Court File No. 36654

IN THE SUPREME COURT OF CANADA
(ON APPEAL FROM THE FEDERAL COURT OF APPEAL)

BETWEEN:

ASTRAZENECA CANADA INC.
ASTRAZENECA AKTIEBOLAG and
ASTRAZENECA UK LIMITED

Appellants

AND:

APOTEX INC. and
APOTEX PHARMACHEM INC.

Respondents

AND:

CANADIAN GENERIC PHARMACEUTICAL ASSOCIATION,
CENTRE FOR INTELLECTUAL PROPERTY POLICY,
FÉDÉRATION INTERNATIONALE DES CONSEILS
EN PROPRIÉTÉ INTELLECTUELLE,
INNOVATIVE MEDICINES CANADA and BIOTECANADA,
INTELLECTUAL PROPERTY INSTITUTE OF CANADA, and
INTELLECTUAL PROPERTY OWNERS ASSOCIATION

Interveners

APPELLANTS' REPLY FACTUM
IN RESPONSE TO FACTUMS OF INTERVENERS

(Order dated September 19, 2016)

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A. Overview – *Quid Pro Quo* Ignored

1. CGPA is the only intervener attempting to defend the Federal Courts' promise doctrine. The defence entails a series of erroneous legal contortions, the combination of which disregards the *quid pro quo* enshrined in the *Patent Act*: the right to prevent trespass for a limited term over an invention defined by a claim, in exchange for disclosure of the invention.

2. CGPA suggests that the patent description, and not the claims, is the "currency" of the bargain. In fact, both are relevant but not in the way suggested by CGPA or meted out under the promise doctrine. The currency for patent grant is two-fold – first, claim an invention, and second, enable it. A condition precedent for the first is that the claimed invention must be "useful". The promise doctrine is supposedly concerned with this condition precedent. Yet, CGPA seeks to resolve the question of utility in an analysis unhinged from the invention claimed.

3. The error begins with CPGA's assertion that the specification, not the claims, defines the invention. This attempts to revive the "spirit" or "substance" of the invention, which was rejected by this Court in *Free World* (paras 31, 43, 50).[1] CGPA next asserts that every utility disclosed is a promise for that "invention". Finally, CGPA asserts, the patent having allegedly made such promises, every *described* "promise" even if *not claimed* must be met by the filing date for there to be any patentable invention at all.

4. The result of this (il)logic is that all clear statements of utility in the specification are effectively treated as "promised uses" that impart patentability. This is a clever (for those attacking validity) but misguided reversal of the pertinent question. Instead of asking "are the claims patentable because due consideration was given", CGPA would have the Court ask an incoherent question: "are all of the promised uses patentable?"

5. By deeming all clearly disclosed utilities to be promises on which patent rights hinge, irrespective of the invention claimed, CGPA has improperly dislodged the patent utility requirement from the *quid quo pro.*

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[1] References to authorities herein are as set out in full in AstraZeneca's factum dated July 4, 2016.

B. The Twofold Consideration

6. To disentangle CGPA's justification of the promise doctrine, it is useful to recall the twofold consideration for the grant of a patent explained in *Consolboard* (AstraZeneca factum, para 44):

> the grant of a patent is in the nature of a bargain between the inventor on the one hand and the Crown, representing the public, on the other hand. The consideration for the grant is twofold: "*first*, there must be a new and useful invention, and *secondly*, the inventor must, in return for the grant of a patent, give to the public an adequate description of *the invention* with sufficiently complete and accurate details as will enable a workman, skilled in the art to which the invention relates, to construct or use *that invention* when the period of the monopoly has expired" [emphasis added].

7. Justice Dickson could not be clearer. The requirement for an invention precedes the requirement to adequately describe it. The requirement to adequately describe the invention presumes the conditions precedent for an invention have been met. This is eminently sensible from the standpoint of the bargain. If the monopoly sought does not define an invention, no rights can be granted and there is no reason to consider the adequacy of the disclosure of the non-invention. It is the particular invention claimed that must be described so as to enable its use once the monopoly expires.

8. CGPA's analysis twists this framework around and is circular. CGPA suggests the requirement to adequately describe the invention means the specification, and not the claims, defines the invention and all clearly disclosed utilities are part of the invention. So defined, proof of all such clearly disclosed utilities are required by the filing date to establish the existence of this invention.

9. These contorted principles and the statutory scheme must be disentangled.

C. Purposive Construction: Of the Claims, in light of the Description (Not the Other Way Around)

10. CGPA is plainly incorrect in contending that patent claims define the monopoly but not the invention (para 14), and thus rejecting the role of the claims in assessing utility. "It is the invention thus claimed to which the patentee receives the "exclusive right, privilege and liberty" of exploitation": *Free World*, para 33.

11. CGPA's distinction between the monopoly (setting fences) and the invention is thus a false dichotomy. Just as infringement is decided based on whether you fall within the fences, invalidity is equally based on whether the area fenced in includes anything old or useless (*Whirlpool*, paras 43, 49). The doctrine of sound prediction is similarly concerned with fair breadth or scope of protection for the disclosure given (*Wellcome*, para 59).

12. Thus, the specification may well describe the invention in wider terms than are claimed, as well as utility that is not claimed, given that an inventor is not obliged to claim as her invention everything new, ingenious and useful disclosed in the specification.

13. It does not follow that the utility requirement exceptionally shifts to the whole patent instead of the claims to decide if there is an invention, as argued by CGPA (paras 10, 17, 28). Inconsistently, CGPA elsewhere refers to the utility of the *claimed* invention (paras 8, 13), but avoids conceding that usefulness is to be analyzed on a claim by claim basis. An incoherent analysis results. The (il)logical conclusion of CGPA's analysis is that assessments of patentability (novelty and inventiveness on the one hand, versus usefulness on the other) are conducted on different "inventions".

14. The absurd consequence is exemplified by the trial judge's requirement for AstraZeneca to establish promised utility for compounds *that were not claimed.* The patentee did not seek and *received nothing* for the unclaimed (+) enantiomer, but was nonetheless required to demonstrate or soundly predict every "promised utility" for this disclaimed compound. Another absurd consequence is that claim 26 was invalidated for lack of "promised" utility, despite the finding that the utility *claimed* was soundly predicted.

D. Purposeless Construction: Deeming Utility Disclosed to be a Promise Made

15. CGPA suggests that any utility that the patentee has chosen to describe or refer to should be assumed to have been intended to obtain some advantage such as imparting patentability (CGPA, para 11). The trial judge's conclusion that the 653 patent is not a new use patent belies CPGA's suggestion.

16. The *Patent Act* also does not operate as CGPA suggests. What is disclosed but not claimed is disclaimed (AstraZeneca factum, para 49; *French's*, p 475). Purposive claim construction, which AstraZeneca urges is the correct approach to identify whether a particular

utility should be required as essential to the invention, fully takes into account the disclosure (AstraZeneca factum, paras 105-131, 154-155).

17. CGPA equates disclosure with promise and suggests purposive construction of the patent is directed to ascertaining whether the patent discloses a particular utility of the claimed invention (CGPA, para 13). CGPA thus emphasizes the patentee's words and language (*e.g.* paras 1, 2, 6, 13, 15, 16), without regard to whether, objectively, the inventor intended to effectively guarantee the utility (akin to identifying whether the inventor intended an element to be essential), by what is claimed. This is not purposive, despite its label.

18. Further, an inventor's objective intent in defining his or her invention is identified from the claim language, which is construed not merely by a literal understanding of the words (AstraZeneca factum, para 99). Purposive claim construction is capable of expanding or limiting a literal text (*Whirlpool*, para 49(h)). Indeed, the disclosure may take on a different meaning in light of the claims than it might otherwise as a matter of first impression (*Sandoz*, pp 1345-1346).

E. The Filing Date Requirement: First, There Must be a New and Useful Invention

19. There is no disagreement that utility is a precondition for the very existence of an invention, as of the filing date (CGPA, para 7).

20. The problem is that by deeming all clearly disclosed utilities to be promises on which patent rights hinge, irrespective of the invention claimed, CGPA has, quite effectively, but improperly, dislodged the utility requirement from the *quid quo pro*. The actual usefulness of a claimed invention is irrelevant under CGPA's theory and the Federal Courts' promise doctrine. Proof of every clearly described utility, at the filing date, is necessary to meet the precondition for an invention (CGPA, para 11).

21. Properly considering the subject-matter claimed in this case, there is no need for the public to verify utility by separating the truly 'inventive wheat' from the 'speculative chaff' (CGPA, para 12). This may apply in cases where the invention lies in the utility. Hence in *Wellcome*, the 'speculative chaff' of treatment of all retroviruses other than HIV was bad; the claim to the soundly predicted use to treat only HIV was valid.

22. But in the case of a claim to a *new* and *unobvious* compound that the skilled person

undoubtedly understands is *useful* (as in this case), there is no need to verify every described utility to identify the 'inventive wheat'. A multitude of other utilities could be described, but this does not change the claimed compound from an invention made to a non-invention.

F. Potential Patentee Misconduct is Already Restrained by the *Patent Act*

23. CGPA's concern that clear statements of utility cannot be ignored is misplaced. CPGA's suggestion that patentees would be encouraged to describe their inventions and how they work so as to prophylactically avoid novelty and obviousness objections, secure in the knowledge that they will never have to defend or support such description (para 11) – is but an oblique charge that patentees will describe their inventions in a way that intentionally misleads the Patent Office or the public.

24. The *Patent Act* already provides the tool to control such deliberate misrepresentations: section 53. Even without deliberate misrepresentations, if the patent description otherwise falls short, the claim or patent will fall, not because there was no invention but because the patent failed to provide an adequate description to support the claim or any claim. These issues do not arise in this appeal.

25. CGPA's argument also incorrectly places validity in the hands of the patentee's description. The true test is objective: whether what is distinguished *by* the claim is *in fact* useful or new, a test not dependent on the patent's description thereof (AstraZeneca factum, paras 108-109

26. Further, CPGA's proposed concern is fully addressed by a single purposive construction for all purposes, with which all other interveners agree. It was AstraZeneca who advanced the *same* construction of the invention on all issues. It was Apotex who advanced distinct constructions for obviousness and utility.

27. CGPA's concern is not borne out by the facts of this case. Instead, CGPA's approach condones and encourages strategic reading down to attack inventiveness, and reading up to attack utility.

G. "A" Utility to a Skilled Person Means Practical Utility, not Trivial Utility

28. Contrary to what may be suggested by CIPP (para 12), AstraZeneca has not argued that a

purposive understanding imposes an extra-statutory requirement.

29. In this regard, CIPP has strangely read AstraZeneca's submission as a suggestion that "useful" only requires an abstract or trivial utility (CIPP, paras 14, 27-29). When AstraZeneca submitted that "useful" means not useless, or not devoid of utility, and that a utility is enough (paras 61, 139-140, 155), the submission was not intended to be read in isolation from AstraZeneca's argument that patents are directed to the skilled addressee.

30. AstraZeneca was not proposing minimal utility (or any threshold). No skilled person would suggest a chemical compound is always useful in the abstract, for example as landfill. Such suggestion is a lawyer's argument. The key point, relevant to the facts of this case, is that multiple utilities are unnecessary to meet the statutory definition of an invention, based on the trial judge's purposive construction of the invention claimed.

31. Of course, in the present case, the trial judge did find the claimed subject-matter has a meaningful and practical utility (as a proton pump inhibitor (PPI), useful for treatment of gastric acid-related diseases), as understood by the skilled person from common general knowledge and/or reading the specification. This finding is dispositive of the issue.

H. An Objective Threshold Utility Standard, Not Harmonization

32. CGPA objects to "harmonization" of Canadian patent law with the laws of other jurisdictions (paras 29-34). In light of this Court's recognition of the importance of global context in patent law (*Sanofi*, paras 55-60), AstraZeneca asks the Court *to consider* the current utility standard in the context of international patent system to which Canada is a party.

I. Post-Filing Evidence May be Relevant

33. CGPA's argument that post-filing evidence of utility is irrelevant – because "the public should not suffer a monopoly where the applicant has no invention" – fails to recall the reasoning in *Wellcome* that such evidence of utility in the case of a new use invention would not change the analysis. CGPA also overlooks that, in expressly considering a hypothetical, adequately described product rather than a new use, *Wellcome* does indicate that post-filing evidence may support sound prediction (AstraZeneca's factum, para 174; *Wellcome*, para 82). If the invention in fact can be made and does as the patent says, then that is good evidence that the inventor was

in possession of an invention when the patent application was filed.

34. Apparently taking a position on the outcome, CGPA argues that even if AstraZeneca's assertion that esomeprazole was later determined to provide reduced interindividual variation were true, it is no answer to the invalidity of the patent (para 28). As already discussed, *Wellcome* indicates otherwise.

J. Proper Scope of Sound Prediction

35. Whether sound prediction is patentee friendly (CGPA, para 21) is beside the point – the question is whether it is properly applied. In *Wellcome*, proof of utility before filing was required where the utility was both claimed and the *gravamen* of invention. This does not apply to the present case where an improved therapeutic profile was not the subject-matter claimed, nor the gravamen. That the claimed invention was useful as a PPI was not in doubt in the eyes of a skilled person (AstraZeneca factum, paras 141-143).

36. Thus, *Wellcome* does not stand for the blanket proposition that the basis for every predicted utility must be disclosed. Rather, *Wellcome* is consistent with the statutory requirement to describe the subject-matter of the invention claimed.

K. Avoidable Distractions

37. Two themes run through the submissions of CGPA and CIPP, unnecessarily muddling the main issues. They may be readily dismissed at the outset.

38. First, it is important to be perfectly clear as to what this case is *not* about. This case has never involved any allegation, evidence, or finding of fact, that the claimed compounds will *not* actually give an improved therapeutic profile such as a lower degree of interindividual variation.

39. Expressed in terms of the CGPA's patent bargain, this is *not* a case where it is alleged that the claimed esomeprazole compound does not do what the patent says it will do such that the inventor's side of the bargain is unmet (para 6), or that the patentee shirked its responsibility to live up to the statements it voluntarily made in the patent (para 8). In terms proposed by CIPP, this is *not* a case where the claimed invention supposedly does not do what the applicant says it does (para 1), or does not have the utility a skilled person determines the applicant to claim (paras 14, 22).

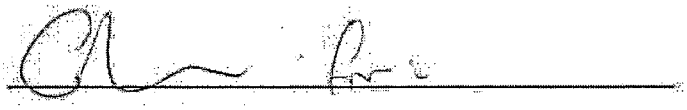
40. CIPP notably does not equate the requirement that an invention "must do" what the applicant says it does, with the requirement for demonstration or sound prediction of "invention" by the filing date. It does not at all attempt to address or resolve the real controversy surrounding the promised utility doctrine – the doctrine's requirement to have established *at the filing date* all clear statements of utility in the description.

41. Second, it is important to observe, and completely reject, any vague suggestion that what is at issue is the application as filed, and not the issued patent. The language "applicant" pervades CIPP's submissions, and appears interchangeably with "patentee" and "inventor" in CGPA's submissions, both with little or no explanation.

42. The suggestion is wholly unsound in principle and should not be entertained. The *quid quo pro* of the patent bargain, as consistently interpreted by this Court, is centred on the grant of the monopoly, *i.e.* the patent claims, purposively construed (*e.g.* AstraZeneca factum, paras 42-45). The application as filed does not bear on purposive construction of the patent (*Free World*, para 66). As CGPA notes, the application may be amended, if no new matter is added (para 33).

October 28, 2016

ALL OF WHICH IS RESPECTFULLY SUBMITTED



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