

AstraZenica's Process Patent Claims for PRILOSEC® Invalidated on "Inherent Anticipation" Grounds

Omeprazole, the generic name for the popular anti-heartburn drug PRILOSEC®, operates in a unique manner by transforming into its active ingredients in the acid-producing cells of the stomach lining and then inhibiting gastric acid production. Because omeprazole degrades in acidic and neutral environments, it must be protected while traveling to the acid-producing cells in the stomach by an enteric layer. AstraZenica's U.S. Patent No. 6,013,281 (the "281 patent") claims a method for making an omeprazole formulation composed of a core containing the active, acid-inhibiting ingredient, a protective, enteric coating surrounding the core, and a water-soluble separating layer between the core and protective layer. Specifically, the patent recites a process for creating the separating layer by causing an *in situ* reaction involving the enteric-coating material and the core, producing an omeprazole formulation having three distinct layers.

In 2001, AstraZenica filed suit for infringement of the '281 patent claims against several pharmaceutical companies seeking permission from the Food and Drug Administration to market generic versions of PRILOSEC®. The district court found that, while the '281 patent claims were

infringed, the claims were invalid in view of a prior Korean patent application that recited or anticipated all of AstraZenica's claim limitations, either explicitly or inherently. In a 2-1 decision (Judge Rader filing the majority opinion with Judge Bryson concurring), the Court of Appeals for the Federal Circuit affirmed the district court decision holding that the *in situ* separation layer was formed when practicing the invention disclosed in the prior art. Therefore it was the natural result of practicing the invention and was inherent to the disclosure even though it was not explicitly disclosed in the Korean patent application.

Judge Rader's majority opinion and Judge Newman's concurring-in-part, dissenting-in-part opinion do differ in what is to be considered "inherent" in a disclosure and in how to evaluate and weigh the proof required to support such a finding. In the present case, questions arose as to whether following the process disclosed in the Korean patent application resulted in the formation of an *in situ* layer under all conditions or only under limited conditions. While this decision appears to have settled the issues present in this case, it certainly leaves room for further discussion of "inherent anticipation."

SWEEPSTAKES AND CONTESTS

A BONANZA OF BRAND AWARENESS OR A POTENTIAL MINEFIELD FOR THE UNWARY

Sweepstakes and contests are two common promotional games that can significantly increase brand awareness and can quickly create a "buzz" around a new product. However, there is a vast array of laws and regulations that pose numerous pitfalls to the unwary game promoter or sponsor. Putting on a sweepstakes or contest involves much more than simply announcing the promotion, collecting entries, and giving away prizes. All

sweepstakes and contests will be subject to both federal and state laws which can vary widely in their complexity and the affirmative steps required of the promoter or sponsor prior to conducting the game. For a nationwide game that means compliance with federal laws and the laws of all 50 states.

The most important requirement that promoters and sponsors must keep in mind is that the game cannot be considered an illegal lottery. That is the game must not require "consideration" to play, hence the common buzz words "No purchase necessary." The defini-

tion of "consideration" varies by state and may include additional prohibitions on what a potential entrant may or may not be required to do or provide to participate in the game. Other potential pitfalls that game promoters and sponsors must be aware of include: (1) registration and bonding requirements (which may require up to 30 days advance registration of a game); (2) satisfying the "alternative means of entry" requirement; (3) requirements for running an "online" game; (4) the amount and detail of disclosure required in "rules" of the game; (5) eligibility of entrants; (6) advertising of sweepstakes; and (7) fulfillment and post-fulfillment issues, including posting a list or lists of winners or sending the winners list to the required state authority and obtaining the proper releases from the winners.

A successful sweepstake or contest will provide invaluable brand awareness, goodwill, and excitement. A promotional game that does not comply will all federal and state laws, however, can lead to civil liability, civil fines, and criminal penalties.

The Muddle in Montenegro

Although almost a year has passed since Montenegro declared its independence from Serbia and became the 192nd member state of the United Nations, Montenegro IP Office (MIPO) has yet to be established and is not expected to open until September 2007 at the earliest. With no Trademark Act or similar legislation currently in place, the mechanics of protecting one's IP rights in Montenegro are far from certain. The transitional provisions were supposed to provide that the trademarks filed or registered in Serbia and Montenegro prior to Montenegro's independence (June 3, 2006) would be revalidated in Montenegro by means of a simple deposit procedure. Since MIPO has yet to become functional, however, the transitional rules have not been finalized.

WIPO has added Montenegro (ME) designation to its Madrid system in December 2006.