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The Promise Doctrine Trends, practice tips, and collateral damage

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- Trends with respect to certain aspects of decisions
- Practice tips
- Collateral damage





POSITA

Apotex v. Pfizer 2011 FCA 236 (F.C.A.)

- Patent for a prostoglandin formulation (including a latanoprost formulation) for the treatment of glaucoma and ocular hypertension.
- FCA: Skilled person would understand that treatment of glaucoma would require chronic treatment, and therefore construe the patent to promise treatment of glaucoma on a chronic use basis
- Patent invalid for failing to demonstrate or soundly predict utility since Pfizer had only conducted “single dose” studies on animals and healthy humans.

Pfizer v. Ranbaxy 2008 FCA 108 (F.C.A.)

- Patent for atorvastatin calcium (“Lipitor”) – selection patent
- Patent promised an “unexpected and surprising inhibition of biosynthesis of cholesterol”
- FCA: Trial judge erred in construing promise of ten-fold increase. POSITA would know that CSI data, which represents the activity of a compound *in vitro*, does not reflect the activity of the compound *in vivo*.





ACE Inhibitors

Laboratoires Servier v. Apotex 2008 FC 676 (F.C.), affirmed 2009 FCA 222 (F.C.A.) (perindopril)

- Patent stated that the compounds are useful as ACE inhibitors.
- Referred to utility to treat hypertension.
- Snider J. concluded that patent stated that the compounds could be put to therapeutic use, but did not promise that all compounds would be useful.

Sanofi-Aventis v. Apotex 2009 FC 676 (F.C.), affirmed 2011 FCA 300 (ramipril)

- Patent stated that the compounds are useful as ACE inhibitors and “They are useful in the treatment of high blood pressure”
- No language putting any limit on the usefulness of the compounds
- Snider J. held that the patent promised that all of the compounds claimed were useful as ACE inhibitors and in the treatment of hypertension





Side Effects

Apotex v. Pfizer 2011 FCA 236 (F.C.A.) (latanoprost)

- Patent claimed therapeutic composition to treat glaucoma ... without causing substantial ocular irritation
- Patent premised on avoiding side effects
- Court construed patent as promising avoidance of side effects.

Pfizer v. Mylan 2012 FCA 103 (F.C.A.) (donepezil)

- Patent for donepezil and construed to promise it as an effective AChE inhibitor and effective for the treatment of Alzheimer's.
- Patent stated prior art compounds used had unsatisfactory effect and side effects.
- Patent said compound had a persistent activity and a high safety as compared to a popular prior art compound. These passages not construed as promises.





Promise in the claims

Purdue v. Pharmascience 2009 FC 726 (F.C.) – Oxycodone patent

- Claims to controlled release dosage form comprising a particular formulation providing a specified dissolution profile
- The claimed invention was limited to compositions having such profile.

Sanofi-Aventis v. Ratiopharm 2010 FC 230 (F.C.), affirmed 2011 FCA 300 (F.C.A.) – Irbesartan patent

- Claim to pharmaceutical composition comprising a particular formulation wherein a tablet formed from such composition has a specified dissolution profile
- Issue whether the dissolution performance was a promise of performance or a limitation on the formulation.
- Held claim promised that if one follows the formulation of components, one will achieve the desired dissolution rate.
- If claim only claimed those of broad range that gave the specified dissolution, it would claim the result.





Practice Tips

- Pfizer v. Mylan (2011)
 - *...the use of the specification of a patent in order to construe its promise "is not to serve as an invitation to a zealous lawyer to read a patent specification in such a way as to persuade a Court, one way or the other, as to what the promise is" ... As recently aptly noted by Zinn J. of the Federal Court, "the jurisprudence does not permit an unescorted and unchaperoned romp through the disclosure"*





Practice Tips

- Stop, look, listen
- Avoid unsupported extrapolation (single use vs chronic use)
- Stick to the facts
- Don't make promises you can't keep





Collateral Damage

- Teva v. Pfizer





Common in pharma and chemistry to have a broad first independent claim covering numerous individual compounds

1. Use of the compound of formula (I) ...



6. Use according to claim 4, where the compound of formula (I) is []

7. Use according to claim 4, where the compound of formula (I) is [sildenafil]





The basis for the grant

- Bargain between State and inventor
- Sufficient support in the description is a prerequisite condition for grant
- Does the public obtain what the public is entitled to?





Sound prediction

- Only applies where utility is not clearly demonstrated in specification
- Utility: does the invention do what it is supposed to?
 - Does it keep its promise?
- Studies clearly showed that sildenafil worked





Disclosure

- FC and FCA: disclosure requirements are to be evaluated only with respect to claim 7
- BUT – s. 36 – look at the specification first
- If the claims are linked but the same inventive concept, it is the same invention





Sufficient disclosure?

A single study had demonstrated that sildenafil was the invention, but Pfizer chose not to disclose this – sildenafil was identified as one of the preferred components, and the claims identify two individual components, without stating which one really works





- Pfizer has asked for a review of the SCC decision, stating that since the decision was taken in the context of NOC proceedings, the Court did not have the legal authority to invalidate the patent





Questions

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