

# TORYS

## Independence of Experts and Dealing with Bias

*The issue of expert “blinding”*

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Friday, November 4, 2016

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- *White Burgess Langille Inman v. Abbott and Haliburton* (2015 SCC 23)
    - independence, objectivity and absence of bias is a pre-requisite for admissibility
    - expert evidence that does not meet these criteria should not be admitted
    - absent a challenge, the expert's recognizing and accepting the duty will generally be sufficient to establish that the threshold test has been met
      - expert code
    - a party who wants to challenge this must show there is a "realistic concern," about one of these things, at which point the burden shifts to the party offering the expert evidence to establish it

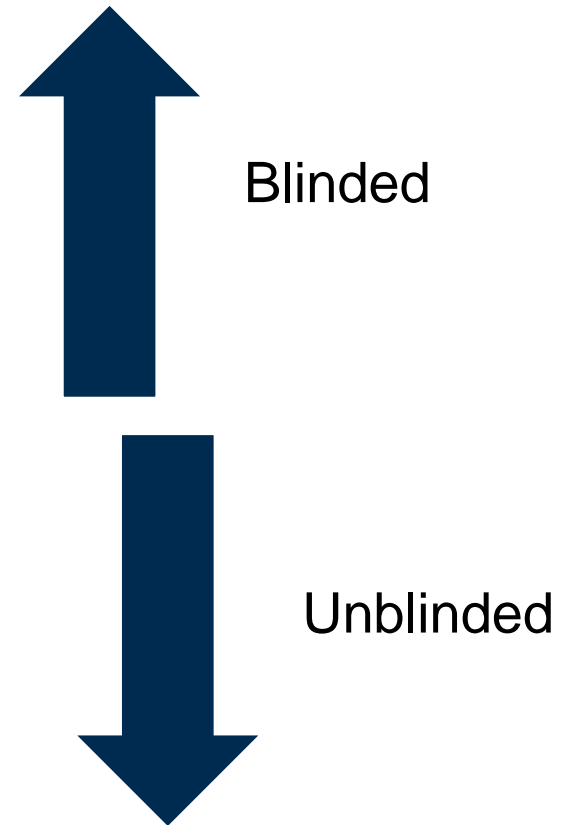
- Does lack of blinding raise a “realistic concern?”
- If so, is there an admissibility problem?
- If not, does it go to weight?
- Is the problem it’s trying to address the expert who is **unwilling** to be unbiased or **unable** to be unbiased?

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- If you don't believe that the expert is **willing**, blinding is of limited value because your expert is dishonest and it's easy for a dishonest expert and an unethical lawyer to circumvent blinding
    - don't show the expert anything, just "have a discussion" about the issues
    - you can claim the expert "blindly" reached their conclusion

# Unable: does blinding prevent unwitting influence?

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- Blinding looks like this:
  - retain the expert
  - ask the expert some questions
  - collect his or her answers
  - “unblind” the expert
  - collect more information
  - finalize the report/affidavit
  - prep the expert for trial
  - the expert testifies at trial and is cross-examined

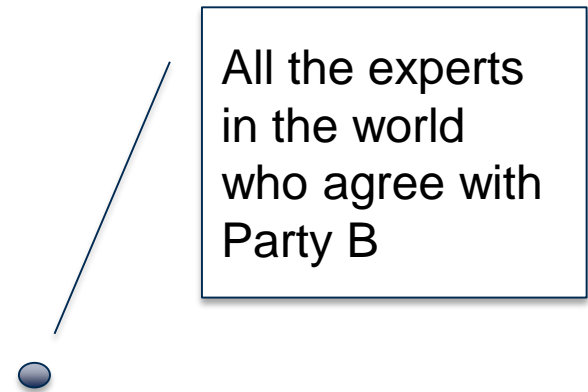


# How useful is blinding in patent cases?

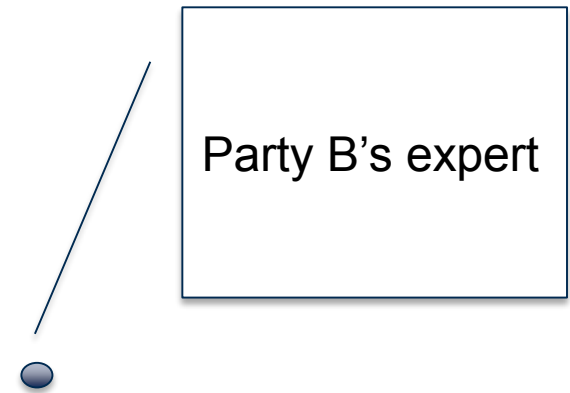
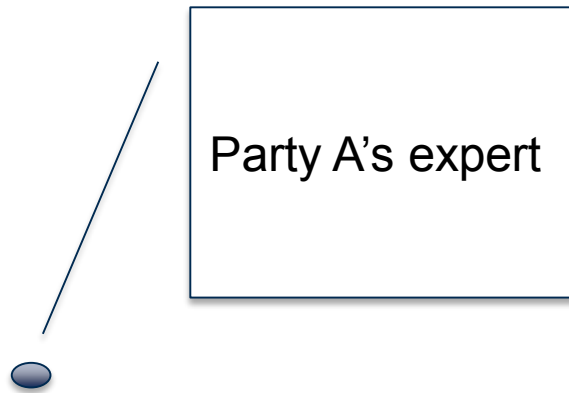
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- Blinding may help with one problem (lack of independence) but does not solve the real problems:
  - experts are being asked to answer questions that they are **not really experts in**
    - claim interpretation
    - promise of the patent
  - blinding or no blinding, you can always find an expert to say what you want him to
    - ask enough of them, eventually one will give you the “right” answer
    - you can shield the rest through litigation privilege

- What the world really looks like



- What the Court sees





# What is the expert being “blinded” to?

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- Notice of allegation / pleadings
- Identity of the party retaining
- Pleaded prior art list
- The patent itself
- The facts and/or productions
- Other expert reports

# Blind to the notice of allegation/pleadings?

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- Sounds like a good idea to prevent the patent challenger's expert from adopting its position
  - certainly we have seen some extreme situations: *Pfizer v. Mylan* 2011 FC 547 (promise list copied directly from the NOA)
- How do you implement this as a patentee?
  - you have to go first and answer all the allegations made
  - what if you need the expert's help to understand the allegations in the first place?

- Nothing inherently harmful here (assuming the experts don't have to run conflict checks) but you have to wonder:
  - are you fooling anyone?
  - in a small bar where the same 10 lawyers act for brands and the same 10 lawyers act for generics, do the experts know who's who anyway?

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- A patent can only be found obvious on the basis of materials that a skilled person would find “on a reasonable and diligent search”
  - In most cases, counsel has to come up with a prior art list before retaining an expert (for an NOA or a pleading)
  - As a patentee, it’s easy: you show the expert the list and he or she says “not obvious in light of this art”
  - As a challenger, it’s a little less intuitive: do you show the expert the list? Do you ask them to do their own searches?
    - does this matter except in the extreme case?
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- *Gilead Sciences, Inc. v. Canada (Minister of Health)*, 2016 FC 857
  - *BMS v. Teva Canada Ltd* (2016 FC 580)
    - Both express concerns about “cherry picking” from the prior art list
    - Is the solution here a shorter list?

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- Most controversial – can the expert give a good opinion without seeing the patent?
  - Sanofi test for obviousness:
    1. identify the skilled person and his/her common general knowledge
    2. identify the inventive concept of the claim
    3. what are the differences between the “state of the art” and the inventive concept
    4. **Viewed without any knowledge of the alleged invention as claimed**, do those differences constitute steps which would have been obvious to the person skilled in the art or do they require any degree of invention?
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**“viewed without any knowledge of the alleged invention as claimed”** has led to a “parlor trick:”

- find an expert and give him or her the prior art
- ask the expert “what would have been obvious in light of the prior art?”
- they say “the invention!” and you rely on this for obviousness

# What is wrong with this approach? (Everything!)

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- It gives the expert the prior art
  - can't ask them to search for art on a patent they've never seen
- It only works one way
  - what does the patentee do to counter it?
- It ignores the role of inventive concept
  - must be construed
- It's actually hard to take the existence of a product that is significant enough in the market that it's worth litigating "out of the mind" of an expert
  - give an expert the racemate of atorvastatin and ask "how would you optimize this?"
  - the expert says "I would separate the enantiomers and get atorvastatin" (the best-selling drug in the world at the time ... is it possible he did not know about it?)



- Can't do the first three parts of the *Sanofi* test without looking at the patent
- Can't answer any construction questions without looking at the patent
- Can't answer any promise questions without looking at the patent

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In the Court's view, Apotex's experts were more credible on certain issues because "they more closely emulated the perspective of the skilled person...with mandates that allowed them to opine on the state of the art... viewed without any knowledge of the alleged invention as claimed..." (para. 321).

## However...

- Rennie J. went on to accept other conclusions put forward by AstraZeneca's experts as more persuasive, despite their **not** being blinded.

Zinn J.:

“...this Court has recognized that evidence from experts who have not seen the patent nor been apprised of the positions of the litigants is to be given greater weight on issues going to obviousness and patent construction than the evidence of an expert with full knowledge of the patent's disclosure and the positions of the parties” (para. 13).

- It's not what “without any knowledge of the alleged invention as claimed” was intended to mean
- It is intended to mean the opposite: that in considering obviousness, the expert should not take into account the **existence of the invention** as a factor weighing in favour of obviousness

# Blind to the facts/documents? (For infringement purposes)

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- No reason in principle why it is problematic to ask the expert to construe a claim before seeing the documents that show what the other side is doing
- No reason in principle why it is necessary either – better to test the coherence of the opinion in cross-examination rather than doubt it because it was unblended.

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## Preference for blinding?

- The Court afforded lesser weight to the interpretation of experts who construed the '310 patent with the allegedly infringing substance in mind (*i.e.*, Teva's "non-blinded" experts).
- Gleason J. expressed a preference for "blind" experts:  
"Secondly, I agree that the manner in which the experts were retained and instructed in this case provides a reason to prefer the evidence of Apotex experts over that of Teva experts" (para. 94).

- Goes without saying that experts on the same side should not see one another's opinions
- Experts have to see the opposing expert report

# Is the Court back-tracking on some of this?

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## Recent cases of interest:

- *AstraZeneca Canada Inc. v. Apotex Inc.*, 2014 FC 638
- *Teva Canada Innovation v. Apotex Inc.*, 2014 FC 1070
- *Eli Lilly Canada Inc. v. Apotex Inc.*, 2015 FC 875
- *Allergan Inc. v. Apotex Inc.*, 2016 FC 344
- *Shire Canada Inc. v. Apotex Inc.*, 2016 FC 382
- *Gilead Sciences, Inc. v. Canada (Minister of Health)*, 2016 FC 857
- *Bayer Inc. v. Cobalt Pharmaceuticals Co.*, 2016 FC 1013
- *Uponor AB v. Heatlink Group Inc.*, 2016 FC 320.



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## **A fact-specific approach to expert blinding:**

- In response to Apotex’s argument that the court should disregard the evidence of Eli Lilly’s “non-blinded” experts, Gleason J clarified her position on blindness by noting, in regard to *Teva* and *AstraZeneca*, that:

“[n]either case can be read for the position that Apotex sought to advance here, namely, that in any case where one party blinds its experts but the other does not, the former’s evidence is to be preferred. Rather, these two decisions must be limited to the facts that arose in these cases” (para. 166).

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**Facts:**

- Shire sought an order prohibiting the Minister of Health from issuing a NOC to Apotex in connection with its patented drug for the treatment of ADHD until after the expiry of Shire's Canadian patent.
- Locke J. dismissed Shire's motion on the basis of non-infringement.

**Apotex's Blind Experts:**

- Apotex's experts never saw the NOA and were never told Apotex's legal position; they were asked to construe the claims of the patent without information about Apotex's product.

## **A cautionary note...**

On the issue of blinding, Locke J. held:

1. Favours the evidence of blinded experts is not a legal principle that must be applied in all cases. It is merely persuasive.
2. The Court is mainly interested in the substance of an expert's opinion and the reasoning that led to that opinion.
3. Expert blinding is no guarantee that the expert evidence is reliable.

**Facts:**

- Gilead sought an order prohibiting the Minister of Health from issuing a NOC in respect of a NOA sent by Apotex to Gilead.
- On the '475 Patent, the Court held that Gilead established that Apotex's allegation of invalidity based on utility was not justified.
- However, the Court dismissed Gilead's application for prohibition on the basis that Gilead did not establish that Apotex's allegation of invalidity on the basis of anticipation and obviousness was not justified.

- On the issue of blinding, Brown J. agreed with Justice Gleason in *Eli Lilly* and Justice Locke in *Shire* that the weighing of expert evidence is a question of fact, and that “the blinding issue is a question of relevance, reliability and weight, and is not a doctrinal matter” (para. 35).

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**Facts:**

- Bayer alleged that Apotex's and Cobalt's (now Actavis Pharma Company) products infringed their '426 Patent.
- Apotex and Cobalt argued that Bayer's claims were invalid on at least one of the following grounds: obviousness, anticipation, overbreadth, insufficiency or ambiguity of the specification, or inutility.
- The Court upheld the validity of the impugned claims, and concluded that Apotex's and Cobalt's products infringed Bayer's '426 Patent.

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**Blind vs. non-blind:**

- **Blind:** Apotex's experts reached their conclusions without knowing the nature and content of the patent in issue or the legal positions of the parties.
- **Non-blind:** Bayer's expert witnesses were not blind to the nature and content of the patent, having testified in support of the '426 patent and similar patents on other occasions.

Justice Fothergill echoed the concerns raised by Justice Lock in *Shire*:

“As Justice Locke has observed, if an expert's opinion is well supported, then there may be no reason to place less weight on the expert's evidence merely because he or she was not blinded to certain facts when forming that opinion ([Shire](#) at para 45). Moreover, the blinding of an expert witness is "no guarantee" that the expert's evidence is reliable. There is always a possibility that an unscrupulous party may seek opinions from a number of blinded experts, and retain only those whose opinions the party considers favourable to its legal position ([Shire](#) at para 46). I have not found the blinding of expert witnesses to be a significant factor in deciding the legal and factual issues raised by this case” (para. 66).

# The limitations of expert blinding

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Tension between relevant evidence and hindsight bias

- *E Mishan & Sons*



# My conclusions from reading the theory and the cases

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- Blinding might be useful in particular circumstances
- Blinding is no substitute for a truly objective expert
- Blinding the expert from the patent has serious limitations
- Blinding is a tool that parties are using to try to bludgeon each other, rather than a good faith attempt to increase the integrity of the process
  - a “formerly blind” expert who has been unblinded by the time cross rolls around should not get any “extra credit”

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- In *Moore*, Justice Wilson addressed the issue of expert bias in the context of expert reports. In her reasons, she emphasized the need to ensure the independence and integrity of expert witnesses:

“The expert’s primary duty is to assist the court. In light of this change in the role of the expert witness, I conclude that counsel’s prior practice of reviewing draft reports should stop. Discussions or meetings between counsel and an expert to review and shape a draft report are no longer acceptable” (para. 50).

- On appeal, Justice Sharpe, writing for the majority, rejected Justice Wilson’s declaration that counsel should no longer view draft reports with experts.

## **In the context of patent litigation...**

- Justice Sharpe remarked that in some highly technical areas, such as patent law, expert witnesses “require a high level of instruction by the lawyers” which may necessitate “a high degree of consultation” involving “an iterative process through a number of drafts” (para. 55).

## Recall Issue #2 - types of expert blinding:

- In *Uponor AB v. Heatlink Group Inc.*, 2016 FC 320, the Federal Court cited *Moore* with approval:

“Undoubtedly, consultation and collaboration between expert witnesses and counsel is a necessary component of litigation, particularly in highly technical cases” (para. 203).

## What about expert assessments of prior art?

- The Court in *Uponor* raised concerns regarding the approach taken by experts in assessing prior art.

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