

Publisher's Note

An Update has Arrived in Your Library for:

| |
|---|
| Please circulate this notice to anyone in your office who may be interested in this publication. <i>Distribution List</i> |
| <input type="checkbox"/> |
| <input type="checkbox"/> |
| <input type="checkbox"/> |
| <input type="checkbox"/> |

| |
|--|
| CANADIAN PATENT ACT ANNOTATED SECOND EDITION Robert H. Barrigar Andrew M. Shaughnessy Release No. 3, September 2024 |
|--|

The *Canadian Patent Act Annotated*, Second Edition, is your one-stop source, bringing together commentary and current case law interpreting patent legislation. This includes all of the relevant statutes, regulations and rules you need to provide your client with the best patent advice available.

What's New in this Update:

This release features updates to the Patent Act – Amended by 2023, c. 26, ss. 487-498 [To come into force January 1, 2025.]. This release also features updates to the Table of Utility – Sound Prediction Cases in Chapter 2. This release also includes updated versions of Appendix P — PCT Applicant's Guide – International Phase, Appendix Q — PCT Applicant's Guide – National Phase and Appendix T — Legal Memos.

THOMSON REUTERS®

Customer Support

1-416-609-3800 (Toronto & International)

1-800-387-5164 (Toll Free Canada & U.S.)

E-mail CustomerSupport.LegalTaxCanada@TR.com

This publisher's note may be scanned electronically and photocopied for the purpose of circulating copies within your organization.

Highlights:

- **Table of Utility — Sound Prediction Cases** — On appeal, Sandoz acknowledged that the Federal Court did not err simply in failing to state that the threshold for a sound prediction is a *prima facie* reasonable inference of utility. However, Sandoz urged the Federal Court of Appeal to infer that the Federal Court failed to apply this threshold because the evidence could not support it. Justice Locke concluded that the circumstances did not suggest that the Federal Court applied a lower threshold for sound prediction than that contemplated in *Wellcome* and *Eli Lilly*. Justice Locke did not accept that, at the time of filing the application for the Patent, the inventors necessarily had no more than a promise that a hypothesis might later prove useful. The fact that more experimentation was required after the rat studies did not necessarily take the utility of the invention outside the scope of a sound prediction. The doctrine of sound prediction, in its nature, presupposes that further work remains to be done. It was up to the Federal Court to weigh the evidence and decide whether the threshold for a sound prediction was met. Justice Locke also did not accept that the Federal Court’s conclusion that published long-term human studies were no more than preliminary evidence that the combination of bosentan and sildenafil would be effective in treating PAH was inconsistent with the conclusion that one could draw a *prima facie* reasonable inference of utility from rat studies measuring systemic blood pressure. Justice Locke explained that the Federal Court’s use of the term “preliminary evidence” was made in the context of its analysis of obviousness, not sound prediction, and was used to contrast “definitive evidence.” Read in context, the Federal Court’s conclusion was that the human studies did not provide definitive evidence that the combination of bosentan and sildenafil would be effective. Moreover, the legal tests for obviousness and for sound prediction are distinct and different. Common general knowledge may be sufficient to support a sound prediction, but not sufficient to find obviousness. Justice Locke was also not prepared to conclude that the fact that the rat studies measured systemic blood pressure rather than pulmonary blood pressure was a difference sufficient to prevent a sound prediction of utility. Sandoz acknowledged that animal studies can be the basis of a sound prediction of utility in humans: *Sandoz Canada Inc. v. Janssen Inc.*, 2023 CarswellNat 4477, 2023 FCA 221 (F.C.A.).