Federal Court of Appeal | Cour d'appel fédérale

Date: 20141030

Dockets: A-194-14
A-94-14

Citation: 2014 FCA 250

CORAM: **NOËL C.J.**
TRUDEL J.A.
BOIVIN J.A.

BETWEEN:

APOTEX INC.

Appellant

and

PFIZER CANADA INC. AND G.D. SEARLE & CO.

Respondents

AND BETWEEN:

MYLAN PHARMACEUTICALS ULC

Appellant

and

PFIZER CANADA INC. AND G.D. SEARLE & CO.

Respondents

Heard at Ottawa, Ontario, on September 30, 2014.

Judgment delivered at Ottawa, Ontario, on October 30 2014.

REASONS FOR JUDGMENT BY: NOËL C.J.

CONCURRED IN BY: TRUDEL J.A.
BOIVIN J.A.

Federal Court of Appeal | Cour d'appel fédérale

Date: 20141030

Dockets: A-194-14
A-94-14

Citation: 2014 FCA 250

CORAM: **NOËL C.J.**
TRUDEL J.A.
BOIVIN J.A.

BETWEEN:

APOTEX INC.

Appellant

and

PFIZER CANADA INC. and G.D. SEARLE & CO.

Respondents

AND BETWEEN:

MYLAN PHARMACEUTICALS ULC

Appellant

and

PFIZER CANADA INC., G.D. SEARLE & CO.

Respondents

REASONS FOR JUDGMENT

NOËL C.J.

[1] These are two appeals brought by Mylan Pharmaceuticals ULC (A-94-14) and Apotex Inc. (A-194-14) (Mylan and Apotex, or the appellants) from decisions of the Federal Court (2014 FC 38, the *Mylan* decision, and 2014 FC 314, the *Apotex* decision), wherein Harrington J. (the Federal Court judge) allowed applications brought by Pfizer Canada Inc. and G.D. Searle & Co. (together, the respondent) and issued orders prohibiting the Minister of Health (the Minister) from issuing notices of compliance (NOC) in respect of celecoxib. These prohibition orders will cease to have effect on November 14, when Canadian Patent No. 2,177,576 (the '576 Patent) which conveys a monopoly over this compound expires.

[2] The main issue in both appeals turns on whether the Federal Court judge properly held that the patent in issue did not promise certain specified results thereby declining to hold that the appellants' allegations of invalidity were justified by reason of the patent's alleged failure to procure these results.

[3] The two decisions under appeal were rendered by the Federal Court judge in separate reasons which however share common lines of reasoning. For that reason, the two appeals were heard together. The reasons which follow dispose of both appeals.

BACKGROUND

[4] For over a century now, inflammation in humans and certain animals has been treated using a particular class of pharmaceuticals known as non-steroidal anti-inflammatory drugs (NSAIDs). These drugs reduce inflammation by inhibiting a certain enzyme called cyclooxygenase (COX).

[5] In the 1970s, researchers began to notice that NSAIDs can have dangerous side effects in the long-run, particularly in the gastrointestinal (GI) tract, where bleeding, ulcers and perforations can take place. The reason for this was determined to be that COX plays an important role in maintaining many tissues, particularly in the GI tract. From that point onwards, North American regulators required that NSAIDs be sold with a warning label addressing these risks.

[6] In the 1990s, researchers discovered that there exist two different COX enzymes. It was hypothesized that, while COX-1 plays a general maintenance role in many tissues, the body produces COX-2 in response to injury, and it is this second enzyme that causes inflammation. The "COX-2 hypothesis" developed by NSAIDs researchers was that, if one could develop a "COX-2 selective" drug that either inhibited COX-2 exclusively or at least inhibited COX-2 significantly more than it did COX-1, then that drug could reduce inflammation without producing the sort of side effects associated with the set of NSAIDs on the market at the time.

[7] It was in this context that the respondent developed a new class of NSAID compounds, including celecoxib. The '576 Patent was granted to the respondent with an effective filing date of November 14, 1994. The Minister subsequently added celecoxib to the Register of Patented Medicines maintained under the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 (the *Regulations*).

[8] The claimed compounds, including celecoxib, were new compounds as of the filing date. At issue are claims 4 and 8 to 13. Claim 4 claims celecoxib; claim 8 claims a therapeutically-effective amount of celecoxib; claims 9 to 13 claim the use of celecoxib to treat inflammation and other specified conditions or disorders (Mylan appeal book, vol. 1, pp. 304 to 305). Also at issue is claim 16 which is directed at the prevention of colorectal cancer.

[9] In the "Description of the Invention" section of the '576 Patent's specification, the inventor described the issue of side effects in the class of NSAIDs on the market around the filing date, and wrote "(t)he compounds are useful as anti-inflammatory agents, such as for the treatment of arthritis, with the additional benefit of having significantly less harmful side effects". In the next paragraph of that section, the inventor stated that the invention "preferably includes" compounds selectively inhibiting COX-2 over COX-1 and that "(s)uch preferred selectivity may indicate an ability to reduce the incidence of common NSAID-induced side effects" (Mylan appeal book, vol. 1, p. 119).

[10] In 2007, the respondent was successful in preventing the Minister from issuing another party an NOC in respect of celecoxib. Novopharm Ltd. had made in respect of the '576 Patent

allegations of insufficiency, lack of utility, obviousness and abandonment. Though the Federal Court (Hughes J.) ruled that the respondent had demonstrated that the first two allegations were not justified, it held that the respondent had failed to make that demonstration with respect to the last two. The respondent's application was accordingly dismissed (*G.D. Searle & Co. v. Novopharm Ltd.*, 2007 FC 81, [2008] 1 F.C.R. 477 [*Novopharm FC*]). The decision was reversed on appeal, where this Court upheld the conclusions on insufficiency and lack of utility, but found that the respondent had also demonstrated that the allegations of obviousness and abandonment were not justified (*G.D. Searle & Co. v. Novopharm Ltd.*, 2007 FCA 173, [2008] 1 F.C.R. 529 [*Novopharm FCA*]).

[11] Five years later, the respondent was again called upon to defend its monopoly over celecoxib further to notices of allegation (NOA) filed by Mylan and Apotex. Each of the two ensuing prohibition applications filed by the respondent were heard by the Federal Court judge, who allowed both in decisions issued on January 28, 2014 (the *Mylan* decision) and on April 15, 2014 (the *Apotex* decision). These are the decisions now under appeal.

THE *MYLAN* DECISION

[12] Before the Federal Court judge, Mylan argued that because the '576 Patent promised reduced side effects in humans and celecoxib did not procure such reduced side effects, the '576 Patent was invalid for lack of utility.

[13] Mylan supported this contention by reference to the language in the specification itself, particularly where it describes the COX-2 hypothesis and where it states "(t)he compounds are

useful as anti-inflammatory agents … with the additional benefit of having significantly less harmful side effects" (Mylan appeal book, vol. 1, pp. 118 to 119).

[14] Mylan also relied on Hughes J.'s construction of the '576 Patent in *Novopharm FC*. In describing the patent in general, he stated "(a)fter some discussion, counsel for the applicants conceded that both the anti-inflammatory properties and lesser side effects were necessary to the utility of the claimed invention" (*Mylan* decision at para. 74, quoting *Novopharm FC* at para. 14). In construing claim 4 of the patent specifically, he further stated (*Mylan* decision at para. 74, quoting *Novopharm FC* at para. 27):

> [No use of (celecoxib) is stated in that claim but,] as conceded by counsel for the applicants, the utility of that compound is set out in the specification as being the duality of treatment of inflammation and reduction of unwanted side effects such as ulcers of the gastrointestinal system.

[15] Relying on the above passages, Mylan argued before the Federal Court judge that because the respondent had conceded in *Novopharm FC* that reduced side effects were necessary to establish celecoxib's utility, its attempt to argue against this very premise before him amounted to an abuse of process.

[16] The respondent resisted these allegations on three alternative grounds, arguing that the '576 Patent did not promise reduced side effects; that, if it had so promised, the promise did not extend to humans and that, if the promise had so extended, celecoxib was in fact proven to have reduced side effects in humans. The respondent placed great emphasis on the equivocal nature of the specification statement that celecoxib "may" reduce side effects.

[17] The Federal Court judge accepted the respondent's first argument, ruling that the '576 Patent did not promise reduced side effects. As to the effect of the prior decision in *Novopharm FC*, he rejected Mylan's contention that this decision bound him to construe the patent so as to promise the utility of reduced side effects in humans. Citing paragraphs 102 and 103 of that decision, he observed that Hughes J. found demonstrated utility in that case (*Mylan* decision at para. 75). However, it was not clear that reduced side effects in humans had been demonstrated (*Mylan* decision at para. 77). The Federal Court judge added that he would have been bound by Hughes J.'s decision had it "turned on" patent construction, as this is a question of law (*Mylan* decision at para. 78). However, he went on to find that as utility, whether demonstrated or predicted is a question of fact, he was not bound by Hughes J.'s decision.

[18] Turning to the construction of the patent, the Federal Court judge accepted the respondent's more limited construction of the patent on two principal grounds. First, he found that the word "may" as it appeared in the specification represented a clear indication that the patent made no promise of reduced side effects. Whether read within the context of standard statutory interpretation principles or from the perspective of a skilled addressee, the word "may" could not be taken to imply anything more than a possibility of reduced side effects (*Mylan* decision at para. 65).

[19] Second, the Federal Court judge observed that the claims themselves were devoid of any mention of reduced side effects. Citing Federal Court jurisprudence, he held that uses which do not appear in the claims specification ought to be considered as mere statements of advantage, absent clear and unequivocal language promising such uses (*Mylan* decision at para. 70, citing

Fournier Pharma Inc. v. Canada (Health), 2012 FC 741, [2012] F.C.J. No. 901 at para. 126 [*Fournier*]). He found further support for the distinction between promises and statements of advantage or potential use in the concurring opinions issued by this Court in *Sanofi-Aventis v. Apotex Inc.* 2013 FCA 186, [2013] F.C.J. No. 856 (Leave to Appeal to SCC granted on January 30, 2014, 35562) [*Plavix FCA*] (*Mylan* decision at paras. 68 and 69).

THE *APOTEX* DECISION

[20] Before the Federal Court judge, Apotex made two submissions very similar to those made by Mylan. First, it argued that the patent promised reduced side effects in humans and that such utility could now be proven not to have been achieved. Second, it argued that, because the respondent conceded before Hughes J. in *Novopharm FC* that utility necessarily included reduced side effects, it would constitute an abuse of process for the respondent to dispute that premise before the Federal Court judge.

[21] Apotex advanced a number of additional arguments. First, it took the position that utility in respect of celecoxib's use as an anti-inflammatory in humans was neither demonstrated nor soundly predicted. Though Apotex conceded that celecoxib had since been proven to be so useful, it asserted that the respondent could neither demonstrate such utility nor provide a sound basis for predicting it, as of the filing date.

[22] Second, Apotex argued on the basis of language in the specification as well as that in claim 16 that the patent had promised the utility of preventing colorectal cancer and that this utility was neither demonstrated nor soundly predicted as of the filing date.

[23] Finally, Apotex attacked the '576 Patent for insufficiency of disclosure. The essence of this argument was that the respondent buried its "true invention", namely the use of celecoxib for treating inflammation, among a smattering of other compounds and claims which it knew in fact to be useless or unfounded. For instance, one particular compound claimed in claim 5 was known to be toxic at the filing date, and was therefore useless.

[24] The Federal Court judge rejected these contentions. On the question of utility in treating inflammation, he accepted the respondent's argument that rats could be considered to constitute "subjects" and that, to the extent that the patent had promised to treat inflammation in a subject, this promise had been demonstrated to have been met (*Apotex* decision at paras. 28 and 29, citing *Plavix FCA* and *Mylan Pharmaceuticals ULC v. Pfizer Canada Inc.*, 2012 FCA 103, 2012 F.C.J. No. 386 [*Donepezil FCA*]).

[25] On the question of utility in treating side effects in humans, the Federal Court judge rejected Apotex' argument on the basis of a revised version of his reasons in the *Mylan* decision. He conceded the "inappropriate" nature of some of his justifications in that decision for ruling that the '576 Patent did not promise reduced side effects in humans, namely his discussion at paragraph 44 of the principle that what is not claimed is generally disclaimed (*Apotex* decision at paras. 30 and 36).

[26] The Federal Court judge concluded, however, that his earlier ruling was nevertheless correct, and reiterated that the side effects statements were excluded from the specification's claims, that the law generally presumes such statements to be aimed at advantages (as opposed to

promises) and that the word "may" as it appears in the specification reflected a critical degree of equivocation.

[27] Further, he rejected Apotex' argument that the less equivocal side effects statement ("…with the additional benefit of … significantly less harmful side effects") referred to one set of side effects (*i.e.* harmful side effects) while the more equivocal statement ("… may indicate an ability to reduce the incidence of common … side effects") referred to another (*i.e.* common side effects). Finally, he rejected Apotex's invitation to apply an English case constructing the European celecoxib patent such that its utility included reduced side effects. In essence, he reasoned that English patent law varies from Canadian patent law in a number of areas, including questions of utility and, more specifically, promise.

[28] The Federal Court judge concluded that part of his analysis by highlighting what was demonstrated by the evidence before him (*Apotex* decision at para. 41):

> What the *in vitro* tests demonstrated was that the compounds tested were COX II selective. That might have led the inventors to hope that eventually it would be established that this COX II selectivity equated with reduced side effects. Perhaps, they could have made a promise, but they did not. Consequently, it is not necessary to decide whether or not the tests as set out in the record establish that Celebrex® has fewer side effects. Pfizer does not have to meet a promise it never made.

[29] Concerning the claim regarding prevention of colorectal cancer, the Federal Court judge concluded that Apotex had provided evidence of the claim's invalidity, but agreed with the respondent that, under section 58 of the *Patent Act*, R.S.C., 1985, c. P-4 (the *Act*), this claim could be severed from the rest, and that the remaining claims could support the prohibition order sought by the respondent.

[30] The Federal Court judge also rejected Apotex' submissions on insufficiency. Although the compound claimed in claim 5 was indeed known to be toxic at high doses, it was nevertheless an effective anti-inflammatory, and the respondent could not be seen to have promised that the compound would receive regulatory approval.

[31] With respect to the question whether the respondent had "obscured" its true invention, the Federal Court judge distinguished the case at bar from *Teva Canada Ltd. v. Pfizer Canada Inc.*, 2012 SCC 60, [2012] 3 S.C.R. 625 [*Teva*], where the Supreme Court of Canada found that the patentee, in claiming two different compounds while knowing that only one was effective, had done exactly that. The Federal Court judge explained that in the case at bar, each of the three compounds claimed had been demonstrated to reduce inflammation (*Apotex* decision at para. 59). Though celecoxib may have been the central compound in the respondent's commercial designs, such designs need not be disclosed, and the '576 Patent's "true invention" remained a class of compounds including celecoxib, rather than celecoxib alone.

[32] The Federal Court judge finally rejected Apotex' claim of abuse of process, observing that the construed utility in *Novopharm FC* had been demonstrated on the basis of proven COX-2 selectivity and not on the basis of the reduction of side effects in humans (*Apotex* decision at para. 62). He further explained that patent construction is a matter of law, and the court is not bound by a party's concession or admission on such questions (*Apotex* decision at para. 61).

POSITION OF THE APPELLANTS

[33] Before this Court, Apotex advances four distinct arguments, namely lack of utility in treating inflammation in humans, lack of utility in reducing side effects, lack of utility in preventing colorectal cancer and insufficient disclosure. Though it frames matters slightly differently, Mylan's submissions all go to the second of these four arguments. The following is a joint summary of the submissions made by the appellants.

[34] In arguing lack of utility in treating inflammation, Apotex argues that the '576 Patent promised to treat inflammation in humans and that, as of the filing date, it could only be demonstrated that celecoxib could reduce inflammation in rats.

[35] Both in stating the utility of its invention and in claiming its monopoly, the '576 Patent speaks of treatment in "a subject". According to Apotex, this subject must be understood to include humans, as the disorders in respect of whose treatment the invented compounds are described and claimed are all suffered by humans and some of them are suffered exclusively by humans. No person of skill in the art (skilled person), asserts Apotex, would take the view that the respondent intended to monopolize the use of the claimed compounds to treat a given set of disorders in a group of "subjects" incapable of suffering the disorders in question (Apotex memorandum at paras. 64 and 65). Furthermore, a patent which lays claim to a particular use necessarily includes a promise in respect of that use (Apotex memorandum at para. 67, citing *Bauer Hockey Corp. v. Easton Sports Canada Inc.*, 2010 FC 361, [2010] F.J.C. No. 431 at para.

289 [*Bauer FC*], aff'd 2011 FCA 83, [2011] F.C.J. No. 331 and *Apotex Inc. v. Wellcome Foundation Ltd.*, 2002 SCC 77, [2002] 4 S.C.R. 153 at para. 92 [*AZT*]).

[36] Apotex further argues that the Federal Court judge erred in citing two cases from this Court to justify rejecting the interpretation advocated by Apotex. First, his reliance on *Plavix FCA* was misplaced, as the patent in issue in that case contained no claims of treatment, let alone treatment of human disorders (Apotex memorandum at para. 70). In *Donepezil FCA*, neither the claims nor the testing mentioned humans, but the promised utility was construed to include treatment of humans on the basis that the specification and claims mentioned treatment of a human disorder (Apotex memorandum at para. 71).

[37] Because the Federal Court judge held that the respondent had neither demonstrated nor been able to soundly predict treatment of inflammation in humans, a finding of invalidity for lack of utility would result automatically if this Court were to conclude that the word "subject" in the '576 Patent extends to humans.

[38] In arguing lack of utility in reducing side effects, the appellants both take the position that *Novopharm FC* was binding on the Federal Court judge so that he had to find a promise of reduced side effects in humans. If the Federal Court judge wanted to depart from this earlier construction, he had to justify that departure, whether on the basis of an error in the earlier construction or because of distinct evidence (Mylan memorandum at para. 43, citing *Apotex Inc. v. Allergan Inc.*, 2012 FCA 308, [2012] F.C.J. No. 1467 [*Allergan*] at paras. 48 and 51; Apotex

memorandum at para. 97). As the Federal Court judge provided no such justification, he erred in not following Hughes J.'s construction.

[39] Apotex further asserts that an innovator cannot relitigate an issue "with additional evidence it chose not to adduce" in earlier proceedings to which it was a party (Apotex memorandum at para. 88 citing *Sanofi-Aventis Inc. v. Novopharm Ltd.*, 2007 FCA 163, [2008] 1 F.C.R. 174 at para. 50 [*Ramipril FCA*]). Nor can an innovator accept and reject the same position in different proceedings under the *Regulations* in respect of the same patent (Apotex memorandum at para. 89, citing *Apotex Inc. v. AstraZeneca Canada Inc.*, 2012 FC 559, [2012] F.C.J. No. 621 [*Omeprazole FC*] at paras. 137 and 138, citing *Johnson v. Agnew*, [1980] A.C. 367 (HL)).

[40] Finally, Mylan submits that, in limiting its NOA to the issue of utility, it expressly relied on the construction of the '576 Patent rendered in *Novopharm FC* and left undisturbed in *Novopharm FCA* (Mylan memorandum at paras. 37 and 41).

[41] Turning to the Federal Court judge's own construction of the '576 Patent, Mylan cites two decisions of this Court in which a promise was found to extend to reduced side effects (Mylan memorandum at paras. 55 and 56, citing *Eli Lilly Canada Inc. v. Novopharm Limited*, 2010 FCA 197, [2012] 1 F.C.R. 349 [*Olanzapine*] at paras. 27 and 99 and *Apotex Inc. v. Pfizer Canada Inc.*, 2011 FCA 236, [2011] F.C.J. No. 1234 [*Latanoprost*]) and two decisions in which a promise was found not to so extend (Mylan memorandum at paras. 58 and 59, citing *Plavix FCA* at para. 67 and *Mylan Pharmaceuticals ULC. v. AstraZeneca Canada Inc.*, 2012 FCA 109,

[2012] F.C.J. No. 422 [*Anastrozole*] at paras. 6, 22, 29 and 30). Mylan argues that the '576 Patent is "qualitatively more similar" to the patents in the first set of cases (Mylan memorandum at para. 60).

[42] Mylan also argues that, in relying on the testimony of the respondent's expert, Dr. Young, to support his construction, the Federal Court judge failed to follow this Court's guidance in *Olanzapine*. While that case made it clear that the judge is required to analyze the expert testimony, the Federal Court judge merely "parlayed and 'broadly agreed'" with the perspective offered by Dr. Young (Mylan memorandum at paras. 75 and 76). Had the Federal Court judge truly analyzed this testimony, he would have noticed multiple statements supporting the view that, at the filing date, the chief goal of NSAID researchers was to develop a COX-2 selective drug with reduced side effects (Mylan memorandum at para. 77).

[43] Mylan further argues for the first time on appeal that, even if the Court finds that the promise of the '576 Patent excludes side effect superiority, it must find that it at least included COX-2 selectivity distinctly higher than existing NSAIDs (Mylan memorandum at para. 85, citing the *Apotex* decision at paras. 38 to 42, 59 and 62).

[44] Finally, consistent with its argument that the '576 Patent did promise reduced side effects, Mylan contends that celecoxib can be shown not to have achieved this result. Specifically, Mylan points to the refusal by the North American regulators to conclude that celecoxib possesses a side effect advantage over pre-existing NSAIDs (Mylan memorandum at paras. 98 to 108) and alleges that the respondent itself cannot provide studies supporting any side

effect superiority unless it presents them in a misleading fashion (Mylan memorandum at paras. 109 to 116). Mylan contends that if the Court construes the '576 Patent as promising an enhanced degree of COX-2 selectivity, celecoxib can be shown to be no more than slightly more selective than pre-existing NSAIDs (Mylan memorandum at paras. 117 to 122).

[45] For its part, Apotex makes two unique submissions attacking the Federal Court judge's conclusion that the '576 Patent's promise did not extend to reduced side effects.

[46] First, Apotex reiterates its proposed distinction between the harmful side effects to which the specification's less qualified statement on side effects would have been directed and those common side effects at which the specification's more qualified statement would have been directed. Furthermore, it attacks the Federal Court judge's rejection of this argument. Although the Federal Court Judge stated that none of the experts saw this distinction, patent construction is a matter for the Court alone to decide (Apotex memorandum at para. 83, citing *Plavix FCA* at para. 33).

[47] Second, Apotex advances a new distinction between these two statements on side effects, suggesting that the less qualified statement set out an explicit promise that the '576 Patent's COX-2 selective compounds would have less side effects than other NSAIDs existing at the time (Apotex memorandum at para. 76). The more qualified statement was not directed at comparing the invention with other NSAIDSs, but rather at comparing different subsets of the compounds disclosed in the specification. Thus, while the first statement went to the utility of the invention, the second one went merely to issues of relative safety among the invented compounds. The

word "may" in the latter only reflects uncertainty as to whether relative COX-2 selectivity among those compounds would result in relative side effect superiority (Apotex memorandum at paras. 78 and 79).

[48] In arguing lack of utility in preventing colorectal cancer, Apotex argues that the Federal Court judge improperly considered its argument on this point as going to insufficiency of disclosure, when Apotex had argued the point in respect of utility (Apotex memorandum at para. 73). The patent explicitly promised utility "for the prevention of colorectal cancer", however, and monopolized this use of the disclosed compounds through claim 16 (Apotex memorandum at para. 72). Where a promise is made in a patent, that promise is "overarching and inherent to the invention and thus all of the claims" (Apotex memorandum at para. 54, citing *Apotex Inc. v. Merck & Co.*, [1995] 2 F.C. 723 (FCA) at para. 33, *Merck & Co. Inc. v. Apotex Inc.*, 2006 FC 524 at paras. 122 to 125 and *Sanofi-Aventis Canada Inc. v. Apotex Inc.*, 2009 FC 676 [*Sanofi*]at paras 119 to 124 and 138, *aff'd* 2011 FCA 300 at para. 3). Where this promise cannot be met the entire patent is rendered invalid (Apotex memorandum at para. 55, citing *AZT* at para. 92, *Plavix FCA* at para. 54, *Pfizer Canada Inc.v. Pharmascience Inc.*, 2008 FC 500 at para. 95, *New Process Screw v. PL Robertson Manufacturing* (1961), 39 C.P.R. 31 [*New Process Screw*] at paras. 27 to 28, 31, and 38 to 39 (CT) and *Turner v. Winter* (1787), 99 ER 1274 at 1276 (KB)). As the Federal Court judge found that the compounds of the invention are not useful in preventing colorectal cancer, this lack of utility goes to the validity of the entire '576 Patent and the respondent's application must be dismissed (Apotex memorandum at para. 104).

[49] In arguing insufficiency of disclosure, Apotex submits that the '576 Patent "played games" with its reader, in that the specification concealed the "true invention" of celecoxib among two other compounds (those claimed in claims 5 and 6) known at the filing date to lack utility (Apotex memorandum at para. 113). The reader would have had to complete more work than the reader in *Teva* in order to discover the true invention of the '576 Patent, and the amount of work required in *Teva* was too great to support a finding of sufficient disclosure (Apotex memorandum at para. 114).

[50] Apotex criticizes the Federal Court judge's specific finding that "the fact that tests had revealed high doses of the compound in [c]laim 5 were toxic in rats does not detract from the fact that [c]laim 5 works as an anti-inflammatory" (Apotex memorandum at para. 116, citing the *Apotex* decision at para. 44). This statement reveals two errors, submits Apotex. First, the Federal Court judge speaks of "high doses", but the actual evidence was not qualified in this respect (Apotex memorandum at para. 117). Second, it is nonsensical to suggest that toxicity in rats would not detract from utility in treating inflammation in rats (Apotex memorandum at para. 117).

[51] Finally, Apotex criticizes the Federal Court judge's conclusion that the compound claimed in claim 6 "worked" because it was "the basis of a treatment of arthritis in dogs" (Apotex memorandum at para. 120, citing the *Apotex* decision at para. 59). That, as it turned out after the filing date, the compound could be put to such use is irrelevant to the sufficiency of the disclosure of the invention as of that date (Apotex memorandum at para. 121).

POSITION OF THE RESPONDENT

[52] The respondent argues that each of the Federal Court judge's decisions withstands the appellants' attacks.

[53] On the question of utility in treating inflammation in humans, the respondent submits that Apotex' argument conflates the scope of a patent's claims with the extent of any utility it may have promised. Once the proper principles on patent construction are applied, one can see that no "promise of (the) specific result" of treatment of inflammation in humans appears in the '576 Patent (memorandum of the respondent in response to Apotex at para. 35, citing *Plavix FCA* at paras. 49 and 50). In any event, the respondent submits that the evidence is clear that treatment in humans was soundly predicted (memorandum of the respondent in response to Apotex at paras. 61 to 67). Although Apotex insists that the Federal Court judge found otherwise at paragraph 17 of the *Apotex* decision, the respondent submits that he was merely describing the position taken by Apotex.

[54] With respect to abuse of process and related doctrines, the respondent submits that *Novopharm FC* was not binding on the Federal Court judge and, even if it had been, it would not have led to the outcome argued before this Court by the appellants, as Hughes J. found utility to have been demonstrated through experiments on rats (memorandum of the respondent in response to Apotex at paras. 80 to 83).

[55] The respondent adds that a change in the law is an important exception to abuse of process and comity. In this respect, the principles for construing the promise of a patent had yet to be articulated when *Novopharm FC* was decided seven years ago (memorandum of the respondent in response to Apotex at para. 82). Given the change in the law, culminating in *Plavix FCA*, the Federal Court judge properly refused to follow *Novopharm FC* (memorandum of the respondent in response to Apotex at para. 83, citing *R. v. Bernard* [1988], 2 S.C.R. 833 at 849 and 855 and *R. v. Chaulk* [1990], 3 S.C.R. 1303 at 1352).

[56] With respect to the claim relating to colorectal cancer, the respondent argues that different claims can contain different promises, and that, contrary to Apotex' claim, not every promise need be construed as "overarching and inherent" to a patent's invention and each of its claims (memorandum of the respondent in response to Apotex at para. 41, citing *Pfizer Canada Inc. v. Apotex Inc.*, 2007 FC 26 at paras. 42 to 43, *Teva Canada Ltd. v. Novartis AG*, 2013 FC 141 [*Imatinib*]at paras. 174 to 180, *Pfizer Canada Inc. v. Mylan Pharmaceuticals ULC*, 2011 FC 547 at paras 191 to 193 and s. 58 of the *Act*). Furthermore, if the '576 Patent made any promise of utility in preventing colorectal cancer, it would be limited to claim 16 as none of the other claims can sensibly be construed to contain such a promise (memorandum of the respondent in response to Apotex at para. 77). As for the statement in the specification that the compounds would be useful for the prevention of colorectal cancer, this was the disclosure that would have enabled claim 16, and not a promise that could be imported into each of the patent's claims (*Ibidem*).

[57] With respect to Apotex' arguments of insufficiency, the respondent submits that these arguments never appeared in Apotex' NOA, and can therefore not be advanced before this Court (memorandum of the respondent in response to Apotex at paras. 87 and 99 to 100).

ANALYSIS AND DECISION

Standard of Review

[58] Broadly speaking, these appeals concern three separate allegations of lack of utility and one allegation of insufficient disclosure. The allegations pertaining to utility raise distinct issues of patent construction and demonstrated or predicted utility.

[59] The parties are in agreement that patent construction gives rise to a question of law which stands to be assessed on a standard of correctness (*Plavix FCA* at para. 33; *Housen v. Nikolaisen*, 2002 SCC 33, [2002] 2 S.C.R. 235 at para. 8 [*Housen*]).

[60] However, whether utility has been made out, by being demonstrated or predicted, is a question of fact to be reviewed only for palpable and overriding error (*Novopharm Limited v. Pfizer Canada Inc.*, 2010 FCA 242, [2012] 2 F.C.R. 69 [*Pfizer*] at paras. 91-93; *Housen* at para. 10). Finally, sufficiency of disclosure, because it gives rise to a mixed question of fact and law, is reviewed only for palpable and overriding error absent an extricable error of law (*Housen* at paras. 36 to 37).

[61] In addition to alleging that the Federal Court judge erred in his construction of the '576 Patent, the appellants also argue that he breached the principles of comity and *stare decisis* in failing to follow the construction reached by Hughes J. in *Novopharm FC* and affirmed by this Court in *Novopharm FCA*. Pursuing the same theme, the appellants argue that the Federal Court judge improperly countenanced an abuse of process on the part of the respondent by allowing it to plead that reduced harmful side effects were not promised whereas it had conceded that point in *Novopharm FC*.

[62] The scope and application of the doctrine of *stare decisis* is a question of law for which the standard of review is correctness (*Air Canada Pilots Association v. Kelly*, 2012 FCA 209, [2013] 1 F.C.R. 308 at para. 40 [*Kelly*]). As to abuse of process, the decision of the Federal Court judge allowing the respondent to argue that reduced side effects were not promised is discretionary in nature, and cannot be overturned absent an error of law or principle, or a wrongful exercise of discretion with respect to the factors considered or not considered (*Ramipril FCA* at para. 13; *Elders Grain Co. v. Ralph Misener (Ship)*, 2005 FCA 139, [2005] 3 F.C.R. 367 at para. 13).

Plan of Analysis

[63] I propose to address these issues under the following headings: Utility in Treating Inflammation in Humans; Utility in Reducing Side Effects; Utility in Preventing Colorectal Cancer; Insufficiency of Disclosure; and Abuse of Process, *Stare Decisis*, and Comity. Consideration of these topics requires a brief discussion about the legal approach set out in *Plavix FCA* and specifically whether it amounts to new law, as the respondent contends.

[64] Under the *Act*, an invention must be useful in order to deserve protection (s. 2). The courts, however, have long held that the minimum requirements for utility under the *Act* are fairly forgiving. First, the inventor need not expressly set out the utility of the invention in the patent (*Consolboard Inc. v. MacMillan Bloedel (Saskatchewan) Ltd.*, [1981] 1 S.C.R. 504 at 525 and 526 [*Consolboard*]. It is merely required that, where the inventor is called upon to prove the utility of the invention, utility can be shown to be demonstrated or soundly predicted as of the patent's filing date (*AZT*). Second, the threshold that must be proven to establish utility is generally quite low, described as being no more than a "scintilla of utility" (*Olanzapine*).

[65] The promise doctrine represents an exception to the above minimum statutory requirements. Though an inventor need not describe any particular utility for the invention, an inventor who explicitly promises a specific result will be held to that promise when called upon to prove utility (*Plavix FCA* at paras. 48 and 49). That the invention may well have satisfied the scintilla threshold is of no assistance in establishing utility where a promise, if it be made, cannot be met (*Plavix FCA* at para. 54).

[66] The promise doctrine will hold an inventor to an elevated standard only where a clear and unambiguous promise has been made. Where the validity of a patent is challenged on the basis of an alleged unfulfilled promise, the patent will be construed in favour of the patentee where it can reasonably be read by the skilled person as excluding this promise. This approach can be traced back to the earliest mentions of the promise doctrine. In *Consolboard*, the source of the promise doctrine in Canadian law, the Supreme Court of Canada reiterated the longstanding principle that

(*Consolboard* at 521, citing *Western Electric Company, Incorporated, and Northern Electric Company v. Baldwin International Radio of Canada*, [1934] S.C.R. 574 at 570):

> … where the language of the specification, upon a reasonable view of it, can be so read as to afford the inventor protection for that which he has actually in good faith invented, the court, as a rule, will endeavour to give effect to that construction.

[67] This rule in favour of saving an invention rather than invalidating it in case of ambiguity has been consistently applied by this Court. While the principle is sometimes invoked by reference to the original language found in *Consolboard* (*Anastrozole* at paras. 17 and 19) affirming *AstraZeneca Canada Inc. v. Mylan Pharmaceuticals ULC*, 2011 FC 1023, [2011] F.C.J. No. 1262 at para. 88), it is at other times given effect through the requirement that promises be "explicit" (see *Olanzapine* at para. 76, *Eli Lilly and Company v. Teva Canada Limited*, 2011 FCA 220, [2011] F.C.J. No. 1028 at paras. 18 to 21 [*Atomexetine*], *Plavix FCA* at para. 49). Drawing an analogy with the threshold test applicable to selection patents, the Court in *Plavix FCA* expressed the need for explicitness by saying that a promise must be supported by language "… at least as clear and unambiguous as that used to establish the advantages of the selection over the compounds of a genus patent" (*Plavix FCA* at para. 66). It follows that it is not enough to merely label a promise as "explicit" if it can only be supported on the basis of equivocal inferences and ambiguous indications (*Plavix FCA* at paras. 64-66).

[68] It is apparent from the foregoing that *Plavix FCA* merely applies a long established legal approach to a new set of facts. Contrary to what the respondent asserts, it does not create new law.

[69] I now turn to the question whether the Federal Court judge correctly construed the '576 Patent in holding that no promise was made that celecoxib would be useful in treating inflammation in humans.

Utility in Treating Inflammation in Humans

[70] Apotex raised the bar by arguing not only that the '576 Patent promised utility in treating inflammation, but that this promise extended to humans. The crux of Apotex' argument is that, where a patent "lays claim" to a particular use, the patent cannot conceivably be read as not including a promise for that very use (Apotex memorandum at para. 67). The only authority cited in support of this categorical proposition is *Bauer FC*. In that case, Gauthier J., sitting as a trial judge, stated (at para. 289):

> It is settled law that results or advantages included in the claims must be met. Similarly, in the context of selection patents where the advantages described are really the basis upon which the patentee is given the right to monopolize a substance or product already covered in a prior patent as part of a larger group of substances or products, the inventor will be held to its promise (*Ratiopharm Inc. v. Pfizer Ltd.*, 2009 FC 711, 76 C.P.R. (4th) 241, 350 F.T.R. 250 (*Pfizer (2009)*).

[71] This passage does not support the broad proposition advanced by Apotex. In my view, Gauthier J. (as she then was) was merely stating that, when a result or advantage is asserted in a patent's claims, it will generally be seen as a promise of utility. This is entirely consistent with

Zinn J.'s warning in *Fournier* at paragraph 126 that statements going to utility are particularly vulnerable to being read as promises when they are expressed in a patent's claims. Apotex has failed to establish how any of the '576 Patent's claims can be shown to describe use in humans as a particular advantage of the claimed compounds.

[72] When the '576 Patent is read in light of the approach set out in *Plavix FCA*, it becomes clear that no explicit promise of treatment in humans was made. Apotex itself recognizes that the claims speak only of "subjects", and nothing outside the claims could be said to represent the sort of unequivocal language contemplated by the reasoning in *Plavix FCA*. In my view, the Federal Court judge correctly held that the promise of the patent did not extend to humans.

[73] The above determination renders irrelevant the question whether, as Apotex alleges, the Federal Court judge found as a fact that treatment in humans was demonstrated or soundly predicted. However, I would agree with the respondent that, on a fair reading of the relevant passage (*Apotex* decision at para. 17), it seems clear that he was merely describing the position taken by Apotex in the matter before him.

Utility in Reducing Side Effects

[74] In the *Mylan* decision, the Federal Court judge began his analysis of the promise of the '576 Patent by carefully canvassing the expert evidence before him (*Mylan* decision at paras. 52-59). He then construed the promise on the basis of the language of the patent, analyzing it from the perspective of the skilled person based on the approach set out in *Plavix FCA* (*Mylan* decision at paras. 60-71). He reaffirmed this analysis in the *Apotex* decision (*Apotex* decision at

paras. 30 and 35). He also rejected Apotex' attempts to distinguish in the disclosure's language between harmful side effects and common side effects, finding that none of the experts read the patent in this manner (*Apotex* decision at paras. 32 and 33).

[75] Mylan seeks to distinguish the case at bar from *Plavix FCA* and *Anastrozole*, arguing that the '576 Patent is "qualitatively more similar" to those in *Olanzapine* and *Latanoprost* (Mylan memorandum at para. 60). However, Mylan provides no arguments in support of this assertion.

[76] Mylan's argument that the Federal Court judge failed to analyze expert testimony, merely "parlay(ing) and broadly agree(ing)" with Dr. Young (the respondent's expert) is unconvincing. The only support for this attack are a number of statements by the expert in question confirming that NSAID researchers were, at the filing date, primarily interested in achieving reduced side effects via the COX-selectivity mechanism. As the Federal Court judge points out however, not every research goal will form the basis for a later patent's promised utility and these statements all spoke merely to goals (*Mylan* decision at para. 68, citing *Plavix FCA*).

[77] The appellants submit that the Federal Court judge erred in holding that a promise must be explicitly stated in a patent's claims. They argue that a promise can also appear in the specification, provided that the language is clear and explicit (Apotex memorandum at para. 85, citing *Fournier*). No doubt that is so. However, I read the reasons of the Federal Court judge as merely acknowledging the principle that statements outside of the claim should not be presumed to be promises (*Mylan* decision at para. 70; *Apotex* decision at para. 36). I can detect no error in this regard.

[78] Mylan also argues that, even if the promise of the '576 Patent is found to have excluded reduced side effects, it must still be construed to have included elevated COX-2 selectivity "that is distinctly higher" than existing NSAIDs because the Federal Court judge "appears to have recognized as much" in the *Apotex* decision (Mylan memorandum at para. 85, citing the *Apotex* decision at paras. 38 to 42, 59 and 62).

[79] There are a number of problems with this submission. In procedural terms, it appears not to have been advanced in Mylan's NOA. Also, it seems that the Federal Court judge would have been *functus* when he made those comments, if correcting his earlier decision was in fact what he was attempting to do. First and foremost, however, the passages cited by Mylan simply do not support this interpretation. In the first set of paragraphs, the Federal Court judge is simply summarizing an English case relied upon by Apotex, and declining to follow it due to variation between English and Canadian patent law (*Apotex* decision at paras. 38 to 40). Though the remaining paragraphs do address COX-2 selectivity, the Federal Court judge merely refers to the same absolute level of selectivity found to be demonstrated by Hughes J. (*Apotex* decision at paras. 41 to 42, 59 and 62). There is no indication whatsoever that he found some particular level of relatively enhanced selectivity to be promised.

[80] The two arguments advanced solely by Apotex on lack of utility in reducing side effects must also be rejected.

[81] First, Apotex reiterates before us the argument presented to and rejected by the Federal Court judge that the specification clearly promised a reduction of harmful side effects, and

merely equivocated when referring to common side effects. The principal basis for attacking the Federal Court judge's rejection of this view is that, in so holding, he abdicated his role by blindly adopting the opinion of the respondent's expert (Apotex memorandum at para. 83).

[82] I would first note that nothing in the reasons suggests that the Federal Court judge viewed the experts' perspectives as controlling his own. Rather, he simply relied on their views to support his own (*Apotex* decision at para. 33). Furthermore, his view that none of the experts adopted the interpretation advanced by Apotex is well-founded. Though Apotex makes multiple references to expert testimony purportedly supportive of the separate side-effect reading, none of this is in fact helpful in establishing its case. For instance, in support of the view that the less equivocal statement on side effects would have been read by the skilled person as referring only to *harmful* side effects, Apotex points to a reference by Dr. Flower to "severe side effects". In the passage in question, however, Dr. Flower merely opines that "significantly less harmful side effects" would be understood to *include* such severe side effects (Apotex' appeal book, vol. 19, p. 5391). This is among Apotex' stronger references.

[83] Furthermore, Apotex argues that the less equivocal side effects statement promised reduced side effects in its invented compounds relative to pre-existing compounds, while the more equivocal side effects statement expressed doubt merely as to whether relative COX-2 selectivity among the invented compounds might correlate to relatively reduced side effects (Apotex memorandum at paras. 78 and 79).

[84] This argument must also fail as Apotex makes no attempt to show that its interpretation is supported by any of the expert evidence. This submission illustrates the sort of "unchaperoned romp through the disclosure" that this Court admonished in *Donepezil FCA* (at para. 57).

Utility in Preventing Colorectal Cancer

[85] In their written and oral submissions, the parties dedicated little attention to this question. The central point at issue is whether, as a matter of law, any given promise made in a patent must be construed as overarching to the invention and all of the patent's claims. As I understand the argument, a patent containing a failed promise cannot be saved by severance pursuant to section 58 of the *Patent Act*.

[86] In effect, Apotex argues that any given promise must be construed as overarching, and that, because the respondent has failed to rebut Apotex' allegation that the promise of preventing colorectal cancer was neither demonstrated nor soundly predicted as of the filing date, the validity of the patent as a whole is undermined. The respondent for its part argues that not every promise need be construed as overarching, and that any promise of preventing colorectal cancer was limited to claim 16 of the '576 Patent.

[87] A review of the jurisprudence reveals a lack of support for the proposition advanced by Apotex. Not one case cited by Apotex stands for the proposition that a promise, once made and shown not to have been met, must be construed as invalidating the invention as a whole. Of the eight cases cited at paragraphs 54 and 55 of Apotex' memorandum of fact and law, only two could be read as addressing the extent to which a given promise may extend to various claims

within the patent containing it (*Sanofi* and *New Process Screw*). Furthermore, each of these cases illustrates, at most, that a promise *can* be construed so as to extend to each of a patent's claims (see *Sanofi* at paras. 119 to 124 or *New Process Screw* at 45 to 46). In each case, the court did no more than construe the promise and made no general statement of law on the matter. The respondent's proposition, namely that some promises are properly construed so as to touch only a subset of claims, is therefore not inconsistent with the cases cited by Apotex, which merely feature promises that were not so narrow.

[88] The respondent provides compelling support for its alternative proposition by citing examples where a promised utility *is* more narrowly construed. Of particular relevance to the case at bar is a decision by Snider J. wherein she specifically distinguished claims for a compound from claims for its uses, and held that the latter are "directed at the use of [the claimed compounds] for specified maladies and their utility should be assessed on that basis" (*Imatinib* at para. 177). The issue is one of patent construction and the respondent's proposition in my view represents the correct approach.

[89] Though I accept that some promises may impose utility requirements across each of a patent's claim, Apotex has offered no reason to depart from the Federal Court judge's determination that the promise of colorectal cancer prevention, if any, can be severed. That his decision to apply s. 58 of the *Act* appeared in the sufficiency of disclosure section of his reasons does not detract from the force of his reasons on this point.

Insufficiency of Disclosure

[90] Apotex' central argument is that the respondent concealed its "true invention" among a group of compounds that it knew not to be useful. In particular, the compound claimed in claim 5 was known to be toxic and the compound claimed in claim 6 was only found after the filing date to be useful in dogs.

[91] I agree with the respondent that this argument is an afterthought triggered by the decision of the Supreme Court in *Teva*, which Apotex' NOA does not announce. Apotex' insufficiency allegation as set out in its NOA is based solely on comparator issues (Apotex' appeal book, vol. 1, p. 98). The allegation is that the respondent failed to clearly identify which drugs its invention would improve upon and which specific side effects would have to be examined to see the improvement.

[92] This Court has long held that subsection 5(3) of the *Regulations* prevents any second person from resisting a prohibition application by advancing any legal or factual basis not stated in its NOA (*AB Hassle v. Canada (Minister of National Health and Welfare)*, [2000] F.C.J. No. 855 at paras. 21 to 24; *Proctor & Gamble Pharmaceuticals Canada, Inc v Canada (Minister of Health)*, 2002 FCA 290, [2003] 1 F.C. 402 at paras. 21 to 24). Critically, none of the insufficiency arguments made before this Court were included in Apotex' NOA, and none of the insufficiency arguments in its NOA are argued here. Apotex has therefore failed to provide this Court any procedurally legitimate arguments in support of its insufficiency allegation.

Abuse of Process, Stare Decisis, and Comity

[93] Though the arguments and analysis pertaining to the doctrines of abuse of process, *stare decisis*, and comity have been intermingled by the parties and the Federal Court judge, it bears emphasizing that these are distinct doctrines that merit separate analysis (see Allergan at para. 39). I first turn to abuse of process.

Abuse of Process

[94] Before the Federal Court judge, the appellants argued that, in disputing whether the '576 Patent promised reduced side effects, the respondent was abusing the process of the court, as it had conceded before Hughes J. in *Novopharm FC* that reduced side effects were necessary to the utility of the claimed invention.

[95] The Federal Court judge dismissed this argument in both cases. In the *Mylan* decision, he ruled that "a concession made by (the respondent) in one NOC proceeding (was) not an admission binding upon it in another" (*Mylan* decision at para. 78). In the *Apotex* decision, he came to the same conclusion, citing Apotex' failure to provide "a single case in which a 'concession' or 'admission' in one in personam case applie(d) in another" (*Apotex* decision at para. 61).

[96] As discussed above, the Federal Court judge's decision to allow the respondent to make the argument that no premise was made as to side effects was discretionary in nature, and can

only be overturned by this Court if he proceeded on the basis of an improper principle, or engaged in a wrongful exercise of discretion.

[97] Before this Court, it is principally Apotex which seeks to overturn the decision of the Federal Court judge on the basis of his alleged failure to give effect to the doctrine of abuse of process. Though Mylan raises the argument in its Notice of Appeal, its memorandum of fact and law does not advance the argument in any detail. Mylan rather argues that the Federal Court judge focused too narrowly on this issue without giving due consideration to the issue of *stare decisis* (Mylan memorandum at para. 44).

[98] For its part, Apotex relies on three distinct, yet related arguments in attacking the Federal Court judge's decision on abuse of process. First, Apotex argues that a patentee cannot "elevate the 'inventive concept' to support non-obviousness and then read down the promised utility" (Apotex memorandum at para. 93, citing *Hoffman-La Roche v. Apotex*, 2011 FC 875, 104 C.P.4. (4th) 233 [*Mycophenolate FC*], *Allergan, Plavix FCA,* and *Olanzapine*). Second, Apotex argues that an innovator such as the respondent cannot "approbate and reprobate by taking fundamentally inconsistent positions in different proceedings under the Regulations in respect of the same patent" (Apotex memorandum at para. 89, citing *Omeprazole FC* at paras. 137 and 138). Third, Apotex argues that an innovator cannot "relitigat(e)…an issue already decided in a proceeding to which it was a party with the aid of additional evidence it chose not to adduce in the earlier proceedings" (Apotex memorandum at para. 88, citing *Ramipril FCA* at para. 50).

[99] Apotex' first argument fails to confront the Federal Court judge's reasons in rejecting it, as the proposition as framed would not apply across proceedings. Indeed, the only cited case which actually applies this proposition does so within the context of a single proceeding (see *Mycophenolate FC*). The Federal Court judge noted that he had not been provided with any authority for the application in one *in personam* case of a concession made in another. None of the cases referred to by Apotex in support of the inventive concept proposition overcome this objection. Apotex' first argument therefore demonstrates no error in the Federal Court judge's exercise of discretion.

[100] Apotex' second argument moves beyond this limitation. The contention is that an innovator cannot switch positions across NOC proceedings on the same patent. The only authority it cites for this proposition, however, is *Omeprazole FC*, a case which, in my view, cannot be read in so broad a manner.

[101] In that case, Apotex successfully argued abuse of process in the course of seeking damages against AstraZeneca pursuant to section 8 of the *Regulations*. Years earlier, Apotex had sought an NOC to market omeprazole capsules, which required it to serve on AstraZeneca a Notice of Allegation addressing the latter's Canadian Patent No. 2,133,762. In response, AstraZeneca applied to prohibit the issuance of an NOC to Apotex until the patent's expiry. Upon O'Keefe J.'s dismissal of AstraZeneca's prohibition application (*AstraZeneca AB v. Apotex Inc.*, 2004 FC 313, 33 C.P.R. (4th) 97), Apotex sought damages under section 8 (*Omeprazole FC*).

[102] When AstraZeneca argued in this latter proceeding that Apotex did not constitute a "second person" within the meaning of the *Regulations,* Hughes J. found an abuse of process. The reason for this was that AstraZeneca's initial application, and the resulting stay against the issuance of an NOC to Apotex, was based on the premise that Apotex was a second person within the meaning of the *Regulations* (*Omeprazole FC* at para. 138). The innovator should not be permitted to take one position to avail itself of the stay, and then resile from that position when the generic seeks compensation for having been subjected to that very stay.

[103] In ascertaining the scope of the principle applied in *Omeprazole FC*, regard must be had to the twin nature of a failed prohibition application and a subsequent claim for section 8 damages. Though the proceedings are technically separate, the second represents the generic's remedy for the losses it incurred as a result of the initiation of the first. The proceedings are between the same parties and jointly dispose of the same underlying dispute. Indeed, it is not without significance that Hughes J. also barred AstraZeneca from taking this position on the alternative ground of issue estoppel, a doctrine which applies only when the same issue has been finally decided between the same parties or their privies (*Omeprazole FC* at paras. 130 to 135).

[104] I accept that there may be instances where a concession made in one proceeding under the *Regulations* may be construed as binding upon the conceding party in a later proceeding involving a different party. However, there is no existing precedent on point, and the Federal Court judge has not been shown to have committed any error in principle in exercising his discretion and deciding not to apply *Omeprazole FC* in favour of the appellants.

[105] Apotex' third argument is based on *Ramipril FCA*. In that case, this Court found an abuse of process where an innovator sought to relitigate in one NOC proceeding an issue it had lost in a prior NOC proceeding. Specifically, the innovator was barred from relying on evidence that it could have adduced in the prior proceeding, but did not. The trial judge in that case had allowed the generic's motion to strike the innovator's prohibition application, on the basis that, due to the determination made in the prior proceeding, it was plain and obvious that the innovator's application had no chance of success (*Ramipril FCA* at para. 29).

[106] On appeal, this Court intervened, as the determination in question had been one of fact, and therefore would not have bound the decision-maker in the second proceeding (*Ramipril FCA* at paras. 30 and 31). However, this Court still found an abuse, as the innovator sought to rely on an enhanced evidentiary record that could have been relied upon in the earlier proceeding (*Ramipril FCA* at para. 47). Were an innovator not required to put its "best foot forward" in response to an initial set of allegations, it would threaten finality and consistency in judicial decision-making, and therefore undermine the credibility of the adjudicative process (*Ramipril FCA* at paras. 35, 36 and 47).

[107] The present case is factually different. First, the respondent in the current proceeding was successful in the dispute disposed of in the earlier proceeding. This Court is therefore being invited to apply a judgment that seeks to achieve finality and consistency so as to reach a different conclusion than the one reached in *Novopharm FCA*. Second, the principal abuse that Apotex complains of in the case at bar is not an attempt to rely upon an enhanced evidentiary record, but rather the respondent's refusal to abide by an earlier concession. Nothing in *Ramipril*

FCA or any of the subsequent decisions cited by Apotex in support of this third argument provide any support for the notion that shifting positions across proceedings is an abuse.

[108] In the present case, the Federal Court judge exercised his discretion to allow the respondent to take a position consistent with the law rather than to compel it to abide by a prior concession which based on the conclusion that he reached, did not conform with the law. I can detect no error in this exercise of discretion.

Stare Decisis and Comity

[109] Turning to the doctrine of *stare decisis*, the appellants argued before the Federal Court judge that he was bound by the construction of the '576 Patent reached by Hughes J. in *Novopharm FC* and affirmed by this Court in *Novopharm FCA*. The Federal Court judge was thus required as a matter of law to conclude that reduced side effects were necessary to the utility of the claimed invention.

[110] The Federal Court judge dismissed this argument in both cases. In the *Mylan* decision, he held that Hughes J.'s ruling in *Novopharm FC* would have bound him by *stare decisis* had it "turned on the construction of the patent", as this is a question of law (*Mylan* decision at para. 78, citing *Apotex Inc. v. Pfizer Ireland Pharmaceuticals*, 2012 FC 1339). Yet because demonstrated utility is a matter of fact, he ruled, he was not bound (*Mylan* decision at para. 78). In the *Apotex* decision, he appears to have disposed of the *stare decisis* argument on the basis that, even if he had applied the *Novopharm FC* construction, this construction does not extend to reduced side effects in humans (*Apotex* decision at para. 62)

[111] Before this Court, it is principally Mylan which advances as a ground of appeal the allegation that the Federal Court judge failed to abide by the doctrine of *stare decisis*. Though Apotex does raise the matter briefly in its memorandum of fact and law, its arguments supporting the application of Hughes J.'s construction are otherwise entirely based on the doctrine of abuse of process (Apotex memorandum at para. 97). Significantly, *stare decisis* is not a ground alleged in Apotex' Notice of Appeal.

[112] Mylan frames its argument on the doctrine of *stare decisis* from two distinct angles. Though a court can be bound by the legal conclusions of a higher court, it must also take into account legal conclusions reached by judges at its own level – *i. e.* comity or "horizontal *stare decisis*" (Mylan memorandum at para. 38). Mylan acknowledges that the doctrine of comity is of limited application in proceedings under the *Regulations*, where differences in allegations and evidence may call for varying conclusions (Mylan memorandum at para. 40). It maintains, however, that a judge of the Federal Court may only depart from a prior construction of a given patent by another judge of the same court where he or she "is convinced that the departure is necessary and can articulate cogent reasons for doing so" (Mylan memorandum at para. 43, citing *Allergan* at paras. 48 and 51).

[113] The Federal Court judge was therefore required as a matter of comity to follow the construction of the '576 Patent set out in *Novopharm FC* unless he could articulate a legitimate reason not to do so. Following *Novopharm FCA*, he was also bound to this construction by vertical operation of *stare decisis* given that the construction remained undisturbed by this Court on appeal.

[114] The doctrine of *stare decisis* requires that "courts render decisions which are consistent with the previous decisions of higher courts" (*Kelly* at para. 54, citing *Canada (Attorney General) v. Bedford*, 2012 ONCA 186, 346 D.L.R. (4th) 385 [*Bedford ONCA*] at para. 56). The doctrine is not unlimited in its scope, however, as not every statement in a given judgment will be binding on lower courts. In determining the authoritative force of any given passage, one must essentially ask "What did the case decide"? (R. v. Henry, 2005 SCC 76, [2005] 3 S.C.R. 609 at para. 57 [*Henry*]). At the very least, an appellate judgment will stand as authority for its own *ratio decidendi*, or the "reasoning that was necessary for the court to reach a result on the issues that were presented to it for a decision" (*Kelly* at paras. 54 and 55, citing *Bedford ONCA*). The remaining *obiter dicta* will vary in authoritative force, ranging from guidance to merely helpful commentary (*Henry* at para. 57).

[115] In contrast, the doctrine of comity or horizontal *stare decisis* is not binding. Mylan cites *Allergan* for the proposition that a Federal Court judge may only with certain justifications adopt a patent construction at odds with a colleague's prior construction. This decision does not go so far. Rather, this Court highlighted the uncertainty that is created when two judges of the same court reach distinct results on the same question of law without explanation. It remains that, as shown by *Allergan*, the only thing that an appellate court can do when this happens is to eliminate the uncertainty by settling the question of law (*Allergan* at para.53). There is no legal sanction for a judge's failure to abide by comity.

[116] It follows that, although I agree that the justification offered by the Federal Court judge in the *Mylan* decision falls short (see paragraph 110 above), nothing turns on this in this appeal.

[117] As for *Novopharm FCA*, the central question is "what did the case decide?" *Novopharm FCA* does not decide that reduced side effects were necessary to the utility of the invention claimed in the '576 Patent. Rather, in that case, this Court was seized of two narrow issues, being the correct claim date for the '576 Patent and the question whether one of the appellants could avail itself of a statutory provision excluding certain public disclosures from consideration in deciding obviousness. Whether the '576 Patent's utility included reduced side effects is not a question to which this Court turned its mind.

[118] The Federal Court judge was not persuaded by the *Novopharm FC* construction, and nothing in the *Novopharm FCA* ruling compelled him to decide differently.

DISPOSITION

[119] For the above reasons, I would dismiss both appeals with costs in each case.

"Marc Noël"

Chief Justice

"I agree
Johanne Trudel J.A."

"I agree
Richard Boivin J.A."

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKET:	A-194-14
STYLE OF CAUSE:	APOTEX INC. v. PFIZER CANADA INC. AND G.D. SEARLE & CO.
AND DOCKET:	A-94-14
STYLE OF CAUSE:	MYLAN PHARMACEUTICALS ULC v. PFIZER CANADA INC. AND G.D. SEARLE & CO.
PLACE OF HEARING:	OTTAWA, ONTARIO
DATE OF HEARING:	SEPTEMBER 30, 2014
REASONS FOR JUDGMENT BY:	NOËL C.J. TRUDEL J.A. BOIVIN J.A.
DATED:	OCTOBER 30, 2014

APPEARANCES:

Andrew Brodkin Jaro Mazzola	FOR THE APPELLANT Apotex INC.
Tim Gilbert Nathaniel Lipkus Matthew Frontini	FOR THE APPELLANT MYLAN PHARMACEUTICALS ULC
Andrew Bernstein W. Grant Worden Yael Bienenstock Rachel Saab	FOR THE RESPONDENTS PFIZER CANADA INC. AND G.D. SEARLE & CO.

SOLICITORS OF RECORD:

GOODMANS LLP Toronto, Ontario	FOR THE APPELLANT APOTEX INC.
GILBERT'S LLP Toronto, Ontario	FOR THE APPELLANT MYLAN PAHRMACEUTICALS ULC
TORYS LLP Toronto, Ontario	FOR THE RESPONDENTS PFIZER CANADA INC. AND G.D. SERALE & CO.