Federal Court  Cour fédérale

Date: 20100122

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Ottawa, Ontario, January 22, 2010

PRESENT: MADAM PROTHONOTARY MIREILLE TABIB

Docket: T-644-09

BETWEEN:

APOTEX INC.

Plaintiff

- and -

SANOFI-AVENTIS

Defendant

Docket: T-933-09

BETWEEN:

SANOFI-AVENTIS and
BRISTOL-MYERS SQUIBB SANOFI
PHARMACEUTICALS HOLDINGS PARTNERSHIP

Plaintiffs

- and -

APOTEX INC.
APOTEX PHARMACHEM INC. and
SIGNA SA de CV

Defendants

REASONS FOR ORDER AND ORDER

[1] The Rules relating to affidavits of documents should be well known by litigants. Yet it seems that parties are either not following them strictly, or are assuming that others are not. In the context of "fast track" or streamlined actions managed pursuant to the Notice to the Parties and to the Profession issued by this Court on May 1, 2009, the importance of ensuring that these rules are understood, followed and strictly applied by both parties cannot be overstated.

[2] I am seized of two reciprocal motions, brought by the parties to this consolidated proceeding, seeking that the opposing party be compelled to provide a further and better affidavit of documents.

[3] Apotex Inc. is the plaintiff in initial Court file T-644-09. It is also, with Apotex Pharmachem Inc., the defendant in the second action, in Court file T-933-09. Apotex Inc. and Apotex Pharmachem Inc. will be jointly referred to in these reasons as "Apotex". Sanofi-Aventis is the defendant in Court file T-644-09. It is also, with Bristol-Myers Squibb Sanofi Pharmaceuticals Holdings Partnership, the plaintiff in the subsequent Court file T-933-09; the Sanofi entities will be jointly referred to in these reasons as "Sanofi".

Background and preliminary remarks

[4] It is I think crucial to note that both parties herein have early on embraced and committed to the Court's initiative to streamline complex litigation and schedule trial dates within two years of

the institution of an action, which is the subject of the above mentioned Notice to the Parties and to the Profession.

[5] Apotex first made its request in May 2009, some 20 days after filing its Statement of Claim in T-644-09. Sanofi joined in that request when it filed the Statement of Claim in T-933-09 in June 2009 and moved, in July 2009 to consolidate the actions so that they can proceed and be heard together, on the same schedule as had already been set for T-644-09.

[6] As a result, tentative trial dates have already been set aside starting in April 2011; early and intensive case management has been implemented, and a schedule has been set for completing all pre-trial steps to meet these dates.

[7] The Court's early trial initiative was a response to the frustration expressed by a significant number of litigants and members of the bar, very notably in the specialized field of intellectual property, that matters were taking too long to get to trial. As the Court began experimenting with this initiative on a case-by-case basis a few years ago, it quickly became obvious that it is not realistic, practical or reasonable to merely shorten the time between the filing of a statement of claim and the start of the trial if the parties and their counsel do not also adapt their litigation practice and strategies to the shorter time frames. Litigation that dragged on for five years or more typically featured three or more "rounds" of discoveries as well as numerous amendments to pleadings, often resulting in more discoveries and affidavits of documents. Attempting to shoe-horn into two years the never-ending discovery and amendments process that used to take five to ten

years is simply unsustainable for most litigants and most lawyers, not to mention the limited resources of the Court.

[8] At the same time, complaints were growing that the discovery process was getting out of hand, becoming too long, too costly and too time consuming. Meanwhile, some of the cases that had been the product of years of unrestrained discoveries finally came to gruelling trials scheduled to run several months, and often further extended, to the exhaustion and frustration of lawyers and Judges alike. A new call is now increasingly being heard from some members of the intellectual property bar and their clients: the length of the trials must be controlled, and parties must be kept to the length of the trials as scheduled.

[9] I make these lengthy observations because they inform and highlight the consequences of both parties' expressed intention to avail themselves of the Court's streamlining and early trial initiative. In pressing for and committing to a trial in the spring of 2011, intended to last five weeks, the parties and their counsel have committed to a schedule that does not allow infinite time for discoveries and to a trial of fixed duration. The parties themselves are extremely sophisticated litigants, with extensive experience before this Court. Their respective counsel are knowledgeable and experienced trial lawyers. One expects and must demand from such parties that with a trial expected to begin in less than 15 months, with pleadings now closed and with the known history of litigation in this and other jurisdictions over the drug at issue, they have a clearly developed and articulated theory of their respective case, of what is required to prove it at trial, and how they intend to do so. There is no time in this schedule – and indeed, precious little trial time – for embarking on

fishing expeditions, for cobbling up a strategy as one goes or for being unable to articulate a coherent theory of the case until all discoveries are completed or until the eve of trial.

[10] In ruling on these motions, I have assumed from the parties that level of professionalism, and I intend, in managing this case to trial, to consistently expect this higher standard. The parties themselves should be able to expect and rely upon the same standard from their opponent. How that assumption will impact the case management of this matter will become apparent as I deal with the various aspects of these motions.

General principles applicable to documentary discovery

[11] The parties are *ad idem* as to the law applicable to motions for further and better affidavits of documents, and it need not be set out at length here. Essentially, it is accepted that the moving party on such a motion has the burden of showing that the affidavit of documents, as delivered, is inadequate or deficient. That is, the moving party must show that further documents likely exist, that these documents would either advance its own case or hurt its opponent's and that the opposing party either has them in its power, possession or control (see Rule 223(2)(a)(i) and (ii)), or is aware that they are in some other third party's power, possession or control (see Rule 223(2)(a)(iv)) .

[12] It bears repeating that a document which can only assist the disclosing party need not be disclosed in the affidavit of documents; indeed, the disclosing party is only required to disclose documents that support its case if it intends to rely upon them at trial. The counterpoint to this principle is that a party who has in its power, possession or control a document which would advance its own case has the obligation to disclose it in its affidavit of documents, failing which,

subject to some exceptions or leave of the Court, it may not be introduced at trial (see Rule 232(1)). The Rules also contemplate several other sanctions to a party's failure to comply with its disclosure obligations, including striking out the defaulting party's pleadings (see Rule 227).

[13] The obligation to disclose documents on which a party intends to rely at trial or which would assist its opponent equally applies to documents that are not in that party's possession, power or control, but in that of a third party. The consequences of the failure to comply with this obligation are, in theory, the same as for documents within the party's own power, possession or control; however, counsel for Sanofi has expressed concerns that, in practice, there is almost no impediment to a party relying on undisclosed third party documents at trial. It is not for the Court, on this motion, to determine and declare how such difficulties, if they arise, are to be resolved at trial. It is sufficient on this motion to recognize that there is a clear, positive duty of inquiry and disclosure on the party proffering an affidavit of documents, and that the due performance of that duty is intended to be ensured by the requirement of a sworn affidavit of the party, backed by a solicitor's certificate, and by a scheme aiming to prevent a litigant being surprised at trial by documents of which the other party or its counsel has long been aware – or should have been if the inquiries required of them had been performed.

[14] As pointed out by the Court in *Poitras v. Twinn*, 2001 FCT 456, "an affidavit of documents is a very solemn document. It is an affidavit and, unless and until the contrary is shown, it is to be taken as setting out what it alleges accurately and fairly and that is why provision is made in the Rules for a solicitor to instruct and advise the person preparing the affidavit as to his or her obligations". I would add that since the affiant must be authorized by the party to make the

affidavit and that the full explanations given by the solicitor must include the possible consequences of failing to make full disclosure (see Rule 224), these statements stand as a solemn statement that:

(a) further relevant documents than those listed do not exist, or if they do;

(b) that they are not likely to assist the other party or hurt the disclosing party's case AND that the disclosing party has made the decision that it will not rely on that document at trial.

[15] Given the sophistication of the parties and the level of preparation expected of them in the circumstances, the presumption that the absence of a document from the affidavit of document signals that if it exists, a strategic and informed decision has been made that it will not be relied on a trial is all the greater. That being the basis of many of the individual determinations made here, I can see no reason why the parties themselves cannot or should not proceed in this litigation in reliance on the same assumption. I also note that if parties can be confident that their opponent will not be entitled to rely upon such documents to their advantage at trial, it should help reduce the length of discoveries, since parties will have no incentive to insist on production of additional documents merely out of fear of being blindsided at trial.

[16] Finally, it should also be remembered that while the Rules provide that a party may correct any inaccuracy or deficiency in an affidavit of documents by serving a supplementary affidavit of documents, this must be done without delay. This is all the more important in actions subject to the streamlining initiative, as the tight schedules afford little "extra" time to re-open discoveries should

new documents be disclosed. Where, on an informal request or a motion for production of further documents, a party's attention is drawn to a particular type or source of documents or to a particular factual issue which it had not considered for relevance, the party's duty to review its disclosure in order to correct any inaccuracy or deficiency in its affidavit of documents is triggered, and should result in such supplementary affidavit of documents as the review may require, without delay, and without the need for a specific order. For that reason, it is unnecessary for the Court to specifically order that a party review its affidavit of documents for completeness, unless the Court has been satisfied that elements are in fact missing from it.

Sanofi's motion

[17] I will examine in turn each category of documents in respect of which Sanofi claims Apotex's affidavit of documents is deficient. Although the notice of motion seeks relief in respect of 24 categories of documents, Sanofi's amended written representations are restricted to 14 categories, listed in lettered paragraphs (at pages 7 and 8 of the written representations).

(a) *Apotex's submission for a Notice of Compliance for clopidogrel besylate and hydrobromide, including updates, supplements and notifiable changes, specifically detailed process and stability information as well as the "Acknowledgement of Receipt of Information and Material" from Health Canada.*

[18] There is no allegation that Apotex is currently manufacturing, importing, selling or exporting clopidogrel besylate or hydrobromide. Apotex does, however, allege that it intends to apply to the Minister of Health seeking a Notice of Compliance to sell these products in Canada,

and it therefore seeks, *inter alia*, a declaration that its proposed products will not infringe Sanofi's patent.

[19] Apotex has not listed in its affidavits of documents any regulatory document whatsoever with respect to clopidogrel besylate or hydrobromide – which is not surprising, since the allegation made in the pleadings is not that Apotex has applied for a Notice of Compliance, but that it intends to apply for a Notice of Compliance. Sanofi argues that if the pleaded intent is more than a vague intention, as is required to establish standing to maintain a declaratory and impeachment action in respect of clopidogrel besylate or hydrobromide, then drafts of regulatory submissions, or at least an outline of what these submissions would contain must surely exist. Sanofi may well be correct as to Apotex's need to put these documents in evidence to support its standing, but the fact remains that the existence and content of these documents, as evidence of standing, could only be of assistance to Apotex. Given the comments made earlier, the absence of such documents from Apotex's affidavit of documents must be taken to mean that there are in existence no documents whatsoever documenting Apotex's intention to apply for a Notice of Compliance for clopidogrel besylate or hydrobromide, or that if they exist, Apotex has made a decision that it will not be using them at trial. As to whether any such documents, if they exist, would directly or indirectly advance Sanofi's case in showing infringement, Sanofi has not led sufficient evidence to discharge its burden.

(b) All Drug Master Files that are relied upon or referred to in any submission for a Notice of Compliance filed by Apotex with regard to clopidogrel bisulfate, besylate or hydrobromide.

[20] Clopidogrel bisulfate is the drug which Apotex allegedly currently manufactures in Canada for export, and for which Apotex currently does not have regulatory approval to sell in Canada. Apotex's statement of claim alleges that Apotex has applied for a Notice of Compliance in Canada for this product. Apotex's affidavits of documents do list some regulatory filings, including some filings which appear to be drawn from a DMF. Sanofi's motion record contains no evidence from which one could conclude that any other document relating to whether or not the proposed product would infringe exists, let alone that such document would assist Sanofi's case or hurt Apotex's.

[21] As for the drug master files for clopidogrel besylate or hydrobromide, the comments made above for category (a) are equally applicable here.

(c) All documents that relate to any work done on the development of clopidogrel besylate and hydrobromide.

[22] There are three issues to which Sanofi argues these documents are relevant:

[23] First, as evidence of an intent to file an application for a Notice of Compliance. As mentioned earlier, their absence from the affidavits of documents can only be interpreted as signifying that such documents do not exist, or that Apotex has chosen not to adduce them at trial.

[24] Second, as evidence that clopidogrel besylate is in fact a pharmaceutically acceptable salt, which would contradict the allegations made in paragraphs 11 and 16 of Apotex's amended statement of claim in respect of invalidity or construction. Counsel for Apotex at the hearing has

confirmed clearly and unequivocally what was suggested in Apotex's motion record: that in support of paragraphs 11 and 16 of the amended statement of claim, Apotex does not intend to lead evidence establishing that, as a fact, besylate is not a pharmaceutically acceptable salt. Given that undertaking, and given that it would have been Apotex's burden to prove this fact, there can be no relevance (as understood in Rule 222(2)) to documents showing the pharmaceutical acceptability of clopidogrel besylate.

[25] Third, as evidence that clopidogrel besylate or hydrobromide do not have the substantial advantages claimed in respect of clopidogrel bisulfate. Apotex has pleaded, at paragraph 36 of its amended statement of claim, that the patent is invalid as a selection patent because the bisulfate does not have substantial advantages over the other compounds disclosed in an earlier patent, which compounds include the besylate and hydrobromide salts. Sanofi, at the hearing, argued that to the extent Apotex has performed development work on these salts, such work might in fact show that these salts do not have the advantages claimed in respect of clopidogrel bisulfate.

[26] First, Sanofi has led no evidence to support the contention that development work was conducted by Apotex, and if it was, that it would likely show the besylate or hydrobromide to be inferior to the bisulfate. Furthermore, that particular argument was not clearly articulated in Sanofi's motion record, and it would be inappropriate for me to formally rule upon it. In any event, as already mentioned, the fact that the argument is now clearly brought to Apotex's attention is sufficient to trigger its obligation to consider whether any documents related to its development work, if they exist, might assist Sanofi or hurt Apotex's case with respect to this particular invalidity allegation. There is not need to order a further remedy.

(d) Process details of the method of manufacture of the API used to make Apotex's clopidogrel bisulfate, besylate and hydrobromide tablets.

[27] Some process information was given for manufacturing the API in clopidogrel bisulfate, but none were given for the besylate or hydrobromide.

[28] As for the besylate and hydrobromide, process details may simply not exist, as there is at present no evidence that manufacture has even commenced.

[29] With respect to the bisulfate, which is currently being produced, Sanofi has led no evidence as to what other documents would be expected to exist that would show the method of manufacture for this API, and on this basis, its motion must fail for this category.

[30] Even if I had been inclined to think that other process documents must surely exist, given that clopidogrel bisulfate does appear to have been manufactured either by Apotex Pharmachem or by Signa SA de CV ("Signa"), and that such documents as were produced do appear somewhat scant, the presumption, from the sworn affidavits of documents of Apotex, must be that Apotex has had access to these documents, has concluded that they can only show that the process used is non-infringing, and has determined that they will not be used at trial.

[31] I include in this remark any process documents that Apotex may believe exist and be in the actual possession of Signa, a company which was, but is no longer, a party to this proceeding (a discontinuance was filed on September 14, 2009). To the extent Apotex, through a contract, an

undertaking or at law, is entitled to obtain from Signa a copy of process or manufacturing documents, such documents are to be considered to be in its possession, power or control, and should have been considered for relevance as Apotex's own documents. If, however, Apotex is not entitled to copies of Signa's documents, then it was still required, pursuant to Rule 223(2)(a)(iv) and 223(2)(e), to consider whether relevant documents were in Signa's possession, and to list those documents it believes exist in schedule (iv) of its affidavits of documents.

(e) All manufacturing tickets (Batch Records) for manufacturing of bulk API on a lot by lot basis.

[32] Apotex has disclosed such batch records, but only in respect of Apotex's own production. No batch records are listed with respect to production of API by Signa.

[33] Given that the evidence shows that Apotex has purchased API from Signa, and that batch records do exist for Pharmachem's production, I am satisfied that batch records for Signa's production likely exist and are relevant.

[34] Apotex's only reply to Sanofi's motion on this category is that Signa is a separate entity from Apotex, is no longer a party, and that it would be "unfair" to visit upon Apotex Signa's discovery obligation in the absence of any evidence that Apotex has power, possession or control over Signa's documents.

[35] In view of the discussion set out above, Apotex's position is clearly flawed. Apotex's obligation to list documents where – as here – it has grounds to either know or believe them to exist and be relevant, is triggered whether or not Signa is an independent third party, and whether or not Apotex is considered to hold power, possession or control over its documents. It is Apotex's representative's responsibility, in fulfilling his obligation to make appropriate inquiries and investigations in order to inform himself to make the affidavit of documents, to determine whether or not Apotex is entitled to obtain the original documents, or copies thereof from Signa, and, as his determination falls, to list the documents in either schedule (i) or schedule (iv) of the affidavit of documents.

[36] As the Court does not have before it sufficient evidence to permit a determination as to whether or not Apotex is to be considered as having power, possession of control over Signa's batch records for the API imported by Apotex, it cannot direct in which schedule these documents ought to be listed. Nevertheless, my finding that the documents likely exist, are relevant and have clearly not been listed in any schedule is sufficient to conclude that Apotex's affidavits of documents are deficient and order that it serve complete affidavits of documents, listing under the appropriate schedule the batch records for the relevant batches manufactured by Signa.

(f) All notes and documents establishing how the documents listed in schedule "A" to the statement of claim were located.

[37] Sanofi argues that, at law, a party who alleges that a patent is void for obviousness in light of specific prior art has the burden of establishing that the said prior art was publicly available and

would have been located by the skilled addressee. Sanofi has, in this case, specifically denied that the prior art listed in schedule "A" to Apotex's statement of claim would have been located at the relevant time by a person skilled in the art conducting a reasonable and diligent search.

[38] Before getting into the issue of the privilege asserted by Apotex, it is appropriate to consider whether such documents would be relevant in the sense contemplated by Rule 222.

[39] Apotex argues that how Apotex or its counsel located the prior art listed is irrelevant, as the only relevant question for obviousness is whether the skilled addressee would have found it. As a general statement of relevance, I disagree with this position. How and whether Apotex, its counsel, or any one else for that matter, did find prior art is evidence that this search, made at that time, would have and did turn up the prior art. Whether a skilled addressee would have considered making that search, and whether the same search at an earlier date would have produced the same result may remain at issue and may be a matter for expert evidence, but the fact of what a specific search, made at a specific date, did turn up could well have probative value at a trial.

[40] Relevance, for the purpose of Apotex's disclosure obligation in an affidavit of documents, requires a further analysis. To the extent documents exist that would show a certain search being made and coming up empty, they would likely assist Sanofi. Such a search would tend to show that the prior art, at least at the date of the search and using its parameters, would not have been located; the question for experts would then be whether the skilled addressee would have made that search. A search merely evidencing the successful location of a piece of prior art would seem only susceptible of assisting Apotex and as a result, would only need to be disclosed if Apotex intended

to rely on it at trial. Sanofi argued that a successful search, but which uses arcane or unusual parameters, would show that the art could not be or would not have been located by a reasonable search. The fact that a piece of prior art can be located by an unconventional search does not, by itself, negate or disprove that a conventional search would not also have served to locate it. However, I can conceive that in conjunction with certain other circumstances, the fact that a piece of prior art was first located through an unusual search might support the argument that another "reasonable" search was only thought of through hindsight. Accordingly, while I agree with Sanofi that documents showing how the art listed in the statement of claim could, depending on what they show, be relevant in the sense that they could assist Sanofi, the material before me falls short of showing that such documents likely exist.

[41] The privilege issue still needs to be addressed, however. To the extent Apotex, or its counsel, did conduct prior art searches for the dominant purpose of litigation, documents resulting therefrom may well be covered by litigation privilege. At this time, the issue is not squarely before me, as there is on record no evidence establishing the existence of such documents, let alone the conditions in which they might have been created and from which privilege would flow. However, to the extent such documents did exist that would either assist Sanofi, or upon which Apotex intends to rely at trial, they would, notwithstanding a claim of privilege, still correspond to the definition of relevant documents. They would then stand to be listed and described in schedule (ii) of the affidavit of documents, along with the grounds for each claim of privilege in respect of them (see Rule 223(2).

[42] At present, schedule (2) of Apotex's affidavits of document reads as follows:

> The following are all of the relevant documents, or bundles of relevant documents, that are or were in Apotex' possession, power or control and for which privilege is claimed:
>
> 1. Documents, including but not limited to reports, notes, memoranda and letters, prepared for the purpose of obtaining and giving legal advice;
>
> 2. Documents, including but not limited to reports, notes, memoranda and letters, prepared for the purpose of assisting counsel in preparing for and prosecuting this action; and
>
> 3. Documents, including but not limited to reports, notes, memoranda and letters, created in contemplation of, in the preparation of or for the prosecution of this action.
>
> 4. Documents received from third party Apotex suppliers in a confidence that they would not be disclosed where the element of confidentiality is essential to the maintenance of the relationship with the third party suppliers, and more particularly: [nothing is listed]
>
> [The note is mine]

[43] Rule 223(4) allows a party to treat a bundle of documents as a single document, but under certain conditions only. The comments made in the decision of this Court in *Canada (Minister of Citizenship and Immigration) v. Dueck*, [1998] F.C.J. No. 449, 146 F.T.R. 89, at paragraphs 7 to 12 are entirely apposite and applicable to the present circumstances:

> "7 Rule 448(3) allows a party to treat a bundle of documents as a single document under two conditions. The first condition is that the documents be of the same "nature". The second condition is that the bundle be described in sufficient detail to enable a clear understanding of its contents. In my view, Bundles "A" through "F" do not meet either of these two conditions.
> 8 Each of Bundles "A" through "F" claim privilege over a wide variety of documentation. Bundle "A" is said to contain a multitude of documents described, inter alia, as "correspondence, memoranda and other communications passing between officers, servants or employees of the Applicant and their legal advisors..."

as well as "documents created or assembled and information acquired by or for the use of Applicant's counsel in the litigation, including investigation reports, briefs, memoranda, translations and working papers". Bundles "B" through "F" then reproduce word for word the description given to the documents contained in Bundle "A". There is no apparent commonality amongst the documents within each bundle. Indeed when pressed, counsel for the applicant conceded that the only common thread running through these documents is the fact that they were all subject to a claim of privilege. Obviously, if this was sufficient to bring documents within Rule 448(3), there would never be any need to list privileged documents.

9 As the documents in question are not of the same nature, the applicant's attempt to describe them in bulk cannot possibly allow the respondent to clearly understand the contents of each bundle as Rule 448(3) requires. In the normal course, where a party resists the production of a document on the ground of privilege it must supply a minimum of particulars in respect of that document so as to allow the opposite party to decide whether a challenge is warranted. A proper description would include a brief description, the date, the sender and recipient if any, etc. However, a practice has developed over time whereby a party claiming privilege over a significant number of documents may separate the documents into classes and arrange them in bundles.[4] Rule 448(3) has codified this practice. In my view, where documents of the same class or nature are organized in bundles it is not necessary to identify each individual document as this would defeat the very advantage of "bundling".[5] However, the less closely related the constituent documents in a bundle, the greater the degree of detail required to adequately describe the bundle's contents.

10 In the instant case, no manner of detail could compensate for the dissimilarity in the medley of documents said to comprise each bundle. I note that the applicant's description of the various bundles is replete with qualifiers such as "including" and the disjunctive "or" and references to "other documents" presumably beyond those specifically noted. These terms offer very little insight and indicate that the applicant does not have a firm grasp of the very documentation over which she claims privilege.

11 Litigation privilege is an exception to the general rule that parties to an action must fully disclose all information relevant to their dispute. It is a substantive rule that must not be asserted lightly.[6] In the words of the House of Lords: "claiming privilege in an affidavit of documents is not like pronouncing a spell, which, once uttered, makes all the documents taboo."[7] The party claiming privilege must file an affidavit that is sufficient in identifying the

> relevant documents and setting forth the particular basis on which the claim rests. As noted by MacKay J. in Samson Indian Band v. Canada, where the Court depends on affidavit evidence it necessarily relies on the due diligence of counsel "as an officer of the court, advising the client upon documents to be listed in full disclosure and upon which ones and for what grounds a claim of privilege may be advanced...".[8]
>
> 12 In the present instance, it is my opinion that counsel for the applicant did not meet a standard of due diligence in preparing Schedule II of the Affidavit of Documents."
>
> (Emphasis mine)

[44] To the extent, then, that the bundles listed in schedule 2 of Apotex's affidavits of documents include documents evidencing a search for prior art which would assist Sanofi or on which Apotex intends to rely at trial, its affidavits of documents would be inadequate. As I cannot determine that such documents are included in the bundles described and as this particular issue was not raised by Sanofi on the motion, I will not declare the affidavits of documents to be inadequate on that ground. I however expect that both Apotex and Sanofi will wish to review the adequacy of their affidavits of documents' schedule (ii).

(g) All testing results and documents on work done on any salts of clopidogrel.

[45] As to relevance, Sanofi argued that such testing would be relevant to Apotex's allegation, at paragraph 36 of its amended statement of claim, that clopidogrel bisulfate does not have substantial advantages over other compounds disclosed in an earlier patent. The comments made and conclusions reached for category (c) above, in regard to the same argument, are equally applicable here. Furthermore, to the extent Apotex has defended that part of Sanofi's motion on the basis of privilege, the comments made in respect of search results, under category (f), also apply to such test results.

(h)(i)(j) Specimen/samples of API, tablets or bottles of clopidogrel bisulfate, besylate and hydrobromide.

[46] I agree with Apotex's submission that specimens and samples of material objects do not meet the definition of "documents", as found in Rule 222. The fact that tablets would likely be impressed with words or letters, or that bottles may have labels affixed on them was an ingenious, but ultimately unsuccessful attempt by Sanofi's counsel to secure production of these samples: even if these objects could be construed as "devices on which information is recorded or stored", I would decline to exercise my discretion to grant a remedy to Sanofi on this part of the motion, as its essential goal is clearly to secure the "device" and not the information that might appear thereon.

(k) All contracts between Apotex and its supplier(s) of API.

[47] The argument made by Sanofi in its written representations is to the effect that these documents may provide the terms of sale and specifically where the sale took place, thus defeating Apotex's pleaded position that "Any export by Apotex to [other] countries did not result in a sale in Canada". This argument is flawed. Whatever its terms, the sale of API to Apotex for the purpose of making tablets which are then sold or exported cannot be characterized as a sale by Apotex, in Canada or elsewhere. At the hearing, counsel instead argued that the act of importation in Canada is an act of infringement, and that the terms of the contract(s) between Signa and Apotex would show who, as between Signa and Apotex, was the actual importer. Sanofi's argument has some merit. However, Apotex appears to have disclosed all purchase orders, invoices and customs documents on a batch-by-batch basis, which would be expected to be far more probative of who is the importer of each actual shipment than a general contract. In view of this, and as I suspect that Sanofi's

interest in this contract has far more to do with what the contract would reveal as to Apotex's right to obtain copies of Signa's documents, I decline to exercise my discretion to grant Sanofi's motion on this aspect. The issue of Apotex's possession, power or control over Signa's documents may become an issue relevant to discovery, but it is not an issue relevant to the facts pleaded in the action.

(l)(m)(n) Letters of permission providing permission for Apotex to export and sell in foreign countries, correspondence "regarding" sales of Apotex's clopidogrel in foreign countries and contracts with local companies who sell Apotex's clopidogrel in foreign countries.

[48] There is no evidence before me that, apart from the actual invoices that have been disclosed by Apotex in respect of clopidogrel exported from Canada, any such correspondence, letters or contracts exist that would tend to support Sanofi's contention that the sales were made in Canada. Nor is there any evidence that such documents exist that would point to the existence of exports to countries other than those specifically identified. Sanofi has therefore not met its burden of establishing the inadequacy of Apotex's affidavits of documents in this regard.

Apotex's motion

[49] Apotex's notice of motion lists ten categories of documents, but all can be dealt with – and were in fact argued – under four general headings.

(a) Documents relating to the negotiations and surrounding circumstances to the agreements entered into in the context of U.S. proceedings between the parties.

[50] Apotex's statement of defence pleads that certain agreements have been entered into between Apotex and Sanofi in the context of a U.S. action involving clopidogrel, whereby Sanofi has agreed to limit and recover exclusively in the U.S. action any loss it has suffered as a result of the export and sale by Apotex of clopidogrel from Canada into the United States. Sanofi's position is that the agreements in question only apply to Sanofi's recovery action in the United States, only to sales made in the United States and that they do not operate to restrict Sanofi's right to claim in Canada its full loss in respect of acts of infringement in Canada (that is, manufacture, sales or exports found to have been made in Canada), subject to credit being given to Apotex for damages that might already have been recovered in the U.S.

[51] Apotex submits that it is obvious that the parties are at odds over the proper interpretation of the contracts, and that as a result, "evidence as to the intentions of the parties, including statements made before and after the agreement, the circumstances when the agreement was made and subsequent conduct of the parties" become relevant to the interpretation of the contract.

[52] As mentioned, the parties are expected to already have a clear idea of what their case is about and what is required to prove it at trial. The facts at issue are expected to be pleaded with some precision and clarity. In this instance, it is clear from both Apotex's pleadings and from Sanofi's that as concerns the effect of the agreements, each party relies on the terms of the agreements alone. Apotex has also specifically pleaded, as part of its arguments of abuse of process and of estoppel, Sanofi's conduct in taking suit in the U.S. and its submissions in opposing, on the basis of the U.S. agreements, proceedings previously brought by Apotex before the Ontario Courts. Beyond those very specific facts, neither Apotex nor Sanofi have pleaded as facts relevant to the

interpretation of the agreement any fact relating to statements made by them or their opponent before or after the agreement, to intentions expressed or held, or to conduct. Surrounding circumstances and the subjective intentions of the parties may in certain circumstances be relevant, but only where the terms of the contract are ambiguous, and only where adequately pleaded. Neither party before me took the position that the contract terms were ambiguous, and as stated, the pleadings of both clearly rely solely on the expressed terms of the contracts. On the pleadings as they exist, this category of documents is irrelevant.

(b) Documents concerning the activities of Sanofi and equivalent patents held by or licensed to it in foreign countries.

[53] The paragraphs of Apotex's statement of defence which speak of Sanofi's activities (or lack thereof) in foreign countries read as follows:

> "7. The Plaintiffs seek by the within action to enforce the '777 patent extraterritorially. However, the '777 patent does not have extraterritorial force and effect. Any attempt to recover for alleged harms occurring outside of Canada must be made under any rights held by the Plaintiffs in foreign jurisdictions, which Apotex denies exist. As a result, the Plaintiffs have no standing to claim in respect of activities alleged to be carried out extraterritorially."
>
> "14. Apotex denies that the Plaintiffs have been harmed by any purported export of clopidogrel bisulfate products to Hong Kong, New Zealand, Iran, Libya, Malaysia and Singapore. Any export by Apotex to the aforementioned countries did not result in a sale in Canada. In addition, the Plaintiffs have either not filed patents corresponding to the '777 patent in these jurisdictions or any such patents have expired. As a result, any sales as a result of the purported exports by Apotex would not have been made by the Plaintiffs if such activity had not occurred."

> "15. Apotex further denies that any of the Plaintiffs carry on business in Hong Kong, New Zealand, Iran, Libya, Malaysia or Singapore. As a result, the Plaintiffs have no claim in respect of these alleged sales and no status to advance such claim."

[54] Thus, Apotex has formally pleaded the following material facts: That Sanofi does not hold rights to the invention in foreign jurisdictions and that Sanofi does not carry on business in Hong Kong, New Zealand, Iran, Libya, Malaysia or Singapore.

[55] In reply, Sanofi has pleaded:

> "3. The Plaintiffs specifically deny and join issue paragraphs 6 to 19 of the Statement of Defence and state that many of the allegations contained therein are irrelevant. Further, the Plaintiffs have suffered harm by virtue of acts of infringement in Canada, including the manufacture of clopidogrel in Canada by Apotex Inc. and Apotex Pharmachem Inc. (the "Defendants")."

[56] It is important to note that Sanofi's position is, and has consistently been, in this and other motions before me, that its action and entitlement to relief are based on its rights flowing from the Canadian patent, and are limited to acts of infringement of the Canadian patent which can be established or deemed to have been made in Canada. Despite the plea contained at paragraph 7 of Apotex's statement of defence, it is therefore clear that there is no issue in dispute between the parties as to whether Sanofi has a right or standing to claim for acts of infringement that occurred outside of Canada or a right or standing to sue under any foreign patent rights. Although the absence of foreign patent rights is a fact specifically pleaded in Apotex's statement of defence, it is clearly an irrelevant allegation which, even if substantiated, cannot affect the result of the action. As such, this allegation cannot be used to establish the relevance of documents for discovery

purposes. (*Apotex v. Merck & Co.*, (2004) 33 C.P.R. (4th) 387 at par. 15, affirmed at (2005) 38 C.P.R. (4th) 289).

[57] As to whether Sanofi carries on any business in foreign jurisdictions, or would have been capable of making the allegedly infringing sales, Sanofi does not dispute that these facts may be relevant to the calculation of the damages suffered by Sanofi. However, it points out that by order dated November 2, 2009, all issues and discovery obligations relating solely to the quantum of damages claimed by Sanofi or profits earned by Apotex and claimed under an accounting of profits have been bifurcated and deferred to be dealt with after the main trial on liability. To the extent Sanofi's business presence or activities relate to whether or not it would have made the allegedly infringing sales, I agree that these facts relate to the bifurcated issues and would give rise to no discovery obligations or rights at this time.

[58] Apotex further argued at the hearing that Sanofi's inability to make sales in foreign countries is not solely a matter of damages, but is also relevant to Sanofi's entitlement to an accounting of profits. That argument is articulated nowhere in Apotex's pleadings or in its motion record. It was raised for the first time at the hearing, and no authorities were provided in its support. It is, I believe, a novel argument, and while I conceive that a plaintiff's demonstrated inability to effect certain sales might arguably disentitled it from claiming the profits generated by the defendant on those sales, I would incline to think that this is a matter going to the quantification of profits in an accounting of profits, rather than one going to entitlement to an accounting of profits at large. If the plaintiff's ability to generate a sale is indeed relevant to an accounting of profits and is a matter going solely to quantification, then Apotex is not entitled to a discovery of documents

relevant thereto at this time. If, on the other hand, this issue is one to be considered in determining whether the plaintiff should be entitled to an accounting of profits at all, then it is not bifurcated and is subject to discovery. I find that I am unable, for lack of adequate submissions by the parties, to make that determination here, and decline to do so.

[59] Even assuming, however, that Sanofi's lack of commercial activity in foreign countries is properly at issue on the main trial of this matter, Sanofi's obligation to disclose would be limited to documents that would assist Apotex in establishing that Sanofi does not carry on business in other countries, or to documents on which Sanofi intends to rely at trial to show that it does.

[60] It is far easier to conceive of the kind of documents that would establish that commercial activity takes place than it is to imagine documents that would prove or establish the absence of activity. Apotex's counsel could only suggest that some corporate reports might provide a list of countries where Sanofi is active, thus indirectly showing where it is not active, or that some corporate documents might exist evidencing a corporate decision to not pursue or to cease activities in a certain country. While possible, the suggestion is at this time entirely speculative. Apotex has therefore not met its burden to show that documents likely exist that would assist it in establishing that Sanofi does not carry on business in any of the subject countries. To the extent documents exist that show that Sanofi does carry on business in those countries, Apotex is entitled to assume that Sanofi has decided not to rely on them at trial. Accordingly, even assuming that the issue of Sanofi's activities in foreign countries is relevant to its entitlement to an accounting of profit, Apotex has not established a deficiency in Sanofi's affidavits of documents.

(c) Documents produced by Sanofi in foreign litigations concerning clopidogrel.

[61] Apotex has pointed to six individual documents as examples of documents which were produced by Sanofi in foreign litigations and which it says are relevant to the issues in dispute here, yet were not disclosed in Sanofi's affidavits of documents. Sanofi disputes the relevance of most of these documents. I need not determine whether each of these documents is in fact relevant, or whether each should have been disclosed by Sanofi. Even assuming that Sanofi's affidavits of documents were deficient as a result of these documents being missing, I can find no common thread between these documents that would indicate that they were overlooked or omitted deliberately, through a systemic flaw in the manner in which Sanofi made its enquiries or considered relevance, or simply through error. As such, one cannot conclude that any further relevant documents likely exist and have been "missed". While some of the documents identified by Apotex are relevant, I certainly would not characterize them as important, obviously relevant or clearly probative, such that the failure of Sanofi to have disclosed them would raise concerns as to its diligence, justifying that it be ordered to review its affidavit of documents.

[62] At best, the motion has brought to Sanofi's attention the potential relevance of documents, if any, that might show Sanofi's knowledge of regulatory requirements to file for patent protection in respect of individual enantiomers (as motivation to separate them) or show its internal assessments as to what to expect, if anything, as to the respective enantiomers' activity and toxicity before they were created and tested. Sanofi's continuing obligation to review its documents in light of these arguments has been triggered. No further order is warranted.

(d) Translation from French to English of documents produced by Sanofi both in this and foreign litigations.

[63] This category does not concern translations that might be in Sanofi's possession, but translations of Sanofi's documents that might have been generated by Apotex or its solicitors in the context of foreign litigation and were not publicly filed as evidence therein.

[64] Apotex concedes that such translations would not be deemed to be within Sanofi's power, possession or control but that they would in fact be in Apotex's own possession. The difficulty is that protective orders or the implied undertaking rules regarding use of discovery documents in these foreign proceedings operate to prevent Apotex's foreign counsel to disclose these translations to Apotex for use in this matter. What Apotex requests is an order requiring Sanofi to relieve Apotex's foreign solicitors from the strictures of these orders or rules, or waive them to permit the communication and use of these translations.

[65] It appears that Sanofi is not averse to agreeing to some form of waiver, but the parties disagree as to the precise mechanism to be used, hence Apotex's present claim for relief. Assuming, but without determining either way, that it is within the Court's power to order a party to renounce or waive the protection of other Court's confidentiality orders or implied undertakings rules, I would nevertheless decline to make such an order in the circumstances.

[66] The operation of these restrictive rules or orders does not prevent Apotex from having access to relevant information. Apotex has, in the original French language, all of Sanofi's relevant

documents. It can have them translated at will, and as French is one of this country's official languages, it cannot be said that the task presents insurmountable logistical difficulties. Apotex's desire to have access to such translations as already exist is merely a matter of cost and convenience. Interfering, even indirectly, with the orders or procedural rules of foreign Courts by ordering a party to waive their protection is not something which this Court should do lightly. If such a power does rest with the Court, it should be used sparingly, and only when it has been demonstrated that such a step is necessary to permit a party to have access to information which is relevant and could not otherwise be obtained. Apotex has means to secure its own translations of the documents, if at a cost. To the extent Apotex can demonstrate that Sanofi has unreasonably withheld its consent, it is a matter which should properly be raised in the context of a motion for direction as to costs, after trial.

Costs

[67] At the beginning of the hearing, both parties agreed that the reasonable costs of each motion, if awarded, should be fixed at $1,500. Apotex's motion was unsuccessful, while Sanofi's motion was granted only in respect of one of the 14 issues argued. Looking simply at the outcome, Sanofi should be entitled to its costs of Apotex's motion, while Apotex should be entitled to the larger part of its costs in defending Sanofi's motion.

[68] I also note that the motions were largely unsuccessful as a result of both parties having failed to meet their burden of proof to show the existence of other relevant documents. In the vast majority of cases, the reason for this was not because of how the Court weighted contradictory evidence, but simply because no evidence was even tendered.

[69] Considering counsel's level of experience, the failure to lead the bare minimum of evidence to succeed on a motion speaks either of lack of preparation or the use of a motion for tactical purposes, neither of which should be condoned or encouraged by an award of costs. There will, accordingly, be no costs awarded on either motion.

ORDER

THIS COURT ORDERS that:

1. Apotex Inc. and Apotex Pharmachem Inc. shall, no later than February 2, 2010, serve and file amended affidavits of documents disclosing, under the appropriate schedule, batch records for the clopidogrel active pharmaceutical ingredient it has purchased from Signa SA de CV and which is at issue in these proceedings.

2. The parties' respective motions are otherwise dismissed.

3. There shall be no costs on these motions.

"Mireille Tabib"
Prothonotary

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-644-09
STYLE OF CAUSE:	APOTEX INC. v. SANOFI-AVENTIS
DOCKET :	T-933-09
STYLE OF CAUSE :	SANOFI-AVENTIS and BRISTOL-MYERS SQUIBB SANOFI PHARMACEUTICALS HOLDINGS PARTNERSHIP v. APOTEX INC., APOTEX PHARMACHEM INC and SIGNA SA de CV
PLACE OF HEARING:	Ottawa, Ontario
DATE OF HEARING:	January 7, 2010
REASONS FOR ORDER:	TABIB P.
DATED:	January 22, 2010

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