

T-698-04

COUR FÉDÉRALE

BETWEEN:

LÉOPOLD DELISLE

Plaintiff

-and-

LE PROCUREUR GÉNÉRAL DU CANADA

-and-

MINISTÈRE DE LA SANTÉ  
(SANTÉ CANADA)

-and-

DIRECTEUR GÉNÉRAL  
DIRECTION DES PRODUITS THÉRAPEUTIQUES (SANTÉ CANADA)

Defendants

T-2138-04

COUR FÉDÉRALE

BETWEEN:

DANY LAFOREST

Plaintiff

-and-

LE PROCUREUR GÉNÉRAL DU CANADA

-and-

MINISTÈRE DE LA SANTÉ  
(SANTÉ CANADA)

-and-

DIRECTEUR GÉNÉRAL  
DIRECTION DES PRODUITS THÉRAPEUTIQUES (SANTÉ CANADA)

Defendants

February 8, 2005

NICOLE L'ABBÉ  
Official Court Reporter

T-2139-04

COUR FÉDÉRALE

BETWEEN:

LAURENT LÉGÈRE

Plaintiff

-and-

LE PROCUREUR GÉNÉRAL DU CANADA

-and-

MINISTÈRE DE LA SANTÉ  
(SANTÉ CANADA)

-and-

DIRECTEUR GÉNÉRAL  
DIRECTION DES PRODUITS THÉRAPEUTIQUES (SANTÉ CANADA)

Defendants

T-2140-04

COUR FÉDÉRALE

BETWEEN:

DANIEL GRANDMONT

Plaintiff

-and-

LE PROCUREUR GÉNÉRAL DU CANADA

-and-

MINISTÈRE DE LA SANTÉ  
(SANTÉ CANADA)

-and-

DIRECTEUR GÉNÉRAL  
DIRECTION DES PRODUITS THÉRAPEUTIQUES (SANTÉ CANADA)

Defendants

RE-EXAMINATION ON AFFIDAVIT  
DEPOSITION OF Mr. IAN MACKAY

APPEARANCES:

Me MICHEL BÉLANGER,  
Me JEAN-SYLVAIN PELLETTIER,  
Counsels for Plaintiffs

Me CARMELA MAIORINO,  
Counsel for Defendants

February 8, 2005

NICOLE L'ABBÉ  
Official Court Reporter

T-698-04  
February 8, 2005

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IAN MACKAY	
RE-EXAMINED BY Me CARMELA MAIORINO	5

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1           IN THE YEAR TWO THOUSAND AND FIVE (2005), on  
2           this eighth (8th) day of February, personally  
3           came and appeared:

4

5           IAN MACKAY, born on October 22, 1964, domiciled  
6           and residing at 16, Ivy Crescent, Ottawa,  
7           Ontario, K1M 1Y2;

8

9           WHOM, after having been duly sworn, doth depose  
10          and say as follows:

11

12          RE-EXAMINED BY Me CARMELA MAIORINO,  
13          Counsel for Defendants:

14

I just have a few questions.

15

Q.   [1] I just would like to clarify some points,  
16          Mr. Mackay. You testified last week with maître  
17          Pelletier concerning, you addressed certain  
18          issues concerning delegation and signing of  
19          documents within your capacity as a unit head.  
20          As I understand correctly, you signed  
21          authorization and denials for the SAP, is that  
22          accurate?

23

A.   ... (no answer).

24

Q.   [2] Or can you explain to me how, what is the  
25          process, who signs the denials and

1 authorizations for SAP generally?

2 A. I sign the authorizations and denials as part of  
3 sort of the daily operations.

4 Q. [3] Uh-huh.

5 A. I described earlier today that we have, on any  
6 given day, we have two times in which they come  
7 to me for review, at eleven o'clock (11:00) and  
8 three o'clock (15:00), and that's when I bring  
9 my mind to each of those requests, and I will  
10 either authorize or deny, or on occasion, I will  
11 send the letter back, send the request back  
12 looking for more information, if I think there  
13 is a deficiency or if I think I need more  
14 information, but I make those decisions.

15 Q. [4] And does it ever happen that Doctor  
16 Gillespie would sign an authorization or a  
17 denial within the SAP?

18 A. No, Doctor Gillespie does not do that on a day-  
19 to-day basis, this is described through the  
20 daily operations as me being in charge, Doctor  
21 Gillespie is busy with other things. There are  
22 many occasions when I'll consult Doctor  
23 Gillespie on things, being the senior medical  
24 advisor within TPD, but the daily operations are  
25 handled by me.

1 Q. [5] There's an exhibit filed by Mr. Delisle, at  
2 Exhibit 13, that's Exhibit 13 entitled:  
3 "Exemples de cas discriminatoires" volume 6, and  
4 there's...  
5 Me JEAN-SYLVAIN PELLETIER:  
6 Just a moment, volume 6?  
7 Me MICHEL BÉLANGER:  
8 Which page?  
9 Me CARMELA MAIORINO:  
10 The pages are not numbered, but it's in Exhibit  
11 13, it's probably the...  
12 Me JEAN-SYLVAIN PELLETIER:  
13 Volume 6, right?  
14 Me CARMELA MAIORINO:  
15 Yes, volume 6.  
16 Me JEAN-SYLVAIN PELLETIER:  
17 It's at the end?  
18 Me CARMELA MAIORINO:  
19 It's towards the end and it says: "Nouveau  
20 patient refusé, patient DG".  
21 Me JEAN-SYLVAIN PELLETIER:  
22 "Nouveau patient refusé"?  
23 Me CARMELA MAIORINO:  
24 Yes, "Nouveau patient refusé".  
25

1 Me JEAN-SYLVAIN PELLETIER:

2 Volume 3, annexe 6?

3 Me CARMELA MAIORINO:

4 Uh-huh.

5 Me JEAN-SYLVAIN PELLETIER:

6 Right, Annex 6?

7 Me CARMELA MAIORINO:

8 Yes, but at the beginning, it's entitled Volume  
9 6, the beginning of that page, anyhow.

10 Q. [6] I'm showing, Mr. Mackay, this document in  
11 volume 13, sorry, in Exhibit 13 of Mr. Delisle's  
12 affidavit, which is entitled: "Nouveau patient  
13 refusé, patient DG", reference Volume 3, Annex  
14 6.

15 A. Yes.

16 Q. [7] Now, this is a... it's a recap of the  
17 denial, I believe? Yes, of a denial for access  
18 to 714-X through SAP, and it's signed by Doctor  
19 Gillespie; would you be able to explain how come  
20 this denial was signed by Doctor Gillespie  
21 instead of yourself?

22 A. Yes. This is a transcription, it looks, I  
23 understand this to be a transcription of the  
24 original denial letter, and because it's a  
25 transcription, it does not have a signature on

1           it. In reviewing the affidavits in preparation  
2           for this case, we reviewed specifically these  
3           documents, and the letter, while it has the  
4           signature block of Doctor Gillespie, it's our  
5           standard practice for the SAP manager to sign on  
6           behalf of Doctor Gillespie; it's an  
7           administrative, it's an operation, a standard  
8           operation that we undertake.

9           So this decision, if you will, was not made  
10          by Doctor Gillespie, it was made by the Special  
11          Access Program, the standard block that we used  
12          for all of going correspondence from the bureau  
13          has his signature block.

14        Q.   [8] Okay. Later on in your deposition last  
15            Thursday, I believe, with maître Pelletier, in  
16            the cross-examination, there was an undertaking  
17            in order for you to be able to provide  
18            information as to how many documents did  
19            physicians generally provide in support of their  
20            requests for access to 714-X; and my question  
21            with respect to that is, would you be able to  
22            describe generally the nature of the documents  
23            that would have been provided by physicians in  
24            support of access to 714-X throughout the years,  
25            is there some sort of general way you can

1 describe me the sources that they provided?  
2 A. Yes. In my experience of considering requests  
3 through the years, the documents that were  
4 submitted by physicians, in response to question  
5 3 of the application, generally fell into three  
6 or four categories, and we routinely saw the  
7 same documents over and over, and commonly,  
8 physicians would provide a reference to or  
9 information from the CERBE Web site, which  
10 contained information about the product, how to  
11 administer it, you know, claims as to how it  
12 works, how it fits with the Somatidian Theory,  
13 that would be a common submission. Others would  
14 submit references to other web sites.

15 The BC Cancer Agency Web Site has a  
16 document that relates to 714-X, and we'd see  
17 that frequently. We would also see frequent  
18 reference to the so-called CMAJ article that was  
19 published in the late nineties ('90s), which,  
20 the author of which was Doctor Keige, I believe,  
21 K-E-I-G-E, I believe we can check that, on  
22 behalf of the Breast Cancer Research Foundation.  
23 She was asked to review the available evidence  
24 supporting the use, safety and efficacy of the  
25 product, and because that was a published

1 document as part of a series in the Canadian  
2 Medical Association Journal, and therefore  
3 available, easily available to physicians across  
4 the country, physicians would routinely use that  
5 as evidence to support the use, safety and  
6 efficacy of the product.

7 Latterly, there was at least one reference  
8 in particular that would submit the document,  
9 the OCCAM document about which we spoke earlier,  
10 to say, to show that they understood the OCCAM  
11 was undertaking a review, so they would submit  
12 that.

13 So, it fell into three or four different  
14 categories of documents, and routinely, we would  
15 see the same documents over and over. We're not  
16 talking about a thousand different documents  
17 here, we're talking about a handful of documents  
18 which we saw frequently.

19 Q. [9] Okay. Now, you mentioned in your cross-  
20 examination that the way the SAP requests are  
21 received is that initially, they're screened by  
22 a clerk, and then once they passed that step,  
23 you review them in your capacity as a reviewer  
24 of the SAP requests.

25 Now, in reviewing the requests, you

1 obviously, you obviously read the information  
2 that, you take note of the information that the  
3 physician submits.

4 Me JEAN-SYLVAIN PELLETIER:

5 Well, maybe you can ask the question instead of  
6 taking for granted some facts.

7 Me CARMELA MAIORINO:

8 Q. [10] What do you do with the SAP request when  
9 you receive it, as a reviewer, in terms of the  
10 information that the physician submits?

11 A. ... (no answer).

12 Me JEAN-SYLVAIN PELLETIER:

13 I think he's answered that numerous times, but  
14 anyway, I will allow the question as a  
15 compassionate matter.

16 THE WITNESS:

17 A. I authorize many, I consider many requests on  
18 any given day, on any given year, as I was  
19 talking about, there's thousands, so I have a  
20 certain amount of time which I can apply to  
21 each; the first thing I do is I scan the first  
22 page, the first page, the doctor's name and the  
23 area, et cetera, I don't generally verify  
24 anything unless there's something obvious.  
25 Sometimes, I will look at legibility, sometimes,

1 my staff will be able to decipher writing better  
2 than I can, so I'll look at it, if I can't read  
3 it, then I can't look at it, and it's not  
4 uncommon that this happens.

5 So I'll quickly take a look at it, I  
6 sometimes will glance at the patient's age to  
7 see what kind of thing we're dealing with, if  
8 we're dealing with a pediatric patient, a  
9 geriatric patient or someone in-between, I'll  
10 take note of the dosage and the total amount  
11 requested, again for the purposes of making sure  
12 the amount of product that's requested is not an  
13 excessive amount for the purpose of meeting the  
14 standard of regulation, whereby I spoke last  
15 week that we don't provide access to a huge  
16 amount of product for a longer period of time,  
17 we're talking about a small amount of product  
18 for a short period of time.

19 I spend most of my time on page 2, where I  
20 look at the information provided by the  
21 practitioner to see what other products have  
22 been used and whether they've failed or whether  
23 they're inappropriate, et cetera, and  
24 specifically, I spend most of my attention on  
25 question 3 of page 2, which has to do with the

1 information that the physician submits to us. So  
2 if there's an attachment, if there's an appendix  
3 that they file, then I will look at that  
4 information to determine whether or not the  
5 information that's provided is credible, if it's  
6 from published information, if there's a web  
7 site, I commonly will go onto the Internet and  
8 look at the web site, if it's a paper that has  
9 an interesting title to it that I may want to  
10 know more about, I'll go down to the library and  
11 retrieve it. So there are a number of things I  
12 do, but in general, I scan the first page and I  
13 spend most of my time on the second page.

14 Me CARMELA MAIORINO:

15 Q. [11] Okay. Earlier today, I think there was some  
16 questions on the number of patients, a line of  
17 questioning as to the number of repeat patients.  
18 My question has to deal with, would you be able  
19 to give us a ballpark figure as to approximately  
20 how many patients had access to 714-X through  
21 SAP in two thousand four (2004)?

22 Me JEAN-SYLVAIN PELLETIER:

23 I think the affidavit speaks by itself. He gave,  
24 I believe...

25

1 Me CARMELA MAIORINO:

2 There's a number of...

3 Me JEAN-SYLVAIN PELLETIER:

4 ... figures...

5 Me CARMELA MAIORINO:

6 ... a number of requests which I believe  
7 certainly is the number of patients.

8 A. I thought I provided that information, but I...

9 Me JEAN-SYLVAIN PELLETIER:

10 Let me take a look, I think we have that  
11 information already. It's 138, it's part of it.

12 Me CARMELA MAIORINO:

13 Well, that is since January two thousand four  
14 (2004).

15 Me JEAN-SYLVAIN PELLETIER:

16 Since January two thousand four (2004), your  
17 question was about...

18 Me CARMELA MAIORINO:

19 Q. [12] Sorry, I meant in two thousand three  
20 (2003).

21 A. Two thousand and three (2003)?

22 Q. [13] Uh-huh, prior to the issuance of the  
23 letter. If in two thousand three (2003), you're  
24 able to give me a ballpark estimate as to how  
25 many patients had access to 714-X, are we

1 dealing with hundreds of thousands or are we  
2 dealing with...

3 A. Definitely not dealing...

4 Q. [14] ... thousands?

5 A. Definitely not dealing with thousands.

6 Me JEAN-SYLVAIN PELLETIER:

7 Millions?

8 THE WITNESS:

9 A. Definitely not millions. It would, ballpark  
10 would be perhaps somewhere between a hundred  
11 (100) and two hundred (200), as a ballpark.

12 Me CARMELA MAIORINO:

13 Q. [15] And is this throughout Canada?

14 A. Yes, for two thousand and three (2003).

15 Q. [16] Okay.

16 A. Then I understand that's a ballpark, because  
17 it's difficult, as I've said last week, to  
18 decipher the number of requests and repeat  
19 requests, et cetera, but I would say that it  
20 would be somewhere between a hundred (100) and  
21 two hundred (200).

22 Q. [17] And one last question with respect to  
23 Paragraph 158 of your affidavit, it's more of a  
24 clarification question. You're referring to  
25 Paragraph 140 within that paragraph, at

1 Paragraph 158, you refer to Paragraph 140, is  
2 this the paragraph you...

3 Me JEAN-SYLVAIN PELLETIER:

4 Where are you at, 158?

5 Me CARMELA MAIORINO:

6 At Paragraph 158, Mr. Mackay refers to the  
7 letter dated December first (1st), two thousand  
8 four (2004) referred to in Paragraph 140, but  
9 Paragraph 140 doesn't refer to that letter as  
10 opposed to Paragraph 141.

11 A. Yes, that's a reference error, it should refer  
12 to Paragraph 141.

13 Q. [18] Okay. During the cross-examination last  
14 week, maître Pelletier referred you to  
15 Paragraphs 26 to 28, sorry, 26 and 27 of your  
16 affidavit...

17 A. Uh-huh.

18 Q. [19] ... and he asked you whether these  
19 paragraphs referred specifically to SAP, and you  
20 responded, you replied no. My question is, do  
21 those paragraphs, is SAP encompassed within  
22 those paragraphs, is SAP subjected to the FDA,  
23 to the FDA scheme?

24 A. Meaning the Food and Drugs Act?

25 Q. [20] Uh-huh.

1     A.     I'm describing the system in general and I'm  
2           describing the overall aims and objectives of  
3           the system, that is the regulatory system, and  
4           the system includes full regulatory review for  
5           marketing purposes, clinical trial applications  
6           and SAP as a part of the system for sure, and  
7           that in 26 and 27, I'm describing the larger  
8           aims and focuses of the system.

9                     However, as I've described earlier, there  
10            are different standards applied to various  
11            components of that system, and so for a full  
12            drug approval, we need a truckload and for SAP,  
13            we need a smaller amount of information, but  
14            it's all within the system wherein we do our  
15            best to try to protect against the real and  
16            perceived, the real and potential risk, and that  
17            a claim made by anyone is appropriately  
18            supported with credible scientific information.

19     Q.     [21] I don't have anymore questions.

20            Me JEAN-SYLVAIN PELLETIER:

21            Me neither.

22

23            AND FURTHER DEPONENT SAITH NOT

24

25

---

1 (OFF THE RECORD DISCUSSION)

2

3 I, the undersigned, NICOLE L'ABBÉ, Official  
4 Court Reporter, do hereby certify under my oath  
5 of office that the foregoing pages are and  
6 contain the exact transcription of the testimony  
7 and pleadings herein, taken by means of  
8 stenomask and according to the law.

9

10 AND I HAVE SIGNED:

11

12

13 \_\_\_\_\_