



The UNITAID Patent Pool: Interview with Ellen F.M. 't Hoen, LL.M.

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Ellen 't Hoen is the Senior Adviser for Intellectual Property and Medicines Patent Pool at UNITAID. She is a lawyer and an expert in medicines policy and intellectual property law. From 1999 until 2009 she was the Director of Policy and Advocacy at Médecins sans Frontières' (MSF) Campaign for Access to Essential Medicines. In 2008 she was a research fellow at the IS HIV/AIDS Academy of the University of Amsterdam. She is the author of the book "The Global Politics of Pharmaceutical Monopoly Power. Drug patents, access, innovation and the application of the WTO Doha Declaration on TRIPS and Public Health." which was published in January 2009.

GP: Before coming to UNITAID you directed the Doctors Without Borders Access to Medicine Campaign and you have written extensively about patent law and pharmaceutical business and the need for medicines in developing countries. In your opinion, what about the patent pool proposal is different from the kind of advocacy for essential medicines that we have seen before and what are some previous landmarks in international law and policy that form the basis for this effort?

Ellen 't Hoen: Well, the Patent Pool proposal originated very much within the Access to Medicines movement, which first taught people to understand how new intellectual property rules can empower us to bring down the prices for essential medicines in developing countries. We learned an enormous amount about AIDS drugs pricing practices, and in particular the power of generic manufacturers to provide essential medicines of quality at much lower costs.

In the movement for universal access to essential medicines, it is becoming understood that pharmaceutical "patent packaging" is

becoming more and more widespread, including in those countries that traditionally served as the "pharmacies" of the developing world – and unless we do something deliberate to find a solution, we will find ourselves back in the situation from 10 years ago, where anti-retroviral drugs (ARVs) were priced very, very high, including in the poorest of countries, putting them out of reach of the vast majority of AIDS patients. This reality is at the root of the proposal by UNITAID to form an international "patent pool" for HIV/AIDS drugs. What the patent pool would do is while the pharmaceutical patent exists, it would allow generic manufacturers to nevertheless play a role in increasing the competition in the market in low-income countries, bringing the costs down. In addition, once you make these patents available to a pool, you also overcome the barriers that exist for the development of a fixed-dose combination of existing drugs, or the development of pediatric formulations. Today, if the patent owner is not interested in working on those, it can also prevent other companies from doing so. Through a patent pool, that will no longer be the case: for example, a researcher who wants to develop a fixed-dose ARV combination could do that by obtaining a license from the pool, and then pay

royalties off the sales of the product to the patent owner. So it is a scheme that will work within the existing framework.

Now with regard to important landmarks – I think in the last decade there have been two major processes. One, the 2001 adoption of the Doha Declaration of interest in public health at the World Trade Organization, which said that while respecting the rules on intellectual property laid down by the WTO, we have to also make sure that those are implemented with high regard for the need to protect the public's health. Parallel to that, there has been very intense debate at the World Health Organization in the context of inter-governmental working group on public health innovation and intellectual property, where more concrete proposals were developed, including looking at patent pools for increasing both innovation and access. The UNITAID Patent Pool initiative is not taking place in isolation, but should be seen in context of those larger global debates. We began to realize that some of these rules [on intellectual property] really aren't in the interest of people in developing countries, and that if there is no deliberate action to put some remedies in place, we would get back to quite a serious access problem.

GP: What are the incentives for different types of pharmaceutical companies, academic researchers, and medical institutions, to participate in the patent pool?

EH: First of all, there is intent of trying to do good. Universities by nature are there to serve the larger public interest, and while drug companies are, of course, driven by profit motives, the life sciences industry also has some commitment to health and the greater good. So that is one very important incentive to collaborate. Second, there is the fact that this proposal will function within the existing intellectual property system. It does not require a revision or a rewriting of any of the rules that exist today. Companies and patent owners will receive

royalties for the sales of the products by generic companies, and they might even receive royalties for sales that they themselves might not have made, for products sold in markets where they are not currently active.

Another important element is that of timing. There is now a much greater drive within the industry to look at models involving collaborative research, sharing of intellectual property (IP) and licensing. It sort of begins to fit as to how changes in the industry are beginning to take place today. There are clear incentives for the potential licensee who will develop and sell products that, in a case of an IP monopoly, may not exist. I think that involving the patent owners is the most important first step for a successful patent pool, because our patent pool is based on the voluntary collaboration of these companies. They need to be clearly incentivized to collaborate, which is where the new sources of royalties under the Patent Pool come in – as does the fact that overall existing frameworks for IP will be preserved, meaning that other international measures may not be necessary if this works. For example, the fear of governments issuing compulsory licenses, or not granting patents for ARVs at all, may form an incentive for the patent-owning companies to collaborate as well. And, of course, the licenses will be available not only to generic companies, but to anyone who could potentially benefit from the pool. So patent-owning companies could obtain licenses from the pool, to develop fixed-dose combinations and other new products that they would otherwise not be able to develop.

GP: Can you discuss the degree to which pharmaceutical companies could expect their profits to be affected by a patent pool system and its affect on research and development?

EH: I think that the patent pool will have a beneficial effect on research and development. First of all, it will encourage development of new drugs and

formulations. We will not see this kind of fixed-dose form or pediatrics form developed by companies whose research and development are determined by profit markets. Pediatric AIDS is a good example, it almost doesn't exist in developed countries. Companies are not so keen to invest in creating products where they do not see a corresponding market. Second, some people argue that if the Patent Pool is going to negatively affect profits, companies will not be able to invest as much in R&D. However, 90% of those profits are made in wealthy countries. Now, developed countries will not be affected by the Patent Pool – any product developed and produced as a result of the pool will only available for marketing in low-income countries. This will have no effect on the bulk of the markets where profit for the pharmaceutical industry is made, so it's hard to see how this would negatively affect their ability to invest in R&D. If anything, this pool will help spur greater adaptation of R&D for products particularly needed in developing countries.

HA: While HIV/AIDS is clearly the focus here, other infectious diseases incur huge burdens of mortality and morbidity in the developing world, such as tuberculosis, which has evolved extremely dangerous forms of multi-drug resistance. Then there are the neglected tropical diseases, which collectively affect over a billion people, but in some cases we haven't seen a single modern drug developed to cure them. Do you think the patent pool is a model that can be expanded for other diseases in developing countries?

EH: We have to be very clear about what this patent pool can do. It's really aimed at making intellectual property available for making ARVs in developing countries. We want to set it up in such a way that it could potentially expand to take up other opportunities, or expand to address needs in other disease areas, so we're not at all saying it will be only about ARVs forever. There are many different reasons why there are access problems, or

why there is lack of R&D to meet health needs in the developing world. The tropical neglected diseases are a very clear example, because we have a global pharmaceutical system today with an R&D agenda based narrowly upon where profits can be made. If you are too poor to pay for a drug, from a market perspective you do not exist. So you will see very little investment. What needs to happen there is a change in the way the R&D is done, and that's also why you see not-for-profit R&D entities emerging, like the Drugs for Neglected Diseases initiative (DNDi). Such efforts can also be faced with patent issues, for instance when researchers need to have access to particular compounds or particular knowledge that is proprietary and owned by for-profit companies. You can imagine that patent pools could be set up where companies that have compound libraries, or have certain know-how, would be able to make that available for low-profit or non-profit drug development. We've seen an initiative by Glaxo-Smith-Kline where GSK has said they will make compounds available for others to do research on and see whether they could do something for the neglected tropical diseases. But to come back to the UNITAID Patent Pool, that patent pool is initially aimed at increasing the availability and the adaptability of ARVs, and while we do that we expect to learn from this experiment much that will play a meaningful role in other areas. Trying to do this for ARVs at this stage is already quite a challenge, but we are not at all closing the door to expanding to other areas.

HA: One major challenge of coordinating research internationally, especially in low-resource settings, as we know, is ensuring that the same scientific and clinical standards are being followed across the board, so that the findings are reproducible and have validity in settings beyond those in which they were originally produced. As something that coordinates vast amounts of international research and cooperation, how does the Patent Pool proposal address the gaps in research and implementation standards from country to country, and who would

get to have input into setting these standards?

EH: Well, the patent pool is doing only one thing, and that is making technology available to produce and develop products. It is not a global regulatory system or a global ethics board. However, there are other systems in place, and we will work hand in hand with those partners. For example, UNITAID is an important supporter of the WHO Pre-Qualification Program. That is a program that tries to ensure that products brought to market or supplied by donors meet international quality standards. So obviously there is almost a natural linkage between the work of UNITAID, the patent pool that will be set up as result of UNITAID's work, and the WHO Pre-Qualification Program. Today, international purchasers and donors of ARVs have already agreed on standards with regards to the procurement of the medicines, and that same system will also help to ensure the quality of the products that are developed and produced as a result of the patent pool. So we do not need an additional layer, or an alternative layer or vehicle, to achieve the same results that are achieved today under existing mechanisms.

HA: Do you see the Patent Pool as a mechanism that can help start-up pharmaceutical companies, or pharmaceutical companies that are based in developing countries, to overcome some of the barriers they face in competing with established US- or European-based companies?

EH: Considering that its geographical scope is limited to developing countries, I think that is where you will find your answer. This is not about competitiveness in the European or North American markets. This is about bringing the costs of products down in the developing countries by increasing competition in the market, and by encouraging the development of adapted and fixed-dose drug combinations, for example. Of course, the companies that are engaged in

this are for-profit entities, and if companies have access to markets they would otherwise not have access to, that would be to their benefit. This fits very much into the UNITAID philosophy of trying to make markets work for the greater global good, for the greater global health, and that's the way we are primarily looking at this. What I'm trying to say is, our initiative is public-health-focused. We work towards it within the global market-based environment, that is the reality we are operating in. But our prime objective is of course to fulfill public health needs.

HA: As part of that big-picture objective, how do you feel about direct public subsidies and directing funding for specific drug research and manufacture on a non-profit basis by states, or from philanthropic or international organizations?

EH: I think it is obvious that where the market fails, you need to step in. We cannot allow the situation where people and their health are solely defined by whether they offer market prospects or not. You mentioned the most neglected diseases, and that is a very good example of where even though many millions of people are affected by those diseases, from a market point of view, these people simply do not exist. That is of course absolutely not acceptable. Financing the R&D that is necessary to bring those products to market is a very good thing. It can also help with the access issues, because if you finance the research and development, you will not need a very strong exclusive market position to recoup the R&D. So it will also help bring those products to market at a very low cost. The DNDi again is a very good example where they take the view, since we finance the R&D the products that go to market as a result of that should be available at the lowest possible cost from day one, so it is possible they should be available as generics from day one. It makes sense because if your R&D fades, because it has already been financed, why would you need an exclusive price to recoup that R&D?

GP: Getting back to the Patent Pool, what do you think are some of the major factors that will determine its success?

EH: The first major factor of course is the willingness of those who own the patents to collaborate. Second, we need to make sure that within the developing countries, generic companies can operate on a scope that is large enough to make the proposals viable from a commercial point of view. Third, it is absolutely key that financing for ARVs remains and even increases as the need for ARVs expands in developing countries. It is very worrisome to see that financing for AIDS threatens to flatline or even go down after initial successes. So having products, generics or not, is not all – we also need the buyers and the donors who are able to purchase these products. I would say those are the three main areas, and if there is a large enough consensus among those areas, I think we have a very good chance to getting to better ground.

GP: Here at AMSA we are seeing a lot of student interest in intellectual property issues in global health - do you have any advice for students who are interested in this? How can they stay informed and become more actively involved?

EH: I think my advice is to inform yourself and get involved, because the best way to change this is to have as many people as possible pushing for change. Among the many innovative proposals out there today, none of them will succeed if there is not a massive push to make it happen. In UAEM and UNITAID, we see a very keen interest in the Patent Pool from students – and we consider it an absolute key ingredient for its success. I talked earlier about the willingness of the patent holders and of the potential licensees to make the pool successful, but of course before we get there, we need massive support from the medical community including the student community. It's exciting to see that growing by the day, and I am sure the work you are doing has a lot to do with that.

GP: What are some ways students can stay involved while they are in school, when they are transitioning into their medical career, or when they graduate?

EH: Well, I think everybody should answer the question for themselves, but first and foremost you have to inform yourself, get together with others, and link together with groups that are working on this and have experience. Around the Patent Pool, there are a number of organizations, discussions, information, and petition campaigns that are very welcoming to students and quite easy to join.

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