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Bradley Arant Boult Cummings

Intent to Deceive and False Marking, a New Standard?

One of the elements of a claim for patent infringement is that the infringer had notice of the infringement and ignored such notice. Marking patented goods with appropriate patent numbers satisfies the notice requirement. However, marking goods as patented comes with a price.

35 U.S.C. 292 provides that all who falsely mark a good as patented or patent pending, when it is unpatented or not patent pending "shall be fined not more than $500 for every such offense" and provides that "any person may sue for the penalty." The elements of a Section 292 claim are falsely marking an unpatented good with intent to deceive the public.

The Federal Circuit Court of Appeals (the "Federal Circuit") recently clarified the law regarding the correct measure of penalties for false marking in *The Forest Group, Inc. v. Bon Tool Company* holding that Section 292 requires a penalty for each unpatented good falsely marked. The *Forest Group* decision is a departure from previous law, which generally provided lower penalties and a more patent-holder-friendly interpretation of Section 292. Accordingly, whether or not a patent holder's actions were intended to deceive the public is now more important than ever and the Federal Circuit recently clarified the law concerning the intent to deceive standard in *Pequignot v. Solo Cup Company*.

Solo is a leading manufacturer of disposable cups, bowls and plates and was the owner of US Patent No. 4,589,569 and Re 28,797 which covered plastic cup lids. Pursuant to 35 U.S.C. 287, Solo marked its patented products with the appropriate patent numbers. A thermoforming stamping machine is used to manufacture the lids that had the appropriate patent numbers added to the molds. The molds can last up to 20 years before needing to be replaced. As Solo's patents began to expire, it sought the advice of counsel concerning whether or not it needed to take the expired patent numbers off of the molds and eventually decided that it would remove expired patent numbers from the molds as they wore out and needed to be replaced. Additionally, on the advice of counsel, Solo added the following to its packaging materials "This product may be covered by one or more US or foreign pending or issued patents" and directed customers to its website for more details. Solo knew that some of the products contained in the packaging were not covered by any valid patent.

In 2007, Pequignot sued Solo under Section 292 alleging false marking of products under the above-referenced patents. Pequignot accused Solo of mis-marking over 21 billion products. The trial court granted Solo's motion for summary judgment finding that Solo did not intend to deceive the public with its patent marking procedure and Pequignot appealed that ruling.

The Federal Circuit affirmed the trial court, finding that Solo did not intend to deceive the public. The Federal Circuit tackled two major issues in the opinion, first, was marking a good that was previously patented (but that patent had expired or become invalid) with a designation that the good "may be patented" false marking under Section 292? Secondly, what is the presumption accompanying the intent to deceive element when the patent holder knowingly makes a false statement concerning a product?

First, the Federal Circuit held that "an article covered by a now-expired patent is unpatented" for Section 292 purposes. The court noted that many of the same public policies apply to marking goods with inapplicable patent numbers and expired patent numbers as determining whether a patent has expired can be a difficult process as the patent term depends on the date the patent was filed and whether or not any patent term extensions or

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adjustments have been granted. Accordingly, articles marked with expired patent numbers are falsely marked for Section 292 purposes.

Secondly, the court tackled the issue of whether Solo's intent to deceive the public had been proven by Solo's admission that it knew some of its patents covering the goods at issue had expired and the labeling of packing with the "may be covered language" while knowing that some products inside the package were not protected. Pequignot argued that if he proved Solo's statements were false and that they knew them to be false, an irrebuttable presumption that Solo intended to deceive the public was created. Solo argued that the presumption was a rebuttable presumption of intent to deceive the public. The court agreed with Solo.

The court noted that the "bar for proving deceptive intent here is particularly high given that [Section 292] is a criminal [statute], despite being punishable with only a civil fine." A purpose of deceit and conscious desire to deceive the public is required under Section 292.

Solo was able to show by a preponderance of the evidence that it did not have the requisite purpose to deceive. First, the court noted that Solo acted, in good faith, on the advice of counsel in adopting and following a policy to remove expired patent numbers from marked goods. Further, Solo's plan to remove expired patent numbers from molds as they replaced worn molds was reasonable and arose out of a desire to reduce costs and business disruption rather than to deceive the public. Next, the court agreed with Solo that the "may be covered language" on its packaging is actually true in many situations, some contents of the package were covered by patents while some were not. The court found it "highly questionable" that the public would be reasonably deceived into believing that the products in the packaging were definitely covered by a patent. Further, Solo again adopted this practice on the advice of counsel. In short, Solo successfully rebutted the presumption that its actions were intended to deceive the public.

Pequignot will undoubtedly influence the constantly changing arena of false marking cases. False marking cases have become more and more numerous since the *Forest Group* decision with approximately 150 new false marking cases being filed since *Forest Group* was decided in December of 2009. *Pequignot* offers patent holders concrete examples of evidence that may rebut any claim that they intended to deceive the public with their patent markings, the most important of which seem to be following advice of counsel and adopting (and following) a patent marking policy that has sound business foundations (such as reducing costs and production delays).

Parallel Review Between the CMS and the FDA

With the recent inking of a Memorandum of Understanding ("MOU") between the Centers for Medicare & Medicaid Services ("CMS") and the Food and Drug Administration ("FDA") concerning sharing information and expertise, these two agencies are inching toward parallel reviews for marketing approval and Medicare coverage.

Although released in early July, the MOU (MOU 225-10--0010) became effective on June 25, 2010. Dr. Jeffrey Shuren (Director, Center for Devices & Radiological Health) announced that the MOU will allow routine and timely sharing of information and expertise between the FDA and CMS. While the goal of this inter-agency information sharing may be to create a mechanism which permits Medicare payment and coverage determinations by CMS and pre-market review by the FDA to occur concurrently, Dr. Shuren made clear in his announcement that these activities would occur at manufacturer's request.

While the FDA and CMS may be on a course toward parallel reviews, the MOU does not address these activities directly and provides a general framework for the two agencies to "work together to promote initiatives related to the review and use of FDA-regulated drugs, biologics, medical devices, and foods, including dietary supplements." In addition to enhancing information sharing through more efficient and robust activities, the MOU goals include promoting efficient utilization of tools and expertise for product analysis, validation, and risk identification and building an infrastructure and processes that meet the common needs for evaluating the safety, efficacy, utilization, coverage, payment, and clinical benefit of drugs, biologics, and medical devices.

Representatives of CMS and the FDA will meet this summer to establish specific procedures and safeguards which are necessary to implement the MOU and then periodically on an as-needed basis thereafter. "Unless and until adequate procedures and safeguards are established and implemented," the two agencies have agreed not to share information under the MOU.

From industry's perspective, the MOU identifies several important guidelines or requirements for the way in which the information sharing procedures will operate:

1. Each agency will appoint a single contact person who will be responsible for facilitating activities under the MOU. The point of contact will receive and act on the other agency's initial request for information; however, assuming agreement to share the requested information, subsequent communications regarding the issue may occur at the staff level.

2. In response to a particular request, each agency may decide not to share information or expertise or to limit the scope of a particular request for information and expertise. The basis for denying a request includes reasonableness of the request, the amount of resources required to perform the request, the responding agency's priorities, and legal restrictions. If the two agencies cannot agree on a decision to share or not to share information, senior officials at each agency will reach a final decision.
3. Certain types of information must be protected from unauthorized disclosure. These include (i) trade secrets and other confidential commercial information and personal privacy information that would be protected under a specific Freedom of Information Act ("FIOA") exemptions and (ii) information that otherwise would be protected under the federal Trade Secret Act, Privacy Act, Food, Drug, and Cosmetic Act, FIOA, and HIPAA and related rules and regulations.
4. Each agency must notify the other of any actual or suspected unauthorized disclosure of shared information. If a third party's confidential information is shared and then improperly disclosed, there is no additional requirement that the originating agency that shared the confidential information give the third party notice of the unauthorized disclosure. Third parties appear to be left to the reporting or notice requirements imposed under statutes or regulations; the MOU does not address this.
5. As part of the MOU implementation, CMS and the FDA must adopt "proper safeguards against unauthorized use and disclosure of the shared information", including policies and procedures to ensure that the information will be used "solely in accordance with" specific federal statutes and related regulations. These include the federal Trade Secrets Act, Privacy Act, Food, Drug, and Cosmetics Act, and FIOA, as well as HIPAA. The MOU also requires CMS and the FDA to establish "appropriate administrative, technical, procedural, and physical safeguards" to protect confidentiality and prevent unauthorized access.
6. Each agency can allow access to the shared information only to its employees, agents, and officials "who require access to perform their official duties" in accordance with the shared information uses outlined in the MOU. CMS and the FDA also must advise these individuals of (i) the confidential nature of the shared information, (ii) the safeguards required to protect the shared information, and (iii) the administrative, civil, and criminal penalties for non-compliance.
7. Any FOIA request will be referred to the originating agency which provided the shared information and the requestor will be notified of the referral and that the originating agency will provide the response.

The MOU also contains restrictions regarding the use of the shared information, including:

a. The shared information may be used "solely for the purposes outlined in the MOU." However, if a requesting agency seeks another use or purpose, this additional use must be submitted to the originating agency in writing, and the originating agency will determine whether or not the requested use is acceptable.
b. The FDA's and CMS' actions under the MOU must be consistent with existing laws and regulations.
c. Nothing in the MOU is to be construed as changing the current requirements and regulations which are administered or enforced by CMS or the FDA (including the federal Food, Drug, and Cosmetics Act and the Public Health Service Act) or is to be a mandate or requirement imposed on either the FDA or CMS that is in addition to those imposed by existing law.

For those who are concerned that this inter-agency information sharing will result in the respective agencies' determination of national cover age for a product (in the case of CMS) and a product's pre-market review (in the case of the FDA) influencing the other, these reminders that the well-developed jurisdictions of the FDA and of CMS are to remain intact and are not be eroded may not be sufficient. The test, of course, is the implementation of the MOU and actual information sharing activities.

While manufacturer's and their investors may want to reduce the time between FDA market approval and CMS approval for national payment, there is potential downside to the supposed efficiencies of a parallel review process. CMS and the FDA historically have had different missions and different perspectives; it is appropriate to co-mingle these? What do third parties risk if their proprietary information is shared with CMS, an agency without a statutory requirement to safeguard third party proprietary information (or, arguably, related cultural imperative to do so)?

Will the FDA's use of CMS' post-market information for products become an accurate and efficient method to speed along the FDA review? Will FDA decisions be made with adequate clinical data to support a CMS determination of national coverage? Do manufacturers and sponsors want to run the risk that the FDA and CMS may collect and interpret seemingly useful information differently and that these differences may result in delays necessitated by required corrections or reinterpretations, as well as unanticipated costs? Will reimbursement planning become a required element for market clearance so that post approval clinical data is no longer essential for reimbursement decision

making? Will these concerns, and others, make manufacturers and sponsors think twice before applauding this information sharing initiative or agreeing that their confidential information can or should be shared?

Given the possibility (or reality) that CMS' reimbursement concerns may become an element in the FDA's determination of the product's safety and market clearance and that implementation of the shared information activities undoubtedly will have some unexpected and unintended consequences, industry members may be pleased that currently the FDA and CMS are moving slowly along a path toward parallel review. And, because of the uncharted details in this arena, they may welcome Dr. Jeffrey Shuren's recent statement to the effect that "parallel review is not a done deal" and the opportunity to monitor the development of parallel review procedures.

Office Locations:

ALABAMA
One Federal Place
1819 Fifth Avenue North
Birmingham, AL 35203
205.521.8000

200 Clinton Avenue West
Suite 900
Huntsville, AL 35801
256.517.5100

The Alabama Center
for Commerce
401 Adams Avenue
Suite 780
Montgomery, AL 36104
334.956.7700

MISSISSIPPI
188 E. Capitol Street
Suite 450
Jackson, MS 39201
601.948.8000

NORTH CAROLINA
100 North Tryon Street
Suite 2690
Charlotte, NC 28202
704.338.6000

TENNESSEE
Roundabout Plaza
1600 Division Street
Suite 700
Nashville, TN 37203
615.244.2582

WASHINGTON, DC
1133 Connecticut Avenue NW
12th Floor
Washington, DC 20036
202.393.7150

Team Members

Keith S. Anderson
(205) 521-8714
kanderson@babc.com

Marc James Ayers
(205) 521-8598
mayers@babc.com

Joseph S. Bird
(205) 521-8473
jbird@babc.com

Hall B. Bryant
(256) 517-5187
hbryant@babc.com

Philip H. Butler
(334) 956-7602
pbutler@babc.com

Frank M. Caprio
(256) 517-5142
fcaprio@babc.com

James W. Childs
(205) 521-8207
jchilds@babc.com

Joycelyn J. Eason
(704) 338-6033
jeason@babc.com

James W. Gewin
(205) 521-8352
jgewin@babc.com

S. Revelle Gwyn
(256) 517-5146
rgwyn@babc.com

Stephen H. Hall
(256) 517-5140
shall@babc.com

Tripp Haston
(205) 521-8303
thaston@babc.com

W. Justin Hendrix
(256) 517-5116
jhendrix@babc.com

Andrew B. Johnson
(205) 521-8295
ajohnson@babc.com

Jonathan D. Kipp
(205) 521-8361
jkipp@babc.com

Nicholas Landau Ph.D.
(205) 521-8545
nlandau@babc.com

Matthew C. Lonergan
(615) 252-2322
mlonergan@babc.com

Scott E. Ludwig
(256) 517-5149
sludwig@babc.com

J. William Manuel
(601) 592-9915
wmanuel@babc.com

Kimberly B. Martin
(256) 517-5155
kmartin@babc.com

Benjamin L. McArthur
(256) 517-5124
bmcarthur@babc.com

William C. McGowin
(334) 956-7664
wmcgowin@babc.com

Elizabeth Brislin Mitchell
(205) 521-8360
emitchell@babc.com

Russell B. Morgan
(615) 252-2311
rmorgan@babc.com

Dorothy Daigle Pak
(205) 521-8279
dpak@babc.com

George R. Parker
(334) 956-7607
gparker@babc.com

Kenneth M. Perry
(205) 521-8312
kperry@babc.com

Gregory T. Peterson
(205) 521-8084
gpeterson@babc.com

Robert Emmett Poundstone
(334) 956-7645
bpoundstone@babc.com

J. Scott Richardson
(615) 252-2353
srichardson@babc.com

Jon Rose
(615) 252-2308
jrose@babc.com

Anne Marie Seibel
(205) 521-8386
aseibel@babc.com

Christopher A. Sloan
(615) 252-2392
csloan@babc.com

Jeremy A. Smith
(256) 517-5141
jasmith@babc.com

Rusha C. Smith
(205) 521-8010
rsmith@babc.com

Charles A. Stewart
(334) 956-7608
cstewart@babc.com

James V. Stewart
(205) 521-8087
jstewart@babc.com

Mark Swanson
(256) 517-5125
mswanson@babc.com

Darrell C. Tucker, II
(205) 521-8356
dtucker@babc.com

Thor Y. Urness
(615) 252-2384
turness@babc.com

Brian Alexander Wahl
(205) 521-8593
bwahl@babc.com

Katherine Suttle Weinert
(205) 521-8802
kweinert@babc.com