To: Hiram H. Bernstein
From: Nancy J. Linck
Subject: Comments re Proposed Rulemaking relating to Rule 56
Date: September 12, 2011

I offer the following comments and suggestions in my personal capacity, as a former Solicitor and APJ who has great interest in the success of the Office, and not as a representative of my firm.

I applaud the Office's proposal to match the materiality standard defined in *Therasense*. Leaving Rules 56 and 555 as they presently read, or offering a different standard, would greatly confuse those before the Office and the courts and would likely frustrate the goals of the Federal Circuit in *Therasense*. Further, defining the standard in terms of *Therasense* will permit the rules to evolve as the *Therasense* standard is further defined by the courts. While some may criticize this fact as a disadvantage, I disagree with such criticism. Tying the rules to the case will avoid the need to revise the rules frequently.

I have two minor suggestions (both made for the same reason):

First, proposed Rule 56 states: "The Office would not allow a claim if it were aware of the information . . . ." I believe language that would better reflect the *Therasense* test is: "The Office would not have allowed a claim if it had been aware of the information . . . ." It seems to me the time frame is important. To determine whether the alleged withholding of the information would have been material to the examination of the application, one should consider the alleged improper withholding at the time it occurred. Thus, the perspective should be at that particular time rather than at present.

Likewise, proposed Rule 555 states: "The Office would not find a claim patentable if it were aware of the information …." Please consider instead: "The Office would not have found the claim patentable if it had been aware of the information . . . ." Again, the time frame is important for the reasons given above.

As to both of these recommended changes, During litigation, the prosecution histories are likely to be used to shed light on the materiality issue. I believe that's appropriate. Such analyses are only relevant, if the time frame is when the alleged withholding took place. At any other time, it will be difficult to conduct a fact-based analysis.

One alternative, unrelated, suggestion: Did you consider getting rid of these rules? Since the Office is not in the business of enforcing them, it might make sense just to eliminate them.