Remedies & Enforcement – Cynthia Tape - November 20, 2006

Remedies

- successful plaintiff in infringement litigation may be entitled to one or more of the following forms of relief:
 - o permanent injunction;
 - o damages;
 - accounting of profits;
 - delivery-up or destruction;
 - o costs;
 - interest;
- permanent injunction:
 - o an injunction is an equitable remedy;
 - various types of injunctions are available:
 - interlocutory (granted during a proceeding; e.g., an interlocutory injunction prohibiting a defendant from making, using or selling the plaintiff's invention lasting for the duration of a patent infringement action until the trial judgment has been rendered); in patent cases, interlocutory injunctions are very difficulty if not impossible to obtain (discussed below);
 - interim (a short-term injunction put in place between the time the plaintiff seeks an interlocutory injunction and the court's decision whether to grant the interlocutory injunction);
 - permanent (granted by a court to a successful plaintiff/patentee at the end of the trial; permanently enjoins the infringer from making, using or selling the patentee's invention;
 - if harm to the plaintiff (e.g., infringement of patent rights) hasn't occurred yet but appears to be on the verge of happening, the court can grant a "quia timet" injunction; rather than force a plaintiff to wait for harm to occur and then seek damages and an injunction, the quia timet injunction is intended to prevent the harm from happening in the first place; there is law about how imminent the harm has to be for the court to grant this type of injunction (beyond the scope of this course; covered in Remedies);

- permanent *quia timet* injunctions are not common, but one was granted in Dableh v. Ontario Hydro, [1996] F.C.J. No. 767 (C.A.); the Court of Appeal at para. 52 held that Ontario Hydro should be prevented from doing anything with Dableh's invention that was outside of its own business and undertakings; that conduct had not yet given rise to infringement (because the other hydro companies had made only experimental use of Dableh's invention) but the Court was persuaded that Dableh shouldn't have to sit by and wait for his patent to be infringed before he could get an injunction against Ontario Hydro; Court was prepared to grant a *quia timet* injunction to stop Ontario Hydro from continuing to share the invention with other companies (because this would inevitably lead to inducement and infringement down the road);
- damages:
 - successful plaintiff/patentee is entitled to damages under section 55(1) of the Patent Act;
 - damages are intended to place the plaintiff in the position he/she would have been in but for the infringement; damages could include, *e.g.*, lost sales (if the plaintiff/patentee was the seller) or lost royalties (if the plaintiff/patentee had licensed the invention to others to be sold);
 - plaintiff/patentee must prove that damages have been suffered and the amount of the loss;
 - note that section 55(1) expressly deals with damages *after* the patent has issued (section refers to period of time "after grant");
 - what about infringing activities *before* the patent issued? for New Act patents, section 55(2) entitles the plaintiff to "reasonable compensation" for infringing activities by the defendant that were ongoing between the publication of the application and the grant of the patent;
- accounting of profits:
 - an accounting of profits awards to the successful plaintiff/patentee the amount of profits wrongfully earned by the infringer;
 - an accounting of profits is an equitable remedy there is no automatic entitlement; rather, it is within the discretion of the court whether to grant an accounting and the court can take into account the usual factors that are considered before granting any equitable remedy (including the conduct of the party);
 - in *Dableh*, the Court of Appeal noted at paras. 51-52 that the conduct of the party should not deprive him or her of an equitable

remedy unless that conduct bears directly on the appropriateness of the remedy; trial judge had found that Dableh's attitude during the development of his patent was objectionable; Court of Appeal disagreed and found that Dableh's pre-patent conduct was irrelevant;

- an accounting of profits was not granted, however, because there was no infringement (that Ontario Hydro was a licensee, and thus not an infringer, and that the other hydro companies were engaged in experimental use of the invention, and therefore also not infringers);
- if court permits the plaintiff/patentee to have an accounting of profits, the plaintiff/patentee must *make an election* between an accounting and damages; the plaintiff cannot have both (obtaining both would result in the plaintiff being overcompensated); the successful plaintiff/patentee can be compensated for his/her own losses, or can be awarded the profits that the infringer made;
- the profits earned by the defendant must be "causally connected" to the infringement; thus, if the infringing article is only one part of the defendant's product, plaintiff may obtain a percentage of the profits earned by the defendant from sales of the product rather than 100% of the profit;
- it may be advantageous for the patentee to seek an accounting rather than damages; plaintiff would not have to prove his/her own loss (and thus could prevent the defendant from scrutinizing the plaintiff's financial information on discovery), only the revenue earned by the infringer would be relevant; on an accounting, the infringer must prove what expenses are to be deducted from revenue (to arrive at the wrongfully earned profit); any doubts are resolved in favour of the plaintiff/patentee;
- in Schmeiser v. Monsanto, Monsanto elected an accounting of profits (presumably because its damages would have been limited to the loss of several years worth of Round-Up Ready canola seed sales to Schmeiser, which Monsanto must have thought would be much less than the profits earned by Schmeiser from his canola crop);
- turned out that Monsanto got nothing on the accounting: because Schmeiser didn't spray the canola with Round-Up, the profit he earned from selling the Round-Up Ready canola was exactly what it would have been had he planted regular (non-Monsanto) canola; as there were no profits causally connected to Schmeiser's infringement, Monsanto was entitled to nothing on the accounting;
- delivery-up or destruction:

- defendant can be ordered to destroy or deliver-up to the plaintiff/patentee all infringing goods (except those subject to section 56);
- if the goods can be modified so as to be non-infringing, court might not order delivery-up/destruction;
- if the goods may be used in an infringing manner but could also be used for some other purpose, court might not order delivery-up/destruction;
- interest and costs:
 - usually awarded to the successful party; costs are in the discretion of the court; successful party who obtains monetary relief also usually gets preand post-judgment interest;

Modifying a patent after grant

- three ways to modify a patent after grant: if there is a clerical error in the patent (we didn't discuss this in class and you are not responsible for it); dedication; reissue;
- dedication:
 - a patentee may wish to dispose of a patent or certain claims in a patent; if the patentee does not want to or cannot assign the entirely of her/his patent rights in the patent, and does not want to wait for the patent to expire, it is possible to "dedicate" some or all claims to the public; "dedicating" a patent to the public means that the patentee is essentially waiving all rights to the patent or to some claims in the patent; the effect is as if the patent had expired on the date of dedication;
 - a patentee may wish to dedicate a patent to the public in order to avoid, for instance, the jurisdiction of the Patented Medicine Prices Review Board (PMPRB);
 - PMPRB is a Federal board that controls the prices charged by drug companies for patented medicines (no jurisdiction over generic drugs); the PMPRB sets that maximum allowable price that the *patentee* can charge (the "factory gate" price, not the retail price); the PMPRB uses the selling price in various other countries as a benchmark for determining the maximum allowable price in Canada; it also categorizes the drug as a breakthrough, or "me too" type of drug; a company will be permitted to charge more for a breakthrough drug for pricing purposes;
 - having a patent for a medicine triggers the jurisdiction of the PMPRB, which may result in the company having to pay money (if

anyone is interested in the details, let me know); so, if the product or process of the patent is not being used by the company or it the patent is otherwise not important, the company may want to get rid of the patent to oust the PMPRB's jurisdiction;

- there is no provision in the *Patent Act* for "dedication" or for surrendering claims or entire patents that the patentee no longer wants;
- although the courts have taken a rather strict approach to the jurisdiction of the Commissioner of Patent (e.g., holding that the lack of any provision in the Patent Act allowing for late payment or "top up" of maintenance fees means that the Commissioner has no jurisdiction to do it even though the Commissioner had been doing it for years), the ability of a patentee to dedicate a patent to the public, and the ability of the Commissioner to accept the dedication, have been recognized;
- in *G.D. Searle & Co. v. Merck & Co.* (2002), 20 C.P.R. (4th) 103 (FCTD), there was a dispute between the parties about the effect of Searle having dedicated certain claims in its patent to the public; Searle alleged that Merck, by selling its VIOXX product, had infringed claims of Searle's patent, including claim 42; Searle had previously dedicated several claims in the patent but not claim 42; Merck moved for summary judgment on the basis that Searle dedicated certain similar claims to the public, and argued that claim 42 should be deemed to have been dedicated as well, thus entitling Merck to use the invention set out in claim 42; Searle argued that certain claims were dedicated and other were not; claim 42 was not dedicated, Merck had infringed that claim and so there was not basis to grant summary judgment to Merck; Court agreed with Searle;
- Court held that: "dedication of certain claims to the public terminates a patentee's rights to a monopoly on the subject matter described in those claims. Such dedication ... does not affect the rights conferred by the remaining claims in the patent. Upon the dedication of the claims, the patent is to be read as if those claims had never issued, subject to any claim for past infringement. Accordingly, the public is entitled to use or manufacture the subject matter in the Dedicated Claims." (at para. 96)
- re-issue:
 - if the patentee determines that certain claims in his/her patent are problematic, s/he can apply *within four years of the original issue date* to have the patent re-issued with amended claims or new claims;
 - the amended and/or new claims must be supported by the disclosure (as per the usual rule);
 - o re-issue is dealt with in section 47 of the Patent Act;

 in Urea Casale S.A. v. Stamicarbon B.V., [2002] 3 F.C. 347 (CA), the plaintiff and the defendant were engaged in litigation about the plaintiff's patent; the defendant attacked the validity of the patent on the basis of a certain piece of prior art; the patentee, during the litigation, applied to have the patent re-issued (to amend the claims so that the prior art could be avoided); the patent was re-issued before the litigation had concluded; case is an example of how re-issue can be used by a patentee to solve unfortunate claims drafting even after the patent has issued;

Enforcement

- litigation process:
 - an action for infringement is brought by the patentee or a person claiming under the patents (recall that per section 55(1), the only entities entitled to damages for infringement are the patentee and persons claiming under the patentee);
 - o Patent Act requires that the patentee be made a party to the proceeding;
 - defendant typically argues non-infringement and counterclaims for a declaration of invalidity of some or all claims of the patent (at least the claims that the defendant may be found by the court to infringe);
 - each side puts forward expert evidence about the interpretation of the claims in issue; the state of the art; etc.; there may be evidence from the patentee about pre-filing experimental data regarding the invention, date of invention (if under the Old Act) or other factual matters;
 - patent litigation is usually not speedy (may typically expect to take several years to get to trial);
 - summary of IP trial procedure will be circulated for your interest only (you are not responsible for it);
 - the law in Canada has developed such that the plaintiff/patentee will very likely not be granted an interlocutory injunction during the pendency of the trial; the reason for this is due to the test for obtaining an interlocutory injunction;
 - test comes from an English case, American Cyanamid v. Ethicon: to obtain an interlocutory injunction, the moving party needs to show that (i) there is a genuine issue to be tried; (ii) irreparable harm will be suffered if the injunction is not granted; and (iii) the balance of convenience favours the granting of the injunction (*i.e.*, the harm suffered by the moving party if the injunction *is not*

granted will be worse than the harm suffered by the defendant if the injunction *is* granted);

- *"irreparable harm*" means harm that cannot be compensated by a monetary award; in patent cases, the court takes the view that there is no irreparable harm because the patentee's lost sales can be compensated by an award of damages if the patentee wins the trial;
- but note: in the pharma patent context, the patentee can expect to experience a dramatic loss in market share while the defendant remains on the market; by the time the trial is completed, which could be many years down the road, it may be very difficult for the patentee to regain that market share, particularly if the patent is getting close to expiry;
- PM(NOC) Regulations:
 - o a special litigation regime just for patented medicines;
 - **the Regulations appearing at page 367 of the text are the Regulations as they existed up until a few weeks ago; the Regulations have been amended**;
 - the Regulations attempt to balance two competing interests: protecting patent rights versus making cheaper generic drugs available to Canadians; on the one hand, the patentee who holds a patent for a medicine is entitled to have those patent rights respected in the same way as any other patent; on the other hand, drugs are expensive and there is a governmental interest in reducing those costs; where the patent is weak and would likely fall in patent infringement litigation, it may be appropriate not to wait until that patent expires and instead allow the cheaper generic product onto market prior to the expiry date;
 - the idea behind the PM(NOC) Regulations is to create a system for determining in which circumstances a generic should be allowed onto the market early (where the generic can establish a *prima facie* case of noninfringement or where the patent looks like it may be invalid) and when the generic should be made to wait (generic product may well infringe and patent looks strong);
 - the generic drug company will be permitted to come onto the market before a patent for the drug has expired if the generic company's allegations of non-infringement and/or validity are found by a court to be "justified";

- the determination whether a generic company's allegations are justified is made in the context of an application brought by the patentee in Federal Court; the patentee seeks an order prohibiting the Minister of Health from issuing a "notice of compliance" (authorization from Health Canada to sell the drug to Canadians) for the generic product until the patent in question has expired; the patentee's basis for the order is that the generic's allegations of non-infringement and invalidity are not justified;
- once the application has been commenced by the patentee, an automatic 24-month stay kicks in; the stay prevents the Minister of Health from granting an NOC to the generic during this time; the stay expires at the earlier of the end of 24 months or when the application is disposed of;
- the court, on the application, determines only whether the allegations are or are not justified; the court does not determine substantively whether the generic does or does not infringe, or whether the patent is or is not valid; as a result, the patentee, if it loses the application and generic is permitted to come onto the market, can immediately proceed to sue the generic for infringement in ordinary patent infringement litigation; however, the patentee will not be able to obtain an injunction pending the outcome of the trial;
- a brief discussion of the regulations is set out in the report at http://www.parl.gc.ca/information/library/PRBpubs/prb0614-e.pdf
- licensing:
 - non-litigious way of resolving a dispute between a patentee and someone who wants to participate in the market for the patented product;
 - patentee and the other party may be able to work out a deal whereby the other party pays a royalty for using the patented invention; the stronger the defendant believes the patent to be, the higher the licensing fee is likely to be; the weaker or more worried the patentee is, the lower the fee; in some cases, there might be no monetary payment at all;
 - note that the other party doesn't actually start making the patentee's product the other party just keeps on making the product that s/he was making or planning to make before licensing deal was concluded; the license simply protects the other party from any allegation of infringement (remember that being a licensee is a defence as in *Dableh* unless the licensee starts doing things that are outside the scope of the license);
 - a paper on licensing is attached for your interest only (you are not responsible for it);