

Exhibit 9

**Presentation to Office of Management and Budget by parties including Polestar
(June 15, 2007)**

Part 5: Attachment N (continued) (P000419-506)



UNITED STATES PATENT AND TRADEMARK OFFICE

OFFICE OF THE GENERAL COUNSEL

Dear Sir/Madam:

Your Freedom of Information Act (FOIA) request was received by the Freedom of Information Officer (FOIA) on 9/13/06.

Your request has been docketed as "**FOIA/PA Request No. 06-359**". Any further inquiries regarding your request should include that number. A copy of your request is attached for reference.

In the event your original request was incorrectly addressed, please address all inquiries regarding your request to:

FREEDOM OF INFORMATION ACT (FOIA) OFFICER
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

Sincerely,

A handwritten signature in black ink, appearing to be "RF", written over a horizontal line.

Robert Fawcett
FOIA Officer

EFOIA

From: Boundy, David [dboundy@willkie.com]
Sent: Tuesday, September 12, 2006 1:44 PM
To: EFOIA
Subject: rulemaking files

OFFICE OF THE
GENERAL COUNSEL

SEP 13 AM 6:20

U.S. PATENT
AND
TRADEMARK OFFICE

01-359

I would like the files for these three rulemaking proceedings. In order to reduce page burden, please exclude the public comments that are posted on the PTO web site -

RIN 0651-AB93 "Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Application Containing Patentably Indistinct Claims" (71 Fed. Reg. 48, January 3, 2006) and

RIN 0651-AB94 "Changes to Practice for the Examination of Claims in Patent Applications" (71 Fed. Reg. 61, January 3, 2006)

RIN 0651-AB95 "Changes to Information Disclosure Statement Requirements and Other Related Matters" (71 Fed. Reg. 38808, July 10, 2006)

David Boundy
Willkie Farr & Gallagher LLP
787 Seventh Avenue
New York, NY 10019
(212) 728 8757
(212) 728 9757 (FAX)



UNITED STATES PATENT AND TRADEMARK OFFICE

GENERAL COUNSEL

OCT 12 2006

Mr. David Boundy
Willkie Farr & Gallagher, LLP
787 Seventh Avenue
New York, NY 10019

Re: Freedom of Information Act (FOIA) Request No. 06-359

Dear Mr. Boundy:

The Office of the General Counsel received your e-mail dated September 12, 2006, requesting, under the Freedom of Information Act (5 U.S.C. § 552) a copy of:

“the files for [RIN 0651-AB93, 0651-AB94, 0651-AB95].”

The United States Patent and Trademark Office (USPTO) identified 114 pages of documents that are responsive to your request and are releasable. A copy of the material is enclosed.

Since the processing costs of this request were less than \$20.00 applicable fees are hereby waived.

Sincerely,

A handwritten signature in black ink, appearing to be "Robert Fawcett", written over a horizontal line.

Robert Fawcett
FOIA Officer

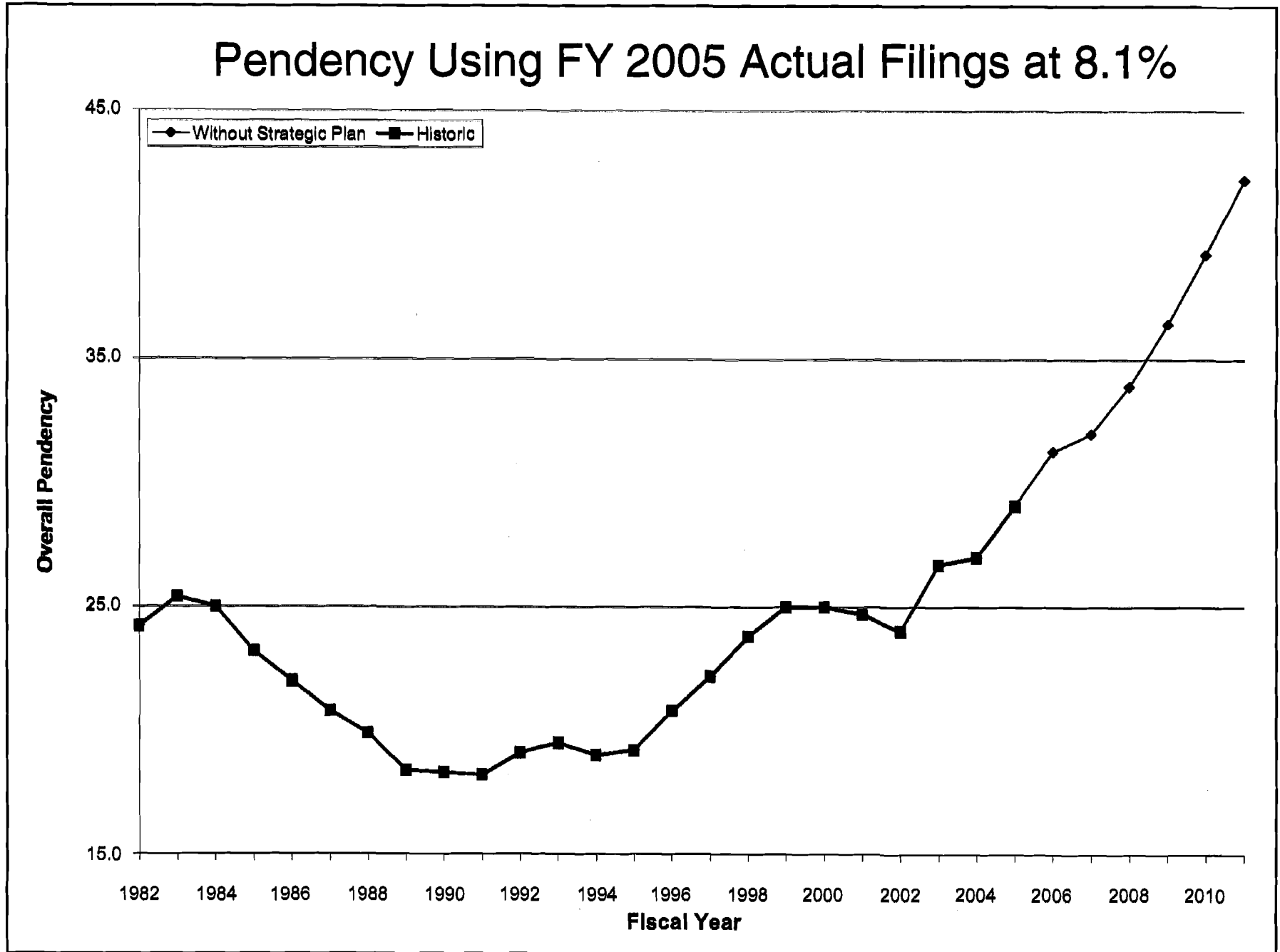
Enclosure



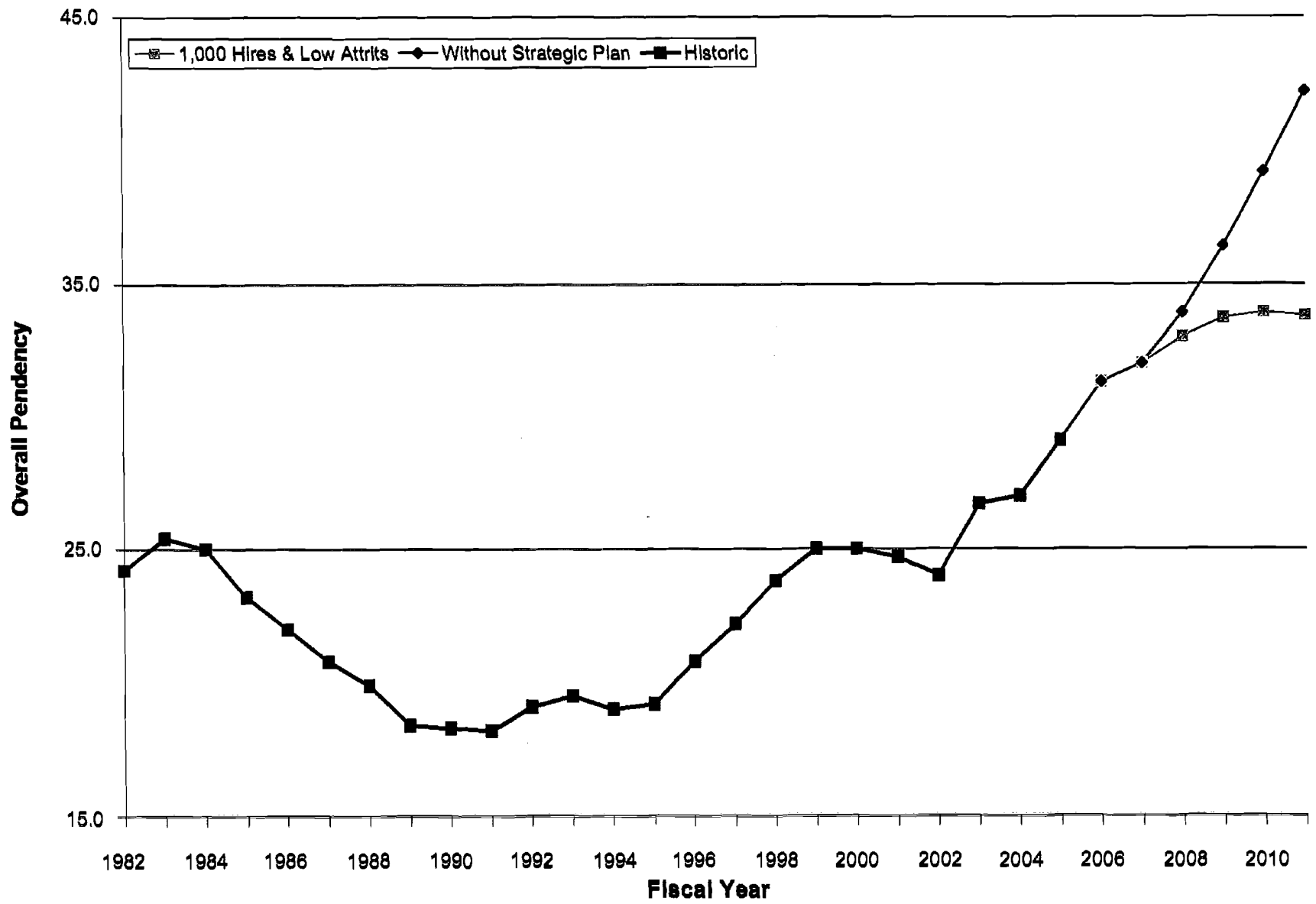
John Doll – Commissioner for Patents

February 1, 2006

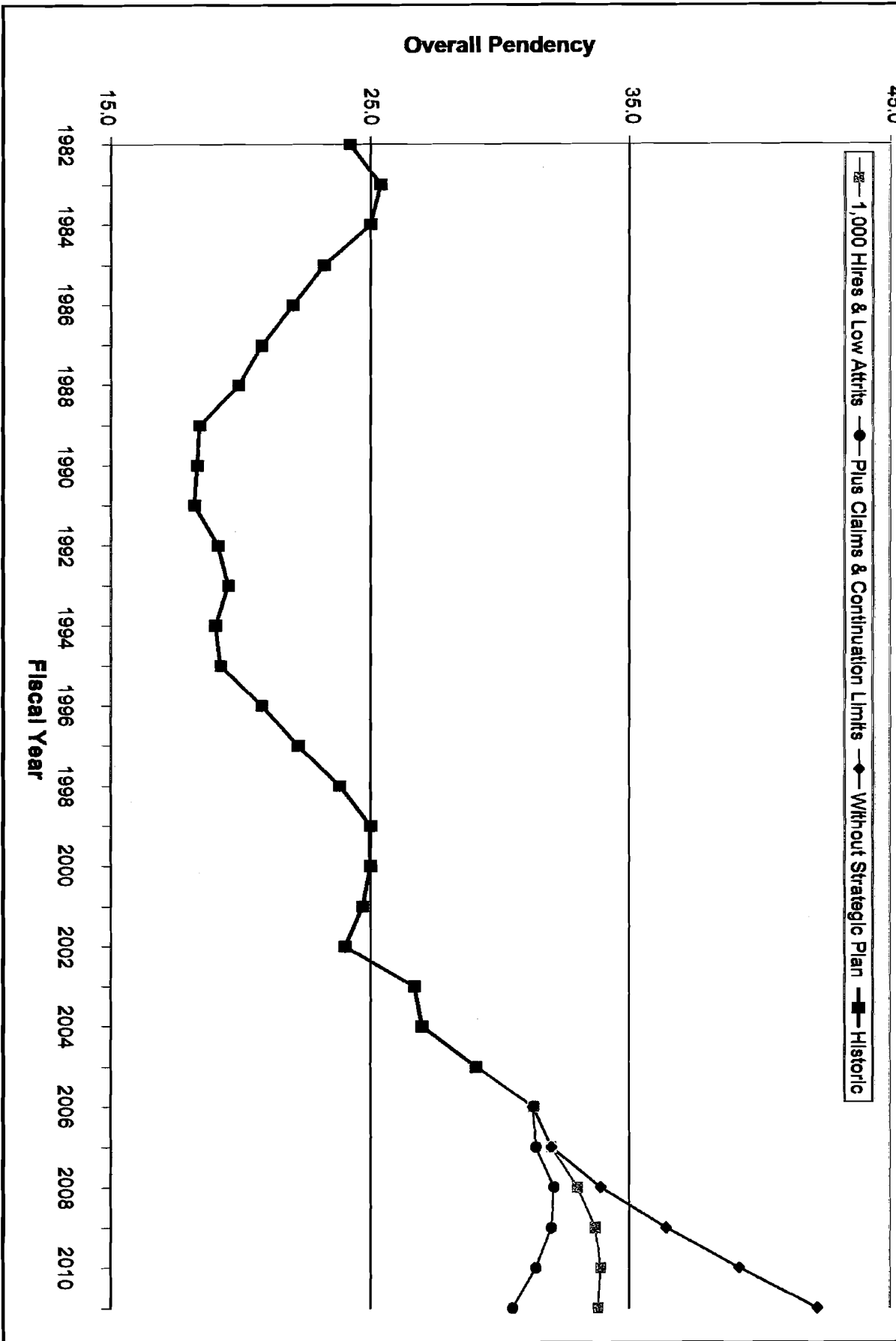
Pendency Projections



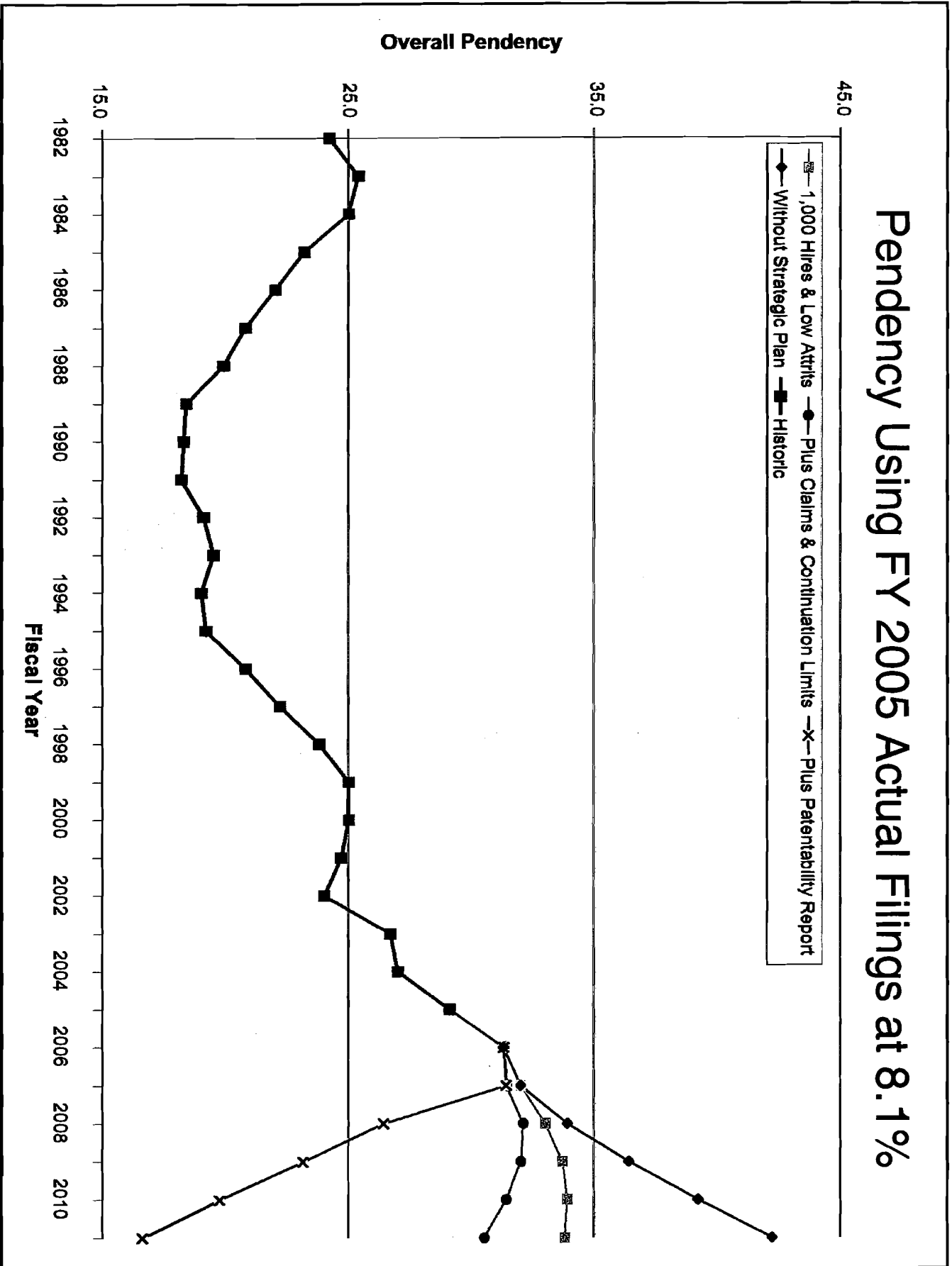
Pendency Using FY 2005 Actual Filings at 8.1%



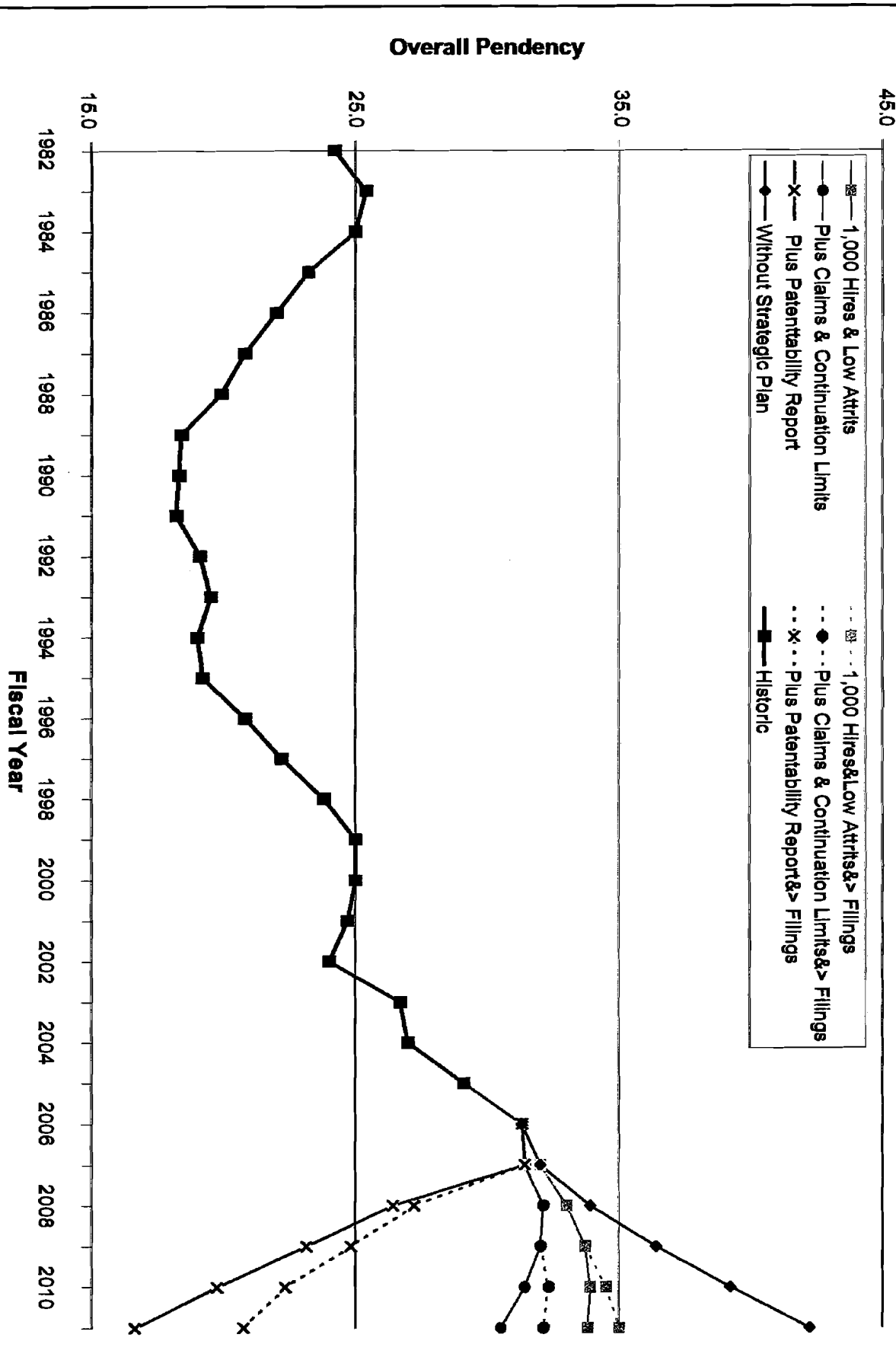
Pendency Using FY 2005 Actual Filings at 8.1%



Pendency Using FY 2005 Actual Filings at 8.1%



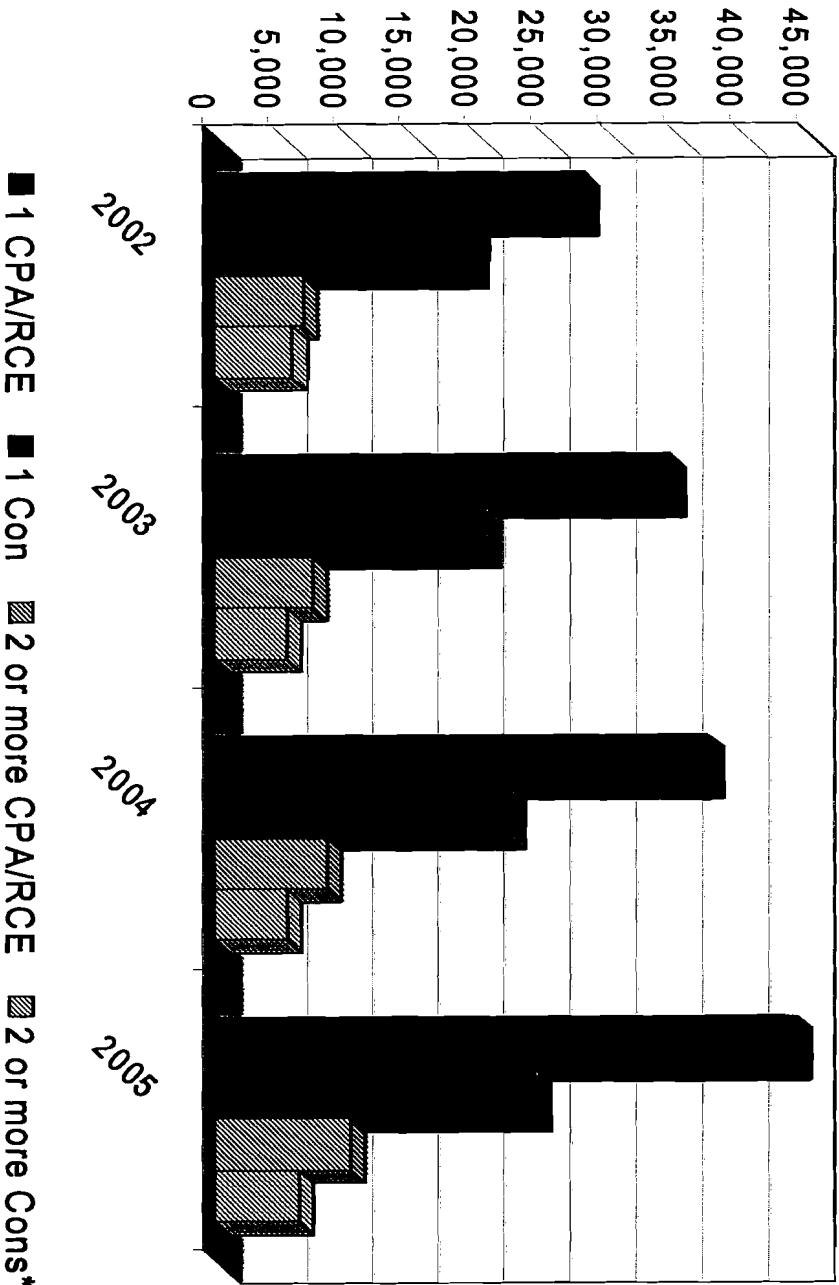
Pendency Using FY 2005 Actual Filings at 8.1%



Stats and stuff



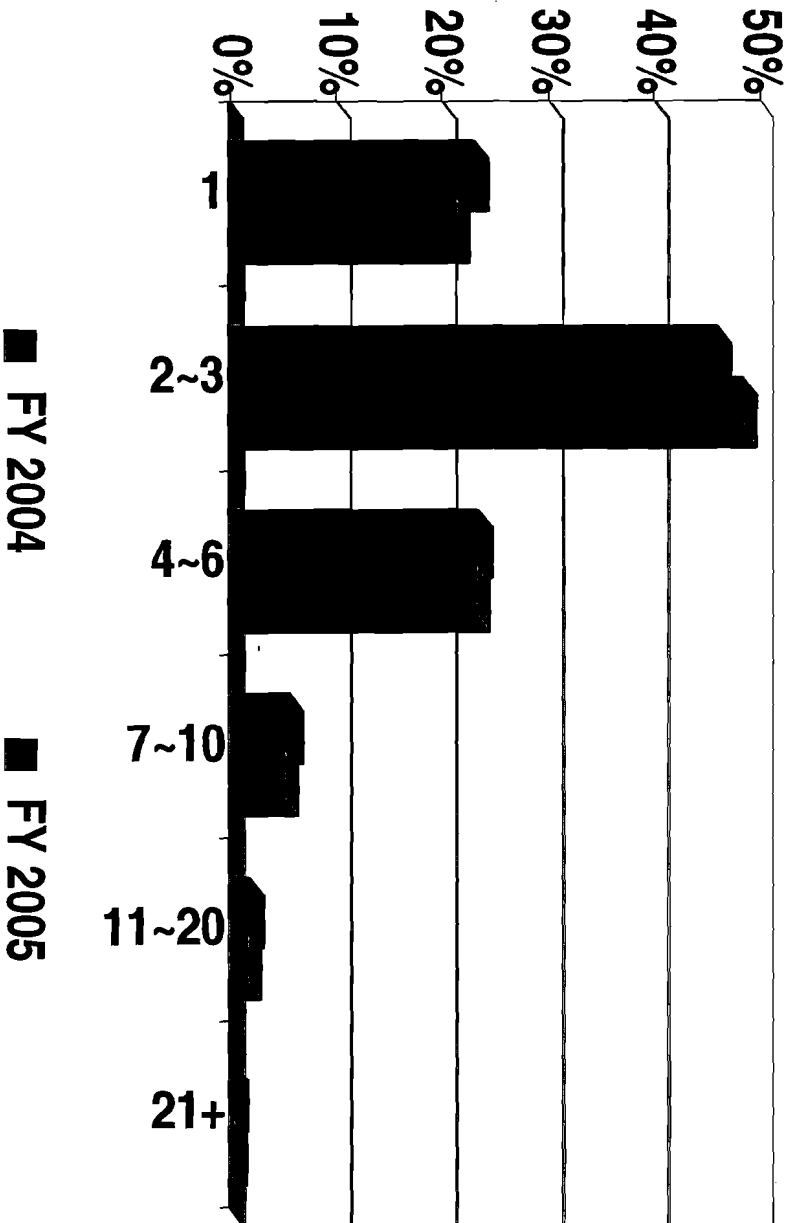
Total Continuation Filing Rates



*Straight Continuations 37 CFR §1.53 (b)(1) – No Divisionals or CIPs – as of 1/17/06

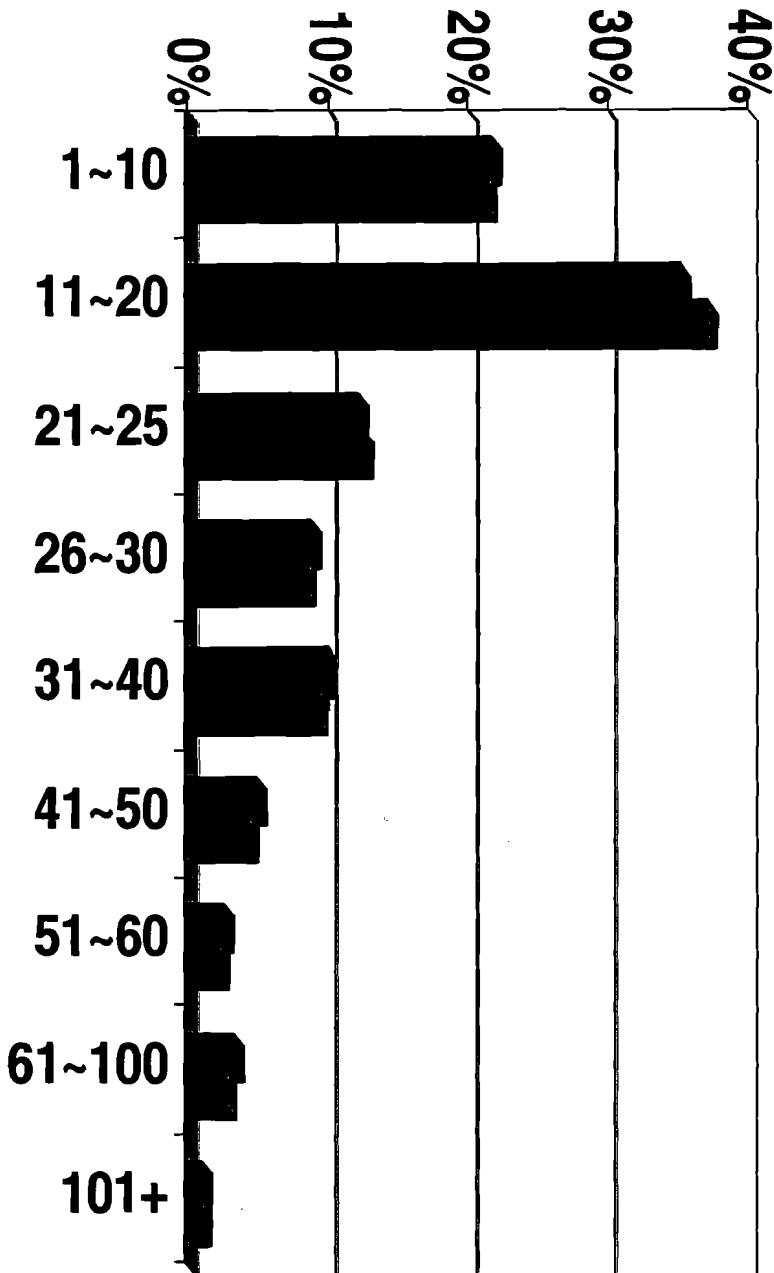


Distribution of Independent Claims at Filing



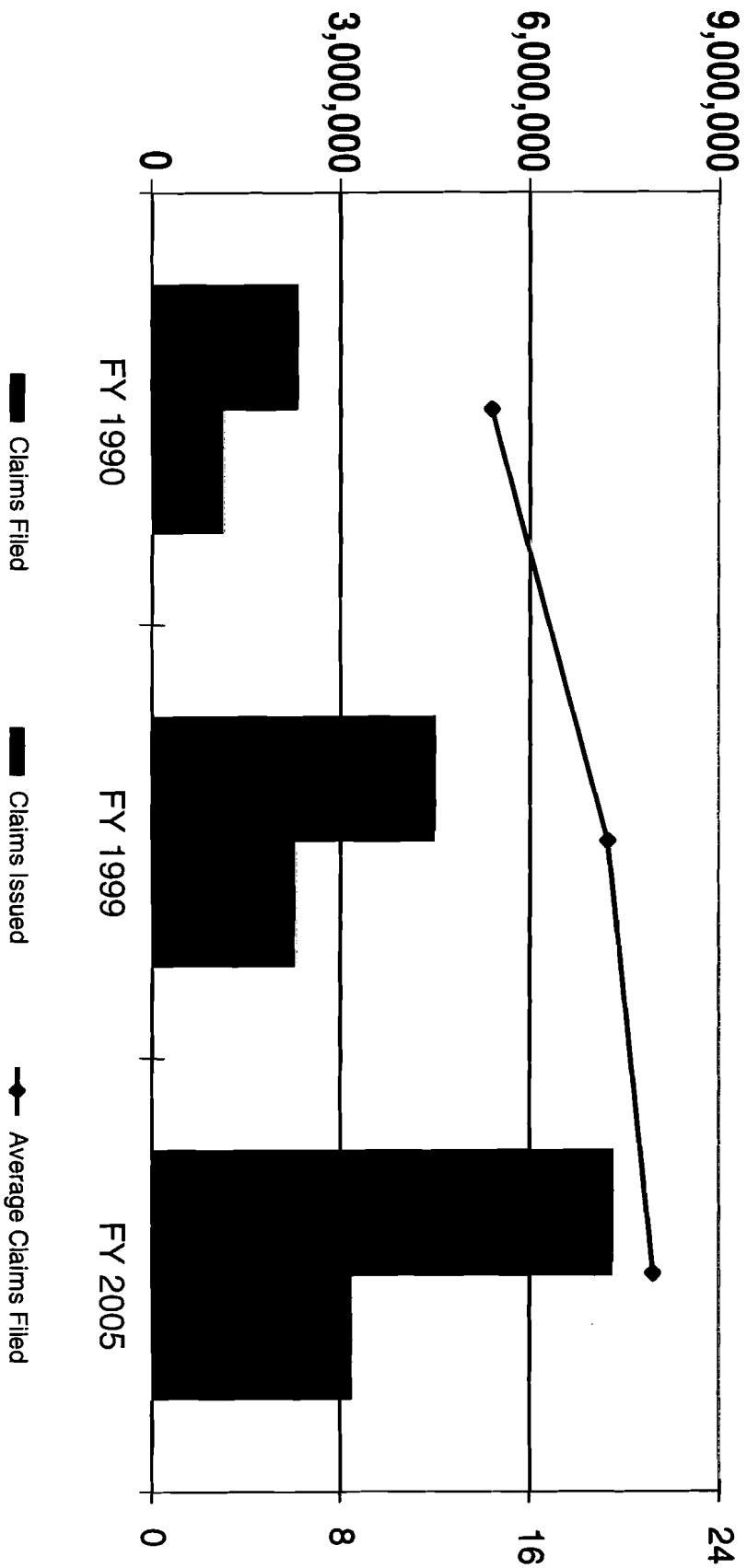


Distribution of Total Claims at Filing



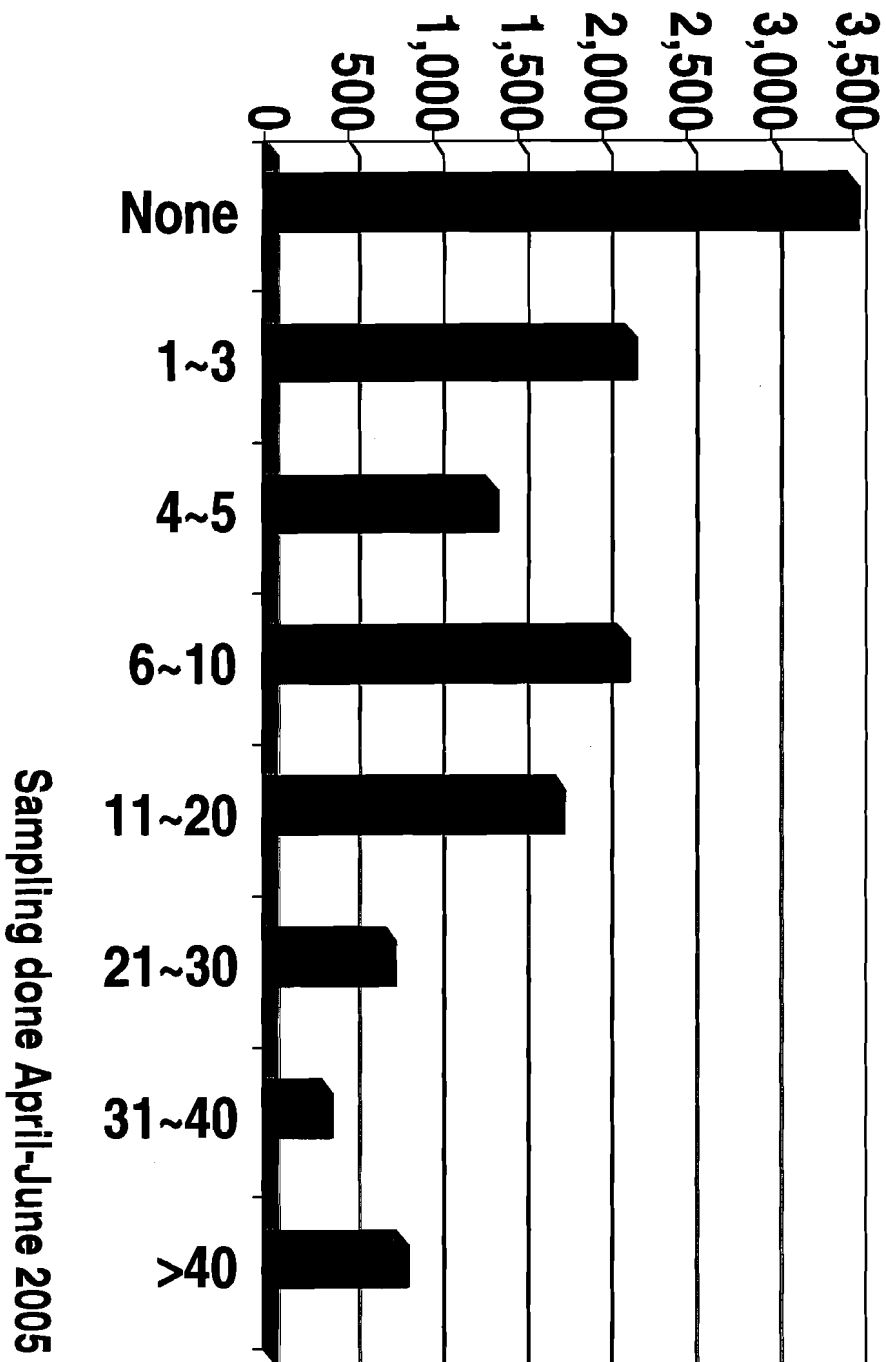


Total Claims at Filing and Issue





Distribution of the Number of References Cited in Applications



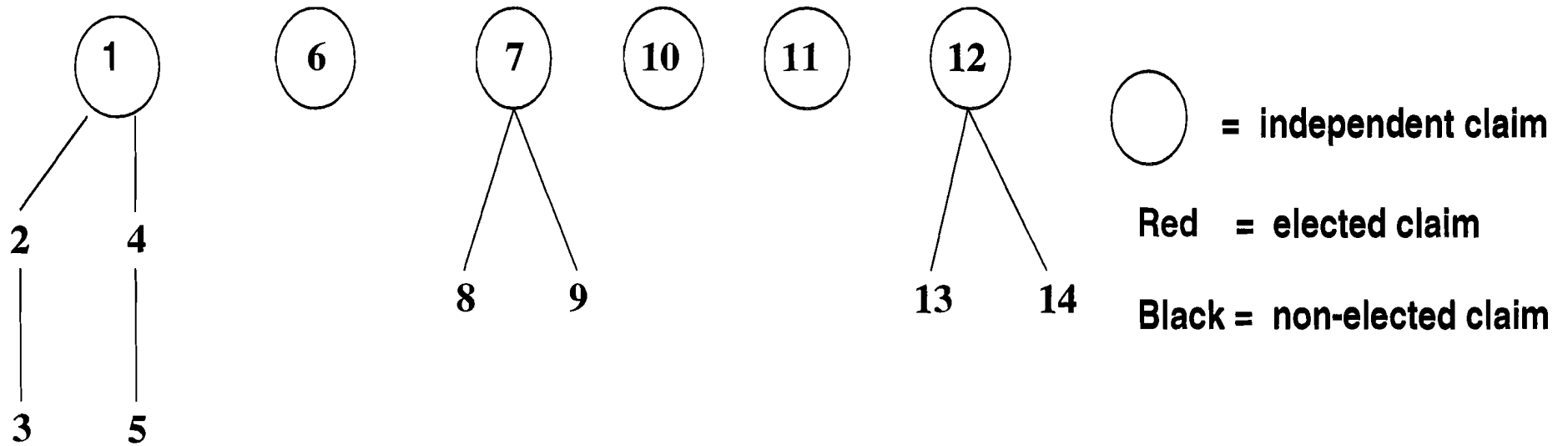


Changes to Practice for the Examination of Claims in Patent Applications

Examples



Election of Claims – Example 1



- All independent claims must be elected.
- The election of claim 3 is improper. An elected dependent claim must depend from another elected claim. Applicant can choose to re-write claim 3 to depend from 1, or also elect claim 2 to be examined.



Election of Claims – Example 2

P000437

Claims

1. An apparatus comprising....
- ...
- ...
7. The method of using the apparatus of claim 1 to

Claim 7 is an independent method claim and will be treated as such for the purposes of claim election. Therefore, it must be elected to be examined.



Election of Claims – Example 3

Claims:

1. An apparatus comprising....
- ...
- ...
4. An apparatus as claimed in one of claims 1-3 further comprising....

For the purposes of election, proper multiply dependent claim 4 will be treated as 3 separate claims. Thus, 3 claims will be counted to determine whether the applicant has exceeded the 10 claim limit to avoid submission of an examiner support document.



Election of Claims – Example 4

P000439

Applicant files an application with claims to a single invention.
The application is filed with 10 total claims: 3 independent claims and 7 dependent claims.

For examination purposes:

- If the applicant designates all 7 dependent claims for initial examination, the Office will give initial examination to all 10 claims.
- If the applicant does not designate any dependent claims for initial examination, the Office will give initial examination only to the 3 independent claims.



Election of claims – Example 5

Applicant files an application with claims to a single invention. The application is filed with 10 total claims: 3 independent claims and 7 dependent claims. The applicant designates all dependent claims, in addition to the independent claims, as representative claims for initial examination.

Applicant files an amendment which (a) cancels 3 claims (1 independent and 2 dependent) and (b) adds 11 claims (4 independent and 7 dependent). The application, as amended, now contains 18 claims: 6 independent claims and 12 dependent claims.

- **If the applicant does not change the original designation of dependent claims,***
 - **the applicant must submit an examination support document covering the 11 representative claims, or**
 - **reduce the number of representative claims to 10 or fewer by canceling independent claims, rescinding the designating of dependent claims for initial examination, or a combination of thereof.**

***In this instance, there are now 11 designated representative claims: 6 independent claims and 5 dependent claims.**



Election of claims – Example 6

Applicant files an application with claims to a single invention. The application is filed with 20 total claims: 3 independent claims and 17 dependent claims.

- **If applicant does not designate any dependent claims for initial examination, the Office will give initial examination only to the 3 independent claims.**
- **If applicant designates 7 dependent claims for initial examination, the Office will give initial examination to 10 claims; 3 independent claims and 7 designated dependent claims.**



Election of Claims – Example 7

Applicant files an application with claims to a single invention. The application is filed with 20 total claims: 3 independent claims and 17 dependent claims.

If applicant designates all 17 dependent claims for initial examination, the application will have 20 representative claims.

Applicant must:

- submit an examination support document covering the 20 representative claims, or**
- reduce the number of representative claims to 10 or fewer by canceling independent claims, rescinding the designating of dependent claims for initial examination, or a combination thereof.**



Election of Claims – Example 8

Example 1: An applicant files an application with claims to 3 distinct inventions. The application is filed with 30 claims: 3 independent claims and 27 dependent claims.

If applicant does not designate any dependent claims for initial examination:

- The Office give initial examination only to the 3 independent claims.**
- The Office may still restrict the application to a single**



Election of Claims – Example 9

An applicant files an application with claims to 3 distinct inventions. The application is filed with 30 claims: 3 independent claims and 27 dependent claims

If the applicant designates 7 dependent claims for initial examination:

- The Office will give initial examination to 10 claims: 3 independent claims and 7 designated dependent claims.**
- The Office may still restrict the application to a single invention.**



Election of Claims – Example 10

An applicant files an application with claims to 3 distinct inventions. The application is filed with 30 claims: 3 independent claims and 27 dependent claims.

If applicant designates all 27 dependent claims for initial examination, the application will have 30 representative claims. The applicant must:

- **submit an examination support document covering the 30 representative claims;**
- **reduce the number of representative claims to 10 or fewer by canceling independent claims, rescinding the designating of dependent claims for initial examination, or a combination thereof; and/or**
- **reduce the number of representative claims to 10 or fewer by suggesting a requirement for restriction and election w/out traverse of such representative claims.**



Changes to Practice for Continuing Applications

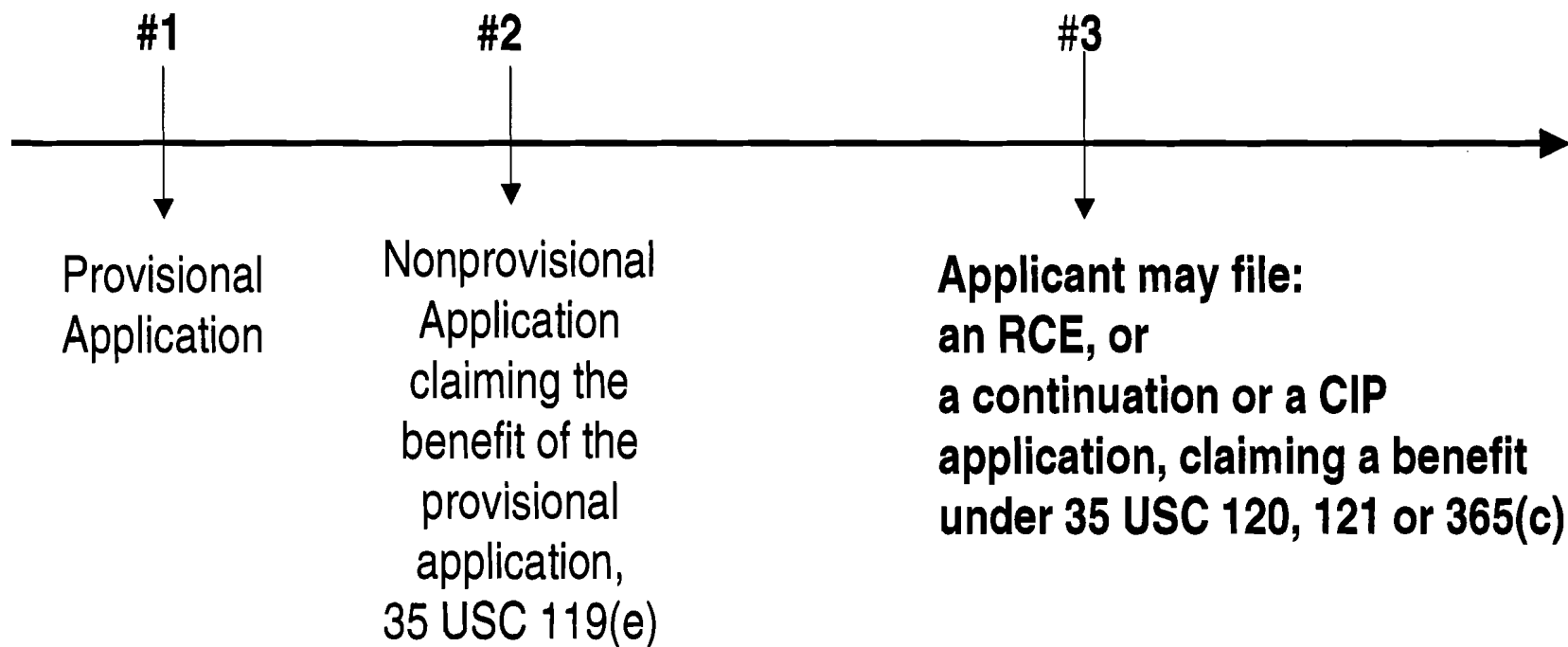
Examples



Continuations

Benefit Claims under 35 USC 120, 121, or 365(c)

One RCE, Continuation, or CIP Permitted

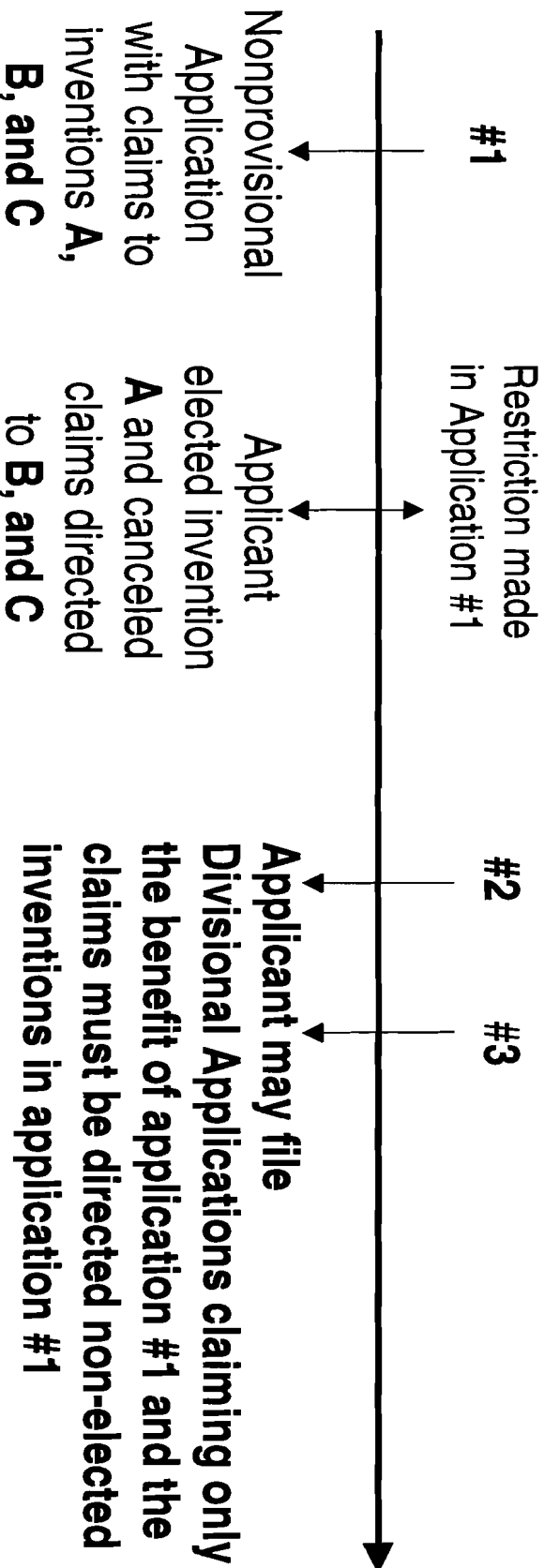




Continuations

Benefit Claims under 35 USC 120, 121, or 365(c)

Divisional Applications Can Only Claim Benefit of One Prior Nonprovisional Application That Was Subject to a Restriction or Unity of Invention Requirement

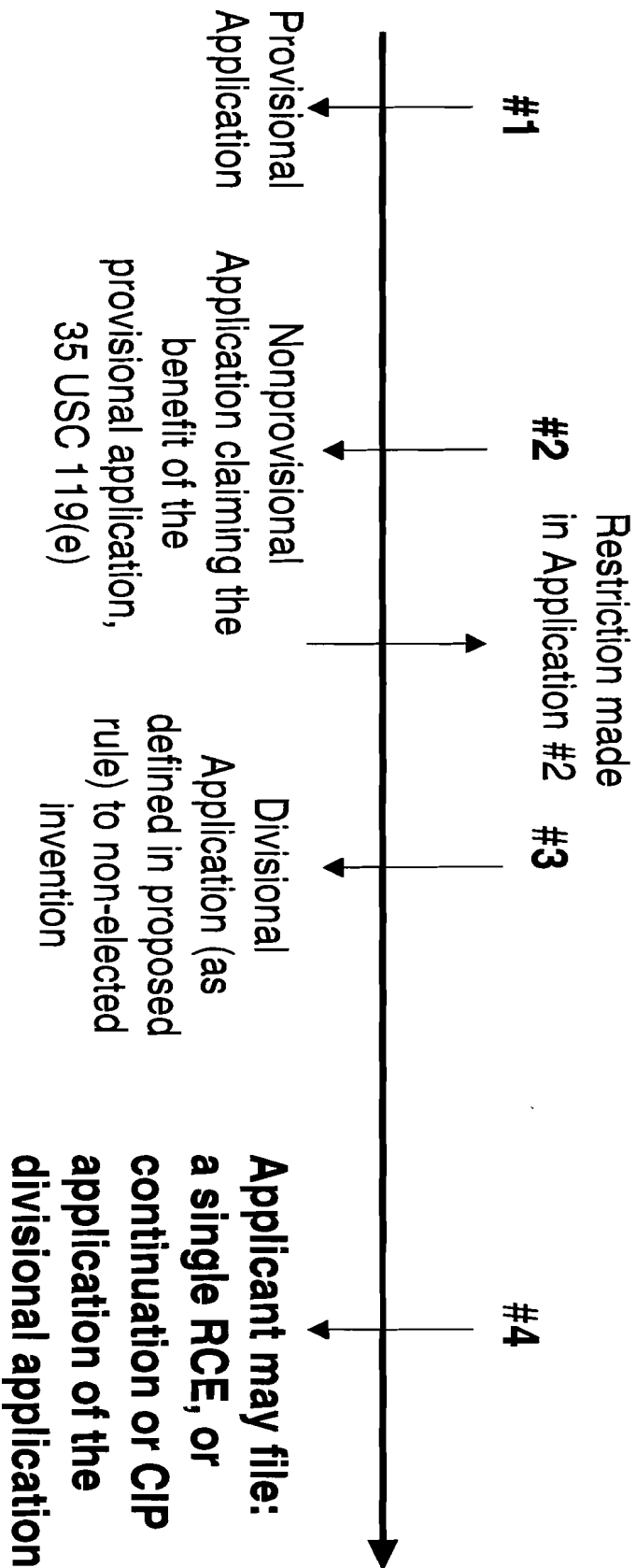




Continuations

Benefit Claims under 35 USC 120, 121, or 365(c)

One Continuing Filing after a Divisional Permitted

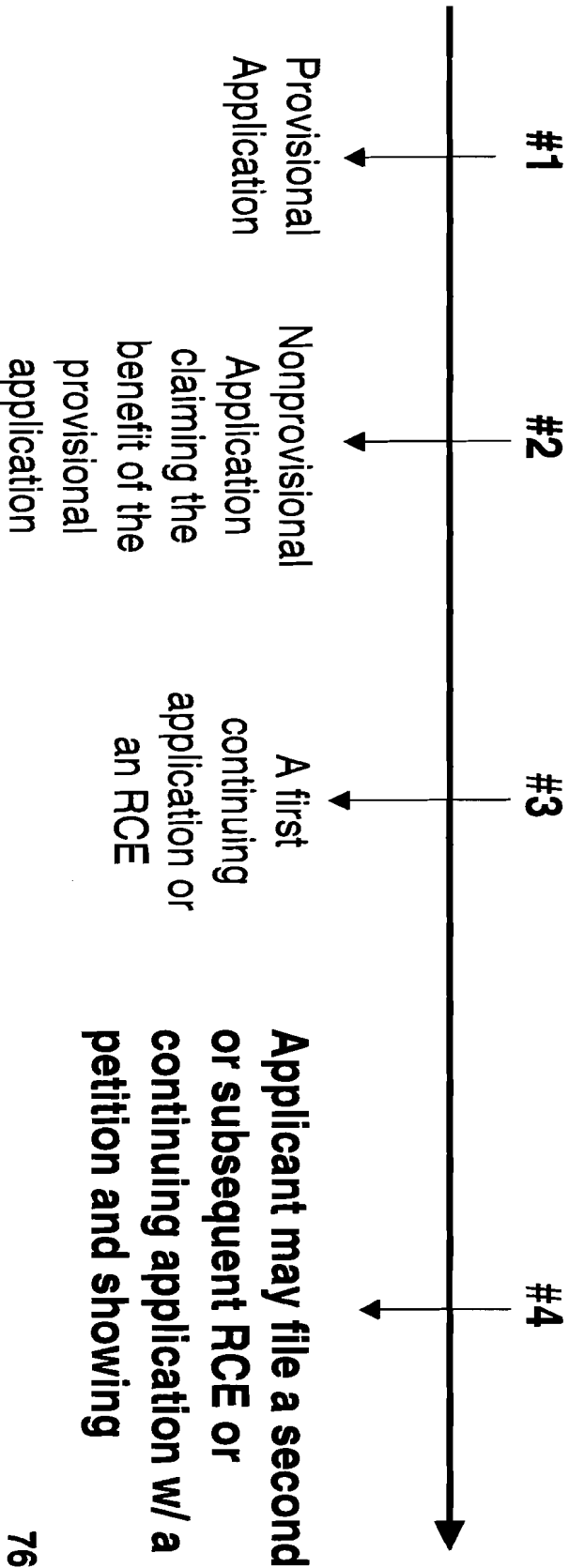




Continuations

Benefit Claims under 35 USC 120, 121, or 365(c)

**Second Continuing Filing Requires Petition & Showing
That the Amendment, Argument, or Evidence Could Not
Have Been Earlier Submitted**





Continuations – Example 1

Scenario: Applicant files application #1 with 65 claims. The USPTO requires restriction between the following groups:

- I. Invention 1 - 15 claims; 3 independent + 12 dependent claims
- II. Invention 2 - 30 claims; 5 independent + 25 dependent claims
- III. Invention 3 - 20 claims; 1 independent + 19 dependent claims

Applicant may file two divisional applications, one each for inventions 2 and 3.

- **But, both will need to be filed during the pendency of application #1 in order to be entitled to claim the benefit of application #1's filing date. If divisional #3 is filed during the pendency of divisional #2, but not during pendency of application #1, it will only be entitled to the filing date of divisional #2.**



Continuations – Example 2

Scenario: Applicant files application #1 claiming only 1 invention. Later, applicant files application #2 with the same disclosure but claims direction to a different invention. In application #2, the applicant claims the priority of application #1's filing date.

This is permitted, but application #2 will be treated as the one continuation of application #1 allowed as a matter of right.

- Therefore, neither applications #1 or #2 can have any additional PCEs or continuations absent a petition.**
- Also, as both applications have the same effective filing date, there will be rebuttable presumption of double patenting. The applicant will need to file a terminal disclaimer or argue persuasively that the claims are patentably distinct.**



Examples of a Showing for Filing a Second Continuing Application

P000453

Example 1: In a continuation application,

- **An interference is declared in an application containing both claims corresponding to the count(s) and claims not corresponding to the count(s), and**
- **The APJ suggests that the claims not corresponding to the count(s) be canceled from the application in interference and pursued in a separate application.**



Examples of a Showing for Filing a Second Continuing Application

Example 2: In a continuation application,

- **Data necessary to support a showing of unexpected results just became available to overcome a final rejection under 35 U.S.C. 103, and**
- **The data is the result of a lengthy experimentation that was started after applicant received the rejection for the first time.**



Examples of a Showing for Filing a Second Continuing Application

P000455

Example 3: In a continuation application,

- **The final rejection contains a new ground of rejection that could not have been anticipated by the applicant, and**
- **The applicant seeks to submit evidence which could not have been submitted earlier to overcome this new rejection.**



Examples of Unacceptable Showing for Filing a Second Continuing Application

P000456

Example 1:

- **An argument that a final rejection in one of the prior applications was premature.**
- **Applicant should address the propriety of the final rejection during prosecution of the prior application, and not collaterally in a petition for a continuation application.**



Examples of Unacceptable Showing for Filing a Second Continuing Application

P000457

Example 2:

- **An argument that an amendment after final rejection should have been entered in the prior application.**
- **Applicant should address the non-entry in the prior application, and not collaterally in a petition for a continuation application.**



To Submit Comments:

Comments should be sent by electronic mail to the following addresses:

- Continuations – AB93Comments@uspto.gov
- Claims – AB94Comments@uspto.gov



Contact Information

■ **John Doll**

Commissioner for Patents

e-mail: john.doll@uspto.gov

Phone: 571 272 8250



John Doll - Commissioner for Patents

February 1, 2006



USPTO Request for Public Input: Strategic Planning

- ◆ **Agency developing new strategic plan**
 - **Part of budget process**
 - **Planning for at least six-year period**
 - **Anticipate, plan for USPTO role in changing environment**
 - **Seeking broad perspective:**
 - **input from interested persons, stakeholders, including**
 - **Industries (large and small business), inventors, employees, practitioners**

- ◆ **Please send ideas/thoughts/suggestions to StrategicPlanning1@uspto.gov**



EFS-Web: Newly Improved On-Line Solution For Patent Filers

- ◆ **EFS-Web will allow patent filers, anywhere, anytime, to submit patent applications, related documents, and pay fees online.**
- ◆ **Currently in Beta-testing**
- ◆ **Rollout to all comers expected mid-March 2006**



EFS-Web Advantages to Patent Filers

P000463

- ◆ **File applications and related documents using existing technologies and workflows.**
- ◆ **Submit applications and related documents by simply attaching PDF files.**
- ◆ **Staff may transmit filing on behalf of patent practitioners.**
- ◆ **Verifies and validates files before submission.**
- ◆ **Automatic electronic acknowledgement receipt confirming submission.**
- ◆ **Rapid access to PAIR to view submission and status and to confirm documents safely and accurately received.**



EFS-Web Schedule and Support

- ◆ **Electronic Business Center (EBC)
support available from 6 a.m. to 12
Midnight Eastern Monday-Friday**
- ◆ **EBC Contact Numbers:**
 - .1-866-217-9197**
 - .571-272-4100**
 - .571-273-0177 (fax)**
- ◆ **E-mail: ebc@uspto.gov**
- ◆ **Online Training Available**



Questions

- ◆ **EFS Web receipt time or filing date is based on USPTO East Coast time as defined by Statute.**
- ◆ **What can be filed in EFS-Web?**
 - **New Applications: Utility, Provisional, Design with Color Drawings, 371 National Stage**
 - **Follow-on submission associated with an Application**
 - **Over 80 document descriptions - Amendments, Petitions, Board of Appeals Documents, Non-Patent Literature, Foreign References Cited etc etc**
 - **Numerous Fees**
 - **Filing Fees**
 - **Extensions of Time**
 - **Petition Fees**



Newly Proposed 12 Month Accelerated Examination Procedure

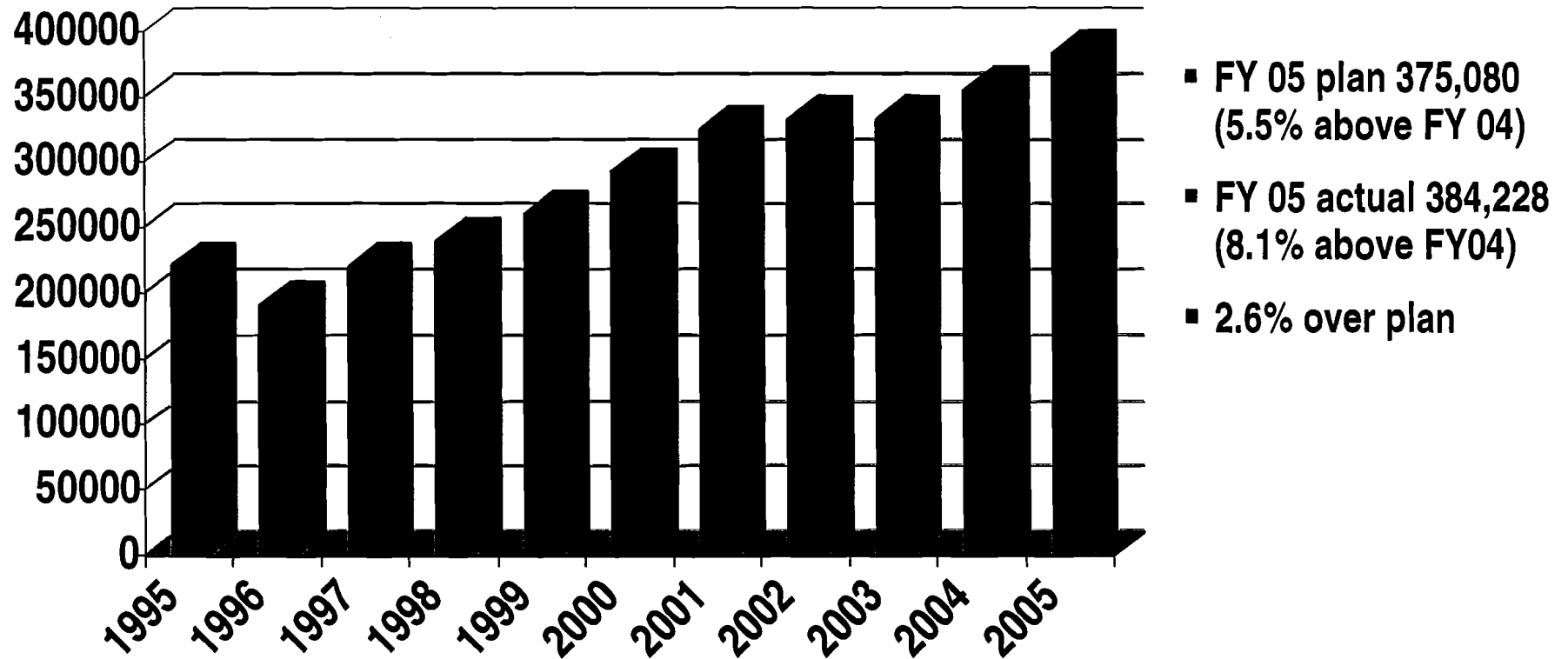
P000466

- **Goal: A final disposition of an application can be reached within 12 months from the filing date of the application.**
 - **Final disposition: allowance, abandonment, or appeal.**
- **An OG notice will soon be published.**
 - **Revising the requirements and procedures for petitions to make special under the accelerated examination program, and 37 CFR 1.102(c)(2), set forth in MPEP 708.02.**

Application Filings and Examiner Production



UPR Applications Filed





Production

	FY 04	FY 05 Target	FY 05
UPR¹ FAOM²	288,315	297,614	297,287
UPR Disposals³	287,188	295,456	279,345
UPR Production Units⁴	287,752	296,535	288,316
PCT Production Units⁵	16,882	22,916	15,147

¹ "UPR" = Utility, Plant, and Reissue Applications.

² "FAOM" = First Action on the Merits – first action count by an examiner after the filing of an application (does not include restrictions or other miscellaneous actions).

³ "Disposal" = An examiner allowance, abandonment, or disposals following a board decision.

⁴ "Production Unit" = First action count plus disposal count divided by 2.

⁵ "PCT" = Patent Cooperation Treaty. PCT applications are processed differently and tracked separately from US National stage applications. For FY 05, 15,147 PU's is 35,389 processed applications.

PENDENCY

... vs the Backlog



First Action Pendency by Art Areas

High Pendency Art Areas	Pendency ¹ (months)	Low Pendency Art Areas	Pendency ¹ (months)
1640 – Immunology, Receptor/ Ligands, Cytokines, Recombinant Hormones, and Molecular Biology	27.7	1620 – Heterocyclic Compounds and Uses	16.9
1743 – Analytic Chemistry & Wave Energy	30.8	1752 – Radiation Imagery	12.1
2123 – Simulation and Modeling, Emulation of Computer Components	39.7	2125 – Manufacturing Control Systems and Chemical/ Mechanical/Electrical Control	20.0
2617 – Interactive Video Distribution	50.4	2651 – Dynamic Information Storage & Retrieval	16.1
2836 – Control Circuits	24.3	2833 – Electrical Connectors	8.8
3628 – Finance & Banking, Accounting	52.1	3612 – Land Vehicles	12.0
3731 – Surgery: Cutting, Clamping, Suturing	30.9	3723 – Tools & Metal Working	10.9

¹ "Average 1st action pendency" is the average age from filing to first action for a newly filed application, completed during October-December 2005.



Inventory by Art Examples

High Inventory Art Areas	Months of Inventory*	Low Inventory Art Areas	Months of Inventory*
1614, 1615, and 1617 – Drugs, Bio-affecting and Body Treatment	38-51	1620 – Organic Chemistry	15
1753 – Radiation Imagery	34	1734 – Adhesive Bonding and Coating Apparatus	10
2127 – Computer Task Management	46	2125 – Manufacturing Control Systems and Chemical/Mechanical/Electrical Control	10
2611 – Interactive Video Distribution	111	2651, 2653 – Information Storage and Retrieval	12
2836 – Control Circuits	22	2831 – Electrical Conductors	8
3620 – Business Methods	25-130	3651 – Conveying	12
3731 and 3737 – Medical Instruments, Diagnostic Equipment	38-47	3742 – Thermal and Combustion Technology	8

*The number of months it would take to reach a first action on the merits (e.g., an action addressing patentability issues) on a new application filed in July 2005 at today's production rate. Today's production rate means that there are no changes in production due to hiring, attrition, changes to examination processing or examination efficiencies, and that applications are taken up in the order of filing in the given art unit/area. Of course, **13** USPTO is taking aggressive steps to ensure changes that will significantly lower the inventory rates in high-inventory art areas.



TC Application Inventory

	1600	1700	2100	2600	2800	3600	3700	Total*	Design
New Applications¹ 9/30/2004	55,402	63,923	71,778	97,380	77,651	56,738	65,005	508,878	18,451
New Applications¹ 9/30/2005	62,644	72,697	76,529	115,585	94,425	70,354	83,225	586,580	24,534
Overall Pending Applications² 9/30/2004	95,006	105,447	102,440	138,822	137,458	101,097	108,039	809,323	27,599
Overall Pending Applications² 9/30/2005	107,647	120,767	117,728	167,721	159,687	117,045	130,168	932,300	38,104

¹ "New Application inventory" is the number of new applications designated or assigned to a technology center awaiting a first action.

² "Overall Pending Application inventory" is the total number of applications designated or assigned to a technology center in an active status. Includes new applications; rejected awaiting response; amended; under appeal or interference; suspended; reexams and allowed applications awaiting grant publication.

*Total inventory includes applications not assigned to a particular TC, awaiting processing either pre- or post-examination.

Patent Quality (Shared Responsibility)



Quality of Products – FY 05

		Fiscal Year 2005									
		FY 04	1600	1700	2100	2600	2800	3600	3700	Design	FY 05
Patent In-Process Examination Compliance Rate ¹		82.0%	81.7%	82.9%	88.1%	84.7%	90.9%	84.4%	86.6%	94.3%	86.2%
Patent Allowance Error Rate ²		5.32%	4.88%	6.46%	3.56%	2.25%	4.43%	4.94%	6.43%	1.6%	4.55%

***Compliance and error rates as measured by OPQA.**

¹Compliance is the percent of office actions reviewed and found to be free of any in-process examination deficiency (an error that has significant adverse impact on patent prosecution).

²Patent allowance error rate is the percent of allowed applications reviewed having at least one claim which is considered unpatentable on a basis for which a court would hold a patent invalid. "Allowance" occurs before a patent is issued, so these errors are caught before any patent is actually granted.

Re-Work



Technology Centers Rework* Statistics

	FY 2002	FY 2003	FY 2004	FY 2005
TC Summary	% FAOM Rework	% FAOM Rework	% FAOM Rework	% FAOM Rework
1600	36.4%	39.7%	40.3%	42.4%
1700	25.2%	26.9%	27.1%	28.0%
2100	23.9%	24.0%	24.6%	28.2%
2600	24.8%	24.2%	24.3%	25.4%
2800	19.1%	22.0%	24.9%	24.1%
3600	17.7%	21.2%	23.2%	28.5%
3700	22.2%	25.1%	24.0%	28.1%
UPR	23.2%	25.3%	26.1%	28.3%

* Rework first actions are those actions that are in a Continuing (CONs and CIPs), RCE, CPA or 129(a) applications (excludes Divisionals).

Hiring and Retention



Hires and Attritions

	1600	1700	2100	2600	2800	3600	3700	Corps	Design
FY 04 Hires	75	35	115	116	31	26	45	443	15
FY 04 Attritions	30	26	58	82	58	43	39	336	4
FY 05 BOY Examiner Staff	417	440	563	658	742	422	439	3681	72
FY 05 Hiring	101	58	225	169	184	91	131	959	19
FY 05 Attrits	42	39	93	92	54	55	50	425	10
FY 06 Hiring Goal	75	35	256	256	178	100	100	1000	20
FY 06 hires (1/25/06)	30	19	75	62	40	22	21	269	0
FY05 Hires as a Percent of Examiner Staffing in the TC	24%	13%	40%	26%	25%	22%	30%	26%	26%

Markush Practice



Markush Practice

1. A cell adhesion protein of formula (1),



or a pharmaceutically acceptable derivative thereof, wherein . . .

wherein:

(A) each of 1 to 22 is a Amer selected from the group of
4mers consisting of WWWWW, WWWXX, WWWYY,
WWWXW, WWWXX, WWWXY, WWYWW, WWYYX,
WWYY, WXXWW, WXXWX, WXXWY, WXXXW, WXXX,
WXXX, WXXYW, WXXX, WXXY, WYWW, WYWX,
WYWW, WYXW, WYXX, WYXY, WYYW, WYYX,
WYYY, XWWW, XWWW, XWWW, XWWW, XWWW,
XWXX, XWYW, XWYX, XWYY, XXXWW, XXXX,
XXXW, XXXW, XXXX, XXXY, XYYW, XYYX,
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XYYX, XYYW, XYYX, XYYY, YWWW, YWWW,
YWWW, YWXX, YWXX, YWXY, YWYW, YWYX,
YWYY, YXWW, YXWX, YXWY, YXXW, YXXX,
YXXY, YXXW, YXXX, YXXY, YYWW, YYWX,
YYWY, YYXW, YYXX, YYXY, YYYW, YYYX, and
YYYY, and

(B) each of 1 to 22 is selected so as to be different from
all of the others of 1 to 22;

(C) each of W, X and Y is a base in which:

(i) (a) W=one of A, T/U, G, and C,

X=one of A, T/U, G, and C,

Y=one of A, T/U, G, and C,

and each of W, X and Y is selected so as to be
different from all of the others of W, X and Y,

(b) an unselected said base of (i)(a) can be substituted
any number of times for any one of W, X and Y, or

(ii) (a) W=G or C,

X=A or T/U,

Y=A or T/U,

and X=Y, and

(b) a base not selected in (ii)(a) can be inserted into
each sequence at one or more locations, the location
of each insertion being the same in all the sequences;

(D) up to three bases can be inserted at any location of any of the sequences or up to three bases can be deleted from any of the sequences;

(E) all of the sequences of a said group of oligonucleotides are read 5' to 3' or are read 3' to 5'; and

wherein each oligonucleotide of a said set has a sequence of at least ten contiguous bases of the sequence on which it is based, provided that:

(F) (I) the quotient of the sum of G and C divided by the sum of A, T/U, G and C for all combined sequences of the set is between about 0.1 and 0.40 and said quotient for each sequence of the set does not vary from the quotient for the combined sequences by more than 0.2; and

(II) for any phantom sequence generated from any pair of first and second sequences of the set L_1 and L_2 in length, respectively, by selection from the first and second sequences of identical bases in identical sequence with each other:

(i) any consecutive sequence of bases in the phantom sequence which is identical to a consecutive sequence of bases in each of the first and second sequences from which it is generated is less than $((\frac{3}{4} \times L) - 1)$ bases in length;

(ii) the phantom sequence, if greater than or equal to $(\frac{5}{6} \times L)$ in length, contains at least three insertions/deletions or mismatches when compared to the first and second sequences from which it is generated; and

(iii) the phantom sequence is not greater than or equal to $(\frac{1}{12} \times L)$ in length;

where $L = L_1$, or if $L_1 \neq L_2$, where L is the greater of L_1 and L_2 ; and

wherein any base present may be substituted by an analogue thereof.

We claim:

1. A penetrating peptide comprising at least one amino acid sequence selected from the group consisting of:

- a) $(BX)_1Z(BX)_2ZXB$;
- b) $ZBXB_2XBXB_2XBX_3BXB_2X_2B_2$;
- c) $ZBZX_2B_4XIB_3ZXIB_4Z_2B_2$;
- d) $ZB_6XIBX_2B_2ZBZXIBX_2$;
- e) $BZIB_6XIB_6X_2ZXB$;
- f) $B_2ZXZB_6XB_2XB_2X_2BZXB_2$;
- g) $XIB_6XIBXB_6X_3B$;
- h) $X_2B_3XIB_4ZBXB_6XB_6XIB$;
- i) $XIB_2XZBZXZB_2ZXBX_3BZXIBX_3B$;
- j) $BZXIBXZX_2B_4XIBX_2B_2XB_4X_2$;
- k) $BZXIBXZX_2B_4XIBX_2B_2XIB_4$;
- l) $B_2XZ_2XIB_6XIBX_2B_5X_2B_2$;

- m) $B_qX_2ZB_mX_qB_qXBX_mB_mZB_2X_2B_2$;
- n) $B_2ZX_3ZB_mX_qB_qXBX_mB_mZB_2X_2B_2$;
- o) $X_3ZB_6XBX_3BZB_2X_2B_2$; and
- p) at least 12 contiguous amino acids of any of peptides a) through o)

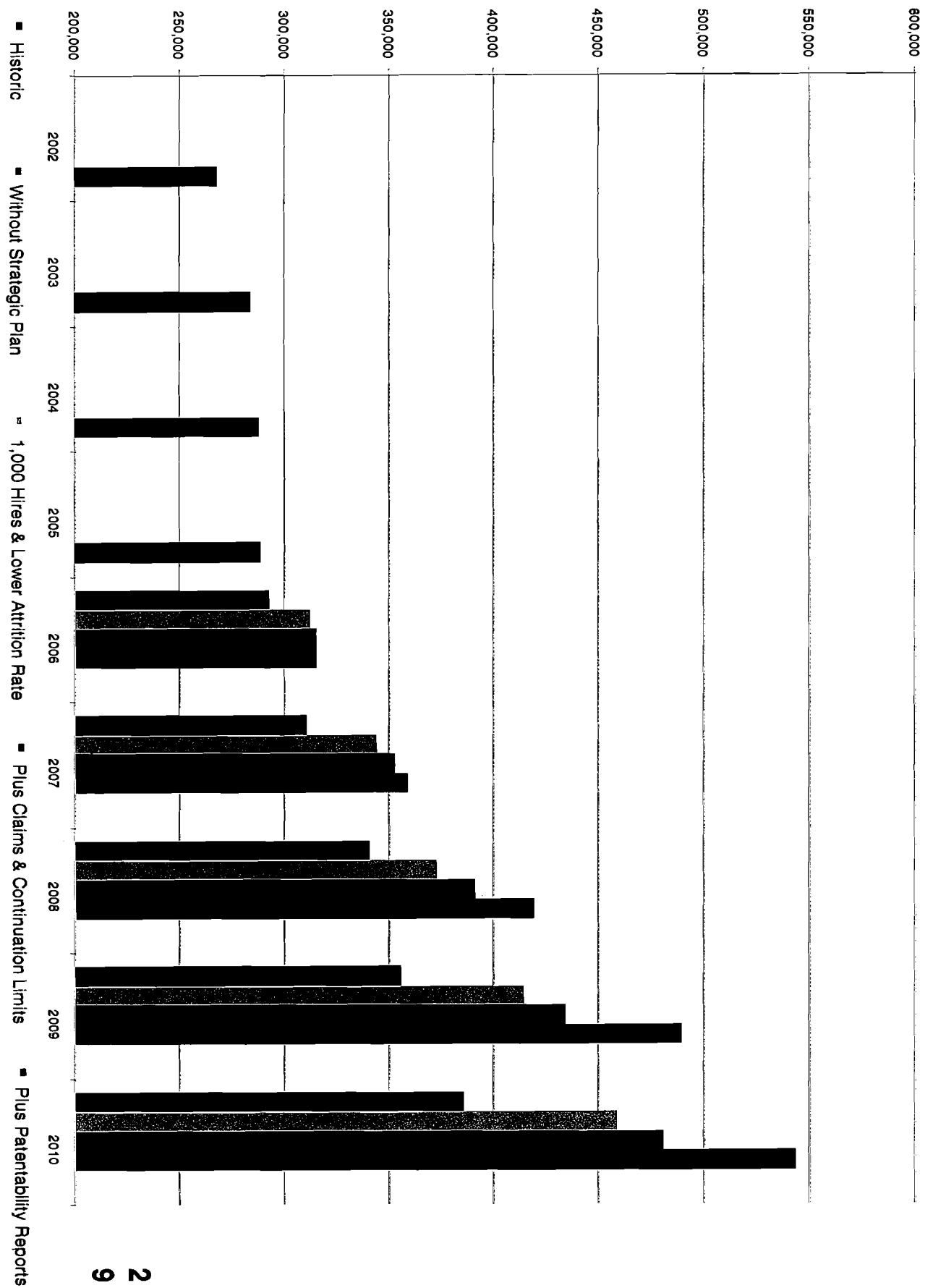
wherein

- q is 0 or 1;
 - m is 1 or 2;
 - n is 2 or 3;
 - l is 1 or 2 or 3; and
 - X is any amino acid;
 - B is a hydrophobic amino acid; and
 - Z is a charged amino acid;
- wherein said penetrating peptide is capable of translocating across a biological barrier.

Production

We Can Not Hire Our Way Out !!

Production





Contact Information

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James Toupin – General Counsel

February 1, 2006

Summary of Proposed Rule Changes to Continuations, Double Patenting, and Claims



Continuations/Double Patenting Proposed Rulemaking

- **Main objectives:**
 - **Assure adequate opportunity for prosecution to provide appropriate invention protection**
 - **Limit the “recycling” of old applications to permit the USPTO to focus examining resources on “new” applications**
 - **Create greater public certainty on scope of patent protection**
 - **Reduce the burden on the USPTO to review applications for double patenting**



Central Provisions on Continuation Practice

- No change for the vast majority of applications
- One continuation (broadly defined) always available as of right, whether in the form of
 - continuation application, or a request for continued examination (RCE); but with
 - with special rules for divisionals and continuations-in-part (CIPs)
- Additional continuations available if applicant can show that the amendment, argument or evidence could not have been earlier submitted



Divisionals

- **Only involuntary divisionals to be permitted:**
 - **Prior application subject to unity of invention (PCT Rule 13) requirement or restriction requirement (35 USC 121); and**
 - **Divisional contains only claims to inventions identified in the requirement and not elected in prior-filed application**
- **Divisional application may claim the benefit of only a single prior-filed nonprovisional application.**



Continuations-in-Part

- **Identify what claims are supported by the parent’s disclosure**
 - **Identified claims (which are supported by parent’s disclosure) are given the earlier filing date**
 - **Claims not identified are only entitled to the filing date of the CIP**

- **A continuation of the CIP is permitted but all claims only entitled to benefit of filing date of CIP**
 - **Practice consequence: Only include “new matter” claims in continuation from CIP**



Identification of Related Applications and Double-Patenting

P000496

- Identify any other application or patent having:
 - Common inventor;
 - Common assignee, or those so treated under CREATE Act; and
 - Filed within two months (taking into account priority/benefit claims)

- A rebuttable presumption of double-patenting is established for identified applications/patents if have:
 - Same effective filing date
 - Substantially overlapping disclosure



Double-Patenting: Rebutting the Rebuttable Presumption

- **Applicant must:**
 - **Show claims of application are patentably distinct from claims of other patent or application, or**
 - **Submit a terminal disclaimer and explanation of why patentably indistinct claims in two or more such applications should be maintained**

- **If USPTO finds claims patentably indistinct, it may merge or require cancellation of indistinct claims unless good and sufficient reason shown**



Claims Proposed Rulemaking

- **Main Purposes**
 - **Applicant Assistance to Improve Focus of Examination**
 - **Narrow scope of initial examination so the examiner is addressing discrete number of issues**
 - **Improve the quality of first Office actions**
 - **Addressing Disproportionate Burdens on Examination System Posed by Applications with Large Numbers of Claims**



Central Provisions: Representative Claims

- **Normal Pattern: Applicant to identify 10 representative claims for initial examination**
 - **Must include all independent claims**
 - **If independent claims fewer than 10, designate additional dependent claims until total of 10 reached**
- **Full initial examination of all designated representative claims**
- **No first action final**



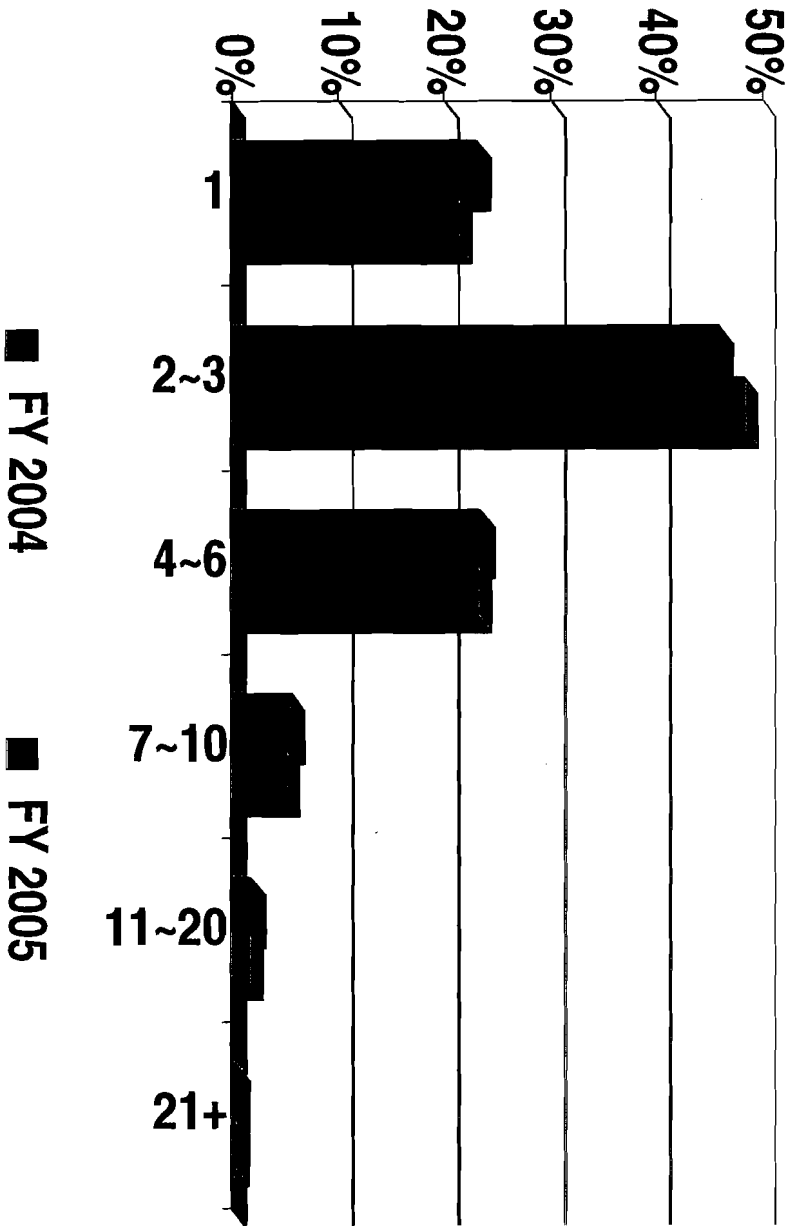
Non-Designated Dependent Claims

P000500

- If representative claim is allowed, all its non-designated dependent claims will be examined for compliance with 35 USC 101 and 112
- If representative claim is rejected, applicant may, for example:
 - Traverse rejection; or
 - Amend the claim, including adding subject matter from a non-designated dependent claim; or
 - Submit substitute representative claim



Distribution of Independent Claims at Filing





Beyond 10 Claims: When Initial Examination of 10 Isn't Enough

- **Circumstance should arise rarely**
- **Circumstance may arise:**
 - **where Applicant needs more than 10 independent claims**
 - **if Applicant cannot prioritize dependent claims so that there are only 10 representative (all independent and designated dependent) claims**



Beyond the 10 Claims: Assistance to Examination Document Required

- **Applicant must:**
 - **Provide search report of all representative claims**
 - **Identify all limitations of representative claims that are disclosed by cited prior art references**
 - **Explain how all representative claims are patentable over the cited references**



Strategic Choices: Before or During Prosecution

- Decision may be made in course of prosecution
 - Applicant may choose additional representative claims after first action. If total available representative claims exceeds 10, examination support document is req'd.
- Rather than provide the support for examination document if there are more than 10 representative claims, applicant may:
 - Cancel designated (or independent) claims
 - Excess Claim fees paid on/after December 8, 2004 refunded
 - Remove designation of dependent claims to bring total representative claims to 10 or less



Comments Appreciated

-
- Proposed Rules published in January 3, 2006, Federal Register
 - Continuations: 71 Fed. Reg. 48
 - Claims: 71 Fed. Reg. 61
 - 120-day comment period
 - Comments due May 3, 2006
 - File by fax, e-mail, mail or Internet



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