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# Patent Rulings on Disclosure will spawn Litigation, not Innovation

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# Disclosure obligations in patent law

Patents are supposed to induce innovation, but a string of recent court rulings will probably lead to more litigation instead. Clear and stable rules are needed if patent law is to fulfil its policy objectives for all stakeholders in the innovation system.



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A patent promises to protect an inventor's exclusive rights for 20 years. In exchange, the inventor promises to tell the public how to make and use the invention. Though simple in principle, the practical nuances of patent law can be thorny.

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The need for inventors to disclose their secrets is the quid pro quo for patent protection; that's society's benefit from the bargain.

Innovators normally try to walk a fine line, disclosing enough information to validate the invention while not overwhelming application examiners and, of course, still preserving some strategic commercial advantage over competitors.

Precisely how much disclosure to provide is a complex matter on which Canadian appellate courts could help by offering clear

guidelines. Unfortunately, the Supreme Court of Canada has never had much to say about the specifics of this fundamental aspect of patent law. Our highest court hasn't discussed the disclosure issue in detail since the 1980s, before the beginning of the biotechnology revolution. More recent patent decisions pay lip service to the conceptual importance of disclosure, but skirt around substantive questions about how this translates into practice.

Meanwhile, judges have been trying to apply vague theories to practical disputes. A recent article in *The Lawyers Weekly* announced optimistically that a Federal Court of Appeal decision, *Eli Lilly v. Apotex*, [2009] F.C.J. No. 404, had clarified the standard of required disclosure for "sound prediction" patents (See: "Appeal court clarifies utility test for patents," May 8, p.9). In effect, however, that decision threw a shroud of doubt over the legal status of many existing and pending patents in Canada.

To see how, you need only a basic understanding of the doctrine of sound prediction. The entire patent system is set up to encourage disclosure of new inventions as early as possible, sometimes even before their usefulness can be concretely proven. The Supreme Court confronted this problem in a significant case about the antiretroviral drug AZT (*Apotex Inc. v. Wellcome Foundation*, [2002] S.C.J. No. 78), and said that predicted utility might suffice, as long as there's a factual basis for it, the prediction is sound and proper disclosure is provided.

But here's the problem: it didn't say what "proper" means. Justice

Binnie expressly left that question open in 2002, and it remains unresolved to this day. Proper disclosure has since been spun into a “heightened obligation” for sound prediction patents, without much thought about the broader implications. This itself is controversial, but less so than the trend revealed by analysis of related cases.

“Selection patents” protect another special class of inventions. These cover inventions selected for their special characteristics from a broader, already-patented class of products or processes. The Supreme Court recently issued a decision upholding the validity of selection patents, so long as the invention is truly new and not something that was anticipated by an earlier invention (*Apotex Inc. v. Sanofi-Synthelabo Canada Inc.*, [2008] S.C.J. No. 63). The novelty and inventiveness that patent law requires were said to come from the fact that the special characteristics of the selected invention weren’t previously known. In this context, the Supreme Court’s decision explains the relevance of previous disclosure in determining the validity of subsequent patents, but again fails to provide any framework for practical assessment of the issue.

So, not surprisingly, lower courts are causing controversy with disclosure obligations in selection patent cases. For example, in *Eli Lilly Canada Inc. v. Novopharm Ltd.*, [2007] F.C.J. No. 800, the court suggested that the patent paperwork should include specific data proving that the selected invention is special compared to other things in the previously claimed class.

That requirement didn’t exist when most applications for issued and

pending patents were drafted, and it still doesn't exist for any other kind of application. The notion that data is needed in the patent itself has, however, been contradicted by other cases (for example, *Pfizer v. Canada*, 2008 FCA 108).

Even more recently, in *Ratiopharm Inc. v. Pfizer Ltd.*, [2009] F.C.J. No. 967, it was added that adjectives and adverbs won't do. Patent applications must apparently match inventors' minds, describing details exactly as contemplated. But because of the somewhat quirky facts and procedural history of this specific case, we're still left with little idea of where the line between a patent and a scientific paper is supposed to be drawn.

The subtle but significant trend here seems to be a shift in Canadian patent law. Substantively, it is becoming harder for inventors to get and, more importantly, maintain patent protection. Even if you think, as I do, that more rigorous standards for patentability are good for improving the quality of the innovation system as a whole, there are problems with the way this change is being effected.

For one, these decisions cause huge headaches for inventors relying on the *Patent Cooperation Treaty*, the international agreement meant to establish uniform disclosure requirements across jurisdictions. Some might try to reason that international norms don't matter here because the issue is one of substance, on which Canada's national law is supreme. But that ignores the practicalities of patent filing. Harmonizing the paperwork required to support a patent application really does matter a great deal. There is a risk that

the procedural advantages of the streamlined processes for patent applications in multiple countries will be undermined by inconsistent documentation standards.

Moreover, without a Supreme Court ruling clarifying the disclosure obligation in Canadian patent law, the only way to resolve widespread uncertainties can be to individually test all of the now suspect patents through lawsuits. No matter which side of the debate you're on, more patent litigation is bad news for everyone but the lawyers. Innovation doesn't occur in courtrooms.

One appellate judge, at least, has seen the confusion now confronting patent examiners and his colleagues on the courts, writing in *Eli Lilly Canada Inc. v. Novopharm Limited*, [2007] F.C.J. No. 1498: "I do not see how the uncertainty... can do other than act as a drag on efficient decision-making in the pharmaceutical industry, or in any other industry which relies on patent protection."

Indeed, in the absence of an up-to-date prescription from the Supreme Court on the specifics of patent disclosure, Canadians are being delivered unhealthy doses of confusion.

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