Health GAP and Médecins Sans Frontières/Doctors Without Borders Conference Call: India's Patent Act to Block Access to Low-Cost Generic AIDS Drugs
Moderator: Asia Russell
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12:00 p.m. ET

Operator: Good day, ladies and gentlemen, and welcome to your Health GAP and Doctors Without Borders conference call. At this time, all participants are in a listen-only mode. Later, we will conduct a brief question and answer session and instructions will follow at that time. If anyone should require assistance during today's program, please press star, then zero on your touchtone telephone.

I would now like to introduce your host for today's conference call, Asia Russell from Health GAP. You may precede, ma'am.

Asia Russell: Thank you. My name is Asia Russell, I work with Health GAP, a U.S. advocacy organization working for increased access to affordable HIV treatment in poor countries. I thank everyone for joining this teleconference today. I just want to say a few words by way of introduction to our topic before each of our three speakers speaks briefly.

In the next hour we'll discuss a dramatic change to India's patent law that will come into effect January 1st, 2005. After this time India will begin to grant 20-year patent monopolies on medicines, in accordance with its obligation as a member of the World Trade Organization. This will affect new medicines, for which patent applications are filed after January 1 2005.

[Ed. note: the changes will also affect generic versions of some older medicines. Anywhere from 4000 to 6000 patent applications on medicines have been filed in India's patent "mailbox" since 1995, pending review by India's patent office starting January 1 2005. When this mailbox is opened on January 1, if patent applications are granted for drugs that are already on the Indian market in generic form, the generic versions of these drugs would be forced off the market. This would drive up drug costs in India and in importing countries in the developing world.]

We believe that these changes will have a significant and harmful impact on efforts to provide treatment to the millions of people living with HIV in poor countries who don't have access to the medicines they need to survive. This includes not only millions of people who have never taken HIV treatment, but also hundreds of thousands of people in poor countries who are currently on triple combination therapy, but will need in the near future to move from their current medicines to a combination of newer and more expensive medicines. Generic competition, which would reduce the cost of these newer medicines, will be blocked if the Indian government decides to change its Patents Act with the amendments that the Indian government is fighting for.

India has played a critical role in the international efforts to increase access to affordable HIV treatment. India is the world's major supplier of generic medicines, and 66.7% of its generic drugs are exported to developing countries. The changes to the Indian Patents Act under consideration mean that the world's major supply of generic AIDS medicines could dry up and disappear. This is a crisis that the Indian government can avoid.

Companies in India that manufacture generic antiretrovirals, as well as other life-extending and important public health products, have shown that generic competition can dramatically reduce the cost in the case of antiretrovirals of a triple combination of HIV treatment, in some cases by as much as 98% compared with the cost of a brand name combination.

The government in India has not given enough consideration to its rights and its recourses as a developing country in order to prioritize access to medicines and public health in implementing changing its Patent Act. We'll here more about this from our first speaker today, Ellen 't Hoen, who is the Director of Policy, Advocacy and Research at the Access to Essential Medicines Campaign of Médecins Sans Frontières/Doctors Without Borders.

Ellen 't Hoen: Thank you, Asia.

Good afternoon and good evening. And thank you for being on this call. I will only speak for a few minutes and explain why we at Médecins sans Frontières, Doctors Without Borders, are concerned about what is about to happen in India.

The rules on intellectual property rights of the World Trade Organization, as laid down in the TRIPS[1] Agreement -- that is the Agreement that lays down the rules -- requires India to be fully TRIPS compliant as of January 1st. That means that India will start granting pharmaceutical product patents, something they have not done since 1970 because India did not consider that in their interest, as patents on medicines lead to high drug prices. The Indian government had very serious concerns about the effect on prices, and for very good reasons.

Now, why are we looking at India today? The reality is that many people in developing countries rely on affordable versions of medicines, in particular of newer medicines, produced in India.

One of the reasons why we at MSF have been able to increase the number of people that receive antiretroviral treatment in our projects -- those are the AIDS medicines that are for many of them a matter of life and death -- is because prices of AIDS medications have come tumbling down in the last five years, from about $10,000 U.S. per patient per year to around between $150 and $300 per patient per year for the triple therapy.

In addition, the Indian manufacturers have been able to produce the fixed dose combinations, the so-called three-in-one pill, which has really revolutionized the AIDS treatment in developing countries because it requires patients only to take one pill twice a day, which of course helps with adherence, with simplification, and with preventing the development of resistance.

These developments, and particularly the price developments, are a direct result of the Indian medicines patent policy. Because of this policy competition between companies has been possible and more affordable versions of medicines have been available in many countries. In fact multiple companies are, and have been, active in the field of AIDS for example.

Now, for newer medicines after January 1st, 2005, that is likely to change. Because India will have to start granting pharmaceutical product patents, we look with great, great concern to the future.

If, for example, under the current day's situation, we would have to switch patients from first line treatment to the next generation of the WHO recommended regimens. That could, in certain circumstances, mean an increase of cost for the drugs alone from $160 for patients per year to $4,000 per patient per year. Because for those newer medicines there will be no generic competition, so we will be largely dependent on single source medicines. Asia referred to the monopolies that are being created through patents, which will make it very, very difficult to bring drug prices down.

Another important question that needs to be resolved is for which drugs is India going to grant patents? Countries have quite a bit of flexibility in determining the patentability. It is not so that

[1] TRIPS is the WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights.

every application should also be awarded with a patent. Technically, it would be fully TRIPS compliant for India, for example, to only grant patents for new chemical entities and not for combinations, for example, or for second use of known molecules. Today, we do not know which way India will go, but those are very important questions we hope the Indian government will answer with great regard to the public health needs of its people and of the people in other countries that depend on Indian manufacturers.

Just to summarize, we are very concerned about the future. We fear that we're going to see an increase in the cost of AIDS treatment unless action is taken. Partly that needs to be done in India. But, it is not only the Indian government's responsibility. It is also the responsibility of the international community. Organizations such as the World Health Organization, but also the Global Fund, should more actively engage in these debates and start formulating proposals and solutions for the problems that are ahead of us.

I'll leave it at that and I'll be happy to take any questions after the other speakers have given their brief introduction.

Asia, back to you.

Asia Russell: Thank you, Ellen.

Our next speaker is Anand Grover, who is the Project Director for the Lawyers Collective HIV/AIDS Unit in Mumbai, India. Anand?

Anand Grover: Thanks, Asia.

I think it's important to explain the background to the Indian Amendment. India, from 1970, has had what is called Process Patent Protection. And it's very important for the audience to understand that patent protections are of two types. One is a product patent and the other one is a process patent. So, any product like a drug can be protected either by virtue of a product patent or a process patent.

Now, one other thing that is very important to understand is that, if you have protection of a product patent, then there is a monopoly. And a monopoly means increasing prices. Whereas, if you don't have protection of a product patent, then you have more producers producing the same product because only a process patent is protected and there can still be competition and a lowering of prices.

Now, that is what we saw in India from 1970. Before that time we had a product and a process patent regime introduced by the British who ruled us before 1950. The Indian government at that time thought, in order to protect the health interests of the public at large in India, only process patents should be protected, which would encourage generic production, more producers, and a lowering of prices.

And that is exactly what happened and the pharmaceutical industry in India grew. And at the end of the day, by 2000, we had huge pharmaceutical companies, which were producing generic products at one-tenth to one-hundredth of the cost of the multinationals' products. And we now know that most of the multinationals were producing drugs at costs that were highly inflated and not commensurate with a reasonable return on the production.

Now, what India is doing right now is introducing a law to become TRIPS compliant. But India is actually doing much more than TRIPS requires. What TRIPS requires is two major things. One is that all countries, which are signatories to the TRIPS Agreement, have to introduce protection for

process patents as well as product patents. Since India already had process patent protection, it had to introduce product patents.

India also had to introduce exclusive marketing rights. Now, India has already amended its law to actually introduce product patent protection and exclusive marketing rights. What it needs to do now is a very simple thing; that is, to actually apply the process for processing the applications for product patents.

And unfortunately, what the Indian government is doing -- and we feel it is doing this because of the pressure of the multinational corporations and the U.S. government -- they are introducing amendments in the law which are not required under the TRIPS. For example, they are introducing a change in the scope of patentability, which far exceeds the norm that is required in the TRIPS. Although TRIPS doesn't require that new usages of known medicines should be protected, that is exactly what the Indian government is planning. TRIPS only requires product patents should be protected. Like Ellen said, genuine new molecules are required to be protected under TRIPS.

But the pressure on the Indian government -- and unfortunately, large elements of the Indian government are actually succumbing to this pressure – is to go beyond TRIPS and require the introduction of patent protection for new usages. This is commonly called patent "evergreening."

Secondly, the TRIPS Agreement does not require the Indian government to do away with public scrutiny of whether or not a patent application should be granted. Under law, in India and elsewhere, a genuine new chemical has to be protected. But suppose somebody's already anticipated it in literature, or somebody's already come up with the invention. Then, it may not be protected. So the public has a right, as the law stands now, to intervene and actually scrutinize whether it's a genuine invention or not. This is known as "pre-grant opposition."

The government wants to do away with that. Now, if pre-grant opposition is done way with, ordinary citizens who are basically interested in affordable drugs, generic drugs, will not have the right to protest and actually object to frivolous patents being granted.

The third thing the Indian government is thinking to introduce, which is again not required under TRIPS, is as Ellen pointed out, is a compulsory licensing regime that is unworkable. Because the vast majority of the developing world depends on the manufacturing capacity of India, preventing generic competition will impact other poor countries outside of India. They don't have manufacturing capacity.

Now, for some reason the Indian government -- and this shows the mindset of the Indian government -- they want an importing country like Tanzania, which is not required to have a patent law until 2016, to issue a compulsory license in order to import drugs that are patent protected in an exporting country like India. But a country must have a patent law in order to issue a compulsory license. Since Tanzania is not required to have a patent law, how are they going to issue a compulsory license to obtain the medicines? But the draft changes to the Patents Act would require that Tanzania issue a compulsory license, which is an absurdity. It is not consistent with WTO agreements on the issue, it exceeds those agreements.

There is a problem with compulsory license for the domestic market in India, as well. If prices are very high and if a monopoly producer does not make available affordable or accessible drugs, India or another government has a right to issue what are known as compulsory licenses.

Now, the Indian procedure for compulsory licenses is so cumbersome that it is impossible to use. Because of the cumbersome nature of the procedures, arms will be twisted at the behest of multinational corporations, in order to make sure that no compulsory licenses are issued and

monopolies are deepened. Amendments to the Patents Act must correct these errors in the compulsory licensing system, but the Indian government is refusing to do that.

Finally, I just want to tell you that the effect of these flawed positions by the Indian government is beginning to be felt already in India. I will give you the example of the drug called Gleevec, which is an anti-cancer drug. The problems we are discussing do not only affect cancer or HIV drugs; it affects all drugs across the board. Gleevec has come out in the market in India. It is a very effective drug for chronic myeloid leukemia. Generic producers are producing this drug at $200 per month. Novartis AG, which has got a patent in Australia and marketing approval, and now has got exclusive marketing rights in India, is now producing Gleevec at $2,000 per month. So, it's a huge jump. This is just a glimpse of what is going to happen throughout India.

So, I want to leave it at that and just say that the Indian government is not required under the TRIPS Agreement to introduce what it is seeking to introduce. The Indian government only needs to change very minimally the law so that India allows product patents to be processed in India so they can be granted if they're genuine. India should not introduce a host of other amendments—the impact will be disastrous. But that is precisely what they are seeking to do.

I'll stop here and take questions later on. Thank you.

Asia Russell: Thank you, Anand.

And our final speaker is Dr. Eric Goemaere, who is the head of Mission at MSF in South Africa.

Dr. Eric Goemaere: Thank you, Asia.

I will speak from South Africa, from our experience here, where we are running two programs. In the one we have close to 2,000 patients now on antiretroviral treatment, and in the other one, in a rural area, another 500. So, they are quite large programs. Now there is close to 2,500 people on the treatment, antiretroviral treatment. Why was that possible?

In the beginning we started to treat our first patients in 2001 and we had that program started in 1999. We had several contacts with the pharmaceutical companies to test the water, to see how much they could reduce the price of these medicines. The best offer we ever got was the offer of the so-called Accelerating Access Initiative, which made the best price for a combination around $1,500 U.S. per year per patient. Nowadays, as Ellen said, we reach prices that are around $140 U.S. per patient per year.

But some of the molecules we are using are not exclusively generics. They are also brand name. It's a mix. We are using the government supplier in South Africa. It's a mix. But, the same people who were telling us that they couldn't do it for less than $1,500 U.S. per year five years ago, are telling us nowadays that they can do it -- well, they're not telling us, they're telling the South African government – that it can be done at $140 U.S. a year. So, what made the difference? The difference was made by the presence of competition and a rival. As a result, very simply, the price has melted. I won't repeat the data given by Ellen.

In terms of numbers, in 2001 the private sector was already treating patients because the private sector consists of people with medical insurance. They were already treating 5,000 patients with antiretrovirals. Nowadays, they treat 45,000 people.

In the public sector it's even more striking. It was zero. We were the first treatment program to start. Nobody dared to start because the price was just not affordable. And nowadays, although the South African government is well known to be a bit reluctant on the subject, we are now end of

this year reaching 20,000 patients under treatment. So, the impact has been immediate in terms of numbers of people -- numbers of people treated as soon as the price went down.

That is the first argument. This price reduction and this access to medicines was created by generics. And it's clear that today, if generics are no longer available -- and we speak now about future regimens -- it's going to jeopardize treatment access efforts. Why so? Because, as everybody knows, patients develop resistance after a certain time. It's not that they are developing resistance more rapidly than in developed countries, in fact to the contrary. With the results and the outcome we have managed to produce data that show that 10 percent of our patients after three years require a second line of treatment. This was less than expected and it is definitely less than some in Europe and in the United States.

But still, 10 percent of them are not -- the virus strain is not sensitive any more to the antiretroviral drugs they started with. And what we would need for them is so-called second line, which are more sophisticated drugs. We need drugs in the future that are more powerful that can go across the resistance, but that are easier to use. We need new formulation that will only be done by generic manufacturers because they are definitely tailored for markets, large-scale public markets in developing countries.

In fact, there is a very strong analogy that can be made with what happened 20 years ago with EPI, the Extended Program of Immunization. Exactly the same kind of debate existed at that time with vaccine producers in the developed world saying "No way you're going to develop generic formulation for your program because it's going to impair our markets." And thanks to UNICEF in that time, an agreement was made to develop different formulations based on the same product, by generic brands so that a very large-scale program could be developed across most of the developing world. This was possible 20 years ago. It might not be possible in the close future anymore because patent protection is more and more tight.

We certainly are very scared what could happen if generic manufacturers are not able anymore to produce. The fixed dose combination we use here, not exclusively, but certainly in our rural program. And to develop a successful rural program, you need to decentralize these as much as possible, so it's run by nurses. And sometimes not even nurses, but assistant nurses. So, there is a key motto, which is simplification. You have to simplify as much as you can.

We benefit there from this famous three-in-one combination pill. Instead of delivering three drugs with three different dosages, there is one pill to be taken in the morning and one pill in the evening. We don't have those treatments for children yet. We are expecting that Cipla, the Indian manufacturer, that they're going to produce one soon especially tailored for kids instead of giving them three different syrup with three different dosage one day. Of course, this makes all of us extremely hopeful that we'll be able to treat children in a very much-simplified way.

But the choices of the Indian government means that one day this may not be possible anymore. If the generic manufacturers are not able to produce those drugs they are going to have to be able to break patents because each of the molecules belong to a different company.

Okay, those are the three points I wanted to make. Thank you.

Asia Russell: Thank you, Eric.

So, I think our speakers have presented a straightforward situation where the future of generic competition that is being threatened. Up until now this competition has been responsible for dramatic reductions in price. And there is an opportunity for the government of India, with the support of the international community, to make some clear decisions that prioritize public health and access to affordable medicine.

So, at this time we'll take any questions that people may have.

Operator: Ladies and gentlemen, if you have a question or a comment at this time, please press the one key on your touchtone telephone. If your question has been answered or you wish to remove yourself from the queue, please press the pound key.

There are no questions at this time.

Ellen Hoen: In that case, Asia, may I add something?

Asia Russell: Absolutely.

Ellen Hoen: I think one of the reasons why we are also looking somewhat with hope to the Indian government, is because we have watched the Indian government really take a leadership role at the international level on the issue of access to medicines. The Indian negotiators, for example at the World Trade Organization's TRIPS Council and in the ministerial meetings -- and particularly in Doha, where the declaration on TRIPS and public health was adopted -- the Indian government played an absolute key role. The Indian government has taken leadership on this issue at the international arena.

And I think that there are many, many people outside India looking at this process, hoping and expecting that the international leadership on the issue of access to medicines will also be translated at the national level, and that the new Indian patent legislation will reflect the priorities India has been very strong on in the international forum.

Anand Grover: Ellen, may I just comment on that? I think it's important to understand that there's been a government change. Not that the [unintelligible] government is better. But both governments have people who are very pro-liberalization. And if I may, with respect, they're very pro-U.S. And they think that getting into the good books of the U.S. is a very important part of the new arrangement of political forces internationally. And they also believe that patent protection is going to actually increase foreign direct investment (FDI). So in the long run, they feel that economic prosperity lies with closer collaboration with the U.S. I think that's one thing one has to understand.

And the Indian government is not the same which negotiated right from the Uruguay round of WTO talks, which led to the TRIPS Agreement, or even the same government that negotiated the historic Doha Declaration on TRIPS and Public Health. There has been a significant change in the composition of the leaders of government. The leaders in government now really believe that privatization, liberalization and, unfortunately, patent protection—which is actually antithetical to liberalization—are very important.

So, I hope that the Indian government doesn't disappoint us or the international community. But, I feel that forces are at work, which may disappoint us. And so we have to work all the more harder to make sure that it doesn't happen.

Operator: Pardon me, Ms. Russell.

Asia Russell: Yes.

Operator: There are two questions now. Our first question comes from line 27. You may ask your question, ma'am. Your line is open.

Maggie Fox: Okay, thanks. This is Maggie Fox with Reuters. I'm just wondering why you think the Indian government should do this? What's in their interest other than it's the right thing to do?

Anand Grover: Who is it addressed to?

Maggie Fox: Anyone.

Anand Grover: Could I answer that?

Asia Russell: Please do.

Anand Grover: I'm from India, and I know that there are different factions in the Indian government who believe differently about this process. I think it's the pressure of the multinational corporations. And unfortunately, there are people in the Indian government who actually are very much influenced by the multinational corporations. Some of them happen to be like me, lawyers, who actually act for the multinational corporations and that's the unfortunate part.

The proposed Patent Act amendments are not in the interest of India or in the interest of the international community from the public health perspective. It's very unfortunate that the Indian government is doing what it is.

Asia Russell: Ellen, do you have a response to the question as well?

Ellen 't Hoen: Well, just to follow on from what Anand said. It also shows that it is very unfortunate that these really important decisions on access to medicines that make a difference in many peoples' lives are mainly taken within trade negotiating frameworks and very little considerations that are health driven actually play a role.

We need an international discussion on access to medicine and what needs to happen to assure that the medicines that are needed are available. We also need to discuss how to ensure that new drugs that are needed are being developed. We see today that we can actually rely less and less on the market forces to deliver what is needed, The current system for setting priorities is mainly patent driven, and that leads to the development of medicines that perhaps from a health point of view are not the priority and it leads to medicines that are very highly priced.

Anand Grover: Can I just add to that, Asia?

Asia Russell: One last quick comment and then we'll move on to the next question.

Anand Grover: Unfortunately, the introduction of the new patent amendment bill is being done without any public discussion. And that's the most unfortunate part of it. Civil society and health groups are just excluded. Not only them but the whole of the public citizenry and Parliament. And this is the ordinance, which has to be deprecated and condemned because it will increase the cost of medicines. The government is actually hiding behind an ordinance. They should be willing to have an open discussion and say what they want to say without hiding behind this kind of ordinance. This is what we call "raj" in India.

Asia Russell: The one last point to recognize is that this isn't just the right thing to do. Access to essential medicines, including medicines to treat HIV, are actually essential to development in poor countries. India's a country with more than five million people living with HIV. And for poor country governments to put tough intellectual property rules into force, tougher than the rules need to be, without being carefully guided by pubic health needs, isn't just the wrong thing to do, it's also a dangerous thing to do. This is true whether you look at it from the point of view of public health or sound economic development, or any other framework.

[Ed. note: some experts argue that it is not in India's economic interest to undermine its domestic industry, and that the speculated benefits, such as increased foreign direct investment, would not actually counterbalance the costs, when you examine the tremendous impact that lack of access to medicines would have on India and on importing countries.]

Operator: Our next question comes from line 28, Sarah Boseley.

Sarah Boseley: Hello. Sarah Boseley from the *Guardian* newspaper. Some of this has just been touched on, actually. But, I wanted to really to ask Anand, is it, about the process that's been gone through here. The Indian government is doing what, exactly? They're discussing it at the moment are they? And I gather this is in secret session. We've heard things about an ordinance route. Could you just explain exactly where we've got to and what you expect to happen?

Plus, a second question is again for you. Could you just tell me again about the myeloid leukemia drug? Are we talking about Gleevec here? I'm not quite sure. If you could just go through that example again that would be useful.

Anand Grover: Well, the first question first. There has been no discussion. As you know, India had an election earlier this year and we had a new government. The earlier government, which was a coalition government, had actually tabled a bill on this issue in 2003, which was available -- but there had been no public discussion on that bill.

The new government has not actually brought about a bill. There has been secret conclaves. There has been a Group of Ministers established to which is supposed to agree or disagree on the amendments. We do not know what they are agreeing or disagreeing to. It's all done behind doors. And there are pressures acting, obviously, with ministers. And as you know, government always react to these pressures.

The latest thing that we have heard is that they will follow what is known as the "ordinance route." Ordinarily, Parliament is presented with a bill, and the bill is discussed in Parliament and outside of Parliament. The ordinance route is what happens when Parliament is not in session so the government just introduces an ordinance as a *fait accompli*. It lasts for a period of six months constitutionally and it has to be ratified by Parliament, otherwise it lapses.

Basically, it means that it is being introduced without discussion. And that's the tragedy of it. They've had two or three years to discuss it. They've discussed it. The public are not involved in the debate. And they know there's intense opposition to it because there has been public protest. There has been demonstrations in Mumbai, Delhi, Bangalore, now Calcutta, and I know [unintelligible] will join in.

The second question, yes, it refers to Gleevec—a drug you must take for the rest of your life. The difference in price between the generic product, which is at $200 a month, and Novartis AG is $2,000 a month. As you know, it is an orphan drug. In the United States they have a specific law, which allows fast tracking of orphan drugs. So, the amount of money that's spent on clinical research by the pharmaceutical company is very low. And the government has pitched in some money. So, we don't know how much Novartis actually spent, but they're selling it at a huge profit; exorbitant profit. In India, too, for nearly $2,000. So, it does refer to Gleevec as you mentioned.

Sarah Boseley: But, you're saying that there is a generic version on the market in India at the moment?

Anand Grover: In the beginning of 2003, there were about eight producers who were producing generic product. Because, it is a pre-1995 molecule. As you know, the new patents law would only apply to post-

1995 drugs. This is a pre-1995 molecule. But the beta isomer of Gleevec, it is known generically as imatinib mesylate, is also active against chronic myeloid leukemia. And they say that because it's a new property of a particular version of that compound, the beta isomer, they're entitled to a product patent.

That's exactly what we want to resist because it's not a new invention at all. It doesn't warrant patent protection. It's not a new chemical entity. But Novartis has a patent granted in Australia, and marketing approval to the subsidiary, which is the Australian company.

But Novartis could not have been granted an exclusive marketing right, even in India, because the law requires that the same entity must get the patent as well as the marketing approval. Unfortunately, the patent controller granted the exclusive marketing right anyway. And now Novartis has injunctions in the Madras (Chennai) High Court against six generic producers of Gleevec. There are also suits pending in the Mumbai High Court against two generic producers. And the cancer patient association has actually filed a petition challenging the constitutional validity of the statute. But the inexcusable thing is that the cancer patients are not getting the drug anymore. So, they are likely die in the near future. That's the unfortunate part.

Sarah Boseley: Okay.

Anand Grover: If the new amendment is allowed, then cancer patients will not be allowed to have drugs at affordable prices. And even the generic versions were not at affordable prices. But if the generic companies had continued for another two or three years, as with antiretroviral drugs, they would have brought the price of Gleevec down because of the large numbers that would be available within two, three, four, five years. There are about 25,000 chronic myeloid leukemia patients every year. And in five years that would be 100,000 so you could bring down prices because of the large number of takers of drugs. But you can't do it anymore.

Technically the existing law requires that that patent applications should be for molecules that are post 1995. Novartis is contending that it's a genuinely new compound because the alpha isomer does not have the properties that the beta isomer has, which is anti-chronic myeloid leukemia. Novartis is open, of course, to argue that. But it is not a new chemical entity, which requires patent protection.

Asia Russell: The example of Gleevec gives us an alarming preview of what will very likely happen to Indian consumers and to consumers in poor countries that rely on Indian generics with antiretrovirals and other critical medicines. We can see this played out in the struggle over access to affordable generic versions of Gleevec. There's a small window of time within which the government of India can still act in order to avert what's a looming disaster.

Ellen 't Hoen: Asia, if I may add something to that?

Asia Russell: Please do.

Ellen 't Hoen: In principle, all new products that have come onto the market since 1995, companies and others actually have been able to post their patent application for those products in what is called the "Indian Mailbox." There are, as far as we understand, about 6,000 applications in this mailbox. These are patent applications waiting for January 1st, 2005. On this date India's patent offices will open the mailbox and start examining these patent applications.

Nobody knows what exactly is in the mailbox. But technically, it is for example possible that there is a patent application for the fixed dose combination of AZT/3TC, also known as GlaxoSmithKline's Combivir. Should Combivir be in the mailbox, the question of which criteria Indian patent examiners are going to use to examine these patent applications is absolutely crucial.

Anand mentioned the fact that India, according to the TRIPS Agreement, is not obliged to grant these type of patents. India could decide to only grant patents for new chemical entities. That will be very, very important because many, many people today around the world depend on generic versions of this particular fixed dose combination. And it would be quite harmful if, for example, in the new year Indian patient offices would grant a patent for this particular product.

Again, we do not know whether an application for this product is in the mailbox, but technically it is possible.

Anand Grover: This is one of the harmful amendments that the government wants to add. There is a draft amendment to the Patent Act to patent what should not be patentable. Patents on new uses are excluded now, genuine new uses, such as a fixed dosed combination like Combivir. It would be patentable in India if this amendment goes through. So, that would be a very dangerous precedent and that's why we need to oppose it, not only in India in the interest of Indian patients, across the board, and not only for HIV patients but for all patients. It's obviously in the interest of the patients in the world at large.

Asia Russell: Are there any additional questions?

Operator: No, there are no questions at this time.

Asia Russell: If there are any brief closing remarks from our speakers, we can hear those and then we can close the call. Journalists on the line should know that a transcript from the call will be available, e-mailed out to you and also on our website at www.healthgap.org.

So, if there are any closing statements from our speakers, we can hear them now.

Ellen 't Hoen: Very briefly, I would like to thank the journalists on this call. Because, what is going to be crucial is more public knowledge and more public debate about these issues. Sometimes these can become very obscure technical legal debates. But at the end of the day, it really is a matter of life and death. Are people in the near future going to have access to these medicines or not? And without having more people know about it and more public discussion and more reporting about this in the media, it's going to be very, very difficult to do anything about it. So, thank you for being on this call.

Asia Russell: Thank you, Ellen.

Anand Grover: While I agree with Ellen that esoterically [unintelligible] actually impact on the life and death situation, we are trying to work with the journalists in India and, fortunately, a lot of people are taking it up. We are actually holding a lot of meetings across the length and breadth of India. We've already had meetings in Mumbai, Bangalore and Delhi, and we are proposing to have them in and other places, [unintelligible], so that the public understands what the issue is all about.

The government doesn't want the public to understand and wants to claim that what they are doing is required under the TRIPS Agreement, which is a blatant lie. And I think, as Ellen said, the journalists have a very important role to play; not only in the interests of Indian patients, but in the interest of a large number of patients, even outside HIV, as the Gleevec example makes very clear.

In the interest of the life and death of people in the world at large, it is very important that the Indian government is made to understand that what they are doing is not in the spirit of what India has done in the past—from negotiations at the Uruguay round, up to what the Doha Declaration on TRIPS and Public Health obliges them to put in place in India as a law.

So, it has to be opposed. We are very happy that all of you have listened to us for a short time. Thank you.

Asia Russell: Eric, do you have any closing comments? Maybe we've lost Eric.

Operator: Eric's disconnected.

Asia Russell: Thank you everyone, particularly our Indian colleagues who have stayed up quite late to participate in this call.

As the one American speaker on this call, I should just say that it's important to note that the pressure from the U.S. government on India has happened without any examination. It is actually the obligation of donor countries around the world, including the U.S. government, to communicate clearly to the government of India that they don't have to compromise public health and access to medicines. For example, the U.S. should be advising the government of India that their standards for patentability can be limited to new chemical entities and not second uses for existing molecules. But instead, the communication from the U.S. government and the U.S. pharmaceutical companies is the opposite. 66.7% of the generic medicines that India makes are exported to developing countries. This means the different between life and death for patients in India and around the world. We must not stand by while U.S. government pressure and other pressures undermine access to AIDS drugs.

So, thanks to everyone again, and we look forward to staying in communication with you in the very near future as there are more developments in India regarding changes to the Patents Act.

Operator: Ladies and gentlemen, this concludes today's presentation. You may now disconnect.