Intellectual Property Weekly Abstracts Bulletin — Week of April 3, 2017

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Patent Decisions

Court provides method for assessing quantum of Teva's section 8 damages
Teva Canada Limited v. Pfizer Canada Inc., 2017 FC 332
Drug: Pregabalin

In this case, the parties had asked the Court for specific rulings and guidance in calculating Teva's section 8 damages. The parties were in agreement that Teva is entitled to recover its losses or damages, but disagreed about many important aspects of how those losses should be determined.

On the issue of the relevant period for damages, both parties agreed that the end date of the liability period was February 14, 2013, the day the underlying applications were discontinued. Despite Teva's submissions for an earlier start date, the Court concluded that the patent hold date in August 2010 was the appropriate start date. The Court found that Ratiopharm (Teva took over Ratiopharm) had taken no steps in the real world to expedite the patent hold letter or even to inquire into its status, or to expedite its product monograph.

In determining Teva's share of the generic market, the Court concluded that there would have been no real impediments in the but-for world for Teva to launch Ratiopharm pregabalin on or about the patent hold date. The Court also found that there would have been no other generics who could have supplied the market at that time.

The Court considered the competitive landscape in the but-for world from third party generics, authorized generics, and Pfizer's own generic GenMed. However, there was insufficient evidence that third party generics could and would have entered the pregabalin market during the liability period, or that some other generic would have entered into an authorized generic agreement. The Court also found that Pfizer failed to establish that it would have launched its GenMed product, or that it would have been an effective competitor even if it had launched.

The Court then considered the other relevant factors, including formulary listing, pricing, trade-spend and other miscellaneous accounting and cost issues.

Order of prohibition dismissed in respect of two patents listed against dasatinib
Bristol-Myers Squibb Canada v. Apotex Inc., 2017 FC 296
Drug: dasatinib

The Court dismissed Bristol Myers Squibb's application for an order prohibiting the Minister from issuing an NOC to Apotex for its generic version of Sprycel®. The application related to two patents. Both patents, the '932 Patent and the '898 Patent, concern cyclic compounds (including dasatinib) and salts thereof, to methods of using such compounds in treating protein tyrosine kinase (PTK) associated disorders such as immunologic and oncologic disorders, and to pharmaceutical compositions containing such compounds.

With respect to the first patent, the Court found that Apotex's allegation of invalidity on the basis of inutility was justified. Contrary to the Applicants submissions, the Court concluded that there are clear references in the specification that support the view of an overarching promise for therapeutic utility against PTK-associated disorders, in addition to the specific therapeutic utilities disclosed in the use claims. The promised utility was not demonstrated, nor soundly predicted as of the relevant date.

With respect to the second patent, the Court found that Apotex's allegation of invalidity on the basis of obviousness and double patenting were justified. The invention in the asserted claims of the '898 Patent, is the oral use of the compound for the treatment of Chronic Myelogenous Leukemia (CML) and imatinib-resistant CML (imatinib was an earlier treatment for CML), respectively. The Court found it clear that, at the relevant time, there was significant motivation in the field of CML research to find an alternative therapy for treating CML and imatinib-resistant CML. Thus, the Court concluded that Apotex's allegation that it was more or less self-evident that trying to treat CML and imatinib-resistant CML with the compound ought to work is justified. The Court also found that Apotex's allegation that the nature of the work required to achieve the invention was routine was justified.

On the issue of double patenting, the parties argued over which date should be relevant to the double patenting analysis: the claim date of the first patent, the priority date of the second patent, or the publication date of the second patent. Only claim was at issue for this allegation, since the parties had agreed that if Apotex's allegation of obviousness for claim 1 was found to be justified, its allegation of obviousness-type double patenting for the same claim would also be justified.

The Court noted that if the relevant date was the first patent's filing date, then claim 3 would not be invalid for obviousness-type double patenting, because imatinib-resistant CML was not well known as of that date. However, if the relevant date was either of the two later dates, then the Court's finding that Apotex's allegation of obviousness for claim 3 was justified entails that claim 3 be invalid for obviousness-type double patenting. The Court agreed with the comments made by Justice Gleason in *E li Lilly Canada Inc v* Apotex Inc, 2015 FC 875, finding that the second patent's priority date was the appropriate date at which double patenting is to be analyzed. Therefore, Apotex's allegations of double patenting were justified for both claim 1 and claim 3 of the '898 Patent.

Trademarks Decisions

Appeal of the Trademark Opposition Board's decision rejecting opposition to HONEY MOMENTS allowed
Mcdowell v. Laverana GmbH & Co. KG, 2017 FC 327

The Court allowed an appeal of the Trademark Opposition Board's decision rejecting Ms. McDowell's opposition to the registration of the HONEY MOMENTS trademark for use in relation to a number of personal care, pharmaceutical and cosmetic products. On appeal, Ms. McDowell filed a substantial amount of new evidence that primarily addressed the extent to which she has used her HONEY marks in Canada. The Court was satisfied that this new evidence would have materially affected the Board's findings of fact and considered the matter de novo , while still taking the Board's decision into account as a relevant consideration.

In applying the test for confusion, the Court found that the factors in subsection 6(5) of the Trademarks Act favoured a finding of confusion. For example, the fact that many of the goods identified in the Respondent's application appear to target similar consumers to those targeted by Ms. McDowell's products, and that the channels of trade for the two sets of products are likely identical or very similar. This, along with Ms. McDowell's affidavit demonstrating continuous use of her HONEY marks in Canada since 2003, weighed heavily in Ms. McDowell's favour.

Additionally, the Court found that Ms. McDowell's HONEY marks possess at least some level of distinctiveness. The Board had originally found that the marks were not inherently distinctive, in light of the laudatory meaning of the word "honey". The Court noted that while the Board is entitled to take judicial notice of dictionary definitions of words found in trademarks, it is not entitled to take judicial notice of a single meaning without evidence, of which there was none in this case.

The Court also noted that the Board erred in drawing a negative inference from the state of the Register, which showed that seven third parties had registered trademarks that contained the word “honey” in association with personal care products. There was no evidence to establish that the marks were currently in use, or that they were in use as at the relevant material dates, nor was there evidence to establish that the marks were used in relation to wares or services that are similar to those of the parties, or the extent of any such use.

Balancing all of the relevant factors and surrounding circumstances, the Court was satisfied that Ms. McDowell had established that there is a real likelihood of confusion between her HONEY marks and the Respondent's HONEY MOMENTS mark. Accordingly, the appeal was allowed.

Other Decisions of Interest

Court dismisses JR of Minister's decision requiring additional information for approval of certain products manufactured or tested at two of Apotex's manufacturing facilities
Apotex Inc. v. Canada (Health), 2017 FC 315

The Court dismissed Apotex's application for judicial review, finding that Therapeutic Products Directorate of Health Canada's ("TPD") decision requiring additional

information prior to completing its review of NOC submissions for approval of certain new products that were manufactured or tested at two of Apotex's manufacturing facilities in India to be neither improper nor unreasonable.

The decision provided a detailed overview of the facts, including the three related decisions rendered by TPD, as well two earlier decisions of the Inspectorate restricting importation of drugs from two of Apotex's drug manufacturing facilities, which were quashed by the Court in 2015 FC 1161 (our summary here) and in 2016 FC 673 (our summary here).

The Court first looked at whether TPD's decision under review should be unlawful based on its proximity to a quashed decision. The Court noted that this is a legal question and reviewed it using a correctness standard.

The Court found that the relief requested could only apply to two drugs, Varenicline and Sitagliptin, whose submissions contain data from stability studies subject to the data integrity concerns. The Court also pointed out that Apotex has complied with TPD's requests for additional information rather than seek judicial review for the other 30 submissions subject to the data integrity concerns

The Court found that the evidence suggested that the importation ban was a catalyst for TPD's decision. However, Apotex was not able to convince the Court that the Minister's refusal to end her prohibition on granting NOCs for products manufactured or tested at two of Apotex's manufacturing facilities in India is inextricably bound up with, and based upon, the quashed importation ban.

Satisfied that the decision at issue was not tainted by the quashed decision, the Court went on to review the TPD's continuing requests for additional data for submissions subject to data integrity concerns on a reasonableness standard. TPD no longer requires additional information to support data generated at these two locations after January 2015. This is because TPD was able to conclude that the corrective and preventative measures implemented by Apotex rendered post-January 2015 data reliable. The Court ultimately concluded that it was not unreasonable for TPD to conduct a fresh review and to request additional information to address the data integrity concerns at those two locations, and those concerns for Varenicline and Sitagliptin in particular.

Industry Updates

Health Canada has released a Notice: Availability of Summary Basis of Decision Documents and Regulatory Decision Summaries on the Drug and Health Products Register.

Health Canada has released a Notice: Tablet Scoring of Subsequent-entry Pharmaceutical Products.

Health Canada and United States Food and Drug Administration have announced a joint public consultation meetings on International Council on Harmonisation Guidelines for Registration of Pharmaceuticals for Human Use. The website indicates that it will take place on April 24, 2017, 11am- 2pm, at the White Oak Campus of the U.S. FDA in Silver

Spring, Maryland, and that stakeholders will also be able to participate by webcast. Health Canada is also offering the opportunity for stakeholders to submit comments in writing for consideration by Health Canada and/or the U.S. FDA. The website indicates that comments will be accepted until April 20, 2017.

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