Federal Court Cour fédérale

Date: 20160531

Docket: T-300-16

Citation: 2016 FC 606

Ottawa, Ontario, May 31, 2016

PRESENT: The Honourable Mr. Justice Manson

BETWEEN:

THE REGENTS OF THE UNIVERSITY OF CALIFORNIA AND TEARLAB CORPORATION

Plaintiffs

and

I-MED PHARMA INC.

Defendant

ORDER AND REASONS

[1] The Plaintiff, TearLab Corporation [TearLab], seeks an interlocutory injunction to prevent the Defendant, I-MED Pharma Inc. [I-MED], from selling its i-Pen osmolarity measuring device and i-Pen microchip Single Use Sensors [collectively, the i-Pen System] pending determination at trial on the issues of patent infringement and validity.

[2] I-MED also seeks security for costs in defending against both the action and the interlocutory injunction, as neither of the Plaintiffs is ordinarily resident in Canada.

I. Background

[3] The undisputed facts were set out by Justice James Russell in his decision in the previous interim injunction motion brought in this case (*University of California v I-MED Pharma Inc*, 2016 FC 350).

[4] The Plaintiff, the Regents of the University of California [the University], owns Canadian Patent No. 2,494,540 [the ‘540 Patent], entitled “Tear Film Osmometry”. The Canadian patent application for the ‘540 Patent was filed on March 25, 2003, and issued on June 3, 2014. It grants the University the exclusive right to make, use, import, and sell, in Canada, the invention claimed in the ‘540 Patent until its expiry on March 25, 2023.

[5] The Plaintiff and moving party on this motion, TearLab, is a public company with shares listed on the Toronto Stock Exchange. TearLab is the exclusive licensee under the ‘540 Patent in Canada. The University consents to the relief sought by TearLab, but is not a moving party.

[6] The ‘540 Patent generally relates to diagnostic devices, systems and methods for measuring the osmolarity of sample fluids, including tear fluid. These measurements of tear fluid are useful for diagnosing and treating dry eye disease [DED], a condition affecting up to 30% of the Canadian population.

[7] TearLab markets the TearLab Osmolarity System [the TearLab System] to Canadian eye-care clinicians, such as optometrists and ophthalmologists, as well as certain Canadian eye-care research organizations.

[8] The TearLab System includes a pen, configured for receiving a test card microchip, and a reader. To perform a test, a clinician inserts a test card microchip into the pen and places the end of the chip along the lower conjunctiva of a patient's eye to collect a sample of the patient's tear film. The pen and chip are then docked into the reader which displays the osmolarity of the tear sample to the clinician by passing an electric current through the tear sample (known as electrical impedance).

[9] TearLab rents or loans the TearLab System to users, who must commit to purchasing a minimum number of test card microchips from TearLab per quarter or year. Users may cancel their contract with TearLab at the end of yearly anniversaries, and thus can return the TearLab System fairly promptly if a competing and lower-priced device entered the market.

[10] TearLab has spent time and substantial economic resources testing the TearLab System in a number of clinical trials to establish its safety, reliability and efficaciousness for regulatory approval.

[11] In December 2009, Health Canada approved the TearLab System for sale in Canada as a Class III Medical Device.

[12] Following approval for the Canadian market, TearLab's initial challenge was convincing eye-care clinicians that hyperosmolarity is a reliable and quantitative indicator of DED. This concept was not well known amongst Canadian clinicians, who were reluctant to accept that measuring osmolarity is an effective diagnostic method for DED.

[13] TearLab conducted numerous further clinical trials and published the results in peer reviewed journals in order to demonstrate that patient symptoms and the pathology of DED were linked to hyperosmolarity. Nonetheless, a significant proportion of Canadian eye-care clinicians have not yet adopted the technology, which TearLab views as a future market opportunity.

[14] In mid-January 2016, TearLab discovered that I-MED, a Montreal-based company that focuses on human and veterinary eye care, was offering for sale a tear osmolarity measuring device called the "i-Pen System", which I-MED initially told Canadian eye-care clinicians would be available in March 2016.

[15] The i-Pen System is a tear-fluid collection and testing device for measuring tear osmolarity in patients using impedance measurements of a tear film sample. The User Manual describes that the i-Pen System consists of a "Single Use Sensor" which is inserted into a hand-held reader unit that displays the osmolarity test result.

[16] I-MED offers for sale the i-Pen System's Single Use Sensors at a substantially lower price than the corresponding chips of the TearLab System. As well, I-MED's customers are not obligated to purchase a minimum number of the Single Use Sensors.

[17] On February 8, 2016, TearLab commenced the present patent infringement proceeding, alleging the i-Pen System, its Single Use Sensor, and the indicated methods of use, each fall within the scope of at least one of claims 1, 2, 5, 6, 8, 13, 14, 16, 25 and 26 of the ‘540 Patent.

[18] On March 1, 2016, TearLab filed this motion for an interlocutory injunction, and on March 18, 2016, TearLab filed a motion for an interim injunction, seeking to enjoin I-MED from launching the i-Pen System in Canada before the hearing of the interlocutory injunction.

[19] I-MED filed its Statement of Defence and Counterclaim dated April 28, 2016, alleging non-infringement (including the Gillette Defence) and invalidity of the ‘540 Patent claims, on the basis of anticipation, obviousness, insufficient disclosure, claim ambiguity, failure to disclose best mode, and claims broader than any invention made or disclosed (in patent jargon, the “litany” of validity attacks).

[20] On March 24, 2016, Justice Russell dismissed TearLab’s motion for an interim injunction (2016 FC 350). He found that TearLab did not establish irreparable harm, particularly on issues of quantification, or that the balance of convenience favoured granting an injunction. Specifically, Justice Russell determined that TearLab’s experts were not qualified to convince the Court that the harm TearLab alleges could not be compensated by way of damages and he gave little or no weight to evidence provided by Mr. Tierney, Dr. Jackson and Mr. Berg. He found:

a) Mr. Tierney, a retired Business Director of Allergen Eye Care with experience in the Canadian Eye Care market, did not establish he was qualified to render an expert opinion

on market forecasting and quantifiable damages, nor did he provide a factual basis for several of his assertions;

b) Dr. Jackson, a practicing ophthalmologist, provided opinions that are speculative and unrelated to quantification issues; and

c) Mr. Berg, TearLab's Vice President of Regulatory, and Mr. Smith, Vice President of International Markets for TearLab, provided no relevant evidence on quantification issues and irreparable harm.

[21] Justice Russell found that I-MED provided direct evidence on the issue of irreparable harm through its witness, Dr. Rosenblatt, an expert in marketing and forecasting in the pharmaceutical and health industry, who was qualified and whose evidence explained why TearLab's feared damages are quantifiable.

[22] At the time of the interim injunction, Justice Russell acknowledged that none of the experts had been cross-examined on their affidavits.

[23] Despite TearLab's requests, I-MED has refused to disclose the launch date of the i-Pen System, and has also refused to provide a minimum number of days of advanced notice pre-launch. The i-Pen System was approved in Canada as a Class II Medical Device in January 2015, the license was suspended on September 23, 2015, and was reinstated on May 13, 2016. In contrast, the TearLab system is categorized as a Class III Medical Device, which requires more stringent qualifications for approval.

[24] TearLab's affidavits filed for the interim injunction from Dr. Sullivan, Mr. Smith, Mr. Berg, Dr. Jackson and Mr. Tierney are deemed to have been filed in this motion. TearLab was also granted leave to file reply evidence of Dr. Hollis and Mr. Smith for this motion.

[25] I-MED responded with the affidavits of Mr. Hofmann, Vice-President of I-MED, and Dr. Rosenblatt, and sur-reply evidence consisting of the affidavit of Denise Pope (a paralegal at Norton Rose) and a second affidavit of Dr. Rosenblatt, sworn April 27, 2016.

II. Issues

A. Whether an interlocutory injunction should be granted to prevent I-MED from distributing and selling the i-Pen System in Canada.

B. Whether the Defendant is entitled to additional security for costs, and if so, how much.

III. Analysis

A. *Interlocutory Injunctions*

[26] The conjunctive three-part test for an interim or interlocutory injunction settled by the Supreme Court of Canada in *RJR - MacDonald Inc v Canada (Attorney General)*, [1994] 1 SCR 311 [*RJR MacDonald*], requires that TearLab establish:

i. a serious issue to be tried;

ii. that they will suffer irreparable harm if the injunction is not granted; and

iii. that the balance of convenience favours the granting of an injunction.

[27] These factors are interrelated and should not be assessed in isolation (*Movel Restaurants Ltd v EAT at Le Marché Inc*, [1994] FCJ No 1950 (Fed TD) at para 9, citing *Turbo Resources Ltd v Petro Canada Inc* (1989), 24 CPR (3d) 1 (FCA) [*Turbo Resources*]).

(1) Serious Issue

[28] The threshold for determining whether there is a serious issue to be tried is low. I agree with TearLab that there is a serious issue to be tried, notwithstanding I-MED's argument there is no serious issue because TearLab only speculated about patent infringement after consulting a draft User's Manual for the i-Pen System.

[29] I-MED's Defence and Counterclaim challenges the validity of the '540 Patent and alleges that the i-Pen System does not infringe any claims of the '540 Patent. However, there is an initial presumption that the '540 Patent is valid, and based on the facts before me there is at least an arguable case and a serious issue that I-MED's i-Pen System, and the specified methods of use, may fall within the scope of one or more of claims 1, 2, 5, 6, 8, 13, 14, 16, 25 and 26 of the '540 Patent.

[30] TearLab has also raised the issue of whether I-MED also entered the Canadian market illegally during the period of September 2015 to April 2016, when their approval from Health Canada was suspended, but I do not find this issue to be of much weight in deciding any of the *RJR-MacDonald* tripartite test.

(2) Irreparable Harm

[31] Though the test is conjunctive and necessitates the weighing of all factors, the pivotal issue before the Court on this motion is whether TearLab has established it will suffer irreparable harm should the injunction not be granted.

[32] In *RJR MacDonald*, above, the Supreme Court defined "irreparable" as referring to "the nature of the harm suffered rather than its magnitude. It is harm which either cannot be quantified in monetary terms or which cannot be cured, usually because one party cannot collect damages from the other" (at para 64). The threshold of establishing irreparable harm is very high: harm is not irreparable solely because precisely calculating damages would be difficult, or because it cannot be exactly quantified, provided there is some reasonably accurate way of measuring those damages (*Merck Frosst Canada Inc v Canada (Minister of Health)* (1997), 74 CPR (3d) 460 at 464 (Fed TD); *Merck & Co v Apotex Inc*, [1993] FCJ No 1095 at para 42).

[33] The plaintiff is required to adduce clear and non-speculative evidence that irreparable harm will follow if the injunction is not granted (*Aventis Pharma SA v Novopharm Ltd*, 2005 FC 815, at paras 59-61 [*Aventis Pharma*] aff'd 2005 FCA 390).

[34] In a *quia timet* application, in which the infringing party is not yet in the marketplace, an applicant may establish irreparable harm by presenting logical inferences from the evidence submitted, as there is usually no evidence of actual harm (*Sports Authority Inc v Vineberg* (1995), 61 CPR (3d) 155 at para 4 (Fed TD)). While the application before me is not strictly a

quia timet proceeding, given there is evidence of I-MED making use of its i-Pen System in Canada, I do accept that the alleged infringing use is, to date, minimal, and that TearLab's primary concern is I-MED's threat to expand such use in the near future as being the substantial threat of irreparable harm.

[35] TearLab alleges it will suffer the following irreparable harm:

i. Harm to TearLab's goodwill and reputation that is impossible to determine;

ii. An unquantifiable and permanent loss of market opportunity;

iii. An inability to quantify damages; and

iv. I-MED's inability to pay a monetary award after trial.

[36] The potential irreparable harm stemming from an inability to quantify damages is the most compelling of TearLab's arguments, and for which they have provided the most substantive and supported evidence.

(a) *Harm to Goodwill and Reputation*

[37] TearLab argues the Court should disregard Dr. Rosenblatt's evidence that TearLab's reputation would not be damaged, given his lack of expertise in the Canadian ophthalmic market. It is evident that Dr. Rosenblatt has more limited experience in the Canadian opthalamic market than TearLab's affiants, and I agree his evidence on the issue of reputation is of little value. However, in the context of this motion, I find he is qualified to express an opinion on whether the market losses of the kind raised by TearLab can be quantified.

[38] Moreover, it is TearLab who bears the onus to provide the Court with clear evidence of irreparable harm to their goodwill and reputation. Though Dr. Jackson and Mr. Tierney are highly knowledgeable in the ophthalmology market, their evidence on the issue of damage to reputation and loss of market share, despite not having been cross-examined upon, remains speculative.

[39] Dr. Jackson's opinion that "eye-care clinicians who purchase the i-Pen System would be upset at TearLab for obtaining an injunction preventing I-MED from selling the microchips" if the i-Pen is taken off the market following trial is speculative. As is Mr. Tierney's evidence, which echoes that "doctors will likely blame TearLab" when they cannot use the i-Pen System they paid for.

[40] I agree with Justice Russell that neither of TearLab's experts provides support for their assertions on the issue of reputational damage, and I am not persuaded that there is any clear, non-speculative evidence that eye care clinicians will think less of TearLab should the injunction not issue. TearLab has not established a basis for clear irreparable harm to goodwill and reputation.

(b) *Permanent Loss of Market Share*

[41] TearLab also relies on the evidence of Dr. Jackson and Mr. Tierney in support of its assertion that the launching of the i-Pen System and its subsequent removal from the marketplace will cause irreparable harm. The evidence alleges that "TearLab will suffer a permanent loss of customers and will not be able to re-establish its current pricing" (Mr. Tierney), as it is

impossible to discern how many clinicians will "refuse to pay an increased post-injunction cost of the chip and how many will, as a direct result, abandon osmolarity testing", or for those who have not used it, may refuse to ever use TearLab's System (Dr. Jackson).

[42] TearLab also analogises the present case to the House of Lords decision in *American Cyanamid v Ethicon Ltd*, [1975] RPC 13 at 542 [*American Cyanamid*], and states that damages would not provide adequate compensation as:

i. TearLab is the exclusive licensee under the '540 Patent and ought to be able to increase its market share;

ii. the i-Pen System is not yet legally present on the market, and while TearLab is establishing a new market for osmolarity testing, many eye-care clinicians have not yet adopted the technology, which represents an unquantifiable market opportunity that will be lost; and

iii. if Canadian eye-care clinicians purchase the i-Pen System, it may be commercially impractical to deprive the public of I-MED's product by insisting on a permanent injunction after trial, as this may have a damaging effect on TearLab in such a specialized market.

[43] In contrast, I-MED argues that the Federal Courts have consistently held that the type of harm TearLab alleges it will suffer is not irreparable (*Aventis Pharma*, above, at paras 33, 34, 36, 38, 40-45; *Merck Frost Canada Inc v Canada (Minister of Health)*, (1997), 74 CPR (3d) 460 at 462 (Fed TD)).

[44] In *Aventis Pharma*, above, the plaintiff claimed it would suffer the same types of irreparable harm as alleged here should an injunction not issue, including permanent loss of market share and loss of opportunity for increasing market share; permanent price reduction; and permanent damage to goodwill and reputation due to the sale of a less efficacious product. On similar evidence to the present case, the Court found insufficient clear evidence that irreparable harm would occur if the injunction were not issued.

[45] While *American Cyanamid*, above, is certainly relevant for the principles underlying interlocutory injunctions, I agree with the Defendant that analogising to a somewhat dated decision of the House of Lords does not trump more recent and relevant decisions of Canadian Courts that have qualified and expanded upon those principles in the Canadian context.

[46] As in *Aventis Pharma*, above, TearLab's arguments of the potential for loss of market share and permanent price reduction of their product are unsubstantiated, unrelated to any issues of whether such alleged damage could be quantified, and are ultimately speculative.

(c) *Inability to quantify damages*

[47] TearLab also submits irreparable harm ensues from the impossibility of calculating lost sales, as there is no reasonable methodology available to quantify the loss arising from I-MED's activities (*Reckitt Benckiser LLC v Jamieson Laboratories Ltd*, 2015 FC 215, aff'd 2015 FCA 104). TearLab claims this is supported by Mr. Tierney's evidence, Dr. Hollis' opinion, Dr. Rosenblatt's incorrect prediction, and the fact that TearLab itself could not properly forecast sales in the Canadian market. Each are dealt with in turn below.

(i) Mr. Tierney's Evidence

[48] Mr. Tierney's evidence was that given the growing market, TearLab's overall losses will be unquantifiable and there is no model to determine what impact I-MED's presence on the Canadian market will have on TearLab. I agree with Justice Russell that Mr. Tierney, although having experience in the Canadian eye-care market, has no expertise in market forecasting or damages assessment, and thus his opinion that losses are unquantifiable is of limited value to the Court.

(ii) Dr. Hollis' Reply Evidence to Dr. Rosenblatt

[49] Defence expert Dr. Rosenblatt's first affidavit proposes that either of two models could be used to estimate damages: (i) an epidemiological model based on the number of patients suffering from DED; or (ii) a quantitative statistical model that forecasts TearLab's "but-for" sales for the period 2016-2018 using monthly sales data from 2012-2016, from which any negative deviation would be attributed to I-MED.

[50] Dr. Hollis' takes issue with Dr. Rosenblatt's epidemiological model, as it requires an accurate estimate of the incidence of DED, which is not currently available. Dr. Rosenblatt's report indicated the incidence of DED in Canada to be between 8% and 29%, yet TearLab has only penetrated a fraction of the affected population to date. Given this range, any estimate of damage quantification would be wholly uninformative. Moreover, Dr. Rosenblatt's testimony on cross-examination demonstrated the multiple layers of analysis and additional research required to predict damages based on epidemiology.

[51] Though TearLab's position on this issue is persuasive, on the evidence in this motion, the non-viability of using Dr. Rosenblatt's epidemiological model for calculating reasonable damages is immaterial. Dr. Rosenblatt testified he was not asked to, and did not, prepare this model, but would be able to after trial, if necessary.

[52] Dr. Hollis' affidavit considers four scenarios depending upon whether the i-Pen System will be perceived as equally effective as the TearLab System and whether the pricing of the systems is the same or different. In my view, only one of the scenarios presented is applicable to the present case.

[53] The hypothetical scenarios wherein the i-Pen System is either clinically superior or inferior than the TearLab System are of little worth to the Court in this motion. Firstly, Dr. Hollis' evidence in these scenarios - that for instance, I-MED's inferior device may result in clinicians' rejection of osmolarity testing as a useful clinical tool altogether - is based on assumption and speculation, rather than fact or experience. Indeed, Dr. Hollis admitted on cross-examination he has no basis to offer an opinion on clinicians' perceptions or experiences.

[54] As well, Dr. Hollis himself opined it is unlikely that sufficient information will be collected to enable a clinical comparison between the I-MED and TearLab Systems by the end of trial. I find the fact that Health Canada has approved the i-Pen System makes any alleged harm based on allegations of reduced efficacy and safety highly speculative (*Aventis Pharma*, above, at para 99).

[55] Dr. Hollis' scenario where the two systems are perceived as equal, yet the I-MED system is cheaper - the situation at hand - is pertinent to the issue of whether damages could be reasonably quantified in this case following trial. This is also the situation to which Dr. Rosenblatt's forecast modelling evidence speaks.

[56] Dr. Hollis criticizes Dr. Rosenblatt's quantitative statistical model on the basis that future prediction based on historic sales data of the TearLab System is impossible.

[57] Not only have TearLab's sales been unstable, but Dr. Hollis asserts that the cheaper cost of the i-Pen System may generate higher sales, which would render inaccurate any prediction of TearLab's damages based on I-MED's sales.

[58] As well, Dr. Hollis claims the volatility of TearLab's data challenges the underlying assumption in Dr. Rosenblatt's model that TearLab's historical sales trends will continue unchanged into the next two years. There is substantial variation by month in the take-up of readers of the TearLab System, which in-turn drives card-sales. Moreover, Dr. Rosenblatt's model has not accounted for the alleged effect I-MED's marketing has already had on sales data, and recent changes to TearLab's marketing strategy in Canada means it is impossible to trend historical data forward to predict damages with any level of certainty.

[59] To challenge Dr. Rosenblatt's model, Dr. Hollis graphically generated a prediction using TearLab's sales data. He claims the range of the confidence interval (a 10-fold range, according to Dr. Hollis' calculations) using the quantitative statistical model based on monthly sales data

will not provide a reasonable estimate of damages suffered by TearLab if an injunction is not issued.

[60] Dr. Hollis also opines that historical sales data for new products does not provide a predictable underlying trend upon which to forecast sales and quantify future damages, as sales growth can take on many forms.

[61] Damages are incalculable, in Dr. Hollis' view, because methodologies from the pharmaceutical market are inapplicable to the medical device market, and no obvious comparator markets to osmolarity testing currently exist. He identifies the following factors that distinguish the pharmaceutical from the tear osmolarity market:

i. the tear osmolarity market is unique and it is difficult to identify a suitable comparator market;
ii. even if there were an adequate comparator market, there is insufficient data, and a lack of experience using such data to make predictions or even identify whether or not the market is an appropriate analogue;
iii. TearLab's sales data is highly volatile, unlike in pharmaceutical cases where the markets are relatively well established, and sales are steady over time;
iv. there is no comparative evidence on the TearLab versus the i-Pen Systems, akin to bioequivalence studies in the pharmaceutical context;
v. in this market, unlike pharmaceuticals, the clinicians are the purchasing customers, in part for patient benefit but also for earning profits.

[62] I have some sympathy for TearLab's position on the lack of comparator data for the market in this particular field of medical devices, yet I find Dr. Rosenblatt's evidence, discussed below, adequately explains that an acceptable analogue could be determined.

[63] Moreover, as I-MED indicates, sales data confirms TearLab has made sales in Canada since November 2009, and it is hardly a "nascent" market. Difficulty in calculating damages in such a market is not indicative, by itself, of irreparable harm, and TearLab's presence in the market for over six years weakens Dr. Hollis' assertion that the nascent market makes damages unquantifiable.

[64] Effectively, TearLab's position is that there is no basis for any sound prediction or estimate of damages in Dr. Rosenblatt's "but-for" forecast of damages – his calculations hinge on an "anything goes" attempt to legitimize his theory which arguably, it may be inferred, is more akin to an intended hypothesis than any viable theory of damages.

[65] Ultimately, though TearLab's assertions may be plausible, the Court is left guessing about the consequences of the alleged market complexities and interrelated variables raised by TearLab. I find the evidence presented by Dr. Hollis insufficient to constitute "clear and not speculative" evidence that actual unquantifiable harm will occur.

[66] Notwithstanding Dr. Hollis' above criticisms, I find that Dr. Rosenblatt's evidence adequately and sufficiently explains that TearLab's past sales can indeed be used to reasonably calculate damages. Dr. Rosenblatt's but-for projection uses historical data and projects it into the

future. On cross-examination he explained that this is the basic assumption of statistical forecasting analysis: that patterns that have existed in the past will continue to occur into the future.

[67] Dr. Rosenblatt's analysis "freeze-framed the world in March of 2016" and made a prediction of TearLab's sales in a scenario where no other events occur. He explains that future changes in the marketplace do not invalidate his model because any intervening and unexpected future events, which would not be hypothetical after trial, would be added to the forecast through an adjustment of the statistical projection.

[68] As well, at this stage of the proceedings, the incomplete information before Dr. Rosenblatt on the alleged effect of I-MED's marketing required to accurately quantify the loss does not undermine his position that there are, and will be after trial, ways of quantifying actual losses in monetary terms.

[69] On the issue of comparator markets, Dr. Rosenblatt acknowledged there is no database currently tracking direct sales of these devices from companies to ophthalmologists or optometrists and then on to patients. However, his testimony was that it is standard practice to consider a variety of comparators to determine acceptable analogues for assessing accuracy of a prediction, including "the type of market the product plays in, possibly the types of physicians, its efficacy, its safety, its clinical benefit, is there a tremendous amount of unmet need, is it an acute product, is it for chronic therapy, et cetera".

[70] Though Dr. Hollis suggested that TearLab's damages could not be estimated with "precision" or "certainty", this standard is much higher than the "reasonable" standard this Court requires. I accept the evidence of Dr. Rosenblatt that, notwithstanding TearLab's general assertions concerning the unique nature of this market and the variables that come into play, there are ways of quantifying the losses TearLab claims will be impossible to predict. His methodology shows that the TearLab sales data provided would permit a qualified expert to estimate damages through trial, and account in the future for other variables prevailing at the time when actual losses will have to be demonstrated. Theoretical complexity in calculation is not alone clear evidence that damages are not capable of reasonable quantification (*Aventis Pharma*, above, at para 70).

[71] Moreover, I-MED raises a valid inconsistency in TearLab's position: though TearLab claims irreparable harm is established on the basis that damages are incalculable, it nevertheless provides an undertaking as to damages (i.e. implicitly acknowledges they are quantifiable) in the event an injunction is granted if they lose at trial. While I appreciate that TearLab has made arguments regarding reputational damage, I find that their only claim with any substance is on the issue of unquantifiability, and if their position is that their undertaking as to damages can be quantified for I-MED following trial, I see no reason why it would be impossible to quantify them for TearLab in the opposite scenario.

(iii) TearLab's Inability to Forecast

[72] Mr. Smith's evidence on cross-examination was that TearLab attempted to apply a mathematical forecasting model to the Canadian market, which was "completely useless" given the insufficiency of the availability of inputs and the history of data.

[73] This factor is unpersuasive and does not support an inability to quantify damages following trial: the Court is provided no reference upon which to discern whether purported inaccuracies in TearLab's forecasting stemmed from the unavailability of data or other unknown factors.

(d) *I-MED's inability to pay a monetary award after trial*

[74] TearLab asserts that a defendant's inability to pay a monetary award after trial can constitute irreparable harm (*Turbo Resources*, above, at para 29).

[75] Mr. Hofmann, I-MED's VP, was asked to bring various financial documents to his cross-examination in a Direction to Attend, which he did not do. Accordingly, TearLab requests that the Court draw an adverse inference that I-MED would not be in a position to pay a monetary award after trial due to its failure to produce documents requested in a Direction to Attend (*Ottawa Athletic Club Inc v Athletic Club Group Inc*, 2014 FC 672 at paras 138, 139; *Eli Lilly Canada Inc v Mylan Pharmaceuticals ULC*, 2015 FC 178 at paras 119-120). Mr. Hofmann admitted he had access to I-MED's records, yet he did not bring these documents to his cross-examination.

[76] Counsel for I-MED refused to allow Mr. Hofmann to answer questions concerning I-MED's financial state, its insurance policy, and its ability to satisfy a monetary judgment after trial, on the basis that I-MED's financial standing and insurance was not relevant: it was not pleaded in the motion, nor was it at issue with respect to Mr. Hofmann's affidavit.

[77] By way of the affidavit of Denise Pope, and supposedly as "sur-reply", I-MED submitted as evidence its insurance policy, not produced during cross-examination, demonstrating that I-MED is insured for the costs of these proceedings and any damages up to a limit of USD $2,000,000 (approximately CAD $2,600,000).

[78] Though I agree with TearLab this is not proper sur-reply evidence, I am unprepared to draw an adverse inference on I-MED's impecuniosity. That issue was raised after the fact, was not plead in the motion for injunction, or addressed or at issue in Mr. Hofmann's affidavit and therefore is not properly before the Court.

(e) *Conclusion on Irreparable Harm*

[79] Patent rights are economic in nature and there is usually no reason why damages ensuing from infringement are unable to be measured or calculated in a reasonably accurate way (*Pfizer Ireland Pharmaceuticals v Lilly Icos LLC*, 2003 FC 1278 at para 27 citing *Cutter Ltd v Baxter Travenol Laboratories of Canada Ltd* (1980), 47 CPR (2d) 53 (FCA), leave to appeal denied (1980), 47 CPR (2d) 249 (note) (SCC)).

[80] In fact, Dr. Hollis himself agreed that in cases for which he has assisted the Court in quantifying damages, although difficult and potentially involving an overwhelming variety of scenarios, he has always been able to determine an appropriate quantum of damages.

[81] This case is no different. TearLab has not provided sufficient clear evidence it will suffer unquantifiable and irreparable harm if the injunction is not issued, while Dr. Rosenblatt's evidence showed that the loss claimed by TearLab is not so unique and exceptional that it falls beyond the possibility of reasonable quantification.

(3) Balance of Convenience

[82] My conclusion on the balance of convenience aspect of the tripartite conjunctive test set out in *RJR MacDonald* flows from my above finding that TearLab has not established it will suffer irreparable harm if an injunction is not issued pending trial, and my conclusion that damages will be an adequate remedy.

[83] I find that the balance of convenience favours I-MED.

[84] TearLab argues maintenance of the *status quo* favours them, in that I-MED would suffer relatively little inconvenience if an interlocutory injunction is issued, compared to the harm TearLab would sustain if the interlocutory injunction were refused and I-MED launched its infringing product (*American Cyanamid*, above, at 542).

[85] I disagree.

[86] Though the i-Pen System was licenced on May 13, 2015, and had only been on the market for four days by the time of the hearing of the injunction motion, the i-Pen System is currently on the market, and I-MED has been educating optometrists and ophthalmologists about it since July 2015. Moreover, preservation of the *status quo* is a consideration "[w]here other factors appear to be evenly balanced" (*American Cyanamid*, above, at 542). That is not the case here.

[87] If an interlocutory injunction is granted, I-MED will be entirely excluded from the market, and will lose all of its potential revenue in respect of the i-Pen System and any strides it has made in the market thus far. If an interlocutory injunction is refused, TearLab will lose some potential revenue, and will be subjected to competition and a resultant modification of the market it has built in Canada until now – which the evidence demonstrates it has not yet been able to truly penetrate.

[88] An interlocutory injunction is an extraordinary remedy. For the reasons provided, given the lack of clear and not speculative evidence of irreparable harm, and the above consideration of the balance of convenience, the application for an interlocutory injunction is dismissed.

B. *Security for Costs*

[89] I-MED requests that the Plaintiffs be ordered to post security for costs in the amount of $100,000.00 to cover I-MED's costs through a first round of discovery, without prejudice to request further security at a later time (Rule 416(2)).

[90] Both Plaintiffs fall under Rule 416(1)(a) of the *Federal Courts Rules*, SOR/98-106: they are ordinarily resident outside of Canada, being non-Canadian corporations incorporated in the United States of America. Accordingly, the Plaintiffs have a burden to demonstrate sufficient Canadian assets to pay costs, and to establish why the Court should not exercise its discretion to grant the security sought by the Defendant (*Moroccanoil Israel Ltd v Shoppers Drug Mart Corp*, 2010 FC 901 at para 6).

[91] I-MED's motion includes a skeleton bill of costs, assessed at the upper end of Column IV of Tariff B, which it asserts is not uncommon for complex intellectual property cases (*Eurocopter v Bell Helicopter Textron Canada Ltee*, 2012 FC 842 at para 22). I-MED submits the initial amount requested corresponds to one-sixth of the full amount of costs awarded by this Court in recent patent infringement and validity proceedings (*Janssen Inc v Teva Canada Ltd*, 2012 FC 48 at para 236; *Hershkovitz v Tyco Safety Products Canada Ltd*, 2010 FC 292 at para 69).

[92] TearLab argues it should not have to pay security for costs: it has bank accounts with the Royal Bank of Canada with a consistently positive balance sufficient to pay I-MED's costs.

[93] Alternatively, TearLab argues its voluntarily payment of $50,000 into Court is adequate. The amounts sought by I-MED are excessive, and at such an early stage of the proceedings, a security for costs order should be taxed in the middle of Column III of Tariff B, as the complexity of the proceedings cannot yet be discerned (*Faulding (Canada) Inc v Pharmacia S.p.A.*, [1997] FCJ No 1490 at para 7; *International Control Systems LLC v Haier America*

Trading LLC, 2012 FC 214 at para 12). Thus, TearLab submits the Court should set security for costs at $42,500. TearLab also asserts the case law cited by I-MED is inapplicable, as those cases address costs after an event or involve the context of a payment into Court by consent.

[94] Security for costs does not relate to the costs of any counterclaim a Canadian defendant makes (*Apotex Inc v H Lundbeck A/S*, 2010 FC 807 at para 21). Any activities in relation to I-MED's counterclaim will not be covered by an award for security for costs.

[95] The Defendant also sought $150,000.00 in security to cover its likely costs of defending against the interlocutory injunction. I agree with TearLab that the request for this relief is not appropriate in the context of security for costs, as this motion was heard on the same day as the motion for interlocutory injunction, and the interim injunction has since passed.

[96] I find that though TearLab has provided some evidence it has assets in Canada, the financial and banking information from TearLab is weak and shows little asset value. I would increase security payable by TearLab into the Court to a total of $100,000 at this stage of the proceeding.

[97] Accordingly, I order that TearLab pay additional security for costs into Court in the amount of CAD $50,000 within two weeks of the date of this Order, with I-MED retaining the right to seek additional security following completion of discoveries.

[98] Costs are awarded to the Defendant on both the motion for security for costs and the interlocutory injunction. The parties are to provide written submissions on costs of this application and on the interim injunction motion pursuant to Justice Russell's Order in that proceeding (2016 FC 350) to the Court within ten days of the date of this Order, not to exceed five pages in length.

[99] Finally, this matter is one that should proceed to trial on an expedited basis, if possible. The parties should seriously consider requesting a trial date at the earliest opportunity.

ORDER

THIS COURT ORDERS that:

1. The motion for an interlocutory injunction is dismissed;
2. TearLab is to pay additional security for costs into Court in the amount of CAD $50,000.00 within two weeks of the date of this Order, with I-MED retaining the right to seek additional security following completion of discoveries;
3. Pursuant to Prothonotary Lafrenière's April 27, 2016 Order, TearLab is granted costs for their informal application seeking leave to file additional affidavit evidence in the amount of $1500.00;
4. Costs are awarded to the Defendant on both the motion for security for costs and the interlocutory injunction. The parties are to provide written submissions on costs of this application and on the interim injunction motion pursuant to Justice Russell's Order in that proceeding (2016 FC 350) to the Court within ten days of the date of this Order, not to exceed five pages in length.

"Michael D. Manson"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

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STYLE OF CAUSE:	THE REGENTS OF THE UNIVERSITY OF CALIFORNIA ET AL v I-MED PHARMA INC
PLACE OF HEARING:	MONTREAL, QUEBEC
DATE OF HEARING:	MAY 17, 2016
ORDER AND REASONS:	MANSON J.
DATED:	MAY 31, 2016

APPEARANCES:

Patrick Smith Scott Foster	FOR THE PLAINTIFF, TEARLAB CORPORATION
Brian Daley Vanessa Rochester	FOR THE DEFENDANT

SOLICITORS OF RECORD:

GOWLING WLG Vancouver, British Columbia	FOR THE PLAINTIFF, TEARLAB CORPORATION
SMART & BIGGER Ottawa, Ontario	FOR THE PLAINTIFF, THE REGENTS OF THE UNIVERSITY OF CALIFORNIA
NORTON ROSE FULBRIGHT LLP Montreal, Quebec	FOR THE DEFENDANT