

Biotech, Chemical & Pharmaceutical Partnership Meeting

March 12, 2008



Worksharing, The Patent Prosecution Highway Pilot Program and the Accelerated Examination Program

Pinchus Laufer, Legal Advisor Office of Patent Legal Administration (OPLA) USPTO





- Overview
- Worksharing Initiatives
 - Patent Prosecution Highway (PPH) Program
 - New Route
 - Strategic Handling of Applications for Rapid Examination (SHARE)
 - TriWay
 - PCT Partnerships
- Accelerated Examination Program





- Programs in which the Office receives additional information that assists the examiner in determining patentability
- Implementation of alternatives to traditional prosecution
- About half of all applications in USPTO are filed by non-residents.
 Foreign residency is a strong indicator of second filings.
- Because of JPO's request for examination system, the percentage of applications where the JPO, as the Office of First Filing (OFF), could provide its search results to the USPTO is less than 10%. 1307 Off. Gaz. Pat. Office 61 (June 13, 2006)
- PPH "Provides applicants at JPO with incentive to file a request for examination at an earlier time and to obtain search & examination results early from the JPO"

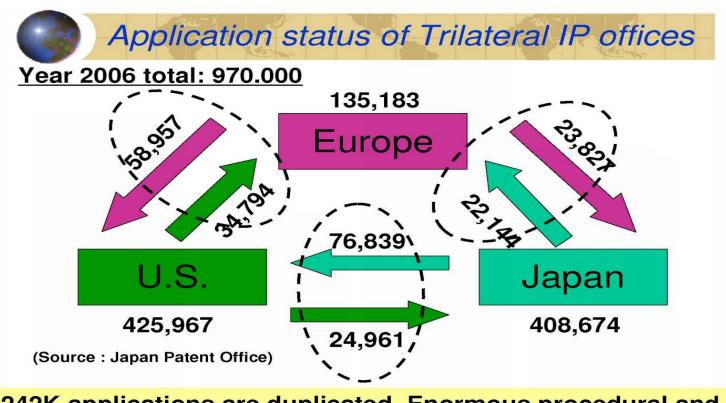




- Office-to-Office Worksharing and related activities are critical to any long-term, viable solution to escalating workloads.
- SHARE is designed to reduce or eliminate the timing imbalances that are preventing our offices from leveraging work done by another office to the maximum extent practicable.
 - Opening Remarks of Jon W. Dudas, Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office, to the Trilateral Users Conference, November 8, 2007
- Need for Sharing Work Based on Information Sharing is Driven by Globalization of IP Distribution & Protection
- Work Sharing contributes to efficiency in patent examination.
 - Presentation of M. Koezuka, Commissioner of the JPO to the Trilateral Users Conference, November 8, 2007 (Koezuka Presentation)



Duplication of Effort



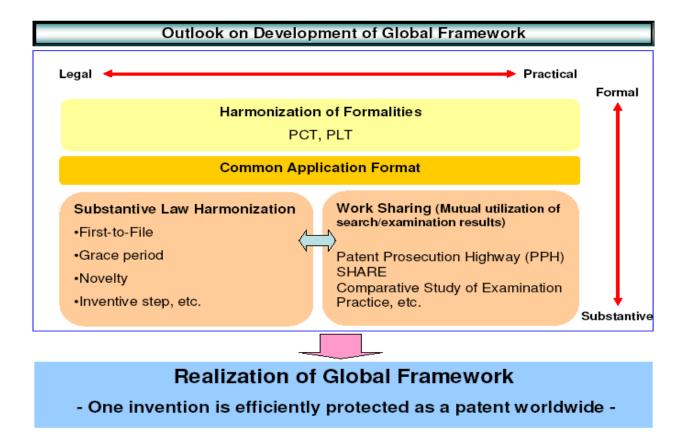
242K applications are duplicated. Enormous procedural and financial burdens to applicants, the Governments

Presentation of Hiroki Naito, Managing Director, Japanese Intellectual Property Association, Nov. 8, 2007

6



Work Sharing Based on Information Sharing

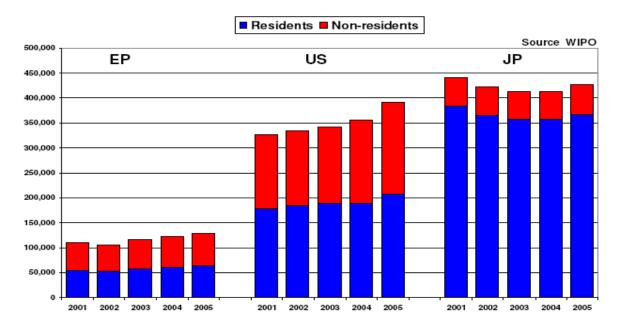


Koezuka Presentation



Workload Distribution

PHILIPS



Trilateral cooperation needed to cope with increasing workload from other countries

Philips Intellectual Property & Standards

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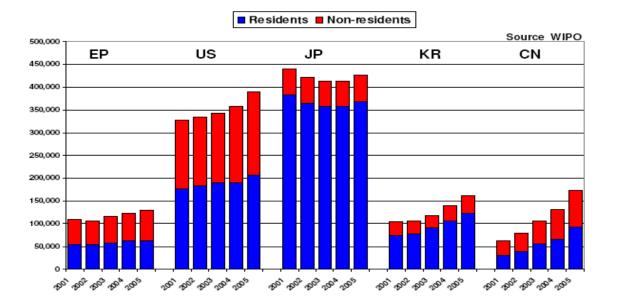
2007-11-08

Presentation of Ruud Peters, CEO, Intellectual Property & Standards, Koninklijke Philips Electronic N.V., to Trilateral Conference Nov. 8, 2007



Workload Distribution

PHILIPS



Closer cooperation with increasing number of patent offices needed

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Philips Intellectual Property & Standards

2007-11-08

Presentation of Ruud Peters, CEO, Intellectual Property & Standards, Koninklijke Philips Electronic N.V., to Trilateral Conference Nov 8, 2007 (Ruud Presentation)



Perceived Industry Needs

- Patent protection in more countries
- Predictable patent systems for efficient, timely issuance of enforceable quality patents at reasonable cost
- Uniformity across geographic boundaries "whether we can sell our products and not where we can sell"
 - Ruud Presentation



USPTO Worksharing Initiatives

Patent Prosecution Highway
 Full Implementation
 New Pilots

- New Route
- SHARE
- TriWay
- PCT Partnerships



Patent Prosecution Highway



 Allows an applicant to fast-track prosecution in second office when first office finds one or more claims allowable in the corresponding application

Benefits

 Second office gets search and examination results from first Office before conducting its own examination. Applicant gets results faster with higher quality.



- The USPTO and the Japan Patent Office (JPO) worked together to establish the PPH Program.
 - See Patent Prosecution Highway Pilot Program between the United States patent and trademark Office and the Japan Patent Office, 1307 Off. Gaz. Pat. Office 61 (June 13, 2006); and
 - Revised Requirements for Requesting Participation in the Patent Prosecution Highway Pilot Program in the USPTO, 1314 Off. Gaz. Pat. Office 1398 (Jan. 30, 2007).
 - Revised Requirements for Requesting Participation in the Patent Prosecution Highway Pilot Program in the USPTO, 1319 Off. Gaz. Pat. Office 63 (June 12, 2007).
 - Notice Regarding Full Implementation of Patent Prosecution Highway Program between the USPTO and the JPO, 1328 Off. Gaz. Pat. Office 44 (March 4, 2008).



- The USPTO and the United Kingdom Intellectual Property Office (UKIPO) launched a PPH Pilot Program.
 - See Patent Prosecution Highway Pilot Program between the United States Patent and Trademark Office and the United Kingdom Intellectual Property Office, 1322 Off. Gaz. Pat. Office 258 (Sept. 25, 2007).
 - Revised Requirements for Requesting Participation in the Patent Prosecution Highway Pilot Program in the USPTO (Between the USPTO and the UKIPO), 1327 Off. Gaz. Pat. Office 54 (Feb. 5, 2008).
- The program commenced September 4, 2007, and is scheduled to run through September 4, 2008.



- The USPTO and the Canadian Intellectual Property Office (CIPO) launched a PPH Pilot Program.
 - See Patent Prosecution Highway Pilot Program between the United States Patent and Trademark Office and the Canadian Intellectual Property Office, 1327 Off. Gaz. Pat. Office 45 (Feb. 5, 2008).
- The USPTO and the Korean Intellectual Property Office (KIPO) launched a PPH Pilot Program.
 - See Patent Prosecution Highway Pilot Program between the United States Patent and Trademark Office and the Korean Intellectual Property Office, 1327 Off. Gaz. Pat. Office 49 (Feb. 5, 2008).
- Both programs commenced January 28, 2008, and are scheduled to run through January 29, 2009.



- Applicants whose claim(s) is determined to be patentable in the office of first filing (OFF) may request that the corresponding application filed in the office of second filing (OSF) be advanced out of turn for examination, provided certain conditions are satisfied.
- The OSF gives priority to the examination of the corresponding application.
- The corresponding application receives a complete examination in the OSF because of differences in the patent laws, including what qualifies as prior art (101, 112, 102(e), claim interpretation, etc.).
- The office of second filing would be able to exploit the search and examination results of the office of first filing.
- Applicant may be able to obtain a patent on the corresponding application filed in the office of second filing faster.



- If the USPTO is the OFF and the U.S. application contains claims that are determined to be allowable, applicants may request to have the corresponding application filed in the OSF or advanced out of turn for examination in the OSF.
- If the JPO, UKIPO, CIPO, or KIPO is the OFF and the application contains claims that are determined to be allowable, applicant may petition to make the U.S. application special under the PPH (pilot) program.
- The UKIPO, CIPO and KIPO programs maintain consistency to the extent possible with the USPTO/JPO program to avoid creating burdens on applicants and Offices, an to ensure maximum worksharing potential.



- The procedures and requirements for filing a request for participation in the fully implemented JPO PPH program are available from:
 - The JPO web site at: http://www.jpo.go.jp/
- The procedures and requirements for filing a request for participation in the UKIPO, CIPO, or KIPO PPH pilot programs are available from:
 - The UKIPO web site at: http://www.ipo.gov.uk/home.htm
 - The CIPO web site at: http://www.cipo.ic.gc.ch/pph/
 - The KIPO web site at: http://www.kipo.go.kr/kpo2/user.tdf?a=user.english.html.HtmlApp&c=6 0622&catmenu=ek60600



Patent Prosecution Highway Pilot Program - Requirements

Requirements:

- The U.S. utility application filed under 35 U.S.C. 111(a) must claim foreign priority to the OFF application under 35 U.S.C. 119(a)-(d) and §1.55 or through a PCT.
- The OFF application must contain at least one claim that was determined by the OFF to be allowable.
- All the claims in the U.S. application (including any subsequently amended or added claims) must sufficiently correspond to the allowable claims in the OFF application.
 - The claims must have the same or similar scope.
 - They could have differences due to translations and claim format requirements.



Patent Prosecution Highway Pilot Program - Requirements

<u>Requirements</u> (continued) - Applicant must file:

- A request for participation in the PPH (pilot) program, and a petition to make special accompanied by the petition fee under § 1.17(h) (see PTO/SB/20) prior to the first Office action on the merits;
- A copy of all OFF Office actions (excluding "Decision to Grant a Patent"). If not in English, an English translation thereof, and a statement that the English translation is accurate;
- An information disclosure statement (IDS) under §§ 1.97 and 1.98 listing the documents cited by the OFF examiner; and
- A copy of the allowable claims in the OFF application. If not in English, an English translation thereof and a statement that the English translation is accurate.



Patent Prosecution Highway Pilot Program - Requirements

Requirements (continued):

- Applicant must submit a claims correspondence table in English to indicate how all of the claims in the U.S. application correspond to the allowable claims in the OFF application (see PTO/SB/20).
 - Updated claims correspondence table may be required for an amendment to the claims.
 - More information regarding the PPH program is available at http://www.uspto.gov/web/patents/pph/pph_index.html
- Inquiries on the pilot program should be directed to Magdalen Greenlief at 571-272-8800 or via e-mail addressed to magdalen.greenlief@uspto.gov



Patent Prosecution Highway Full Implementation Differences

- Papers must be filed through EFS-Web.
- Only a copy of the JPO Office action just prior to the "Decision to Grant a Patent" (e.g., the latest "Notification of Reasons for Refusal") along with an English translation thereof, and a statement that the English translation is accurate need be submitted.
- If there was no "Refusal" then applicant should indicate on the request form that no JPO action is submitted since the JPO application was allowed on first action.



- Outcome
 - Accelerated examination in OSF
 - Faster patentability determination in OSF
 - Work-sharing benefit
- As of January 4, 2008
 - Commenced permanent PPH program with JPO
- On-going PPH pilot with UK IPO since Sept. 4, 2007
- As of January 28, 2008
 - Commenced PPH pilot with CIPO and KIPO
- All PPH submissions must be filed via EFS-Web



- Empirical Observations by US Examiners
 - Claim sets narrower than in a typical US case
 - Fewer claims than in a typical US case
 - Focused US search on non-Japanese language art
- Anecdotal Feedback of Advantages
 - Narrower field of search
 - Fewer claims = faster processing
 - Better base of prior art (from which to start)
- But there are Issues
 - Search History documentation
 - Reasons for Allowance would be helpful



Request for Participation in the Patent Prosecution Highway (PPH) Pilot Program Between the (1) JPO Or (2) UKIPO, and the USPTO(PTO/SB/20)

PTO/SB/20 (09-07)

Approved for use through 12/31/2008. OMB 0651-0058 U.S. Patent and Trademark Office: U.S DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

REQUEST FOR PARTICIPATION IN THE PATENT PROSECUTION HIGHWAY (PPH) PILOT PROGRAM BETWEEN THE (1) JPO OR (2) UKIPO, AND THE USPTO					
Application No.:	F	First Named Inventor:			
Filing Date:	A	Attorney Docket No.:			
Title of the Invention:					
THIS REQUEST FOR PARTICIPATION IN THE PPH PILOT PROGRAM MUST BE FAXED TO: THE OFFICE OF THE COMMISSIONER FOR PATENTS AT 571-273-0125 DIRECTED TO THE ATTENTION OF MAGDALEN GREENLIEF					
APPLICANT HEREBY REQUESTS PARTICIPATION IN THE PATENT PROSECUTION HIGHWAY (PPH) PILOT PROGRAM AND PETITIONS TO MAKE THE ABOVE-IDENTIFIED APPLICATION SPECIAL UNDER THE PPH PILOT PROGRAM.					
The above-identified application validly claims priority under 35 U.S.C. 119(a) and 37 CFR 1.55 to one or more corresponding JPO application(s) or UKIPO application(s).					
The JPO UKIPO application number(s) is/are:					
The filing date of the 🔲 JPO 🔲 UKIPO application(s) is/are:					



New Route

- Concept
 - Similar to PCT, but with less administrative overhead and costs
 - ◆ filing in one member office is deemed a filing in all member offices
 - ♦ 30-month processing and 18 month publication by first office

Benefits

- All designated second offices get search and examination results from first Office prior to "national stage" examination
- Applicants save money, get higher quality patents
- New Route Pilot Project between the United States Patent and Trademark Office and the Japan Patent Office (signed 24 January 2008) http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/new_route_pilot_012008.pdf



<u>Strategic Handling of Applications for</u> <u>Rapid Examination - SHARE</u>

- SHARE is a proposal to implement a policy of prioritizing search and examination of first filings, with the stated goal of leveraging the work of the Office of First Filing (OFF) to enhance the throughput and quality at the Office of Second Filing (OSF).
- The SHARE proposal would prioritize examination of applications by giving precedence in examination of applications filed with the OFF.
- SHARE has a goal of leveraging worksharing to the maximum extent possible consistent with appropriate examination under each Office's statutory framework.





Concept

- USPTO initiative to leverage the expertise of each Office in searching its own documentation and/or documentation in its native language (e.g., Japanese documentation searched by JPO)
- Each Office searches corresponding application and provides results to other offices for use in examination

Benefits

Higher quality search and examination



PCT Partnership

Concept

Outsourcing PCT Chapter I by contract

 Designating alternative ISAs for US applicants filing in RO/US or RO/IB - EP & KR

Benefit

- Frees up USPTO examining resources by having other entities do PCT Chapter I work
- Reduces Pendency of National Applications



Outsourcing of Chapter I PCTs

- Work is outsourced via 4 contracts
- 50 applications were completed in Swedish Patent Office pilot project, and the work is currently undergoing quality review
- Australian Patent Office handles up to 100 applications per month
- Two private contractors: one is limited to specific technologies; other works on all technologies
- USPTO projects 280/week will be outsourced to private contractors for the remainder of FY2008 subject to budget limitations
- All outsourced work is reviewed by USPTO personnel prior to mailing



Choice of ISA for International Applications filed in RO/US

	ISA/US	ISA/EP	ISA/KR
Aug 2007	56%	40%	4%
Sep 2007	57%	37%	6%
Oct 2007	54%	40%	6%
Nov 2007*	51%	40%	9%
Dec 2007	40%	46%	14%
Jan 2008	45%	40%	15%
Feb 2008	42%	42%	16%

Search Fee:	
ISA/US:	\$1800
ISA/EP:	\$2274
ISA/KR:	\$244

* Increase of ISA/US search fee on 09 Nov 2007



Accelerated Examination



- Overview
- Filing Requirements
- Examination Procedure
- Statistics to Date



Accelerated Examination Overview

- GOAL: Achieve a final decision by the examiner within 12 months from the filing date
- Effective August 25, 2006
 - Petitions prior to this date are not included
- The new requirements apply to <u>all</u> petitions to make special, except for:
 - Age and health
 - Patent Prosecution Highway



Accelerated Examination Filing Requirements

- The application must:
 - Be filed electronically
 - Be complete at filing
 - Contain 3/20 total claims or fewer directed to a single invention
 - Include a petition
 - Include a fee (unless the claims are directed to environmental quality, energy, or countering terrorism)



Accelerated Examination Filing Requirements (cont.)

The petition must include statements that applicant:

- Will make election without traverse
- Will have an interview
- Will not separately argue any dependent claim during appeal

• The petition must be accompanied by:

- A pre-examination search
- An accelerated examination support document (ESD)



Accelerated Examination Review Within the USPTO

Petition will be initially denied if:

- It fails to meet filing requirements
- Application is not eligible (plant, reissue, reexam, 371)
- Petition will be dismissed if it has defects:
 - Defects will be specifically noted
 - Applicant has one chance to cure
- Petition will be ultimately denied if:
 - Applicant was unable to cure defects in prescribed time period



Accelerated Examination The Pre-Examination Search

- The pre-examination search must include a search of:
 - U.S. Patents
 - Patent application publications
 - Foreign patent documents
 - Non-patent literature
- Search directed to the claimed invention giving claims their broadest reasonable interpretation
- Include a classified search and text search



Accelerated Examination If the Search is Deficient

Petition Dismissal or Denial:

- Will include specifics of deficiency with suggestions for overcoming it
- Unless it is readily apparent that the applicant's search is wholly deficient
 - Here, only general guidance directed at improving the search will be given in the decision



Accelerated Examination The Examination Support Document

The accelerated examination support document must include:

- An <u>information disclosure statement</u> citing each reference deemed most closely related to the claims
- An identification of <u>where each limitation disclosed</u> in each reference is found
 - Refer to specific paragraphs or drawing elements
- A <u>detailed explanation</u> of how each claim is patentable over each reference
 - Be specific general statements are not sufficient



Accelerated Examination The Examination Support Document

- A concise <u>statement of utility</u> of the invention
- A showing of <u>support for each claim</u> limitation in the specification
 - Point to page, line numbers or drawing elements
- An identification of any cited reference(s) that may be disqualified as prior art under <u>35 U.S.C. 103(c)</u>



Accelerated Examination Examination Processing

- The application will be taken up for action shortly after petition decision
- The examiner will complete a prior art search
- Prior to any first Office action rejection:
 - Conference held to confirm rejection
 - Telephone or personal interview is conducted
- An additional conference will be held prior to any final rejection



Accelerated Examination Applicant's Reply

- Shorter Statutory Periods (SSP) for applicant reply:
 - 1-month (or 30 days) SSP for any action except final rejection or allowance
 - No time extensions under Section 1.136(a) only 1.136(b).
 - Failure to timely reply results in abandonment
- If response includes either amended or newly-added claims:
 - An updated search will be required if claims are not encompassed by the pre-examination search
 - An updated AE support document will be required if claims are not encompassed by original AE support document



Accelerated Examination Applicant's Reply (cont.)

The Office will treat any amendments (including after final amendments and RCE submissions) as not being fully responsive if the amendment:

- Exceeds the 3/20 claim limit;
- Presents claims to a non-elected invention;
- Presents claims not encompassed by the pre-examination search, or an updated search; or
- Presents claims requiring an updated AE support document, which is not submitted.



Accelerated Examination Tips for Getting a Petition Granted

- Search the claimed invention. The search must be commensurate in scope with the claims.
- Search should include U.S. Patents and pubs, foreign patents & pubs and non-patent literature.
- Provide the text search logic. A listing of terms will not suffice.
- Show support in the specification and/or drawings for each limitation of each claim. Be specific.
- Clearly and specifically identify the limitations in each claim found in each reference. A chart is a clear, convenient format.
- Clearly point out by specific claim language how each claim is patentable over each reference.

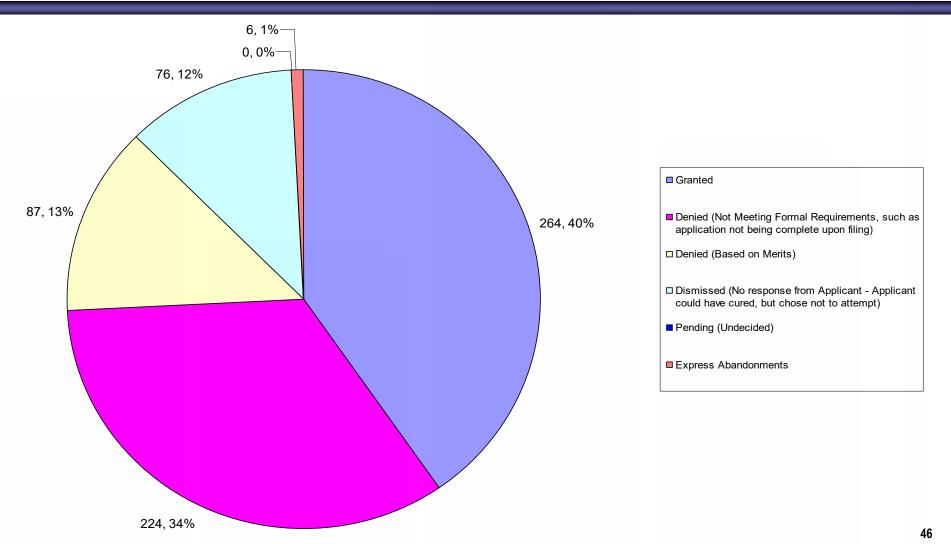


Accelerated Examination Statistics to Date (2/18/08)

٠	Petitions Received	1096	
٠	Petitions Granted	344	
٠	Petitions Out of Program	483	
٠	Petitions Pending	269	
٠	Patents issued	73	
٠	Average Pendency (to com	plete of prosecution)	184 days
	 To issue 	240 days	
	Minimum	75 days	
	Maximum	466 days (ind	cluding RCE)

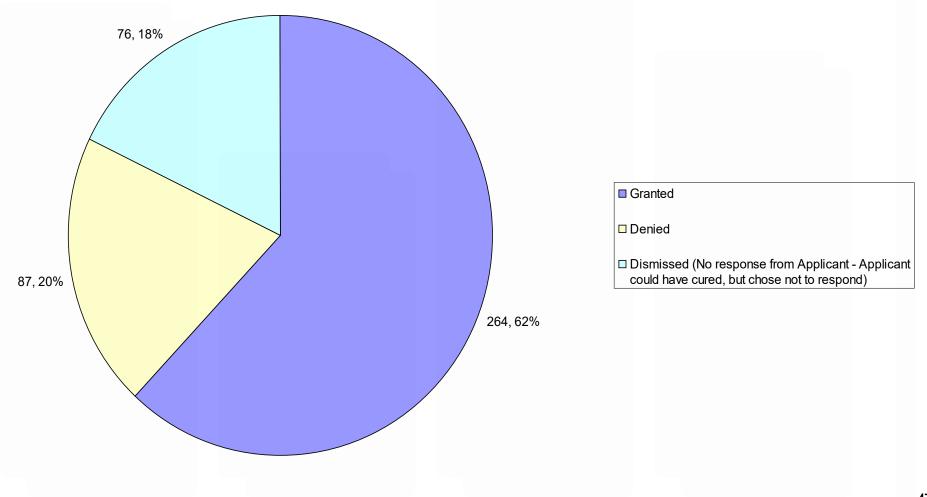


AE Petitions Status as of 2/20/08 (All filed N=657 as of 8/31/07)





AEs Decided on Merits/Substance 2/20/08 (Met formal req'ts, N=427 as of 8/31/07)





Accelerated Examination Statistics to Date (9/1/07 - 2/18/08)

 Petitions Received 	439	
 Petitions Granted 	80	
 Petitions Denied Ineligible/Merits 	72 51/21	
 Petition Decisions not res — Formalities/Merits Merits: Substantive defect not 	3/12	e period
 Petitions Pending 	269	
Abandoned	3	



AE Statistics on First Year Filings (As of 2/20/08)

	AE Petition Status		
Petition Status	Number of Applications	Percentage	
Granted	264	40.2%	
Denied (Not Meeting Formal			
Requirements, such as application			
not being complete upon filing)	224	34.1%	
Denied (Based on Merits)	87	13.2%	
Dismissed (No response from			
Applicant - Applicant could have			
cured, but chose not to attempt)	76	11.6%	
Pending (Undecided)	0	0.0%	
Express Abandonments	6	0.9%	
Total	657		
	AE Prosecution Status		
	Number of Applications	Percentage	
Total	264	100%	
Pending	170	64.4%	
Completed Prosecution	206		
Allowed	90	30.0%	
Abandoned	4	0.9%	
		AE Final Disposition	
	(as defined in the Fed		
A.I	Number of Applications	Percentage	
Allowed	90		
Abandoned	4		
Final Rejection	112	70.00/	
Total Dending Final Dispessition	206	78.0%	
Pending Final Disposition	58	22.0%	



Accelerated Examination Information Links

- ◆ AE Home Page: http://www.uspto.gov/web/patents/accelerated
- ♦ AE Federal Register Notice: http://www.uspto.gov/web/offices/com/sol/notices/71fr36323.pdf
- Sample AE Petition Form SB/2B: http://www.uspto.gov/web/forms/sb0028_fil.pdf
- Sample AE Pre-Examination Search Document: http://www.uspto.gov/web/patents/accelerated/ae_presearch_sample.doc
- Sample AE Support Document: http://www.uspto.gov/web/patents/accelerated/ae_support_document_sample.doc
- FAQs: http://www.uspto.gov/web/patents/accelerated/ae_faq.htm



Thank You!