Federal Court  Cour fédérale

**Date: 20110126**

**Docket: T-575-04**

**Citation: 2011FC88**

**BETWEEN:**

**APOTEX INC.**

**Plaintiff/**
**Defendant by**
**Counterclaim**

**and**

**H. LUNDBECK A/S AND**
**LUNDBECK CANADA INC.**

**Defendants/**
**Plaintiffs by**
**Counterclaim**

## REASONS FOR ORDER

**TABIB P.**

[1] The Court is seized of two motions for the issuance of Letters of Request or Letters Rogatory seeking the assistance of foreign Courts in securing the testimony of persons residing in their jurisdiction.

[2] The Plaintiff, Apotex Inc. ("Apotex") seeks to examine Dr. Robert Michael Adlington out of Court, in England, for trial.

[3] The Defendant, H. Lundbeck A/S and Lundbeck Canada Inc. ("Lundbeck") seeks to examine a representative or representatives of Matrix Laboratories Ltd., on discovery, in India.

**The proceedings**

[4] Apotex commenced the within action against Lundbeck for damages caused to Apotex by the exclusion of its citalopram drug product from the market in Canada in the period from July 24, 2002 to January 7, 2004, pursuant to Section 8 of the *Patented Medicines (Notice of Compliance) Regulations*.

[5] Lundbeck defended the action and counterclaimed for damages for infringement of several patents, including Canadian Letters Patent No. 2,360,287 (the "287 Patent") in the period from 2001 to date. It appears that Apotex, even though it was not authorized to sell citalopram in Canada until January 7, 2004, was nevertheless importing citalopram and formulating same into tablets during that period, stockpiling same in preparation of future sales. Apotex defended the infringement counterclaim, inter alia, on the basis that the '287 Patent was not infringed.

[6] The '287 Patent covers part of the process for manufacturing citalopram as an active pharmaceutical ingredient ("API"), in particular, the process involving the formation of citalopram base in crystalline form.

[7] The API for Apotex's citalopram drug product was, at the relevant time, manufactured and supplied by Matrix Laboratories Ltd. ("Matrix") in India.

[8] One of the central and highly contentious issues in this action is whether, in the period from 2001 to 2004 inclusive, Matrix did supply to Apotex or was capable of supplying to Apotex citalopram API manufactured through a non-infringing process.

[9] To date, Matrix has only supplied batch records for some batches manufactured in 2005. Apotex reports that Matrix has informed it that it had destroyed all batch records for citalopram API manufactured for Apotex prior to 2005, pursuant to its record destruction policy.

[10] In 2002, Dr. Adlington, a chemistry professor at Oxford University, in the context of European proceedings instituted by Lundbeck against Lagap Pharmaceuticals, another generic pharmaceutical company sourcing its product from Matrix, visited Matrix and produced a number of reports based on his observations and conclusions. These reports dealt with the nature of the Matrix process and whether it could operate on an industrial scale and was in fact operating on such a scale. Apotex wishes to secure Dr. Adlington's testimony for the trial herein.

[11] With respect to Lundbeck's request to have discovery of a representative of Matrix, Apotex has announced that, despite the destruction of batch manufacturing records created prior to 2005, it would call as a witness at trial a representative of Matrix to testify orally to Matrix's method of production of the citalopram supplied to Apotex. Lundbeck has long asserted that, in those circumstances, it should have the right to have full and complete discovery of Matrix prior to the trial.

[12] As some of the facts and considerations relevant to both motions were interrelated, the motions were heard together. At the hearing, counsel for Lundbeck sought to introduce an unsworn statement in response from its Indian law expert; Apotex objected. As the written statement consisted mainly of bare assertions of disagreement with the opinions of Apotex's expert – themselves consisting mostly of bare assertions, and as the Court considered that the issues addressed in the proposed reply were sufficiently addressed in the parties' respective records, leave to file the reply was not granted and the reply was not considered.

**Dr. Adlington**

[13] Evidence at trial is to be given orally at the trial, but the Court has discretion to permit evidence to be taken out of Court. Where the witness to be examined will not voluntarily appear to give evidence and is not within the Court's territorial jurisdiction, the Court may also exercise its discretion to seek the assistance of the judicial authority where the witness is located to compel the attendance of the witness. Taking the evidence of a witness for trial in a foreign jurisdiction pursuant to letters of request may be done out of Court, that is, outside the presence of the trial Judge, or may be done as part of the trial, in the presence of the trial Judge, so that it then becomes evidence given orally at the trial. Here, Apotex requests both that Dr. Adlington's evidence be taken out of Court and that it be compelled through letters rogatory addressed to the English Court.

[14] It is trite law that, in both cases, (examinations out of Court for trial and issuance of letters rogatory) the moving party must satisfy the Court that there is a good reason why the witness cannot be brought before the Court or will not attend to testify at the trial.

[15] The only evidence provided by Apotex as to the reasons given by Dr. Adlington for not voluntarily giving evidence in this matter, either at the trial or in Canada, is by way of double hearsay: Mr. Topolski's affidavit reports that Dr. Scott, a scientist in the employ of Goodmans, informed him that he had contacted Dr. Adlington on October 27, 2010 to determine his availability to give evidence and that Dr. Adlington advised Dr. Scott on October 28, 2010 that "in his view, he could not provide evidence voluntarily because of an agreement between Lagap and Lundbeck that he would not be retained by another generic in matters relating to the Matrix process". The confirmation letter sent to Dr. Adlington by Mr. Crofoot, of Goodmans, on December 3, 2010 is slightly different, citing the reason as "a result of terms of agreement entered into with Lundbeck". The affidavit of William Dixon, the English law expert of Apotex, states on the other hand that he was advised by Mr. Crofoot that Dr. Adlington had given as reasons "the terms of the settlement agreements between Lagap Pharmaceuticals and Lundbeck entered into in or about 2004".

[16] Anticipating that the precise terms and scope of any agreement or order preventing Dr. Adlington from testifying would become relevant on this motion, I directed Lundbeck's counsel on December 13, 2010 to "continue their efforts to secure copies of relevant confidentiality orders or agreements covering information, documents and/or evidence generated, obtained or produced in the context of foreign proceedings relating to Matrix's method of manufacture" and to communicate same to the Court and to Apotex as soon as it was received.

[17] Lundbeck's response to that direction is apparently contained in the evidence tendered in response to Apotex's motion. On that evidence, the only known impediment to the testimony of Dr. Adlington arises from the confidentiality Orders issued by the English High Court of Justice,

one of which was made as a result of the settlement agreement between Lundbeck and Lagap/Sandoz. There may also have been independent confidentiality undertakings signed by Dr. Adlington in favour of Lagap and/or Matrix, but that is a matter of speculation. I note, in any event, that this type of confidentiality undertaking would be quite different from an agreement "with Lundbeck" or "between Lundbeck and Lagap", as reportedly referred to by Dr. Adlington.

[18] The wording used in the affidavits of Neil Jenkins, the English solicitor who acted for Lundbeck in the English proceedings, and of John Meidahl Petersen, a representative of Lundbeck, might be open to some interpretation, suggesting that there might be other agreements entered into between Lundbeck and Lagap, Sandoz or Dr. Adlington that would prevent Dr. Adlington from testifying in this matter, of which Mr. Jenkins would be unaware. However, such an interpretation would be most contrived. Further, in view of the clear direction issued on December 13, 2010 and the fact that a representative of Lundbeck swore a responding affidavit to Apotex's motion that is entirely silent as to any such agreement, it is presumed that if Lundbeck was aware of such an agreement, it has chosen not to disclose or rely upon it. Counsel for Lundbeck at the hearing confirmed, in any event, that to the extent such agreements existed in favour of Lundbeck, Lundbeck was indeed waiving the benefit of confidentiality in respect of Dr. Adlington's evidence (subject of course to Lundbeck's objection to the admissibility of Dr. Adlington's evidence if confidentiality restrictions were to prevent Lundbeck from conducting a full and fair cross-examination (see below)).

[19] Thus, on the evidence before me, the only things standing in the way of Dr. Adlington voluntarily coming to testify in Canada are the confidentiality Orders of the English High Court of

Justice dated November 8, 2002, November 18, 2002 and October 13, 2003. These Orders clearly stipulate that Lundbeck and all individuals listed in Schedule "A" of the Orders, of which Dr. Adlington is one, are to keep the information at issue confidential and not use it other than for the purpose of the English proceedings "except with the written consent of Matrix".

[20] Matrix has, expressly and in writing, consented "to release Dr. Adlington and the parties to that litigation [UK proceedings] from any pledge of confidentiality respecting specifically Dr. Adlington's reports, notes, records, observations and conclusions" for the purposes of the proceedings herein and subject to the maintenance of confidentiality of the information.

[21] In addition, the Orders issued by the English Court specifically exempt from the confidentiality obligation the reports of Dr. Adlington dated October 6 and/or October 31, 2002, which appear to relate to the first attendance of Dr. Adlington at Matrix's premises in October 2002, or any report or evidence filed by Lagap or Matrix in parallel litigation concerning the patents. From that, one can infer that Lagap and Matrix may have previously publicly filed evidence, including evidence from Dr. Adlington, relating to Matrix's process, and that Dr. Adlington was never prevented from testifying as to that evidence. The Orders appear designed to apply to such evidence as concern the joint attendance of experts and representatives of Lundbeck and Lagap at Matrix's premises in November 2002.

[22] Whether Dr. Adlington required Matrix's leave to offer any testimony in this matter, or could have offered some testimony in any event, the fact of the matter is that, on the evidence before me, the reason given by Dr. Adlington to decline to attend to give evidence at trial and/or in Canada

does not or no longer exists. Apotex has failed to show a good reason why Dr. Adlington cannot or will not attend at the trial in Canada to give evidence, and that is enough to dispose of the motion.

[23] I note that Lundbeck raised, as part of its objection to Apotex's motion, the inherent unfairness of allowing Dr. Adlington to testify as to his observations, reports or opinions, when the specific and limited waiver of confidentiality given by Matrix might prevent Lundbeck from using the observations, reports and opinions of its own experts and observers who were present at Matrix's facilities in November 2002 to cross-examine or contradict the evidence of Dr. Adlington.

[24] Counsel for Apotex suggested that it would be appropriate for letters of request to be addressed to the English judicial authorities, as that would allow the English High Court to resolve any issue as to the application of its own confidentiality Orders.

[25] In my view, it is not appropriate to issue letters of request for such a purpose, nor would it likely be effective in this instance. The Orders of the English Court are clear: Matrix's consent is all that is needed to release any party or individual listed in the Orders' schedule from their obligation. Whether Matrix's written consent, as now given, includes or necessarily implies an additional waiver to permit effective or fair use of Dr. Adlington's evidence in this action, whether Dr. Adlington's evidence should be admitted in evidence if fair use of that evidence cannot be ensured, and the extent to which any question that may be posed by Lundbeck in cross-examination is permissible in view of any remaining confidentiality stricture are all matters for the trial Judge in this action. I very much doubt that the High Court of Justice could or would wade into these debates in the course of receiving letters rogatory in any but the most superficial manner.

[26] In any event, Apotex suggested at the hearing that Matrix had not had an opportunity to consider Lundbeck's request for confirmation that its waiver should include all the individuals listed in the schedule to the English Orders and all materials used in the UK proceedings, and that Matrix may yet do so, thus obviating the problem. I note also that to the extent there are indeed issues arising from the confidentiality Orders or from Matrix's partial waiver that can only be resolved by application to the High Court of Justice, the parties themselves are capable of bringing such an application to the High Court independently of any letters of request. It is not appropriate to use letters of request for judicial assistance from this Court as a vehicle to seek rulings by a foreign court as to the scope or application of its orders.

[27] Finally, considering the scope and subject matter of the evidence proposed to be canvassed by Apotex with Dr. Adlington, as set out in the draft letters of request, it appears that much of the proposed evidence might involve the expression of an opinion by Dr. Adlington. Apotex has not yet served or filed an affidavit or statement of expert evidence from Dr. Adlington, and any attempt to elicit opinion evidence from him without prior delivery of an expert report will undoubtedly raise objections requiring immediate rulings. It would thus be essential that any testimony to be given by Dr. Adlington be given in the presence of the trial Judge, and not out of Court.

**Matrix's representatives**

*a) The right to discovery*

[28] The first issue to be determined on Lundbeck's motion for the issuance of letters rogatory for the discovery of a representative of Matrix in India is whether Lundbeck should be given leave

to compel the attendance of a third party on discovery. The criteria to be met by Lundbeck for that are as follows:

(a) That the third party may have information on an issue in the action;

(b) That the party has been unable to obtain the information informally from the person or from another source by any other reasonable means;

(c) That it would be unfair not to allow the party an opportunity to question the person before trial; and

(d) That the questioning will not cause undue delay, inconvenience or expense to the person or to the other parties.

[29] Of paramount issue in this proceeding is the question of whether the citalopram supplied by Matrix to Apotex between the beginning of 2001 and the end of 2004 was manufactured in accordance with a process infringing the '287 Patent owned by Lundbeck. Matrix, as a manufacturer, clearly has information on that issue.

[30] Apotex claims that Lundbeck has not satisfied the second criteria of the test, because Matrix has "fully" cooperated in providing information when requested by Apotex, and that Lundbeck's request for discovery from Matrix ought to have been or to be submitted to Matrix through the discovery of Apotex.

[31] Apotex's position that Matrix has been or is "fully" cooperating is contradicted by the evidence before me. On May 27, 2005, Lundbeck examined a representative of Apotex on discovery and specifically asked Apotex to provide "the detailed manufacturing process for the

active ingredient, the batch records for the chemical manufacturing and the DMF", "a copy of the batch records, the processing instructions, the master formula, the Q & A analysis and the DMF between 2002 and 2004", and all documents in regard of Matrix's change to its process over time. To all questions, Apotex responded on September 24, 2007 that: "While Apotex has made enquiries for the information from its supplier, it has not been provided copies of these documents. If same are made available to Apotex, it will provide same to the Defendants."

[32] Matrix did not cooperate with Apotex on that occasion and did not provide the manufacturing documents sought – it still has not.

[33] On October 17, 2008, the Court ordered Apotex to forward to Matrix a letter requesting Matrix to answer certain questions asked on discovery; the Order provided that "should Matrix fail to provide the requested information, Lundbeck would be at liberty to move for examination for discovery of a representative of Matrix". Apotex wrote, enclosing the Court's Order, asking for a response within 30 days of its letter. Matrix did not comply.

[34] More troubling still is the advice given by Apotex to the Court to the effect that Matrix had destroyed all batch production records for the citalopram it manufactured for Apotex prior to 2005, pursuant to its document control policy. Given Lundbeck's request for those documents through Apotex and given the importance of these documents, that they would have been destroyed by Matrix is troubling indeed. To further add to this, I note that the document control policy in question, as submitted by Apotex on its motion, provides for a retention policy of 6 years; yet, in the fall of 2010, when the advice was given that documents pre-dating 2005 had been destroyed,

documents relating to production in 2004 should not yet have been destroyed. The policy in question also provides that "documents relating to any legal proceedings must not be destroyed until the legal proceedings are declared closed"; on the evidence before me, it appears that Matrix was very well aware of the proceedings herein and had pledged to Apotex in 2004 that it would extend any help that may be required in this proceeding.

[35] On the basis of the above, it is abundantly clear that Matrix is not fully cooperating, that Apotex is unable or unwilling to ensure full cooperation from Matrix, or that Matrix's idea of fully cooperating with Apotex may involve tactics with which Apotex may think better than to be associated with.

[36] In addition, Apotex and Matrix have now confirmed that they intend to have a representative of Matrix appear at trial to give oral evidence of Matrix's manufacturing process between 2001 and 2004, when the contemporary documents that might have corroborated or contradicted that evidence have reportedly been destroyed, when the matter is crucial to the outcome of the proceedings and vigorously contested, and when the interpretation and credibility of the evidence will likely require expert opinion. Given these circumstances, it is clear that it would be unfair not to allow Lundbeck an opportunity to question the representative of Matrix before trial, and that questioning of Matrix through questions addressed to Apotex – even if Matrix could be relied upon to fully cooperate from this point on – would not be reasonably effective, given the complexity of the issues, to ensure that Lundbeck obtain all relevant information from Matrix prior to trial.

[37] Given that the reported destruction of the batch records for citalopram supplied to Apotex by Matrix between 2001 and 2004 and the announced attendance of Matrix at trial are the most important factors in my determination that Lundbeck be granted leave to examine Matrix on discovery, and given that both Matrix and Apotex could have prevented that situation from arising, any inconvenience or expense to Apotex or Matrix from the questioning would not be undue, in the circumstances.

*b) Identification of Matrix's representative*

[38] As part of its motion, Lundbeck also asks that Apotex be compelled to disclose to it and to the Court the identity of the representative or representatives of Matrix capable of answering questions relating to Matrix's manufacturing processes and which Apotex intends to call as witnesses at trial. Apotex has so far refused that request on the basis that it is under no obligation to do so. Neither party could refer to any precedent where the issue has been considered by the Court.

[39] It seems to me well within the powers of a case management Judge to order Apotex to disclose the precise identity of the representative or representatives of Matrix whom it intends or expects to call at trial to ensure that Lundbeck be allowed to question on discovery the very same person or persons. Because the representatives of Matrix to be called at trial will presumably be testifying on the basis of their personal knowledge, one expects that they will be knowledgeable of the subject matters to which they will testify and that they are therefore the appropriate representatives to be discovered. And because the discovery transcript of a third party may only be used at trial to cross-examine that third party if he or she is called as a witness at trial, justice,

fairness and the achievement of the purpose of the necessary discovery require that the discovery be made of the same individual or individuals who will be testifying at trial.

*c) The form of the letter of request*

[40] The experts for Lundbeck and Apotex both agree that Indian judicial authorities would, in principle, accept to give effect to letters of request from this Court for the purposes of compelling a witness in India to subject to an examination on discovery and to produce documents. The expert for Apotex, however, opined that the proposed letters of request, as originally submitted by Lundbeck, failed to be sufficiently precise as to the nature and time period of the documents to be produced and the subject matter about which the witnesses are to be questioned. When Lundbeck submitted, at the Court's request, a revised draft of the letters of request containing further specifics, Apotex objected to most of the proposed subject matters and documents, on the ground of relevance, over-breadth, lack of specificity and/or lack of necessity, as the information would be obtainable directly from Apotex.

[41] The Court is satisfied that the subject matters proposed for questioning and the documentary production requested by Lundbeck are generally appropriate.

[42] As mentioned in the direction of December 13, 2010, in the reported absence of the batch records for the citalopram actually supplied to Apotex, evidence showing that Matrix was manufacturing or was capable of manufacturing citalopram for other generics by a non-infringing process might be used to show a likelihood that Matrix also manufactured citalopram for Apotex by that same process – hence Apotex's desire to secure the testimony of Dr. Adlington. As case

management Judge, I am also aware that documents have been produced indicating that Matrix may have patented that process, and that Matrix's prices for supply of citalopram produced by that process were reported to be higher than prices quoted for citalopram produced by an infringing process. Enquiries into Matrix's comparative costs and prices for citalopram may therefore provide further indications of the process used in Apotex's case. As Apotex and Matrix allege that Matrix moved from an infringing process to a non-infringing process around September 2001, Matrix's policies as to the filing of applications for patents may also throw light on the timing of the alleged change.

[43] The orders and judgments of the Danish and Norwegian Courts on motions for interlocutory injunctions, submitted by Apotex in support of its motion, also show that there was significant controversy in those proceedings as to whether the sample batch production records produced by Matrix in these proceedings were authentic and whether the process witnessed could form the basis of commercial scale production, or at a rate sufficient to account for the volumes supplied by Matrix. It was noted by both Courts that the purposes of the attendance at Matrix had been the observation of the process, not the investigation of the authenticity of the documents. The trial here will be on the merits; the same issues are likely to arise; thus, Lundbeck's proposed enquiry into steps upstream and downstream of the patented process and any changes thereto, into the documents surrounding chemical and quality control analyses and into the quantities of citalopram produced in the relevant period are all potentially relevant to verify, corroborate or contradict Matrix and Apotex's allegations.

[44] As regards the subject matters concerning which Lundbeck has already had discovery of Apotex, or which it could have explored on discovery of Apotex, I do not find that Lundbeck should be prevented from exploring those questions with Matrix as well, especially since they are issues upon which Matrix has direct knowledge.

[45] Apotex objects that a request for production of "any documents" that would show Matrix's capacity to use a non-infringing process is improper, overly broad and open-ended, and that it would require the witness to make judgments as to what certain documents reveal. I do not accept Apotex's argument in the circumstances.

[46] Matrix is quoted by its Canadian agent as having made the following written statements:

> "(d) Matrix spent significant sums of money and organizational resources such as R&D and top management time in helping their European generic customers to successfully handle these litigations.
>
> (e) Matrix is willing to use their above experience and thus strengthen Apotex's case resulting out of the innovator suing Apotex over CA2360287.
>
> (f) Matrix is willing to share all details pertaining to their process and extend any help that may be required including the presence of Matrix personnel in Canada during the litigation if necessary, in order to assist Apotex."
>
> (See exhibit A to the affidavit of Jerry Topolski)

[47] Thus, it is expected that Matrix will know very specifically what documents are in its possession to show that very fact. As mentioned, if Matrix is to voluntarily appear at trial in Canada to assist Apotex in establishing both that it has manufactured citalopram for Apotex with a non-infringing process and that it had the capacity to do so, then any document it might seek to tender

for that purpose must be disclosed to Lundbeck well before trial and Lundbeck be given an opportunity to have discovery thereon. It is also fair that Lundbeck be permitted to directly put to Matrix, and well before trial, requests for production of any such documents, if only to be able to argue, if no documents have been produced and no explanation given, that a negative inference should be drawn.

[48] It should be remembered that in all examinations on discovery, whether a specific question, falling within a broadly relevant subject matter, is nevertheless relevant, appropriate or necessary, is a matter of appreciation, which cannot be ruled upon in advance. No doubt Apotex or Matrix will voice objections to specific questions where appropriate. Hopefully, all parties will cooperate to reformulate or narrow questions, where appropriate, or agree to allow the witness to answer under reserve of objection.

[49] With respect to Apotex's expert's comment to the effect that the proposed letter of request "does not include any statement providing for the reimbursement of the costs of the witness", he does not go further to say that this would be a formal requirement for the letter of request to be received by the Indian Court. To the extent the Indian Court requires an undertaking that the witness's costs be reimbursed, this obligation should fall on Lundbeck, and it is expected that Lundbeck or its Indian counsel on its behalf, will include the appropriate undertaking when they present the letter of request to the Indian Court.

[50] Finally, Apotex's Indian law expert opined that advanced production of documents, as requested by Lundbeck, "is not provided for under the applicable Indian Rules (Order XXVII rules 19-22)". The expert of Lundbeck, however, rendered an opinion to the effect that the

commissioners to be appointed by the Indian Court would have, by virtue of rule 16 of Order XXVII (referred to in rule 22 of the said Order), the power to ask the witness to submit documents in advance of the examination. Lundbeck's expert's reliance on a specific provision, not directly addressed by Apotex's expert, satisfies me that there is a reasonable likelihood that the Indian Courts would give effect to the proposed letter of request as drafted. To the extent the receiving Court is of the view that the commissioner's powers cannot include the power to request advanced production of documents, this Court hopes that the Indian Court will make such adaptations to the request as will give it effect to the extent permissible under Indian Law.

[51] I would add that, given that this Court has now ruled that Lundbeck is entitled to examine a representative of Matrix on discovery on all the proposed subject matters, and that the documentary production sought from it is appropriate, and given that Apotex and Matrix have professed full cooperation, it would be disappointing that Apotex or Matrix would demand that a formal order from an Indian Court be issued before producing or making available for inspection and copying the documents requested, or indeed, before the representative of Matrix who will be coming to testify at trial will voluntarily make himself or herself available to be examined on discovery. Indeed, in the circumstances, should for any reason Lundbeck be unable or precluded from having discovery of a representative of Matrix subsequently called to testify at trial, the admissibility, credibility or weight to be given to the testimony of that witness would be a matter within the discretion of the trial Judge.

"Mireille Tabib"

Prothonotary

Ottawa, Ontario
January 26, 2011

**FEDERAL COURT**

**SOLICITORS OF RECORD**

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| **DOCKET:** | T-575-04 |
| **STYLE OF CAUSE:** | APOTEX INC. v. H. LUNDBECK A/S ET AL. |
| **PLACE OF HEARING:** | OTTAWA |
| **DATE OF HEARING:** | JANUARY 17, 2011 |
| **REASONS FOR ORDER:** | TABIB P. |
| **DATED:** | JANUARY 26, 2011 |

**APPEARANCES:**

| | |
|---|---|
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| HILAL EL AYOUBI<br>MARIE LAFLEUR<br>PIERRE LEFEBVRE | FOR THE DEFENDANTS |

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