Product Liability

New Swords and Shields: The Canadian Regulatory Approval Process and Novel Claims and Defenses in Product Liability Litigation

Barry Leon and Cynthia Tape

ABSTRACT

The regulatory approval process for biologics, pharmaceuticals and medical devices continues to give rise to novel claims and defenses against manufacturers and regulatory authorities in Canada. This article highlights recent court decisions and pharmaceutical product liability issues.

INTRODUCTION

The regulatory approval process for biologics, pharmaceuticals and medical devices continues to give rise to novel claims and defenses against manufacturers and regulatory authorities in Canada. Court decisions to date suggest that regulatory misstatements could give rise to claims in negligence and, interestingly, negligent or fraudulent misrepresentation. A defense of regulatory approval may also be available in some circumstances. In light of the intense activity in the pharmaceutical product liability area — including several proposed Vioxx class actions in which regulatory claims appear to be raised — important rulings on whether regulatory claims and defenses form part of Canadian law may not be far off. Significant changes — both positive and negative — could be in store for plaintiffs, and for the regulators and manufacturers of drugs and medical devices, should any of these claims and defenses be recognized.

Regulatory Misrepresentation as a Claim

Biologics, pharmaceuticals and medical devices may be marketed in Canada only after the manufacturer obtains approval of the product from Health Canada. Product approval is based on the submission of potentially extensive safety and efficacy data, as well as product monograph and patient information, which Health Canada scrutinizes over an extended period. The stringency of federal governmental authority to control the approval and marketing of these products has given rise to novel theories of liability, not only for manufacturers but also for the government regulators themselves.

Plaintiffs have alleged, as part of misrepresentation claims, that manufacturers have made misstatements to regulatory authorities during the drug approval process. The nature of these allegations is that but for the defendant's misstatements Health Canada would never have granted a notice of compliance for the product, and so the drug in question would never have reached the market in general or the plaintiff in particular.

In *Andersen v. St. Jude Medical Inc.*,[1] a claim of regulatory misrepresentation was rejected. In that case (a proposed class action concerning defective heart valves), the plaintiffs contended that the defendants negligently or fraudulently misrepresented the safety and efficacy of the product to the regulators. The plaintiffs further alleged that the defendants knew that the misrepresentations would be relied on as a basis for approval of the product, and that doctors, hospitals and device recipients "would" rely on regulatory approval (as opposed to *did* rely on the misrepresentation, which is the normal requirement to prove negligent misrepresentation) as an indication of the product's safety and efficacy.

The Court struck out the claim of "indirect misrepresentation" because the plaintiffs made no allegation that they or their doctors were even aware of any representations by the defendants. An assertion that the plaintiffs' reliance was on regulatory approval *per se* was held not to be sufficient.

WWW.BIOLAWBUSINESS.COM

Barry Leon practices business litigation and dispute resolution in the Toronto office of Torys LLP. His practice includes class actions, intellectual property litigation and product liability litigation.

Cynthia Tape practices intellectual property law in the Toronto office of Torys LLP, primarily in the pharmaceutical field, and food and drug regulatory law.

Cite as: Barry Leon and Cynthia Tape, *New Swords and Shields: The Canadian Regulatory Approval Process and Novel Claims and Defenses in Product Liability Litigation*. J. BIOLAW & BUS., Vol. 8, No. 2, 2005.

While the certification of a class action in *Wilson v. Servier Canada Inc.*[2] (regarding the diet drug fenfluramine) included a claim of regulatory misrepresentation, the motions judge in that case made no comment on the viability of the claim. The action has since been settled.

There was a more elaborate discussion of the point in *Boulanger v. Johnson & Johnson Corp.* (a proposed class action regarding the drug Prepulsid). In that case, the plaintiffs sought damages for, among other things, the defendant's "fraudulent and/or negligent filings with Health Canada to obtain its approval for Prepulsid..."[3] The defendant brought a motion to strike those allegations on the basis that no cause of action was disclosed.

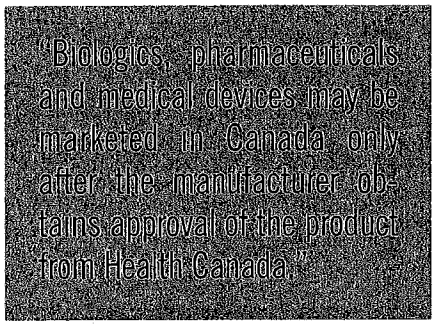
Justice Nordheimer approached the allegations as raising a claim for misrepresentation. He agreed for the following reasons that no cause of action was disclosed. First, Justice Nordheimer distinguished *Wilson*, observing that the motions judge in that case was dealing not with a motion to strike but rather with a motion for certification on the basis of the statement of claim as a whole.

Second, he found no authority to justify the recognition of "indirect reliance" as the basis for a claim of misrepresentation in Ontario. Although the plaintiff relied on U.S. authorities that were said to hold a manufacturer liable for misrepresentations not actually communicated to the plaintiff, Justice Nordheimer observed that some sort of allegation of reliance was required even in cases recognizing "indirect reliance" (usually reliance allegedly by the plaintiff's physician, who relied on the misrepresentations in deciding to prescribe the drug). No reliance of any sort was alleged by the plaintiff in *Boulanger*.

Third, Justice Nordheimer found that the regulatory misrepresentation claim really amounted to a claim for breach of statutory duty. Breach of statutory duty is not itself a cause of action in Canada.[4]

Finally, Justice Nordheimer held that allegations of regulatory misrepresentations added nothing to what the plaintiff needed to establish to prove the defendant's liability. If the defendant's product was negligently manufactured, the plaintiff's case was made out regardless of any failings in the regulatory approval process. If the product was not negligently manufactured, then any misleading statements made to Health Canada could not themselves found a cause of action.

On appeal, the Court of Appeal for Ontario agreed that the regulatory misrepresentations as pleaded did not disclose a reasonable cause of action based on negligent misrepresentation:



> It is clear that in Canada, actual reliance is a necessary element of an action in negligent misrepresentation and its absence will mean that the action cannot succeed. See *Hercules Managements Ltd. v. Ernst & Young*, [1997] 2 S.C.R. 165 at para. 18. Here there is absolutely no assertion of reliance by the appellant (or by anyone on her behalf) on the representations of the respondents to Health Canada. Indeed there is no pleading of reliance on the fact of regulatory approval. This complete absence of reliance is fatal to a negligent misrepresentation claim.[5]

However, the Court went on to find that because the plaintiff's allegations were broadly pleaded, they were sustainable as a claim for negligence:

> The appellant's allegation is that the standard of care required of the respondents includes taking reasonable care in the filings they made to obtain regulatory approval and that without that approval, Prepulsid would not have been available to harm the appellant. These filings are pleaded as an aspect of the respondents' conduct which caused the appellant harm and which fell below the standard required of a reasonable drug manufacturer. They are one of the ways in which the appellant says the respondents were negligent. Framed this way, I cannot say that it is plain and obvious that such a clam will fail. Indeed the claim could appropriately be viewed as one of negligent misstatement. See *Haskett v. Equifax Canada Inc.*[6]

In *Haskett v. Equifax Canada Inc.*,[7] a proposed class action was brought against credit reporting agencies on the basis that they "improperly and illegally included information in [the plaintiff's] credit report" that allegedly caused the plaintiff harm. The motions judge struck out the plaintiff's action, but the Court of Appeal permitted it to proceed to trial as a claim in negligence. Justice Feldman, writing for the Court, held that the relationship between a credit reporting agency and the subject of the report was analogous to the relationship that founds a cause of action in negligent misrepresentation:

> In this case we have the elements of negligent misrepresentation without reliance by the affected consumer, but where the representor has effectively assumed responsibility for the accuracy of the information because of the potential harm which could be caused to the consumer if the contents are inaccurate. This makes the case one that arguably does not fit exactly within negligent misrepresentation, but one that is analogous to it.[8]

Alternatively, even if the facts of the case did not fit negligent misrepresentation, the Court held that in this novel situation a new duty of care should be recognized.

In coming to the conclusion that a cause of action in negligent misrepresentation could be recognized even without direct reliance, the Court of Appeal in *Haskett* referred to the decision of the House of Lords in *Spring v. Guardian Assurance plc*,[9] in which the issue was whether the negligent preparer of a reference letter for employment could be held liable to the subject employee:

> [The House of Lords in *Spring*] held that there was a duty of care owed to the subject of the reference by the provider of the reference not to prepare the reference negligently. In their analyses, both Lord Goff and Lord Woolf referred to the case of *Hedley Byrne* ... in holding that the relationship was one which gave rise to a duty of care. Lord Goff opined that a duty of care arises not only where the recipient of a statement acts in reliance upon it, but also where employees who do not receive the representation nevertheless rely upon the employer to exercise care in preparing the reference before making it available to the recipient.... In this regard, he wrote:
>
> > The fact that the inquiry in *Hedley Byrne* itself was directed ... to whether the maker of the statement was liable to a recipient of it who had acted in reliance upon it, may have given the impression that this is the only way in which liability can arise under the principle in respect of a misstatement. But, having regard to the breadth of the principle as stated in *Hedley Byrne* itself, I cannot see why this should be so.[10]

In view of the Court of Appeal for Ontario's commentary in *Boulanger* and *Haskett*, allegations of regulatory misstatements could be recognized as giving rise to claims in negligence and negligent misrepresentation, in the latter case even in the absence of direct reliance by the plaintiff. It is important to note, however, that consistent with the obligation of the courts not to strike out novel claims at the outset, these decisions have merely permitted the claims to proceed to trial. To date, there has been no determination that these novel kinds of claims will be accepted by our courts. Given the level of litigation activity in the pharmaceutical product liability sector, however, a ruling on the tenability of regulatory misrepresentation claims against manufacturers may well be on the horizon.

Claims of "regulatory misrepresentation" have also been directed at the federal government as regulator — for example, in *Harrington v. Canada (Minister of Health)*.[11] In this case, the plaintiff in a proposed class action in British Columbia asserted a claim for damages against the Minister of Health on the basis that the sale of breast implants was approved when these devices were in fact not safe.[12] The basis for the claim was not that regulatory approval of the implants had been granted after negligent testing of the devices, but rather that the government had "failed to test or require that testing be done ... in a manner which would fully disclose the magnitude of the risks."[13] According to the plaintiff,

> by giving its regulatory approval to breast implants for sale and use in Canada, [the Crown] represented to each member of the Plaintiff class that breast implants were safe. Each plaintiff was required by statute to rely on the Defendant's representation that breast implants were safe, as they could not purchase breast implants without the Defendant's representation.[14]

The plaintiff admitted that there had been "no individual reliance in the classical sense,"[15] as would ordinarily be required to establish a cause of action in negligent misrepresentation. However, there was "statutory" or "deemed" reliance because the breast implants could not be purchased without the Minister's representation that they were safe. The plaintiff relied on the Medical Devices Regulations of the Food and Drugs Act,[16] which provides that medical devices may not be sold in Canada unless tests have been conducted to indicate that any claimed benefits of the device or its performance are justified. The failure of the government to prohibit the sale of silicone gel breast implants in Canada amounted to a representation to the public that the implants were safe.

On a motion by the Minister for particulars, the Court found the plaintiff's pleading to be deficient. The Court noted that no mandatory testing obligations were imposed on government officials under the Medical Devices Regulations. While the government may be subject to vicarious tort liability when public officials are negligent in carrying out their statutory powers,

> [c]ounsel pointed to no case in which it had been found or even alleged that an enactment conferring non-mandatory powers on public officials amounts to a 'representation' or 'misrepresentation' that those powers will be carried out in a particular way or with a particular beneficial effect, even if that beneficial effect is alluded to in general terms in the enactment. [...]
>
> The plaintiff here is pleading a new theory of Crown liability through reliance by the public on an alleged representation by enactments that government officials would do certain things not mandated under the pleaded enactments of Parliament. The plaintiff does not allege the representation was made otherwise than through the enactments pleaded.

> The pleadings ... do not explain how failure to prohibit the sale of untested devices, when the sale of untested devices is prohibited by s. 14 of the [Medical Devices Regulations], amounts to 'regulatory approval'.[17]

As a result, the Court ordered the plaintiff to provide further and better particulars of her "novel theory."

A similar claim had somewhat more success in *Attis v. Canada (Minister of Health)*.[18] In this case, the plaintiff in a proposed Ontario class action sought damages from the Attorney General of Canada on behalf of all women who received breast implants. The alleged cause of action was that "the government was negligent in permitting the distribution and sale of the implants thereby leading to personal injuries being suffered by the recipients."[19] On a motion brought by the federal government, the Court declined to strike out the claim because "the plaintiffs may be able to establish the liability of the Attorney General in respect of the implants."[20] Unlike in *Harrington*, the Court did not engage in any detailed discussion of the basis for the plaintiff's allegation. It will be interesting to compare developments in *Harrington* and *Attis* as these cases progress.

Regulatory Approval as a Defense

Can a manufacturer defend itself in product liability litigation on the basis that Health Canada carefully scrutinized the product and deemed it to be safe? It is settled law that breach of statutory duty is not negligence *per se*. But it is an open question whether compliance with a statutory duty is a defense.

In *Buchan v. Ortho Pharmaceutical (Canada) Ltd.*,[21] two issues before the Court were the content of the manufacturer's duty to warn of material risks associated with an oral contraceptive product, and to whom any such duty was owed. Ortho, the manufacturer, argued that it had no duty to consumers, relying instead on the learned intermediary rule. Alternatively, if a duty to consumers existed, Ortho's compliance with the statutory standard of disclosure satisfied any such duty, and it had no additional obligation to provide consumers with supplementary information or to issue additional warnings. The trial judge held that Ortho's compliance with the labeling requirements set out in the Food and Drugs Act and Regulations did not relieve it of the duty to provide a proper warning to both consumers and physicians, which in the circumstances Ortho had failed to do.

On appeal, the Court of Appeal took a different approach. It assumed, without deciding, that Ortho's position — that it could avail itself of the learned intermediary defense and warn only physicians — was correct. On this assumption, it was "unnecessary to decide whether the statutory labeling and packing requirements pre-empt or define the bounds of the common law duty to warn consumers directly."[22] While the Court held that Ortho was liable on the basis that the warning to physicians was inadequate, the question whether regulatory compliance or approval could replace the common law duty to warn consumers was left open.

> "As the number and size of pharmaceutical product liability claims continue to grow through the availability of class actions, we are likely to see greater numbers of court decisions dealing with these novel claims and defenses."

Since the decision in *Buchan* in 1986, the question whether a regulatory compliance defense should be recognized in the pharmaceutical products liability arena has not been settled. In other areas — for instance, the liability of railways — regulatory compliance does not foreclose a finding of negligence.[23] In *Ryan*, the Supreme Court of Canada jettisoned an old rule that railways were required to do no more than comply with statutory obligations to meet the standard of reasonable care. The Court commented on the defense of statutory compliance as follows:

> Legislative standards are relevant to the common law standard of care, but the two are not necessarily co-extensive. The fact that a statute prescribes or prohibits certain activities may constitute evidence of reasonable conduct in a given situation, but it does not extinguish the underlying obligation of reasonableness.... Thus, a statutory breach does not automatically give rise to civil liability; it is merely some evidence of negligence.... By the same token, mere compliance with a statute does not, in and of itself, preclude a finding of civil liability. ... Statutory standards can, however, be highly relevant to the assessment of reasonable conduct in a particular case, and in fact may render reasonable an act or omission which would otherwise appear to be negligent. [...]
>
> Where a statute authorizes certain activities and strictly defines the manner of performance and the precautions to be taken, it is more likely to be found that compliance with the statute constitutes reasonable care and that no additional measures are required.[24]

It appears that this issue has yet to be considered further in the pharmaceutical products liability context. Given the rigorous review process to which pharmaceuticals are subjected, however, there may be a viable argument that regulatory approval is co-extensive with the common law standard of care, or at least raises a rebuttable presumption that the compliant manufacturer was not negligent.[25]

SUMMARY

As the number and size of pharmaceutical product liability claims continue to grow through the availability of class actions, we are likely to see greater numbers of court decisions dealing with these novel claims and defenses. We can also expect more frequent access-to-information requests by plaintiffs for regulatory filings, and closer scrutiny of those filings by manufacturers and regulators. One thing is clear: the roles and responsibilities of regulators and regulatory affairs personnel will be an increasing focus of litigation in the pharmaceutical and medical device litigation area.

ENDNOTES

1. [2002] O.J. No. 260 (S.C.J.).
2. (2000), 50 O.R. (3d) 219 at 234 (S.C.J.); leave to appeal to Div. Ct. refused (2000), 52 O.R. (3d) 20; leave to appeal to S.C.C. refused, [2001] S.C.C.A. No. 88 [*Wilson*].
3. *Boulanger v. Johnson & Johnson Corp.*, [2002] O.J. No. 1075 at ¶5 (S.C.J.), aff'd on this point [2003] O.J. No. 2218 at ¶11 (C.A.). The Superior Court decision is reported at (2002) 14 C.C.L.T. (3d) 233 [*Boulanger*].
4. *The Queen v. Saskatchewan Wheat Pool*, [1983] 1 S.C.R. 205.
5. *Boulanger, supra* note 3 at ¶11 (C.A.).
6. *Boulanger, supra* note 3 at ¶14 (C.A.).
7. (2003), 63 O.R. (3d) 577 (C.A.), leave to appeal to S.C.C. refused, [2003] S.C.C.A. No 208 [*Haskett*].
8. *Ibid.* at 591.
9. [1994] 2 All E.R. 129 (H.L.).
10. *Haskett, supra* note 7 at 591, citing *Spring v. Guardian Assurance plc, supra* note 9, at pp. 146-147.
11. (2003), 20 C.C.L.T. (3d) 17 (B.C.S.C.) [*Harrington*].
12. *Harrington* (and *Attis, infra* note 16) is a companion case to an existing class action brought against breast implant manufacturers.
13. *Harrington, supra* note 11 at ¶16.
14. *Harrington, supra* note 11 at ¶6.
15. *Harrington, supra* note 11 at ¶10.
16. C.R.C. 1978, c. 871 (now SOR/98-282). The plaintiff relied on various sections of these regulations, including sections 14, 15, 16, 29 and 30.
17. *Harrington, supra* note 9 at ¶26, 31, 32.
18. (2003), 29 C.P.C. (5th) 242 (Ont. Sup. Ct.) [*Attis*].
19. *Ibid.* at ¶1.
20. *Ibid.* at ¶40.
21. (1986), 54 O.R. (2d) 92 (C.A.) [*Buchan*].
22. *Ibid.* at 107.
23. See, for example, *Ryan v. Victoria (City)*, [1999] 1 S.C.R. 201 [*Ryan*].
24. *Ibid.* at 222, 229.
25. Some commentators have objected to the recognition of any defense of regulatory or statutory compliance because the objectives of regulatory control and compensation through the tort liability system are not the same: see, for example, S.M. Waddams, *Products Liability*, 4th ed. (Carswell: Toronto, 2002) at 135-138.