Federal Court  Cour fédérale

Date: 20100218

Citation: 2010FC182

Ottawa, Ontario, Thursday, this 18th day of February 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] Apotex Inc. started action T-644-09 in May 2009, seeking a declaration that the product it intends to manufacture and sell in Canada, made with clopidogrel bisulfate and/or clopidogrel besylate, will not infringe Sanofi-Aventis' Canadian Patent '777, and seeking a declaration that the said patent is invalid. One month later, Sanofi-Aventis and Bristol-Myers Squibb Sanofi Pharmaceutical Holdings Partnership (jointly "Sanofi") sued Apotex Inc. and Apotex Pharmachem Inc. (jointly "Apotex") alleging that Apotex is already manufacturing and exporting for sale in various countries a clopidogrel bisulfate product, infringing the '777 patent. Both parties requested that early trial dates be set. The actions were consolidated and trial dates have been set aside for the trial to begin in April 2011.

The motion:

[2] By this motion, Apotex seeks to "consolidate" its statement of claim in T-644-09 and its defence to the T-933-09 action into a single defence and counterclaim to the T-933-09 action, as well as to:

(a) Make several cosmetic and definitional changes intended to clarify the pleadings, without affecting their substance.

(b) Add certain factual admissions about the activities of Apotex relating to the manufacture and sale of clopidogrel-containing products.

(c) Include additional pieces of prior art in the schedule to its pleading.

(d) Specifically plead the experimental use and related exceptions to infringement provided for in the *Patent Act* and at law.

(e) Include its claim for a declaration of non-infringement with respect to three salt forms of clopidogrel in its counterclaim to the T-933-09 action, including with respect to a new salt form, the hydrobromide salt.

(f) Add a defence of limitation based on the application of the *Ontario Limitation Act* 2002, S.O. 2002 c.24.

(g) Add a defence of set-off based on the "break fee" contained in the "March 2006 Agreement".

(h) Add a defence of set-off based on the tort of deceit.

(i) Add a defence of set-off based on abuse of process.

(j) Add details about the circumstances giving rise to the "2006 Agreements" already pleaded and the legal effects of certain provisions as they related to the action.

(k) Add details as to a defence of disentitlement to monetary remedies.

[3] Sanofi objects in principle to Apotex "consolidating" into a counterclaim to the T-933-09 action the action for impeachment and declaration of non-infringement originally brought by Apotex Inc. in the T-644-09 action. As to the modifications and additions themselves, Sanofi:

- Takes no issue with those set out in paragraphs (a), (b) and (c) above.
- Agrees to the addition of details for the experimental use and other exemptions ((d)), provided that Apotex be ordered to provide particulars as to the quantities and specific exemptions to be applied.

- Objects to the addition of a declaration of non-infringement in respect of salts other than the besylate as a counterclaim ((e)), as being based on a mere intention and therefore premature and having no practical effect.

- Objects to the addition of a limitation defence ((f)) as not disclosing a reasonable defence and failing to plead all relevant facts necessary to its application.

- Objects to the addition of the claims for set-off ((g), (h) and (i)) on the basis that they are outside the Court's jurisdiction, are not properly pleaded, disclose no reasonable defence or cause of action and are scandalous, frivolous and vexatious.

- Objects to the addition of circumstances giving rise to the 2006 Agreements ((j)) as seeking to contravene the parole evidence rule and as being an attempt to improperly broaden discoveries, to the prejudice and inconvenience of Sanofi.

- Objects to item (k) insofar as it relates to the new allegations relating to set-off (for the same reasons as given above) and insofar as they purport to apply to Sanofi's claim for damages pursuant to the *Patent Act*.

Preliminary observations:

[4] Not a single one of Apotex's proposed new allegations could not have been made at the time Apotex filed its original pleadings. I repeat here the comments made in the Reasons for Order issued in this consolidated action on January 22, 2010 (*Apotex Inc. v. Sanofi-Aventis*, 2010 FC 77):

> "[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.

[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."

(Emphasis added)

[5] Either Apotex is only belatedly taking these comments to heart, and the proposed amendments reflects a now clearly developed and articulated theory of the case, or this new pleading represents the very illustration of the fishing expeditions, cobbled strategy and inability to articulate a coherent theory of the case which the Court then censured.

Prejudice:

[6] Apotex has taken the view that its amendments are sought at an "early stage", and cannot prejudice Sanofi or the conduct of these proceedings. Apotex takes this view, it appears, because discoveries have not yet been completed (Apotex has had discovery of the inventors and of Sanofi on scientific issues, but some three days of discoveries are contemplated with a representative of Sanofi on non-scientific issues and the discovery of Apotex by Sanofi has not yet commenced). Apotex also asserts that the amendments, if allowed, would not require more than the three days already contemplated to complete discovery of Sanofi and would not require any additional trial time over and above the five weeks already set aside.

[7] I must disagree with Apotex on its characterization. As a streamlined proceeding, a schedule was set whereby the "first round" of discoveries of all parties was meant to have been completed by February 1, 2010. Two motions for further and better affidavits of documents have already been heard and determined. As a result of the outcome of one of these motions, the discovery of Apotex by Sanofi would have been slightly delayed, but completion of Sanofi's discovery by Apotex should not have been affected. The very filing of Apotex's motion to amend,

on January 25, 2010, has caused the discoveries to be further delayed. If the amendments are permitted, discoveries will be delayed even more by the need for Sanofi to prepare and file amended pleadings in response and the need for the parties to serve supplementary affidavits of documents relating to the amendments. Notably, some of the amendments now proposed would require the documents sought by Apotex on its motion for a further and better affidavit of documents, found irrelevant on the basis of Apotex's then pleadings, to be considered anew for relevance. Even in the best-case scenario, the earliest the "first round" of discoveries could be concluded would be the end of March 2010, a delay of two months from the initial schedule, with barely twelve months left before the trial, and with motions arising out of discoveries, re-attendances, further motions thereon and expert reports still to be done.

[8] If this litigation is still in its "early stages", it should not be. The extensive amendments now sought to be made would cause the litigation to remain at this "early stage" well passed the time where discoveries should be winding down.

[9] The delay, in turn, will inevitably compress the schedule for the remaining months before trial. It will leave even less margin for unforeseen events. It will put more pressure on the parties, including Sanofi, to complete discoveries and prepare for trial in a shorter time frame, and on the Court to schedule and determine interlocutory motions.

[10] As to the time required for trial, unless it is suggested that both parties knowingly inflated the time they estimated necessary for trial when it was originally set, it is plain that the extensive new facts alleged by Apotex will require more evidence at trial than originally contemplated, and should therefore require some additional trial time over and above the time already contemplated. Apotex's assertion that no more than the already scheduled time will be required implies that Apotex is prepared to make compromises in its use of its portion of the allotted trial time, either to cram in imperfectly all of its evidence or to scrimp on that evidence it had initially intended to bring when the issues were narrower. It is certainly at liberty to do so, but adding all these issues without extending the trial time – or at least Sanofi's portion of the trial time – would force Sanofi to make similar compromises as to its use of its own allotted trial time. Apotex therefore cannot claim that Sanofi will not be prejudiced by the addition of all of these new facts if the trial time is to remain the same. Nor is it an answer for the trial simply to be adjourned or for additional weeks to be scheduled. These trial dates were set aside over six months ago; other trials have since been fixed before and after them. The trial cannot be extended without re-scheduling previously scheduled hearings or causing serious inconvenience to the administration of this Court. As to adjourning the dates, both parties had specifically requested early hearing dates and accepted the resulting obligation upon them to do what was required to meet theses dates and keep to them. The Court accommodated their request. If, by their conduct, the parties make it impossible to keep the dates set aside, they cannot expect the Court to simply accommodate them again, by again reserving in advance of a formal pre-trial conference dates that could be used for trials that are actually ready to proceed. To the extent Sanofi shared Apotex's desire for early trial dates, an adjournment would therefore also cause prejudice to Sanofi as it would delay trial by as much as one year.

[11] Despite the lack of any direct evidence on record by Sanofi as to how it might be prejudiced by the amendments, I am satisfied, on the basis of the observations made above, that if all of the amendments proposed by Apotex are allowed, Sanofi is more likely than not to be prejudiced, either as a result of a compressed schedule and of having to fit more evidence into the same allotted trial time, or as a result of a delayed trial.

[12] That is not to say that the amendments should be denied for that reason. There are several groups of amendments, some of which are discrete and involve few facts, some of which are interrelated and call upon a substantial body of facts. The likelihood of prejudice depends on the number and nature of the amendments that are, otherwise, permissible (i.e. that should not otherwise be refused as disclosing no reasonable defence or being frivolous or vexatious).

[13] Furthermore, even if all or most of the amendments were found to be proper, the prejudice identified above could be avoided or mitigated by imposing other conditions, such as restricting discoveries by Apotex or re-bifurcating the issues so that the subject matter of the new amendments be reserved to be dealt with at the “damages” stage, after the issues going very specifically to infringement and invalidity have been resolved.

[14] It is therefore appropriate to consider, in turn, each proposed group of amendments to determine whether, apart from the potential prejudice to Sanofi, they are otherwise appropriate.

Experimental use and other exemptions:

[15] The proposed paragraphs to be added by Apotex read as follows:

> "83. Further, the Apotex Defendants plead and rely upon the common law "experimental use" exception to infringement. The Apotex Defendants also plead and rely upon subsections 55.2(1) and (6) of the *Patent Act*, as they read at all material times, dealing with the manufacture, construction, use or sale (collectively, for the purposes of paragraphs 83 to 84, "use") of a patented invention relating to the development of regulatory submissions, private use and experimental use.
>
> 84. In this respect, the Apotex Defendants state that one or more of the foregoing exceptions would exempt from infringement the following uses of clopidogrel:
>
> (a) use of clopidogrel for research and development purposes;
> (b) use of clopidogrel for internal and external quality control purposes; and
> (c) use of clopidogrel in compliance with regulatory requirements specified in the *Food and Drug Regulations* (Canada), provincial regulatory requirements (section 6 of Regulation 935, *Drug Interchangeability and Dispensing Fee Act* (Ontario) and foreign regulatory requirements."

[16] It As mentioned, Sanofi does not object to an amendment that would specifically plead these exemptions, and indeed, the parties' representations in earlier motions seemed to assume that these exemptions would be relied upon. Sanofi however argues that the proposed pleading "is deficient in that insufficient particulars, including the quantities and specific exemptions to be applied, have not been provided". I agree. The pleading as proposed is no more than a bare recital of "one or more" of the common law or statutory exceptions that "would" exempt certain uses of clopidogrel from infringement. It does not allege that the exemptions in fact apply, in that it does not allege that

Apotex in fact used any clopidogrel for any exempted use. It does not provide any material fact as to any particular research and development purpose, any particular internal or external quality control or identify for which foreign regulatory requirement(s) clopidogrel was used. It does not state the quantities for which each exemption is sought.

[17] This is not a matter for discovery, especially not in a streamlined proceeding. Pleadings are meant to define the facts a party intends to prove at trial. They also frame and define the scope of discovery. As proposed, the pleading leaves entirely unclear whether the exemptions are sought in respect of one kilogram or one ton of clopidogrel, of one percent or of ninety percent of Apotex's production and whether there are any material facts that would support Apotex's contention that any of those quantities were actually used for any of the purposes alluded to. It leaves open for potential questioning on discovery the use of every gram of clopidogrel produced by Apotex. It negates any possibility that Sanofi could, upon considering the quantities and purposes defined and finding them reasonable, narrow the pleadings and the scope of discovery by admitting all or parts of the exemptions sought. The amendments are therefore permitted, but on condition that Apotex provide particulars of the quantities claimed for each exemption, and of the material facts in support of each exemption.

Declaration of non-infringement with respect to other salts:

[18] A declaration of non-infringement in respect of the besylate salt was already sought on the basis of the same allegations of "intent" in Apotex's T-644-09 action. Sanofi did not move then to

strike the pleading, and it is not appropriate for it to seize the opportunity presented by Apotex's desire to transport the same allegations from its statement of claim in T-644-09 action to its counterclaim in T-933-09 to mount a belated challenge to the sufficiency of these allegations. Similarly, Sanofi's motion for a further and better affidavit of documents was heard on the understanding that the parties had agreed between themselves that Apotex would and could amend its pleadings in T-644-09 to add a declaration of non-infringement in respect of the hydrobromide salt, in all appearances on the same allegations of intent as were made for the besylate. Sanofi's belated objection is untimely and improper.

[19] Although it was not raised by Sanofi on this motion, I note that in moving the claim for a declaration of non-infringement from the T-644-09 action (where only Apotex Inc. was the plaintiff), to a counterclaim in the T-933-09 action (where Apotex Inc. and Apotex Pharmachem Inc. are defendants), Apotex has included Apotex Pharmachem Inc. in the scope of its declaration of non-infringement:

> "121. The Apotex Defendants (plaintiffs by counterclaim) seek:
>
> (b) An order that their clopidogrel (…) will not infringe (…)".
>
> (Emphasis mine)

[20] Yet the factual allegations supporting this request, imported from the T-644-09 action, are in respect of Apotex Inc.'s product and intended manufacture only. There is no allegation whatsoever relating to Apotex Pharmachem's proposed manufacture or sale. A declaration that Apotex Pharmachem's product will not infringe is therefore plainly and obviously unsustainable, as there

are no material facts pleaded with respect to Apotex Pharmachem. The amendment at paragraph 121(b) would therefore have to be modified to be restricted to Apotex Inc.

The defence of limitation:

[21] Although section 55.01 of the *Patent Act* provides for a six year limitation period, it is common ground between the parties that the transitional provisions relating to this section could arguably be read as excluding from its application actions for infringement of patents issued under the "Old Act". Sanofi of course argues that properly interpreted, the transitional provisions provide for the application of section 55.01 in this case, but it properly conceded at the hearing that Apotex's position to the contrary is at least arguable.

[22] Apotex wishes to plead that if section 55.01 does not apply, then the two year limitation provided by the *Ontario Limitations Act* applies, as "the cause of action" arose entirely in the province of Ontario. To this effect, it seeks to add the following allegations of fact:

> "59. Any manufacture, sale or use of clopidogrel or any clopidogrel-containing product by Apotex Inc. or Apotex Pharmachem took place in and only in Ontario. Any manufacture, sale or use of clopidogrel or any clopidogrel-containing product by Apotex Inc. or Apotex Pharmachem outside of Ontario, which is denied, does not constitute infringement of the '777 patent.
>
> 60. Specifically with respect to the U.S., the Apotex Defendants state that, at all times prior to June 9, 2007, the Plaintiffs knew that the U.S. Apo-clopidogrel Product:
>
> (a) Did not involve Apotex Pharmachem in any manner; and

(b) Was manufactured, sold and used (if at all) by Apotex Inc. solely in Ontario, Canada."

[23] Sanofi argues that for a provincial limitation period to apply, all constituent elements of a cause of action must have occurred in the province, including the damage suffered and the act that caused the damage (*Canada v. Maritime Group (Canada) Inc.*, [1995] 3 F.C. 124). It argues that the proposed pleading is deficient and insufficient because it fails to address where exportation (an act of infringement specifically pleaded) occurred, and fails to address where the damage was suffered.

[24] As to where damage occurred, Sanofi asserts, but does not point to any authority to support its assertion, that damage is necessary located at the place where the plaintiff resides. Assuming – but without deciding – that this proposition is plain and obvious at law, what is not plain and obvious is that the "cause of action" in a patent infringement action requires, as a necessary or essential component, that damage be suffered. *Canada v. Maritime Group* involved a tort, and it was specifically found that damage (in that case, the loss of a ship on the high seas) was indeed an essential element of the tort without which the cause of action would not arise. It is not plain and obvious to me that a monetary loss is an essential element or requirement for a cause of action for patent infringement to arise. Indeed, an injunction is one of the remedies available in a patent infringement action, regardless of whether or not a loss was suffered. It is true that Sanofi here also claims damages, but I cannot agree that the mere fact that damages are an available remedy must, plainly and obviously, mean that for the purpose of section 39(1) of the *Federal Courts Act*, those

damages can be characterized as a constituent element of the cause of action, such that the place where they were suffered determines the applicable limitation.

[25] The pleading is therefore not plainly and obviously deficient at law for failing to allege that the damage was suffered in Ontario.

[26] I now turn to the pleading's failure to address the place where the export, as an alleged act of infringement, occurred. The proposed pleading contains a clear statement to the effect that any sales of clopidogrel by Apotex occurred in Ontario and in Ontario only. As such, Apotex's position on the pleadings negates and denies any export by Apotex, and its defence of limitation would accordingly be complete without reference to the place where export, which is essentially denied, occurred.

[27] The proposed pleadings contain new admissions to the effect that Apotex Pharmachem has manufactured the bulk product in Ontario and sold and delivered same to Apotex Inc. in Ontario (paragraph 6), that Apotex Inc. has made a clopidogrel bulk product into tablets in Ontario, that neither Apotex Inc. nor Apotex Pharmachem have marketed or sold clopidogrel in the U.S. (paragraph 7) and that, rather, sales in the U.S. were made by Apotex Corp. (not a party to this action) using Apotex Inc.'s product (paragraphs 7, 15 and 19). It becomes inescapable on the pleadings as proposed, that as Apotex Inc. admits that <u>any</u> sale it has made was made in Ontario,

any sales by Apotex Inc. of product eventually sold in the U.S. were made in Ontario, either directly to Apotex Corp. or to an intermediary, and that any export was therefore made by Apotex Corp. or this intermediary.

[28] The proposed pleading at paragraph 59 is not limited to product eventually sold in the U.S., but is general and absolute. It also covers sales of product eventually sold in other jurisdictions. I am mindful that there is a potential ambiguity with the allegations found in paragraph 16, relating to other jurisdictions. It is said in that paragraph that "the Apotex defendants deny that the plaintiffs have been harmed by the sale in Hong Kong, New Zealand, Iran, Libya, Malaysia and Singapore of clopidogrel bisulfate made in Canada. Any export by Apotex Inc. to the aforementioned countries did not result in a sale in Canada". Read alone, these sentences could be thought to imply a recognition that Apotex Inc. might have exported the product to those other countries, and perhaps there sold it, but with the contention that such sales were not made in Canada. However, the clear, unambiguous and most recent amendments that "any(…) sale(…) by Apotex Inc.(…) took place in and only in Ontario", and that "any(…) sale(…) by Apotex outside Ontario, which is denied(…)" take precedence over and resolve such potential ambiguity. Paragraph 16 must therefore be read as a mere pleading that if Apotex were to be found to have exported the product, the resulting sales in foreign countries (necessarily by a third party since Apotex denies any sale outside Ontario) cannot equate to sales in Canada. This is quite consistent since, according to paragraph 59, Apotex's sale of the product, and its loss of ownership of the product, would have taken place in Ontario, prior to export.

[29] I am therefore satisfied that, even as regards the alleged export of clopidogrel for sale in countries other than the U.S., Apotex's failure to plead the location of the alleged export is not a fatal flaw to its plea of limitation.

[30] I note in passing that the new pleadings and the admission that all sales of clopidogrel by Apotex were made in Canada have the potential to substantially narrow the issues in dispute and the scope of discoveries, at least to the extent Sanofi were to accept the admissions of Apotex that all its sales took place in Ontario. Indeed, I understand that much documentary discovery has been concerned with pinpointing the place where sales were made, inasmuch as Apotex's previous pleadings appeared to deny any sale by Apotex in Canada.

Set off: Jurisdiction and general principles:

[31] Apotex's proposed amendments seek to introduce three new defences of set-off: One based on an alleged debt for a "break fee" arising out of the March 2006 Settlement Agreement, one based on the tort of deceit, and one based on the tort of abuse of process.

[32] Counsel for Apotex at the hearing conceded that the tort of deceit and the claim for the "break fee", would not, if brought as independent actions or as counterclaims, fall within the jurisdiction of this Court. However, Apotex argued that these two claims, because they are pleaded

here as a defence of set-off rather than as independent counterclaims, can validly be heard and adjudicated by the Court regardless of the Court's lack of jurisdiction over their subject matter.

[33] I agree that cross-claims arising out of matters over which the Court would not have jurisdiction could perhaps arguably be raised as a defence of set-off in this Court, but if, and only if, they meet the jurisprudential criteria to qualify as a defence of equitable set-off.

[34] General speaking, set-off is the process whereby two mutual claims for money are set-off against each other to produce a balance before any party is called upon to execute its obligation. The essence of a set-off is the existence of cross-demands, that is, the existence – or assertion of – a mutual claim for money.

[35] Canadian law recognizes two general types of set-off: Legal or statutory set-off, and equitable set-off. Whereas it seems that equitable set-off may be a substantive defence, it is plain that legal, or statutory set-off is a procedural defence and not a substantive defence to an action.

[36] The history of the development of the law of set-off, and particularly, of legal set-off, as set out in the leading Supreme Court decision of *Holt v. Telford* [1987] 2, S.C.R. 193, and as discussed in Kelly R. Palmer, *The Law of Set-Off in Canada*, (Aurora: Canada Law Books Inc., 1993 at pages

5 to 9), shows clearly that it was created and continued to evolve as a procedural means to allow the resolution in a single hearing and a single judgment of separate monetary claims mutually asserted between parties so as to prevent multiplicity of litigation, much like the procedural right to assert a cross-claim by way of counterclaim. Its procedural nature is confirmed by the fact that while it was originally promulgated by specific statute in England, it is now generally found, both in Canada and in England, in the applicable judicature acts or rules of Court, as it is indeed found in our *Federal Courts Rules* at Rule 186. As telling is the fact that statutes establishing the right to assert a monetary cross-claim as a "defence" of set-off generally allow the choice of asserting this claim as a defence or as a counterclaim, the main practical difference being that whereas a counterclaim will result in a separate judgment, with its own award of costs, a cross-claim asserted as a defence of set-off will result in a single judgment and cost award.

[37] That a procedural means is developed for a particular right to be determined does not elevate that procedural means into a substantive right or defence. The right to assert a monetary claim as set-off does not detract from the fact that the debt so asserted remains to be heard and adjudicated by the Court, and that this debt, if found to be valid, is effectively enforced by reducing the amount of the judgment that would otherwise be pronounced in favour of the plaintiff. The provision of a procedural means to assert a right does not vest the Court with jurisdiction it would not otherwise have to hear, determine and enforce the substantive matter brought before it through that procedural means. To allow any monetary cross-claim to be asserted and determined in defence to an action before this Court when it could not be asserted and determined as a counterclaim, merely because the procedural vehicle is contemplated in Rule 186 of the *Federal Courts Rules*, would allow the

Court to do indirectly what it cannot do directly and to accept that the Court can give itself jurisdiction not otherwise given to it by statute, through a simple rule of procedure.

[38] As mentioned above, it is at least arguable that a defence of set-off that meets the criteria for equitable set-off could be considered a substantive defence to a claim, and thus be amenable to be considered and determined by the Court even though it would not independently fall within its jurisdiction.

[39] The criteria for equitable set-off, as found in *Coba Industries Limited v. Millie's Holdings (Canada) Limited and Tsang* [1985] 6 W.W.R. 14 at page 22, and approved by the Supreme Court of Canada in *Holt v. Telford*, at page 213, are the following:

> "1. The party relying on a set-off must show some equitable ground for being protected against his adversary's demands: Rawson et al v. Samuel (1841), Cr. & Ph. 161, 41 E.R. 451.
>
> 2. The equitable ground must go to the very root of the plaintiff's claim before a set-off will be allowed: British Anzani.
>
> 3. A cross-claim must be so clearly connected with the demand of the plaintiff that it would be manifestly unjust to allow the plaintiff to enforce payment without taking into consideration the cross-claim: Federal Commerce & Navigation Ltd.
> 4. The plaintiff's claim and the cross-claim need not arise out of the same contract: Bankes v. Jarvis, [1903] 1 K.B. 549; British Anzani.
>
> 5. Unliquidated claims are on the same footing as liquidated claims: the Newfoundland case."
>
> (Emphasis mine)

[40] It appears that the requirement that the equitable ground go to the very root of the Plaintiff's claim is what raises equitable set-off to the level of a substantive defence, allowing it to be asserted even where the cross-claim is not otherwise enforceable by reason of limitations (unlike statutory set-off, which is affected by expiration of a limitation period, see *Canada Trustco. Mortgage Co. v. Pierce Estate*; *Pierce v. Canada Trustco. Mortage Co.* (2005) 254 D.L.R. (4th) 79, 197 O.A.C. 369) and allowing it to be used even against an assignee, avoiding the requirement of mutuality which is a condition of statutory set-off, as was the case in *Holt v. Telford*. The possibility of equitable set-off having the status of a true substantive defence, tentatively discussed in Canada in *The Law of Set-Off in Canada* at pages 9 to 12, now appears to have been generally accepted (see most recently *Eli Lilly and Co. v. Apotex Inc.* 2009 FC 991 at paragraphs 636 to 639. For further discussion, see R. Derham, *The Law of Set-Off* (Oxford: Oxford University Press, 2003 at pages 93 to 105). While it remains to be specifically determined whether the status of equitable set-off as a substantive defence would overcome the Court's lack of jurisdiction over the subject matter of the cross-claim, I am satisfied that the issue is at least arguable, considering the discussions in *Innovation and Development Partners/IDP Inc. v. Canada*, [1992] F.C.J. No. 203, *Castlemore Marketing Inc. v. Intercontinental Trade and Finance Corp.*, [1996] F.C.J. No. 302 and *Bristol-Myers Squibb Co. v. Apotex Inc.*, 2008 FC 1196, amongst others.

[41] Accordingly, I am satisfied that to the extent any of Apotex's claims for set-off could arguably constitute equitable set-off, it is not plain and obvious that this Court would not have jurisdiction to consider same as a defence to Sanofi's action for infringement. However, if it is plain and obvious that a claim of set-off does not meet the requirement of equitable set-off and is not

otherwise within the Court's jurisdiction, then the Court would lack jurisdiction to hear and determine same and the claim will be struck.

[42] I now turn to consider each individual claim of set-off proposed to be pleaded by Apotex.

The "break fee" arising out of the March 2006 Agreement:

[43] Apotex alleges that Sanofi and it entered into a series of related agreements (the "2006 Agreements") to settle litigation between them in the U.S. involving clopidogrel, the drug at issue in this action. The 2006 Agreements were pleaded in Apotex's original statement of defence, but for the proposition that the May 2006 Agreement barred Sanofi from claiming against Apotex in this Court in relation to U.S. sales of clopidogrel, and for the proposition that Sanofi's action for "alleged harms governed by this contractual relationship" was an abuse of process, Sanofi having successfully objected to the Ontario Court's jurisdiction when Apotex earlier attempted to enforce the "break fee" arising out of the March 2006 Agreement.

[44] It is this very "break fee" which Apotex now wishes to set-off against Sanofi's claim for damages for infringement.

[45] While the "break fee" is part of the 2006 Agreements by which Apotex submits Sanofi agreed to limit any claim "related to" infringing U.S. sales, it is clear that the alleged "break fee", claimed to be due pursuant to the March 2006 Agreement, has nothing whatsoever to do with any sales in the U.S. and therefore, with any alleged or actual infringement. According to the March 2006 Agreement, as pleaded, the "break fee" became due simply as a result of the State Attorney General declining to approve the March 2006 Settlement Agreement, irrespective of whether Apotex decided to launch "at risk" in the U.S. or not. It is plain and obvious that the contractual claim for payment of the "break fee" has no connection whatsoever with the claim for infringement asserted by Sanofi. It is equally clear that there is no equitable ground to that claim and that the fact that the "break fee" is allegedly due to be paid to Apotex in no way impeaches Sanofi's claim. It is therefore plain and obvious that the defence of set-off based on the alleged "break fee" cannot amount to an equitable set-off.

[46] As conceded by Apotex's counsel at the hearing, the claim for the "break fee" is contractual in nature and this Court would have no jurisdiction to hear and determine that claim as a counterclaim or as an independent action. For the reasons given above, I am satisfied that the Court has equally no jurisdiction to hear and determine same in the context of a defence of set-off.

[47] Even if I am wrong in this, raising a claim based on the "break fee" as set-off in this action is clearly abusive and vexatious. Apotex's pleadings admit that Apotex attempted to have this very claim litigated before the Ontario Courts, and that the Ontario Superior Court, affirmed on appeal,

found both that it did not have jurisdiction to hear it and that Ontario was *forum non conveniens*. Apotex's proposed pleadings further admit that Apotex has since instituted proceedings in the Superior Court of New Jersey, over twelve months ago, to recover from Sanofi that very debt, and that it is currently proceeding with that action. There is no conceivable reason why this Court should be asked to consider and rule upon a claim which is already being actively prosecuted in another jurisdiction, with the obvious risk of contradictory judgments. For Apotex to seek to submit this dispute to this Court for parallel adjudication is all the more clearly abusive that the New Jersey Court has been found to be the most appropriate Court to determine that dispute, not only by the Ontario Superior Court but by the United States' Federal Court, as admitted by Apotex itself in its proposed pleading.

[48] Apotex's proposed amendment to include a claim for the "break fee" as set-off is clearly abusive and vexatious.

The tort of deceit:

[49] Apotex's initial defence alleges that the 2006 Agreements govern any claims, including those asserted by Sanofi in this action, related to sales in the U.S. of clopidogrel made by Apotex in Canada. Specifically, it alleges that Sanofi, through the "Liability Exposure Provision" found in the May 2006 Agreement, has agreed that its recovery in respect of sales in the U.S. of infringing clopidogrel made by Apotex in Canada is to be limited to fifty percent of Apotex's net sales of

clopidogrel in the U.S. The proposed amended pleading adds numerous particulars going to Apotex's contention that either explicitly, by contextual interpretation or by implied terms, the Liability Exposure Provision applies to this action in respect of clopidogrel ultimately sold in the U.S.

[50] The claim for set-off based on tort is an alternative plea to this defence. In essence, it alleges that if the Liability Exposure Provision does not apply to limit Sanofi's recovery as argued, then Apotex will suffer damage equivalent to the difference between the amount awarded to Sanofi in this action for clopidogrel ultimately sold in the U.S. and the amount to which it was entitled in respect of these sales in the U.S. litigation applying the Liability Exposure Provision. Apotex alleges that Sanofi breached a duty of care towards Apotex by misleading it as to the meaning and application of the Liability Exposure Provision, in that Sanofi led Apotex to believe that the Liability Exposure Provision would apply to infringement actions outside the U.S., such as the present one, and, knowing that Apotex erroneously believed that it did, failed to take steps to dissuade Apotex from that belief. Apotex then alleges that had Sanofi not so misled it, i.e. had Apotex known that the Liability Exposure Provision did not apply in a Canadian infringement action, Apotex would not have launched its product in the U.S., and would therefore not be subject to recovery of damage for those sales.

[51] Apotex characterizes these pleadings as allegations sounding in the tort of deceit. Counsel for Apotex, while acknowledging that the tort would not fall within the Court's jurisdiction if

brought as a counterclaim, asserted that it amounts to a substantive defence of equitable set-off and can therefore in any event be pleaded as a set-off. Apotex essentially argues that, had deceit not occurred, Apotex would simply not have infringed, so that there is a clear connection between the claim of infringement and the deceit alleged to have been practised by Sanofi, going to the very root of Sanofi's claim and making it unjust to allow Sanofi to recover for these claims.

[52] I have very serious doubts as to whether this claim would constitute an equitable set-off, as despite the cause and effect pleaded by Apotex, the alleged tort does not impeach the claim for patent infringement, or in any way deny that infringement did take place. It does not allege that Sanofi encouraged or induced the infringement itself, or that the infringement was justified. Rather, it essentially accepts that Apotex voluntarily launched at risk and that both parties contemplated that at least one claim for damages for infringement would result from its launch. The alleged deceit goes not to whether the patent was valid or would be infringed but merely to how much money Apotex would be required to pay in compensation when and if it was determined that the patent was valid and infringed. I do not however need to determine whether Apotex's contention that its alleged tort of deceit arguably constitutes a substantive defence of equitable set-off, as I am otherwise convinced that Apotex's claim cannot succeed on the facts as pleaded, and is, furthermore, scandalous and vexatious.

[53] The tort of deceit is distinct from the tort of negligent misrepresentation, in that it includes a necessary element of fraud or moral wrongdoing. Indeed, liability for economic loss arising out of

deceit was accepted over eighty years before the Courts finally recognized that economic loss could be recoverable for mere negligent misrepresentation. The essential elements of the tort of deceit are the following: A false statement, knowledge of the falsity, an intention to deceive, reliance by the plaintiff and damage caused by the reliance (G.H.L. Fridman, *The Law of Torts in Canada*, 2nd ed., Toronto: Carswell, 2002 at page 747).

[54] Unlike negligent misrepresentation, which might, in appropriate cases, contemplate negligent advice or promises, "Deceit involves statements of fact, not opinion, estimates, advice or promise" (Fridman, page 748).

[55] There is strictly no allegation anywhere in the proposed pleadings of any statement of fact, let alone of a false one, having been made by Sanofi either directly or by omission at any time. The pleadings therefore fail to plead an essential component of the tort of deceit and cannot possibly succeed.

[56] While Apotex has not argued before me that the pleadings might otherwise sustain a claim based on the tort of negligent misrepresentation, I will nevertheless consider the pleadings from that angle.

[57] The constituent elements of the tort of negligent misrepresentation are: A duty of care based on a special relationship between the representor and the representee, an untrue, inaccurate or misleading representation, negligence in making the misrepresentation, reasonable reliance and damages resulting therefrom (Fridman, page 610).

[58] The proposed pleadings state that Apotex and Sanofi "were in a relationship of sufficient proximity that it was reasonably foreseeable that if [Sanofi] misled Apotex about the Liability Exposure Provision (…) harm to Apotex would ensue". There are, however, no facts pleaded in the section of the proposed pleading identified as going to this claim of set-off upon which a special relationship or reasonable foreseeability of harm might be found. There are, further, no allegations, general or specific, to the effect that Apotex in fact relied on Sanofi's representations as to the effect of the Liability Exposure Provision, or as to why such reliance would be reasonable.

[59] Reading the pleadings as a whole and giving them as generous an interpretation as possible, the only factual allegations that might go to the relationship, the foreseeability of harm, the reliance or the reasonability thereof are the facts pleaded in paragraphs 23 to 55. Essentially, these paragraphs state that Apotex and Sanofi had been engaged in litigation in the U.S. over the validity and infringement of the U.S. counterpart of the patent at issue since 2002, that in January 2006, the parties entered into negotiations to settle the litigation, that four negotiation meetings occurred between January 31, 2006 and March 2006 (all with counsel for both parties in attendance), that during those meetings, Apotex expressly demanded as a condition of settlement that provision be

made to limit its monetary liability in the event that it proceeded to commence potentially infringing sales in the U.S., that Sanofi expressed a willingness to negotiate such a condition, that the March 2006 Agreement resulted from the negotiation, that regulatory approval was declined with respect to that Agreement, and that further negotiations took place resulting in the May 2006 Agreement.

[60] The relationship described by these facts is plainly that of two pharmaceutical companies engaged as adversaries in litigation, negotiating and arriving at an agreement to settle the litigation, each assisted by their respective counsel.

[61] As mentioned, the alleged deceit or misrepresentation is not with respect to any fact imparted by Sanofi to Apotex, but with respect to the effect and application of the clauses of the agreements resulting from these negotiations. There is no reasonable possibility that a Judge could conclude that these facts give rise to a relationship wherein Sanofi could foresee that Apotex would rely on any representations it might have made as to the effect of any clause of the agreement to be negotiated, or that such reliance would be reasonable. Parties engaged in an adversarial situation cannot be expected to know or foresee that their representations will be relied upon blindly by their opponent, especially on matters of law or construction of contract. (Fridman, page 362, and see for example *Dorsch v. Weyburn (City)* (1985) 23 DLR (4th) 379 (Sask.) at par. 35 and *Silzinger v. C.K. Alexander Ltd.*, [1972] 1 O.R. 720).

[62] There is, further, no allegation of any representation made by Sanofi other than the representation that Sanofi was willing to negotiate Apotex's demand for a limitation to its monetary liability, which representation was made before the first agreement was concluded.

[63] An expressed willingness to negotiate a demand asserted by the other party to a negotiation cannot, by any stretch of the imagination, be equated with an expression of agreement to that demand or a representation that any contract ultimately concluded will satisfy the demand. The pleadings therefore fail to plead any fact upon which a finding of untrue, inaccurate or misleading misrepresentation could be made.

[64] It is also to be noted that Apotex does not plead that it was misled into executing or entering into the March 2006 or May 2006 Agreements or that it has suffered damage as a result of entering into these Agreements. Apotex does not plead that, had it not been for Sanofi's misrepresentation, it would not have entered into the Agreements. Rather, Apotex pleads that had Sanofi not misled it as to the effect of these Agreements, it would have chosen not to launch at risk or begin sales in the U.S. and therefore would not have infringed. Sanofi cannot possibly have misled Apotex, or made any representation to it, as to the interpretation and effect of a contract before that contract had been reduced to writing or executed. Sanofi could therefore not possibly have made a representation as to the effect or application of the May 2006 Agreement prior to its conclusion. As there is no allegation whatsoever of any interaction having taken place between Apotex and Sanofi after the conclusion of the May 2006 Agreement and before Apotex's first sales in the U.S., it is plain and

obvious that the pleadings fail to plead any material fact upon which a Court could find that Sanofi made any misrepresentation to Apotex as to the effect of the contract as executed. In the end, the pleadings do no more than state that Apotex misconstrued or was mistaken as to the effect or application of the Liability Exposure Provision, without pleading any material fact from which one could conclude that this misconception or error was in any way induced by Sanofi.

[65] Finally, Apotex's proposed plea is to the effect that, as a result of Sanofi's breaches of duty, "Apotex changed its position" and that "Apotex would not have launched at risk in the U.S." had it known that Sanofi did not agree that the Liability Exposure Provision applied to actions other than in the U.S. This plea is in direct opposition to the express allegation that in October 2005, Apotex advised Sanofi that "it intended to launch its product as soon as possible after FDA approval" (par. 28 of the proposed pleading). Apotex's admission that it specifically advised Sanofi of its intention to launch its product at risk negates any possibility that Sanofi could have foreseen that Apotex would rely on its representations in deciding whether or not to launch at risk.

[66] I am therefore satisfied that Apotex's claim of set-off on the basis of the tort of deceit or negligent misrepresentation has not the slightest chance of success, and is frivolous and vexatious.

Abuse of process:

[67] Apotex wishes to plead that Sanofi's within action is an abuse of process having caused it damages that should be set-off against any award made in favour of Sanofi.

[68] It is unnecessary to consider whether the abuse of process asserted here amounts to equitable set-off, or whether, if it does not, there is sufficient authority in *Tractor Supply Co. of Texas, LP v. TSC Stores LP*, 2009 FC 154; [2009] F.C.J. No. 199 (upheld on appeal at 2009 FCA 352) to hold that this Court arguably has jurisdiction over any counterclaim sounding in abuse of process, as I am satisfied that the proposed pleading fails to plead the required element of unlawful or improper purpose, and therefore cannot possibly succeed.

[69] The facts pleaded in support of this claim are essentially that Sanofi did not believe it had a right to take the present action in view of the Liability Exposure Provision and did not intend to take this action until Apotex sought a declaration of non-infringement and invalidity in the T-644-09 action, that Sanofi's real purpose in taking this action was to discourage Apotex's action and that Sanofi's predominant purpose in taking this action is to financially injure Apotex by making it pay more than the amount of liability contemplated in the Liability Exposure Provision. Apotex concludes that as a result, it has suffered damage in the form of any liability it might incur over and above the liability that would have been contemplated had the Liability Exposure Provision applied.

[70] As with the alleged set-off based on the torts of deceit or misrepresentation, this claim is in the alternative to the defence based on the application of the Liability Exposure Provision. Indeed, if the Liability Exposure Provision is interpreted as barring any claim "related" to U.S. sales, there can be no damage, and therefore no tort.

[71] The tort of abuse of process requires that the litigation be pursued, not for the legitimate purposes of the claim asserted, but "for an ulterior or collateral purpose. It is defined as the misusing of the process of the courts to coerce someone in some way entirely outside the ambit of the legal claim upon which the court is asked to adjudicate". (*Levi Strauss & Co. v. Roadrunner Apparel Inc.* (1997) 76 C.P.R. (3d) 129 (FCA), emphasis added).

[72] The Federal Court of Appeal in *Levi Strauss* goes on to state:

> "A review of the authorities shows that the essential element of the tort of abuse of process is that the abuser must have used the legal process for a purpose other than that which it was designed to serve, in other words for a collateral, extraneous, ulterior, improper or illicit purpose. The gist of the tort is the misuse of or perversion of the Court's process and there is no abuse when a litigant employs regular legal process to its proper conclusion, even with bad intentions."
>
> (Emphasis added)

[73] The alleged improper purpose, as pleaded, is "discouraging Apotex's challenge to the validity of '777 patent", the very patent which Sanofi claims has been infringed by Apotex, and

to “financially injure the Apotex defendants and, more particularly, to subject them to monetary liability in excess of the amounts contemplated by the Liability Exposure Provision”, which is the very right and proper conclusion sought by Sanofi in this action. It is plain and obvious that there can be no abuse where an action is taken, as here, to assert a right in response to an action by which the very foundation of the right is sought to be impugned, or to extract from the defendant the very sum for which the action properly seeks to recover. Apotex has pleaded no collateral, extraneous, ulterior, improper or illicit purpose, and its defence of set-off is bound to fail.

Further details as to the negotiations leading to the 2006 Agreements

[74] These amendments are contained in paragraphs 23 to 56 of the proposed amended pleading. As mentioned in an earlier decision rendered in this matter, Apotex’s pleadings, as they originally stood, relied exclusively on the express terms of the May 2006 Agreement to assert the effect of the Liability Exposure Provision. In this new pleading, Apotex seeks to introduce facts going to the circumstances surrounding the negotiation and conclusion of the 2006 Agreements to support a conclusion that the May 2006 Agreement also implicitly limits the Plaintiff’s available monetary recovery in respect of sales related to the U.S., that if ambiguous, the terms of the May 2006 Agreement, when read in context, are to be construed as precluding any claim outside the U.S. relating to U.S. sales, or that if it does not have this effect, then it is an implied term of the May 2006 Agreement that claims for monetary relief for such sales outside the U.S., including this action, should be precluded. Apotex would also use those new facts to

argue that preclusion of action outside the U.S. should be an implied term of the May 2006 Agreement, based on the presumed intention of the parties, in order to give it business efficacy or as necessary to a fair functioning of the Agreement.

[75] Most of the proposed amendments do indeed flesh out the circumstances in which the 2006 Agreements came to be negotiated and concluded. Sanofi's first objection to these new allegations was to the effect that the May 2006 Agreement is clear and unambiguous and that external circumstances are both unnecessary and inadmissible to aid in its interpretation. I indicated at the hearing that I was not prepared to hold that it was plain and obvious that the May 2006 Agreement is so clear and unambiguous that evidence of the context in which it was negotiated and concluded would be irrelevant. On that basis, counsel for Sanofi conceded that paragraphs 23 to 29 would be proper.

[76] Sanofi however maintains its objection to paragraphs 30 to 43, as it says that they can only go to the introduction of evidence as to the state of mind of the parties when they negotiated the settlement. Sanofi argues that on the basis of the Supreme Court decision in *Eli Lilly and Co. v. Novopharm Ltd.*, [1998] 2 S.C.R. 129 (particularly, at par. 58), evidence as to the subjective intentions of the parties at the time of drafting is inadmissible by virtue of the parole evidence rule.

[77] I would agree with Sanofi if any of the impugned paragraphs indeed went to the subjective intentions of the parties at the time they negotiated or signed the agreements. However, with the exception of some possible ambiguities in the wording of paragraphs 42 and 43 of the proposed pleading (which are specifically addressed and resolved below), I am satisfied that paragraphs 30 to 43 of the proposed pleadings do not plead or bring into issue the subjective intentions of either Apotex or Sanofi.

[78] Paragraphs 30 to 38, as conceded by counsel for Sanofi, are purely factual. Paragraph 39 is the paragraph wherein it is alleged that Apotex expressed a demand that, as a condition of settlement, provision be made to limit its monetary liability for U.S.-related sales. Apotex, however, does not state that it in fact intended to make that demand a condition of settlement, but merely that it declared having that intention. There is a large difference between the two, and I cannot find that it is plain and obvious that what was said and expressed in the course of negotiations cannot be possibly be relevant to interpreting the contract or ascertaining the parties' intentions in case of ambiguity.

[79] As to paragraph 40, it asserts that Sanofi indicated a willingness to negotiate the condition "demanded" by Apotex. Again, the allegation does not assert anything other than what Sanofi communicated to Apotex. Allegations of what the parties negotiated may be relevant, if only to establish that the parties in fact discussed the issue. Such allegations do not assert or go to any party's subjective intentions or state of mind. In the same vein, paragraph 41 sets out the

various mechanisms that were discussed relating to that issue, clearly without asserting, alleging or raising any party's subjective intentions.

[80] Paragraphs 42 and 43, as mentioned above, are unfortunately worded. In particular they use words like "the parties' agreement to limit Apotex's monetary liability" and "it was clear to all that the condition to be agreed upon was meant to (…)". Such expressions might be thought to include or imply allegations putting in issue whether the parties had actually "agreed to agree" on the condition demanded by Apotex, whether they agreed as to what it meant or agreed to limit Apotex's liability as suggested.

[81] It is appropriate to consider proposed pleadings carefully in order to ascertain their true intent, meaning in scope, prior to amendments being granted, especially in the context of a streamlined proceeding such as this one, as the pleadings will define the scope of the discoveries.

[82] Having extensively questioned counsel for Apotex as to what these paragraphs meant or did not mean, I am satisfied that paragraph 42 refers solely to the agreement of the parties as set out in the March 2006 Agreement, and that neither paragraph 42 nor paragraph 43 allege, imply or raise an independent oral agreement between the parties or seek to put in issue the parties' subjective intents. Further, as to paragraph 43 specifically, it is to be understood as a conclusory paragraph, containing the conclusions which Apotex will argue are to be drawn from the

particular facts specifically pleaded elsewhere. It is not intended to contain or raise any self-standing allegation, or to imply or raise as an issue that Sanofi had undertaken to include Apotex's demand in the ultimate agreement. I reach this conclusion from the specific representations of counsel for Apotex at the hearing, but also on the basis that, where specific facts and allegations are made in a pleading (as they are made in great details in paragraphs 19 to 41), they are to be taken to be exhaustive so that general or vague allegations which do not refer to or plead any specific facts must be taken to be particularized by those other specific pleadings. It is also to be noted that, had I not been satisfied that paragraphs 42 and 43 did not refer to the parties' intent and did not expand the scope of the facts pleaded elsewhere, I would not have permitted the amendment, as being insufficiently particularized allegations of a state of mind, contrary to Rule 181(b) and likely to embarrass the conduct of the proceedings.

[83] Sanofi has no specific objection to paragraphs 44 and 45, and indeed, paragraph 44 merely sets out Apotex's position as to the substance of the March 2006 Agreement and paragraph 45 is purely factual.

[84] Paragraph 46 and 47 relate solely to the allegation that Sanofi is indebted to Apotex for the "break fee", and relates directly and solely to Apotex's claim for set-off based on the "break fee", which I have ruled should not be allowed. These paragraphs are accordingly irrelevant and cannot be included in the proposed new pleading.

[85] Paragraphs 48 to 51 are purely factual and relate to the circumstances of the negotiation of the May 2006 Agreement and set out Apotex's position as to its substance. They are as such proper.

[86] Paragraph 52 pleads an oral agreement, in addition to the May 2006 Agreement, whereby: (a) Sanofi would have agreed not to launch an authorized generic during Apotex's period of exclusivity (if the May 2006 Agreement was approved) and (b) whereby Apotex's signing of the May 2006 Agreement was not to be taken as a waiver of Apotex's "vested right" to the "break fee". While I am puzzled as to the relevance of Sanofi's alleged agreement not to launch an authorized generic, it is at this point not plain and obvious that it may not have some relevance to the overall circumstances. However, that part of the alleged oral agreement whereby it was allegedly agreed that Apotex's signing of the agreement would not constitute a waiver of Apotex's right to the "break fee" can have no possible relevance in view of the determination that the "break fee" cannot be asserted in these proceedings. Paragraph 52(b) therefore cannot be included in the proposed amendment.

[87] Paragraph 53 sets out certain facts which Apotex asserts had been "understood and agreed" by the parties throughout the negotiations leading to the March and May 2006 Agreements. In the course of the hearing, counsel for Apotex agreed to modify the opening sentence of paragraph 53 so as to remove the words "and agreed" so that the paragraph be restricted to facts that were understood by the parties in the course of the negotiations. Counsel

for Apotex further clarified that paragraph 54 contains the particulars of the facts upon which Sanofi is to be taken as having understood the facts set out in paragraph 53. With that modification and clarification, the pleading is proper. Paragraph 55 is a recitation of certain elements of the 2006 Agreements which Apotex alleges assist in its interpretation, and is proper.

[88] Finally, paragraphs 56 to 56E set out the basis upon which Apotex concludes, on the facts alleged in the previous paragraphs, that the Liability Exposure Provision has, explicitly or by implied terms, the effect of limiting or precluding Sanofi's claim in respect of U.S. sales. These allegations are proper.

Details of a defence of disentitlement to monetary remedies:

[89] Paragraphs 117 to 119 set out, but by strict reference to the specific facts pleaded earlier in the proposed amended pleadings, arguments as to why Sanofi should be disentitled to any monetary relief, or to an accounting of profits, in connection with U.S. sales or in connection with sales in other jurisdictions. Sanofi's objections with respect to those amendments, insofar as they relate to the claims of set-off, have been dealt with as I have found that the proposed amendments relating to the claims of set-off should not be allowed.

[90] Sanofi further objects to these paragraphs insofar as they purport to apply to Sanofi's claim for damages (as opposed to its claim for the equitable relief of an accounting of profits). The bulk of these paragraphs pleads conclusions of law from facts that are otherwise properly pleaded and relevant to other allowable defences. There is little usefulness in enquiring into and determining whether the proposed conclusions of law are tenable if the facts on which they are based are otherwise properly pleaded. There is no harm and no prejudice to Sanofi in allowing Apotex to also assert, as a matter of law, that the same facts would also preclude recovery of damages. A determination at this stage would not change the factual issues framed in the pleadings or the scope of discovery or trial, and the matter is therefore one to be left to the Judge hearing the trial on the merits.

[91] I should note, for completeness, that whereas the other paragraphs and sub-paragraphs in that grouping do not plead additional facts but refer specifically to such facts as are alleged elsewhere in the statement of defence and counterclaim, paragraph 118(c) does plead additional facts, being the availability to Apotex of alternatives for the manufacture and sale of clopidogrel in the U.S. which would not have constituted an infringement of the '777 patent. Sanofi has not raised any particular objection to these allegations, and I see no reason why they would be improper.

“Consolidation” of the action in T-644-09 into a defence and counterclaim to T-933-09:

[92] The basis of Sanofi’s objection, in principle, to Apotex transporting the substance of its action in T-644-09 into a counterclaim to Sanofi’s action in T-933-09 is that it is unnecessary, but also, that it would effectively change Apotex’s status from that of a plaintiff to that of a defendant, removing from it the burden of having the carriage of the litigation, and shifting the burden of proof.

[93] I agree that consolidation is unnecessary, although I can see one potential benefit of the proposed consolidation: to avoid having to amend two sets of pleadings if further amendments are eventually proposed to be made in respect of facts pleaded in both actions, such as, for example, Apotex’s proposed addition of additional prior art. As such, consolidation is not necessary, but it might be procedurally convenient.

[94] As to Sanofi’s principal objection, to the effect that it shifts from Apotex to Sanofi the burden of carrying the litigation and, possibly, the burden of proof, I cannot agree with Sanofi’s assessment. First, Apotex’s counsel had made it clear at the hearing that Apotex is not seeking to remove from the record its original statement of claim or to resile from its status as the original plaintiff in the original action. That status is, otherwise, reflected in the style of cause of this consolidated action, which style of cause I see no reason to change. As case management

Judge, I am also very well aware of the origins of this action and the evolution of the pleadings cannot detract or subtract from that history. Finally, I cannot agree that by moving the allegations originally made in its statement of claim in T-644-09 to a counterclaim in T-933-09, Apotex removes from itself any burden of proof it would otherwise have had. The pleadings still make it clear that Sanofi's claim of infringement is with respect to past manufacture and sale of clopidogrel bisulfate by Apotex, and that Apotex's counterclaim for a declaration of non-infringement is with respect to intended future production of clopidogrel bisulfate, clopidogrel besylate and clopidogrel hydrobromide. Apotex still has both an independent action (in the form of a counterclaim) for impeachment and a defence of invalidity. The burden of proof in the actions, counterclaim and defence is not affected by the fact that Apotex's initial action is reprised as a counterclaim; it is, indeed, clear from the rules of the Court that a claim asserted as a counterclaim remains a separate and distinct cause of action. As to the order in which evidence is to be led at trial, it remains within the complete discretion of the trial Judge whether evidence relating to the counterclaim is to be led before the evidence relating to the action, just as the trial Judge would have had discretion to determine whether evidence related to the T-644-09 action should be led after the evidence related to the T-933-09 action. In the circumstances of this case, I can see no reason why consolidation necessarily affects the order in which evidence is to be led at trial.

[95] In conclusion, while the advantages of consolidating the pleadings are extremely minimal, I cannot see any prejudice being suffered by Sanofi as a result of the proposed consolidation that cannot be compensated by costs. As to costs, Apotex would be required, as a

condition of being allowed to made the amendment, to pay to Sanofi the costs of preparing, serving and filing a responding pleading, in any event of the cause.

Conclusion:

[96] Having concluded that Apotex's proposed new grounds of defence relating to set-off cannot be allowed and considering that these proposed defences appeared, by far, to involve the most far reaching allegations of fact, it is not certain at this point that allowing the other amendments would cause substantial additional delays in the prosecution of this action or would prejudice the presentation of Sanofi's case at trial within the time currently contemplated. Indeed, although the factual allegations relating to the circumstances surrounding the 2006 Agreements are detailed and intricate, it is too early to know whether those facts are controversial. Discovery and evidence at trial could be radically contained if Sanofi's amended reply admits all or most of those facts. In addition, there is a real possibility that the scope of discovery and of trial could be reduced if Sanofi accepts Apotex's new admission as to the place where all of its sales took place.

[97] On final analysis, I am not convinced that allowing the amendments which I have found proper will effectively cause prejudice to Sanofi that cannot be compensated by costs. Further, to the extent it becomes apparent, after the close of the pleadings as amended, that there are

significant facts in controversy and that it is neither practical nor reasonable to expect the parties to complete full discoveries on those facts within the time remaining before trial or that there will be insufficient time to canvass these issues at trial, the possibility of bifurcating the new issues to the second phase of the trial can be revisited.

[98] In ending, I should mention that Sanofi had also argued, in opposition to this motion, that the proposed amendments were a disguised and improper attempt by Apotex to obtain discovery relating to the negotiation and interpretation of the 2006 Agreements, which discovery had been specifically denied to it in the context of U.S. litigation, which discovery Apotex had specifically stated was necessary to it when it attempted to enforce the "break fee" before the Courts of Ontario, and which discovery I had only last month denied Apotex in the context of its motion for a further and better affidavit of documents. As I have resolved the issues raised by this motion on different grounds, I have not felt it necessary to address this specific argument. I will note, however, that the circumstances and timing of Apotex's motion to amend, the convoluted nature of the proposed amendments involving inquiries into the state of mind of Sanofi and their general lack of reasonable foundation would tend to support Sanofi's contention that for a large part, Apotex's motion to amend was driven more by the desire for unrestricted discovery of all aspects of the negotiation of the 2006 Agreements than by the belief in the existence of a reasonably arguable case.

Costs:

[99] The lateness of Apotex's motion, the unreasonable nature of a large part of the amendments sought and the generally accepted principle that the costs of amendment should be borne by the amending party all militate in favour of awarding the costs of this motion to Sanofi, at the high end of Column IV of the Tariff, and including a provision for the assistance of second counsel.

ORDER

IT IS ORDERED THAT:

1. Apotex Inc. and Apotex Pharmachem Inc. (jointly, "Apotex") have leave to serve and file, no later than 3 days from the date of this Order, an amended statement of defence and counterclaim in the form set out in Schedule B to their notice of motion ("the proposed pleading"), with the additional amendments and deletions, and on the terms and conditions set out below.

2. The title of the amended pleading shall be "Amended Statement of Defence and Counterclaim of Apotex Inc. and Apotex Pharmachem Inc. in response to the Statement of Claim originally filed in Court file T-933-09".

3. The amended pleading shall bear both styles of cause, as provided in the Order dated November 2, 2009.

4. The following paragraphs of the proposed pleading shall be deleted and shall not appear in the amended pleading: 46, 47, 52(b), 57, 57A, 57B, 57C, 57D and 57E.

5. Paragraph 53 of the proposed pleading will be further amended by removing, in the second line, the words "and agreed".

6. Paragraphs 83 and 84 of the proposed pleading shall be further amended by the inclusion of particulars as to the quantities to which each exception is alleged to apply and particulars as to the material facts in support of each exception claimed.

7. Paragraph 121(b) of the proposed pleading shall be removed, with leave to include an additional but separate paragraph setting out a claim by Apotex Inc. only for an order declaring that Apotex Inc.'s clopidogrel bisulfate, clopidogrel hydrobromide and clopidogrel besylate tablets will not infringe any valid claim of the '777 patent.

8. It is a condition of leave to amend being granted that Apotex shall pay the costs of Sanofi Aventis and Bristol-Myers Squibb Sanofi Pharmaceuticals Holding Partnership (jointly, "Sanofi") of preparing, serving and filing an amended reply and defence to counterclaim in response to the amended pleading, in any event of the cause.

9. Costs of this motion are awarded in favour of Sanofi and against Apotex, at the high end of Column IV of the Tariff, including a provision for the services of second counsel, payable in any event of the cause.

10. The parties shall, no later than February 26, 2010, provide their joint dates of availability to participate in a case management telephone conference for the purpose of:

(a) setting a new schedule for completion of discoveries and the steps leading up to motions arising from discoveries;

(b) determining deadlines to be fixed for the parties to disclose results of tests that may already have been performed and on which they intend to rely at trial and any other documents (such as prior art search results) on which litigation privilege previously claimed may be waived as a result of the parties' eventual expressed intention to call expert evidence at trial; and

(c) determining whether a deadline should be fixed after which service of supplementary affidavits of documents will require the consent of the other party or leave of the Court.

11. In preparation for the case management telephone conference contemplated in the above paragraph, Sanofi shall, ideally, have prepared at least a draft of its proposed amended pleading in response to Apotex's amended statement of defence and counterclaim, or at a minimum, be prepared to indicate which new allegation of the amended statement of defence and counterclaim is expected to be controversial and require significant discovery.

"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 :	ANOFI-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:	February 9 & 11, 2010
REASONS FOR ORDER:	TABIB P.
DATED:	February 18, 2010

APPEARANCES:

Mr. Nando De Luca Mr. Sandon Shogilev	FOR APOTEX INC.
Mr. Marc Richard Ms. Cristin Wagner	SANOFI-AVENTIS .

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GOWLING LAFLEUR HENDERSON LLP OTTAWA, ONTARIO	SANOFI-AVENTIS .