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• UPDATE ON PHYSICIAN-ASSISTED DEATH: SUPERIOR COURT ISSUES PRACTICE DIRECTION WITH REQUIREMENTS FOR BRINGING AN APPLICATION •

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• In This Issue •

On January 15, 2016, the Supreme Court of Canada granted the Attorney General a further four-month extension of the suspension of invalidity of the *Criminal Code*[1] provisions relating to physician-assisted death (*i.e.*, to June 6, 2016). In addition, the Court allowed individuals to bring an application to the Superior Court of Justice for an order that would authorize a physician-assisted death during the four-month extension. On January 29, 2016, the Ontario Superior Court released a practice direction[2] on what will be required for that Court to hear such an application and grant the relief sought.

The Evidence

In order to bring an application, the individual must file evidence in the form of affidavits from

- the applicant seeking the relief, with background biographical information, medical conditions, the reasons for the applicant's request (addressing the criteria set out in the *Carter*[3] case), the manner, means and timing of the physician- assisted death, and whether the applicant is aware that this request may be withdrawn at any time;

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- the applicant's attending physician, with evidence about the grievous irremediable medication condition, the applicant's suffering as a result of the medical condition, the applicant's mental capacity, whether or not the applicant is or will be physically incapable of ending her life, and whether the applicant is aware that she may withdraw the request at any time;
- a consulting psychiatrist who attests to, among other things, whether the patient has the mental capacity to make a clear, free and informed decision about physician-assisted death; and
- the physician who will be authorized to assist the applicant's death, who may be the attending physician or another physician. This affidavit would address, among other things, the manner and means and timing of the physician-assisted death, whether the physician is willing to assist the applicant in dying, whether the physician believes that his or her providing assistance would be clearly consistent with the applicant's wishes and whether the physician understands that the decision is entirely the applicant's to make.

We note that the Interim Guidance Document from the College of Physicians and Surgeons[4] and the Canadian Medical Association's Recommendations[5] do not require that the second opinion be from a psychiatrist, but rather just from another physician. The requirement for a psychiatric opinion is, however, in line with the process outlined by Justice Lynn Smith of the British Columbia Supreme Court when she carved out a specific exemption for Gloria Taylor, one of the plaintiffs in the *Carter* case, so that she would not have to wait out the appeal process should she desire a physician-assisted death.[6]

Who Must Be Provided with Notice of the Application?

Importantly, the Ontario Superior Court has further directed that the application must be served on the Attorney General for Canada and the Attorney General for Ontario. In addition, depending on the circumstances, the Court *may* require that a notice of the application be served on the applicant's spouse or partner, children, parents, grandparents, siblings or any other person who will be affected by the order sought. Such notice is beyond that contemplated by Smith J. in the *Carter* case, as she did not require that any notice be given of the application other than to the Court. It remains to be seen whether the federal or Ontario Attorneys General will participate in any hearing upon being provided with notice, and under what circumstances the Court will require that notice be provided to family members.

How, If At All, Will the Applicant's Privacy Be Protected If So Desired?

Another unique feature of the Ontario Superior Court's practice direction is a requirement that the notice of application should set out whether the applicant intends to seek a publication ban, an order to have the application heard in the absence of the public, or an order to seal the file, as well as the grounds for seeking such an order. It is notable that the practice direction does not require that the media be put on notice of the request. This suggests that the Court is at least open to taking steps to preserve the very private nature of the situation if asked, although it is not yet clear that they would in fact take these steps. This might also underlie the Court's decision to require that the Attorneys General be notified of the application so that the governments' position on this public interest issue may be brought to bear.

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1 R.S.C. 1985, c. C-46.

2 <http://www.ontariocourts.ca/scj/practice/application-judicial-authorization-carter/>.

3 See *Carter v. Canada (Attorney General)*, [2016] S.C.J. No. 4, 2016 SCC 4; *Carter v. Canada (Attorney General)*, [2015] S.C.J. No. 5, 2015 SCC 5.

[4] <http://www.cpso.on.ca/Policies-Publications/Policy/Interim-Guidance-on-Physician-Assisted-Death>.

[5] <https://www.cma.ca/Assets/assets-library/document/en/advocacy/cma-framework_assisted-dying_final-jan2016.pdf#search=Principles-based%20Recommendations%20for%20a%20Canadian%20Approach%20to%20Assisted%20Dying>.

[6] See *Carter v. Canada (Attorney General)*, [2011] B.C.J. No. 1897, 2011 BCSC 1371.

• B.C. COURT OF APPEAL OVERTURNS CLASS CERTIFICATION IN PATENTS CASE, FINDING PATENT REGIME TO BE COMPLETE CODE IN RESPECT OF REMEDIES •

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In *Low v. Pfizer Canada Inc.*,[1] a unanimous division of the Court of Appeal for British Columbia restricted the ability of consumers to make claims based on alleged unlawful acts under the *Patent Act*[2] and associated regulations. In so doing, the Court of Appeal reversed the certification of the *Low* class proceeding by the trial court and dismissed the action.

This result continues the development of a line of authority that will be important to inventors and manufacturers using the patent system, as any remedies in respect of invalid patents will be limited to those set out in the statutes and regulations. No rights at common law are available to consumers in respect of breach of the *Patent Act*.

Patent Regulatory Regime in Canada

Patent rights are a creature of statute; there is no right to patents at common law. The patent system provides to the inventor the benefit of a monopoly on a new invention for a limited period. In exchange, information must be disclosed regarding the product, such that a reasonably informed artisan can create the item in question and make it publicly available at the expiry of the monopoly.

The validity of patents may be challenged through special proceedings. If the patent is successfully challenged by a generic manufacturer and the patent is found to be invalid, the generic manufacturer will then obtain rights under the patent system to market their drug. The generic manufacturer is also provided with a right to claim compensation from the unsuccessful manufacturer for loss suffered by reason of delayed market entry.

There is no remedy in the patent system available to consumers for conduct alleged to have breached the *Patent Act* or the regulations.

Background of the Case

Pfizer obtained a patent for its drug Viagra. The active ingredient is sildenafil citrate. After obtaining the patent for the use of sildenafil citrate, as well as "about 260 quintillion" other compounds, in the treatment of erectile dysfunction, Pfizer had a monopoly on the sale of sildenafil in Canada and prevented generic manufacturers from introducing a generic version until the patent expired or was invalidated.

Generic manufacturers challenged the patent, and proceedings were commenced in respect of the patent. Ultimately, the Supreme Court of Canada determined in 2012 that Pfizer's patent was invalid, and generic drug manufacturers then entered the market, selling generic versions of Viagra at lower prices.

The plaintiff Low commenced a claim, alleging that Pfizer had unlawfully abused the patent

system to obtain a monopoly over sildenafil citrate, and as a result, overcharged the purchasers of Viagra. Low alleged that the difference between (1) the revenue Pfizer collected by charging the actual price of Viagra and (2) the revenue it would have collected in the presence of generic competition represents "ill-gotten gains". Low framed his claim under the tort of unlawful interference with economic relations and in unjust enrichment. Low sought to certify his action as a class action in the Supreme Court of British Columbia.

Supreme Court of British Columbia Certifies Low's Claim

In 2014, the certification judge found that Low's claim disclosed valid causes of action.[3]

Pfizer argued that the patent system, which included several statutes and regulations, completely governed the marketing of patented drugs and included within it all rights and remedies. In the absence of a cause of action for individual consumers, Pfizer argued Low's claim could not succeed.

The certification judge reviewed the recent consumer remedy class action law in British Columbia, focusing on Koubi v. Mazda Canada Inc. [Koubi],[4] Wakelam v. Wyeth Consumer Healthcare/Wyeth Soins de Sante Inc. [Wakelam],[5] and Macaraeg v. E Care Contact Centres Ltd.[6] The certification judge held that these cases stood for the proposition that statutory remedies available to the plaintiffs replaced and excluded remedies the plaintiffs might otherwise have at common law. On this basis, he distinguished them from the statutes governing the patent system, which were silent as to consumer remedies.

The certification judge held that because Parliament created no right of action for consumers arising directly out of a breach of the *Patent Act*, there was no bar to an action by consumers if the conduct in breach of statute was also relevant to a cause of action. Finding that the *Patent Act* was not a complete bar to a consumer remedy, the chambers judge then analyzed the alleged tort of unlawful interference with economic relations. He concluded that if a generic manufacturer could obtain compensation as a result of an invalid patent, that could satisfy the "unlawful means" element of the tort. He concluded that the unlawful interference with economic relations claim was not bound to fail.

The certification judge also considered whether the claim in unjust enrichment was bound to fail. On this point, the analysis turned on whether Pfizer could establish that any enrichment it may have received was due to a juristic reason. Pfizer argued that it had marketed Viagra pursuant to statutory rights. The court held while activity pursuant to statutory rights may be a juristic reason, that is not always the case. Accordingly, it was not certain that the cause of action was bound to fail for this juristic reason. The court went on to hold that contracts between direct purchasers and Pfizer for the sale and purchase of the drug were not illegal or void for mutual mistake. There were no pleaded facts suggesting that the price was a fundamental fact on which the contracts were based, or that the plaintiff or other class members would have refused to pay had they known of the patent's possible invalidity. Despite these findings, he concluded that the claim in unjust enrichment was not bound to fail.

Court of Appeal Reverses Certification, Finding that the Patent System Is a Complete Code

Pfizer argued on appeal that because Low's claims are entirely derived from the *Patent Act*, Low must look to the statute for a remedy, which does not exist. Low submitted that his claim is based in the common law, and the complete code argument does not apply.

Low did concede that the patent statutory regime is a complete code as regards the relationship between generic and brand name manufacturers. Low argued, however, that because the Patent-related statutes and regulations are silent as to consumer rights and remedies for breach of the *Patent Act*, it cannot be a complete code. The proper question to ask, he submitted, was whether the legislature intended to "oust" consumer rights of action, not whether it intended to create them.

The Court of Appeal did not agree that silence in the legislation must be taken as an indication that a right to civil action should be inferred. The Court of Appeal relied on the decision in *R. v. Saskatchewan Wheat Pool*,[7] which is authority for the proposition that there is no common law tort of breach of statute. The Court of Appeal held that Low's claim is fundamentally a claim for breach of statute, as his right to recovery is said to arise out of "abuse of the Patent system".

The Court of Appeal concluded that the Patent system is a complete code and forecloses parallel civil actions by consumers rooted in breach of the *Patent Act*. Importantly, patent rights are a construct of statute and, as such, patent rights do not exist at common law. The Court held that in circumstances such as these, where Parliament has comprehensively legislated a particular area of the law, the reasonable inference is that it did not intend to extend rights of recovery beyond those embodied in the regime. The Court held that this is a complete bar to Low's claim.

The Court of Appeal then continued, in the alternative, to consider whether the certification judge was correct in his analysis of the causes of action. It found that he was not, specifically erring in his analysis of "unlawful means" and "juristic reason". First, the certification judge should have considered whether there was actionable conduct to support the tort claim. The Court of Appeal found that there was no actionable claim outside the statutory regime, so the parasitic claim in tort could not succeed. Second, the Court held that the contracts between Pfizer and the direct consumers were juristic reasons that barred the claim in unjust enrichment. The claim, therefore, had no prospect of success, notwithstanding any uncertainty concerning whether the Patent system provides a juristic reason.

The Court of Appeal reaffirmed its earlier decisions in *Koubi* and *Wakelam*, and held that *Wakelam*, in particular, stands as authority that complete statutory codes exclude equitable claims in unjust enrichment.

Impact on Inventors and Manufacturers

Critically, the Court of Appeal decision restricts the ability of plaintiffs to bring equitable and tort claims based on breach of the *Patent Act*. This decision, along with the Court of Appeal's decisions in *Koubi* and *Wakelam*, is of significance to any manufacturer who may face claims from direct consumers. Expect statutory regimes to be more carefully scrutinized on a summary basis without the need of a full trial.

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2012 BCCA 310, leave to appeal to Supreme Court of Canada denied with costs (January 17, 2013).]

[1] [2015] B.C.J. No. 2689, 2015 BCCA 506.
[2] R.S.C. 1985, c. P-4.
[3] *Low v. Pfizer Canada Inc.*, [2014] B.C.J. No. 2028, 2014 BCSC 1469.
[4] [2012] B.C.J. No. 1464, 2012 BCCA 310.
[5] [2014] B.C.J. No. 167, 2014 BCCA 36.
[6] [2008] B.C.J. No. 765, 2008 BCCA 182.
[7] [1983] S.C.J. No. 14, [1983] 1 S.C.R. 205.

• PROPOSED CHANGES TO ONTARIO'S HEALTH PRIVACY LAWS •

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What Do These Changes Mean for Regulators?

On September 16, 2015, Bill 119 (the "Bill") was introduced by the Minister of Health and Long-Term Care into the Ontario legislative assembly and is now in second reading.[1] A previous iteration of the Bill died on the order paper in advance of the 2014 provincial election. It proposes to amend the *Personal Health Information Protection Act, 2004* [*PHIPA*].[2] The Bill addresses the development and maintenance of an electronic health record ("EHR") and the collection, use and disclosure of personal health information ("PHI") by means of the EHR. The Bill also proposes to amend the *Regulated Health Professions Act, 1991* [*RHPA*][3] and other legislation.

If passed, the Bill has important consequences for regulators. In this article, we canvass three matters of particular interest: (1) provider registry, (2) mandatory reporting obligations and (3) provincial offences.

Provider Registry

Bill 119 proposes amendments to the *RHPA* to develop and implement a provider registry that contains certain information about regulated health care providers. The Bill would permit the Minister of Health and Long-Term Care to make regulations requiring the College of a regulated health profession to collect information about its members that is necessary for the purpose of developing and maintaining the EHR. The Bill also requires the College to provide the information to the prescribed organization (which is expected to be eHealth Ontario) in the form, manner and timeframe specified by the prescribed organization.

One of the purposes of the provider registry is to establish a registry of authorized health care providers who will have access to the EHR based on their status in the registry. This process is designed to ensure that only authorized health care providers have access to PHI in the EHR. It is therefore key that the information provided by the Colleges is accurate, complete and up to date. Additional costs may be associated with the collection of personal information from Colleges' members and providing it in the requisite form, manner and timeframe to the prescribed organization. There is no required consultation prior to the regulation being passed by the Minister of Health and Long-Term Care as to what information is to be collected by a College. Similarly, there is no required consultation prior to the prescribed organization's direction respecting the form, manner and timeframe for providing information. Therefore, it would be advisable for Colleges to seek consultations with the Ministry and eHealth Ontario (assuming it is the prescribed organization) so that the requirements of collecting members' personal information and disclosing it to eHealth Ontario are reasonable.

Mandatory Reporting

Health privacy violations appear to be on the increase. If passed, the Bill will impose new mandatory reporting obligations on health information custodians. It will require employers that are health information custodians ("HICs") who employ health care practitioners (*e.g.*, nurses, physiotherapists, respiratory therapists and social workers) to report health privacy breaches to the College of the regulated health profession under the RHPA or to the Ontario College of Social Workers and Social Service Workers ("OCSWSSW"), as well as to the Ontario Information and Privacy Commissioner.

This obligation is triggered under two circumstances:

1. If the employee is terminated, suspended, or subject to disciplinary action as a result of a health privacy breach.
2. If the employee resigns and the HIC believes that the resignation is related to an investigation or other action by the HIC with respect to an alleged health privacy breach.[4]

There are similar mandatory reporting provisions that will apply to HICs that extend privileges to health care practitioners (*e.g.*, physicians) where there is a health privacy breach.

If a HIC employs a health care practitioner who is a member of a health regulatory College or the OCSWSSW, the HIC must give the College written notice within 30 days if the health care practitioner is terminated, suspended, subject to disciplinary action or resigns due to the practitioner's actual or suspected health privacy breach. In a similar vein, if a HIC extends privileges to a health care practitioner who is a member of a health regulatory College or the OCSWSSW, the HIC must give the College written notice within 30 days if the health care practitioner's privileges or affiliations are revoked, suspended or restricted, or the practitioner relinquishes his or her privileges or affiliation due to the practitioner's actual or alleged health privacy breach.

Provincial Offences

Other amendments to the *PHIPA* deal with the prosecution of health privacy breaches. The Bill will double the maximum fines for offences under the *PHIPA* to a maximum of $100,000 for individuals and $500,000 for corporations. The amendments will also eliminate the six-month limitation period for commencing a prosecution. Lastly, in order to commence a prosecution, the consent of the Attorney General will be required, thereby relieving the Attorney General of commencing the prosecution itself. Amendments to the Bill may be made through Standing Committee hearings.

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1 As of February 1, 2016, the bill was still in second reading.

2 S.O. 2004, c. 3, Sch. A.

3 S.O. 1991, c. 18.

4 There may be regulations made under the *PHIPA*, which provide exceptions and additional requirements related to this obligation.