PATENT PROSECUTION HIGHWAY (PPH); BIOLOGICS; SOFTWARE AND BUSINESS METHOD PATENTS; SWISS TYPE CLAIMS

HERSHKOVITZ IP GROUP

Presented by Abe Hershkovitz

HERSHKOVITZ & ASSOCIATES, LLC

www.hershkovitzipgroup.com

What is PPH?

- A work sharing program
  - Lets examiners utilize the search and examination results from other patent offices
  - Examiners are still required to conduct their own search and examination
- Expedites examination
  - Application examined out-of-turn
- Based on agreements with other national/regional patent offices

Three Types of Patent Prosecution Highway

- **Paris Convention**
  - Uses national work product from a qualifying office
    - Search, opinion, allowance
  - Work product from office of first filing (OFF) may be used in office of second filing (OSF) to expedite examination in the OSF
- **PCT PPH**
  - Uses international stage work product
    - Search/written opinion, IPRP
  - Work product may be used in prior or later filed national application as well as the national stage applications
- **Mottainai (Japanese word, search result sharing)**
  - Similar to Paris Convention PPH but uses an “Office of Earlier Examination (OEE)” and “Office of Later Examination (OLE)” framework

Mechanics of PPH

- **Four requirements to request entry into PPH at the USPTO**
  - **The U.S. application must have a specified relationship with foreign application (national or PCT);**
  - **At least one claim in the foreign application must be indicated as patentable by work product from the foreign patent office;**
  - **All of the claims in the U.S. application must "sufficiently correspond" to the patentable claims in the foreign application; and**
  - **Before start of Substantive examination of the U.S. application**

Mechanics of PPH (cont'd)

- **If all requirements are met**
  - **(1) Submit request to enter PPH by EFS to the USPTO with Form PTO/SB/20**
  - **(2) Submit copies of all relied-upon work product indicating the patentable subject matter (e.g., office actions, WO/ISA, WO/IPRP, WO/IPEA, EESR)**
  - **(3) Submit an IDS including the documents in (2) and cited references (include certified translations if necessary)**
  - **(4) Show claim "correspondence" in the request form of (1) or in a separate table**

Worldwide PPH Agreements

- Australia (IPAU)
- Austria (APO)
- Canada (CIPO)
- China (SIPO)
- Denmark (DKPTO)
- Europe (EPO)
- Finland (NBPR)
- Germany (DPMA)
- Hungary (HPO)
- Iceland (IPO)
- Israel (ILPO)
- Japan (JPO)
- Korea (KIPO)
- Mexico (IMPI)
- Nordic (NPI)
- Norway (NIPO)
- Portugal (INPI)
- Russia (ROSPATENT)
- Singapore (IPOS)
- Spain (SPTO)
- Sweden (PRV)
- Taiwan (TIPO)
- United Kingdom (UKIPO)
- United States (USPTO)

USPTO PPH Agreements

- **Paris Convention**
  - Australia, Austria, Canada, Denmark, Europe, Finland, Germany, Hungary, Japan, Korea, Russia, Singapore, Spain, UK, Singapore, Mexico, Israel, Taiwan
- **PCT**
  - Japan, Korea, Australia, Europe, Finland, Russia, Austria, Spain, Sweden, Norway
- **Mottainai**
  - Japan, UK, Canada, Australia, Finland, Russia, Spain

Useful Information

- Dedicated USPTO PPH web page (http://www.uspto.gov/patents/init_events/pph/index.jsp) including links to:
  - FAQs and forms
  - PPH “how-to” and informational video
  - Downloadable information brochure
  - Question and feedback e-mail inbox
- PPH information portal site with statistics and other information from all participating offices (http://www.jpo.go.jp/cgi/linke.cgi?url=/ppph-portal/index.htm)

Benefits of Patent Prosecution Highway

- PPH Requests filed in the U.S.: 4,388 (12/31/11)
- Application Grant Rate 87% (vs. 49% for total)
- 1st Action Allowance Rate 26% (vs. 14% for total)
- Pendency from PPH Request to 1st Action 6.1 Months (vs. 23.6 months for all cases)
- Pendency from PPH Request to Final Decision 11.6 Months (vs. 33.8 months for all cases)
- Number of PTO Actions 2.3 (vs. 2.6 for total)

Benefits of Patent Prosecution Highway (cont'd)

- PCT PPH Requests filed in the U.S.: 172 (12/31/11)
- Application Grant Rate 91% (vs. 49% for total)
- 1st Action Allowance Rate 19% (vs. 14% for total)
- Pendency from PPH Request to 1st Action 4.3 Months (vs. 23.6 months for all cases)
- Pendency from PPH Request to Final Decision 7.0 Months (vs. 33.8 months for all cases)
- Number of PTO Actions 1.6 (vs. 2.6 for total)

Benefits of Patent Prosecution Highway (cont'd)

- **Decreased Cost of Prosecution**
  - **Based on AIPLA Report of the Economic Survey the USPTO publishes, the average cost per action is about $2,100**
  - **Based on the decreased number of actions:**
    - **PCT PPH saves about $2,100 per case**
    - **Paris PPH saves about $630 per case**

Benefits of Patent Prosecution Highway (cont'd)

- Reduced Pendency
  - PPH enables applications filed in multiple jurisdictions to be fast tracked based on another Office's work product.
  - Faster portfolio building
- Simple, Inexpensive Request
  - The USPTO eliminated the petition and fee in May 2010
- Reduced File History
  - Fewer office actions to respond to
  - Smaller file history compared with other Accelerated Examination programs
  - No admissions against interest need be made

“Claim Correspondence”

- **Rule - All claims on file, as originally filed or as amended, for examination under the PPH must “sufficiently correspond” to one or more of those claims indicated as patentable by the OFF/ISA**
- **Claim correspondence must be maintained throughout prosecution**

Claim Correspondence (cont'd)

- Claims are considered to "sufficiently correspond" where, accounting for differences due to translations and claim format:
  - Paris Convention PPH (except Japan)
    - the claims in the OSF are of the same or similar scope as the claims in the OFF
  - PCT PPH & Japan
    - the claims in the OSF are of the same or similar scope as the claims in the OFF/ISA, or the claims in the OSF are ***narrower in scope*** than the claims in the OFF/ISA

Sufficiently Correspond

- "accounting for differences due to translations and claim format"
  - U.S. examiners should allow a claim to be presented in the U.S. application that does not match word-for-word with the previously examined claim
  - The applicant may present claims in "U.S." style even if the examined claims were not, provided the scope of the presented claims meets the rule
  - Claims drafted in "Jepson" style in Europe may be presented in U.S. style and still maintain "sufficient correspondence"
  - Multiple dependent claims that were previously examined do not need to be in multiple dependent form in the U.S.

Sufficiently Correspond- Best Practice

- File a preliminary amendment with request if changes are desired, while maintaining correspondence
- Present claims that are closest to the exact language of the previously examined claims
- Include a new claims correspondence table when filing an amendment

Sufficiently Correspond – Points to Remember

- **Examiners have some discretion to allow amendments that do not, strictly, maintain claim correspondence**
  - **If claim correspondence cannot be maintained, a continuation can be filed and the application is no longer in the PPH.**
- **Review the specification for subject matter to add as dependent claims to independent claims that sufficiently correspond to claims indicated as patentable by the ISA when filing a PCT PPH request**

Litigation Issues to Consider

- **Statements Made in Claims Correspondence Table**
  - **Possible opportunity for later attack**
- **Claim Scope**
  - **Claims filed in some foreign patent offices may originally be narrower as compared to those filed in the U.S.**
- **Not Litigation Tested in the U.S.**
  - **Courts have not had the opportunity to address patents issued through the PPH**
  - **Impact of foreign prosecution history to construe claims in U.S. patents**

Ways to Best Use PPH to Expedite Examination

- Two Strategies:
  - Maintain current filing strategy and look for applications in which PPH may be used
  - Develop a filing strategy that takes advantage of PPH
- U.S. “first filing” model
  - PPH not available for first-filed U.S. application unless: (1) foreign filing is through PCT, or (2) Mottainai can be used
  - PPH can save time and costs in foreign applications based on U.S. patentable claims
- PPH model
  - Location of first-filed application may rest on how best to expedite all applications through PPH

Ways to Best Use PPH to Expedite Examination (cont'd)

- **Where to file first - considerations**
  - **Where is coverage sought?**
  - **PCT application is typically filed?**
  - **Typical pendency times to first action**
    - **USPTO is about 31 month for communications**
    - **EPO is about 6 months if original case**
  - **Timeliness of search/exam authorities?**
  - **Quality of search/exam authorities?**
  - **Subject matter searched?**
  - **Leverage USPTO web of PPH agreements?**

PCT PPH Search/Exam Authorities

- USPTO
  - Business methods
  - Different searcher than US Examiner (outsourced)
- EPO
  - High quality search/opinion
  - Can expedite EP prosecution
  - No business methods
- KPO
  - Inexpensive for additional inventions
  - Lower quality search
- Russia
  - New

PPH Developments in Mexico

- PPH Between USPTO and IMPI (Pilot) Enacted on 3/31/11 to Run until 2/19/12, extended until 8/31/12
- Procedures and Requirements for Filing a PPH Request with IMPI During Pilot Available at www.impi.gob.mx/wb/IMPI/proyecto_piloto_sobre_el_procedimiento_acelerado

How Will Biologics Fare under the AIA

- **In 2006, Venture Capital (VC) investing in the Life Sciences Sector which includes biotechnology and medical devices reached a record high of approx. $7 billion**
- It costs nearly $1 billion in capital investment to bring a biologic drug to market (from discovery through clinical trials and FDA approval)
- Only 10% of drugs discovered actually make it to market, and despite the more than $50 billion spent on biotech drugs in 2006, the large majority of early-stage companies never reach the point of net profitability

Biologics under the AIA (cont'd)

- Intellectual property protection is critical to the start-up biotech company and to its VC investors — without assurance that there exists adequate market exclusivity to allow a successful biologic product to earn adequate profits, VC investors have no guarantee of a return on investment, and will be hesitant to direct their funds to the Life Sciences sector.
- Most biologics are licensed for marketing by the Food and Drug Administration (FDA)

Biologics under the AIA (cont'd)

- The 1984 landmark Hatch-Waxman Act created a shorter path for approval, which allowed generic versions of brand drugs to be approved without clinical studies. If the generic company could show its product was bioequivalent to the brand compound, it could rely on approval of the brand drug as evidence that the generic drug was safe and effective and therefore could also be FDA approved.

Biologics under the AIA (cont'd)

- Under Hatch-Waxman, a small-molecule generic drug must be the same as the brand innovator drug to obtain approval. Because the active ingredient of the generic and brand compound is identical, innovator patents generally protect the brand drug from generic infringers until expiration of the patent.
- The award of damages for patent infringement is critical to patent enforcement. The threat of significant monetary liability is often a deterrent to keep a potential infringer from engaging in infringing behavior.

Biologics under the AIA (cont'd)

- In the context of biotechnology, damages protect the patent holder as well as the VC investor who has funded the emerging biotech company. Under current patent law, damages are awarded to a successful patent owner in an infringement suit either based on the patent owner's lost profits or, more frequently, in the amount of a "reasonable royalty."

Biologics under the AIA (cont'd)

- **Post-Grant Review**

Virtually anyone may administratively challenge the validity of a patent during a "second window" for post-grant opposition proceedings after the patent is granted. Under the new law, a potential infringer who can reasonably show that the patent would cause it "significant economic harm" may, through a petition to the USPTO, challenge the validity of the patent, provided certain conditions are met. Such a challenger can raise all sorts of invalidity defenses, not just an objective presentation of prior-art patents and printed publications.

Biologics under the AIA (cont'd)

- **Post-Grant Review**

Together, the follow-on biologics and patent reform changes could weaken intellectual property protection for biotechnology companies, creating disincentives for VC investment in biotechnology. This would be particularly harmful to small, start-up biotechs which depend most heavily on VC funding.

Current State of Software and Business Method Patents

- **The U.S. Patent and Trademark Office grants patents to provide protection for business methods, so that one can exclude competitors from doing business in the same way. Business method claims can be patented in the U.S. But, proper drafting and reciting details on practical implementation is important.**
- **In 1995, the Federal Circuit decision in *In re Beauregard* indicated that computer software was patentable. 53 F.3d 1583 (1995). The USPTO issued an initial set of Examination Guidelines for Computer-Implemented Inventions in 1996 (61 Fed. Reg. 7478).**

Examples of Business Method Patents

- **U.S. Patent No. 6,003,018, Michaud Partners LLP**

A method for evaluating an existing or potential portfolio having a plurality of assets. A mean-variance portfolio is calculated for numerous simulations of input data consistent with expected return and expected standard deviation of return in view with a specified risk objective.

Examples of Business Method Patents

- **U.S. Patent No. 5,960,414, Hewlett-Packard Co**

A method for monitoring excess inventory and managing information from a material requirements planning (MRP) system and allowing the forecasting and updating of excess inventory data

Examples of Business Method Patents

- **U.S. Patent No. 5,794,207, Priceline**

Priceline.com patented a reverse auction method that makes bids available to multiple sellers . This invention allows prospective buyers of goods and services to communicate a binding purchase order globally to potential sellers

- **U.S. Patent No. 5,960,411, Amazon**

Amazon.com patented a method and system for placing an order to purchase an item via the Internet using a one-click of a mouse ordering system

Current State of Business Method Patents

- **The Federal Circuit clarified this machine-or-transformation test and issued it as a mandate in *In re Bilski*, 545 F.3d 943 (2008). The USPTO followed suit by issuing its August 2009 Interim Examination Instructions for Evaluating Subject Matter Eligibility Under 35 U.S.C. § 101. These Instructions indicated that all processes must satisfy the machine-or-transformation test in order to be statutory.**

Current State of Business Method Patents

- **The U.S. Supreme Court in *Bilski v. Kappos* disagreed, saying that the machine-or-transformation test was not the only test for patent eligibility. 130 S.Ct. 3218 (2010). Specifically, business method inventions, as a group, are not excluded from patent eligibility. Rather, the USPTO and courts should look to whether the claim recites an abstract idea, a law of nature, or natural phenomenon, which would be considered non-statutory. The claim on appeal in *Bilski* was held non-statutory as directed to an abstract idea, but the decision was seen as a "win" among business method patent applicants.**

Current State of Business Method Patents

- **On July 27, 2010, the USPTO issued a set of guidelines that patent examiners should use when examining business method patent applications. These guidelines provide factors both in favor of and against patent-eligibility, that examiners are to use when evaluating patent-eligibility of a claim.**

Current State of Business Method Patents

- **Factors weighing in favor of patent-eligibility include:**

  The claim recites a machine or transformation

  The claim is directed towards applying a law of nature

  The claim is more than a mere statement of concept

Current State of Business Method Patents

- **Factors weighing against patent-eligibility include:**

  No recitation of a machine or transformation (either express or inherent)

  The claim is not directed to an application of a law of nature

  The claim is a mere statement of a general concept (e.g., basic economic practices, mathematical concepts, mental activity)

Current State of Business Method Patents

- **Since *Bilski v. Kappos*, some trends have developed in decided cases at the Board of Patent Appeals and Interferences. The BPAI is imposing strict limits on business method patents, with a high percentage of cases on appeal being found non-statutory. The BPAI's analysis is generally the same for all types of claims, not just method claims. But, the overall allowance rate for business method applications has also increased above 20%.**

Swiss Type Claims in USPTO Practice

- **The U.S. and the EPC do not allow so-called Swiss type claims, but they do allow practitioners to overcome inherency rejections by focusing on a particular use that was not contemplated by the prior art – if the claim is properly worded. In a 2005 case , the Federal Circuit considered validity of five very similar claims to treating sunburn set forth in U.S. patents 5409693 and 5574063.**

Swiss Type Claims in USPTO Practice

- **1. ['693 patent] A method for treating skin sunburn comprising topically *applying to the skin sunburn* . . .**
- **8. ['693 patent] A method for preventing sunburn damage to exposed skin surfaces, comprising topically *applying to said skin surfaces* . . . .**
- **1. ['063 patent] A method for the treatment of skin disorders which arise because of depleted or inhibited collagen synthesis which comprises topically *applying to affected skin areas* . . . .**

Swiss Type Claims in USPTO Practice

- **9. ['063 patent] A method for the treatment of skin damaged or aged by . . . which comprises topically *applying to affected skin areas* a composition containing . . . .**
- **16. ['063 patent] A method for the treatment [*23] of damaged or aging skin and epithelial tissue disorders. . . said treatment comprising topically *applying to affected tissue areas* the combination of . . . .**

Swiss Type Claims in USPTO Practice

- **At the trial court level, the court found that a prior art reference, Pereira, inherently anticipated all five claims because the reference included all of the components of the claimed sunburn composition, and also stated that the cosmetic compositions are "suitable for topical application to the skin or hair". The Federal Circuit reversed as to claim 1 of the '693 patent, however, on the narrow distinction of having recited application of the composition to "skin sunburn" as opposed to merely "skin surfaces" or "affected tissue areas". In the Court's words:**

Swiss Type Claims in USPTO Practice

- **"The issue is not, as the dissent and District Court imply, whether Pereira's lotion if applied to skin sunburn would inherently treat that damage, but whether Pereira discloses the application of its composition to skin sunburn. It does not. This court explained in *Catalina Marketing International, Inc. v. Cool Savings.com, Inc.* that a patent to an apparatus does not necessarily prevent a subsequent inventor from obtaining a patent on a new method of using the apparatus. 289 F.3d 801, 809 (Fed. Cir. 2002).**

Swiss Type Claims in USPTO Practice

- **New uses of old products or processes are patentable subject matter. See 35 U.S.C. § 101 (2000) (identifying as patentable "any new and useful improvements" of a process, machine, manufacture, etc.); *In re King*, 801 F.2d 1324, 1326 (Fed. Cir. 1986) (principles of inherency do not prohibit a process patent for a new use of an old structure). That principle governs in this case as well".**

Thank You

- Abe Hershkovitz

You can reach me for questions at:

- patent@hershkovitz.net
- 703-370-4800 (phone)
- 703-370-4809 (fax)
- www.hershkovitz.net