Federal Court Rejects Invalidity Arguments Relating to Metformin Extended Release Tablets

March 08, 2019

Valeant Canada LP v Generic Partners Canada Inc, 2019 FC 253

In this case, the Federal Court granted Valeant Canada LP (Valeant), an order prohibiting the Minister of Health from issuing a Notice of Compliance to Generic Partners Canada Inc. (Generic Partners) for their 500mg extended release tablets of metformin. Valeant markets tablets containing metformin in 500mg and 1000mg. In granting the order, the Federal Court rejected Generic Partners' argument that the 671 Patent is invalid for: (1) anticipation, (2) obviousness, (3) double-patenting in relation to the 624 Patent, or (4) insufficiency.

The Court found the inventive concept for the 671 Patent to be a controlled-release oral dosage form having three essential elements, relating to size, time, and shape. Further, when the three essential elements are combined, they create a gastric-retentive dosage form that provides for enhanced drug release in the stomach and upper gastrointestinal tract.

In rejecting the argument that the 671 Patent is invalid for anticipation, the Court held that the prior art document relied on by Generic Partners did not disclose the shape element of the 671 Patent.

In rejecting the argument that the 671 Patent is invalid for obviousness, the Court held that in the prior art relied on by Generic Partners, it was not suggested that the shapes were a central component of gastric retention. Without this insight, it could not be obvious to try the invention. The Court also held that the perfect embodiment of the tablet in the prior art document gave rise to the problem that the 671 Patent claimed to solve.

In rejecting the argument that the 671 Patent was invalid for double-patenting in respect to the 624 Patent, the prior art document relied on by Generic Partners was the basis for the 624 patent. The Court had already concluded that the prior art document did not anticipate the 671 Patent and therefore it was not possible for the 624 Patent to support an allegation of same-invention double-patenting. Similarly, the Court held that if the

consideration of all prior art did not make the 671 Patent obvious, the more restricted analysis based only on the 624 Patent also could not.

In rejecting the argument that the 671 Patent is invalid for insufficiency, the Court held that it is not necessary for an inventor to outline a theory of why the invention works. Thus, the lack of data and examples provided in the 671 Patent in support of the invention was deemed irrelevant to sufficiency. The Court therefore agreed with Valeant that the allegation of insufficiency was without merit.

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