as a leader in the IP area. Foley has offices in 16 cities within the United States and two offices outside of the U.S. In addition, we just filed an application to open an office in Shanghai, and once approved this office in Shanghai will focus on IP matters. We're all very excited about that.

¶8 We have helped many of our clients expand their business in China. One of the major concerns they have when expanding business to China is the protection of their intellectual property rights. China has gone a long way in the past 20-plus years developing its legal framework to protect intellectual property rights. Great progress has been made. On the books China's IP law is comprehensive and generally meets the requirement of the WTO. However, in practice loose implementing regulations and sporadic enforcement still frustrate foreign businesses conducting business in China.

¶9 Today I'm going to talk about two things. First, a brief overview of China's legal framework about IP protection, and secondly some practical suggestions about things that a business can do to protect their IP rights in China.

¶10 The basic legal framework for trademark protection in China is set forth in the trademark law and implementing regulations. Under Chinese law trademark registrations are valid for ten years and may be renewed for additional ten-year periods. A registered trademark may be canceled due to a variety of reasons, including that a trademark has not been used for three consecutive years or that there is fraudulent intent or action involved in the registration process.

¶11 Generally trademarks that are protected in other countries are not protected in China unless you go through the registration process, unless such trademark qualifies as something known as well-known marks. A well-known trademark refers to registered trademarks which enjoy a relatively high reputation in the market and are well known to the relevant public. However, because of the uncertainties surrounding whether a mark will qualify as a well-known mark it's always a good idea to register a trademark to avoid any uncertainties.

¶12 When registering a trademark in China a foreign company can choose between two mechanisms, international application under the Madrid protocol or registration with China's trademark office.

¶13 China adopts the first-to-file system, which means that a business doesn't need to use its trademark anywhere in the world, either in commerce or in other areas, before applying for a trademark. That's an important issue that when a business goes to China you always want to file for trademark protection before a counterfeiter does it for you.

¶14 When registering a trademark in China it is also important to register both the English version as well as the Chinese language version of the mark. Because if you don't do it, again, the Chinese counterfeiters may do that for you. And the Chinese customers may also come up with a nickname for your product, and there are a few problems with this. First, this increases the risk of piracy; and worse yet, the prevailing Chinese mark may be registered by your competitor in China.

¶15 In addition, your business may suffer if the Chinese prevailing mark has an negative connotation. In the Chinese culture the name is actually quite important, so if you have -- if the product has a negative connotation, the business will be negatively affected. One of the best examples I could think of about trademark is Coca-Cola's

Chinese trademark, which is "Ko Kou Ko Le." It means something that tastes good and makes you happy, and you don't get a drink much better than that.

¶16 Enforcement matters. I think the next panel is going to pay more close attention regarding enforcement issues. I just want to mention that enforcement has improved, as you may have known in the well-published case of Starbucks, which was a trademark case last year in Shanghai court.

¶17 The patent law and its implementing regulations govern the protection of inventions, utility models and designs. A U.S. company may choose between two mechanisms to apply for patents in China. It can do so through international registration through the Patent Cooperation Treaty. China should be designated as a country where protection is sought. This is generally a very expensive option unless a patent holder wants to apply for patents in multiple jurisdictions.

¶18 The second option is to apply with China's State Intellectual Property Office. Utility patents are generally good for 20 years, and utility model patents and design patents are generally good for ten years starting from the priority date.

¶19 Under Chinese law chemical and pharmaceutical products, as well as food, beverages and flavorings, are all patentable. The patentee must pay an annual fee to maintain the patent, otherwise the patent may be canceled. I think this is a feature that applies in many jurisdictions in the world.

¶20 Again, for patent protection, China adopts the first-to-file system. So if you want to file for patent protection in China, again, it's a good idea to start early.

¶21 Enforcement of IP rights, again, is getting better. And recently 3M won an enforcement case. From the government -- the government is also making efforts focusing on the training and certification program for patent officials and regulators.

¶22 The copyright law and its implementing rules protect literary works, fine art, engineering drawings, design drawings, graphic works, computer software and other works. Copyrighted works do not require registration with any governmental entity in order to obtain protection. However, it's generally a good idea for a copyright holder to register with China's National Copyright Administration to establish evidence of ownership; because if later there is an enforcement action, registration with the National Copyright Administration will save you a lot of trouble.

¶23 Again, enforcement efforts on copyright matters have grown in the past years in China. The government has started several national campaigns to crack down on copyright infringers. In 2005 one of the national campaigns, which is the Hawk action, resulted in nearly 6,000 counterfeiters being arrested.

¶24 Another piece of legislation which is relevant for IP protection is anti-unfair competition law. The law provides some protection for unregistered trademarks, trade dress, and trade secrets. I think the anti-unfair competition law is especially important for the protection of trade secrets. With respect to trade secrets, the law prohibits businesses from obtaining commercial secrets by unfair means. It also prevents businesses from disclosing, using or permitting others to use confidential information without authorization. It also plainly prohibits breaching confidentiality agreements.

¶25 Another thing I want to mention is that under the TRIPS agreement China is obligated to protect confidential information that was submitted to the governmental agencies for regulatory approval purposes.

¶26 Once you obtain your IP protection in China, whether it is patents or trademarks or other things, you can register your IP rights with China's General Administration of Customs. Following such registration, a company may petition the Customs to seize and impound any suspected infringing goods. As a practical matter, we cannot expect the Customs office to pay close attention as to what products actually infringe on your IP rights, so such registration can't wait until after you find infringing goods because then you need to put up a bond to make sure that whatever you're asking the Customs to do is something worthwhile, and if somebody claims a damage against the Customs they can pay the other party from the bond that you put up.

¶27 In the next segment I'm going to talk about some practical measures to protect IP rights in China. In the United States in the real estate business we talk about location, location, location. In China it's relationship, relationship, relationship. There are two elements to this issue. One is relationship with your local business partner, and the second element is maintain a good relationship with the Chinese government.

¶28 First it's important to choose the right local partner. If a company does business in China, no matter what you do you're going to be doing business with your Chinese business partners and one needs to be careful about the partner selection. Do the homework and understand the people you're dealing with, which includes visiting their plants, talking to their customers and do some other due diligence. One can also get help from agencies about the Chinese business partner. For example, the U.S. Department of Commerce has a service providing background information on certain Chinese companies, and I think they charge a pretty reasonable fee for doing that.

¶29 It's also important to maintain a good relationship with the government. When you do business in China, a lot of the things will be approved by the government, and especially in some areas the government has the discretion to quickly approve your application or not act on your application for a while. So if you maintain a good relationship with the government it can ensure that your application gets processed quickly.

¶30 The other thing is when we talk about enforcement actions, if you want to file an -- if you file a complaint with a governmental agency, the government has the discretion to allocate available resources to investigate your complaint. So it's always good to have the government on your side.

¶31 It's also important for a manufacturing company to control the production process. That can include a few things, including incorporating anti-counterfeiting elements into the product and production processes. It may also make sense to divide the production process among different units and source key components from different companies to prevent one manufacturer from having access to the complete product.

¶32 When we are talking about protecting trade secrets, employees frequently represent a stronger threat than your competitors because of the employee's access to confidential information. So for business which has an important goal of protecting confidential information and trade secrets, the company need to establish good policies and procedures about dealings with employees. For example, it may make sense under certain circumstances to require all employees to sign confidentiality agreements and to require key employees to sign noncompete agreements. Signing the agreements is not the end of the story, however. It's also important to educate the employees and it's important to translate the relevant agreements into the language that the employees understand.

¶33 Another matter that a company should think about is to control the information. For example, it may make sense to disseminate confidential information on a need-to-know basis, and it may also make sense to control the physical custody of the information.

¶34 Another element that should be considered is the separation of engineers who have knowledge about the production process and the salespeople who have access to customers because when these two groups of people get together sometimes a new competitor may emerge.

¶35 It's also important to protect -- to provide adequate protection in contracts. Again, for a manufacturing business it's important to retain ownership of tooling so that if unauthorized use is discovered the owner can retain tooling. It's also important to specify in the contract that the patent owner -- the IP owner has the right to continuously monitor and control IP rights. And once you have such a clause, it's important for the company to actually use the right of containing the -- all right. It looks like my time is up. But anyway, let me just finish the contract protection.

¶36 The other thing I want to mention is -- let me just finish the control and monitor IP rights. It is actually important to follow-up and actually do that, to visit the plant upon short notice. And the other thing is to obligate your Chinese business partners to help you to protect your IP rights through contractual relationships.

¶37 The last thing I just want to really quickly mention about technology transfer. You cannot freely transfer technology into or out of China. There are certain regulations which restrict what a foreign company can do, so one needs to consult the relevant regulations before transferring technology into or out of China.

¶38 Thank you.

¶39 (Applause.)

¶40 MR. AHDIEH: Good afternoon. Thank you to the organizers for having me here. I am especially grateful to them for their kindness in inviting someone who does not teach intellectual property. I hope you all forgive me for whatever impact that has on my presentation. I've also already apologized to my fellow panelists for not having a Power Point. As I say, I'm not sufficiently technological advanced, also relevant to the Journal, to get it right often enough. So whether I lose the Power Point or send the wrong one, I don't have one for you today.

¶41 What I want to do is, like a number of the presentations we've had already today, divide up my remarks into two parts. First I want to say a few words about the status of IP protection or IP issues in Russia today, again not being an expert in IP per se, though working in international trade I'll use as my preference point the issue of Russia's accession to the WTO. I just want to spend a couple minutes, and then I want to spend the balance of my time sort of again taking a slightly different angle and talking about the question of contract enforcement in emerging markets, including BRIC countries, and thinking about whether there might be an alternative regime or approach to contract enforcement, contracts being my area of expertise. That might be sort of more effective than what we tend to use now.

¶42 So first a little about Russia and IPR.

¶43 Russia has been seeking admission to the WTO now for almost 15 years. One of the longest sort of periods of time that a country has spent trying to join the WTO. IPR, intellectual property rights, are considered to be one of the two main obstacles to Russia's

membership in the WTO, the other being agricultural protections. To date the only major economy that has reached agreement with Russia on a bilateral market access agreement is, in fact, the United States. No other country has done so to date.

¶44 The International Intellectual Property Alliance has estimated that Russian piracy of IP costs U.S. industries \$1.7 billion in 2005 alone, and the estimate is \$6.5 billion over the last five years.

¶45 Interestingly Russia, this is not primarily, but the general view is that it's not primarily an issue of the legal regime. You'll see discussions about the question of reform to the trademark, copyright or patent regime, but they tend to be sort of surrogates for really what everyone wants to talk about, which is the issue of lack of enforcement. It's clear that in the area of enforcement big changes are needed in Russia. Among those, lack of transparency in the enforcement regime, the relative fragmentation or sort of poor construction, or poor organization you might say, of the federal bureaucracy responsible for intellectual property rights, role of organized crime unfortunately has become increasingly important, and courts that are very oriented towards the concrete and the specific in many cases in enforcement cases rather than trying to understand the dynamic of what is going on. That oftentimes will include a preference or a desire to favor physical or natural persons over corporate entities in IPR enforcement.

¶46 Some of the area in which we see problems in Russia, optical disc production, so CDs, DVDs, whatnot, internet piracy. All of MP3.com. You may be aware that that's where all these students buy or they don't, where some people go and buy their MP3s. And retail sale, quite vibrant. When you go to Moscow there is a vibrant sale of pirated goods on the streets and in the markets.

¶47 If anything, on these issues it is getting worse. Perhaps indicative of this there is now a proposal on the table to adopt sort of a long-awaited part four of the Russian civil code, which is the IP provision. It has been on hold in large part because when the civil code was first revived, now some 15 years ago, more than 15 years ago, the standards of IP were very different. They were more Soviet-oriented standards. In essence that same draft from 15 years ago is now being seriously considered for adoption and there are various concerns of what that will mean.

¶48 What's going on with enforcement in Russia? Why are we seeing these enforcement problems? A range of things might be contributing. Lack of political will to engage and sort of address the issue of enforcement. Some sense of confidence that they can only keep us out of the WTO so long, that eventually they're going to let us in so we're just going to hold out. Some sense of pride, growing pride in sort of this is the Russian way. Basic incompetence of the enforcement structures to some extent. There clearly are sort of dimensions of Soviet think still in the notions of intellectual property that are there. And perhaps more importantly, they're really rich right now. With the price of oil remaining high they can afford not to spend much time worrying about the demands of the United States and other developed countries.

¶49 A final thing that sort of has been a breakpoint or sort of a point of resistance in these negotiations is the resistance of Russia to the effort of its WTO counterparts to insist on greater specificity and greater detail in the enumeration of its enforcement obligation. In essence, the proposed terms for Russia's accession are dramatically more detailed in terms of IPR enforcement. Russia sees that as being sort of a WTO demand that Russia conforms to standards that no one else has had to. The response that has

generally been given is that sort of we are -- the standards are not different, we're just realizing that their effective articulation requires more detailed enumeration. So that's a fight that is going on.

¶50 It is clear that in the last couple of years there has been some uptick in the amount of -- what I would call the amount of enforcement activity going on, but to date we haven't seen much by way of result. So there is lots more prosecutions being initiated but not many more convictions being won.

¶51 So that's just a little bit about where Russia stands in terms of intellectual property enforcement.

¶52 So what about this idea of self -- a new way to approach contract enforcement in the BRICs and other emerging markets? I want to sort of spend the remainder of my time talking about the notion of self-enforcing contracts and whether we can develop some notion of self-enforcing contracts that might be useful or applicable to emerging market economies.

¶53 What does it mean to talk about self-enforcing contracts? First, what it doesn't mean. It does not mean, you know, some deus ex machina concept that the contract enforces itself in some magical fashion. What we're talking about is some notion that sort of there are structures in place and institutions in place that facilitate, encourage contract compliance without the availability, even in the absence of formal mechanisms of enforcement or control.

¶54 I think a useful place to begin sort of an analysis of this is an economist's sort of characterization of what they generally will term self-enforcing agreements as those which induce voluntary compliance. That's good work of economists, to say "What's a self-enforcing agreement?" Those that induce voluntary compliance. What does that mean?

¶55 Only slightly more elaborately, Lester Telser describes such agreements as self-enforcing where the expected gains from adherence exceed the current gain from violation. So the expected gain from adherence exceeds the current gain from violation.

¶56 So what would be involved to create such a self-enforcing contract regime. I want to look to three sources. I'll identify them and then see what they might point to in terms of the elements of a self-enforcing contract regime. The three sources. First, the work of Bernie Black and Reinier Kraakman; second, an article by Bob Scott; and third, the work of Thomas Schelling, recent Nobel laureate.

¶57 So the first proposal by Bernie Black and Kraakman, actually which they drafted by way of a -- as a proposal to Russia and one that Russia ultimately adopted, of a self-enforcing corporate law regime. Self-enforcing corporate law regime. In essence this regime offered parties to the web of corporate contracts the means to protect their interests. The notion was that they wanted to harvest the incentives of the relevant players, parties to these corporate contracts, to facilitate enforcement even in the absence of formal mechanisms of public enforcement or even private enforcement.

¶58 There were three characteristics that Black and Kraakman identified. The first is a strong process orientation. Very little orientation to define the substantive standards of corporate law. You know, you can't do this or you must do this. Instead, a process orientation that says you can do whatever you want but you've got to go through certain procedural steps in order to do this. So first, process orientation.

¶59 Second, bright line and simple rules. Bright line and simple rules, and particularly bright line and simple rules that are sort of tailored to or specifically directed to the relevant jurisdiction in the emerging market that they're being applied to. And third, the third element of their self-enforcing model talks about severe sanctions, and I mean what you'd describe as draconian sanctions for noncompliance with the relevant procedural applications. This is the first element, Black and Kraakman's self-enforcing corporate law regime.

¶60 The second rather distinct angle from which I think we might think about self-enforcing contract regimes for the BRICs and for other emerging markets comes from Bob Scott, Professor Bob Scott. Bob Scott a couple years ago, I think 2003, publishes an article, I think in the Columbia Law Review, in which he sort of suggests that a broader universe of agreements may in fact be susceptible to self-enforcement. To get to that result he points to sort of recent experimental evidence that suggests that approximately half of all contracting parties have some affirmative preference for what they term reciprocity or fairness in contract. So half of contracting parties were anxious or valued in their contracting some dimension of reciprocity or fairness.

¶61 The relevant experimental data that you may be familiar with is this ultimatum game idea that I have \$100 and I have to offer some portion of that to you. If you accept what I offer you, you get what I offer you and I get what I kept. Right? And if you reject it, neither of us get anything. In that dynamic, the rational behavior is to accept whatever I offer. So if I offer you one dollar, or one cent for that matter, the rational behavior is for you to accept it. In fact, there is a number, and it varies in the studies from 19 percent to about 23 percent. When it falls below that number, so that would be \$19 to \$23, almost everyone rejects the offer. So completely irrational behavior. And Scott relies on this to suggest that what these people are looking for is a fair deal, or some kind of reciprocity. When they get that, they contract. And when they won't, they don't, they don't agree with it. So that's the piece that comes from Bob Scott.

¶62 Thomas Schelling, finally, whose work is of great interest to me, sort of doesn't directly talk about enforcement, or self-enforcement for that matter, but he does talk about the question of how do you reach agreements or how do we create agreements in which deviation or sort of -- yeah, deviation from the agreement is undesirable, is not desired by the parties. The notion -- his notion is one of coordination. How do we create coordination in the contract and behavior of parties. How do we get to situations in which -- and this is his language. Situations in which the party's dominant incentive is to coordinate their actions. Their dominant incentive is to coordinate their actions.

¶63 So how might we put these elements together into a self-enforcing regime of contract law for emerging markets? Two major elements, and then three smaller ones, and I'll see where I get to in terms of the smaller ones.

¶64 The two big ones. The first is the question of internalizing the mechanisms of enforcement to the parties. How do we internalize the enforcement process to the parties themselves? In order for a contract regime to be in fact self-enforcing there has got to be some such internalization.

¶65 As Black and Kraakman describe it, self-enforcement rests with the direct participants in the transaction. So you and I enter into a contract, and self-enforce it means somehow between us we are effectively enforcing the contract. In contract versus corporate law this is harder to imagine, it is harder to come up with because in corporate

law there is the web of contract, whereas in ordinary contracts there is not necessarily any such web, it is a contract between you and I.

¶66 Something similar might be achieved, however, if we were to internalize a broader collection of parties into the relevant agreement. Thus, we might imagine that sort of a self-enforcing contract regime in an emerging market might draw additional parties into the relationship. So, for example, you might require cosigners. You might say the contract in certain circumstances actually requires cosigners, and in that, then, we're expanding the circle of contracting parties.

¶67 We might also sort of think about other parties that might be incorporated. Insurers, for example. Bringing in insurers into the contract would sort of be another set of parties that would facilitate internalization and play a part in this.

¶68 Even though lawyers, although as lawyers we don't like the idea, even lawyers might be dragged into the mess by essentially sort of requiring lawyers, as we do in securities transactions, to in some sense represent the enforceability of the contract.

¶69 Second element, and then I'll stop there because of time, how do we, in essence, build reciprocity or coordination, the element we get from Bob Scott and Tom Schelling, into the agreement.

¶70 Schelling talks about the idea that if you want parties to effectively coordinate, he uses the example of a treasure map or a gun. He says with a treasure map you rip the map in half, I keep one half and you keep the other half. With the gun, I've got the gun and you've got the bullets. In essence, we are forced to coordinate in those situations.

¶71 How would that translate into a contract regime in emerging markets? Posting of bonds or other forms of collateral. In the extreme case we might actually require such bonds, but if we were to do something of this sort we would in a sense intertwine the parties' interests in this way.

¶72 Other forms of, again, what economists of this sort talk about, this term hostage taking, might also be done, other situations in which we create some tit for tat relationship between the parties. We might also find a way for tax regimes to encourage repeat contracting, so in essence favor joint ventures of a sort that would in essence create the repeat contracting situation in which reciprocity becomes more important.

¶73 So these are a few examples of things you might do and think about in trying to address the fact that sort of no matter how strong the IP regime or other rules are in emerging markets, in the absence of strong formal enforcement mechanisms, or strong formal institutions, some kind of self-enforcement will be necessary.

¶74 Thank you.

¶75 (Applause.)

¶76 MS. RAGAVAN: Thank you very much.

¶77 I'm glad you can all see me, I have that problem wherever I go.

¶78 Thank you very much for the opportunity. Unlike Bob, I do not teach international trade, I teach intellectual property, but I write in international trade. So that tells you about American academics, we do not teach things we know. That's some cause for you to rejoice.

¶79 My presentation is India as a BRIC. India 1.0 was launched and signified the beginning of a unified country in 1947. The current Prime Minister, Dr. Manmohan Singh, when he was the finance minister launched India 2.0 by liberalizing the economy. India 3.0 has just begin. With the end of 2005 India entered its 3.0 phase, which

basically requires the country -- India itself showed an interest to enter the next level. Basically it determined that it had achieved a certain level of self-sustenance and launched into a 3.0 phase which required the country to comply with international obligations.

¶80 Now, post the 3.0 phase we see India amending several of its laws. FERA became FEMA, Foreign Exchange Regulation changed to Foreign Exchange Management statute. Import and export statutes were amended, and so was the IP laws.

¶81 The most controversial of all of these is the amendment to the intellectual property law, particularly the Indian Patents Act of 1970. Before we talk about why it's controversial, I do want to give you a brief background of what the Indian Patents Act of 1970 is. The Indian Patents Act of 1970 was a completely conscious effort to do what it did. Most of us here, most Westerners if I can safely use that expression, like to think that what it did was an allowance to copying, and that's not true. What it did was to promote only process innovation, and that's what the Indian Patents Act of 1970 did. It promoted process innovation and to that extent stopped what we call as product innovation.

¶82 And I'll tell you the difference between each these, but before that I just want to say that India itself decided to embrace, when it did away with the process patent regime because of what we all the Ayyangar Committee. The Ayyangar Committee was set up in the end of the 1950s because India launched the Russian model of five-year plans. It took stock of how the country was going. At the end of every five years India to decided how the country was progressing.

¶83 The initial phase of the first five-year plans showed (a) that the income from industries was very low, only 6.6 percent of gross national income came from industries. There was high poverty level, there was also low industrial employment, and a high rate of mortality from epidemic diseases, coupled with all of this was high priced drugs. So considering all of this, India felt that one of the best ways to safeguard its productivity, and at that point it thought labor was its main factor of productivity, was to have a healthy population. And to have a healthy population it decided it had to stop importing drugs. Over 95 percent of drugs at that point in time at the end -- at the beginning of the first five-year plan over 95 percent of drugs was being imported, and India felt, you know what, we have to begin local production. And for the first time India decided to amend its patent legislation and launch the Indian Patents Act, or it created the Indian Patents Act of 1970.

¶84 Now, the patent act did pay off. What the Indian Patents Act of 1970 does it has -- it embraced what is called as the process patent regime for food and for pharmaceutical innovation. Food, pharmaceuticals and chemicals, actually, innovation. What it tells us, unlike in the United States if you invent this pen, the pen is never subject to a patent. What is patented is the method of making a pen. So it leads to more competition, it leads to other people innovating on the methods of making the same product, and that's how it launched the generic drug industry.

¶85 Today the generic drug industry stands as one of the success stories of India, and it has catered to the Indian constitutional objective. 70 percent of India's 1 billion people do get access to medication, and medication in India is dirt cheap. I do see some Indian faces, and I can vouch for the fact that medication in India is available, accessible, even to the poor people. The question is did India want it? India wanted it and got it.

¶86 Now, at the end of 2005, as I told you, India went to the next phase which required it to comply with its international obligation, and with that came the product patent amendment. India became a member of the WTO and with that it had to sign on to the requirements of the TRIPS agreement and it embraced what is called as a product patent agreement.

¶87 The current Indian statute, the Indian Patents Act of 1970 as amended three times, 1999, 2002, and 2005, now incorporates a product patent regime and fully, I believe, complies with TRIPS. It includes the current Article 31 BIS of the TRIPS agreement, as amended in the Hong Kong declaration or as declared in the Hong Kong declaration.

¶88 The biggest controversy -- I just want to tell you what's happening in India, though. The biggest controversy remains, though, Section 3 of the Indian Patents Act. Section 3 of the Indian Patents Act outlines some of the exclusions to patentability, and it basically excludes new methods or new uses for known chemicals. Salts, esters, isomers, et cetera, of known chemicals are excluded from patentability unless, of course, they differ significantly in property or show increased efficiency. So that's where we stand as far as India itself is concerned.

¶89 The outstanding question for India today is basically balancing trade with welfare. This is something the very first panelist dealt with today, Professor Yueh, I believe, from University of Oxford, and she talked about how on the one hand TRIPS will increase income inequality while on the other hand it could, it could is probably the right word, increase foreign investments as well. That's the balance between trade and welfare. India has about 300 million people, and that's equal to the population of United States, below the poverty level. We are talking 1 billion people, 300 million below the poverty level. Except for 100 million, the rest of them form what we call the middle class and they cannot necessarily afford branded pharmaceuticals.

¶90 Now, if you're talking about a BRIC, a developing BRIC economy in India, then the biggest question is is trade so exclusive that we exclude 900 million people out of that whole rat race? And that's the biggest question countries like India are facing, especially considering that trickle-down is not a model that is happening. Yes, there is more FDI. Yes, the rich are becoming richer. But don't we have a constitution, doesn't it mandate that we help the poor cross the poverty line?

¶91 Now, considering these questions countries like India basically look at how a developing country like India can enable access to low-cost medication. As I told you, India continues to believe that good health, right to good life and right to life, which is a fundamental right guaranteed under the constitution, also includes right to good health. And India firmly believes, constitutionally mandated that the government should try as much as possible to guarantee a right to good health. So then the question is how do you ensure low-cost access to medication.

¶92 Now, looking at it from an economic perspective low-cost access to medication is important because labor is one of the biggest factors of productivity in the country. So the more people get sick, the more your economy is going to come down. And it is important for a country like India to ensure that there is no public health crisis.

¶93 We saw that in South Africa. The more people got infected with AIDS, the more able-bodied people succumbed to the disease, the more the medical insurance cost rose, the less industrial production, and it was a vicious cycle. And that's precisely what a country like India has to avoid at this point in time.

¶94 The second, of course, goes back to promoting its generic drug industry. Having nurtured the generic drug industry, India now wants to promote it. The generic drug industry does lead to process innovation. While some people do not believe that's innovation enough, that's not the question. Does it have some innovation? Yes, it has some innovation. Does it have some value? Yes, it has some value. Some of these industries want to move on and compete with product patents, some of these want to cater to the generic market level. So India does want to promote some of these as well.

¶95 Now, in a product -- and so I want to confine my discussion with the access to drug question. Here I have one major theme that I want to talk about. The myth that seems to generally prevail is that in a product patent regime all people, including poor people, have to basically only afford high-cost branded drugs. Well, that need not necessarily be true. And I would like to float price control as a possible solution. In doing so, I do want to highlight, in reality, even rich countries like the United States allow for low-cost drugs for its poor people.

¶96 At this point I want to highlight some of the things that happened in the United States, and possibly even in the United Kingdom, to show how even rich countries seem to enable low-cost medication for its poor people.

¶97 This was right just around the time September 11 happened and states were having a big financial crunch, they had a budget crunch. Maine was the first state in the United States which floated what is called as the Fair Pricing of Prescription Drugs Act of 2000. In doing so, Maine floated what is called as the RX Plus program for pricing and profits. What the RX Plus program did is basically mandated manufacturers to discount prices. You either discount the prices or it created what is called as the prior authorization requirements. The procedural burdens of the prior authorization requirements were so high, in fact, it was so humongous, that manufacturers would automatically go ahead and discount the prices of drugs, what we call as indirect price control.

¶98 PhRMA, of course, argued that it violated the common cause by affecting our state commerce. The First Circuit basically did not agree with PhRMA.

¶99 Florida imitated the program, and Florida has what is called a preferred list. If you want to be on the preferred list, which is a list from which the pharmacists will dispense medication, you basically have to slash down the cost of drugs. PhRMA again argued; Eleventh Circuit disagreed.

¶100 Then comes the biggest question, which is the Michigan program. In trying to imitate Maine and Florida, Michigan came up with what is called as the best practices initiative, and in doing so set a common low common denominator for all drug prices. Basically this is what we pay, you either give us the price or don't give us the price.

¶101 Now, what Michigan did, though, if a manufacturer refused to give that price, to reduce the cost of its drugs, manufacturers could avoid the prior authorization requirement by (a) matching the lowest drug in that class, or (b) reducing the price of a non-Medicaid drug.

¶102 I mean, if this is not price control, then I surely do not know what else is price control. Manufacturers can avoid a prior authorization requirement by reducing the price of a non-Medicaid drug.

¶103 PhRMA challenged the authority of the Secretary of Health and Human Services to approve the plan. Again, PhRMA did not succeed.

¶104 Vermont imitated the program and saved more than \$1.6 million in three months. Again, PhRMA contended; the district court rejected.

¶105 I'm not going to go into the contentions of PhRMA because time is of the essence and I am trying to concentrate on the BRIC itself, in this case India.

¶106 But the Court of Appeals for the D.C. Circuit upheld PhRMA's argument basically holding that barring Congressional approval the Social Security Act does not include manufacturer's rebates as part of the state expenditure. At this point PhRMA threatened to go back and reinitiate its suit in Maine, and because of the conflict between the various circuits the Supreme Court took up the case.

¶107 On cert the Supreme Court in 2003 held that the Maine program was not preempted by the federal Medicaid statute and the commerce clause. Justice Thomas, of all people, you will be surprised, posits that the state governments' attempt is an essential if not commendable delicate balance.

¶108 Well, what do they think India and China were doing all these days? Justice Thomas basically says it's a commendable delicate balance between competing interest. Of course, the Court of Appeal for the Fourth Circuit had noted in appreciation of the balancing measures when people whose income fall outside the Medicaid eligibility are unable to purchase necessary medication their conditions worsen and therefore it's important to reduce prices.

¶109 Now, the Federal Circuit is also going to look at the D.C. prescription drug pricing act and it is going to look at whether -- I'm sorry. I got distracted because of the time.

¶110 With this I just want to highlight the United Kingdom also follows something very similar. It does price control and it controls the prices very delicately.

¶111 Now, what lesson does this hold for a country like India?

¶112 Can I take like a minute or so?

¶113 What lesson does this hold for a country like India? Basically the signing of the TRIPS agreement does not diminish the sovereign rights of nations. The people of India have a constitutional right and it is important to safeguard those rights.

¶114 A couple of things that India can do is (a) revive the drug price control order. It was present under the 1970 Patents Act. Revive the drug price control order for patented product. TRIPS has no specific provision against price control. Doha, read with Article 7 and 8, would allow price control as a means to balance rights and obligations of nations. Use the flexibility in TRIPS to the maximum. Broad definition and interpretation of what amounts to public interest. If the public interest could affect even a small section of society, be aware that a potential public interest issue can be prevented by using one of the Doha exceptions.

¶115 What I call as patent hangover. At the time of prosecution -- huge issue now in India. Novartis is taking the government of India to court. It is now in the general high court. It's a huge issue. Because Novartis feels its drug Glivec was approved by the European Union and the United States and therefore India has to approve -- India has to deem that drug as patentable. The director of the Chennai patent office said, "Un-uh. It's not patentable. I find it too obvious." And obviously Novartis is not happy with it.

¶116 And that's exactly what India has to do. It has to aggressively challenge and review based on local requirements. And just because the United States -- we know how efficient the USPTO is, nothing against it. Just because the USPTO approves it does not

necessarily mean that the patent office abroad should basically take the same stance with respect to obviousness.

¶117 Developing nations have to make a conscious choice of the boundaries of patentability. What are the boundaries the non-obviousness? Well, we have good claim drafting mechanisms, that's the procedure, and use sophisticated claim drafting techniques to ensure or fine-tune whether we want minor innovations to be patented or whether we do not want to allow minor innovations to be patented. It is a policy decision that BRIC economies have to sit down and take, and this is the right time to do that.

¶118 With that a couple of other issues that is currently happening in India. It needs an aggressive stockpiling exception, should oppose introduction of data exclusivity, industry should pursue markets outside of India where the invention falls in public domain and that would allow the generic drug companies to survive.

¶119 There is only one last point, and with that I hope to wind up. Something that I believe that international trade regimes should take into consideration and what I call the theory -- that I call as the reverse interest lobby. Initially we tried when we had TRIPS and when we had the international trade arrangements, what we tried to award is for local industries to lobby for protectionism, and that's not a bad thing. We felt we should award local industries lobbying for protectionism. Now we see what is called as the reverse interest lobbies. We see lobby groups outside of the country lobbying against even minimal protectionism in other countries. So that has -- somehow that has to be balanced with trade interests of that particular country itself.

¶120 With that, thank you very much for the time, and the extra time.

¶121 (Applause.)

¶122 MR. NOONAN: Thank you. I'd like to thank the organizers for inviting me here.

¶123 I'm going to focus on essentially one thing pharma with Brazil. I'm going to tell a cautionary tale that kind of dovetails with what Sri just said. The cautionary tale is be careful what you wish for. Because the United States, and the West in general, for many years promoted the idea that we needed to have an international patent scheme that had as its basis the fact that countries such as the BRIC countries would respect patent rights, to avoid protectionism and allow, to be honest in pharma, Western, predominately U.S. companies to protect their molecules and their drugs in their countries. And thence came TRIPS.

¶124 The interesting thing is that the law is a great thing. You can interpret it and adopt it and fashion it for your own purposes, no matter what it really says, and that in fact has happened in a very clever way in Brazil. It is funny. When people talk about these big countries, I think people think about India and China immediately, but don't forget Brazil. It is the fifth largest country in the world, it has about 190 million people, and it has the ninth largest GNP, about \$1.6 billion. So a huge country, a huge internal market, but a lot of inequality in the way that the wealth of the country is distributed, and with that of course about a 19 percent poverty rate. Not as bad as 50 percent in India, but not very good either.

¶125 Added to that recently, as we've seen in a lot of countries, we now have AIDS entering the country. This number of about half a million is probably off by anywhere from two- to five-fold. So just an incredible burden on the country.

¶126 Paradoxically they have a growing generic drug industry. And I want to quote, and I'm going to read it because I don't want to misquote him, Carlos Correa from the

University of Buenos Aires says the reality is that drug patents have led to a significant reduction in foreign investment in pharma in South America.

¶127 And if you think about that for a minute, for all of the Adam Smith capitalist type of rhetoric that we hear, if a Western country can protect its patents, its drugs by patent in, say, Brazil, then what's the incentive for that country to make the drug in Brazil? They can make the drugs here, or anywhere else they make them, and import them into Brazil. So, in fact, you would expect, and I think that in fact it has happened according to Professor Correa, that you're not getting foreign investment, which certainly was one of the carrots, I think, that was extended to countries like the BRIC countries about why it would be a good thing to have a patent scheme.

¶128 The interesting thing about Brazil is it has been involved in international patent schemes for most of its history, as long as there have been patent schemes. The Paris Convention, the Patent Cooperation Treaty, the Berne Convention, all of those were signed by and adopted by Brazil. However, local law permitted them not to allow pharma, drugs, to be patented in their country, so that was one of the big problems. The Brazilian government modified its patent laws, this is the 9279 law, in 1996, became effective for some things in 1997, and in fact it mandated that drugs would be patented like anything else.

¶129 Now, if you look at Brazil's behavior, I said it was involved in international patent law, and it has been; it's been particularly aggressive, in a good way, in defending its own self-interest. One thing in particular is the UN Convention on Biological Diversity. It's very concerned with bio piracy because most of the world's biological diversity these days is, guess where, in Brazil in the Amazon basin, and the country has been very strong in international talks about trying to get a contract with anybody who wants to come into their country and take a plant or an animal and bring it back and develop it and patent it in the United States. They want to have some agreement so that they're compensated for that.

¶130 This is something that has happened over the years. Puerto Rico had an argument about this in the Law of the Sea with molybdenum nodules in the '70s. This is kind of the way that countries that have this natural resource try to protect it.

¶131 The Doha declaration, I think Sri mentioned it, very important later on in the talk. But it just happened in Qatar, Doha, Qatar, at a World Trade Organization meeting in 2001 in which the countries of the world at that meeting said that there is an inherent right for patent laws and other laws to be modified and international agreements to be modified when you have a national health emergency and gave -- and I'll talk in a little bit more detail later. Gave countries the ability to make these changes in the face of an emergency, and of course AIDS is the emergency we're going to talk about.

¶132 The government at least has been very involved in adopting open source software now, and even though there is copyright protection in Brazil, there has been quite a bit of copyright enforcement, and I'll talk about that in a minute, but open source is the way they're going. And particularly when it comes to the biodiversity matters there is an attempt these days to get a broader international patent law treaty. PLT, the Patent Law Treaty, and SPLT, the Substantive Patent Law Treaty. And the United States and Europe and Japan as recently as 2005 thought they had gotten an agreement to actually have this proceed, and Brazil and a number of other countries stopped them because the agreement

had nothing to do with what Brazil thought was important, biodiversity, genetic inheritance, that sort of thing.

¶133 The thing that Brazil has done, and done remarkably well, is used TRIPS as a sword as a way to in fact find its own ends within the TRIPS scheme. The problem, and we've talked about it a little bit here, pharmaceuticals is the problem. If you think about it, in 2006 between January and April 11 million pirated CDs were confiscated in Brazil. Copyright and that sort of infringement is a bad thing, but when you talk about drugs and health care you get a whole other wrath of interest groups and politics involved, the UN Commission on Human Rights, Doctors Without Borders, every charitable group in the world. And, frankly, anybody who believes that there is a human right to health care is going to butt up against a strict regime of protecting pharma and pharma profits, especially when you have the inability of people to pay.

¶134 In fact, if you think about what we've talked about here, we've talked a lot about how governments have dealt with this. You know, Julie talked about you kind of have to partner with government, with the Chinese government. Well, that's part of it. And Bob talked about fairness, and obviously this is going to be an element of these things.

¶135 This is really the principal thing that has to be resolved, these competing interests, especially when health care is involved.

¶136 Let's just talk about a couple of these provisions. It is interesting how the Brazilians did this. This is Article 68 of that 9279 law I talked about, and this is compulsory licensing. This is the way that I think that traditionally people think about governments being able to deal with these issues.

¶137 Here -- and if you think about it, abuse of economic power could be thought of as anti-trust, for example, that sort of monopolization. So this part of the law looks like, okay, you can get a compulsory license if you've done a bad thing, if you've been predatory, and that proven under the terms of law by an administrative court decision gives a patina of due process to the whole thing. But Subsection 1 of this law also says that non-exploitation of the subject matter in the territory of Brazil by lack of manufacture can also prompt a compulsory license.

¶138 Now this changes things because now what I said in the beginning about the lack of foreign investment, well, Brazil has a way to deal with that. If you don't invest in their pharma industry, if you don't help them make drugs in their country, then the government has the right to grant a compulsory license to somebody who will, and this prevents Western companies, mostly in pharma, from importing their drugs and not actually contributing by foreign investment in Brazil.

¶139 What Brazil did initially is use this as a negotiating tool. Initially they -- in fact, this was before 9/11 and it was probably in June of 2001, the Bush administration filed a complaint in the WTO against Brazil for exactly this, using its compulsory license threat to get Roche at that time to reduce its NEH drug, and finally dropped it because they realized that the WTO process was going to be too slow, they were alienating what they wanted to be an ally, and Brazil wasn't going to budge. I think it was 2005 was the 21-day ultimatum.

¶140 So that was a negotiating tool, but then Brazil did one more thing. We talked about Doha. Article 5 of the Doha Declaration says that member states have the right to put aside patent laws or modify patent laws, grant compulsory licenses for example, if there is a national health emergency, which makes sense. It also says, in subsection D or so,

that parallel importing, in other words, the ability of a third-party, not the patentee, to import drugs into your country would be left up to the member states.

¶141 So what Brazil did was, and this is another article that said in the case of a national emergency then the federal executive power -- and Brazil is remarkably like this country in the sense that it has a federal -- a president and a bicameral legislature. But what the federal can do is by executive order grant a nonexclusive compulsory license to someone if the patent owner can't satisfy the need.

¶142 Well, that's not -- do not satisfy or doesn't satisfy is interesting language because it can mean that you cannot make enough of it or it may mean you can't make enough of it cheaply enough. Of the half a million people who suffer from AIDS in Brazil, those people are pretty much totally supported in their drugs by the government. The government provides those drugs free of charge to its people because the people cannot afford it. So as the price of the drugs, the NEH drugs kept on increasing over the course of 1996 or so through about 2002 or 2003 and these negotiation and coercion tactics weren't working, what Brazil did was it declared AIDS a national emergency and therefore under the terms of the Doha agreement it could grant compulsory licenses, and that's what it did. That's one of the reasons why the generic drug industry is blossoming in Brazil.

¶143 Now, I don't think they could do this for Nasonex or something like that. Obviously this is going to be a limited source of what can be done; but if you think about it, they've developed through this a native generic drug industry. So what was promised to them, foreign investment to help them build up their pharma, as well as other industries, they've actually gotten but gotten there in a totally different way than I think was envisioned at time.

¶144 But the other part of this is that the UN Commission on Human Rights had declared that it was a human right for someone with AIDS to be able to obtain an anti-AIDS drug. And remember, Doha Declaration said that there is -- leave up to the local states whether or not parallel importing can happen. So not only does Brazil's generic drug industry feed its own internal market, but now it's the major source of a lot of anti-AIDS drugs in Africa because that generic drug industry is now being able to export and those in African countries to import the drugs at much, much lower prices.

¶145 So what do you do? I think that certainly for a generic drug company there is going to be an opportunity for that company to partner with people in Brazil and help them to develop further their industry, and I think that is an opportunity. That even if it was only internal, there is a huge market in Brazil. They already have the seed there for the anti-AIDS drugs, so now you do have an opportunity if you're a generic company to invest there and maybe they'll get the foreign investment that they intended. This is true for innovative companies as well.

¶146 I think that the experience says that it's sort of like the irresistible force and the immovable object. Patent law is not the immovable object. We've gotten where we wanted to get, I think, in the patent regime. I'm a patent lawyer, I love patents, they're great. But there are limits to everything, so I think what we have to -- and what people here have said is that you have to deal with those limits both economically and culturally in order to get where we all need to be.

¶147 On the one hand, it's valid to say that you need to have the kind of investment and the kind of return on your investment in order for there to be a patent regime and for that

economic part of it to work, especially in pharma that is very true. But the other side of the coin is that in order to get -- you cannot force people to be your customers and if you don't deal with the realities in the different countries and if you don't adapt the system in a way that locally the political structure can handle that, that's not going to work either because, you know, Brazil, China, India, and Russia to a certain extent who just hasn't done anything, has left the law festering for 15 years, I think the answer is not, and I think we've come past the time where economic pressure from the West can force people to do what we want them to do. That sounds nice. But I think now what we have to do is figure out a way to recognize at what point we have to modify our expectations when it comes to certain things, pharma is one of them, and yet at the same time try to prevent, because I think -- I don't think it is necessarily a good idea that Nasonex could be next, and I don't think that would be good either. There has to be a balance.

¶148 One of the ways that the balance is trying to be struck is in this patent law treaty negotiations. But I have to tell you that even the most recent rounds are not getting anywhere because the logjam hasn't moved yet, and probably won't move for another five years. But I do think it will because it will have to.

¶149 I'm not a Brazilian lawyer, so I would like to thank the people who are Brazilian lawyers who I spoke with to try to give me some background, and I'd like to thank all of you for your attention.

¶150 (Applause.)

¶151 MR. FRANCIS: I thank the panelists very much. At this stage we open the floor for questions or comments on the respective presentations.

¶152 Yes?

¶153 UNIDENTIFIED SPEAKER: I have a question for Professor Ragavan. I'm not sure this is completely related to the subject, but one time when I was in India, I've been there a few times, I got sick, so my friend there took me to a street. And you're right, drugs are really, really cheap. So we bought some Cipro, which is an antibiotic. And this morning I listened to NPR and it says there are serious problems of resistance for Cipro now, which is very bad news because Cipro has been a super drug.

¶154 So I can't help thinking, you know, India's patent law is partially responsible for killing a very good drug that potentially can save more people. What do you think about that? Is there any way that that can be -- that that can be more flexible in places like India?

¶155 MS. RAGAVAN: Why do think India's patent law, because India allowed a lot of people to consume Cipro?

¶156 UNIDENTIFIED SPEAKER: Not really. That's not what I'm asking you to comment on that. Watching the market of selling Cipro I don't get a feeling that they are -- whoever makes Cipro actually gets some -- you know, in the U.S. or Europe, actually, gets a really good cut out of it. So I'm just thinking --

¶157 MS. RAGAVAN: Well, I do not know if I've got the question fully, but suffice to say that if people believe most drugs are only for people who live or are citizens of the United States, then now that expectation has to change because the more drugs coming we want the whole world to benefit from it. And if that causes resistance for whatever reason, then I guess that's something we have to deal with.

¶158 Have I even gotten your question correctly?

¶159 UNIDENTIFIED SPEAKER: Well, the way antibiotics work is -- it is different from other drugs. The way antibiotics work is because abuse of or if you've used it too widely then the bacteria come back easily, so it is a special category compared with high blood pressure or AIDS, I don't know. So that's why I'm putting this out, because -- so for drugs like this usually there are more like restrictions on the prescription, there is a reason why it was more. That's what I mean.

¶160 MS. RAGAVAN: I thought as much too.

¶161 A couple of things. Better India should make it a prescription drug, or any part of the world should, that is a little bit different. To the extent that -- even India has some drugs that are only prescription drugs. Cipro certainly is not, and whether that is good or bad is a different issue altogether. But whether Cipro was overused because India had generic versions of Cipro and therefore a lot more people had access to Cipro and therefore there is now resistance developing, I mean, that's what is going to happen when pharmaceuticals become accessible to the whole world, and we do want pharmaceuticals to be accessible to the whole world. We cannot say, "I only want rich people to access pharmaceuticals because if poor people also start accessing it is going to increase resistance." Does that somehow --

¶162 MR. AHDIEH: If I could add something. It is an interesting question. If you think in numbers the reality is sort of as you expand to certain countries you're going to get big numbers, right? But it is not necessarily a proportion of the whole. It need not be a proportion of the whole. So it may not be because it is disproportionately a low-priced product, it may simply be that, I don't know, 10 percent of Americans have had to take Cipro and 10 percent of Indians have taken Cipro, so that's the first thing you would want to know in some sense was the proportionate consumption. Second issue would be is it prescription or not, and that might be something you would modify in that vein.

¶163 But the other challenge with that is you could probably do that here too, I imagine, right? I mean, you could make the same claim that sort of Cipro -- every time I take my four-year-old or one-year-old to the doctor, the doctor says, "Go take antibiotics." I suspect if instead of \$2 I paid for it or \$10 I paid for it, it was \$60 I would say no to the doctor more often than I do. So I think that's the challenge.

¶164 I think it is a very good -- I think it is a challenging one to assess.

¶165 UNIDENTIFIED SPEAKER: One of the whole ideas with the patent system is to foster innovation. Just with respect to pharmaceuticals you mentioned the belief that drugs should be available to everyone and not for the rich. But these pharmaceuticals, especially U.S. pharmaceutical companies, are seeking a larger return on their investment, and of course they are targeting the richer people as opposed to maybe the BRICs where there is not a guarantee or they can be undercut by generics, or state-fostered generics such as in the case of Brazil.

¶166 Is there a concern that the U.S. companies, which they've already shown a tendency to do, is to narrow their focus now to higher-end drugs, such as prevention of, you know, less lethal diseases away from AIDS and similar disease, maybe like Prevacid or allergy medicine or medicines that really only can be afforded or sought by the most industrialized countries, and that we're leaving that other innovation behind because it is not quite so lucrative anymore? Is it a concern or how should we address that?

¶167 MS. RAGAVAN: I'll take that question.

- ¶168 I do think it is a big concern, that innovation in pharmaceuticals is more and more tuned to what the rich people can access. That's something several of the NGOs have highlighted that. Because some of the developing countries' diseases like malaria, tuberculosis, you know, we don't spend money on that those because who can pay for it if we actually do spend money on those. So it is a big concern, do they have an ethical code that requires them to also spend on poor people disease. It is a big concern too.
- ¶169 But as far as India itself goes, since we're talking about India. After the product patent regime kicked in, there has been a huge controversy because Roche's drug, I forget the name of the drug, Hyprin, Heprin (phonetic), I'm not even sure, is valued at about \$12,000 or maybe \$20,000 for one set of prescriptions. The idea is only about 100 million people can access it at the very most. It a heart disease drug and I think it is more prevalent in India than just 100 million people, and Roche just said that's too bad.
- ¶170 That's also with Glivec. Glivec was priced much higher, and because the Chennai patent office denied a patent on it a generic drug company immediately started manufacturing it and manufactured it for two thousand six hundred, which is one-sixth or one-eighth of the price, really much cheaper. And it is now available for the same disease.
- ¶171 So now BRIC countries are starting to think, "What are we getting?" Novartis is not starting up a new manufacturing facility in India, just like what Kevin said, and they're able to do the same thing by themselves.
- ¶172 MR. NOONAN: I have two points. One is it is hard to think of a disease -- of a drug for treating a disease that hurts millions of people being an orphan drug, but trypanosomiasis and things like that that you never see in the States or in Europe and yet are the predominant types of diseases that are in Africa, and obviously AIDS has taken over a lot of that, but besides AIDS in Africa and places like that. I say orphan drugs because I do think that that is a place where you can see the capitalist patent kind of system is not going to make a drug for that if we just leave it alone, so you have to figure out a way, whether it is through government or internationally or UN or World Health Organization or something, we have to figure out a way to deal with that.
- ¶173 And I'll just flip it and say if it was a pandemic of avian flu we would all figure out a way to fix the problem, right. So I think we need to try to -- that's a political answer but I think that's what you're going to need because there is always going to be have-nots with have-not diseases, just like there are orphan drugs in this country.
- ¶174 The other thing is the biologics, what's going to happen to generic biologics. It's a lot tougher to make a biologic than it is to make Cipro, so it will be interesting to see how that -- as more and more companies make more and more biologically based drugs, we're going to have to deal with that as well because it is not going to be as easy to make a generic of that in Brazil or China or India.
- ¶175 UNIDENTIFIED SPEAKER: This question is for Mr. Noonan. I read and actually wrote a little something, and I don't know what the state of the law is on this right now, about cross-retaliation under WTO treaties. There is an article of the dispute resolution system in the WTO that authorizes retaliation under GATT that violates TRIPS and vice versa. I know that at least some South American countries have used that, Ecuador most recently, to suspend their obligation of TRIPS for patents in pharmaceuticals, and I think Brazil tried to do that as well. I was wondering if you knew anything about that.

¶176 MR. NOONAN: It is another option. I think Brazil for a lot of reasons was able -- given the fact that it is a big enough country, had a big enough infrastructure, was able to start making AIDS generics and exporting them, it dealt with that. But you're right, there are other mechanisms, but they're not -- I mean, we just filed against China last week, or two days ago.

¶177 The WTO is a blunt tool and it can do some things, but it certainly isn't a world court. All you can do is try to mediate as opposed to in this country it is mediation versus litigation. The parties have to agree that when the WTO comes down with something they're going to abide by it and work it out, so really it is more of a facilitator for issues that ultimately are going to be -- are going to be political because you're dealing with nation states, and when you're dealing with nation states, and I was in international law a very long time ago, individuals and even individual companies don't count, it is China and Russia or United States or Brazil, or whoever they are, you're dealing with it at that level.

¶178 So those things are ways that we can kick sand at each other. But since you're not going to go to war over it you really have to come to some political accommodation, and so maybe we sell you some of our wheat for less than we would have and you import some of our pharma for more than you would have and that sort of thing. But that's kind of -- if you don't get a more global system where people agree, whether it is the index prices or what have you, you're not going to really -- it is going to be very sporadic and it is going to be incident by incident.

¶179 (WHEREUPON, Ms. Zhu (Julie) Lee left the deposition proceedings.)

¶180 MR. FRANCIS: One last question. Sri is an advocate of price control, I'm an advocate of time control, but I seem to be a miserable failure.

¶181 Dan.

¶182 MR. LEV: Well, my question was going to be for Ms. Lee, but I think maybe Ms. Ragavan and any of the other panelists could answer it.

¶183 You spoke of drugs that have high value to -- are basically high value to a limited number of people but it makes sense to make them and to invest in them. I think that in China, and this gets into the technology transfer issue because that is sort of what I was expecting Ms. Lee to say, but Novartis is there. You talk about Novartis not wanting to get into India. Novartis is huge in China. They have two research facilities now, or one and they're building another one. And the medical device companies are huge in China. I heard something like certain medical devices they sell more in China and there are all these statistics about being more millionaires in China than anywhere else today.

¶184 I was kind of wondering, you seem to be very in favor of this centralized control, price control model in order to bring Western or foreign innovations cheaply into the country to resolve an immediate problem, but I think the approach that China is taking might be better in the long run, which is to encourage the foreign investors to come in, grant them the intellectual property rights, and actually now you see that China has this developing nascent pharmaceutical, innovation pharmaceutical not generic pharmaceutical industry, and a very strong innovator in medical devices too.

¶185 MS. RAGAVAN: I'll go first on this. Well, two things. One is it is true that China is -- well, what was your first question?

¶186 MR. LEV: The first thing was the contrast you said with Novartis because Novartis is very big in China. And the second one was about I think in the long run

maybe that this system is actually better than the one that solves the immediate health issue.

¶187 MS. RAGAVAN: Let me address the first one, which is FDI. China is more open to allowing foreign direct investments than India, and China does have a high level of poverty index too. China also has a high level of poverty index. And a problem, if it is a problem at all, right, is India has a constitution where it decided, it basically says we'll provide social and economic benefits.

¶188 While I do think China is not wrong in prioritizing only foreign direct investments, I do think that India is also not wrong in saying we want to balance it. We want to balance trade with welfare, we want to open up foreign direct investment while at the same time ensuring poor people get some of these benefits too.

¶189 So both of these could be viewed as complimenting each other, but it can also be viewed as different models.

¶190 Well, unfortunately what happens is in the West we only look at how much foreign direct investment flows in and has it helped. It clearly has helped the upper crust of people, but India wants to do an overall development and that is not wrong too. That's the problem. It is hard to convince sometimes developed countries that we want to balance trade with welfare because we believe that, you know, at some point it will trickle down. It may, but it hasn't so far, so BRIC countries are well within their rights to say that we want to prioritize trickle-down.

¶191 MR. NOONAN: Plus, I think the government in China can make it trickle down a lot faster than the government in India.

¶192 MS. RAGAVAN: Oh, yes, because of lack of democracy.

¶193 MR. NOONAN: Yes, but I think that's the difference because if you think about it if you have the big bully Novartis and the less -- I mean, the Chinese bully is bigger than Novartis, whereas I think in India it would be much harder to control because of the public/private interactions. Whereas in China, as I think Julie would tell you, as she said, relationship, relationship, relationship. Well, with whom? With the government. So I think that they can pretty much call the shots and are less, probably, sensitive to the degradations of foreign investment because foreigners want to invest there and they tell them how they get to do it.

¶194 MS. RAGAVAN: There are also studies in India which show that after the product patent regime kicked in, the process innovations have come down in India. That always happens.

¶195 MR. FRANCIS: At this juncture I think we will call an end to this panel. I very much appreciate the efforts that the panel have put into their presentations, and I urge you to express this with appreciation.

¶196 (Applause.)

¶197 MR. LEV: Right now there is a break until 4:00.

¶198 I also want to especially acknowledge McDonnell, Boehnen, Hulbert & Berghoff for being the sponsor of this panel, and I think there is materials for any of the students or anyone else looking for a job in this room, or are looking for a law firm to hire.

¶199 So we'll be back here at 4:00 for the final panel, From Innovation to Infringement.

¶200 (The panel discussion was concluded.)