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Chair

Mr. David Sweet

Standing Committee on Industry, Science and Technology

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• (1000)

[English]

The Chair (Mr. David Sweet (Ancaster—Dundas—Flamborough—Westdale, CPC)): Good morning, ladies and gentlemen. This meeting will come to order. It is meeting number 42 of the Standing Committee on Industry, Science and Technology.

I introduced the witnesses at the last meeting.

I hope you'll allow your introduction to stand, just as it does for the members here.

We'll begin.

(On clause 4)

The Chair: We left off last time with clause 4 and amendment Lib-2. We have a brand new package. I hope all members have the new package of amendments in front of them. They should have been distributed.

I will let Mr. Garneau explain the intention of the new package of amendments, and then, of course, I'll open the floor to any rebuttal or debate.

Mr. Garneau.

Mr. Marc Garneau (Westmount—Ville-Marie, Lib.): Thank you, Mr. Chair.

As you remember and as all of the members will recall, at the last meeting on Thursday, I had put forward what's called the old amendment Lib-1. It had created a certain amount of confusion, not only with some of the experts, but also with me.

Just to summarize, my intention had been to reinstate schedule 1 of medications that are in the Patent Act, to bring it into Bill C-393, and also to establish that any medications that would be used under CAMR had to have Health Canada approval.

Well, I didn't realize there were a number of other definitions that had been removed in Bill C-393 that were really required to be reinstated because they were called up, notably the definition of "patented product", "WTO", and things like that. It's also to make sure, as I said, that medications allowed under CAMR would meet Health Canada approval.

I got together with the legislative assistant on Thursday afternoon, which gave rise to a number of alternate amendments called Lib-1.1 through to Lib-1.6. That's really the new part of it, what is being introduced here this morning, which I believe will rectify the problems that were identified last Thursday afternoon.

Thank you, Mr. Chair.

The Chair: Thank you.

Mr. Brown.

Mr. Gordon Brown (Leeds—Grenville, CPC): Thank you, Mr. Chairman.

There is a little bit of confusion amongst committee members on exactly what we did pass on Thursday. Maybe we can get an understanding from the clerk of what amendments did pass and if an amendment did pass and there's the wish of the committee to repeal the amendment that was passed. I'm a little unsure exactly what the status is, so could we get a clarification on that, please?

The Chair: Sure. I'll let the legislative clerk just give you a rundown, but I think it's identified in your sheets.

Mr. Mike MacPherson (Procedural Clerk): Yes. In the new package that was distributed, it is indicated at the bottom of each amendment. If there's nothing indicated at the bottom of the amendment, it hasn't been debated or had any decision on it.

Lib-1 was withdrawn. Today we're resuming debate on Lib-2.

As Mr. Garneau indicated, Lib-1.1 to Lib-1.6 are new and haven't been debated yet. Lib-4 was adopted because it was a consequential amendment to Lib-5. Lib-5 was adopted, as was Lib-6. That's where we stand now.

The committee had also negatived clause 2 of the bill at the last meeting.

The Chair: We'll continue with—

Yes?

I'm sorry, Mr. Lake. I'll just allow Mr. Masse and then Mr. Lake.

Mr. Brian Masse (Windsor West, NDP): I just want to make sure, Mr. Garneau. Are you aware that this amendment would restrict the list of drugs available back to 2004, even Health Canada drugs that had no objection back in 2004, including Moxifloxacin, which was lobbied by Bayer to stay off the list. My concern with this amendment is that WTO and TRIPS and the Doha didn't have a restricted requirement of drugs on the list.

We've already seen some active campaigning by the pharmaceutical industry. It actually made the headlines of the *Ottawa Citizen* back in 2004 because it defeated the whole purpose of lists. I'd just like to see if there are any reassurances or any changes because we would be restricting the list to what currently exists and the process for adding a drug is rather cumbersome.

•(1005)

Mr. Marc Garneau: Can I respond to that?

The Chair: Yes, Mr. Garneau.

Mr. Marc Garneau: In reply to Mr. Masse, there are really three things that I'm concerned about. One is reinstating the list that was approved back in 2004. Secondly, I am concerned with making sure that any additions to that list will have Health Canada approval. Thirdly, I am concerned that the process is one whereby new medications can be added. You say it's a cumbersome process. I can't speak to that.

I think it's important to make sure that any medication that Canada is going to authorize under CAMR is looked at and, in particular, that it has Health Canada approval. That really was my intent in making the amendments that I proposed.

The Chair: Mr. Lake and then Mr. Malo.

Mr. Mike Lake (Edmonton—Mill Woods—Beaumont, CPC): Is this regarding the clauses that passed? That's my question. We talked about the amendments, but where are we at with which clauses were actually passed or voted against?

The Chair: Clause 2 was struck down. Clause 3 we didn't deal with. Remember, we were prioritizing on the clauses that had amendments. We're presently on clause 4.

Mr. Mike Lake: Amendments were made on other clauses. Did we vote for those clauses, though, or did we just vote for the amendments? Can you remind me?

The Chair: Yes. On clause 15, I believe, we passed that amendment as adopted.

Mr. Mike Lake: The actual clause was as well?

The Chair: Yes.

Mr. Mike Lake: Okay.

As we go through the discussion, and if we're going to go back and get into some semblance of order, perhaps we should step back to clause 3 now that there are amendments on clause 3 and try to continue to go in order.

The Chair: I'm at the behest of the committee always, Mr. Lake. We ended the day with Liberal-2, clause 4. If there's consent to move back to clause 3, then we'll certainly do that.

Mr. Masse, it looks like you have a comment you want to make directly on that issue. Then I'll go to Mr. Malo.

Mr. Brian Masse: We were just on Lib-1.1, were we not? We're moving around. We need to find a grounding base here. I'm open to whatever works.

The Chair: When we adjourned the last meeting, we were on clause 4, Liberal amendment 2. That's what we were debating.

Mr. Brian Masse: Okay.

Mr. Mike Lake: In fairness, this amendment, Liberal 1.1, is amending a clause that we voted against, that we defeated, so we can't even address Liberal 1.1, right?

The Chair: That's right. With unanimous consent we can do anything, but right now that clause has been struck down.

Mr. Malo.

Mr. Mike Lake: Okay.

[*Translation*]

Mr. Luc Malo (Verchères—Les Patriotes, BQ): I just want to make sure I understand. We are indeed talking about amendment LIB-1.1 and those following, right?

[*English*]

The Chair: No. Right now we are on clause 4, Liberal amendment 2. That's where our debate ended when we adjourned the last meeting.

[*Translation*]

Mr. Luc Malo: Then why did Mr. Garneau just explain the scope of amendments LIB-1 to LIB-6, and why did Mr. Masse comment on it? I thought we were going to go back to proposed amendment LIB-1, put that to bed and then move on to amendment LIB-2.

[*English*]

The Chair: If I created any confusion in your mind, I apologize for that, Mr. Malo. My reasoning to have Mr. Garneau speak right from the top was that there was an entirely new package of amendments. I wanted to make sure that everyone knew what the intention was and to make sure we had some clarity moving forward.

If everybody is agreed that we'll go back to clause 3, then we can do that, but we did end with clause 4, Liberal amendment 2, when we adjourned at the last meeting.

Mr. Garneau.

•(1010)

Mr. Marc Garneau: Mr. Chair, certainly the members of the Liberal Party would be quite happy to go ahead with Lib-1 to Lib-1.6 if it had the consent of the committee.

(On clause 3)

The Chair: Members, that's back in clause 3.

Pardon me?

Mr. Mike Lake: I think that's clause 4, according to the sheet I'm looking at.

Mr. Marc Garneau: It's Lib-1.1 to Lib-1.6

The Chair: Oh. Actually, Lib-1.1 is with a clause that we've already struck down, Mr. Garneau.

Mr. Marc Garneau: No. Amendment Lib-1 is what we struck down. Lib-1.1 to Lib-1.6 are the replacements. Just to repeat, Lib-1.1 to Lib-1.6 are the repair to be done on Lib-1, which has been withdrawn. It's to address the shortcomings of the old Lib-1 amendment.

The Chair: Okay, Mr. Garneau, I just want to bring to your attention that Liberal-1.1 presently deals with a clause that we struck down.

Liberal amendments 1.2, 1.3, 1.4, 1.5, and 1.6 deal with clause 3. We can deal with that now.

Mr. Marc Garneau: All right. I'm easy.

Mr. Mike Lake: Can I move that in the interests of moving along we start with Lib-1.2 on clause 3?

The Chair: Is everybody agreed? It looks like we have consent. That's what we'll do.

Please turn to Lib-1.2 and clause 3 in your package.

I'll look for those who would like to speak to it.

Mr. McTeague.

Hon. Dan McTeague (Pickering—Scarborough East, Lib.): I just need a clarification. If Lib-1.1 was indeed struck—and I'm at the behest of the chair on this—could the analyst explain if there is any effect on Lib-1.2?

It seems to me that the purpose for which Mr. Garneau brought forth these amendments was to address the initial concern in Lib-1, which was either (a) withdrawn or (b) struck down. If the essence of what Mr. Garneau is trying to achieve has already made redundant or moot, is there any point in proceeding with these amendments?

The Chair: Just to clarify, I'll go to the clerk right now.

The original amendment Lib-1 was withdrawn. Then the clause was defeated by the committee.

His question is whether these amendments make any sense without Lib-1.1.

Mr. Mike MacPherson: Liberal-5 from the past meeting had the effect of leaving in the original schedule 1 of the Patent Act, and the schedule in Bill C-393 would then become schedule 2. So most of the amendments—1.3 to 1.6—just correct references to schedule 2. I believe that Liberal-1.2 reinstates the minister's power to add drugs to the list, the schedule, but the officials at the back would be in a better position to speak to that.

Hon. Dan McTeague: I sense, Chair, that the purpose for asking the question might be to obviate the need for other questions on a similar matter. I notice some heads moving over there. Perhaps we could ask the officials.

The Chair: Mr. Garneau.

Mr. Marc Garneau: I do want to clarify that, as I understand it, at some point we need to deal with Lib-1.1. I know it's clause 2, but it incorporates definitions that are required for the rest of the amendments to be acceptable.

The Chair: Are there any other comments on this?

Mr. Mike Lake: I'll ask I guess a substantive question about Lib-1.2 without getting into Lib-1.1 on clause 2, which has already been defeated.

I'll ask the officials. In terms of the impact of Lib-1.2, could they first of all maybe speak to clause 3, because we haven't spoken about clause 3 yet at all, and the impact it would have on the existing legislation? Then, how would Liberal amendment 1.2 affect clause 3?

•(1015)

Ms. Colette Downie (Director General, Marketplace Framework Policy Branch, Department of Industry): We're happy to answer that question.

The second set of Liberal amendments in our package don't have numbers on them, so it's a bit difficult to follow which is Lib-1.1 and which is Lib-1.2. Is Lib-1.2 the amendment that replaces line 1 on page 2 with some text? Is it subclause 21.03(2)?

The Chair: Is that the case with all the officials? That none of them have numbers? amendments?

All right, Mr. Lake. We'll need to make sure they get copies. That's happening right now.

Madam Frendo.

Ms. Mona Frendo (Director, Patent and Trade-mark Policy Directorate, Department of Industry): Clause 3 of Bill C-393 would remove the process that's currently in the Patent Act for adding or removing products from schedule 1, the list of eligible drugs for export under Canada's access to medicines regime. That process currently involves the Governor in Council making changes to the list based on the recommendations of the ministers: the Minister of Industry and the Minister of Health.

It would do a number of other things as well. It would collapse into one what are currently three schedules of countries in the Patent Act. This is all under Bill C-393. It would limit the process of amending to that list of countries, which was referred to as "the Schedule" in Bill C-393. That's basically what clause 3 of Bill C-393 would do.

As I understand Liberal amendment 1.2, it would reinsert the process for amending schedule 1, the list of eligible products for export under the Patent Act, because as a result of Liberal amendment 4 and Liberal amendment 2, which was withdrawn, schedule 1 has been reinserted into the Patent Act. That whole process of adding or removing to schedule 1 has been reinserted into the text of the Patent Act as a result of Liberal amendment 1.2.

I would say that there is no change to what is I guess now schedule 2, this list of countries, and the process of amending that schedule. That is not referred to in either Bill C-393 or in the Liberal amendments as far as I can see, but I'll have to check. It may be in further amendments.

The Chair: Our conversation is isolated specifically on 1.2.

Are there any other comments or debate on 1.2?

Mr. Malo.

[Translation]

Mr. Luc Malo: On Thursday, we adopted the fourth Liberal amendment, which restores to the bill the process related to Schedule 1, where it lists the medications that can be sent. I thought there was no provision in the current bill, Bill C-393, stating who could add medications to the list or remove them from it. So it was important to clarify that; otherwise, there would have been a gap in the bill.

Do I understand correctly?

[English]

Ms. Mona Frendo: I think that's correct that there is now a process or that there has been reinserted, effectively, the process for amending schedule 1 for the list of products.

Mr. Luc Malo: Okay.

The Chair: Is there any other debate?

Seeing none, does Liberal-1.2 carry? I had better get a show of hands.

Does Liberal-1.2 carry? Can I see a show of hands, please? Six hands? Okay. Those opposed?

(Amendment agreed to)

The Chair: Okay. It's carried.

Now we're on Liberal-1.3.

• (1020)

Mr. Mike Lake: It's clause 3 again? Okay.

The Chair: Liberal 1.2 to 1.6 are all on clause 3. Now it's Liberal 1.3.

Is there any debate or a comment or a question?

Would you like to speak to it, Mr. Garneau?

Mr. Marc Garneau: As I understand it, Mr. Chair, this is really just to correct the fact that in Bill C-393 for the moment they refer to “the Schedule” because there is only one schedule. Now there are two schedules. This is to correct where it says “the Schedule” to say “Schedule 2”.

The Chair: Thank you, Mr. Garneau.

Is there any debate?

I'll call the question on amendment 1.3.

(Amendment agreed to)

The Chair: Again, on clause 3, we have Liberal 1.4.

Mr. Garneau, we'll have a brief explanation, and then we'll see if there's any debate.

Mr. Marc Garneau: On Liberal amendment 1.4, it's just the same as what I said before.

The Chair: Thank you, Mr. Garneau.

Is there any debate?

(Amendment agreed to)

The Chair: On Liberal amendment 1.5, is it the same explanation, Mr. Garneau?

Mr. Lake.

Mr. Mike Lake: Liberal amendment 1.5 deals with clause 4, I believe, so we should probably finish dealing with clause 3.

The Chair: Yes, I'm sorry. We have a schedule that says it's clause 3, but you're absolutely correct, Mr. Lake. These are for clause 4.

Mr. Masse, did you have a comment?

All right. So now that we have it sorted out here that Liberal amendments 1.5 and 1.6 deal with clause 4, I'll call the question on clause 3.

Mr. Lake.

Mr. Mike Lake: Sorry. I do have some questions now on clause 3. I just want to get back to the officials.

Again, what is the impact of clause 3 on the entire regime that we have? Could we have a conversation? Do you have hesitations on clause 3?

The Chair: As it stands amended?

Mr. Mike Lake: As it stands amended, yes.

Ms. Colette Downie: As it stands without the amendments that are proposed—just as clause 3 stands—or as the amendments are proposed to clause 3 in Bill C-393: is that the question?

Mr. Mike Lake: Right. What does it impact and what concerns might you have, if you have any?

Ms. Colette Downie: This is the one that would have completely removed the process for amending schedule 1 to CAMR, the access to medicines regime. It would collapse schedules 2 to 4, the lists of countries, into one list, without any additional requirements or parameters around those lists.

So what it would mean is that a number of fairly well-developed countries would be eligible for exports of drugs under this proposed bill. Countries like Mexico, Singapore, Brazil, and China, which might or do otherwise have pharmaceutical manufacturing capacity, would be eligible to receive medicines under this regime.

Mr. Mike Lake: Does that remain? Okay—

Sorry. Mr. Sutherland-Brown?

Mr. Rob Sutherland-Brown (Senior Counsel, Legal Services, Justice Canada, Department of Industry): I'd just like to add to that briefly. In the waiver decision, the WTO negotiators set up different classes of what they called “eligible importer” and that's what the current schedules 2 to 4 do. So when you get rid of those, there is no distinction between eligibility that would be compliant with the scheme set out by the WTO negotiators.

The other thing it does is this. It seems to eliminate the requirement that a country or jurisdiction that wishes to use the scheme has to give notice to the WTO, written notice, or even verbal notice would do, but there has to be a notice to the WTO by the requesting country of the product they need and the quantum they need. That's all in the conditions that were set out in those “how you amend the lists”.

Thank you.

• (1025)

Mr. Mike Lake: It strikes me in looking at the bill that we've struck out a substantial portion of the Patents Act and replaced it with 26 lines. In terms of what's being struck out there, what is the impact? On the things that have been struck out, what was the purpose for having those in there?

When we're making these changes or proposing these changes, I think it's important for us to understand. When I'm looking at what looks like dozens and dozens of lines that are being struck out that refer to WTO members and TRIPS councils and all sorts of different things that seem to be important from a trade standpoint, for example, it's important to know what is actually being struck out.

Ms. Mona Frendo: I'll try to answer that.

Paragraph 21.03(1)(a) of the Patent Act, which has been struck out—but then effectively some sort of mechanism has been reinserted—is the process of amending schedule 1, the list of drugs for export. Paragraphs 21.03(1)(b) to (d) and subsection 21.03(2) of the Patent Act—that's basically the rest of section 21.03—have also been effectively removed. Those paragraphs and the subsection describe the processes and requirements for adding and removing a country from what were schedules 2 and 3 of the Patent Act, those lists of countries Mr. Sutherland-Brown was referring to that had various requirements for using the WTO waiver as per the international rules.

What clause 3 of Bill C-393 would do is, for these lists of countries, effectively modify that process so that only two factors—and there were many more in the Patent Act—could be taken into consideration for adding or removing an eligible country from the new schedule. This would significantly limit the ability to amend that list and take action.

I can give you a couple of examples of what clause 3 would eliminate, if that would help.

Mr. Mike Lake: Yes, it would.

Ms. Mona Frendo: It would eliminate the government's ability to remove from this eligible importers list countries that permit imported products to be used for commercial purposes contrary to the humanitarian objectives of the WTO waiver.

It would eliminate the government's ability to remove countries from the eligible importers list that import drugs under the waiver but fail to take reasonable measures to prevent these drugs from being diverted and re-exported outside of their territories, again contrary to the objectives of the waiver.

Finally, it would limit the government's ability to remove from the eligible importers list countries that state that they will only import drugs under the terms of the WTO waiver in situations of national emergency or extreme urgency. There were a number of countries that told the WTO they would only use the waiver in those special circumstances, but then they proceed to import in other circumstances, so they don't abide by their self-declarations to the WTO.

Mr. Mike Lake: Does Mr. Garneau's amendment address any of those circumstances?

Ms. Mona Frendo: No.

The Chair: Thank you, Mr. Lake.

Mr. Masse.

Mr. Brian Masse: The point is that some of those countries, such as Mexico, stated they would use it for domestic emergency circumstances only.

The Chair: Mr. Malo.

[Translation]

Mr. Luc Malo: Mr. Masse, I will put my question to you.

When Judy Wasylycia-Leis was drafting the bill, why did she think it was important to remove that barrier? What did it change? What did it add? Why was it necessary to do that?

• (1030)

[English]

Mr. Brian Masse: Well, the Patent Act schedules of countries and drugs were never part of the WTO decision. That was something that we made up here in Canada; it wasn't required. It was never part of the original agreement internationally; we just invented that here.

When we invented that here, one of the things we raised was that there would be active lobbying to keep certain drugs and certain countries off the list. That happened with Bayer: they actually started to lobby to keep a drug off the list.

So the schedules become a big problem in many respects, because we just made up the rules and the countries and the drugs to put on a list when we didn't have to require that. Some of the testimony we've heard over this period of time is that the lists and schedules were not necessary.

In the spirit of compromise, I've agreed to maintain the status quo or, if Mr. Garneau has a better system here, to support that. That's the reason I will continue to accept the fact that if we have countries and schedules, it's because there seems to be a greater want for this made-up system that we created back in 2004.

However, I never believed it was necessary to begin with and it certainly created real problems that made headlines here in Canada. As I mentioned, there was an argument that companies would lobby the ministers and other people to keep their drugs off the list, and it turned out that Bayer was actually doing that as we had hearings here in Ottawa.

[Translation]

Mr. Luc Malo: Do you understand why it might be important for the government, or even Parliament, to be able to determine what can be sent and where? Ultimately, do you think we can have that oversight?

[English]

Mr. Brian Masse: Once again, the WTO didn't require that as part of the decision, so to me, as long as this is being done ethically—and there hasn't been an indication that it would not be—then I don't believe that lists are necessary. Because we see the problem that's emerging now, for example, with India, let's say. Their patent restrictions are coming into place and the new HIV drugs that are necessary to go to the next level of treatment are going to be problematic. That was the testimony we heard from several organizations here. To me, by putting in those lists, you restrict the formulary necessary to treat people, and that adds another level of barrier. To me, it's critical.

The WTO divines who is a developing nation. We've only seen one case in the last number of years that this has been used; we haven't seen the widespread abuse that was predicted, even under the current model, and the insinuations that places such as Mexico and so forth were going to abuse this type of regime just have not come to fruition, in my opinion.

Putting the drugs on a list requires another level of barrier to add those drugs that often could be the proper formula for treatment. But I'm willing to accept the status quo or a model similar to it for the greater good of trying to improve the bill.

The Chair: Thank you, Mr. Malo and Mr. Masse.

Now we'll go on to Mr. Braid.

Mr. Peter Braid (Kitchener—Waterloo, CPC): Thank you very much, Mr. Chair.

I want to ask whether we could turn to the officials to ask what the purpose of the original country list was when CAMR was first drafted, why the countries were subdivided into the three different categories, and what the consequences of consolidating the list will now be. It is a question about background, purpose, and then impacts.

I have a couple of follow-up questions as well.

Mr. Rob Sutherland-Brown: Starting at the top, concerning schedule 1, the comment is correct: there is no WTO requirement of which I am aware that says you have to put drugs on a list. They just were happy with a definition of—

Mr. Peter Braid: I'm referring to the country list.

Mr. Rob Sutherland-Brown: Yes, the country list; I wanted to start at the top. The rationale for the country list, as I tried to explain earlier, was to recognize the different categories of eligible importer that the WTO negotiators had identified. For instance, the least developed countries are eligible by presumption, and they don't really have to do anything.

Others, as people have noted before me, have said to the WTO that they will only use this in case of a domestic national emergency. In giving notice to the WTO, they would have to call attention to the fact that they are having an emergency, in their view, and therefore that they are eligible.

That was the rationale for it. It made it very simple: you knew what class you were in and you knew, therefore, what you had to demonstrate to the Commissioner of Patents when you went forward with an application for an authorization. That's the simple rationale, the easy reference, and quick to do.

• (1035)

Mr. Peter Braid: Okay. Hearing that drugs can be exported for commercial purposes and not for humanitarian purposes, either because of clause 3 or the consolidation of the country list—I'm not sure which, and perhaps both—greatly concerns me. Is it by virtue of clause 3 that this can happen or is it by virtue of the consolidation of the country list? And does this not set aside and abandon the ultimate purpose of the WTO negotiations on CAMR, which was to ensure that drugs were exported for humanitarian purposes?

Mr. Rob Sutherland-Brown: I think that's a fair comment. The non-commercial character of the scheme was something that was set out in what is referred to as the chairman's statement, and that, by definition of the General Council decision in the Patent Act, was incorporated into the Canadian legislation because we thought it was an important element of the whole scheme that was created at the WTO.

So it is an important element and it runs through our legislation as it exists prior to Bill C-393. It's reflected in the provisions whereby the Federal Court can review an authorization to see whether, at the price the drug is being exported, it is for a non-commercial purpose or at a commercial price as opposed to a "humanitarian price". It was an important element in the scheme, yes.

Mr. Peter Braid: Finally, did I hear you correctly when the statement was made that, again, clause 3 opens up the risk of diversion because an importing country can re-export. Is that correct?

Mr. Rob Sutherland-Brown: There are a number of elements in Bill C-393. As I think I said last Thursday, this is very intricate: A goes to B to go to C, etc., so you have to follow the thread through the fabric, so to speak. But yes, I think that's a fair comment.

Some of the anti-abuse provisions that were in the Patent Act are removed by the proposals in Bill C-393. If you remove those anti-diversion or anti-abuse provisions, then you are in a very difficult situation if you try to enforce the limitations of the waiver agreement and the scheme for exporting drugs under compulsory licence.

Thank you, Mr. Chair.

The Chair: Thank you, Mr. Braid.

Mr. Lake.

Mr. Mike Lake: I want to clarify the meaning of some phrases here. The area that's being struck out refers several times to this: "has failed to adopt the measures referred to in Article 4 of the General Council Decision". We're talking about countries who have failed to adopt them.

What does that mean again...? Could you reiterate that? I guess it would be paragraph 21.03(3)(a), under the heading "Removal from Schedules 2 to 4", in the Patent Act.

Ms. Mona Frenedo: Article 4 of the WTO waiver—or the WTO decision, as we've been using those terms interchangeably—talks about the obligations that importing countries shall take. I can quote it for you, but basically they are measures they must take to prevent trade diversion.

If they import drugs under the WTO system, they have to make sure that the drugs stay within their jurisdiction and aren't re-exported. They must also prevent re-exportation of the products that have actually been imported into the countries. That's basically what it says.

• (1040)

Mr. Mike Lake: Okay. In a couple of cases here, we're striking down the ability to remove the names of countries that fail to adopt the measures referred to in article 4 of the waiver that allows us to have CAMR in the first place, in a sense, right?

Ms. Mona Frenedo: That's right. The WTO waiver set out or imposed requirements on both the exporters that would send the drugs to countries in need and the importing countries that would receive them. One of the requirements, as set out in article 4 of the WTO decision, is that importing countries that receive these drugs take reasonable measures to prevent trade diversion.

Mr. Mike Lake: Okay.

By way of a comment, I'm surprised, Mr. Chair, that this is something that the Liberals would actually even consider. Clearly, the impact on a trade agreement.... I'll just leave it at that, I guess.

The Chair: Thank you, Mr. Lake.

Do we have any other debate or comments?

We'll move to the clause itself. Shall clause 3 carry as amended? All in favour? Opposed?

(Clause 3 as amended agreed to)

The Chair: We'll now go to clause 4, which has three amendments: Liberal-1.5, Liberal-1.6, and Liberal-2. That's where we left off our debate the last time: at Liberal-2.

Mr. Garneau, I'll let you move them and speak to them as well, Lib-1.5 and Lib 1.6, to give us an understanding of that, and then Mr. Malo—

Oh, go ahead, Mr. Malo. Sorry, Mr. Garneau.

[*Translation*]

Mr. Luc Malo: Thank you very much.

I would like to apply the same logic we used when looking at amendments LIB-1 to LIB-6. Before we consider amendments LIB-2 and LIB-3, would it not be possible to finish with amendment LIB-4? We have already adopted amendment LIB-4, but amendment LIB-4.1 was added to the book. We need to deal with that part before moving on to amendment LIB-2.

[*English*]

The Chair: You're speaking of amendment Lib-4.1 in clause 13. Is that correct?

[*Translation*]

Mr. Luc Malo: Yes, because we have already adopted amendments LIB-4, LIB-5 and LIB-6. We just need to finish with that section. Then we can come back to amendments LIB-2 and LIB-3.

I imagine it will not take too long to adopt the amendment.

[*English*]

The Chair: Is everybody agreed we'll move to Lib-4.1, then, in clause 13?

Some hon. members: Agreed.

(On clause 13)

The Chair: I'm sorry, Mr. Garneau. I won't need you to speak to those others, but if you'd speak to amendment Lib-4.1, that would be great. Consider it moved as you speak to it.

Mr. Marc Garneau: That's Lib-4.1?

The Chair: In clause 13, that's correct.

Mr. Marc Garneau: Yes, Mr. Chair.

This amendment is an amendment to clause 13 of Bill C-393. It's to restore the existing paragraph 21.16(1)(a) because it's connected to the restoration of the existing application process in accordance with amendment Lib-2, which deleted, as you know, subclause 4(2).

That's essentially what it is. It's related to clause 4, but it is in clause 13.

The Chair: Thank you, Mr. Garneau.

Mr. Malo, did you have some comments on it, since you directed us here?

[*Translation*]

Mr. Luc Malo: Unless I am mistaken, Liberal amendment LIB 4-1, which seeks to amend clause 13, refers to clause 4, which we have just adopted. Is that correct?

An hon. member: We did not adopt clause 4.

Mr. Luc Malo: We did not adopt clause 4?

[*English*]

The Chair: No, we didn't. No, we haven't.

[*Translation*]

Mr. Luc Malo: Oh, okay then. So we just adopted clause 3.

• (1045)

[*English*]

The Chair: Yes, we just adopted clause 3, Mr. Malo. We have not moved on to clause 4, which has three different amendments: Lib-1.5, Lib-1.6, and Lib-2.

[*Translation*]

Mr. Luc Malo: Fine. We need to come back to amendment LIB-1.5 then.

I apologize, Mr. Chair.

[*English*]

The Chair: Okay. The amendment has been moved on clause 13 now, so rather than go back and forth, we'll finish this debate and then go back. Is that okay?

[*Translation*]

Mr. Luc Malo: It is just that I thought....

[*English*]

The Chair: Mr. Masse.

Mr. Brian Masse: Mr. Chair, on a point of clarification, which clause is tied to amendment Lib-4.1? Are we going back to—

The Chair: Right now we are directed to clause 13 and amendment Lib-4.1. I think there was an issue with the numbering and Mr. Malo was confused on that.

[*Translation*]

Mr. Luc Malo: Mr. Chair, I thought that the Liberals' amendment.... I should have asked the question before asking that we discuss it. I thought the clause that amendment LIB-4.1 seeks to amend was directly related to the adoption of amendment LIB-4, which refers to clause 12. I was just wondering why it had been numbered as LIB-4.1. I was under the impression that it was amending clause 12, as well.

My mistake. I apologize.

[*English*]

The Chair: Mr. Masse, then Mr. Garneau.

Mr. Brian Masse: If we all agree, we can go back to amendment Lib-1.5. I think if you seek it, you will find consent to go back to amendment Lib-1.5.

The Chair: Great minds think alike. Thank you, Mr. Masse.

Some hon. members: Agreed.

(On clause 4)

The Chair: So we're back now at clause 4, then. I'll remind you again that Liberal-1.5, Liberal-1.6, and Liberal-2 refer to that. I think Mr. Garneau is just going to move amendment Lib-1.5 and speak to it.

Mr. Marc Garneau: Yes, Mr. Chair. In fact, Lib-1.5 and Lib-1.6 do the same as Lib-1.3 and Lib-1.4. They clarify that we're now dealing with schedule 2, that list of countries that used to be "the Schedule" in Bill C-393 but has now become schedule 2. It's really just a minor clarification.

The Chair: Mr. Lake.

Mr. Mike Lake: I have a quick question for the officials. This clause 4 would amend subsection 21.04(1) of the Patent Act. I just want to start by asking you what the purpose is of subsection 21.04(1).

Ms. Mona Frendo: That subsection states that the Commissioner of Patents "shall...authorize the person to make, construct and use a patented invention solely for the purposes directly related to the manufacture of the pharmaceutical product named in the application".

So it ties the authorization to a specific product named in the application. It also ties it to a particular country that would be listed in schedules 2 to 4 of the Patent Act—to the original three country lists also named in the application.

So there are two critical parts of subsection 21.04(1): that the product has to be named in the application and that the country has to be named in the application. The authorization is tied to those two elements.

Clause 4 of Bill C-393 would significantly alter this authorization by the Commissioner of Patents. It would allow the Commissioner of Patents to authorize any person to manufacture more than one pharmaceutical product under the Patent Act and sell it for export to more than one country. It would also eliminate the requirements that the product be named in the application and that the country be named in the application. Again, it unties the process. It adopts what was referred to previously in this committee as a one licence solution.

Mr. Mike Lake: Why is it so important they are tied one-to-one like that?

Ms. Mona Frendo: Tying the authorization is important because this mechanism, the WTO decision that CAMR is based on and that Canada adopted, was carefully defined and limited.

It was not intended to be a broad-based infringement of existing intellectual property rights, but in the circumstances of there being a particular need identified by a particular country for a particular quantity of drugs, there would be a mechanism consistent with international rules allowing Canada to send drugs.

So untying the system from this particular need being identified in terms of quantity and by country is different from what was envisaged by countries.

• (1050)

Mr. Mike Lake: Does the amendment that we are talking about deal with the issues you've brought forward as problems with Bill C-393?

Ms. Mona Frendo: Are we talking about the Liberal amendment?

Mr. Mike Lake: Yes, it's Liberal amendment 1.5, I guess.

Ms. Mona Frendo: No. As I understand it, that's simply a technical amendment that references schedule 2. So the country list would be referred to as schedule 2 rather than schedules 2, 3 and 4. That doesn't deal with the authorization—

Mr. Mike Lake: So the amendment doesn't deal with the authorization issues at all.

Ms. Mona Frendo: No, it does not.

Mr. Mike Lake: Okay.

The Chair: Is there any other debate? Shall amendment 1.5 carry?

Some hon. members: Agreed.

The Chair: Opposed?

That's carried.

(Amendment agreed to)

The Chair: Is there any debate on Lib-1.6?

Mr. Lake.

Mr. Mike Lake: Perhaps I could hear Mr. Garneau explain it again, if he could.

Mr. Marc Garneau: Once again, it is to allow for the fact that in the new amended Bill C-393, there is a schedule 1 for medications and a schedule 2, which is the old unique schedule. Now we have to allow for the fact that this original unique schedule is now renumbered as schedule 2.

Mr. Mike Lake: If I could ask Mr. Garneau this, does this amendment deal with any of the problems that Ms. Frendo brought up?

Mr. Marc Garneau: No. It's strictly a renumbering.

Mr. Mike Lake: Okay.

(Amendment agreed to)

The Chair: Now we're back to where we left off the last time. We're resuming debate on Lib-2 on page 8 of your amendments, pertaining to clause 4.

Mr. Masse.

Mr. Brian Masse: Can we have Mr. Garneau explain this?

The Chair: Yes.

Could you please give a recap on this, Mr. Garneau?

Mr. Marc Garneau: Yes, certainly.

The proposal with respect to subclause 4(2) specifically was that under the current legislation, a pharmaceutical manufacturer applying for a compulsory licence under CAMR—under the current legislation, not under Bill C-393—is required to include information about the version of the product, the quantity of the product to be exported, the name of the patent holder, the name of the importing country, and the name of the importing entity. I would like to restore the legislation. I would like to make sure that Bill C-393 reflects that requirement.

The Chair: Thank you, Mr. Garneau.

Mr. Masse.

Mr. Brian Masse: Thank you, Mr. Chair.

I'm speaking against this amendment. This virtually guts the one licence solution. We heard testimony from witnesses who, first of all, explained that what we did created a regime that wasn't necessary. It wasn't required under the WTO to create some of the barriers that we have.

One of the problems that we faced in the access to this legislation is pure-out intimidation and threats. Some of them have been public, as in the Indonesian situation, for example. Others have been impossibly difficult to get over, requiring a series of attempts to move, to get CAMR to work, especially the one in the Rwanda situation. We heard that, yes, some elements from the technical aspect, once it got through, were okay, but because of the process involved in terms of identifying the country right away, identifying the drug right away, and identifying the quantity, it restricted the interests of those who wanted to use this legislation. Hence, the Canadian model, which is sometimes proposed as being very effective, really isn't being accessed.

It's also important to know that for some of the things that were contentious in this bill, we've decided to drop those clauses. Some of the things I don't think are necessary, but at the same time, there have been some good concerns raised on everything from the food and drug and safety act—that's the Health Canada provisions—to others as well, relating to diversions. But this particular element here would create the same system that exists today. We have our only customer—that being Apotex, which looked at this as a potential thing—saying they won't do it. They've also identified that they would actually, if we'd traded a different regime, look at getting pediatric drugs immediately overseas as well.

It's very important that this part of the bill be defeated in terms of this amendment. I believe we won't see the wanton abuse of patent elements in Bill C-393, which has the one licence solution in it. I don't think any evidence of that has been produced. I haven't seen any evidence from the generic companies or from the pharmaceutical companies that there would be problems.

It was interesting, though, because when we had GlaxoSmithKline testifying in front of us here about how they wanted to ensure safety and a series of products that weren't substandard, they were actually settling a \$760-million lawsuit in the United States for having products that were deficient, including baby ointment.

We've set up a system here that clearly isn't working. It's one that we've designed. This is a critical part that I hope gets defeated. If not,

we will see similar situations take place, in my opinion, where the licensing won't be granted.

Once again, I think the best evidence we have is from the one company that actually tried to use this bill. We had incredible testimony here from a number of different NGOs about the restrictions and the problems. We had some other good testimony from experts like Mr. Abbott who were there and who know we're not violating anything by going ahead.

I'm hoping this motion will be defeated. I would call for a recorded vote when it is appropriate.

• (1055)

The Chair: Thank you, Mr. Masse.

Mr. Malo.

[*Translation*]

Mr. Luc Malo: Thank you very much, Mr. Chair.

Obviously, I will have some questions for my Liberal colleague, but I want to come back to one thing first.

On Thursday, we discussed this clause. You will recall, Mr. Masse, that you suggested removing a certain number of clauses. I asked the officials who were testifying a question. I asked them how they viewed or interpreted the removal of the clauses you suggested.

I just want to know whether you had time to take a closer look at that in the past few days.

[*English*]

Mr. Rob Sutherland-Brown: As I recall the proceedings from last Thursday, the proposal was that the sponsors of the bill would be prepared to drop clauses 6, 7, 8, 11, 12, 14, 16, and 17.

Clause 6 proposes to repeal section 21.06 of the Patent Act, the website disclosure, and in its place it proposes a more limited disclosure: the name of the product; the name of the importer; and distinctive features and labels in accord with the regulation requirement, which is not yet in place.

If you drop that proposal, you would revive subsection 21.06(1) of the Patent Act, so there would be a duty to disclose the authorized quantity. That would conflict with the repeal of section 21.04 in clause 4. It revives Health Canada's review and regulation—product features, labels, and packaging. Depending on the outcome of these other things, that would also conflict with the clause 4 authorization provisions. It revives the duty to disclose the name of every known party that would be handling the product while in transit from Canada to the importing jurisdiction. It also uses WTO language, but I understand that some of the amendments probably fix that.

Clause 7 of Bill C-393 purports to repeal section 21.07 of the Patent Act. This is the provision that requires the exporter to give an export notice. It is required to give that notice to the patentee, to the importing jurisdiction, and to whoever it is within that jurisdiction, or on behalf of that jurisdiction, who has purchased the product. This would create some problems for the anti-abuse provisions. By virtue of the repeal of section 21.04, application requirements, there is no way you can verify the disclosure to the patentee, as they are not identified in the new authorization process. It also uses WTO language, which would be fixed.

Clause 8 in Bill C-393 would amend the existing royalty provisions and it would remove the Federal Court review, at the instance of the patentee, of a royalty rate, which would be determined in accordance with the regulatory scheme but nevertheless in the judgment of the patentee was inadequate in the circumstances. The revival will bring this back into compliance with that review process. The review process is not required by the waiver decision itself but there is a requirement in article 31 of the TRIPS agreement that any decision as to the remuneration given to the patentee must be reviewable by a distinct higher authority. In the Canadian case, for a federal decision, that would be the Federal Court. This provision also uses the WTO language, which may well be fixed.

Clause 11 in Bill C-393 deals with section 21.13 in the Patent Act. That is a clause that deals with termination on the happening of a statutory event. These events are things such as the expiry of the two-year term certain for an initial authorization and the expiry of a two-year term certain renewal authorization, on the happening of the Minister of Health notifying the commissioner and others that the product at issue is no longer compliant with Health Canada efficacy regulations or the labelling and appearance regulations.

• (1100)

It also allows for automatic termination where a country has been removed from one of the country lists. So if you revive section 21.13, as the proposal to drop would do, you revive the concept of a two-year set term for initial authorization. You also revive a reference to re-authorization for another up to two years. So there's a conflict there between what's in Bill C-393 and what would stay in the Patent Act. Well, as the trade dress issues as defined by Health Canada regulations would be revived, and it revives the concept of a named product in an authorized quantity, all of that creates some tensions within what would remain if the bill proceeds.

Clause 12 is a termination clause on the instant or the suit of the patentee for a number of reasons. The termination for failure to label accurately and failure to give export notice—that could be okay if clause 7 is dropped, because that would revive the export notice. It would also replace Bill C-393's definition of a regional trade agreement with the original version in the Patent Act that was drafted to comply with the definition used in the WTO waiver decision.

Clause 14 would repeal sections 21.17 to 21.2. Section 21.17 is on termination in circumstances where bad faith is alleged because the contract is being used for commercial purposes. Section 21.18 is on the advisory committee designed to assist the Governor in Council and ministers in determining whether a drug should be added to schedule 1.

In section 21.19, a website is to be established by Canada to disclose applications that are made to it by a non-WTO member that would not have had an obligation to give notice to the TRIPS council under the WTO scheme. Canada went beyond its strict obligations in this regard, because they thought everybody should have access to the system on equal footing. We had to design something where a focal point for the notice from the demanding jurisdiction could be made public and transparent to the world.

Section 21.2 was a requirement for a ministerial review and reporting to Parliament, and that's essentially spent, so it would be removed in a housekeeping bill and not with whatever you do here.

That's it. There are several places where Health Canada is referenced. I'm not sure in which particular clauses. Perhaps we can deal with those when we come to them.

• (1105)

[Translation]

Mr. Luc Malo: My understanding, from your comments, was that a number of the clauses that could be dropped had little or no effect on the rest of the bill. In other cases, removing those clauses from Bill C-393 could have an impact on other clauses in the bill. That was my understanding, especially with regard to the first two clauses that could be removed, clauses 6 and 7.

The last clause you mentioned, however, clause 14, might be worth keeping, because it directly addresses the question I put to Mr. Masse on the addition or removal of listed products. That could give Parliament somewhat of an advisory role in the process. Of all the clauses you mentioned, I think that would be the one most worth keeping. So we are talking about clauses 21.17 to 21.2.

It is not with this addition or removal of clauses, as far as Bill C-393 goes, that we can really consider the second Liberal amendment. That amendment deals with another aspect of the bill and seeks to delete lines 15 to 18 of clause 4. My understanding, from what most of the witnesses said, was that that part was the real bone of contention.

I first want to ask Mr. Masse about that, since he is the one responsible for the bill right now. In your opinion, lines 15 to 18 of clause 4 speak to the heart of the bill. Without them, there is no bill.

[English]

Mr. Brian Masse: No. It's this amendment here. I think the other ones that I'm prepared to drop are going to enhance certain elements of the bill. I would point to the food and drugs and safety act amendments in particular, because concern was raised about Health Canada saying that it would not be part of the process to look at drugs for export. We've already said, for example, that's off the table, so that's off the table and the objections from Health Canada are off the table. Objections from any member here about Health Canada drugs going out are off the table.

The others, the changes to the website and a whole series of reporting changes and so forth, were seen by other members and the department as not being good ideas. Facing that, we're willing to go back to the other parts of the bill. There will be some reporting things that water down even what I'm suggesting by keeping the one licence and one solution. But it's still better than what we have. If we go ahead with this amendment, it will gut the bill significantly.

Lib-3 is problematic as well. We might have a solution for that.

But at any rate, I think this is critical. If we don't defeat this amendment, it will all be for naught. We've heard that in the testimony from the non-governmental agencies and we've heard it from the generics that wanted to try to use this. It's about making sure that the preconditions by which a country can procure medicines are done in a way such that they can do so without intimidation, without fear, and according to the needs of their nation. Then we will still follow a lot of the regimental regime behind CAMR that was originally created in the first legislation.

• (1110)

[*Translation*]

Mr. Luc Malo: So you see lines 15 to 18 as being the heart of clause 4.

[*English*]

Mr. Brian Masse: Yes.

[*Translation*]

Mr. Luc Malo: Now I will ask Mr. Garneau. If lines 15 to 18 are at the heart of clause 4, why not vote against clause 4? Why put forward this amendment? Do you have a different understanding of all the testimony we heard in favour of Bill C-393?

As Mr. Masse said, everyone who argued in favour of Bill C-393 saw the problems that lines 15 to 18 presented. Yet it is those very lines that your amendment seeks to remove. Why not just vote against clause 4? Why do you want to remove those lines? Is your understanding different from mine?

Mr. Marc Garneau: Thank you, Mr. Chair.

When I began studying Bill C-393, I wanted to understand why Canada's Access to Medicines Regime, CAMR, did not seem to be working—meaning that it worked once. I took it upon myself to do an in-depth analysis of why that was. I was also aware that similar regimes in other countries had not worked. I would say I approached the matter objectively. Of course, CAMR was almost never used, except in the case of Rwanda, with Apotex.

I wanted to know why a system that had been put in place with such good intentions and that, I would repeat, was designed to provide very important medicines to developing nations—especially to treat AIDS, malaria and tuberculosis—had not worked.

Let's consider the case of Rwanda with Apotex. I always come back to one thing. When Apotex applied for a licence to three pharmaceutical companies, the process took 68 days the first time. One year later, the first shipment of medicines arrived in Rwanda. Then, when they applied a second time, it took the pharmaceutical companies a week to authorize the application, if memory serves.

In my view, that does not explain why CAMR seems to be hampered or ineffective. The Liberal Party, which wants to provide medicines to the third world, where the need is greatest, has a proposal to guarantee that much-needed medicines will get to where they need to go. That is the approach the Liberal Party wants to adopt, one that does not include the proposed changes in Bill C-393.

Keep in mind, as well, that what this private member's bill, Bill C-393, inherently does is alter our obligations regarding intellectual property, our international obligations. Of course, there are arguments both in favour of and against that position. Some say that it could lead to problems with the international community, while others claim that would not be the case.

I think that Canada has to send a message about intellectual property, because it is crucial to research and development. After all, it is the pharmaceutical companies doing the research and development to come up with products that can then be passed on to generic drug manufacturers.

In short, we cannot lose sight of the real source of the problem. Everything I discovered regarding Rwanda has led me to believe that the problem does not lie with CAMR right now. It may be necessary to make some minor adjustments, but we need to find another way to accomplish what we all want to accomplish.

• (1115)

That is why I cannot support the proposed change in clause 4; I do not think that it focuses in on the real problem.

[*English*]

The Chair: Mr. Malo.

[*Translation*]

Mr. Luc Malo: I am still trying to wrap my head around this. Why do you not simply vote against clause 4, instead of trying to amend it by removing, as I was saying earlier, the heart of the changes that all the witnesses who spoke in favour of Bill C-393 want, as does the New Democratic Party, which introduced the bill?

Why not just vote against clause 4? Why did you decide to move an amendment that would remove lines 15 to 18?

Mr. Marc Garneau: I will repeat myself. I wanted to make sure that the application process would be restored. In speaking with the experts, I learned that amendment LIB-2, dealing with clause 4, reflected my concerns.

[*English*]

The Chair: Thank you.

Mr. Masse.

Mr. Brian Masse: I want to quickly correct the record from the testimony we heard. The problem that Apotex faced, as well as the NGOs, was identifying the country up front. That process took a year or more. That was the real problem.

The way that CAMR is built requires certain elements that create the barriers from the operational standpoint to be triggered later on, once those things are completed, so this is what this is about. It's to fix that critical fatal flaw of process that will allow the medicines to be negotiated from the countries, the NGOs. From Mr. Abbott's testimony, we do know that this is WTO compliant.

• (1120)

The Chair: Thank you, Mr. Masse.

Are there any other questions or any other debate? All right. I'll call the question on the Liberal-2 amendment. We've been asked by a member for a recorded vote.

(Amendment negated [See *Minutes of Proceedings*])

The Chair: It's quite clear. The amendment is defeated.

[*Applause*]

The Chair: We will now move to the question on clause 4 as amended. Those in favour of clause 4?

An hon. member: It was amended?

The Chair: Yes. It was amended. We passed two amendments to clause 4: Lib-1.5 and Lib-1.6.

Mr. Malo.

[*Translation*]

Mr. Luc Malo: Mr. Chair, before we vote on clause 4, since that is really the substance of this bill, would you be so kind as to suspend the sitting for a few minutes? I would like to speak with Mr. Bouchard before we vote. Could you give me ten minutes or so, until 11:30 a.m.?

The Chair: The sitting is suspended.

• (1120)

(Pause)

• (1130)

[*English*]

The Chair: Ladies and gentlemen, we'll now return to our meeting.

I sensed that there was agreement from the committee members, as they were leaving the table, to extend our time to 12:10 to make up for the suspension.

Monsieur Malo.

[*Translation*]

Mr. Luc Malo: Thank you very much, Mr. Chair.

When we discussed clause 3, our Conservative colleagues voiced their concern that Bill C-393 would divert Canada's Access to Medicines Regime from its primary objective. They were concerned that the resulting bill, act or regime would serve commercial interests more than humanitarian ones. I am certain that is not the intention; nor is it the intention of all those witnesses who testified throughout the proceedings that we needed to provide appropriate aid to children with AIDS, to their families—those mothers, fathers and grandmothers who are worried about the future of their children and grandchildren. So that is not what the people who introduced

Bill C-393 wanted; nevertheless, the concerns are there, and they are legitimate.

Throughout the debate on Bill C-393, I often encouraged the committee members to come up with other solutions. There are actually other solutions; there is a way to help facilitate the current regime, in order to build more examples, more experience, for analysis purposes.

If the committee does not adopt Bill C-393, there will be nothing to take its place—no report, no other solutions. There is only one solution before us, and that is Bill C-393, which seeks to amend the current regime.

I wonder how we can view this amended regime and ensure that it does not exceed the limits we want to see imposed. We do not want the regime to stop serving humanitarian interests, and humanitarian interests only. I was discussing it with my colleague, Robert Bouchard, and our only solution may be to adopt Bill C-393 and turn it into a pilot project.

I would encourage my colleague from the New Democratic Party to sit down, after the committee stage, and see what amendments could be made, at the report stage, to turn this into a pilot project. A sunset clause comes to mind first and foremost, in order to put a time limit on the bill.

The way I see it, we should have come up with a proposal when we originally began studying this bill. Unfortunately, this is the only proposal we have. The government members have not shown a willingness to find a way to improve the current regime and make it more usable. A system that has been used just one time has not really been used at all. We cannot even say whether it works or not. Well, I suppose it does work, since it has a 100% success rate based on the one time it was used.

As I already mentioned, Mr. Chair, we are going to support clause 4, we are going to support all the other clauses, and we are also going to support our colleague from the New Democratic Party, who wants to remove certain clauses to bring the regime in line with the Food and Drugs Act and to strengthen Parliament's role. Clearly, we will propose some amendments at the report stage to ensure that the regime serves solely humanitarian interests, as originally intended.

• (1135)

[*English*]

The Chair: Thank you, Mr. Malo.

Mr. Lake.

Mr. Mike Lake: Thank you, Mr. Chair.

Thank you to my honourable colleague. There was some stuff in there that I agree with. We had a conversation the other day. He is very passionate about the issue of helping people in Africa who need help. He mentioned that we have one solution before us and I've said repeatedly that I would disagree with that. I don't think we have any solution before us in this bill. I don't think this bill offers the solution we're looking for.

He mentioned the government and what the government is or isn't doing. I would argue that what this government is doing is working on solutions that are making a difference and increasing funding, our investment, in the global fund. Where other countries are not doing that, our country is increasing the investment and taking advantage of our role in leading the G-8 this past summer to put forward an initiative on maternal and infant health. That is tremendously important and it is something that is looking forward, looking toward the solution.

Unfortunately, I don't see a solution in this bill. Maybe when this is all done, we'll have the chance to talk. Those of us in committee who want to continue to look at ideas that might help can have conversations. I have committed to continuing the conversation with some of the folks who have been before the committee as witnesses as it relates to trying to have an impact on the devastation that is happening in parts of the world, where things are a little different from what they are here.

To go back to the bill here, if I could, we're on clause 4 right now. If I can bring the discussion back to clause 4 and taking a look at what clause 4 does, I'll give some explanation as to why I would vote against the Liberal amendment.

Clause 4 takes section 21.04 of the Patent Act and basically and systematically, in three subclauses of Bill C-393, wipes out three subsections of the Patent Act. Again, large portions of the Patent Act will be wiped out by this one clause, clause 4, in Bill C-393, and are replaced with a few paragraphs. For subsection 21.04(1), I think it adds one word, for subsection 21.04(2) it adds one word, and for subsection 21.04(3) I think it adds 16 words in replacing paragraph after paragraph of references to the WTO and TRIPS and those things.

So again, we see wording in a bill amending something as important as the Patent Act in a way that wipes out massive portions of it, and again, I think with substantial potential for very negative unintended consequences in the long run. The Liberal amendment addressed only one of the subsections that was being wiped out and left completely unaddressed the most substantial parts that were wiped out. That would be why I voted against the amendment and will be voting against clause 4 of Bill C-393.

• (1140)

The Chair: Seeing no other debate, we will do a recorded vote on clause 4.

Shall clause 4 carry as amended?

(Clause 4 as amended negatived [See *Minutes of Proceedings*])

The Chair: The clause is defeated.

(On clause 5)

The Chair: We'll carry on to clause 5.

I believe Liberal amendment 3 does not need to be moved here. From what I understand, this amendment is not required and it creates an actual conflict later. But I'll let Mr. Garneau speak to that.

Mr. Marc Garneau: I concur with you, Mr. Chair. I'd like to withdraw it.

(Amendment withdrawn)

The Chair: That will be withdrawn, then, and we'll deal with the actual clause itself.

Is there any debate on clause 5 before we move to the question?

Mr. Lake.

Mr. Mike Lake: If I could, I'd like to go to the officials to have them explain what section 21.05 of the act does, first, and how it came about, and what the rationale is for 21.05 in the first place, and then what clause 5 of Bill C-393 would do—and what the effect would be.

The Chair: Ms. Frendo.

Ms. Mona Frendo: Section 21.05 of the Patent Act presently states that the quantity of the pharmaceutical product that can be authorized for export—so that's manufactured and sent—to an importing country, may not be more than the amount that the importing country stated in its notification. Again, it ties CAMR back to this WTO decision, this WTO waiver, that it was founded upon. In that decision it was specifically stated that the country that needed a particular amount of drug would say so in their notification to the WTO, and CAMR was developed to respond to that need. In our process, section 25.01 of the act says that you cannot export, under this special regime, more than the importing country specifically stated it needed.

• (1145)

Mr. Mike Lake: On a point of clarification, I think you said section 25.01, but you meant section 21.05.

Ms. Mona Frendo: I'm sorry. I meant section 21.05.

Clause 5 of Bill C-393 would change the current provisions in section 21.05 of the Patent Act by deleting all the references to quantity. It would also add a new proposed section, 21.051, that would put the onus on the authorization holder—the first or the manufacturer who is authorized under Canada's access to medicines regime to export. You would put the onus on that person to bear the responsibility of ensuring that the products that are sent are correctly labelled, as prescribed in the regulations.

Mr. Mike Lake: As opposed to...? Whose responsibility is it now?

Ms. Mona Frendo: I'm sorry. I didn't hear you.

Mr. Mike Lake: Whose responsibility is it now?

Ms. Mona Frendo: Currently it's the Minister of Health who would verify that the labelling requirements, which are a WTO requirement, are met. That's currently in section 21.04 of the Patent Act.

Mr. Mike Lake: Brian, what's the rationale for that, if you could answer?

The Chair: Go right ahead, sir.

Mr. Brian Masse: Thank you.

It's because of what we've seen. Because of this regime, countries have to guess at how many drugs they need when they go through the whole rigmarole of the application process. They're doing their best guesstimate. Yes, they can go back a second time to request more, but as we've seen in the case of Rwanda, that could be time-consuming, but it could also be larger than their original request.

This empowers them to have the capability to respond to those changing needs that would happen in the actual treatment, whether it be of HIV, malaria, tuberculosis, or whatever it is. With clause 4 not being adopted, it would be absolutely cruel to pass legislation in which, for example, just because they guessed wrong on the original application, they couldn't treat people with the increased drugs that are necessary.

The bill has already been pared down quite significantly with the defeat of clause 4. This is just at least a modest attempt to allow some flexibility. You have to remember that everybody still wants to be WTO compliant. The whole sinister set of stories and plots—of diversions and replicas and knock-offs, and that whole series of things—is unfounded; there's been no evidence of any of these things at all. At the very least, we could err on the side of flexibility, so that if their judgment is wrong when they apply for the number of medicines, there could be some flexibility to make sure that the shortfall can be made up at the end of the day, rather than making people and countries go through a whole new set of application processes.

It would also allow the generics to know that they could ramp up production, if necessary. It costs them to do this as well, and that's the worst thing: the pharmaceutical companies are going to get more profit, because they're actually getting royalties.

Mr. Mike Lake: Could I come back to the officials, then, to comment on Mr. Masse's comments concerning the WTO? It sounds as though the trade arguments are rather fictitious. Maybe you could comment on that.

Ms. Mona Frendo: Perhaps I'll start, and then others can respond.

As I mentioned earlier on the WTO waiver decision, in light of the concern that there was a need in developing countries but that there was this existing international intellectual property obligation system in place and the model was not going to be revamped entirely, the decision was carefully defined and limited to provide this limited exception to existing intellectual property rights and standards.

Within that carefully defined model and structure, certain obligations were waived under the WTO decision, but it was specifically stated that the intent of the waiver was to respond to a country's need for a particular amount of drugs. To allow for an unlimited export may not be in the spirit of that decision.

• (1150)

Mr. Mike Lake: Mr. Masse made a comment about how time-consuming it was to go back in the Rwanda case. Can you attach some numbers to that specific case? Are you able to do that in terms of the Apotex case?

Ms. Mona Frendo: I'm sorry. Could you repeat the question for me, please?

Mr. Mike Lake: In terms of the Apotex case, Mr. Masse referred to how time-consuming it is to add on if you guess the number wrong, using Mr. Masse's words, how time-consuming it is under the process to add on and get the number "right", in a sense.

Ms. Mona Frendo: I guess we're dealing with the hypothetical, because it didn't happen in the Apotex example.

Mr. Mike Lake: Yes, okay. I'm sorry.

Ms. Mona Frendo: If we use that as an example, Apotex had already gone through the approval process with Health Canada for that particular drug; that was met. When it applied for the first time for its authorization under CAMR, it took less than two weeks for the Commissioner of Patents to issue that authorization, so it was an extremely timely response, very quickly done.

Had the situation arisen that another country wanted that same product and Apotex was able to respond to that need, I would assume that it would simply be reapplying for that particular drug. They had all the information done, they had done all the checks they needed to do with the patentees, they had received all the information they needed, and they had filled out all the forms. It would just have been a resubmission. That didn't happen in this case because no other country notified.

But assuming that all of those requirements were met, it would have been a very timely response, I would imagine.

Mr. Mike Lake: I have just one final question, because we do tend to get caught up—and I've heard this from some of the witnesses—in this discussion about intellectual property. It sounds very dry and it doesn't sound like a very good excuse for not doing something.

How important are the rules around intellectual property, the sort of strictness of the regime in terms of development of new treatments or of the very treatments that we talk about, the first-, second-, and third-generation treatments for pharmaceuticals? How important is a good intellectual property regime in encouraging the development of new treatments for not only HIV and AIDS but for cancers and other diseases that people around the world would be faced with?

I think that's the crux of some of our hesitation with this bill, and I sense some of the hesitation of some witnesses towards this legislation: that it's around IP, which tends to be a dry subject. But it's a question of getting our heads around how important good IP policy is to the development of the pharmaceuticals we need.

It's a pretty broad question, I know.

Ms. Colette Downie: I think we all agree that it's a pretty dry subject area, but it's an important area, because basically the patent system is set up to reward investment, particularly in the area of medicines, where the investment can be huge to develop new medicines and bring them to production. The idea is that in exchange for investing in the development of those products, companies get a 20-year exclusive period to sell the particular results of that investment.

The idea with CAMR, though, is that there is an exception to that, so it's structured to make sure that you continue to have incentives to invest and develop products and actually sell them in Canada, while at the same time allowing for the provision in emergencies or in a situation of a particular health crisis to make an exception to that particular regime.

That's the reason why... Preserving that incentive for investment is the reason why CAMR is delineated in the way that it is. The restrictions are designed to make sure that the definition is very clear, while at the same time preserving incentives to continue to develop products and sell them in Canada.

•(1155)

Mr. Mike Lake: Thank you.

The Chair: Thank you, Mr. Lake.

Mr. Masse.

Mr. Brian Masse: Mr. Chair, I've tried to restrict my interventions over the last two days because I was conscious of the time. I hope we're going to agree to finish this bill.

The WTO talked about expected quantities, not CAMR's maximum. So I find it hard to believe that you'd actually have a WTO challenge if, for example, Rwanda went back and asked for another \$200,000 in pills for children for the treatment of HIV, tuberculosis, or malaria. I hope we can move on.

The Chair: Seeing no other comments, shall clause 5 carry? I need a show of hands, please.

(Clause 5 agreed to)

The Chair: Clause 5 carries.

(On clause 13)

The Chair: Moving along in the spirit of dealing with the amendments first, the last clause we have is clause 13, with amendment Lib-4.1. However, then we will have to deal with the oft-talked about withdrawal of certain clauses, but first let's talk about Lib-4.1 in clause 13.

Mr. Garneau.

Mr. Marc Garneau: One moment, please.

Well, as I mentioned before, Chair, the purpose of the amendment to clause 13 was to restore the existing section 21.16, which is connected to the restoration of the existing application process, in accordance with the amendment that was defeated, amendment Lib-2, which deleted subclause 4(2). So I'm not 100% sure at this point whether it still needs to be debated.

The Chair: Okay. Is there any debate on that, or any comments, or will we go right to the question?

Mr. Lake.

Mr. Mike Lake: Again, I would want to understand the impacts. Dealing with clause 13, what is it that clause 13 would change in the act? It impacts section 21.16. Starting with what the purpose of section 21.16 is, what would clause 13 do to change it?

Mr. Marc Garneau: I'm not an expert on it, but as I understand it, if amendment Lib-2 had been adopted, then it would be important to make this change, but since it wasn't, it's really a moot point at this stage.

Mr. Mike Lake: Are you withdrawing the amendment?

Mr. Marc Garneau: I'm willing to withdraw it, yes.

The Chair: Are you willing to withdraw that amendment?

Mr. Marc Garneau: Agreed.

(Amendment withdrawn)

The Chair: Okay.

Mr. Mike Lake: Then, Mr. Chair, obviously we are on clause 13, so can I suggest that we move back and go in the proper order and get back to clause 6 now? We'll come back to clause 13 in order.

The Chair: We'll come back to clause 6, then, I believe. Clause 5?

The first clause without amendment is clause 1.

Shall clause 1 carry?

Mr. Mike Lake: Clause 1 is just the purpose, the intent, of the bill.

The Chair: Okay. Shall clause 1 carry, then?

Some hon. members: Agreed.

(Clause 1 agreed to)

(On clause 6)

The Chair: Now we move on to clause 6.

Mr. Masse, I'm advised by our legislative expert that the committee will have to defeat clauses 6, 7, 8, 11, 12, 14, and 16, which you previously identified, to remove them. Is that correct?

Mr. Brian Masse: Yes, and clause 17 is on that list.

•(1200)

The Chair: And 17?

Mr. Brian Masse: Yes.

The Chair: Okay. Actually, we can do something that we are very familiar with. Just to confirm again, for clauses 6, 7, 8, 11, 12, 14, 16, and 17, we can vote on clause 6 and then we can apply the vote to those others identified, if that has the agreement of the committee.

Some hon. members: Agreed.

Mr. Mike Lake: Can you just go through those numbers one more time?

The Chair: Sure. I'll confirm them with you, Mr. Lake. They are clauses 6, 7, 8, 11, 12, 14, 16, and 17.

Mr. Mike Lake: That will leave us with clauses 9, 10, 13, and 15. Is that correct?

The Chair: That's correct. So shall clause 6 carry?

Some hon. members: No.

The Chair: Is it agreed to apply that to the rest of them so identified?

Some hon. members: Agreed.

(Clauses 6, 7, 8, 11, 12, 14, 16, and 17 negatived)

(On clause 9)

The Chair: Go ahead, Mr. Lake.

Mr. Mike Lake: Mr. Masse wiped out eight clauses, so obviously he has defended the clauses that he thinks are the most important.

Before I go to the officials, maybe he could give a justification for what clause 9 would accomplish that he's looking to accomplish here.

Mr. Brian Masse: In my understanding, clauses 9 and 10 eliminate the two-year limit, so the actual drugs could be sent to the country in that timeframe. It gets rid of the two-year restriction.

Mr. Mike Lake: Okay. Again I'll ask the officials, if I could, for the purpose of section 21.09 in the first place. That would be the portion of the act that would be repealed through clause 9, which is a pretty short clause. What would the ramifications be? It's pretty clear what the impact would be if we just repealed the whole clause. What would be the ramifications of that?

Ms. Mona Frendo: Mr. Masse is correct. Currently, section 21.09 of the Patent Act states that a CAMR authorization is valid for two years from the date of the grant. That was reflective of several WTO requirements in the decision, including paragraph 2(c) of the waiver, which requires a country that authorizes the export—so a country like Canada—of a pharmaceutical product under its regime to notify the WTO of the quantities for which the authorization has been granted and the duration. Reflective of that and other WTO requirements, section 21.09 of the Patent Act presently describes the duration of an export, and it says that it would be valid for two years from the date of grant.

Clause 9 of Bill C-393 would delete this section altogether. It's a short section, but it is an important section in the regime.

Mr. Mike Lake: Where did it come from? Why is it two years? What's the rationale for or origin of the two years?

Ms. Mona Frendo: When CAMR was developed and reviewed by Parliament, there was testimony by several pharmaceutical manufacturing companies that the duration of the average pharmaceutical supply contract was two years, so that was taken into consideration.

There was also the interest in making sure that importing countries that chose to use the decision to receive drugs wouldn't be tied to an indefinite contract. They could go out and seek the best price in the marketplace at that time and there wouldn't be an unlimited duration of a contract under CAMR.

• (1205)

The Chair: Thank you, Mr. Lake.

Mr. Garneau.

Mr. Marc Garneau: I just have a point of clarification, if I might ask.

You mentioned a two-year maximum duration for the licence. Is there a possibility of an additional or second two-year period? Is that included in there?

Ms. Mona Frendo: It's in clause 10 of the bill, which speaks to the renewal of the authorization under CAMR. So yes, there would be the possibility, if the need were identified, that the authorization under CAMR could be extended for another two years to deal with any circumstances that may arise.

Mr. Marc Garneau: Okay. So it's for up to four years.

Ms. Mona Frendo: Yes.

The Chair: Thank you.

Just to be clear, that's clause 10 of this bill you are talking about, not the section in the existing legislation

Ms. Mona Frendo: Right, it's clause 10, which deals with section 21.12 of the Patent Act.

Clause 9 deals with section 21.09 of the Patent Act and clause 10 deals with section 21.12.

The Chair: Thank you.

Mr. Masse.

Mr. Brian Masse: Just to be clear, clause 10 allows the extension of...not the quantity of drugs. It just provides more flexibility and consistency to apply the drugs to the country. That's why we have both clauses 9 and 10 in there.

Mr. Mike Lake: Because Mr. Masse is talking about clauses 9 and 10 together, I just want to get some clarification on how they work together.

How do sections 21.09 and 21.12 work? I understand that under section 21.12 the authorization may only be renewed once, so that's one of the restrictions in section 21.12. I know we're dealing with a different clause for that, but they do work together.

Again, what would be the effect of wiping out section 21.12 altogether? What would that do? It seems as if it is unlimited at that point, right? Am I missing something?

Ms. Mona Frendo: Yes, if you read clauses 9 and 10 of Bill C-393 together, they would allow a CAMR authorization holder to produce and export the drugs authorized in the application indefinitely. That is the consequence of clauses 9 and 10 read together, because there would be no limit to the duration of a CAMR authorization and no need for renewal because it would be indefinite.

The Chair: Mr. Garneau.

Mr. Marc Garneau: So if clause 9 were rejected and did not carry, would that make clause 10 a moot point?

Ms. Mona Frendo: If clause 9 were struck down? Is that what you're suggesting?

Mr. Marc Garneau: Yes, I'm sorry.

Ms. Mona Frendo: If clause 9 were struck down.... I'll just take a look at it.

Mr. Rob Sutherland-Brown: If there is no section 21.09 then section 21.12 doesn't arise. If you don't have an initial term, you would not have a renewed term.

Mr. Marc Garneau: If clause 9 carries, but clause 10 does not, what is the bottom line there?

Ms. Mona Frendo: If clause 9 carries, then the licence is indefinite, because there is no limit to the duration of the licence. Clause 9 is the provision in the Patent Act that deals with the original duration of a CAMR authorization. Section 21.12 only deals with the renewal, in the circumstances that it is needed, but section 21.09 is the original provision that deals with the original duration of the licence.

The Chair: Thank you.

Mr. Mike Lake: I'd like to follow up on that line of questioning because this is kind of tricky. So if clause 9 passes, then, you'll never get to the point of needing a renewal, because it would be indefinite right off the bat. Is that accurate?

Ms. Mona Frendo: That's my understanding. Yes.

Mr. Mike Lake: So section 21.12 of the Patent Act becomes useless anyway. If we defeat clause 9, then we still have the two-year limit and you could still pass clause 10. But the ramifications of passing clause 10 would actually be the opposite of what Mr. Masse intends, because you would have no option for renewal at all if clause 9 were defeated and we passed clause 10. Could you just clarify?

• (1210)

Ms. Colette Downie: My understanding is that if clause 9 is defeated—

Mr. Mike Lake: No, because if clause 9 were defeated it would leave the duration intact, and then if clause 10 were passed you'd actually lose all rights for any kind of renewal.

Ms. Colette Downie: That's right.

Ms. Mona Frendo: That's right. The key provision on duration is clause 9. Clause 10 deals only with the renewal. If there is no limit on duration as a result of clause 9, then there is no consequence for clause 10.

The Chair: Mr. Braid.

Mr. Peter Braid: I have one final question, then. If there is an unlimited timeframe during which these medications can be exported, does that in any way dilute intellectual property rights? And if so, how?

Ms. Mona Frendo: I'm sorry. Can you repeat the question? I apologize, but I didn't hear the front end of that question.

Mr. Peter Braid: If there is an unlimited period of time during which a medication can be exported, does that dilute intellectual property rights at all?

Ms. Mona Frendo: It dilutes them less than would be the case if there were no time limit on export, because the WTO decision and CAMR in turn provide opportunities for a generic version of patented products to be made. These are protected products in Canada that will be made and sent to other countries. If there were no time limit on the manufacture of these drugs, there would be more of a concern for companies.

Mr. Peter Braid: Would IPRs be more diluted as a result?

Ms. Mona Frendo: I think patentees would have that concern, certainly.

Mr. Rob Sutherland-Brown: If I could add to that, there is a general provision in the TRIPS article that allows for compulsory licensing in the domestic setting. It stipulates that when you allow an authorization or when you allow for compulsory licensing, you must have a feature so you can review it.

You must also have a feature that provides the patentee with an opportunity to bring forth evidence showing that the circumstances that gave rise to the issuance of a compulsory licence no longer exist and so the authority should terminate. It's a general proposition that is designed to defend the intellectual property system.

Mr. Peter Braid: Thank you.

Mr. Mike Lake: Along that line of questioning, because it's kind of interesting, was there a reference to a time limit anywhere in the waiver?

Mr. Rob Sutherland-Brown: No, but it's in article 31 of the TRIPS agreement itself. Anybody who chooses to adopt legislation implementing a waiver still is responsible for meeting its obligations under the remaining articles or paragraphs of article 31 and TRIPS, which control the use of compulsory licensing in a domestic setting.

Mr. Mike Lake: So by definition, I guess, if it's not actually changed in the waiver, then TRIPS still applies.

Mr. Rob Sutherland-Brown: Yes, that's right.

The Chair: All right, members.

Seeing no other questions or debate, shall clause 9 carry? I had better get a show of hands. I see five hands. Opposed? Six hands.

(Clause 9 negated)

(Clause 10 negated)

(On clause 13)

The Chair: If you remember, the amendment on clause 13 was withdrawn, I believe. Shall clause 13—

Mr. Lake. I'm sorry. I got ahead of myself.

• (1215)

Mr. Mike Lake: No. That's okay. I want to fully understand the ramifications of clause 13. Again, clause 13 now deals with section 21.16. I again want to come back to section 21.16, what the purpose is of section 21.16 in the first place, and maybe the rationale that goes into it, and then the effect clause 13 would have on that.

Ms. Mona Frendo: Section 21.16 of the Patent Act presently describes the obligation on the authorization holder to provide the patentee or patentees, as the case may be—and it was that case in the Apotex example—as well as the Commissioner of Patents with a copy of the agreement. So once the agreement is signed with an importing country or user to supply a particular drug to a particular country, that's the obligation that appears. Currently in the Patent Act, under section 21.16, it's an obligation to provide a copy of the contract, basically.

Clause 13 of Bill C-393 would change the section. It would eliminate the requirement that the agreement to supply include the name and the particulars of the authorized product for export, the name of the country, and the name of the drug purchaser as applicable. It would remove a number of pieces of information that would have to be provided. It's of concern because, when read with other changes in Bill C-393, it would reduce the transparency in the system.

Mr. Mike Lake: Mr. Masse, if I could again, there were three clauses that you thought were important enough to leave in when you struck out the other eight. What is it about this one? Why is it critical?

Mr. Brian Masse: It's the time of when entering the agreement, and once again, it's the amount of information and requirements that seem to convolute the application for it. It's less of consequence now that clause 4 has been basically defeated, but to me, it's not as important as previous ones. It takes away entering into an agreement so it gives a little more flexibility for those who are making application.

I still don't believe, despite clause 4 not being changed, we still have.... I don't know where the abuse elements that seem to be suggested would take place. I don't know where they keep coming from, because they don't exist in reality. To me, it's a modest change.

Mr. Mike Lake: Again, on that comment about the abuse elements not actually taking place in reality, could you comment on that? As we've gone through the bill, the potential for abuse seems to be a real concern.

Ms. Colette Downie: Right. I guess the way we would think about the issue is that the regime in CAMR is not enforced by the government; it's meant to be enforced by rights holders. So the transparency requirements—for example, some of the things that are dealt with in section 21.16 of the Patent Act and that clause 13 would amend—are meant to assist that private enforcement of the regime. If there's no transparency about the name of the country or the particulars of the authorized product for export, it's very difficult to then enforce those requirements should they not be respected.

Mr. Mike Lake: Okay.

So again, the transparency—

I'm sorry. Go ahead, Ms. Frendo.

Ms. Mona Frendo: I'm sorry. I was just simply going to add to that point that, as has been mentioned before, throughout this regime it tries to ensure that the drugs are not exported for commercial purposes.

So again, providing this kind of information as part of providing an obligation on the authorization holder to provide a copy of the agreement, when signed, to the patentee and to the importing countries, helps ensure that there is transparency, but also that there are measures in place to ensure the regime is not used for commercial purposes, which would be contrary to the objectives of the WTO decision.

• (1220)

The Chair: Thank you.

Mr. Braid.

Mr. Peter Braid: Thank you, Mr. Chair.

Quickly cutting to the chase, then, are you saying—and I will get you to confirm—that the reason to address Mr. Masse's point that there hasn't been abuse is that there are safeguards in place, those safeguards have helped to prevent abuse, and Bill C-393 removes many of the safeguards?

Ms. Mona Frendo: Certainly, there were a number of safeguards built into the Patent Act to ensure that the regime would be used and applied in accordance with the WTO decision and the objectives by which it was implemented in Canada. Bill C-393 does remove a number of those amendments. I'm not going to go through it now that we've had various changes and amendments, but Bill C-393 does remove a number of those safeguards.

The Chair: Thank you.

That appears to be the end of our debate.

Shall clause 13 carry? Can I see a show of hands again, please?

(Clause 13 agreed to)

The Chair: All right.

Shall the schedule as amended carry?

Mr. Lake.

Mr. Mike Lake: I have a quick question. Could you summarize what the changes were to all the schedules? We had four schedules that are now two, right?

The Chair: I would need some assistance on that myself.

Mr. Mike Lake: That's why I'm asking. Maybe the researchers or the analysts...?

Mr. Mark Mahabir (Committee Researcher): The schedule in the bill has been renamed schedule 2.

Mr. Mike Lake: So schedule 1 is what now in the amended bill?

Mr. Mike MacPherson: Right now, the bill as amended by the committee leaves schedule 1 of the Patent Act intact, and the schedule that was found in Bill C-393 now becomes schedule 2. There are two schedules. The first schedule, schedule 1, was the list of pharmaceutical products or drugs or—

Mr. Mike Lake: But schedule 2 replaces the three schedules that were—

Mr. Mike MacPherson: Exactly. The new schedule 2 is a list of countries. That basically consolidates the three other schedules that listed countries. Now we just have one list of countries and that would be schedule 2.

Mr. Mike Lake: So what are we voting on right now?

The Chair: The schedule as amended.

Mr. Mike Lake: But there are two schedules. Are we voting on both of them in one vote?

An hon. member: No.

Mr. Mike Lake: So we are just voting on schedule 2, the country list. If we vote yes for the country list, we're saying that it is a better option than having the three country lists that we did previously. I want to make sure we're clear on that.

Mr. Mike MacPherson: It's my understanding that the three country lists have been—

Mr. Mike Lake: —dealt with within the clauses of the bill. Okay.

The Chair: Are there further questions?

Seeing none, shall the schedule as amended carry?

Some hon. members: Agreed.

The Chair: Shall the title carry?

Some hon. members: Agreed.

The Chair: That's agreed. That seems to be the same division.

Shall the bill as amended carry?

An hon. member: Could I ask for a recorded vote on that?

The Chair: Yes, let's do a recorded vote.

(Bill as amended agreed to [See *Minutes of Proceedings*])

The Chair: Shall I report the bill as amended to the House?

Some hon. members: Agreed.

The Chair: All right. This bill is carried as amended.

The Chair: Shall the committee order a reprint of the bill?

Some hon. members: Agreed.

That will mean that our meeting is adjourned.

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