



## Federal Circuit Review

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### Patent Office Must Prove Prior Art Reference Is Enabling

In *In Re Steve Morsa*, Appeal No. 12-1609, the Federal Circuit affirmed the Board's rejection of certain claims as obvious, vacated the Board's rejection of certain claims as anticipated, and remanded for a proper enablement analysis.

Morsa filed several hundred claims directed to a benefits information database, two of which were rejected as anticipated by a short press release that announced the launch of an Internet-based benefit database product. Morsa appealed the anticipation rejection to the Board, arguing that the press release was not an enabling disclosure. The Board sustained the rejection and subsequently denied two requests for a rehearing on the issue of anticipation.

The Federal Circuit found that the Board had not performed a proper enablement analysis. In particular, the Federal Circuit rejected the Board's position that Morsa was required to submit affidavits or declarations from experts in the field in order to challenge the enablement of the press release.

The Federal Circuit explained that, while a prior art reference cited by an examiner is initially presumed to be enabling, the burden to demonstrate enablement shifts to the Patent Office after an applicant makes a "non-frivolous" argument that the reference is not enabling. If a reference does not appear to be enabling on its face, expert declarations are not necessary. The Federal Circuit determined that Morsa had satisfied his burden by providing "specific, concrete reasons" that the short and "less than illuminating" press release was not enabling.

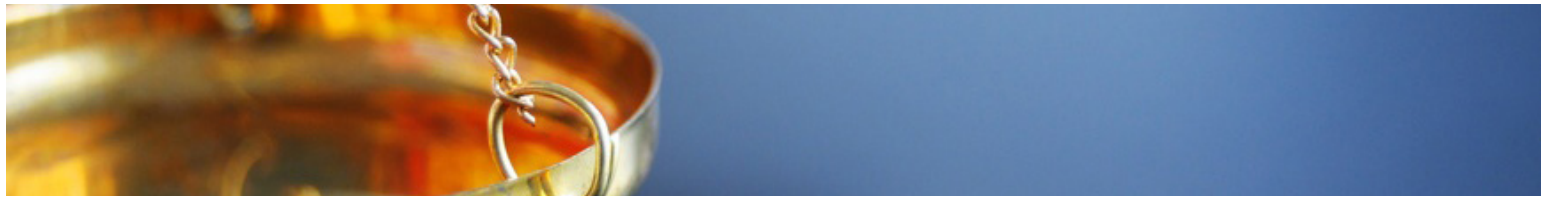
### Complaint Was Adequate Despite Non-Infringing Possibilities

In *K-TECH Telecommunications v. Time Warner Cable*, Appeal No. 12-1425, the Federal Circuit reversed the district court's dismissal of the plaintiff's complaint for failure to allege facts sufficient to state a plausible claim for patent infringement.

The district court granted Time Warner Cable's motion to dismiss K-TECH's complaint for patent infringement under Federal Rule of Civil Procedure 12(b)(6). In particular, the district court held that the complaint lacked sufficient factual specificity to state a cause of action for patent infringement under the standards articulated by *Twombly* and *Iqbal* because K-TECH merely alleged that TMC must operate some product or process in some way that infringes some claim of the asserted patents.

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- Complaint Was Adequate Despite Non-Infringing Possibilities
- FDA Approval Not Relevant to Obviousness Analysis



The Federal Circuit reversed, finding that K-TECH's amended complaint was adequate. The Federal Circuit rejected the district court's requirement that K-TECH preemptively identify and rebut potential non-infringing alternatives practiced by the defendant. Instead, the court found that FRCP Form 18, *Twombly*, and *Iqbal* require only notice and plausibility, and the adequacy of the facts pled depends on the breadth and complexity of both the asserted patent and the accused system, and the nature of the defendant's business activities. Given that the specific manner of operation of TWC's broadcast system is not ascertainable without discovery, K-TECH's complaint was adequate because it provided notice to TWC of K-TECH's patent claim, what K-TECH asserts TWC's systems do, and why TWC's systems allegedly infringe K-TECH's claims.

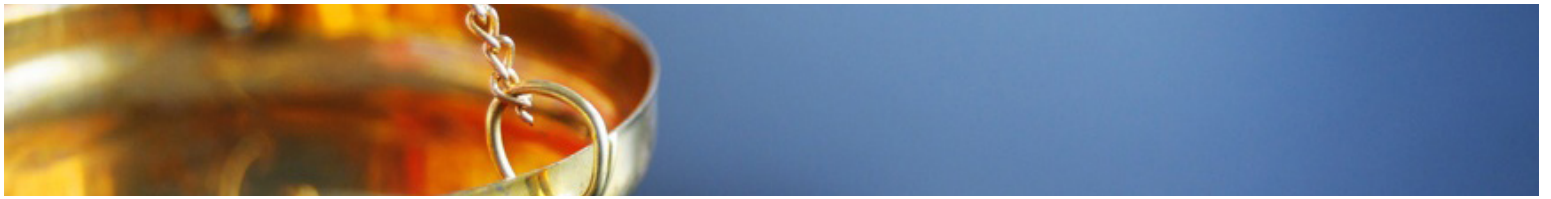
## **FDA Approval Not Relevant to Obviousness Analysis**

In *Allergan, Inc. v. Sandoz Inc.*, Appeal No. 11-1619, the Federal Circuit affirmed the district court's judgment of nonobviousness with respect to one claim and reversed the judgment with respect to other claims.

After a bench trial, the district court found that the asserted claims of four patents directed to a combination drug treatment were not obvious. Reversing in part, the Federal Circuit found a group of the asserted claims obvious. The Federal Circuit determined that the individual components of the claimed drug composition were available in the claimed concentration in the prior art and that the prior art provided motivation for the composition. The Federal Circuit disagreed with the district court that one of ordinary skill would not have been motivated to develop a fixed combination product to increase patient compliance because the FDA did not consider that particular motivation when evaluating drug applications. The Federal Circuit noted that there is no requirement in patent law that the person of ordinary skill be motivated to develop the claimed invention based on a rationale that forms the basis for FDA approval. In addition, the Federal Circuit emphasized that Sandoz must only show a reasonable expectation of success in developing the claimed invention, not in developing the product sold by Allergan.

Affirming in part, the Federal Circuit concluded that one asserted claim was not obvious. Sandoz failed to show that the prior art taught a reduction of doses of the claimed composition without a loss of efficacy. Moreover, Sandoz failed to argue that the efficacy limitation was inherent in the claimed composition or that a dose reduction without loss of efficacy would inherently flow from the obvious combination.

Judge Dyk dissented in part, arguing that all the asserted claims were obvious and that the limitation of avoiding a loss of efficacy was merely a result. A newly discovered result or property of an existing or obvious method of use is not patentable.



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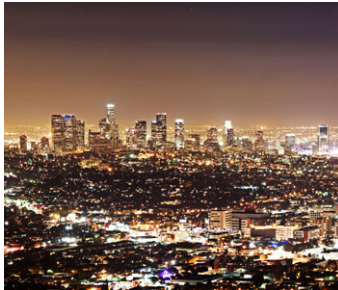
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