Date: 20090402

Docket: T-51-08

Citation: 2009FC345

Ottawa, Ontario, April 2, 09

PRESENT: Madam Prothonotary Mireille Tabib

BETWEEN:

ELI LILLY CANADA INC. and
ELI LILLY AND COMPANY

Plaintiffs

- and -

SANDOZ CANADA INCORPORATED

Defendant

AND BETWEEN:

SANDOZ CANADA INCORPORATED

Plaintiff by Counterclaim

- and -

ELI LILLY CANADA INC. and
ELI LILLY AND COMPANY

Defendants to the Counterclaim

REASONS FOR ORDER AND ORDER

[1] I am seized of a motion by the Plaintiffs, Eli Lilly Canada Inc. and Eli Lilly and Company (hereinafter jointly referred to as "Lilly") for an Order compelling the Defendant Sandoz Canada

Incorporated ("Sandoz") to produce a further and better affidavit of documents. The motion also seeks an Order that Sandoz produce unredacted and complete copies of documents produced in a redacted or incomplete form, and that it be compelled to request and obtain from persons related to it and from its supplier, ScinoPharm Taiwan Ltd. ("ScinoPharm"), documents relating to the process used to make Sandoz' product and an Order requiring the Minister of Health to produce documents relating to Sandoz' product in its possession.

[2] Although it has ultimately been unnecessary to formally determine the issues originally raised in this motion, these reasons are issued in the hope that they will draw the profession's attention to common difficulties and inefficiencies in the discovery process of intellectual property matters, and provide some guidance as to how certain best practices could be considered or developed to avoid or better manage these difficulties.

[3] The motion is brought in the context of a patent infringement action brought by Lilly against Sandoz. The patents at issue are Canadian Patents No. 2,098,881 ("'881 Patent") and 2,098,886 ("'886 Patent"), both of which cover processes useful in the preparation and production of the anti-cancer drug gemcitabine. The patents do not claim gemcitabine itself but only certain aspects of processes for making gemcitabine and an intermediate in its preparation. It is admitted that Sandoz imports, markets and sells in Canada gemcitabine made by ScinoPharm. For the purposes of Lilly's motion, the issue between the parties in this action is whether the process used by ScinoPharm in making the gemcitabine supplied to Sandoz falls within the claims of the '881 or '886 Patents. For the purpose of this motion, it is also not in dispute that ScinoPharm is a third party not related to

Sandoz. From this, one already understands that to the extent documents exist which might establish that the process actually used ScinoPharm falls within the claims of the patents, these documents primarily originate from ScinoPharm any documents which Sandoz might have in its current possession and which the Minister of Health might have as a result of regulatory filings would also have originated from ScinoPharm.

[4] The motion was initially filed in September 2008 and the materials in support and in opposition to the motion have increased exponentially since the initial motion record was filed, with ScinoPharm intervening to oppose Lilly's motion requiring production from the Minister of Health and seeking modifications to an existing Protective Order to afford further protection to the documents it would voluntarily produce through Sandoz. At the same time, Sandoz was in the process of communicating to Lilly documents it had received from ScinoPharm and listed in its affidavit of documents but had yet to deliver at the time the initial motion was brought. It became apparent that those documents were heavily redacted and appeared to be in many cases portions of larger documents. This led of course to further affidavits, counter-affidavits, cross-examinations on affidavits, and supplementary and further supplementary records of arguments.

[5] It would clearly have been far preferable for the parties to have devised an informal, yet clearly structured process to exchange requests for specific documents they believed were missing from the production, responses thereto and additional disclosures before bringing formal motions. Absent agreement as to the details of such a process and the deadlines for compliance, the parties could and should have moved for case management at an early date to devise such a process. This

would have fostered a better understanding between the parties of their respective positions and concerns and the legal and factual grounds for same. The parties would then have been able to narrow their arguments much faster and present to the Court focussed and helpful evidence and submissions through a single exchange of records. Instead the Court was faced with a constantly evolving stream of further and supplemental records through which the Court had to sift in an attempt to understand which issues have been resolved, which issues remain and which resulting new issue must be addressed.

[6] As of the second and final hearing day of this motion, the positions of the parties and of ScinoPharm were are follows:

[7] Lilly's demand for further disclosure of documents was somewhat narrowed. Several additional documents had been produced by Sandoz, albeit with redactions. Lilly acknowledged that some of the information claimed to have been missing from the redacted documents was in fact provided in other documents or parts thereof. It was also understood that some of the redacted or missing parts of documents may not be as relevant as originally claimed.

[8] Sandoz came to realize some shortcomings in its documentary disclosure and the process it had utilized in redacting documents. It acknowledged that some of the redactions should not have been made; it recognized that some additional documents should be requested from ScinoPharm; it recognized the need for a corporate representative of Sandoz to actually review the unredacted

versions of the documents it had obtained from ScinoPharm and consider the relevance of the redacted portions of these documents.

[9] For its part, ScinoPharm, having been comforted by the variations to the terms of the Confidentiality Order which were ordered pursuant to its companion motion, confirmed that it would continue to cooperate with Sandoz' requests for communication of documents. It confirmed that its concerns related purely to the protection of its trade secrets and that it would take no position and would not intervene on the issue of the relevance of the documents requested from it by Sandoz.

[10] On the whole, given that Sandoz had undertaken to review and turn its own mind to the question of the relevance of documents provided by ScinoPharm, and given that it had undertaken to consider the existence of other potentially relevant documents in ScinoPharm's possession and make the appropriate request for production, it became clear that a further and better affidavit of documents would in any event be voluntarily produced by Sandoz.

[11] It further appeared to me that with the exception of some regulatory filings made by ScinoPharm (in Canada and in other jurisdictions) which may remain in issue in any event, it is very likely that Sandoz' own review of the unexpurgated documents and its efforts to obtain from ScinoPharm further relevant documents could potentially resolve any remaining issues between the parties. Sandoz' review process of course will be carried out in light of the parties' better understanding of the issues at play, gained through the briefing and hearing of this motion. To the extent any issues remain between the parties after this process is completed, such new issues will

most probably be further refinements of arguments canvassed on this motion. Attempting to craft specific directions to Sandoz to cover and anticipate these issues would likely create more difficulties than it would resolve.

[12] Trusting in the good faith and good cooperation which both parties and ScinoPharm professed at the hearing, the present order will therefore not dictate which parts of which documents should be "unredacted", which additional documents should be sought from ScinoPharm and which missing parts of documents should be produced. Nevertheless, the following general comments should be borne in mind by the parties.

[13] The redactions currently made to ScinoPharm's documents were obviously driven as much, if not more, by its desire to protect its trade secrets than by a cogent analysis of relevance. Pinpoint redactions were sometimes made in sections of documents directly relevant to the allegedly infringing process. Lilly has argued that a description of the relevant parts of a chemical process cannot be validated as representative of the process actually taking place if they are not disclosed in their full context, including a verifiable starting point, intermediary reactions and verifiable products and bi-products. I find this argument compelling, and as a consequence, would caution Sandoz against taking too narrow a view of relevance, and redacting parts of process documents which, although describing parts of the process falling outside the claims of the patents, are nevertheless necessary to validate the representativity or commercial viability of the process allegedly described in the documents.

[14] I do not accept Lilly's argument that where a document contains relevant information and is disclosed in an affidavit of documents, the receiving party is in all cases entitled to production of the entire, unredacted document. Very large documents that have identifiable and relatively independent sections lend themselves well to partial production. When it comes to redacting portions of text within a disclosed part or section of a document, redactions may also be permissible but the following considerations should apply: The redacted portion should be clearly irrelevant to the issues in dispute and would clearly not assist in properly understanding those parts of the documents which are relevant. Redactions should also only be resorted to where important confidentiality concerns exist. In circumstances such as the present action, where enhanced confidentiality protection is afforded to certain types of information, the case for redactions is weaker. Where a redaction is nevertheless made and its propriety is contested, mechanisms should be provided for outside counsel for the receiving party to view the unredacted document to ascertain the basis for the redactions.

[15] The Plaintiffs are not entitled to demand that Sandoz provide translations of documents written in a foreign language. To the extent a translation exists, that translation is likely itself a relevant document to be disclosed. However, where a translation does not exist, the producing party is not required to create one unless and until it tenders the document as evidence in the proceeding.

[16] I am not prepared at this stage to order the Minister of Health to produce documents in its possession. Such documents as the Minister of Health does have in its possession are also in ScinoPharm's possession and the evidence before me establishes that to the extent they are relevant,

Sandoz has undertaken to request them from ScinoPharm and ScinoPharm has expressed a willingness to provide them. Indeed, some productions from the Canadian regulatory filings have already been made and the Court expects that Sandoz will include these documents in its review process, so as to eventually disclose and produce to Lilly all relevant portions of these documents.

[17] As for regulatory filings made by ScinoPharm in other jurisdiction than Canada, Sandoz has taken the position that they are not relevant. By this, I take Sandoz to indicate that it will not request ScinoPharm to produce them to it so that it can in turn produce them to Lilly. Sandoz says that foreign regulatory filings are not probative of the process actually used by ScinoPharm to produce the gemcitabine sold by Sandoz in Canada. Sandoz adds that since it has requested from ScinoPharm and produced to Lilly the actual batch production records for the gemcitabine actually distributed in Canada, it has produced the best and most relevant information. The problem with that approach is that it assumes that the records Sandoz received from ScinoPharm are unimpeachable and must be accepted as conclusive evidence of the ScinoPharm process. There is merit to Lilly's argument that the regulatory filings are a possible source of information as to what the ScinoPharm process might be. There is also merit to Sandoz's counterargument that if the regulatory filings exactly match the production records obtained from ScinoPharm, ScinoPharm's production records would be the best evidence of the process actually used, and the regulatory filing far less relevant. At this point, however, Lilly is entitled to disclosure by Sandoz of all documents of which Sandoz has knowledge and which may assist Lilly in establishing that ScinoPharm's process infringes its patents. It is not up to Sandoz to select, from several documentary sources of

relevant information, which one is the most probative or the most useful to Lilly or to decide which documents should be disclosed and which can be discounted.

[18] This is not to say that I will now order Sandoz to request these documents from ScinoPharm or that I consider that the time is now ripe for Lilly to pursue motions for production of foreign regulatory filings by third parties. As a source of information from which Lilly could establish infringement, foreign regulatory filings are sufficiently relevant, on their face, that they should be disclosed in Sandoz' affidavit of documents and produced to Lilly if they were in Sandoz' power, possession or control. However, from the evidence before me, it appears that these documents are not in Sandoz' possession but in that of ScinoPharm and the relevant regulatory authorities. As such, they would fall to be listed in Schedule IV of Sandoz' affidavit of documents (documents which may be relevant but are in the possession of a person not a party to the action). The Court's discretion to order production from a third party would seem to me to go beyond mere relevance for the purposes of an affidavit of documents; it may require weighing the necessity and probative value of the documents sought in light of the documents already disclosed. At this point, it would be premature to exercise my discretion to order Sandoz to request those documents from ScinoPharm.

[19] The main reason for my reluctance is the unsatisfactory state of the pleadings in this case, a state which I trust the parties will remedy sooner rather later, and in any event before further motions for production by third parties are made.

[20] As it stands, the Plaintiffs' statement of claim clearly sets out a claim based on the "new product" presumption found in Section 55.1 of the *Patent Act*, as well as a claim that the ScinoPharm process must infringe the patents since there exists no other commercially viable processes for these aspects of the preparation. Other than those allegations and some very general allegations, there are no detailed and direct allegations as to the processes actually used by ScinoPharm. This is particularly troubling given the fact that the action asserts infringement of several claims of the '881 Patent describing different and sometimes contradictory processes. Notwithstanding this lack of particulars, it appears that Sandoz is content to take Lilly's statement of claim as including direct allegations that the ScinoPharm process falls within the claims of the patents.

[21] Sandoz for its part opposes Lilly's allegation with no more than broad denials. Sandoz denies Lilly's allegation that there are no other commercially viable processes but makes no positive allegations as to what other commercially viable processes might exist. It denies that the process used by ScinoPharm would infringe the patents but makes no positive allegation as to what the ScinoPharm process might consist of.

[22] The clear impression with which one is left from those pleadings is that at the time they were drafted, neither the Plaintiffs nor the Defendant had any idea whatsoever as to what the ScinoPharm process might consist of. Yet both were quite content to join issue on the question of whether that process infringed or not, presumably on the understanding that both would eventually

learn from ScinoPharm what the process actually is and would form their respective positions accordingly.

[23] It seems to me that such an approach to pleadings assumes, and at the outset sanctions, discovery by way of a wide-ranging fishing expedition, a process which is neither contemplated by the *Federal Courts Rules* nor condoned in the decisions of this Court. If, at the time it filed the action, Lilly had in reality formed the belief that Sandoz' product was made through an infringing process on the sole basis that its patents covered the only known commercially viable processes, then its allegations should have stopped at that. It would have been up to Sandoz to either join issue with Lilly's assertion that no other viable process existed generally, or to make its own enquiries as to the process actually used by ScinoPharm, and if it considered that particular process to be non-infringing, to make very specific allegations as to what that process was and why it did not infringe. Such allegations by Sandoz as to the specific process used could, in those aspects covered by the claims of the patents, have stood as admissions binding upon Sandoz, and so restricted the scope of Lilly's discovery. Lilly would have been entitled to discovery on only to those aspects of the process which Sandoz claimed fell outside the specific claims of the patents. It would have also put Lilly to the task of articulating a position, in fact or on its interpretation of the patents, as to why the process alleged to be carried out by ScinoPharm was either not correctly described or infringing.

[24] This exercise was not made, and Sandoz has so far contented itself to act as a conduit for documents identified and selected by ScinoPharm, without itself taking any position on these issues. It does not lie in Sandoz' mouth to say that Lilly should be content with this production and accept

it as fully representative of the process that will be proven at trial. Nor is it acceptable for Lilly to ask the Court to assist it in conducting its fishing expedition into the files of non-parties such as ScinoPharm or the regulatory authorities without attempting to narrow the issues or the scope of relevant documents.

[25] It became apparent at the hearing that counsel for Sandoz and for Lilly have already gained, from the productions made so far, a much better understanding of what the ScinoPharm process might be, of which claims might in fact be at issue, and of which aspects of specific claims will be particularly controversial. Through Sandoz' voluntary undertaking to request further documents and review their production to remove some of the redactions made, this mutual understanding is expected to be further refined. As of the time of the hearing, whatever understanding existed between the parties remained quite opaque to the Court. I am afraid that until such time as the parties are prepared to translate that understanding into some defined pleadings or particulars that would both clarify and narrow the issues for discovery, Lilly will find it difficult to convince the Court to exercise its discretion to compel discovery from third parties and Sandoz will find it difficult to persuade the Court that Lilly's enquiries as to relevant aspects of the ScinoPharm process have been sufficiently explored.

ORDER

IT IS ORDERED THAT:

1. The Defendant shall provide to the Plaintiff a revised affidavit of documents, in accordance with the schedule and procedure to be agreed to by the parties in light of these reasons.

2. Within ten days of this Order, the parties shall provide the Court with a draft Order setting out a procedure and schedule for the provision of further and better affidavits of documents by both parties, communication of documents, provisions of particulars, discoveries, and other steps to be taken in this action.

3. Costs to the Plaintiffs in the cause. The parties may include in the draft order such fixed amount of costs as they might have agreed.

"Mireille Tabib"
Prothonotary

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-51-08
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