



TOGETHER TO HEAL

**Eleventh Executive Board Session  
Special Session on Patent Pool  
5 February 2010, WHO - HQ Geneva**

**Provisional Minutes**

**1. Welcome and opening of the Session**

The meeting began at 09:10 and was opened by its CHAIR, Philippe Douste-Blazy. He welcomed members of the UNITAID Executive Board to its Special Session on Patent Pool.

He recalled the Implementation Plan that the Board had adopted in its resolution UNITAID/EB11/2009/R5 and the request for an analysis of the appropriate legal structure and its close relationship to UNITAID. He informed the Board that the Secretariat, with the assistance of the Swiss law firm Lenz & Staehelin and support of Accenture Development Partnerships, had now completed this analysis, as contained in document UNITAID/EB11/SSPP/2010/3.

**2. Adoption of the Agenda**

The CHAIR, at the request of the UNITED KINGDOM, reiterated the confidential nature of the day's discussions and stressed the need for all members of the Executive Board to respect the privacy of the meeting. The CHAIR's comments were supported by another member.

NORWAY proposed that a discussion on UNITAID's key performance indicators (KPIs), specifically in terms of process and not content, should be added to the agenda. The UNITAID KPIs had not been included in discussions when the strategy had been agreed in December but, given their importance, a proper decision on the process and timeline was needed.

The CHAIR clarified that these issues could not be added to the provisional agenda. The Executive Board had previously agreed to discuss only the Patent Pool during the Special Session and, given that it was a highly important topic, the Board were asked to keep their discussion focused on the Patent Pool.

**DECISION**

**The Executive Board adopted the agenda without amendment.**

**3. Progress report and recent developments regarding the establishment of the Patent Pool Entity**

#### **a) EB11/2009/R5 Action requested by the Board**

The CHAIR reminded the Board that they were meeting to discuss two issues raised at the previous Executive Board session in relation to the Patent Pool. He requested that they limit their discussion to these issues:

1. Analysis of the possible legal structure of the Patent Pool;
2. The nature of the close relationship between UNITAID and the Patent Pool.

#### **b) Actions taken by the Secretariat**

The EXECUTIVE SECRETARY presented a progress report:

- The Secretariat has collaborated with law firm Lenz & Staehelin and consulted with WHO to ensure their concerns were addressed.
- There has been extensive media coverage of the proposed Patent Pool following EB11 and the Secretariat had received requests for information from numerous stakeholders and partners.
- The Secretariat has responded in writing to questions raised by Brazil and France and distributed these documents to the rest of the Board. The Secretariat was willing to provide further clarification if necessary.
- There is an urgent need for the Patent Pool and solutions must be implemented as soon as possible.

An overview of the documents distributed to the Board members was provided.

### **4. Patent Pool entity**

#### **a) Introduction to Patent Pool entity background document**

The SECRETARIAT gave a presentation on the Patent Pool Implementation Plan, copies of which were made available to the board. Since EB11, in December 2009, the Patent Pool Implementation Team has analysed location options, hosting options, options to ensure the close relationship between UNITAID and the Patent Pool entity, and the steps required to establish the Patent Pool entity. Lenz & Staehelin were asked to advise on the most appropriate legal structure to serve the Patent Pool and the liability risks to UNITAID/WHO with regard to patent pool governance, branding and financing.

As regards location options, revised criteria based on Board feedback at EB11 was applied in order to re-evaluate the original possible sites identified in the Implementation Plan. On the basis of those revised criteria, Switzerland, specifically Geneva, was found to be the best location option.

Three hosting options for the Patent Pool were evaluated: UNITAID/WHO or another United Nations agency; an independent third party; or a new separate legal entity. The option of a third party host was deemed unsuitable as any potential party would be required under Swiss law to amend its mandate to align with the specific objectives of the Patent Pool. Asking an existing foundation to host the Patent Pool would therefore impose several serious obstacles as it would have to take on an entirely different function to that for which it was originally established, and may even require the amending of the foundation's statutes and changes in the composition of its board.

Thus the analysis focused on the two remaining options: UNITAID/WHO hosting option, or a new separate legal entity. The criteria applied fall under the categories of governance, legal aspects, financial aspects and efficiency. After evaluating both options based on these criteria, a separate legal entity was found to be the more sensible hosting option.

## **b) Options and legal analysis for the establishment and governance of a legal entity for the Patent Pool**

A representative of Lenz & Staehelin gave a presentation on the legal analysis of the Patent Pool establishment and governance, focusing on the following key areas:

### *1. Hosting options and needs for a separate/independent legal entity*

- UNITAID could not host the Patent Pool, owing to its lack of legal personality.
- WHO could not host the Pool, as its privileges and immunities – particularly of jurisdiction – would render it difficult to enter into contracts with licensors and licensees.
- UNITAID's lack of legal personality has broader implications for the project in regard of both governance and liability, particularly for those entities represented on the UNITAID Executive Board, including WHO.
- Lenz & Staehelin recommends that the Patent Pool be established as a new independent legal entity and not incorporated into one that already exists.

### *2. Not-for-profit entity*

- The Patent Pool should be established as a charitable initiative, with no profit-making objective.

### *3. Choice of jurisdiction*

- Switzerland, specifically Geneva, would be the most appropriate choice of jurisdiction, owing to:
  - proximity to UNITAID/WHO, other organizations and key stakeholders active in global health,
  - long-standing political and legal environment promoting the presence of the United Nations and charitable foundations,
  - well-recognized legal system,
  - good general infrastructure.

### *4. Recommended form of independent, not-for-profit, legal entity*

- Swiss law offers two forms of legal entity designed for not-for-profit purposes: the association and the foundation.
- Associations have members who constitute the governing body of the entity; this type of entity can thus be excluded when considering the Patent Pool.
- The Swiss foundation represents the most suitable entity for the Pool.

## 5. *Incorporation, organization and funding of the Patent Pool foundation*

- A Swiss foundation has its own independent legal personality and must be founded by parties with independent legal personalities; UNITAID does not possess independent legal personality and cannot therefore be the founder of the Patent Pool entity.
- The name of the Patent Pool entity can be chosen freely but for reasons of limitation of liability of WHO/UNITAID it is advisable not to refer to UNITAID in this name. If UNITAID became an independent legal entity in the future this issue would be less problematic and nothing would prevent a name change at a later date.
- The statutes governing the Patent Pool foundation may only be amended in exceptional circumstances and with prior approval of the Swiss Supervisory Board of Foundations, with the exception of the purpose clause, which will ensure that the Patent Pool Foundation fulfils the mandate set out by UNITAID.
- The mandatory corporate bodies of the foundation will be the board of directors (the supreme body) and the statutory external auditors. Appointing an executive secretary and expert advisory group is common under Swiss foundation law and practice.
- Board members have fiduciary duties to the foundation only and must abstain from voting on certain issues if there is a conflict of interest.
- The Patent Pool foundation should be financially independent from the outset. Its founders should endow the minimum initial capital required by Swiss law, i.e. CHF 50 000, to be followed by a substantial grant from UNITAID at the discretion of its Board.
- Swiss law would not prevent the Patent Pool foundation, within its statutory scope, from organizing its activity commercially, e.g. invoicing brokerage fees or commissions.
- The Patent Pool foundation should benefit from a tax exception ruling owing to its not-for-profit status.
- In regard of VAT, no exemption would apply to the foundation under Swiss law.

## 6. *Relationship between the Patent Pool Foundation and UNITAID*

To ensure a close relationship between the two entities the following actions are suggested:

- The statutory purpose of the Patent Pool foundation should be in line with that of UNITAID.
- A Memorandum of Understanding (MoU) containing clear objectives should be signed between UNITAID and the Patent Pool entity.
- There should be a bilateral funding agreement, whereby the renewing of funding by UNITAID is subject to the approval of the Boards of UNITAID and the Patent Pool initiative.
- A member of UNITAID should be a part of the Board of the Patent Pool entity, although it is recommended they have observer status only to limit WHO/UNITAID's liability.
- UNITAID should not appoint the Board members of the Patent Pool.
- The Patent Pool entity employees should not also be WHO/UNITAID employees, and nor should there be secondment between the two entities.

7. *Potential liability risks for the Patent Pool foundation and individual Board members arising out of the Patent Pool foundation's operations*

There would be the risk of patent- and/or contract-related litigation and possibly product-liability litigation. It would be possible to avoid these risks by including provisions for the limitation of liability, indemnification and proper insurance coverage within contracts with licensors and licensees. Furthermore, the members of the Board would not incur any personal liability in relation to the entity's activities.

8. *Potential liability risks for WHO/UNITAID (and other UNITAID stakeholders) relation to the operations of the Patent Pool Foundation and ways to mitigate such risks*

Liability risks to WHO/UNITAID are unlikely, provided certain measures are taken, including:

- The selection of Board members of the Patent Pool entity is based on their knowledge and experience. UNITAID is not to appoint members;
- A conflict of interest policy is adopted by the Patent Pool entity;
- The Patent Pool entity is financially independent;
- There is no sharing of employees or offices or use of similar business names;
- UNITAID's funding of the Patent Pool entity is contingent upon approval by UNITAID of proposals that set out clear milestones and deliverables.

**c) Analysis of future relationships between UNITAID and Patent Pool**

The SECRETARIAT provided more detailed information on the nature of the relationship between UNITAID and the Patent Pool entity in relation to the following key aspects:

1. *Shared mission with UNITAID*

- The Patent Pool entity's mission is closely aligned with that of UNITAID, so elements of the UNITAID Constitution or Strategy could be reflected in the entity's statutes.
- Swiss law does not allow foundations to change their statutory purpose solely at the discretion of the entity's Board.

2. *Contractual relationship to UNITAID*

- The Patent Pool entity will be held accountable to UNITAID through an MoU which will describe:
  - The expected results
  - How the funds will be used by the entity
  - Reporting processes and frequency
  - Joint communication and approval process

3. *Patent Pool Governance*

- UNITAID does not have legal personality and therefore will not be able to designate Patent Pool board members.
- However, it would be possible for the Patent Pool entity statutes to contain a provision for a UNITAID appointee to hold observer status on the Patent Pool Board. This would reduce the risk of liability for UNITAID, but still maintain a close relationship between the two entities.

#### 4. *Physical Proximity to UNITAID*

- If the Patent Pool entity was based in Geneva, then its close physical proximity to UNITAID will facilitate collaboration and communication between the two bodies.

#### 5. *Public Affiliation with UNITAID*

- It is important that the public continues to be aware of the close affiliation between UNITAID and the Patent Pool entity.
- This could be achieved through measures such as joint press releases, press conferences and workshops.

#### 6. *Strategic Partnership with UNITAID*

- The partnership would allow UNITAID to capitalize upon opportunities created by the Patent Pool, for example through providing a market commitment for a new paediatric formulation or committing to finance formulation development costs.
- A member of the secretariat's staff should be designated to follow the Patent Pool's activities to ensure that it contributes to the objectives of UNITAID.

The presentation also included a proposed list and timetable for the next steps required to create the Patent Pool entity, which were made available to board members.

## 5. **Discussion of next steps**

Several Board members indicated that Switzerland, specifically Geneva, is the most appropriate location option for the Patent Pool entity.

Some members felt that the debate should go beyond just the legal status and location of the entity, in order to define which kind of entity they would be creating, including its mechanics and internal workings. BRAZIL wanted assurances that the Patent Pool would not undermine the spirit of agreements already signed by member states. It was suggested that the Patent Pool should: complement those agreements, particularly the TRIPS Agreement and flexibilities; have as its main purpose the scaling-up of access to affordable medicines in the developing world; include in its statutes incentives to promote technology transfer, capacity-building and local manufacturing of medicines in the developing world, which could perhaps be funded from royalties from Pool activities; and set standard licence agreements on a non-exclusive, non-discriminatory basis. It was stressed that all developing countries should be in the geographical scope of the Pool. Given that granting patents was a

matter of national sovereignty, the Pool should account for different patentability criteria and ensure that no royalties are paid on invalid or non-existing patents. Brazil expressed the view that the Board needs to discuss and agree on parameters and guidelines for terms and conditions of license agreements.

On the relationship between UNITAID and the entity some members had concerns regarding the degree of influence that UNITAID would have according to the arrangements proposed, other members were content with the degree of influence that UNITAID would have according to the arrangements proposed in the secretariat's back ground materials. There were questions about the status of UNITAID as a legal entity and the implications this would have on its relationship with the Patent Pool. CHILE indicated that if UNITAID has legal personality enough to sign a contract to finance the Pool, it is not clear why Lenz & Staehelin advised that UNITAID could legally neither host the Pool nor nominate members to its board. CHILE also indicated that, in its opinion there was insufficient analysis in regard of public international law, which is in its view essential as funds would be provided primarily by States, and more specifically, their taxpayers. The OBSERVER FOR SPAIN expressed the need to address these questions about legal personality and analysis before further discussions took place. UNITAID's board should be closely involved in the key processes relating to establishment of the entity, such as the MoU, its statutes and business model.

NORWAY stated that confirmation was needed on the assumption that the legal assessment relating to the Patent Pool entity is compliant with the TRIPS agreement.

The OBSERVER FOR SPAIN expressed concern over the implications that establishing the Patent Pool could have on research for new medicines. This issue should be addressed in the MoU with UNITAID, as the Pool should not just promote affordable access but should also support research and development.

There was some disagreement among members on what elements of the Patent Pool entity should be agreed upon before the legal entity was established. NORWAY and FRANCE acknowledged the importance of giving serious consideration to the establishment process to ensure that the appropriate decisions were made at the appropriate time, and stated that, given the importance of the matter in hand, it was essential to reach consensus on the relevant aspects of the entity, such as establishing safeguards.

THE UNITED KINGDOM, NGOS and the COMMUNITIES LIVING WITH THE DISEASES expressed enthusiasm for the plans presented and stressed the need to move quickly in their decision-making on establishing the legal entity for the sake of public health. It was agreed some initial safeguards were essential in order to ensure that the Patent Pool would uphold the objectives of UNITAID, but there was a greater necessity to realize the establishment of the entity, in whichever form it would take, otherwise the initiative would never get off the ground. While agreement on the MoU and on funding is needed, if the Board does not release funding for the Pool until all such details are finalized then the initiative risks suffocation.

CHILE, acknowledging this point, said that they should not rush the process for the sake of it, indicating strong safeguards are necessary before establishing the legal entity otherwise they could risk establishing a defective entity.

The SECRETARIAT said that the Pool and its envisaged operations could facilitate both technology transfer and local production of medicines as, through the

arrangement whereby patent holders agree to license patents to the pool, the monopolies that would otherwise exist will be opened up to generic competition. The Patent Pool will grant licenses on a non-exclusive and non-discriminatory basis; anyone wishing to obtain a licence from the pool to produce locally should in principle be able to do so. Those arrangements, according to generic manufacturers, are sufficient in regard of current products but it might be the case that in the future, for some new medicines, additional agreement on technology transfer would be necessary.

Through licences, the Patent Pool would also aim to ensure availability of data, should that be required for regulatory purposes. This is being discussed with companies and it is understood that this aspect is essential if the Pool is to work in practice.

Responding to questions raised by FRANCE, the SECRETARIAT explained that a patent is intellectual property; once access to the intellectual property has been granted, a generic version of a medicine can be produced. If the decision can be made to make intellectual property available at the initial stage it would already achieve a great deal in lowering prices and increasing the number of adapted formulations of a medicine. Generic companies have stressed the need for this access at an early stage. However, in the future this access may not be sufficient and companies could be helped if their ability to produce a generic product was sped up by a direct transfer of a technology by those that own the technology.

The members of the Board moved the discussion onto the legal personality of UNITAID. In response to questions from BRAZIL and the AFRICAN COUNTRIES, the WHO LEGAL COUNSEL affirmed that the previously expressed opinion of CHILE that the legal personality of UNITAID is derived, and not distinct, from that of WHO, on account of the fact that UNITAID was established as a partnership and not as either a foundation under Swiss law or as a new agency. Its founders sought the institutional support of WHO and, for that reason and in accordance with the MoU between UNITAID and WHO, UNITAID itself has no distinct legal personality. UNITAID is thus afforded a high level of legal protection as it enjoys the same status as WHO in regard of its privileges and immunities and also because WHO accepts UNITAID actions as part of its own functions as an organization.

The WHO LEGAL COUNSEL said that the question on why UNITAID could not appoint members to the board of the Patent Pool but could finance the Pool is precisely what Lenz & Staehelin addressed when they gave their legal opinion. He agreed that the right balance should be found between ensuring the independence of the Pool as a viable legal entity that can carry out its purpose and ensuring that UNITAID maintains an appropriate level of influence so as to verify that the Patent Pool pursues the objective set by UNITAID. The balance that is reached will influence the level of liability that, through the Pool, is placed on UNITAID. If UNITAID were to control the Pool and any claims of liability were brought against it, that liability would fall on members of the UNITAID Board as well as WHO. Such a possibility is therefore of concern to WHO.

The UNITED KINGDOM, while expressing regret that the resolution arrived so late as it would have appreciated more time to review the text, felt that its essential propositions were appropriate, including the recommendation for location in Switzerland, the establishment of an independent legal entity and the arrangements for an appropriate amount of influence by UNITAID in creating the entity. The member offered proposed text to revise the draft resolution.



Several members agreed that it would be appropriate to establish the Patent Pool as a separate legal entity in Switzerland, i.e. a Swiss foundation. The ASIAN COUNTRIES expressed a preference for the Pool to be hosted by UNITAID/WHO but would not insist on this if consensus on a separate legal entity was reached by all other members of the Board.

CHILE expressed doubts on the suitability of establishing the Patent Pool as a separate legal entity, and expressed the view that it would be cheaper for UNITAID/WHO to host the entity. Furthermore, as the WHO Secretariat is obliged to follow the rulings of its Executive Board and the World Health Assembly, if the Member States represented on the UNITAID Board introduced a resolution that passed at either of those governing bodies that WHO should host the Patent Pool, WHO would be obliged to do so. CHILE also expressed a concern that the legal analysis provided had looked at only one option for hosting. It would have been preferable to see an in-depth analysis of at least two of the options in order to allow a side-by-side comparison.

The WHO LEGAL COUNSEL indicated that the current mandate of the WHO, as laid out in World Health Assembly resolutions, does not extend to the hosting of patent pools, although as CHILE pointed out, if the governing bodies adopted an appropriate resolution, this policy could be changed. However, as an intergovernmental organization, WHO is not subject to national laws, and, although this immunity can be waived on a case by case basis, it is not properly equipped to deal with the legal issues raised by hosting a patent pool. This could be a problem for companies who would consider licensing to or from the pool, as they would want to have legal certainty that they can enforce any potential claims against the Patent Pool entity. With respect to the cost of a WHO/UNITAID hosting option, owing to indemnification and liability insurance requirements of a patent pool, costs would increase. Furthermore, the commercial activities of the Patent Pool would conflict with the public mandate of the WHO, and could expose WHO to the possibility of liability and litigation.

The SECRETARIAT, responding to a previous question from a member on whether they were sufficiently sure the Patent Pool would fit within existing intellectual property frameworks and patent law, said that one advantage to a voluntary patent pool is that it can be established and can function within the existing intellectual property framework, thus requiring no change to national patent law or international laws, such as the TRIPS agreement.

The SECRETARIAT also indicated that when deciding how to move forward, the Board should remember that the degree of willingness to collaborate with the pool thus far demonstrated by potential licensors or licensees has been measured against what had already been proposed as a viable mechanism, which was an entity independent of WHO/UNITAID. If the Board were to depart radically from this plan, then the same degree of willingness to collaborate could not be taken for granted and would have to be reassessed.

BRAZIL said that more analysis on the impact of the Patent Pool on pre-existing agreements such as the TRIPS agreement was still required. However, the UNITED KINGDOM recalled resolution EB/11/2009/R5, which expressly reaffirmed the primacy of the TRIPS agreement, and in which the Board had agreed that the current meeting would only cover two issues: the legal structure of the Patent Pool entity and the

nature of its close relationship with UNITAID, and it had been agreed that there was sufficient analysis of the other issues to move forward.

The NGOs expressed concern that if WHO/UNITAID was chosen to host the Patent Pool, it would require the agreement at the World Health Assembly, which would slow down the project substantially.

The CHAIR and the UNITED KINGDOM indicated that there had already been a lot of analysis and that any remaining issues would be solved during the implementation phase. There were now three or four pharmaceutical companies that agreed with the idea of the Patent Pool, and it was essential to move forward as soon as possible to capitalize on their interest.

FRANCE reiterated that it was important to agree on the nature of the relationship between UNITAID and the Patent Pool entity and that this relationship should be dynamic and have room for improvement in the future. The member agreed with the statement by the UNITED KINGDOM that a MoU between UNITAID and the patent pool entity should be satisfactory to flesh out additional details about their relationship.

FRANCE requested that the secretariat should prepare a business plan, a detailed budget and indicators before the creation of the independent entity.

BRAZIL acknowledged that resolution EB11/2009/R5 expressly stated that the Patent Pool would not inhibit countries' abilities to use TRIPS flexibilities and called for a similar provision to be included in the draft resolution.

BRAZIL wished to propose some additional amendments for draft resolution EB11/SSPP/2010/R1 and suggested that, since there were now three versions of the draft resolution, the meeting break for a short period in order to produce a consolidated version of the text.

There was an appeal to the Board by the NGOs to keep the text and provisions of the draft resolution as short as possible, as more issues often leads to less consensus.

### **The Session broke for informal consultations in order to consolidate the three versions of draft resolution EB11/SSPP/2010/R1**

The draft resolution was presented to the meeting. This resolution noted, among other, that the Board will approve the MoU once it has discussed and agreed upon a matters regarding the new entity specified on page 13 of document UNITAID/EB11/SSPP/2010/3, a year one business plan, budget and key performance indicators and other issues presented in the annex.

In response to a request from CHILE, the amendments made by the drafting group were explained.

FRANCE proposed the following addition to the Annex:

9. Put in place mechanisms to ensure the quality and safety of products.

The NGOs, with the agreement of Lenz & Staehelin, proposed that paragraph 2.2 be changed to read:

“will approve the MoU on the basis of it having addressed”

However several members preferred that the original wording be maintained.

With reference to its view that Lenz & Staehelin's analysis of the possible hosting options was incomplete, CHILE suggested that "welcomes" in paragraph 2 be replaced with "takes note with appreciation". The member also requested that the wording of the paragraph 2.2 a) explain what is meant by "the matters specified on page 13 of the document.

The COMMUNITIES LIVING WITH THE DISEASES member felt that agreement on the draft resolution should be reached so that next steps detailed on page 13 of document EB11/SSPP/2010/3 could be started.

The CHAIR proposed that a formal vote on the draft resolution be held in the two weeks following the meeting in order to allow members to review the newly consolidated draft version, and reminded the Board that the aim of the meeting had been to agree on the basic principles for the patent pool. He suggested a seminar may be arranged in March 2010 to allow informal discussion on the MoU so that the Board could agree on a draft by May 2010, or an earlier deadline if possible.

A number of members were satisfied with the draft resolution and agreed with the Chair's suggestion for a vote. The UNITED KINGDOM expressed a preference for a vote via teleconference. However, BRAZIL preferred that they met in person, unless there were no further changes to the draft resolution, in which case a vote via email would be satisfactory. CHILE and the ASIAN COUNTRIES suggested that proposal for a seminar in March 2010 should be included in the draft resolution.

NORWAY commended the Secretariat for the information and timetable that it had provided. However, in order to provide a clearer picture of the project deliverables, a specific timetable detailing when each required document will be drafted and provided to the Board should also be required. This timetable should be included as an annex to the draft resolution.

The UNITED KINGDOM encouraged the Board not to amend the current draft resolution further so that the focus could be shifted to strategic matters. BRAZIL agreed with the call for no more amendments, but also agreed with the suggestion regarding the need for a clear timetable of the next steps and deliverables. There should be a meeting on the MoU before June in order to comply with paragraph 2.2 of draft resolution. The brainstorming seminar was a good suggestion but it should not replace negotiation meetings.

With the agreement of the Board that further amendments were unlikely, the CHAIR requested the Secretariat to organize a date for the email vote and suggest dates for the meetings that had been proposed.

Brazil cast its vote in favour of the resolution.

### **DECISION**

**It was agreed that the draft resolution would be circulated for formal approval by Board members within the next ten days.**

#### **7. Close (Executive Secretary and Chair)**

Since there were no further items on the agenda, the CHAIR thanked all participants and closed the meeting at 16:05.