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Inherency Revisited

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In affirming a decision of the **U.S. Patent and Trademark Office (PTO)** Board of Patent Appeals and Interferences (Board) decision that affirmed an examiner's rejection of claims as being inherently anticipated, a divided panel of the U.S. Court of Appeals for the Federal Circuit reiterated that inherent anticipation requires enablement, but does not require that the inherent features are appreciated. *In re Montgomery et al.*, Case No. 11-1376 (Fed. Cir., May 8, 2011) (Dyk, J.) (Lourie, J., dissenting).

The Montgomery patent application claimed a method for the treatment or prevention of stoke by administering to a person diagnosed as in need of such treatment or prevention an inhibitor of the **rennin-angiotensin system (RAS)**. During examination of the application, the examiner finally rejected the claims as anticipated by each of four prior art references, including the HOPE reference. Each of the prior art references describe administering the drug ramipril, a known RAS inhibitor, to subjects who had known risk factors for stroke, such as hypertension. The HOPE reference described the design of a clinical study in which ramipril would be administered to more than 9,000 subjects "at high risk for cardiovascular events such as myocardial infarction and stroke." The HOPE reference discloses that patients had received ramipril or placebo for at least one month as of the publication date.

The Board affirmed the examiner's rejections finding that the claims had two elements: administering a RAS inhibitor, and to subjects diagnosed as requiring stroke treatment or prevention. According to the Board, both elements were met by the prior art administration of ramipril to subjects with hypertension and at risk of

stroke. Montgomery appealed.

On appeal, the Court construed the claims as requiring 1) administering ramipril, 2) to subjects diagnosed as requiring stroke treatment or prevention, and 3) for the treatment or prevention of stroke. It then focused its analysis on the HOPE reference in light of the claims. Montgomery did not contest that elements 1 and 2 were met by HOPE, but urged that HOPE did not disclose actual performance of the claimed method because it did not disclose actual administration of ramipril in amounts that treat or prevent stroke.

The panel majority disagreed, stating that their precedent holds that anticipation requires enablement, not actual reduction to practice. In addition, the Court found that the actual administration of ramipril in the HOPE reference treated hypertension, a risk factor for stroke, and therefore HOPE inherently discloses stroke prevention even if it was not appreciated by the authors. A further factor was a concession at oral argument that the HOPE authors could have obtained the claims at issue based on their disclosure.

In dissent, Judge Lourie criticized the application of an "unbounded" concept of inherency that prevents patenting of inventions that were not known, used or benefited from. In his view, the keystone of inherency is that the claimed invention must have necessarily resulted from the practice of the prior art reference, and HOPE did not meet this standard.

Practice Note: The majority decision focused on whether the claimed method had been performed in the prior art and whether the results needed to be appreciated. In 2003 Judge Lourie similarly dissented in the denial of the petition for rehearing *en banc* in *Schering Corp. v. Geneva Pharmaceuticals* (see *IP Update, Vol. 6, No. 8*), cited by the majority that held inherent anticipation requires enabling disclosure but not actual performance and rejected the notion that inherent results must be appreciated in the prior art.