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# Biotechnology and Pharmaceutical Litigation

Ernie Linek

## Bits & Pieces—Update on Inequitable Conduct

On April 26, 2010, the Court of Appeals for the Federal Circuit issued an order granting en banc review of the panel decision in *Therasense v. Becton Dickinson & Co.* [Appeal No. 2008-1511].

This case originally came to the Federal Circuit following a bench trial at which the Northern District of California court found that claims 1–4 of U.S. Patent No. 5,820,551 were invalid due to obviousness and that the entire '551 patent was unenforceable due to inequitable conduct.

The original Federal Circuit panel of Judges Dyk, Linn, and Friedman (with Dyk writing for the panel and Linn dissenting relating to the inequitable conduct ruling) affirmed.

The original decision was reported in my last column, and as I stated there, the duty of disclosure once again was expanded by the Federal Circuit such that patent practitioners must now consider citing all information from the prosecution of related foreign patent applications. Also in my last column I asked: How is the default position of “cite everything,” which can entail hundreds (or thousands) of documents, helpful to a patent examiner?

It now looks like the Federal Circuit is willing to rethink its position on this subject. The order granting en banc review stated that:

1. The petition of Plaintiffs-Appellants Abbott Diabetes Care, et al. for panel rehearing is denied.

2. The petition of Plaintiffs-Appellants Abbott Diabetes Care, et al. for rehearing en banc is granted.

3. The court's January 25, 2010, opinion is vacated, and the appeal is reinstated.

4. The parties are requested to file new briefs addressing the following issues:

a. Should the materiality-intent-balancing framework for inequitable conduct be modified or replaced?

b. If so, how? In particular, should the standard be tied directly to fraud or unclean hands? [See *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806 (1945); *Hazel-Atlas Glass Co. v. Hartford-Empire Co.*, 322 U.S. 238 (1944), overruled on other grounds by *Standard Oil Co. v. United States*, 429 U.S. 17 (1976); *Keystone Driller Co. v. Gen. Excavator Co.*, 290 U.S. 240 (1933).] If so, what is the appropriate standard for fraud or unclean hands?

c. What is the proper standard for materiality? What role should the US Patent and Trademark Office's rules play in defining materiality? Should a finding of materiality require that but for the alleged misconduct, one or more claims would not have issued?

d. Under what circumstances is it proper to infer intent from materiality? [See

*Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867 (Fed. Cir. 1988) (en banc).]

e. Should the balancing inquiry (balancing materiality and intent) be abandoned?

f. Whether the standards for materiality and intent in other federal agency contexts or at common law shed light on the appropriate standards to be applied in the patent context.

This appeal will be heard en banc on the basis of the original filed briefs, additional briefing ordered, and oral argument. Patent prosecutors will want to monitor this case and review the briefs filed—as they should prove to be very interesting. Clearly this issue is out of control and some rational changes are required. Unfortunately, I do not foresee the Court making sweeping changes in this area. I believe that the proper remedial action will have to come from Congress.

## Bilski Update

We continue to wait for the Supreme Court's decision in the *Bilski* case. My prediction is a decision much like the Supreme Court's *KSR* decision—the “rigid” test of the Federal Circuit will be criticized as being too rigid—but, as in *KSR*, the machine or transformation test may be appropriate in certain cases, but it will not necessarily apply to all cases, and some guidance will be given by the Court, as was done in *KSR*.

## Patent Term Adjustment Updates

Patentees who have filed Requests for Recalculation of Patent Term Adjustments (PTAs) in view of the *Wyeth* case should now be receiving decisions on those Requests. These decisions should be reviewed very carefully, as mistakes have been found in PTA calculations made under the

*Wyeth* standard. One error that has been detected recently involves patents in which an after-allowance filing occurred, such as an Information Disclosure Statement or Amendment under 37 C.F.R. §1.312.

In these cases, the PTO has been erroneously charging applicants for a “delay” based on the time from the filing of these documents until the grant date of the patent. Instead the PTO should be calculating the “delay” period from these filings only until the date on which the after-allowance filings received a response from the PTO, as required under 37 C.F.R. §1.704(c)(10)(i).

Responding to a telephone inquiry from a Banner & Witcoff lawyer, a PTO official acknowledged this new PTO error and indicated that they are working to issue new decisions for patents with the errors to replace the mistaken decisions as soon as possible.

The intent is that applicants will not need to file Requests For Reconsideration of Decision under 37 C.F.R. §1.705(b)(2). Such a request has a period for filing of the longer of 30 days or one month from the date of decision, is not extendible and inclusive of a fee. The PTO official suggested that those in need wait until the last possible day before filing a Request for Reconsideration, in hope that the PTO will have mooted the need to do so by issuing a new Decision on Request For Recalculation.

So check your PTA determinations and look for errors that must be addressed within the timeframe for filing a Request for Reconsideration.

### ***New PTA Cases***

Plaintiff: Schering Corporation  
Defendant: David Kappos (USPTO)  
Patent Number: 7,612,058  
Date Filed: 4/30/2010

Plaintiff: Kinaxis Holdings Inc.  
Defendant: David Kappos (USPTO)  
Patent Number: 7,610,212

Date Filed: 4/2/2010

Plaintiff: Tepha, Inc.  
Defendant: David Kappos (USPTO)  
Patent Number: 7,025,980  
Date Filed: 4/12/2010

Plaintiff: Cummins-Allison Corporation  
Defendant: David Kappos (USPTO)  
Patent Number: 7,602,956  
Date Filed: 4/8/2010

### ***Fed. R. Civ. P. 8— Plausible Pleadings***

A complaint for patent infringement that conforms to Form 18 of the Federal Rules of Civil Procedure has been held to be sufficient to withstand a motion to dismiss under the plausible pleadings requirements set down by the Supreme Court in *Bell Atlantic v. Twombly* [550 U.S. 544 (2007)] and in *Ashcroft v. Iqbal* [129 S. Ct. 1937 (2009)]. See Federal Circuit case decision—Form 18 OK!

So far, one District Court has held that Form 18 satisfies the plausible pleadings requirements of these cases. Chief Judge Robinson of the US District Court for the District of Delaware has confirmed that a complaint alleging infringement based on Fed. R. Civ. P. Form 18 (2006) will be sufficient to survive a motion to dismiss. [S.O.I.TEC Silicon On Insulator Technologies, S.A. v. MEMC Electronic Materials, Inc., C.A. No. 08-292-SLR, Memo. Order (D. Del. Feb. 20, 2009).]

The Court found that a plaintiff does not need to specify particular products or manufacturing details nor does a plaintiff need to set forth specific factual allegations in support of a claim for willful infringement.

### ***False Marking Cases—Update***

The patent laws have imposed liability for “false patent marking” since the Patent Act of 1842. Until recently, relatively few false marking

cases were filed. However, between January 1, 2010 and April 26, 2010, over 200 such cases have been filed with many more expected.

Section 292(a) provides for a penalty against “[w]hoever marks upon, or affixes to, or uses in advertising in connection with any unpatented article, the word ‘patent’ or any word or number importing that the same is patented, for the purpose of deceiving the public.”

These *qui tam* cases are filed by a party on behalf of the Federal Government, and each will receive one half of any damages award. These cases are based on old British legal actions that were designated as “*qui tam pro domino rege quam pro se ipso in hac parte sequitur*” literally, “who pursues this action on our Lord the King’s behalf as well as his own.”

In December 2009, the Court of Appeals for the Federal Circuit issued its decision in *Forest Group, Inc. v. Bon Tool Co.* [(S.D. Tex 2010)]. This case rejected a century-old interpretation of the false marking statute, 35 U.S.C. §292, which had held that the mismarking of a number of products was one violation of the statute. In *Forest Group*, the court held that each individual mismarked product was now a violation of the statute and thus, each product was subject to the statutory maximum fine of \$500.

The term “unpatented article” means “that the article in question is not covered by at least one claim of each patent with which the article is marked.” [*Clontech Laboratories Inc. v. Invitrogen Corp.*, 406 F.3d 1347, 1352, 74 U.S.P.Q. 1598 (Fed. Cir. 2005) (93 PTD, 05/16/05).]

More importantly (and I believe erroneously) “an article that was once covered by a patent that has now expired is, for the purposes of the statute, an “unpatented article.” [*See Pequignot v. Solo Cup Co.*, 540 F. Supp. 2d 649, 653, 87 USPQ 1365 (E.D. Va. 2008) (62 PTD, 04/1/08).]

In my opinion, once a patent has been granted on a product that product is forever “a patented product.” The fact that the patent has expired does not change the fact that the product is a “patented product.” The notice function of the marking statute has two aspects: First, it gives the public notice that the patent exists, and they can see what is protected by the claims; but equally as important is the second function, namely the patent marking allows the public to readily determine what is now in the public domain once the patent has expired.

### ***Remand Decision in Forest Group v. Bon Tool***

In its 2009 decision, the Federal Circuit remanded the *Bon Tool* case with instructions to the district court to recalculate the false marking fine owed to the defendant-counterclaimant.

In particular, the Federal Circuit held that each falsely marked article represented a separate and distinct act of false marking, each subject to a fine of up to \$500.

On remand, Judge Atlas of the Southern District of Texas determined that the false-marking fine should at least recapture all of the revenue generated from the sale Forest’s falsely-marked products.

Here, Forest had sold falsely marked stilts “at prices between \$103.00 and \$180.00.” The court then set the false-marking fine at the highest price-point of \$180 per article. Because only 38 pair of falsely marked stilts was sold, the total fine was relatively small—less than \$7,000. Half of the fine will be given to the US Government and half collected by Bon Tool.

The Court found that the appropriate fine in this case is \$180.00 per article, the highest point of the price range. According to the judge, this fine will deprive Forest of more than it received for the falsely-marked stilts, fulfilling the deterrent goal of Section 292’s “fine provision.” Based on the \$180.00 per article fine for the 38 falsely-marked stilts of which there was evidence at trial, the Court imposes against Forest a fine of \$6,840.00 pursuant to Section 292.

Judge Atlas based her decision on the Federal Circuit’s three stated policy goals of Section 292, namely: (1) discouraging mismarking; (2) encouraging enforcement; and (3) avoiding “disproportionately large penalties.” Bon Tool had asked for the maximum \$500 per offense (\$19,000). Forest argued that the fine should be limited to its profits on the falsely-marked products of \$2,400.

Congress is not pleased with the rash of false marking cases that

recently have been filed in the Federal Courts. Presently, 35 U.S.C. §292(b) provides that “[a]ny person may sue for the [false marking] penalty, in which event one-half shall go to the person suing and the other to the use of the United States.” The Senate has proposed legislation that amends Section 292(b) to read as follows:

(b) A person who has suffered a competitive injury as a result of a violation of this section may file a civil action in a district court of the United States for recovery of damages adequate to compensate for the injury.

The proposed legislation is designed to be retroactive. As it states, the amendment would “apply to all cases, without exception, pending on or after the date of the enactment of this Act.”

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*Ernie Linek is a principal shareholder of Banner & Witcoff, Ltd. This article is for educational and informational purposes only and should not be construed in any way as legal advice. The article reflects the opinion of the author and should not be attributed to the firm Banner & Witcoff or to any of its clients. Mr. Linek may be contacted at [ELinek@bannerwitcoff.com](mailto:ELinek@bannerwitcoff.com)*

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