



PEOPLE BEFORE PATENTS

**Press Teleconference
Friday, January 26, 2007
10:00 AM ET**

Participants:

- **Unni Karunakara**, MD, Medical Director, Campaign for Access to Essential Medicines, Médecins Sans Frontières (MSF)
- **Ellen 't Hoen**, LLM, Policy and Advocacy Director, Campaign for Access to Essential Medicines, Médecins Sans Frontières (MSF)
- **Loon Gangte**, Regional Coordinator, South Asia Collaborative Fund for HIV Treatment Preparedness (formerly from Delhi Network of Positive People)
- **Christine Geneviev**, Head of Mission for MSF's AIDS Treatment Programs in Kenya

Operator:

Good day, ladies and gentlemen, and welcome to the People Before Patents conference call. I would like to introduce your host for today's conference, Mr. Kevin Phelan. Sir, you may begin.

Kevin Phelan:

Good morning, everyone, and welcome to the People Before Patents press teleconference. We are fortunate today to have with us Dr. Unni Karunakara, the Medical Director for the Campaign for Access to Essential Medicines, and Ellen 't Hoen, the Policy and Advocacy Director, as well as Loon Gangte, the Regional Coordinator of the South Asia Collaborative Fund for HIV Treatment Preparedness, and also the President of Delhi Network of Positive People; and finally, Christine Geneviev, the head of Missions for MSF's AIDS Treatment Program in Kenya.

I would like to introduce our first speaker, Dr. Unni Karunakara.

Unni Karunakara:

Good morning, everybody. So, I'll go straight into the matter: India is a large producer of affordable medicines for people living in developing countries, and MSF, as a large medical humanitarian organization, now treats about 80,000 AIDS patients around the world. And 80 percent of these patients are being treated by generic drugs from India. Now, this is, I think, quite similar to what other NGOs are also doing. Over half the medicines currently used for AIDS treatment in developing countries come from India. So, India is therefore an indispensable source of life-saving generic drugs in the world today.

India is, however, drying up as a source of affordable versions of newer and future medicines. Widespread medicines patenting in India could mean that affordable versions of new medicines will no longer be able to be produced by Indian manufacturers. And this is absolutely key for our programs and also for our patients.

Now, access to affordable newer and improved drugs is absolutely crucial in the care of people living with HIV and AIDS. After a certain amount of time, people become resistant to the drug combinations they take and inevitably need to be switched to newer second-line drug regimens.

Data from just one of our treatment programs in Khayelitsha (South Africa) I think it has been running for over five years now, shows that 17.4 percent of people who have been on treatment for five years have had to switch to second-line therapy, and this we are seeing more and more in our other projects as well.

So, as the programs mature, we will need to put more and more people on second-line therapy.

Additionally, improved first-line medicines, as we discover that certain drugs that are currently used have side effects and we come up with new drugs, we need to incorporate that into the first-line therapy.

The lack of competition on newer AIDS drugs today has resulted in the price of these medicines remaining much higher than those for older drugs. So, as the time goes by we need new drugs, and these are now frightfully expensive. If the situation continues as it is today, then running programs will become more and more difficult.

Now, if Novartis succeeds in its challenge against Section 3(d) of India's Patent Act, patents could end up being granted in India just as broadly as they are in other countries. This would really mean that no generic versions of newer drugs could be produced by Indian manufacturers during a period of 20 years, which is usually what the patent terms are.

This would mean that much of the developing countries would no longer be able to rely on Indian manufacturers for their supply of affordable essential medicines. Remember that much of the 3 by 5 initiatives and the Global Fund programs, a lot of them, all of them depend largely on Indian manufacturers for the provision of medicines.

Now, if you take just one example, one of the many drugs awaiting patent examination in India, for example, is valganciclovir. Now, this is produced by Roche and it's an oral treatment for an opportunistic infection called CMV retinitis -- cytomegalovirus that affects the retinas. Now, 10 percent to 20 percent of HIV-infected patients worldwide can be expected to lose their vision as a result of this disease.

Now, current costs in Europe of this therapy varies from US \$7,000 to \$10,000. Now, we recently had meetings with Roche and they've agreed to bring down the price to about US \$1,800, which is still outrageously expensive and out of reach for most people living in high burden countries.

Now, if we are to prevent blindness in people living with HIV/AIDS, and CMV retinitis is the largest cause of blindness in people living with HIV/AIDS, there needs to be access to affordable generic sources of valganciclovir.

This is just one example; there are many other drugs which are under examination in India by the patent authorities that are so crucial if we want to scale a program, if we want to change, if we want to move patients away from first-line to second-line treatment. All of this will not be possible if Novartis manages to win its challenge against Indian government.

So, public health concerns must and should take primacy over IP considerations. People need to be put before patents and Novartis must, in the interest of global health, drop the case. Thanks.

Kevin Phelan:

Thank you very much, Dr. Karunakara. For further on the Novartis case against the Indian government, I now turn to Ellen 't Hoen.

Ellen 't Hoen:

Thank you, Kevin. I will give a little bit of background to the case and a little bit of background to the Indian Patents Act. The reason why Novartis is challenging an important section of the Indian Patents Act is because they were rejected a patent for one of their products, named Gleevec. Gleevec is an anti-cancer drug. As a result, Novartis has started these legal proceedings where they both ask to overturn the decision by the Indian patents office to not grant a patent for Gleevec, but they also challenge the part of the Indian Patents Act that forms in fact the basis for the patents office decision.

A bit of background to that particular provision: Some of you may know that when India, in 1970, amended its Patents Act to no longer allow pharmaceutical patenting, that was the start signal for the development of the current Indian generics industry. You can say that the fact that we have been able to put 80,000 people on an antiretroviral treatment for AIDS today is largely thanks to that decision in 1970.

Now, that Patents Act had to be changed in 2005, as a consequence of the World Trade Organization's global rules on pharmaceutical patenting. No country that is a member of the World Trade Organization is allowed to exclude pharmaceutical product patenting from happening in its country.

India became compliant with the TRIPS obligations, with the WTO rules in 2005, but in 2001, the Doha Declaration on TRIPS and Public Health was adopted by the WTO, and that declaration in a way said the interest of public health, the interest of people who need access to medicine, takes precedence over the commercial interest. And that declaration was taken at heart very seriously by the Indian legislators, and the Indian Patents Act is drafted in such a way that there is a lot of attention to the protection of public health. There was also extensive debate in the Indian parliament about the role of India globally with regard to access to medicines.

Unni already mentioned that about 85 percent of the people we provide with AIDS medicines depend on Indian generics. Sixty-seven percent of India's export goes to developing countries. Seventy percent of the 900,000 people receiving treatment through the Global Fund and other donors rely on Indian generics. And, also, the U.S. President's Program, the PEPFAR Program, has been able to make cost savings up to 90 percent because of the purchase of generic medicines.

Now, what will happen if Novartis is successful next week? If that would lead to the scrapping of Article 3(d), it could mean that India would start to grant pharmaceutical patents very much along the lines of wealthy countries. Today, 6,000 patents are awaiting examination in the so-called Indian mailbox. We know that many of those patents are a concern; we are using medicines that are already generically produced in India, for example, and we're very concerned about the consequences of that.

Now, the Novartis case in a way is an example of something we've seen in the last few years. While true the WTO levels of intellectual property protection in the pharmaceutical arena have dramatically increased globally, the good news is at the Doha meeting, and the Doha declaration in a way recognized that problem and said "your country should really implement this with a lot of attention to public health." But what we have seen since then is a lot of activities by the companies to seek higher levels of intellectual property protection than countries are obliged to provide under the international rules. We've seen it in free trade agreements, and now we see it through court procedures, such as the Novartis one in India. We're very concerned about the consequences, not only for people in India, but for people globally, and we have joined forces with many to demand from Novartis to drop the case.

Thank you.

Kevin Phelan:

Thank you very much, Ellen. Now, to get a perspective of civil society opposition within India and Novartis's present case, we turn to Loon Gangte.

Loon Gangte:

Thank you, Kevin. I want to talk about this case, and let me explain in brief about why this case is very, very important. This Novartis case is very important for the people living with HIV/AIDS, not just in India, but as Ellen said, for the rest of the people in the developing countries who are relying on, and who are living today because of, access to Indian generic drugs.

Why it is very important is because the very clause that Novartis challenged in the Indian high court, which will be in a hearing January 29, is the Section 3(d) of the Indian Patent Act. That is what they challenged. And why this case is important is that this Section 3(d) is not just for Novartis, but the people living with HIV/AIDS in this civil society in India. Today so far we have about 15 anti-retroviral drugs and one opposing these drugs for the [inaudible] operation. Most of, if not all, most of the [inaudible] operation that is [inaudible] Section 3(d) of the Indian Patent Act that would prohibit the pharmaceutical companies for ever gaining process of patenting the their [inaudible].

So, this case is very, very crucial for us, not just for the Novartis case, but also for the 15 anti-retroviral drugs so far that we have for further preventive operations in India.

So, if tomorrow Novartis will win it will set a precedent for the patent and for the pharmaceutical companies and many of the generic drugs that have been available will be left out in the pharmacy counter and people will not be able to access these medicines. But why we fight these guys, it's not about the generic or multinational, but it's about trying to save the lives of people living with HIV/AIDS in India, who are relying on generic drugs.

So, this is the reason we have been opposing this and demanding Novartis drop the case. Thank you.

Kevin Phelan:

Thank you very much, Loon. Now to get a perspective from the field, we turn to Christine Geneviev, the head of Mission for MSF AIDS treatment programs in Kenya.

Christine Geneviev:

Good morning or afternoon for everybody. It's clear that Kenya would not reached where we are or maybe started patients on treatment, early treatment, without the generics. Our patients are poor and live in areas where prevalence is very high, meaning we still have a problem today where not all the patients in need of drugs are getting them. We, of course, are targeting the best quality for our patients, which involves a lot of [inaudible] in the infrastructure and, of course, a variability of [inaudible] drugs.

To date we are treating 20,000 patients on average, and we still have 6,000 who are [inaudible] who sooner or later will need [inaudible].

In Kenya, about 90,000 patients are under treatment and we are sure that at least 100,000 more are still in need of it. It's not only MSF who manage to do this for the patients, but also the ministry [inaudible] thanks to the generics, because I don't think that Global [inaudible] would have avail all these tens of thousands of treatments without the [inaudible] that was given.

Our concern today if this case is not dropped is that we are going to have among our patients a proportion which unfortunately will increase resistance to the first-line drug. These will need second-line drugs, which are at the moment are still too expensive. It is about ten times more expensive than the drugs they are getting with first-line generics.

This will be extremely difficult to afford for MSF and for the ministries in Africa.

Another big concern we have is that at the moment the treatments we are using showing now some projects on the [inaudible] who have been for quite some time on the treatment, and we know that if a drug -- if a new drug could be available for them if available in generics.

So, of course what we would like is to have good treatment and that the treatment also follows [inaudible] of what happens to our patients as the time goes and as they are [inaudible] over the years. And I don't think this can be possible without the generics. Thank you.

Kevin Phelan: Thank you very much, Christine. Now, we will move to a question-and-answer session.

Caller: Oh, I'm just wondering if you could repeat what level of court this is in and how long the case is expected to take? Everyone has talked as if it's going to be settled on the 29th, but I'm wondering what's actually expected in terms of the case and if there is any appeal procedures as well? I know you want them to drop it, but I'm wondering what the procedure would be if they don't?

Kevin Phelan: Ellen or Loon?

Ellen 't Hoen: Yes, I can answer that. Indeed, we hope we don't have to focus on that, because we do hope Novartis will drop the case before it gets to that. But the case is at the moment at the high court in Chennai. It is a -- Novartis is claiming that the Indian Patents Act, the provision 3(d) in the Indian Patents Act is unconstitutional because it would violate India's obligations under the TRIPS Agreement. There is indeed an appeal possibility to the supreme court after this level.

Today we do not know how long the case will go on. We know it opens on the 29th, but there are different scenarios possible. It is, for example, possible that the judge says I am not competent, in which case at the end of the day it will be over. Novartis will then have the possibility as far as we understand to appeal. It may also be that hearings will continue throughout the week. There is also the possibility that the judge gives a ruling next week. But today we do not know which date that would be. But we would be happy to keep anyone who wants to be kept informed up-to-date throughout the week.

Caller: And just a quick follow-up. Are other companies lining up to challenge the same section?

Ellen 't Hoen: We don't know that. We know that this case has been followed very closely by many, by companies, but also by others. For example, today we heard that following questions in the European Parliament; Commissioner for Trade Mendelsohn has said that he's following the case closely and that he was asked whether he was going to intervene and he said not at this stage, only when necessary. So, also at a political level people are following this case very closely.

The minister of development corporation in Germany has added her voice to the many -- to the hundreds of thousands of people who have called Novartis to drop the case, and has called upon Novartis to indeed do that.

With regard to further legal action, we do know that Novartis has already said in its petition to the court in India that if they succeed in receiving a patent for Gleevec and having that decision overturned, that they may challenge other sections of the Indian Patents Act they consider not compliant with the TRIPS Agreement.

So, even at the end -- if this case is ended, more challenges to the Indian Patents Act may be in the works. We don't know of any formal actions planned by other drug companies at this moment.

Caller: Thank you.

Caller: Hi. Can you talk about how the concept is being discussed as part of the WHO R&D framework would affect a situation like this?

Kevin Phelan: Ellen, that seems best for you as well.

Ellen 't Hoen: Yeah. A little bit of background perhaps to this question. There is -- globally there are discussions ongoing at the WHO in the Intergovernmental Working Group on Intellectual Property Innovation and Public Health about different ways of financing innovation, different ways of encouraging the development of new essential health products. And the link with this case is that often when you see the problems patents cause, you ask yourself the questions, but why do we have patents to begin with? It seems to be all pain and no gain. Because the thinking behind these higher levels of intellectual property protection was, and that's also how it was sold to the developing countries during the Uruguay round, if you provide higher levels of intellectual property protection and particularly pharmaceutical patents, you will kickstart research and development in areas where you have needs in areas where that is not happening today. And at the end of the day even though you'll pay somewhat higher prices, the society as a whole will benefit from that innovation.

Now, we know today that that is not the case. There have been numerous reports including the recent WHO report on Intellectual Property Innovation and Public Health that says the system doesn't work, particularly not to address the needs in developing countries.

So, there is now a debate -- started globally -- on what are the alternatives, what are additional mechanisms to make sure that health research meets real health needs, and that it is financed in such a way that it is not entirely dependent on high drug prices. Because that is the current model. Drug research and development is financed through asking high drug prices, but as a result, a large part of the world population does not have access to it.

So, these discussions are about how can you have innovation and access at the same time. Now, the link with this case, of course, is that even if Novartis drops this case tomorrow, there are still a lot of problems to be solved. Novartis is not entirely to blame for what is happening today in the world with access. The problem is in that we only have one predominant model for stimulating research and development, and that is ever higher levels of intellectual property protection.

Now, if you can somehow cause a shift in that and find other ways to do that so that it is not dependent on high prices, a lot of the problems we're faced with today could be addressed.

Another link with these debates is, of course, what is happening today in Thailand. Thailand has issued compulsory licenses -- has issued a compulsory license for an AIDS drug, efavirenz, for example, and has placed an order with Indian companies. And here's another example of how important the role of Indian manufacture is, that it would be very difficult for other developing countries to exercise their rights under the Doha declaration on TRIPS and Public Health if sources of generic production are drying up. Kevin?

Kevin Phelan: Thank you.

Caller: Hi there. Yeah, it seems a fairly simple life or death humane decision. What is Novartis's explanation? Do they recognize the human need? Have they made any statement on that?

Ellen't Hoen: There was a hearing in the European parliament this week, where Novartis spoke, and Novartis's position is -- and, of course, you should also call them and get their take on it - - but what they say is this is not about access, this is about protecting intellectual property, which is a bit of an odd statement, because we know that those two are directly linked.

Novartis is -- with regard to the one drug, Gleevec, I'm sure some of you may know that Novartis has put in place a donation program in certain countries for poor people who cannot afford the product, including in India.

So, if you would ask Novartis to respond, they will tell you a lot about that donation program. And while it is, of course, very good that the few thousand people that benefit from that donation program live because of that, because they would probably not be able to afford the price Novartis is charging, it also has to be recognized that in a world where almost all medicines can become patentable, drug donations cannot be a sustainable way of solving the problem. I don't see all drug companies say okay, we're going to provide the entire developing world with medicines for free.

In a sense, we're making this challenge because we don't think India is compliant with its obligation under the TRIPS Agreement, and it has thrown in this threat to further challenges of the Indian Patents Act. And they maintain the position that this is only about IP, this is not about access, and our response to that is if you have higher levels of IP, you run into greater problems with access. Those two are related.

Caller: Sure. Could I just follow-up on that? I mean, do these companies, do they put forward the usual explanation, which is that drugs have to be competitive to ensure that medical advances are made? Is that being said and how do you respond to that?

Ellen 't Hoen: Yeah. Novartis, indeed, said that this is all about competitiveness and being competitive in India. It is a bit of an odd statement because, in fact, what Novartis wants is a monopoly. They don't want to compete, they want a monopoly. They want to be the only one, and the only one for 20 years that can sell this drug and can determine what price they ask.

Caller: But do you agree that being competitive and keeping things profitable does bring along medical advances, that that is the way advances can be made by people [so going] for the money?

Ellen 't Hoen: Under certain circumstances, the patent system and pharmaceutical patenting encourages innovation. In many, many situations it does not. I think there is no denying that even in the world as we have seen it in the last few decades, large pharmaceutical companies have been able to do very, very well. Today we're looking at a 600 billion dollar pharmaceutical industry. Novartis has made with the Gleevec product alone 7.5 billion dollars sales in less than five years, even though in a number of countries they have not obtained a patent for this drug.

So, even if you allow for a world in which you have very diverse patenting practices and patent rules, there's plenty of opportunity for large pharma to make their money.

Caller: Sure. Thank you.

Operator: We have a follow-up question from Ann Silverside. Your question?

Caller: Two questions. One is that just -- it sounds like the possibility, of course, is just fighting brush fires all the time. If it's not Novartis, it's somebody else. I mean, I think that's what's been happening anyway in terms of challenges, isn't it? So, it's just ongoing having to deal with these kinds of assaults on the follow through from Doha.

I mean, what's happened in Canada, difficulties getting the drugs out, even though we passed the legislation, it seems like a never-ending kind of battle.

Ellen 't Hoen: Yes. I think you're right. We're sort of down to hand-to-hand combat on these things, and we often feel that we have to put out fires left and right, which is not a very good way to go. We do, however, feel obliged to do so, because if we just let every step, every effort that is made to arrive at higher levels of intellectual property protection in pharmaceuticals happen, we sort of grease the slippery slope even further.

That is also why these international discussions on is this really the way to go are so very important. It is in a way encouraging that also people within the pharmaceutical industry acknowledge that there are fundamental problems that need to be address.

And actually, not so long ago, in September last year, Daniel Vasella, the CEO of Novartis, said in the *Financial Times*, and this is a literal quote, "We have no model which would meet the need for new drugs in a sustainable way. We can't expect for profit organizations to do this in a large scale. If you want to establish a system where companies systematically invest in this kind of area, you need a different system."

We agree with him very much. That's also why we regret that in fact what they're seeking in India today is more of the same and not so much a different system. But we also hope that these kinds of confrontations will also lead to an opportunity to have a more fundamental discussion about what would a different system for supplying affordable essential medicines to the developing world look like.

Caller: Right. Thank you. And just a quick thing. Someone mentioned evergreening, and I forget what that means. Is it a question of things that are already produced and are they coming under patent in India?

Ellen 't Hoen: No, evergreening is something that is used by pharmaceutical companies to, in a way, extend the patent life of a product, by changing, making trivial changes and with that obtaining another 20 years or less exclusive rights.

Unni Karunakara: And this is exactly why the Gleevec case initially failed the patent examination, because it was considered, I think, by the patent office that it was not innovation in itself.

Caller: Hi. Sorry if I missed this piece of information earlier. I wondered if there's an estimation how many people do you think the ruling will affect?

Kevin Phelan: Ellen or Unni?

Ellen 't Hoen: We're talking about millions, because it will affect the ability to ensure that a large number of medicines will continue to be available as generic, or will become available as generic medicine. So, potentially, this can affect millions. If you only look at HIV/AIDS, we're talking about millions.

Unni Karunakara: And like in our older programs, the programs which are almost like five years old, we are finding that one out of every five patients now need second-line treatment. And second-line treatment at the moment is very, very, very expensive. If you don't have affordable alternatives, then treating them is not for a humanitarian organization or even for a big government, it's not going to be possible. It's just not going to be possible.

So, even though there are people who are on first-line treatment, in a few years they will need second-line treatment -- so, it's going to affect almost everybody, all people living with HIV/AIDS and other diseases as well.

Caller: Thanks.

Caller: Hi. I was just wondering if you could explain if -- what the link is between evergreening and second-line drugs? If I understand it correctly, Gleevec, the original patent, will have expired and so that original drug can be made generically now and it would be this patent on another version of the drug; is that correct?

Ellen't Hoen: With regard to Gleevec, the situation is a bit more complex, because the original compound patent on Gleevec, which perhaps would have gotten a patent in India stems from '93. In '93, India did not grant pharmaceutical product patents yet, and also had not opened its mailbox. So, that drug, that product will never become a patented product in India.

In '98, Novartis applied for a patent of a version of that original molecule, which was then subsequently rejected because, in fact, what the Indian patent office would have said was, well, we would have given you a patent for the '93 molecule but not for the one that you brought to us in '98.

A number of the patent applications that are waiting in the mailbox are of a similar nature, or are, for example, for combinations. The applications do not only concern original molecules, but a lot of the applications concern combinations or follow-on developments of the original molecule.

Caller: So, are there other companies that are waiting, doing the same thing, trying to get patents on drugs that were pre-1995?

Ellen 't Hoen: Yes, yes, there are.

Caller: Okay. Thank you.

Caller: Oh, hi, yes. Just to pick up a point that Ellen raised earlier. She said that we need a different system, a different model. I just wondered what MSF thinks such a model might look like?

Ellen 't Hoen: Well, that is a pretty big question. I think that today nobody has a blueprint that says here is the one and only way to do it, and there probably is no such thing as a one and only way. But what we do see is the one and only way, really, we have today and that is primarily financing research and development through high drug prices leads to which companies can charge, because they've got exclusive rights through patenting, leads to exclusion, leads to huge access problems.

So, what we would like to see is policies on approaches that looks at what are the real health needs. What would a real health needs driven research and development agenda look like? How much would that actually cost to pursue some of those objectives? And we would like to see that not dependent on the high drug prices, so that you would have much more, in fact, generic production. If you figure out a way to finance the research and development, then you're not dependent on the high drug prices anymore to do them.

And in a way, MSF is part -- we're one of the co-founders of a very small scale initiative that sort of tries to do that. It's called Drugs for Neglected Diseases Initiative, which is a not-for-profit drug development initiative in the area of neglected diseases, where the research and the development of the product is paid for upfront, and the initiative aims at

putting the drugs, the results of its research patent-free on the market and encourages multiple producers to produce it.

Kevin Phelan: And if I may add, they'll be coming out with a fixed dose combination ACT malaria treatment.

Kevin Phelan: Before the next question, I would like to just raise the attention to everybody that there will be a group of civil society organizations in Washington D.C. on Monday, delivering a prize that they are calling a "Golden Coffin" award to Novartis's CEO, Daniel Vasella, in Washington D.C. on Monday, the same day as the court case at 2 p.m.

Caller: Oh, just somebody threw in there and I wasn't sure, is it DNDi that have come out with the fixed drug malaria combination?

Kevin Phelan: Uh-huh.

Caller: Okay, thank you.

Kevin Phelan: Okay. I want to thank everyone for their participation in today's press call, People Before Patents, in which MSF and others are calling for Novartis to drop its case against the Indian government. If anybody needs any follow-up interviews, they are free to call Michael Goldfarb or myself, Kevin Phelan, here at MSF's New York offices.

Thank you very much.