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SUPERIOR COURT OF JUSTICE - ONTARIO

RE: Apotex Inc. v. Abbott Laboratories, Limited

Apotex Inc. v. Takeda Pharmaceuticals America, Inc. and Takeda Pharmaceuticals Company Limited

BEFORE: Swinton J.

COUNSEL: Andrew Reddon and David Tait for the Defendant Abbott (Moving Party)

Christopher C. Van Barr for the Takeda Defendants (Moving Parties)

Andrew Brodkin and Julie Rosenthal for the Plaintiff Apotex (Responding Party)

HEARD: June 21, 2011

ENDORSEMENT

[1] Abbott Laboratories, Limited and Takeda Pharmaceuticals America, Inc. and Takeda Pharmaceuticals Company Limited ("the Defendants") seek leave to appeal from the order of Whitaker J. dated December 15, 2010, in which he dismissed their Rule 21.01(1)(b) motion to strike out the unjust enrichment claims of the Plaintiff, Apotex Inc.

[2] The motions judge held that it was not plain and obvious that the claims would fail. The issue to be determined on these motions for leave is whether there is good reason to doubt the correctness of this decision and whether the appeals would raise issues of general importance. For the reasons that follow, I would dismiss the motions.

[3] The Defendants argue that it is plain and obvious that the Plaintiff would be unable to establish there was a lack of a juristic reason for the Defendants' enrichment, because the provisions of the *Patented Medicines (Notice of Compliance) Regulations* ("*PMNOCR*") provide the requisite juristic reason. They argue that the motions judge erred in his application of the Supreme Court of Canada jurisprudence in *Garland v. Consumers' Gas Co.*, [2004] 1 S.C.R. 629 and *Gladstone v. Canada (Attorney General)*, 2005 SCC 21. They also argue that he erred by failing to consider the case of *Lomas v. Rio Algom*, 2010 ONCA 175.

[4] Pursuant to the *PMNOCR*, a generic drug producer like the Plaintiff cannot obtain a Notice of Compliance ("NOC") for a new product under the *Food and Drugs Act*, R.S.C. 1985,

c. F-27 without giving a Notice of Allegation ("NOA") to the holder of any patents respecting the drug in question. The NOA must state that the new generic drug will not infringe a patent.

[5] The patent holder then has a 45 day window in which to exercise its option to commence an application, usually in the Federal Court, seeking an order prohibiting the Minister of Health from issuing the NOC to the generic manufacturer until the expiry of its patent.

[6] If the application is commenced, the issuance of the generic manufacturer's NOC is automatically enjoined for 24 months or until the application is determined (whichever occurs first). A generic manufacturer who successfully defends a prohibition application may commence an action for compensation for its losses suffered pursuant to s. 8 of the *PMNOCR*.

[7] Despite the argument of the Takeda defendants, I am not satisfied that there is a conflicting decision within the meaning of Rule 62.02(4)(a). The motions judge correctly set out the principles from the Rule 21 jurisprudence and applied it to the pleadings before him. He correctly stated that courts should not strike a claim at this stage where the law is unsettled (*Nash v. Ontario*, [2005] O.J. No. 4043 (C.A.) at para. 11).

[8] The real question is whether the Defendants have met the test in Rule 62.02(4)(b), which first requires them to show that there is good reason to doubt the correctness of the decision.

[9] To prove unjust enrichment, a plaintiff must prove an enrichment of the defendants, a corresponding deprivation and the absence of a juristic reason for the enrichment (*Garland*, above at para. 38).

[10] There are no cases that have been decided on the precise point in issue in this litigation – namely, whether the decision of a patent holder to commence a proceeding under the *PMNOCR* that is unmeritorious might give rise to a cause of action in unjust enrichment by the generic drug manufacturer.

[11] The Defendants argue that the motions judge erred in his application of the legal principles from *Garland* and *Gladstone,* above.

[12] In *Garland,* the Supreme Court of Canada set out a two part test to determine whether recovery should be denied because of a lack of juristic reason, even though there has been a benefit to the defendant and a corresponding deprivation to the plaintiff. First, the plaintiff has the onus to show there is no juristic reason from an established category that exists to deny recovery. Those categories include "a disposition of law". Second, if there is no juristic reason from an established category, the onus shifts to the defendant to show that there is another reason to deny recovery, taking into account reasonable expectations and public policy (at paras. 44-45).

[13] Iacobucci J. went on to discuss the meaning of "disposition of law", quoting (at para. 49) from J. McCamus and P. Maddaugh, *The Law of Restitution,* where the authors stated:

> ... it is perhaps self-evident that an unjust enrichment will not be established in any case where enrichment of the defendant at the plaintiff's expense is required by law.

[14] In *Garland*, Consumers' Gas was required to charge rates approved by the Ontario Energy Board, including the Late Payment Penalty in issue. However, the requirement to charge such rates could not provide a juristic reason for the enrichment in that case because the order of the Ontario Energy Board was inoperative due to conflict with the federal prohibition on criminal rates of interest.

[15] The motions judge made reference to *Garland*, stating that, "The only arguable ground in this case would be disposition of law and this has been understood to mean enrichment and deprivation 'required' by law..." He concluded that the defendants were not required by law to invoke the *PMNOCR*; "at best, it was entitled to do so" (Reasons, at para. 59). He then concluded that the Defendants would have the burden to prove there is some other reason in the circumstances to justify the enrichment, concluding that it was not plain and obvious that Apotex has failed to plead material facts in support of its claim.

[16] While I would not have analyzed this issue, as he did, under the heading "has Apotex pleaded sufficient material facts", I nevertheless conclude that after using the Rule 21 analysis, it is not plain and obvious that this claim will fail. Nor is it arguable that the motions judge's conclusion was incorrect. Nothing in *Garland,* in my opinion, confirms that the Defendants' reliance on a permissive law constitutes a juristic reason for enrichment.

[17] The motions judge did not mention *Gladstone*, upon which the Defendants place great weight. There, federal fisheries legislation gave the Minister the authority to seize and sell fish spawn and provided a mechanism for repayment. The legislation said nothing about the payment of interest when monies were returned. The Supreme Court of Canada rejected a claim in unjust enrichment by those seeking interest on return of funds, holding that the *Fisheries Act* was a complete code dealing with the return of seized property (at para. 22).

[18] It is not plain and obvious that the *PMNOCR* constitutes a complete code, as in *Gladstone,* nor that an order for compensation based on unjust enrichment would undermine the purpose of the regulation. The Court of Appeal in *Central Guaranty Trust Co. v. Dixdale Mortgage Investment Corp.* (1994), 24 O.R. (3d) 506 found that the statutory provisions governing the priorities on the discharge of a mortgage were not dispositive, and "[i]n an appropriate case a court may give effect to the principle of unjust enrichment despite the terms of a statute" (at pp. 515-516).

[19] It appears that the law is not settled as to the circumstances in which a statute will provide a juristic reason for enrichment. Here, it is not settled that the *PMNOCR* is a complete code. Nor is it clear that the Defendants' decision to invoke the prohibition proceeding will provide a juristic reason for the benefit, if it is proven that the Plaintiff did not infringe any of the Defendants' patents.

[20] The Defendants also argue that the motions judge erred in failing to consider *Lomas*, above. In that case, the Ontario Court of Appeal held that since courts do not have jurisdiction to order the wind up of a pension plan under the *Pension Benefits Act*, they do not have jurisdiction to order a company to commence a wind-up proceeding. Otherwise, the court would be doing indirectly what it cannot do directly.

[21] In the present case, it is not obvious that the Plaintiff is attempting to do indirectly what it cannot do directly under the statutory scheme. The Federal Court of Appeal decision in *Apotex Inc. v. Merck & Co.*, 2009 FCA 187 at paras. 82-91 determined that s. 8 of the *PMNOCR* does not give rise to a claim for the profits of the patent holder. It made no determination as to whether a generic manufacturer can claim those profits pursuant to common law and equitable causes of action.

[22] Takeda also argues that the decision of the Supreme Court of Canada in *Jedfro Investments (U.S.A.) Ltd. v. Jacyk*, 2007 SCC 55 supports its position. However, in that case, the Court based its decision on a finding that the enrichment was pursuant to a valid contract between the parties (at paras. 33-34). The Court went on to hold that foreclosure proceedings "may" also provide a juristic reason for enforcement, as they were a "known and procedurally fair consequence of not paying the amount due" (at para. 35). In my view, *Jedfro* is distinguishable, as it deals with rights arising from contract. It is not clear that the same result would occur where a party invokes a statutory regime like the *PMNOCR*.

[23] Thus, it is not plain and obvious that the Plaintiff will fail. Given that the regulations create a permissive regime, and given the facts pleaded, it is not clear that compensation for unjust enrichment would undermine the statutory policy.

[24] That brings me to the issue of "corresponding deprivation". In the motion before the motions judge, Takeda relied on Abbott's submissions. Abbott did not argue that the plaintiff had failed to plead the material facts to show there was a deprivation corresponding to the benefit enjoyed by it. In the factum before the motions judge, Abbott stated (at para. 44):

> Essentially, Apotex alleges that Abbott enjoyed what it calls a "windfall gain" and that Apotex had a corresponding detriment through lost sales that would have been made had Abbott not invoked the *NOC Regulations* and thereby delayed Apotex's market entry. These allegations may be sufficient to establish what is known as the "enrichment-detriment" aspect of a claim for unjust enrichment.

[25] I find it difficult to accept that the motions judge erred with respect to the issue of deprivation, when the Defendants conceded that point before him. In any event, Apotex has pleaded facts showing that the Defendants' gains correspond to its deprivation, and it is not plain and obvious that the claim would fail on this ground.

[26] Given my conclusion that the Defendants have not satisfied the first part of the test in Rule 62.02(4)(b), I need not consider the second issue - whether the appeal would raise an issue of general importance.

[27] For these reasons, the motions for leave to appeal are dismissed. The parties agreed on the quantum of costs for the motions. Therefore, costs to the Plaintiff Apotex are fixed at $9,500.00 payable jointly and severally by the Defendants within 30 days.

K. Swinton J.
Swinton J.

Released: July 4, 2011