Christopher Van Barr

Grant Tisdall

gowlings

Leaving their mark

Canada's courts have clarified patent law in a number of areas in the last year. Christopher Van Barr and Grant Tisdall report.

Over the past year, Canadian Federal Courts left their juristic mark on patent law. This article highlights recent patent decisions addressing the idiosyncratic Canadian concepts of "promise of the patent," "sound prediction," our treatment of methods for medical treatment, and our evolving management of remedies in patent cases. Canadian patent drafting and prosecution tips are also highlighted.

Plavix: The "promise of the patent"

Canada's Federal Courts continue to wrestle with the "promise of the patent" doctrine. The "promise," which invokes the language of guarantee and warranty, refers to the patent's utility. In some cases, the Courts have ventured beyond explicit promises made in the patent to dissect the specification and elevate statements of benefit or advantage to become promises of utility. Where those benefits or advantages were neither demonstrated nor soundly predicted, patents were invalidated for want of utility.

In *Sanofi-Aventis v Apotex Inc.*, 2013 FCA 186, the Court of Appeal addressed the validity of the Plavix® patent through the lens of the patent's "promise." Previously, the trial judge in an impeachment action brought by Apotex found the patent invalid on the bases of inutility and obviousness. The trial judge made his finding notwithstanding an earlier decision of the Supreme Court of Canada in 2008, made in the context of a *Patented Medicines (Notice of Compliance) Regulations* proceeding, which endorsed the patent's inventiveness.

At trial, the judge held that the patent promised the claimed compound could be used in humans. He then found that although there was a factual basis and sound line of reasoning for such use, the patent claims were invalid for lack of sound prediction of utility on the basis that the patent included insufficient disclosure to support the prediction.

On appeal, the Federal Court of Appeal disagreed with the trial judge's finding of lack of utility. In particular, the Court of Appeal clarified that the "promise of the patent" doctrine does not apply in all cases. Where there is no explicit promise in a patent description, no promise should be "read in" to a patent. In the case of Plavix, there was no explicit promise of use in humans, but rather a mere identification of certain advantages over the prior art. As such, because those advantages were demonstrated by the patentee, the patent was declared to be useful. In addition, the Court of Appeal overturned the trial judge's finding of obviousness.

The Court of Appeal's decision is not the end of the road for the Plavix patent. Recently, Apotex was granted leave to appeal the Court of Appeal's decision to the Supreme Court of Canada. A hearing is scheduled for November 3, 2014.

Eurocopter: Sound prediction and punitive damages

In *Bell Helicopter Textron Canada v Eurocopter*, 2013 FCA 219, the Court of Appeal addressed the issue of sound prediction in the context of a mechanical invention. In Canada, the requirement for patent utility may be satisfied by evidence of demonstrated utility or a sound prediction of utility. Until *Eurocopter*, the concept of sound prediction had been applied to pharmaceutical and chemical patents. Indeed, Eurocopter argued that the doctrine of sound prediction could only apply to inventions in those fields since, for example, results in those fields are difficult to predict. In contrast, the utility of mechanical inventions can be demonstrated through mathematical calculations and known rules of physics.

Résumés

Christopher Van Barr, Partner and Patent Agent

Christopher Van Barr is a partner in Gowlings' Ottawa office and is former Chair of its firm-wide IP Litigation Group. He specializes in complex patent, PM(NOC), regulatory, and trade-secret litigation. Chris is ranked as a leading IP litigator by the world's foremost organizations. He is, and has been, successful lead trial and appeal counsel on numerous cases in the Federal and Provincial courts in Canada. Chris also advises on patent life cycle management, became a registered patent agent in 2000, and was Adjunct Professor at the University of Ottawa Faculty of Law for eight years.

Grant Tisdall, Partner and Patent Agent

Grant is a patent prosecutor and leader of Gowlings' Patent Group and a Toronto leader of the firm's Technology Group. Grant is registered patent agent with both the Canadian Intellectual Property Office and the United States Patent and Trademark Office. He advises clients on strategic global aspects of intellectual property and assists in the co-ordination of company R&D activities through the building and managing of IP portfolios for first/next generation technologies. He guides technology companies in developing customized innovation programs that best formalize their intellectual assets in alignment with their business direction and is actively involved in drafting and prosecuting of respective patent applications.

The Court of Appeal disagreed with Eurocopter's arguments, holding that sound prediction may be relevant in mechanical or other non-pharmaceutical inventions. The Court of Appeal found that if there is no evidence of demonstrated utility, and merely "calculations to the effect that the embodiment should work in the manner claimed in the patent, or should give rise to the advantages," then utility must be soundly predicted if it is to be useful.

However, the Court of Appeal made the following comment which arguably softens the harshness of the doctrine in the mechanical fields:

> "where the sound prediction is based on knowledge forming part of the common general knowledge and on a line of reasoning which would be apparent to the skilled person (which is often the case in mechanical inventions), the requirements of disclosure may readily be met by simply describing the invention in sufficient detail such that it can be practiced. A contextual approach is thus appropriate in each case."

Novartis: Methods of medical treatment

In *Novartis Pharmaceuticals Canada Inc v Cobalt Pharmaceuticals*, 2014 FCA 17, the Federal Court of Appeal grappled, albeit briefly, with Canadian law on methods of medical treatment. Previously, the Federal Court had dismissed Novartis' application for an order prohibiting Cobalt's generic zoledronate, finding Novartis' patent claims to be invalid as they were directed to a method of medical treatment. The patent claims at issue included intermittent administration of "about" once a year for the treatment of osteoporosis.

The Court stated that in order to fall outside the scope of a method of medical treatment, the frequency of administration must not be in the form of a range. Rather, it must be in "vendible product" form and not in the form of a guideline to physicians. The Court indicated that a claim for proper subject matter should be construed as, for example, "the substance X in the form of a 5mg tablet for the treatment of Y." The use of the word "about" was construed by the Court to require the intervention of a physician.

Every claim of Novartis' patent included directions that zoledronic acid was to be used to treat a bone condition. Some claims specified an exact dosage while others specified a dosage range or no specific dosage at all. However, every claim specified that the substance was to be used for intermittent administration. The Court held that the subject matter of these claims lay within the skill of the medical practitioner, and thus the claims were invalid. The Court found that a patent attempting to monopolize a treatment regimen would interfere with the ability of physicians to exercise their judgment, as physicians prescribing the patented drug in the manner disclosed in the patent would be infringing. The Court of Appeal agreed.

Canadian patent laws and regulatory practices possess certain subtleties that should be accounted for when filing patent applications in Canada. Accordingly, companies seeking Canadian patent protection for their innovations need to be aware of unique aspects of Canadian patent law and Canadian Intellectual Property Office (CIPO) practice that can significantly influence the scope and costs of obtaining patent protection in Canada.

Concerning computer implemented acceptable subject matter, it is important to recognize that most, but not all, technology may be considered patentable in Canada if given careful consideration from a Canadian perspective. The Canadian courts have confirmed that business methods are patentable in Canada, which can provide for increased scope of patent protection in computer-related arts concerning some forms of software and business processes, as long as the patent specification is drafted to reflect the intent of a computer as an essential element of the invention directed to unique business method or software implemented features.

Concerning medical-related acceptable subject matter, claim format and content can make the difference between acceptance or rejection for certain technologies. For example, methods that provide practical therapeutic benefits to subjects may be considered "methods of medical treatment" that are not patentable in Canada. However suitable claims may be drafted to instead claim an allowable "use." Also, higher life forms – such as mice or other mammals, and plants – are not patentable in Canada, however a higher life form can still be patented by directing the claims to a cell comprising a patentable nucleic acid.

Refining remedies in patent cases

***Apotex v Takeda and Abbott*, 2013 ONCA 555 – (no to innovator profits):** In this case, the Ontario Court of Appeal upheld the summary judgment dismissal of Apotex's claim for disgorgement of Takeda's and Abbott's profits in the context of a Section 8 PM(NOC) proceeding. Section 8 provides a generic drug manufacturer with the ability to claim compensation for losses suffered as a result of a delayed market entry caused by a patentee's application to prohibit such generic's market entry. A key finding of the Court of Appeal was that, according to section 8, the recoverable loss may be no more than the generic's damages and does not extend to an innovator's profits. In addition, the Court of Appeal rejected Apotex's allegation of unjust enrichment on the basis that the PM (NOC) Regulations provide a valid juristic reason for an innovator's exclusive presence in the market.

***Bell Helicopter v Eurocopter*, 2013 FCA 219 – (yes to punitive damages in Non-PM (NOC) patent cases):** In addition to the Court's findings on sound prediction, *Eurocopter* is also notable for its ruling on punitive damages. Previously in Canada, punitive damages were not available for so-called wilful infringement. However, the Court of Appeal in *Eurocopter* upheld the order for punitive damages on the basis of Bell Helicopter's "slavish" copying of Eurocopter's patented product, and the fact that Bell Helicopter, as a "sophisticated" company, ought to have known of Eurocopter's patent. The Court of Appeal cautioned that punitive damages are only available in patent cases where "the evidence shows that there has been high-handed, malicious, arbitrary or highly reprehensible conduct that departs to a marked degree from the ordinary standards of decent behaviour." Nevertheless, the only remarkable behaviour in this case was the defendant's copying with imputed knowledge of the patent.

***Teva v Pfizer*, 2014 FCA 138 – (no to punitive damages in PM (NOC) cases):** On May 27, 2014, the Federal Court of Appeal upheld the striking of Teva's claim for punitive and exemplary damages in its action for damages under section 8 of the *Patented Medicines (Notice of Compliance) Regulations*. Teva claimed such damages following Pfizer's failed prohibition proceedings involving the drug sildenafil, marketed by Pfizer as VIAGRA®. The Court noted that punitive damages may be awarded in patent actions generally (see *Eurocopter*, above) but held that the PM (NOC) Regulations specifically preclude claims for punitive and exemplary damages because the regulatory scheme is limited to providing *compensatory* relief. The

Court noted that, by their very nature, punitive damages are not compensatory. The Court also held that section 8(5), which permits the Court to "take into account all matters" in assessing the "amount of compensation," cannot sustain a claim for punitive damages.

***Apotex v Sanofi-Aventis*, 2014 FCA 68/ *Teva v Sanofi-Aventis*, 2014 FCA 67 – (yes to regulations in the "hypothetical world"):** In concurrent cases involving ramipril, the Federal Court of Appeal further defined the scope of section 8 of the PM(NOC) Regulations. Section 8 damages are calculated by considering the generic manufacturer's loss in a hypothetical world where it starts selling without the delay occasioned by the Regulations. The Court of Appeal addressed the unique facts presented and made the following more notable findings:

- Both generic claimants and generic competitors are subject to the Regulations in the hypothetical world, except for the sole purpose of determining the start date of the period of liability.
- As they are subject to the Regulations, generic claimants in the hypothetical world will send Notices of Allegation to address patents listed against the drugs they seek to copy thus largely erasing the notion that innovators will be "taken by surprise" by a generic launch.
- Generic claimants will be subject to a reduction in revenues for "ramp-up" in the hypothetical world.

***AbbVie v Janssen*, 2014 FC 489 – (yes to modified permanent injunctions):** In its decision of May 22, 2014, the Court addressed whether AbbVie was entitled to an injunction notwithstanding the fact its own product did not fall within the scope of the patent claims at issue. In Canada, a permanent injunction will normally follow once the Court finds that a patent is valid and infringed. In the unique circumstances of this case, the Court balanced AbbVie's rights to exclusive use of its claimed invention with the public need to have continued access to the infringing drug which could only be obtained from Janssen. The Court granted a limited form of injunction, which permits physicians to continue prescribing Janssen's infringing product to patients already receiving that drug and to new patients, provided that their own physicians have determined it's necessary for treatment. Janssen was required to pay a royalty to AbbVie for any continuing sales.

Sufficiency of disclosure of the Canadian patent application is an important consideration, as support for the required claim form or content must be found in the patent application description as filed. Therefore, consideration should be given to the way in which the subject matter of the Canadian patent application is described in order to best capitalize on Canadian patent protection for the invention. Important ramifications on actual content of the disclosure are related to promise of the patent and sound prediction principles recently decided upon by Canadian courts. Further consideration and care should be taken to have sufficient support in the disclosure to support claiming of feasible alternative embodiments.

Examination of a Canadian patent application is not automatic upon filing and must be requested by the applicant within up to five years from the Canadian application filing date. During this time, the applicant can take advantage of deferred examination to properly assess the best manner in which the Canadian patent claims should be pursued. For example, examination results obtained from corresponding patent applications in other countries can be influential once starting the Canadian examination process, which can be used to make sure that proper claim content is present in the patent.

Proper claim content in a Canadian patent should be considered as Canada does not use terminal disclaimers between applications owned by the same party. This can influence filing divisional applications in Canada, where it is advisable to include or add all desired claims in a pending patent application to allow the Canadian examiner to determine whether separate inventions are claimed, which can help avoid a later allegation in the courts of "double patenting". The divisional practice in Canada is something that should be considered by applicants when a number of alternative embodiments are desirable.