

Boston Congress

Plenary Session I

Question Q202: The impact of public health issues on exclusive patent rights

Monday, 8 September 2008 (11:00 – 12:30 and 14:00 – 15:00)

Chair of Session: Jorge OTAMENDI (JO)
Working Committee Chair: Sarah MATHESON (SM)
Responsible Reporter: Thierry CALAME, Deputy Reporter General (TC)
Introductory presentation by: Jayashree WATAL, WTO, Geneva

The Chair welcomed the audience and speakers and introduced Mrs. Watal.

Mrs. WATAL spoke on some of the public health implications on exclusive patent rights from the viewpoint of WTO.

The Chair then acknowledged the Responsible Reporter (TC).

TC introduced the Question as set out in the Working Guidelines and summarised the discussions of the Working Committee.

In particular, TC referred to the fact that certain policy considerations are inherent in patent law. The access to medicines issue is a very complicated issue. The Working Question was limited to restrictions in the exclusive protection granted by patent rights and does not address patentability criteria etc.

The chair then acknowledged the Working Committee Chair (SM).

SM introduced the members of the Working Committee.

SM introduced the Draft Resolution.

The Chair then put the Draft Resolution to the debate, proposing to debate the resolution points before discussing the recital part of the Draft Resolution.

Paragraph 1.1:

Mr. Wouter PORS (NL) speaking on his own behalf argued that the proposed text goes too far. It means that patentees lose a very important part of their protection. This should only be allowed for non-commercial purposes.

SM explained that it is hard to imagine experimental use that does not or could not ultimately have a commercial aim. If the use is truly experimental, it should not matter whether or not it has or may have an ultimate aim that is commercial.

TC observed that there was absolute consensus in the WC that the ultimate aim of the experiment should not matter.

JO put Paragraph 1.1 to the vote.

Paragraph 1.1 was carried by a large majority.

Paragraph 1.2:

Noone wished to take the floor.

JO put this Paragraph to the vote.

Paragraph 1.2 was carried by a substantial majority.

Paragraph 2:

Mr. Pierre VERON (FR) proposed to substitute the words "may provide" for "should provide" because it is not necessary to require states to introduce such an exception. It is sufficient to allow the exception.

Mr. Alain GALLOCHAT (FR), speaking on his own behalf, observed that he was uncomfortable with the notion "other medical products" which is unclear. It should be clarified.

A member of the Uruguay Group proposed to amend the end of Paragraph 2 by inserting: "subject to regulatory approval involving human clinical trials", in order to clarify.

Mr. PORS spoke against that amendment.

TC observed that substituting "may" for "should" would substantially weaken the Resolution by not recommending a mandatory rule binding all countries and leaving it as an optional rule.

SM supported the observations of TC.

Mr. GALLOCHAT proposed to add "such as..." at the end of Paragraph 2 and insert some examples to clarify what is meant by "other medical products".

Mr. Fernand DE VISSCHER (BE) on his own behalf observed that the proposed Paragraph 2 is far broader than what is known as the bolar exception.

TC confirmed that this is the case and that this was the intention of the WC.

Mr. GALLOCHAT reiterated the proposal to give examples of medical products but spoke against qualifying them by referring to their need for clinical trials.

Mr. VERON'S amendment was put to the vote.

The amendment was defeated by a large majority.

The Uruguay Group's amendment to add "subject to regulatory approval involving human clinical trials" was put to the vote.

The Uruguay Group's amendment was defeated by a large majority.

The addition of examples at the end of Paragraph 2 was accepted by the WC and will be included in a final draft.

Paragraph 2 was put to the vote.

Paragraph 2 was carried by a large majority.

Paragraph 3:

Noone wished to speak to this Paragraph.

Paragraph 3 was put to the vote.

Paragraph 3 was carried by an overwhelming majority.

Paragraph 4:

Mr. Chris CHALSEN (US) proposed to make a full stop after "individual patient" and delete the remaining text. This would avoid unclarity caused by the fact that the term "large scale" is undefined.

TC accepted the amendment on behalf of the Working Committee.

Mr. Ivan HJERTMAN (SE) spoke against Mr. CHALSEN'S amendment.

TC withdrew his acceptance of Mr. CHALSEN'S amendment in light of Mr. HJERTMAN'S intervention.

Mr. Luiz AMAEAR (BR) spoke against the proposed amendment and suggested that the US Group put forward a text that could clarify without deleting any of the current text.

Mr. Jeremy BROWN (UK) proposed to substitute "larger" for "large" to overcome the concerns of Mr. CHALSEN.

Mr. Jack GOLDSTEIN (US) proposed to insert some text clarifying that the product manufactured individually for one patient could not be used for another patient.

Mr. CHALSEN accepted Mr. BROWN'S amendment.

Mr. BROWN'S amendment was put to the vote.

It was carried by a substantial majority.

Paragraph 4 as a whole was then put to the vote.

It was carried by an overwhelming majority.

Paragraph 5:

Noone wished to speak to this Paragraph.

Paragraph 5 was put to the vote.

It was carried by an overwhelming majority.

Paragraph 6

Mr. Mike KIRK (US) proposed to delete this Paragraph. It would put AIPPI on record as supporting compulsory licences in a general way that goes beyond TRIPS Article 31 bis. This should not be endorsed by AIPPI.

Mr. Thierry MOLLET-VIÉVILLE (FR), Vice President of AIPPI, observed that Paragraph 6 has to be seen within the framework of the Question that is limited to public health implications. Mr. MOLLET-VIÉVILLE also proposed to merge points 6 and 7.

TC commented on Mr. KIRK'S amendment and observed that it was not the intention of the WC to endorse a broad scope for compulsory licences. There was complete consensus that it should apply only in extremely rare cases. TC proposed to make an amendment rather than delete the Paragraph.

Mr. John PEGRAM (US) observed that the statement may be misused by those that are unfavourable to the patent system and who deliberately read the statement in a broader sense.

Mr. GALLOCHAT observed that the French Group is clearly in favour of draft Paragraph 6 because there are rare situations where compulsory licensing is justified. The wording could be redrafted, if necessary, but the message is right and in any case follows from TRIPS.

Mr. Claudio BARBOSA (BR) proposed to substitute "compulsory licence but" by "that".

TC accepted the amendment on behalf of the WC.

Mr. KIRK (US) spoke against a broad wording of Paragraph 6 that is not restricted to situations where public health concerns are relevant. Mr. KIRK proposed to amend the text by inserting a new introduction, such as: "To the extent that the patent law provides for compulsory licensing, this should be limited to...".

Mr. GALLOCHAT proposed to merge Paragraphs 6 and 8. They should both address only situations where public health concerns apply.

Mr. KIRK would support Mr. GALLOCHAT'S amendment if it were further amended to read "may" rather than "should".

Mr. GALLOCHAT would not support the substitution of "may" for "should".

TC observed that using the word "may" would dilute the Resolution.

Mr. BARBOSA (BR) supported Mr. GALLOCHAT'S amendment.

Mrs. Hoda SERAGELDINE (EG) spoke in support of Mr. GALLOCHAT'S amendment.

Clause 6 with Mr. GALLOCHAT'S amendment was put to the vote.

Paragraph 6 was carried by a large majority.

Mr. GALLOCHAT'S proposal to merge Paragraphs 6 and 8 was put to the vote.

It was carried by a substantial majority.

Mr. KIRK withdrew his proposal to amend or delete the original draft Paragraph 6.

The merged Paragraphs 6 and 8 (now 6.a and 6.b) were put to the vote.

They were carried by a large majority.

Paragraph 7:

Noone wished to speak to this Paragraph.

Paragraph 7 was put to the vote.

Paragraph 7 was carried by an overwhelming majority.

Recital points 1-8:

Mr. DE VISSCHER observed that it was not clear in point 4 what countries A and B are.

TC observed that the reference to countries A and B is taken from the Barcelona Resolution to which point 4 refers.

Mr. DE VISSCHER proposed to clarify this by inserting some additional text.

TC accepted this on behalf of the WC.

Recital points 1-8 (Noting that) were put to the vote.

Recital points 1-8 (Noting that) were carried by an overwhelming majority.

Recital points 1-2 (Considering that):

Noone wished to speak to these Paragraphs.

Recital points 1-2 (Considering that) were put to the vote.

Recital points 1-2 (Considering that) were carried by an overwhelming majority.

The whole Resolution was then put to the vote.

The Resolution was carried by an overwhelming majority (91%).

The Chair closed the meeting.

Minutes written by:

Nicolai LINDGREEN
Assistant to the Reporter General

September 8, 2008