

## IP monitor

### No harm, no foul: Establish irreparable harm clearly when seeking interlocutory injunctions

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Intellectual property

Federal Court denies interlocutory injunction for moving party's failure to provide sufficiently clear evidence that it would suffer irreparable harm if the injunction was not issued.

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A recent case before the Federal Court, *The Regents of the University of California et al v I-Med Pharma Inc*<sup>1</sup>, reaffirmed that in order to establish irreparable harm when seeking an interlocutory injunction in the context of an action for patent infringement, sufficiently clear evidence demonstrating irreparable harm was necessary. In denying the motion for interlocutory injunction, Justice Manson made several interesting observations about the arguments presented by the moving party. Justice Manson also ordered the Plaintiffs to post security for costs.

The Plaintiff and moving party, TearLab Corporation (**TearLab**), is an exclusive licensee of Canadian Patent No. 2,494,540 (the '**540 Patent**'), which is owned by the other Plaintiff in this case, the Regents of the University of California (**University**). The '540 Patent generally relates to diagnostic devices, systems, and methods for measuring the osmolarity of tears, said to be useful for diagnosing and treating dry eye disease.

TearLab sought an interlocutory injunction to prevent the Defendant, I-MED Pharma Inc (**I-MED**), from selling its ophthalmic medical device pending determination at trial on the issues of patent infringement and validity.

I-MED sought security for costs for defending the present interlocutory motion and the patent infringement action as neither TearLab nor the University are ordinarily resident in Canada.

#### Interlocutory injunction

The three-part test for an interlocutory injunction as outlined by the Supreme Court of Canada<sup>2</sup> requires that TearLab establish:

1. a serious issue to be tried;
2. that it will suffer irreparable harm if the injunction is not granted; and
3. that the balance of convenience favours the granting of an injunction.

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<sup>1</sup> 2016 FC 606.

<sup>2</sup> *RJR-MacDonald Inc v Canada (Attorney General)*, [1994] 1 SCR 311 at 347-349.

The Federal Court did not grant TearLab an interlocutory injunction. Justice Manson held that TearLab did not provide sufficiently clear evidence that it would suffer unquantifiable and irreparable harm if the injunction was not issued. TearLab presented four arguments, but was unsuccessful on all four fronts.

### ***Harm to TearLab's goodwill and reputation***

TearLab argued that I-MED's product might be inferior to TearLab's product, thereby causing irreparable harm by turning ophthalmologists off of TearLab's technology. Justice Manson ruled that the evidence in support of this argument was speculative and unclear, especially since I-MED's device was approved by Health Canada.

### ***Loss of market opportunity***

TearLab also argued that without an interlocutory injunction, it would suffer permanent loss of market share, loss of opportunity to increase its market share, and permanent damage to its goodwill and reputation. Again, Justice Manson held that this argument was unsubstantiated as TearLab's evidence was speculative. Justice Manson noted that TearLab relied heavily on *American Cyanamid v Ethicon Ltd*<sup>3</sup>, a 1975 House of Lords decision. While Justice Manson acknowledged that this decision was relevant, it did not trump more recent and relevant decisions of Canadian Courts.

### ***Inability to quantify damages***

TearLab argued that irreparable harm ensued from the impossibility of calculating lost sales, as there was no reasonable methodology available to quantify the Defendant's activities. I-MED's expert testified that either (i) an epidemiological model or (ii) a quantitative statistical model could be used to estimate damages.

TearLab's expert argued that the epidemiological model was not viable as additional data, research, and analysis were required to predict damages using the model. Justice Manson held that the non-viability of the epidemiological model was immaterial, as it could be used to calculate reasonable damages if no injunction were granted following trial.

TearLab's expert also criticized the statistical model proposed by I-MED's expert on the basis that future prediction based on TearLab's historical sales data was impossible. TearLab's expert argued that incomplete data, market complexities, and interrelated variables rendered the predicted damages by the statistical model inadequate. Justice Manson found that the evidence submitted by TearLab's expert was insufficient to constitute "clear and not speculative" evidence that actual unquantifiable harm would occur. Furthermore, Justice Manson held that after trial, there were ways of quantifying actual losses in monetary terms even if no injunction were granted. The incomplete information before I-MED's expert at this time would no longer be hypothetical after trial. Data from any intervening and unexpected future events could be incorporated into the statistical model to adjust the projection of losses. Justice Manson stated that "[t]heoretical complexity in calculation is not alone clear evidence that damages are not capable of reasonable quantification".<sup>4</sup>

Moreover, in rejecting TearLab's claim that its losses were unquantifiable, Justice Manson accepted I-MED's argument that TearLab's position was inconsistent. TearLab argued that, because of the unique nature of the market, its losses could not be quantified if an injunction were refused and it prevailed at trial. Yet, TearLab offered an undertaking to compensate I-MED for I-MED's losses if an injunction were granted and TearLab lost at trial. If I-MED's damages could be quantified if an interlocutory injunction were granted and I-MED prevailed at trial, he saw no reason why TearLab's damages could not be quantified in the opposite scenario.

### ***Ability to pay damages was not properly before the Court***

TearLab attempted to argue that I-MED would be unable to pay a monetary award after trial, notwithstanding that it neither alleged, nor led evidence on, this issue. TearLab served a direction to attend on an affiant from the Defendant, requiring him to bring voluminous financial information to his cross-examination. No such documents were produced. Justice Manson refused to draw an adverse inference as the issue was not pleaded in the motion or addressed in the evidence.

<sup>3</sup> [1975] RPC 13 at 542.

<sup>4</sup> *The Regents of the University of California et al v I-Med Pharma Inc*, 2016 FC 606 at para 70.

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## Security for costs

I-MED brought a motion for security for costs. Justice Manson followed a trend that requires substantial security to be posted in stages and ordered TearLab (which has virtually no assets in Canada) to post \$100,000 through the discovery process with I-MED entitled to seek additional security later in the proceedings.

This decision by the Federal Court reaffirms that it is generally difficult for a moving party seeking an interlocutory injunction to sufficiently and clearly establish that it will experience irreparable harm if the injunction is not granted.

TearLab has appealed the decision.

### Link to decision:

[2016 FC 606](#)

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