



January 30, 2012

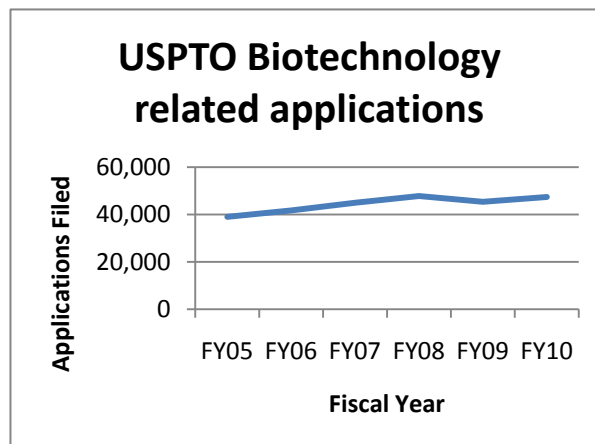
Azam Khan
Deputy Chief of Staff,
Office of the Under Secretary and Director
United States Patent and Trademark Office,
Alexandria, VA 22313

Re: Request for Comments on Additional USPTO Satellite Offices for Nationwide Workforce Program

Dear Deputy Khan,

The Biotechnology Industry Organization (BIO) appreciates this opportunity to comment on possible United States Patent and Trademark Office (USPTO) Satellite Office placement. BIO represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnology products.

At a recent BIO IP Counsels meeting, former USPTO Patent Commissioner Robert Stoll pointed out that biotechnology leads all technology fields in research and development investments in the United States and abroad and those investments have increased 6.2%. Stoll also pointed out that biotechnology inputs more investment dollars than the technology or automotive industries. Finally, you can see from the chart below that biotechnology firms file a significant amount of patent applications per year and that the number of applications filed continues to increase (slides attached).



A disproportionately large share of biotechnology applications is of domestic origin. For example, the data compiled in the WIPO 2011 World Intellectual Property Indicators report show that the United States is by far the biggest originator of internationally-filed biotech patent applications. From 2000-2009, United States applicants filed 116,145 international biotechnology patent applications. Japan came in second with 37,754, China third with 24,135, and Germany fourth with 23,818.¹ Indeed, it appears that U.S. dominance as an originator of patent applications is nowhere as pronounced as it is in the biomedical arts. In fact, the United States has a biotech patenting ratio of more than 3 US biotech applications to 1 foreign-originated biotech application. This ratio is unmatched in any other technology field with large amounts of US patenting activity. The closest patenting ratio advantage of approximately 2.4:1 occurs in the Medical Technology Instrument field which encompasses many biotechnology related inventions.²

Given this high rate of domestic biotechnology investment, innovation, and patenting, the USPTO shoulders a disproportionately large share of original, substantive patent examination in the biomedical fields. Accordingly, the Office should consider satellite locations that would make it easier to attract experienced biotech professionals for its examiner corps, and to be able to more directly interact with its biotech user community. Moreover, placing a satellite office in a biotechnology “hotspot” would provide the USPTO with access to local, established ecosystems of scientists, universities, research institutions, biotech companies and patent practitioners. Such access would help facilitate staffing and other needs of the USPTO satellite office.

Accordingly, we strongly recommend that the USPTO consider one of the large U.S. biotechnology hubs, such as California (SF Bay Area or San Diego), Massachusetts, or North Carolina, for a satellite office.

Respectfully submitted,



Hans Sauer
Deputy General Counsel, Intellectual Property
Biotechnology Industry Organization

¹ Accessed at <http://www.wipo.int/ipstats/en/statistics/patents/> under the table Patent Application Filings: Patent publications by field of technology (2000-2009) by leading countries.

² *Id.* Compare aggregate data from 2000-2009 in categories with largest U.S. filings (greater than 100K) versus closest country in same categories (Japan is closest competitor with a few exceptions).

Bio IP Counsels Committee Conference

Robert L. Stoll

**Commissioner for Patents
United States Patent and Trademark Office**

November 3, 2011



Biotechnology as an Industry

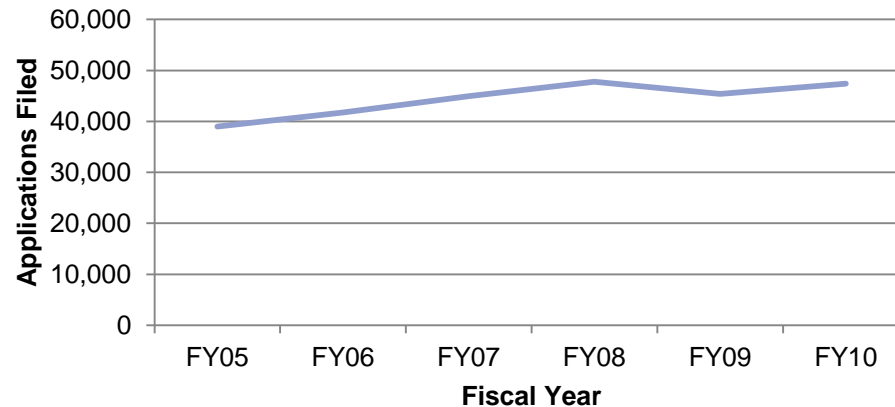
A dynamic Industry

- Leading in R&D investments US and abroad – up 6.2%
- More investment dollars than technology or automotive industries

Difficult issues

- Significant decline in venture capital – down 8%
- Uncertainty in approvals and commercialization prospects

USPTO Biotechnology related applications



IP Today

- Highly innovative firms rely on patents to attract venture capital—76% of startup managers' report that venture capital investors consider patents when making funding decisions.
- Innovation is linked to three-quarters of America's post-WW II growth rate.
- Capital investment and increased efficiency represent roughly 70 percent -- of the 3.4 percent average annual growth rate achieved since the 1940's.
- New ventures create 2 out of every 3 new jobs in our country.



USPTO Overview – Fiscal Year Data

- Approximately 535K applications filed in FY 2011
- Increased filings of approximately 4.9% over fiscal year 2010
- Backlog reduced to 669,625
- Applications in progress = 1,217,842
- Our production rate has remained very high

First Office Action Pendency = 28.0 months

Total Pendency = 33.7 months

Allowance Rate = 48.0%

- The EFS filing rate for FY '11 was 93.1% compared to 89.5% in FY '10.



Initiatives

COPA – Clearing the Oldest Patent Applications.

- Over 300,000 applications identified
- 257,642 First Office actions completed - 20,000 over the goal

Patent Examiner Technical Training Program (PETTP)

- 30 organizations have participated
- 14,000 hours of examiner training

First Action Interview Program

- Applicants embrace this change, and the pilot has been well received, with a doubling of participants from 1,133 to 2,310.

E-Petition

- 8 new web-based ePetitions were launched on March, 2011



Quality Metrics

Existing Measures:

Final Disposition Compliance Rate (95.4%)

- *propriety of final dispositions of applications*

In-Process Compliance Rate (95.2%)

- *propriety of Office actions on the merits during the prosecution*

New Measures:

Pre-First Action on the Merits Search Review (94.6%)

- *degree to which the search conforms with the best practices of the USPTO*

Complete First Action on the Merits Review (90.9%)

- *degree to which the first action on the merits in an application conforms with the best practices of the USPTO*

Quality Index Report (QIR) (89.4%)

- *statistical representation of quality-related events in the prosecution of the patent application*

External Quality Survey (3.0 ratio of positive to negative responses)

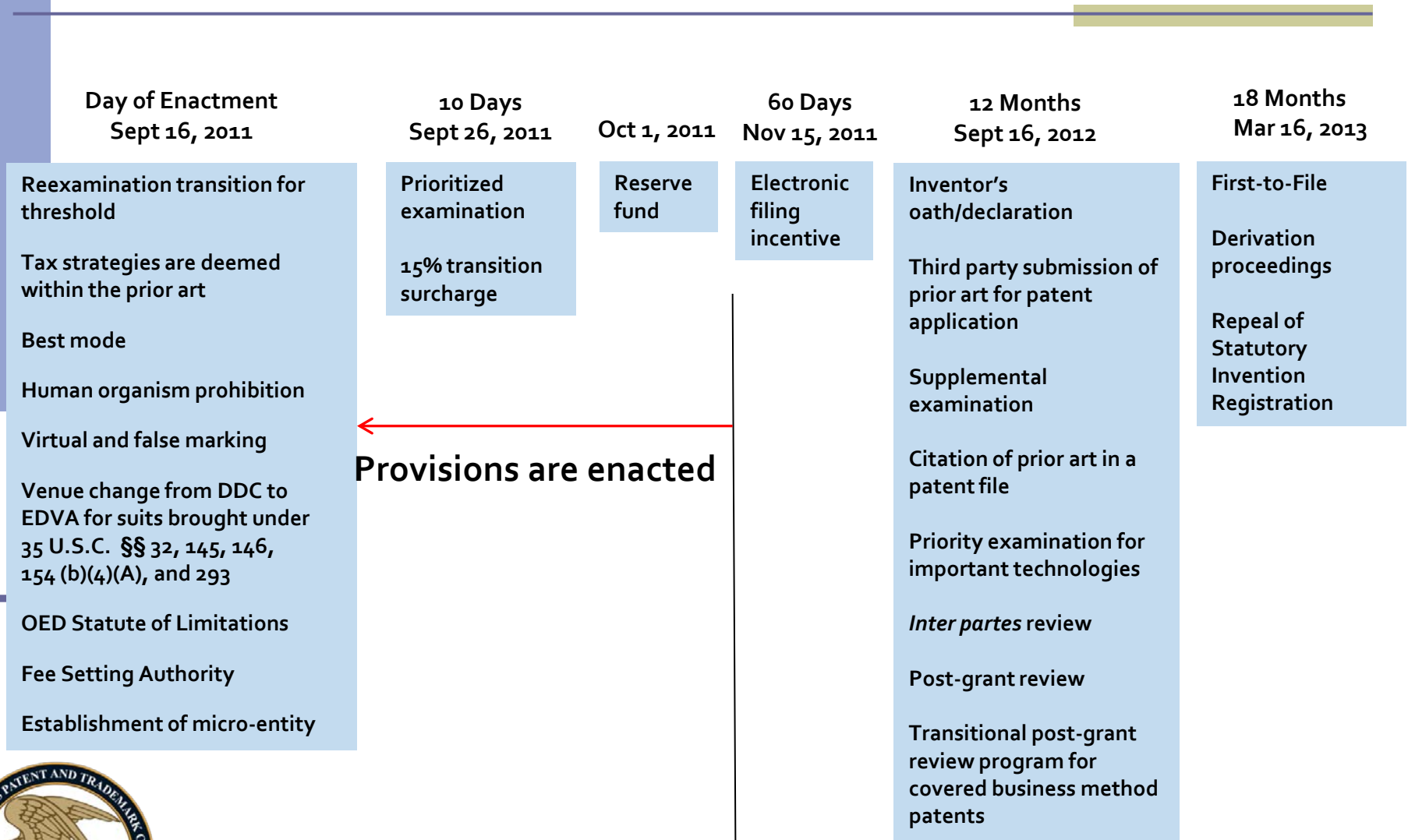
- *experiences of patent applicants and practitioners with USPTO personnel and examination issues*

Internal Quality Survey (4.3 ratio of positive to negative responses)

- *experiences of examiners with internal and external interactions and issues*



Leahy-Smith America Invents Act



Fees and Funding Provisions

Sept 16, 2011

- Fee setting authority (effective after rule making)
- Micro-Entity (effective after rule making)

Sept 26, 2011

- 15% Transition surcharge

Oct 1, 2011 – Start of Fiscal Year 2012

- Reserve fund
- Funding issues

Nov 15, 2011

- Electronic filing incentive - incentive to file applications electronically by applying an additional \$400.00 fee to paper submissions



Track I – Prioritized Examination

- 853 Applications filed in FY 2011; 241 filed in FY 2012
- 1,094 total applications received as of 10/18/11
- Final disposition on average within 12 months of prioritized examination request grant.
- Utility applications must be filed via the Office's electronic filing system (EFS-Web).
- Plant applications must be filed via paper.
- The application contains or is amended to contain no more than 4 independent claims and 30 total claims.



First to File

- Transitions the U.S. to a first-to-file patent system while maintaining a 1-year grace period for inventor disclosures.
- Establishes “derivation” proceeding in place of interference proceeding for first-to-file applications and patents.
- A prior public use or prior sale anywhere qualifies as prior art (prior public use and sale is no longer limited to the U.S.).
- U.S. patents and patent application publications are effective as prior art as of their priority date (no longer limited to U.S. priority date), provided that the subject matter relied upon is disclosed in the priority application.



Work Sharing Initiatives

PPH

PCT-PPH Pilots

SHARE-type initiatives

PCT

IP5 Foundation Projects



Patent Prosecution Highway

Benefits to Applicants:

Cost Reduction

- Reduces cost of US prosecution
- Reduced RCE's and Appeals
- Avoid cost of accelerated exam requirements

Higher Quality Decisions

Speeds Examination:

- Consistent with Compact Prosecution
- Consistent with Early Interviews



Patent Prosecution Highway

Volume of PPH and related applications filed since 2006

2009	2400
2010	4850
2011	7702

Paris PPH Cases – 5675
PCT-PPH Cases – 2027

Grant Rates (allowances/Total Number of Disposals)

Paris PPH	89%
PCT-PPH	96%
All Cases	48%



PPH 2.0

More streamlined and user-friendly PPH framework

Move to a centralized framework – a “Plurilateral PPH”

Minimizes differences in practice, procedure and interpretation of basic requirements among participating offices

Easier navigation of the PPH landscape



Gathering Public Input

Federal Register Notices:

Prioritized Examination (Track 1)

Changes to the fee schedule

Changes to Inter Partes Reexamination threshold

Notice on Public Hearing on Study of International Patent Protection for Small Businesses

Notice of Public Hearing on Prior User Rights study

November 15th is the deadline for informal comments

Formal comments will be collected in mid-January 2012

Public roundtables to be announced



Summary

Looking ahead

- Hire 1500 new examiners
- Collect surcharge funds and apply to IT and process solutions

Application Examination Timing

- PPH offers a good interim solution for all applicants
- Track 1

Collaboration and cooperation remain a top USPTO priority



Thank You

