

SHIRE DEVELOPMENT, LLC v. WATSON PHARMACEUTICALS, INC., Appeal No. 2016-1785 (Fed. Cir. February 10, 2017). Before Prost, Taranto, and Hughes. Appealed from S.D. Fla. (Judge Middlebrooks).

Background:

Watson filed an ANDA with the FDA seeking permission to market a generic version of Shire's patented drug, Lialda®, which is used to treat inflammatory bowel diseases. Shire sued Watson for infringement based on the ANDA filing.

Claim 1 of Shire's patent requires, among other things, (1) an inner lipophilic matrix consisting of the substances selected from the group consisting of the lipophilic substances recited therein, and (2) an outer hydrophilic matrix consisting of compounds selected from the group consisting of the hydrophilic compounds recited therein.

In Watson's drug, the alleged outer hydrophilic matrix contains a lipophilic substance. The district court found that Watson's lipophilic substance was "overwhelmed" by the hydrophilic matrix, and thus its presence was "unrelated" to Shire's invention. Because the lipophilic substance was unrelated to the invention, the lipophilic substance fell within the exception announced in *Norian Corp. v. Stryker Corp.*, 363 F.3d 1321 (Fed Cir. 2004) (infringement of a "consisting" claim is not avoided by including a component that is unrelated to the invention). Thus, the district court concluded that Watson infringed Shire's claims.

Issue/Holding:

Is the added component unrelated to Shire's invention? No, reversed and remanded.

Discussion:

The Federal Circuit found that Shire's invention is a multimatrix system that relies on the hydrophilic and lipophilic characteristics of the matrices to release the active component in the colon in a sustained and uniform manner. The Federal Circuit also found that the lipophilic substance does not lose its lipophilic properties when in the outer hydrophilic matrix. Because the lipophilic substance retains its lipophilic properties, the court further found that the inclusion of the lipophilic substance both structurally and functionally relates to Shire's invention. Therefore, the Federal Circuit concluded that the lipophilic substance is related to Shire's invention, and that the "consisting of" in Shire's claims excluded a lipophilic substance in the outer hydrophilic matrix. Thus, the *Norian* exception did not apply, and Watson did not infringe Shire's patent.

Shire argued that the purpose of Watson's lipophilic substance was for use as a lubricant, and that the lipophilic substance was not sufficient to render Watson's outer matrix lipophilic. Therefore, it was unrelated to the invention. Shire also argued that the Examples in its patent included a lipophilic substance in the outer hydrophilic matrix. Thus, the claims must be interpreted to cover this embodiment.

However, the Federal Circuit disagreed, finding that *Norian* did not restrict "related" components to only those that advance or are intended to advance a Markush group's allegedly inventive elements. The court reasoned that such a requirement would, in effect, equate the scope of a Markush group's "consisting of" language with either "comprising" or "consisting essentially of." The court also found that the presence of Examples in the specification is not sufficient to overcome the "exceptionally strong presumption" that "consisting of" is closed.