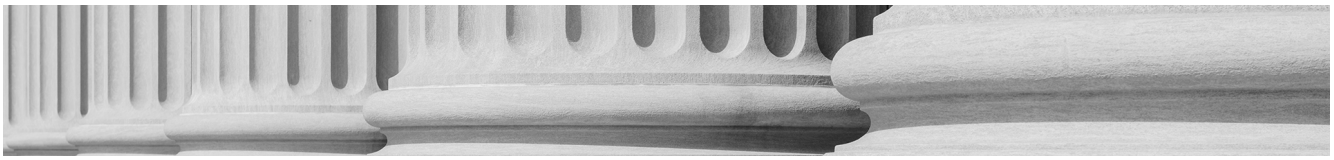

Update: The Promise Doctrine and Utility Post *Astrazeneca*

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Introduction

Despite the collective sigh of relief uttered by patentees following the Supreme Court's apparent abolition of the promise doctrine in the *AstraZeneca* judgment rendered June 30, 2017, [1] some doubt remained as to how lower courts would apply the decision.

First, commentary by the court about the mischief of overpromising and potential consequences under sections 27(3) and 53 of the *Patent Act*, as well as for overly broad claims,[2] led to arguments being advanced that the promise doctrine endured (albeit under different auspices). Second, in articulating the test for utility under section 2, the court set the standard at whether the subject matter of the claimed invention was "capable of a practical purpose (i.e. an actual result)", but then went on to say that a scintilla of utility will do, [3] arguably leaving some room for debate.

These issues have since been addressed in a number of cases. The Federal Court, Federal Court of Appeal and Ontario Superior Court of Justice have consistently refused to revive the promise doctrine and applied a scintilla of utility standard. Most recently in *Hospira Healthcare Corp v Kennedy Trust for Rheumatology Research*, Justice Phelan stated:

> [257] The law has returned to the principle that utility is met if a "scintilla" of utility is demonstrated. …
>
> [258] Hospira attempts to import the discarded "promise" doctrine into insufficiency and overbreadth. Certainly AstraZeneca does not do so and it would be inconsistent to discard that doctrine only to have it resurface under another principle without clear language to do so.

Hospira and the other cases addressing these issues are presented and summarized below.

The Cases

Bristol-Meyers Squibb v. Apotex, 2017 FCA 190

In the first Post-*AstraZeneca* decision on patent utility, the Federal Court of Appeal elaborated on the meaning of a "mere scintilla" of utility and commented that this standard is a "minimal utility requirement." This case concerned the validity of Bristol-Meyers Squibb's (BMS) patent for its leukemia drug SPRYCEL® (dasatinib). The Federal Court previously held that BMS's patent lacked utility as BMS had not demonstrated or soundly predicted all of the promised utilities for one of the claims as of the relevant date. Justice Gleason, applying the new test for utility set out in *AstraZeneca*, held that utility was in fact demonstrated as of the relevant date, and overturned the Federal Court's decision.

On the first step of the test, Gleason J. identified the subject-matter of the invention as claimed as "merely the compound", rejecting Apotex's argument that the subject-matter was the potential therapeutic uses of the drug. On the second step, Gleason J. noted the "minimal utility requirement" set out by the Supreme Court, and found that dasatinib's ability to inhibit certain proteins constituted a scintilla of utility. Establishing that a compound has the ability to inhibit a biological target implicated in disease is a useful discovery (i.e. capable of a practical purpose). She expressly rejected Apotex's argument that the binding of dasatinib to isolated enzymes in a test tube could not satisfy the utility requirement, and found that BMS

had demonstrated utility as of the relevant date:

> [37] Insofar as concerns the first point, contrary to what Apotex asserts in its supplemental written submissions, the subject-matter of claim 27 of the 932 patent is not the potential therapeutic uses for dasatinib. Rather, the subject-matter of claim 27 is merely the compound, dasatinib, itself. This is all that claim 27 claims, and it is erroneous to expand the subject-matter of the claim beyond what it says. In Esomeprazole, the Supreme Court found the subject-matter of a similar compound claim to be simply the compound itself (Esomeprazole at para. 61). Thus, contrary to what Apotex says, the relevant subject-matter in issue is merely the compound, dasatinib.
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> [38] The second step of the requisite analysis involves determining whether BMS has demonstrated or soundly predicted as of the relevant date that dasatinib had at least a scintilla of utility. In my view, BMS has so demonstrated as it is conceded that as of the filing date it demonstrated that dasatinib acted to inhibit Src-family PTKs. Such demonstration is referred to in the specification of the 932 patent, itself (the 932 patent at pp. 50-51), and confirmed in the evidence of the inventors that BMS filed.
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> [39] While conceding that BMS did demonstrate as of the relevant date that dasatinib acted to inhibit Src-family PTKs, Apotex nonetheless asserts that such demonstration does not establish a scintilla of utility as it says that showing "the binding of dasatinib to certain isolated enzymes in a test tube [...] cannot satisfy the utility requirement" (supplemental written submissions of Apotex at para. 5).
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> [40] I disagree. Establishing that a compound has the ability to inhibit a biological target implicated in disease is doubtlessly a useful discovery. Here, it was known as of the relevant date that enhanced activity of PTK was involved in many diseases, as stated in the specification and confirmed in the evidence of several of the experts. Thus, discovery of a substance that acted to inhibit certain PTKs represented an important advance and certainly meets the minimal utility requirements that are now applicable following the decision of the Supreme Court in Esomeprazole. [Emphasis Added]

Pfizer Canada Inc v. Apotex Inc, 2017 FC 774

In one of the first Federal Court decisions applying the *AstraZeneca* test for utility, Justice Brown held that the utility of the patented drug in question—Pfizer's PRISTIQ® (desvenlafaxine) drug for the treatment of depression—was the drug's usefulness in a stable, solid state; not its treatment efficacy. Brown J. rejected Apotex's argument that the utility is "what the drug can do as a practical matter (i.e. treat disease) and not its properties", holding that the practical usefulness of the drug in a solid state alone is sufficient utility:

> [340] Pfizer says that the usefulness, the utility, of Claims and 9 is its usefulness as a stable, solid state form of ODV succinate. I agree. I also agree that this use is directly related to the subject matter of Claims 8 and 9. Stability (i.e., the tendency not to change to other forms) is an important property for a new crystal form and there is ample evidence that stability was required for this pharmaceutical development.
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> [341] Apotex disagrees saying that stability is one of the physical properties of the drug (e.g., mass, colour, melting point, stability, etc.), and that utility it is what the drug can do as a practical matter (i.e. treat disease) and not its properties. I disagree: in my respectful view a drug that is not stable across the manufacturing, distribution and storage processes cannot readily be seen as useful. Rather, in my view the reverse. I am not persuaded by Apotex's arguments on this point particularly because it is the solid state stability of Form I that makes it possible to use Form I ODV succinate in formulation i.e., as a drug … While Apotex argues that the stability Pfizer asserts is only the stability of ODV-S Form I (ground), Pfizer correctly observes that this argument is of no moment for the purposes of the AstraZeneca utility analysis because even if the claim were limited to "ground" Form I, which I have held is not the case, it was still shown to be useful.
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> [344] Pfizer also argued that the practical usefulness of the drug as a stable solid form is alone sufficient utility under AstraZeneca in this context, and I agree. [Emphasis Added]

The Federal Court also expressly rejected argument that the Supreme Court imported promise doctrine principles into the law of sufficiency when it stated in *AstraZeneca* that the "mischief of overpromising" violates the requirements of s. 27(3) of the *Patent Act*. Apotex had argued that Pfizer's patent "overpromises" and thus was invalid for insufficiency. Justice Brown disagreed, noting that if the Supreme Court had intended to say that the Promise Doctrine was not good law in terms of

utility under s. 2, but was good law in terms of patent specifications under subsection 27(3) it could have done so. It did not. Thus, there is no rationale for the argument that the Supreme Court transplanted the Promise Doctrine into the sufficiency analysis in the manner Apotex proposed:

> [360] I also observe that the alleged overpromises resemble the promise arguments advanced by Apotex, which are no longer valid having regard to AstraZeneca. If the Supreme Court intended to say, in effect, that the Promise Doctrine was not good law in terms of utility under s 2, but was good law in terms of patent specifications under subsection 27(3) it could have done so; it did not.
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> [363] It seems to me that Pfizer is correct. I am unable to see a rationale for the argument that the Supreme Court of Canada removed the Promise Doctrine from the utility analysis yet simultaneously required it to be considered, in the manner Apotex proposes, in the specification analysis. If that was the case, a major underlying problem identified by the Supreme Court itself would remain, namely that "a patentee will be dissuaded from stating the invention can be used for things that are not sufficiently established at the time of filing if doing so would risk invalidating the entire patent." See AstraZeneca para 45.
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> [365] I see nothing in AstraZeneca that alters what I take from the foregoing namely that the specifications analysis under subsection 27(3) requires the patentee to define the precise and exact extent of the exclusive property and privilege claimed. In addition, nothing in AstraZeneca departs from the proposition that under subsection 27(3), "the applicant must disclose everything that is essential for the invention to function properly. To be complete, it must meet two conditions: it must describe the invention and define the way it is produced or built ... [Emphasis Added]

Pfizer Canada Inc v. Teva Canada Limited, 2017 FC 777

In another decision of Justice Brown concerning Pfizer's patent for PRISTIQ® (reasons issued on same date as 2017 FC 774, above), application of the *AstraZeneca* test led to a finding of demonstrated utility. This decision does not provide any further insight into the utility analysis, but is worth noting as another decision in which the Federal Court made clear that the promise doctrine is dead, and has not been imported into the law of sufficiency of disclosure. Brown J.'s reasons are substantially similar to those set out in depth above in 2017 FC 774.

Regents of the University of California v. I-MED Pharma Inc, 2018 FC 164

This decision presents another example of the new minimal utility requirement in action. Applying the Supreme Court's instruction that demonstration or sound prediction of a single use related to the nature of the subject matter of the claim is sufficient to establish utility, Justice Manson found the patentee's demonstration that its device could measure osmolarity in one type of bodily fluid was sufficient to demonstrate utility in other types of bodily fluids. Utility was disposed of in the following three paragraphs:

> [198] The subject matter of the '540 Patent is a sample receiving chip used to measure osmolarity of tear fluid, and a tear fluid osmolarity measurement system, meant to be used in a clinical setting.
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> [199] The evidence shows that by late 2002, Dr. Sullivan's device exhibited at least a scintilla of utility with respect to that subject matter. That is approximately when Dr. Sullivan began using an AC signal instead of a DC signal and overcame polarization issues to obtain stable osmolarity readings. Dr. Sullivan explained that the device he had in late 2002 was essentially the same as the one he used during clinical trials in 2004, in which the device showed some ability to differentiate between normal and DED patients.
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> [200] I accept that the device may not have been perfected as of the filing date -- some aspects needed improvement, such as the sample collection and delivery methods, as well as the chip design -- but there is no question there was demonstrated utility for measuring tear fluid osmolarity at the relevant date. While it may be true that no such demonstrated utility was shown for measuring other bodily fluids, or that utility may not have been soundly predicted for such other bodily fluids, that is not the test to be applied following the decision of the Supreme Court of Canada in AstraZeneca. I need not analyze this issue further. [Emphasis Added]

Sernova Corp v. Shapiro, 2018 ONSC 841

The Ontario Superior Court considered the Post-*AstraZeneca* utility requirement that an invention have "a clear purpose" in the context of an application to determine the ownership of a family of patent applications. The claimed invention is a small

device implanted in the body through which therapeutic cells are transplanted into compartments for the treatment of diseases such as diabetes. The Court explained that under the new utility requirements, the patentee need not show the device is capable of being used to treat diabetes to establish utility. Rather, the patentee need only show that the device is capable of forming a cavity that therapeutic cells can be placed in—that is the "clear purpose" against which utility should be measured:

> [151] In AstraZeneca Canada Inc. and Apotex Inc. v. Sanofi-Synthelabo Canada Inc., 2008 SCC 61, the Supreme Court was clear that "a scintilla of utility" is sufficient to satisfy the usefulness requirement of an invention.
>
> [158] Under the Supreme Court's ruling on utility and the requirement of a clear purpose, the Respondents do not have to show that the DLI was capable of being used to reverse diabetes, but rather could show that the DLI was capable of forming a cavity that therapeutic cells (which could potentially treat multiple diseases) could be placed in. Therefore, based on the Respondents' evidence about the growth of tissue around the DLI in 2006-2007, the DLI did have utility in 2006-2007. The DLI was able to create a cavity surrounded by tissue suitable to receive transplanted cells which was "a more islet friendly environment" as claimed. [Emphasis Added]

Lantech.com, LLC v. Wulftec International Inc, 2018 FC 41

On a motion to re-amend a Statement of Defence and Counterclaim, the Court rejected the Plaintiff's new allegations of inutility grounded in the promise doctrine on the basis the allegations failed to disclose a reasonable cause of action. The Court held that the Plaintiff presented no material facts to support an allegation that any one claim of the asserted patent failed to possess a scintilla of utility:

> [6] Lantech argues that rather than focus on the claims of the asserted patents, Wulftec has incorrectly based its allegations on an alleged promise of utility in the patent description contrary to the Supreme Court decision in AstraZeneca Canada Inc v Apotex Inc, 2017 SCC 36 at paras 54-55 [AstraZeneca SCC] and irrelevant commercial embodiments. Moreover, Wulftec has presented no material facts to support an allegation that any one claim of the asserted patents fails to possess a scintilla of utility.
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> [7] The Court agrees with these submissions. Wulftec's reference in paragraph 34 to "[t]he description provided in the Patents claims to solve the problem of unequal film stretching caused by the shape of the load being wrapped", does not address the utility of the inventions being limited to the claims in the asserted patents as required by AstraZeneca SCC. Moreover, the proposed amendments appear to be based on the premise that because the commercial embodiments solve a particular problem in a certain way they do not possess a scintilla utility, which is not the test … [Emphasis Added]

Apotex Inc v. AstraZeneca Canada Inc, 2018 FC 181

Justice Locke, in this section 8 damages decision, noted with approval Justice Brown's reasoning in the desvenlafaxine decisions (2017 FC 774 and 2017 FC 777, discussed above) that the Supreme Court in *AstraZeneca* did not intend to import the promise doctrine into other grounds of patent invalidity when it abolished the doctrine from Canadian law on patent utility:

> [34] I also see no indication that the SCC intended to change the state of the law as concerns other grounds of patent invalidity. I agree with my colleague Justice Henry S. Brown who recently observed that, if the SCC wanted to state that the Promise Doctrine remains good law for other grounds of patent invalidity, it could have, but it did not: Pfizer Canada Inc v Apotex Inc, 2017 FC 774 at para 360.

Hospira Healthcare Corp v. Kennedy Trust for Rheumatology Research, 2018 FC 259

Consistent with other Post-*AstraZeneca* cases, Justice Phelan explained that the Supreme Court did not import the discarded promise doctrine into the law of sufficiency and overbreadth. Rather, Phelan J. instructed that the controlling feature in an insufficiency analysis is the specification. In this case, the disclosure in the specification was sufficient because a skilled person could follow the examples in the disclosure to put the invention into practice:

> [257] The law has returned to the principle that utility is met if a "scintilla" of utility is demonstrated. All the experts agreed that the 630 Patent possessed a "scintilla of utility that related to its subject matter".
>
> [258] Hospira attempts to import the discarded "promise" doctrine into insufficiency and overbreadth. Certainly

AstraZeneca does not do so and it would be inconsistent to discard that doctrine only to have it resurface under another principle without clear language to do so.

[262] In respect of insufficiency in relation to utility, it is the Specifications which are the controlling feature. In this present case, a POSITA could follow the steps in the Disclosure and Examples to put the invention into practice. Hospira's reliance on the trial decision in the AstraZeneca litigation is misplaced. [Emphasis Added]

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[1] *AstraZeneca Canada Inc v. Apotex Inc*, 2017 SCC 36 [*AstraZeneca*]

[2] *Ibid* at para 46

[3] *Ibid* at paras 54-55