

USPTO: There's a New Sheriff in Town

On August 7, 2009, President Obama's nominee David Kappos was sworn in as the new Director of the United States Patent and Trademark Office. Mr. Kappos has a long and distinguished career in intellectual property, having once served as Vice President and Assistant General Counsel for IBM, where he was responsible for management of that company's extensive global patent and trademark

portfolio. He takes over management of an Office that had become well-known for a significant backlog and is also the center of much controversy and litigation regarding various rules issued by the former Director.

At the time of Mr. Kappos's confirmation, the USPTO was defending the validity

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Surviving the Plague: Federal Circuit Finds No Inequitable Conduct in Procuring AstraZeneca's Quetiapine (Seroquel®) Patent

In *AstraZeneca Pharmaceuticals LP v. Teva Pharmaceuticals USA*, issued September 25, 2009, the Federal Circuit upheld the District Court's finding of no inequitable conduct in the prosecution of US Patent No. 4,879,288 ("the '288 patent"). The '288 patent has survived what Federal Circuit judges call a "plague" on US patents—allegations of inequitable conduct (wrongdoing) which may be easily pled, but not easily dismissed.

by disclosing data only on prior art compounds that would help but not hinder prosecution. The Federal Circuit found that AstraZeneca's submission of data relating to closest prior-art compounds satisfied its duties to the USPTO during prosecution. AstraZeneca's selective submission and omission of data relating to other structurally-similar compounds was not inequitable conduct in procuring the '288 patent.

In the present case, Teva alleged that AstraZeneca misled the Examiner during prosecution of the '288 patent

As inequitable conduct was the only issue on appeal, Teva Pharmaceuticals issued

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ICANN Gains Independence

The Internet Corporation for Assigned Names and Numbers (ICANN), the body responsible for managing the core mechanisms of the internet, has recently gained some independence from the US control. ICANN was originally created in 1998 through a Memorandum of Understanding between the US Department of Commerce and ICANN with the purpose of transitioning management of the Domain Name System (DNS) from the US government to the global community. Although ICANN is a private not-for-profit organization where policies are developed from the bottom up, through global constituencies often representing competing interests, it was ultimately accountable only to the US government. At the end of September, the

Department of Commerce allowed the last MOU to expire, thereby declaring that ICANN is mature enough to move on to the next stage of its global development. However, the US has retained some minimal control through a new agreement called an Affirmation of Commitments.

The Affirmation of Commitments commits ICANN to remaining a private not-for-profit organization, but declares that ICANN is independent and not controlled by any one entity. It further commits ICANN to reviews performed by the entire multi-stakeholder global community, such as constituencies representing registries, registrars, registrants, trademark owners, and other commercial and non-commer-

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Focus on Patents

IpHorgan is delighted to welcome Michael L. Kenaga and Valerie Neymeyer-Tynkov to its Patent Group. Michael has nearly 20 years of experience handling United States and foreign patent issues for large and mid-sized companies while Valerie has a depth of experience in the medical technology fields, as a practitioner, an academic and a researcher. Indeed, all members of the group acquired field experience in their chosen areas prior to entering law school and becoming patent attorneys. The team now includes:

Michael L. Kenaga is the Director of Patents. He is a registered patent attorney and his 20 years of patent experience include advising and counseling on patentability, providing infringement opinions, and preparing, filing and prosecuting domestic and foreign patent applications in the electrical and mechanical arts for large and mid-sized corporations. He has substantial experience in IP due diligence in connection with potential acquisitions of companies and his practice includes license-agreement work and litigation support. Michael is a regular speaker and lecturer on issues related to US and foreign patent practice. He is an electrical engineer by training (BSEE) and prior to law school worked for a telecom company and for a military and government contractor. Michael is a member of the Chicago Bar Association, Chair of the Intellectual Property Committee (2004-2005), The Intellectual Property Law Association of Chicago, Past Treasurer (1997-1999), American Intellectual Property Law Association and the Licensing Executives Society.

Sean Swidler prosecutes a broad range of patents, including those for medical, mechanical and electro-mechanical devices along with software and business methods inventions. He is also experienced in all phases of patent litigation

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of a number of controversial and sweeping changes to the Office's patent practice which were ostensibly meant to streamline and simplify patent practice. Though the rules at issue were never fully enacted (since enactment was stayed during litigation over same), one of Mr. Kappos's first major acts as Director was to issue a new rule withdrawing the highly-controversial rule changes that were in litigation. This action cleared the way for the USPTO to refocus resources and efforts toward management of the Office and to work on development of new rules that would be more acceptable to the users of USPTO services, namely inventors and trademark owners, and that would streamline the process of obtaining intellectual property protection and bring goods and services to the market.

Though the final form of many new rules is still on the horizon, Mr. Kappos recently outlined some of the items the Office intends to focus on with respect to trademark practice. Mr. Kappos indicated that the USPTO will continue its trademark IT system modernization project. Ultimately, the Office hopes to provide applicants, registrants and their counsel with real-time access to trademark files and even the ability to manage USPTO dockets online. Such functionality could considerably ease trademark practice before the USPTO.

In addition, since Mr. Kappos took the helm, the USPTO has redesigned and revamped its website, including many of the document and application-filing interfaces. Though the changes to date have been rather minor, the Director stressed that the Office will work closely with the Trademark Public Advisory Committee to further develop and refine USPTO website functionality.

On the substantive side of trademark practice, Mr. Kappos indicated the Office

may likely issue new rules in response to the recent decision in *Bose Corp. v. Hexwave Inc.* addressing the question of fraud on the Trademark Office and may also review how that ruling would apply to use-based trademark applications and declarations of use. The Director also indicated the Office may likely re-evaluate statement of use requirements and sufficiency of specimens in the context of intent-to-use applications identifying multiple goods within a single class. As with the website issues, the Director has pledged to work with the parties most impacted by any new rules or decisions in this area—trademark registrants, owners and practitioners.

Finally, in August, President Obama signed legislation authorizing the Director of the USPTO to shift revenues received from trademark application filings to fund internal patent practice operations. Though Director Kappos has indicated he would "prefer not to use" such funds for internal costs, the ability of the Director to tap this source of revenue to fund operations could minimize or eliminate potential PTO down-sizing which, in the end, would aid in the overall streamlining of the Office, since decreases in staff and examiners could be held to a minimum.

It appears that Mr. Kappos intends to shake things up at the USPTO. By rescinding the sweeping rules instituted by his predecessor and committing to re-evaluate and revamp both patent and trademark practices before the Office, a new era may be near and the Office may be able to create policies and practices that better mirror the market realities faced by inventors and trademark owners and to embrace available technologies to streamline the process. The Office appears on the verge of shifting from an agent of delay and expense to a catalyst in the process of obtaining patent and trademark rights.

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cial interests. The agreement is intended to be long-standing and gives ICANN some autonomy. However, it also reaffirms the role of the Government Advisory Committee, which is a key participant in selecting the membership of the review teams. Rather than ICANN being reviewed by just the US government, under the new relationship, these reviews will be developed by an international committee of parties representing over 100 countries around the world, with the US government still having a seat at the table. All of these reviews will also be submitted for public comment, thereby creating accountability to the full international community.

ICANN Approves Local Language Domain Names for Country-Code Top-Level Domains

ICANN is moving forward with plans to allow country-code Internationalized Domain Names (IDNs). IDNs are domain names displayed in a language-specific, non-Latin script or alphabet, such as Chinese, Russian, Arabic, or Hebrew. The inclusion of country-code IDNs in the domain name system will enable countries and territories to offer domain names in their native languages to the more than 60 percent of internet users who are not English speakers. This change will also allow users of languages based on right-to-left scripts or users of languages based on non-alphabetic scripts, such as Mandarin Chinese, to participate.

The IDNs will initially be available as ccTLDs, such as .рф (Cyrillic for .RF or Russian Federation), if the IDN is based on non-Latin script(s) that are considered official in the corresponding country or territory. The registries will only be available to the governments and administrators of countries and territories listed in the ISO 3166-1 standard, or their designated representatives. After the requester for an IDN registry has been

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a press release on September 25, 2009, stating it expects to market quetiapine compositions after the expiration of the '288 patent. The '288 patent covers AstraZeneca's antipsychotic drug "Seroquel" (active ingredient: quetiapine), having 2008 sales in excess of \$4.4 billion.

Summary of the case

AstraZeneca alleged infringement of the '288 patent by generic drug makers Teva Pharmaceuticals and Sandoz, Inc. (collectively, "Teva"), in response to the generic companies' ANDA filings for approval to sell generic quetiapine compositions in the United States. AstraZeneca moved for summary judgment against Teva's assertions that the '288 patent was unenforceable due to inequitable conduct; the District Court found for AstraZeneca, and Teva appealed to the Federal Circuit.

The '288 patent discloses that antipsychotic drugs typically cause undesired, involuntary movements, and that quetiapine is atypical in that it causes fewer and less intense involuntary movements (see, e.g., US Patent No. 4,879,288 column 1 lines 41-68 and Example 9). Claim 1 of the '288 patent is directed to a compound having the chemical structure of quetiapine, a dibenzothiazepine having a piperazine ring N-substituted with $-\text{CH}_2\text{CH}_2\text{O}-\text{CH}_2\text{CH}_2\text{OH}$. During prosecution of the '288 patent, the Examiner rejected claims to quetiapine as obvious in view of two prior-art compounds the Examiner identified as the structurally-closest prior art – "Schmutz X" and "Horrom" – where Schmutz X was N-substituted with $-\text{CH}_2\text{CH}_3$, and Horrom was a chlorinated diazepine. The Examiner required submission of data comparing atypical properties of quetiapine with Schmutz X and Horrom to overcome the rejection.

In response, AstraZeneca submitted a declaration with already-existing internal data comparing quetiapine with Horrom, noting that quetiapine caused atypical side effects and Horrom did not. The declaration also advised that internal data was not readily available regarding Schmutz X, and that generating such data would be very expensive. However, the declaration submitted that prior-art compound Schmutz B (N-substituted with $-\text{CH}_2\text{CH}_2\text{OH}$) was structurally closer to quetiapine ($-\text{CH}_2\text{CH}_2\text{OCH}_2\text{CH}_2\text{OH}$) than Schmutz X ($-\text{CH}_2\text{CH}_3$), and provided data to show that quetiapine caused atypical side effects and Schmutz B did not. The declaration also volunteered that another compound, Schmutz A (a chlorinated compound having an N-substituted $-\text{CH}_3$ group on the piperazine ring), did not provide antipsychotic effects, emphasizing that structurally-similar compounds did not necessarily provide the same pharmacological results. The Examiner accepted the substitution of Schmutz B for Schmutz X as the closest prior art and allowed claims to quetiapine to issue to grant.

To prove inequitable conduct, a challenger must show a patent applicant (1) misrepresented material information (2) with an intent to deceive the USPTO. Teva alleged that AstraZeneca misrepresented material information because the substitution of Schmutz B for Schmutz X, the omission of data relating to other structurally-similar compounds, and the selective submission of data regarding Schmutz A were meant to lead the Examiner away from data AstraZeneca knew would be or could be damaging to its quetiapine application.

In considering the issue, the Federal Circuit decided that Schmutz B was, in fact, structurally more similar to quetiapine than Schmutz X, and that a reasonable examiner would have accepted AstraZeneca's substitution of Schmutz B

for Schmutz X as the structurally-closest prior art. AstraZeneca's omission of data relating to other structurally-similar compounds and selective disclosure of information relating to Schmutz A were therefore not material misrepresentations because the Examiner and applicant reasonably identified and focused on the closest prior art, and found that structural similarities or differences were not determinative of typical or atypical side effects. The Court also noted that Teva did not show that AstraZeneca had data for Schmutz X and withheld it, and that Teva did not present its own evidence that Schmutz X is an atypical antipsychotic agent; whether these circumstances would have altered the Court's opinion is not clear from the record.

Teva also alleged AstraZeneca intended to deceive the Examiner during prosecution of the '288 patent by not preparing and submitting data on Schmutz X and other compounds, and by submitting information on Schmutz A. The Federal Circuit held that an intent to withhold data on structurally similar compounds is not an intent to deceive, particularly where plausible reasons are given for withholding information:

an applicant would not know how much of its research must be filed with the PTO, although of no interest to the Examiner, or run the risk of wrongdoing no matter where the line is drawn.

Overall, AstraZeneca's disclosure of comparative information regarding the structurally-closest prior-art compounds was enough to satisfy duties imposed by the USPTO on a patent applicant. AstraZeneca's selective submission and omission of data relating to other structurally-similar compounds was not seen as materially misrepresenting information to, or intending to deceive, the USPTO examiner.

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approved, the domain names will be available to the public for registration. It is anticipated that the first IDN registrations will become available in the middle of 2010, with each registry providing its set of rules and guidelines for registrations. While some countries may give existing ccTLD holders rights to the new IDN ccTLD, this will not be required.

New Generic and Brand-Driven TLDs Delayed Pending Further Review and Opinions

As we have previously reported, ICANN is still proceeding with the expansion into generic and brand-driven top-level domains, gTLDs (generic top-level domains), allowing alternatives to .COM, .ORG, .BIZ, etc, such as .YOURCOMPANYNAME. The new gTLDs may also expand to include IDN gTLDs in addition to the new IDN ccTLDs. While ICANN has recently released for review and comment the Third Draft Applicant Guidebook relating to the proposal, it appears that the timeline for implementation has slowed down. At its recent meeting in Seoul, Korea, indications from the Board of ICANN were that there may be at least one more draft Guidebook prior to a Final Guidebook. These delays are due to significant disagreements amongst competing interests in the internet community, and the calls to further evaluate difficult issues. These include: conducting economic analysis to determine whether new gTLDs are necessary; analyzing the cumulative effect of the new IDNs and other implementations on the scalability of the domain name system; weighing additional considerations relating to trademark protection; and appointing evaluators for the new gTLD application process.

In the latest draft of the Guidebook, ICANN included some recommendations by the Implementation Response Team (IRT) concerning trademark protection. The IRT included members of the Intel-

lectual Property Constituency (IPC) comprised of representatives from a variety of constituencies, including private practitioners, in-house attorneys for brand owners, registry and registrar representatives, and other domain-name and trademark experts from around the world. The recommendations included in the Draft relate to a number of trademark-owner protection mechanisms. These include a requirement for a registry to maintain a thick WHOIS database at the registry level, rather than the current method of WHOIS information being provided at the registrar level, to provide further safeguards for the maintenance of accurate information. In addition, there are provisions for creation of an IP Clearinghouse, which would make verification of rights easier when a new gTLD is in a sunrise period prior to launch. The Draft also includes the creation of a Uniform Rapid Suspension System ("URS"), which is a post-delegation dispute-resolution mechanism intended to address the most obvious cases of trademark infringement and cybersquatting more swiftly and economically. However, the Globally Protected Marks List, which had been proposed earlier, was not included in the Draft.

The Third Draft Applicant Guidebook is subject to a public comment period, including trademark protection solutions, until November 22, 2009. It is anticipated that following the comment period, and after further discussion and studies amongst the constituencies and ICANN, that another draft of the guidebook would be issued in Q1 of 2010. Rather than provide another timeline that it would not be able to meet, ICANN has chosen to further address a variety of issues in the time necessary to properly achieve a sound implementation, instead of hastily proceeding at the expense of proper protection mechanisms. As a result, implementation of the new gTLD program may be delayed until mid 2010, if not later. Comments on the guidebook, along

with comments on other pending ICANN proposals, are encouraged by interested parties, and can be lodged at www.icann.org.

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and has spent significant time litigating patent claims associated with generic drug applications and medical devices. Sean also counsels clients in patent portfolio development and management, assisting clients in developing protection strategies and tailoring patent portfolios to specific business interests and market factors. Before attending law school, he also spent time working in the construction engineering field, conducting chemical analyses of concrete samples and developing application-specific concrete compositions. Sean has an undergraduate degree in Biomedical Engineering from the University of Iowa and his J.D. from the Chicago-Kent College of Law.

Valerie Neymeyer-Tynkov focuses on drafting and prosecuting patents in the pharmaceutical, biotechnological, medical and chemical arts; preparing legal opinions; devising cost-saving strategies; and troubleshooting patent-related problems for clients. Her technical expertise includes over six years of bench experience in R&D and academic laboratories, including experience manufacturing product under cGMP protocols. Valerie obtained a J.D. with Honors from the Chicago-Kent College of Law, where she has since taught International Patent Law for several years as an Adjunct Professor of Law. Her educational background includes an M.S. in Pharmacology and a B.A. (with Honors) in Literature, Science and the Arts with a minor in Chemistry from the University of Iowa.