RUTGERS
Law School

Rutgers, The State University of New Jersey
217 N. Fifth Street
Camden, NJ 08102-1203

Michael A. Carrier
Distinguished Professor

mcarrier@camlaw.rutgers.edu
Tel: (856) 225-6380

August 25, 2016

Comments on Proposed Update on Intellectual Property Licensing Guidelines

I applaud the agencies for updating the Intellectual Property (IP) Licensing Guidelines. I have two general reactions.

First, in these (or supplemental) guidelines, the agencies could consider addressing IP licensing issues related to (1) standard essential patents (SEPs), (2) patent assertion entities (PAEs), and (3) drug patent settlements. Although addressed in agency orders and speeches, each of these topics could benefit from further elaboration in the form of guidelines.

Second, to offer a more nuanced analysis, the agencies in three places could recognize the crucial regulatory and industry context.

Suggestion 1: At the end of footnote 13 on page 6, consider adding this sentence: "This general statement may be modified given the regulatory context."

Reason: Regulatory regimes may promote goals other than fostering incentives for investment and innovation. Brand drug companies, for example, have used restricted-distribution schemes to prevent generic firms from engaging in bioequivalence testing, which prevents them from entering the market. This contravenes a central objective of the Hatch-Waxman Act of encouraging generic entry and is the focus of the pending bipartisan CREATES Act. The regulatory setting was vital to the *Trinko* decision, and absent a recognition of this context, the agencies' proposed revision could neglect important government objectives.

Suggestion 2: At the end of footnote 17 on page 9, consider adding this sentence: "On the other hand, the creation and exploitation of massive patent portfolios could threaten concern as they are valuable because of their size rather than the validity of each patent in the portfolio."

Reason: Although aggregation could address the "double marginalization" problem in which different firms apply their own markups, large patent portfolios also could present significant anticompetitive effects including patent holdup, raising rivals' costs, and even increased price and reduced innovation. *See* Michael A. Carrier, *Patent Assertion Entities: Six Actions the Antitrust Agencies Can Take*, at 2-3, CPI ANTITRUST CHRONICLE (Jan. 2013).

Suggestion 3: Consider adding a footnote after "specific firms" on the last line of text on page 16 and then adding a new footnote: "The anticompetitive effects presented in, and need for the use of, research-and-development markets may vary based on industry."

Reason: Many of the criticisms that have been leveled against R&D markets apply much less, if at all, in certain settings. Pharmaceutical R&D, for example, is characterized by specific firms that can be identified, the absence of inefficient duplication, and the importance of competition for innovation. *See* Michael A. Carrier, *Two Puzzles Resolved: Of the Schumpeter-Arrow Stalemate and Pharmaceutical Innovation Markets*, 93 IOWA L. REV. 393, 401-14 (2008).

Thank you for your consideration.

[REDACTED]

Michael A. Carrier