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Reexamination Practice of Biotech/Pharma Patents in Group Art Unit 3991

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Abstract

This paper² addresses reexamination practice of patents in the Biotechnology/Pharmaceutical arts, specifically Group Art Unit 3991 (AU 3991) of the Central Reexamination Unit (CRU) of the United States Patent and Trademark Office (USPTO). Analysis of several specific areas of AU 3991 reexamination is provided, including analysis of (1) reexamination of patents listed in the FDA's Orange Book, (2) all *inter partes* reexaminations from 1999-2009, (3) general *ex parte* reexamination statistics from 2002 and 2008, and (4) in-depth statistical analysis of *ex parte* reexaminations in 2008. Based on this survey, several concluding observations are provided in the final section of the paper.

I. Introduction

In writing this paper, the authors have assumed that a general understanding of reexamination practice is known by the reader. If not, the reader's attention is kindly directed to the recently published 9th edition of "Reexamination Practice with Concurrent District Court Litigation or Section 337 USITC Investigations," by Robert Greene Sterne, Jon E. Wright, and Lori A. Gordon³, which can be used as a resource to orient the reader.

The goal of this paper is to build on the previous paper by providing an overview of the biotechnology and pharmaceutical patents examined in AU 3991 in the CRU. In particular, this paper provides a survey of reexamination statistics and procedures particular to the

¹ Copyright 2010 Sterne, Kessler, Goldstein & Fox P.L.L.C. (SKGF). All rights reserved. The authors gratefully acknowledge the expertise and assistance of Pauline Pelletier of SKGF for the reexamination research, extensive data gathering, and review of data presented in this article. This paper accompanied the presentation on reexamination law on January 21, 2010, at The Fifth Annual Advanced Patent Law Institute in Alexandria, Virginia, USA.

² Authors' Note: Version 1 of this paper subscribes to the format of the Sedona Conference®, whose mission is to "engage in true dialogue, not debate, all in an effort to move the law forward in a reasoned and just way." See, http://www.thesedonaconference.org/content/tsc_mission/show_page.html. The paper therefore subscribes to a neutral "Swiss" approach of presenting all sides of an issue and not taking sides so that the Sedona-like dialogue on the topic can ensue. The authors have devoted substantial portions of their practices to reexaminations on behalf of both patent owners and third party requesters. However, the views expressed herein are for purposes of deep dialogue and do not necessarily reflect those of any author or contributor.

³ Paper available from The Sedona Conference (<http://www.thesedonaconference.com/contact.html>). The prior Version 8 can be downloaded from The Reexamination Center, the leading website on reexamination. See <http://reexamcenter.com/wp-content/uploads/2009/08/ACPC-Reexam-Paper.pdf>.

biotechnology/pharmaceutical arts of AU 3991, and the conclusions that can be reached from the survey.

II. Group Art Unit (AU) 3991

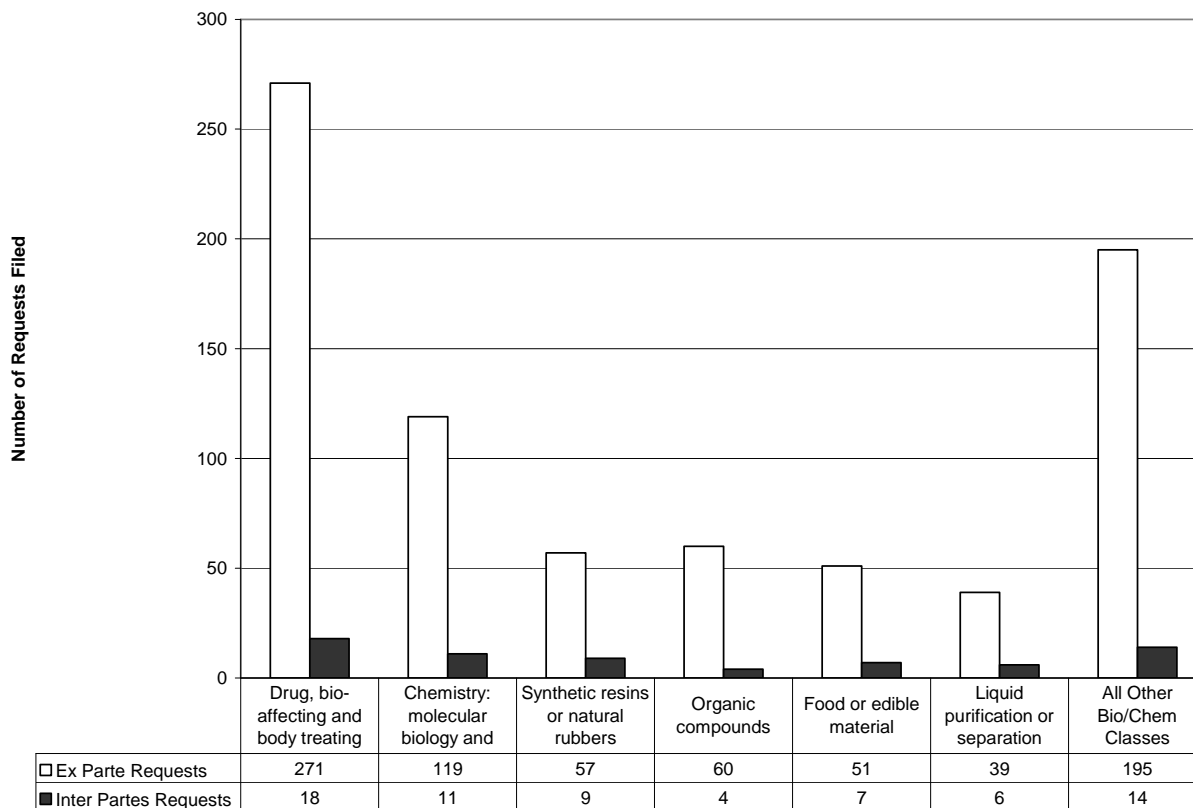
The CRU is currently made up of three Group Art Units: AU 3991, AU 3992, and AU 3993. Group AU 3991 is the art unit within CRU that handles those reexamination proceedings involving biological, chemical, and pharmaceutical patents. AU 3991 is headed by supervisory patent reexamination examiner (SPRE) Deborah D. Jones. In June 2008, AU 3991 contained 10 patent examiners. As of the writing of this paper, there are now 13 patent examiners in AU 3991, including the SPRE.

III. Scope of the Survey

In this paper, data and analysis is presented for requests for reexamination noticed in the Official Gazette between January 1, 1999, and January 1, 2009. For the most part, the data and analysis presented herein was independently developed and analyzed, and thus is not available from other public sources. This time period spans the inception of *inter partes* reexamination on November 29, 1999. The term "noticed" means that a request for reexamination was filed, accorded a filing date, and published in the Official Gazette (MPEP 2215). A total of 4,849 *ex parte* (EPR) and *inter partes* reexamination requests (IPR) were identified over this 10 year period. From this comprehensive index of 4,331 *ex parte* and 518 *inter partes* requests, a subset of classes representative of the biotechnology and pharmaceutical landscape examined by AU 3991 were identified and isolated for more in-depth analysis.

The subset of 66 classes chosen for this survey of the biotechnology and pharmaceutical area is set forth in Appendix A. This subset of classes represents 792 out of 4,331 (or 18.3 %) of all *ex parte* requests filed, and 69 out of 518 (or 13.3 %) of all *inter partes* requests filed during this ten year period of review. The top six classes dominate this disciplinary subset, accounting for 78.38% of the *ex parte* and 79.71% of the *inter partes* reexaminations (*see* Figure 1). Not surprisingly, the top two classes alone, bio-affecting and body treating compositions (drugs) and molecular biology and microbiology, account for 33.57% and 15.10% of all *ex parte* and *inter partes* requests filed in the specified subset, respectively.

Figure 1: Top Biotechnology Classes in Disciplinary Subset of AU 3991 Requests



Classes excluded from this survey include biomedical or mechanical devices (e.g., surgery), plastic article or earthenware shaping, coating processes, combustion, heating, abrading, and solid anti-friction devices. Thus, the classes selected are not comprehensive of *all* technology classes examined by AU 3991. The intent of the paper was not to provide statistics for AU 3991 generally, but rather to focus on technology areas of relevance to the biotechnology and pharmaceutical practice area.

Analysis of the Disciplinary Subset

Focusing on the disciplinary subset of the 66 classes identified above, a comprehensive inventory of events in the file history and/or other proceedings of interest was undertaken.

First, in Section IV of this paper, reexaminations of patents appearing in the Food and Drug Administration ("FDA") Orange Book of Approved Drug Products with Therapeutic Equivalence Evaluations current through October 2009 were reviewed. Out of 792 *ex parte* requests in the AU 3991 subset, 52 (6.6 %) were associated with an FDA approved product. Conversely, out of 69 *inter partes* proceedings in the AU 3991 subset, 3 (4.3 %) were associated with an FDA approved product. A series of Tables regarding the 55 FDA approved drugs with patents associated with reexamination proceedings is provided as Appendix B.1-4.

Second, in Section V of this paper, all 69 *inter partes* proceedings during this ten year period were reviewed to determine whether: (1) Rule 130, 131, or 132 affidavits had been filed; (2) petitions had been filed for any reason; (3) the request was substantively denied or terminated before completion; (4) the PTO issued a Notice of Intent to Issue a Reexamination Certificate ("NIRC"); and/or (5) the PTO issued a Right of Appeal Notice ("RAN") or the owner filed a Notice of Appeal.

Third, in Section VI of this paper, reexamination requests in representative years (excluding those associated with FDA approved products) were reviewed. Specifically, a subset of 70 *ex parte* requests filed in 2002 and 80 *ex parte* requests filed in 2008 were analyzed. The respective norms for these two years were compared for each item above. Those requests filed in 2002 have received a NIRC or were appealed. Those filed in 2008 are representative of more recent filing trends.

Fourth, in Section VII of this paper, each of the 80 *ex parte* requests for reexamination in the AU 3991 subset filed in 2008 were closely reviewed to obtain a general sense, considering the early stage of the proceeding, regarding: (a) how many SNQs were raised, and whether those SNQs were based on old or new art; (b) what grounds of rejection were adopted by the Examiner in the first office action; (c) how detailed (length) were the requests as filed and the resulting office actions; (d) how many proceedings contained submissions of external evidence and the nature of the evidence presented; (e) what percentage of proceedings were concurrently involved in litigation, and (f) what percentage of proceedings had requests for extensions of time and other petitions.

Fifth, in Section VIII, EPR, IPR and FDA approved product-associated reexaminations are compared to demonstrate and compare trends (*see* Figure 11).

Finally, in Section IX, concluding observations are provided based on the trends observed in Sections IV - VIII.

Of note, the most recent USPTO Operations Statistics dated September 30, 2009, state that the average pendency is 24.7 months for an *ex parte* reexamination and 34.5 months for an *inter partes* reexamination as of Q4 (*see* <http://reexamcenter.com/essentials/statistics/>). This average may not be representative of cases that are appealed. Throughout, indications of whether the proceeding was initiated by the Patent Owner or a Third-Party illustrates trends influenced by strategic considerations.

IV. All FDA Approved Products in Reexamination Between 1999-2009

Patents undergoing reexaminations were linked with FDA approved products using publicly available data on the FDA's website (*see* Approved Drug Products with Therapeutic Equivalence Evaluations, Orange Book⁴). Using this method, 52 *ex parte* proceedings and 3 *inter parte* proceedings were associated with FDA approved products (*see* Appendix B). The proceedings were identified as being owner or third-party initiated and it was determine if: (1) Rule 130, 131, or 132 affidavits had been filed; (2) petitions had been filed for any reason; (3)

⁴ <http://www.fda.gov/Drugs/InformationOnDrugs/ucm129662.htm> (last accessed Dec. 13, 2009)

the request was substantively denied or terminated before completion; (4) the PTO issued a NIRC; and (5) the PTO issued a RAN or the owner filed a Notice of Appeal (*see* Table 1).

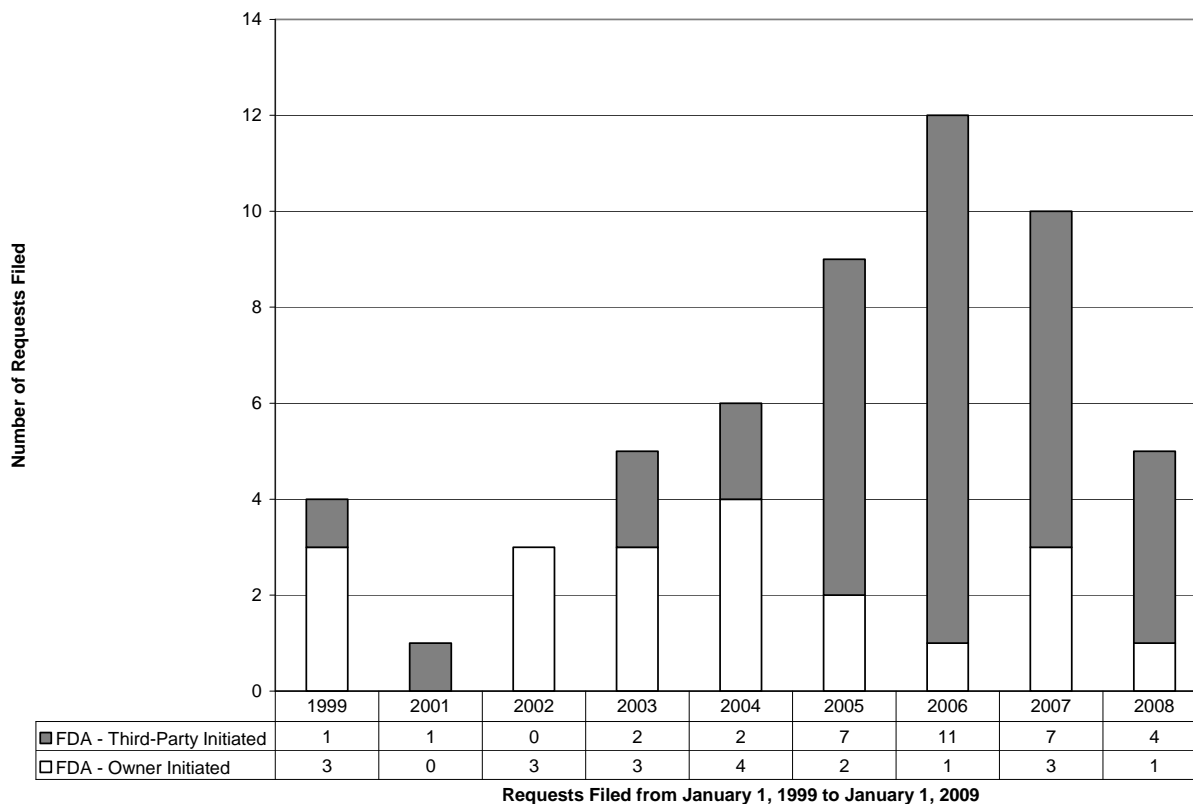
Table 1: Patents to FDA Approved Products Associated with Reexamination Proceedings

FDA Associated Reexaminations	Affidavits Filed	Petitions Filed	NIRC Issued	RAN Issued	Denied Request	Total
Owner Initiated	45% (9)	25% (5)	80% (16)	25% (5)	10% (2)	20
Third-Party Initiated	69% (24)	46% (16)	51% (18)	40% (14)	11% (4)	35
Total (Combined)	60% (33)	38% (21)	62% (34)	35% (19)	11% (6)	55

In the context of Abbreviated New Drug Application (ANDA) challenges of FDA approved drugs, many have speculated that competitors would make frequent use of the reexamination proceedings by filing a reexamination request rather than challenging the patent in court. Based on the data that was identified and reviewed, it would appear that this is a relatively rare occurrence as only 55 out of 861 patent reexaminations (or 6.4 %) in this survey are associated with an FDA approved drug.

As can be seen from Table 1 and Figure 2 below, 20 out of 55 requests were owner initiated, whereas 35 were third-party initiated. Affidavits were filed 45 % of the time in owner initiated reexaminations as compared to 69 % of the time in third-party initiated reexaminations. Similarly, petitions were filed more often in third-party initiated reexaminations (46 %) than in owner initiated reexaminations (25 %). Interestingly, in 80 % of owner initiated reexaminations a NIRC issued, whereas this has occurred in only 51 % of third-party initiated reexaminations, suggesting that a higher number of third party initiated cases are still pending. Correspondingly, only a quarter of owner initiated reexaminations received a Right of Appeal Notice as compared with 40 % of third-party initiated reexaminations. Consistent with PTO statistics, requests are denied infrequently.

Figure 2: FDA Product Associated Reexamination Proceedings from 1999 to 2009

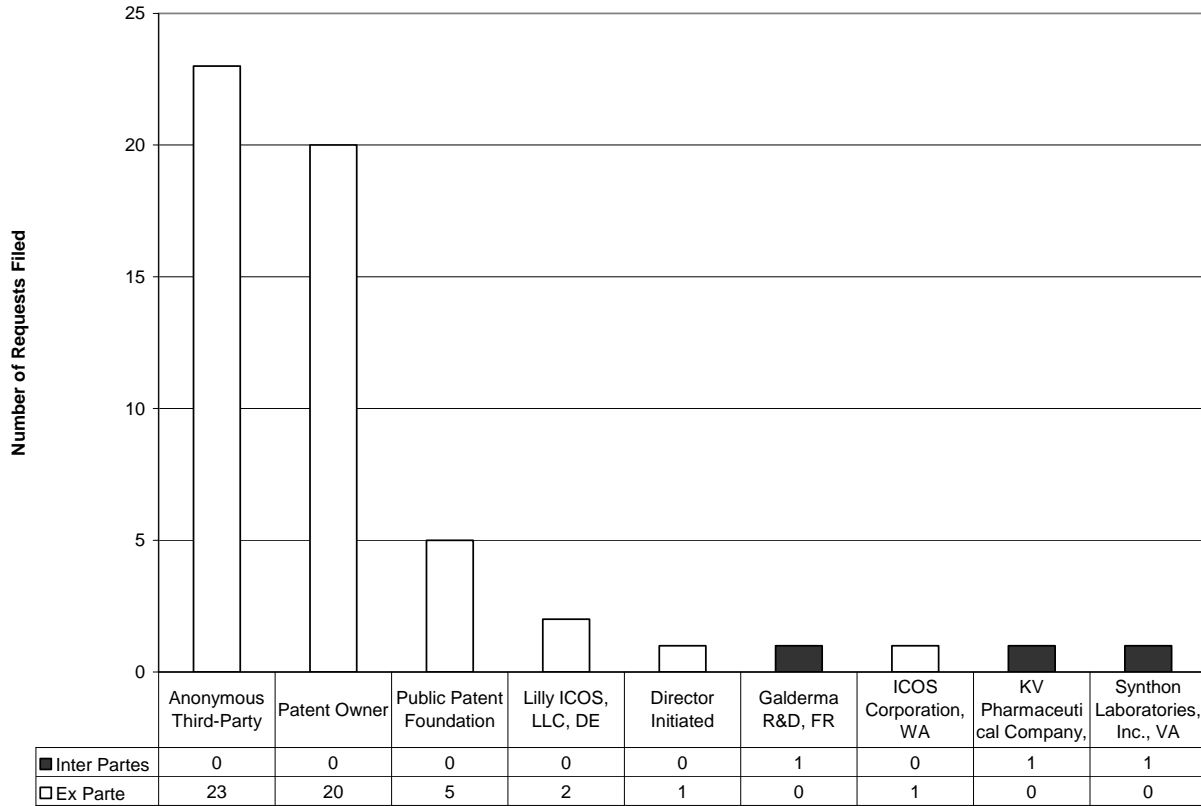


Compared with owner initiated reexaminations it appears that proceedings initiated by a third-party have a tendency to involve: a) affidavits, b) petitions, and c) appeals. The same trends appear in *inter partes* proceedings generally (*see* Section V). Thus, it can be said that where a commercial product is involved in a defensive proceeding, part of the owner's strategy often includes submission of affidavits and active petitioning before the office. Half of these proceedings have not been issued a NIRC yet and 40% have the right to appeal which signifies the number that will likely be (or have already been) heard by the Board.

As part of this survey, the top requesters of reexaminations of FDA product associated patents in both *ex parte* and *inter partes* proceedings over the 1999-2009 period were also investigated. While owner initiated requests have been relatively stable over the past decade, there appears to be a pronounced rise in third-party initiated proceedings, peaking in 2006 (*see* Figure 2).

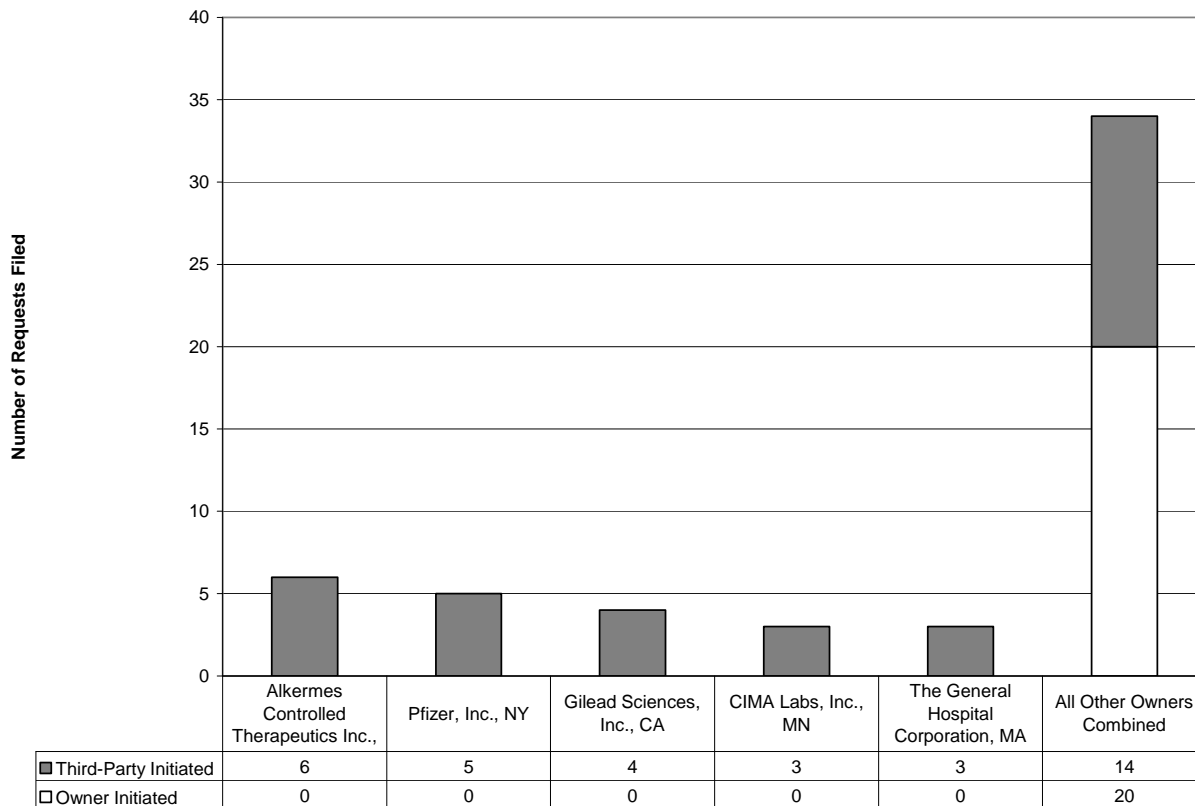
As shown in Figure 3 below, of the 52 *ex parte* reexaminations, 23 were requested by anonymous third parties, 20 by the patent owner, 5 by the Public Patent Foundation, 2 by Lilly ICOS, 1 was director-initiated, and 1 was requested by ICOS Corporation. Of the 3 *inter partes* requests, 1 was requested by Galderma R&D, 1 by KV Pharmaceutical and 1 by Synthon Laboratories, Inc.

Figure 3: Top Requesters of FDA Product Associated Reexamination Proceedings



The top owners of FDA approved patents and products put into reexamination during the 1999-2009 period were also identified. These parties represent ownership of 21 of the 55 patents or 38% of the total. As shown in Figure 4 below, 6 patents assigned to Alkermes Controlled Therapeutics Inc. were put into *ex parte* reexamination, 5 Pfizer patents, 4 Gilead Sciences, Inc. patents, 3 Cima Labs, Inc. patents (2 *ex parte* and 1 *inter partes*), and 3 patents assigned to General Hospital Corporation. Somewhat surprisingly, *all* of the proceedings associated with these top owners were initiated by a third-party.

Figure 4: Top Patent Owners of FDA Associated Reexamination Proceedings



As shown in Appendix B.4, 6 out of 20 (or 30 %) of owner initiated reexamination proceedings are associated with litigation as compared with 16 out of 35 (or 46 %) of third-party initiated reexamination proceedings. This information was gathered by performing a litigation search for each patent undergoing reexamination associated with an FDA approved product.

V. All *Inter Partes* Requests Filed in AU 3991 Subset Between 1999-2009

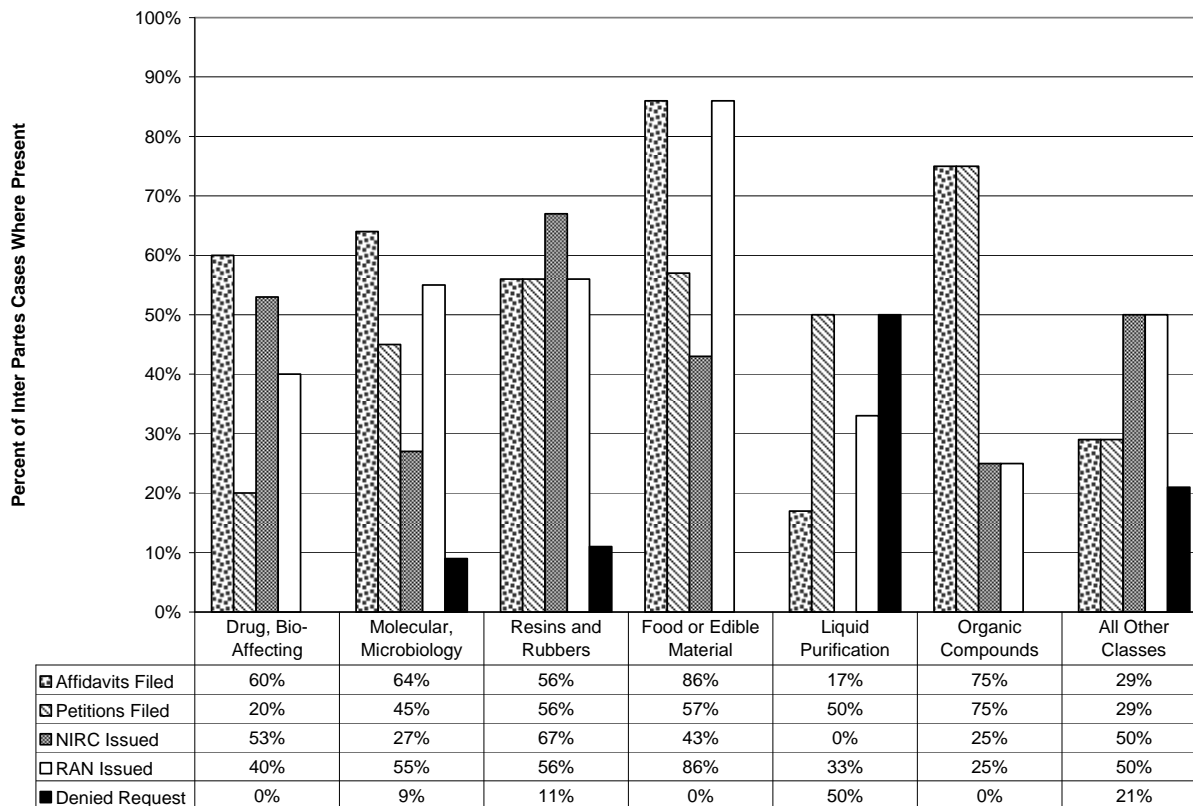
The 69 *inter partes* proceedings in the disciplinary subset are by definition filed by third-parties not in privity with the patent owner. The 3 known to be associated with an FDA approved product are excluded as previously discussed. The top classes (*e.g.*, Drugs and Bio-Affecting, Molecular and Microbiology, Resins and Rubbers, Food or Edible Material, Liquid Purification, and Organic Compounds) represent 52 of the 66 (or 79%) and are isolated for comparison.

As with the other samples, all 66 *inter partes* proceedings were reviewed to determine whether: (1) Rule 130, 131, or 132 affidavits had been filed; (2) petitions had been filed for any reason; (3) the request was substantively denied or terminated before completion; (4) the PTO issued a NIRC; and (5) the PTO issued a RAN or the owner filed a Notice of Appeal.

As illustrated in Figure 5 below, the frequency of filing affidavits in the subset of *inter partes* proceedings ranged from 17% to 86% depending on class or on average 53% of the time

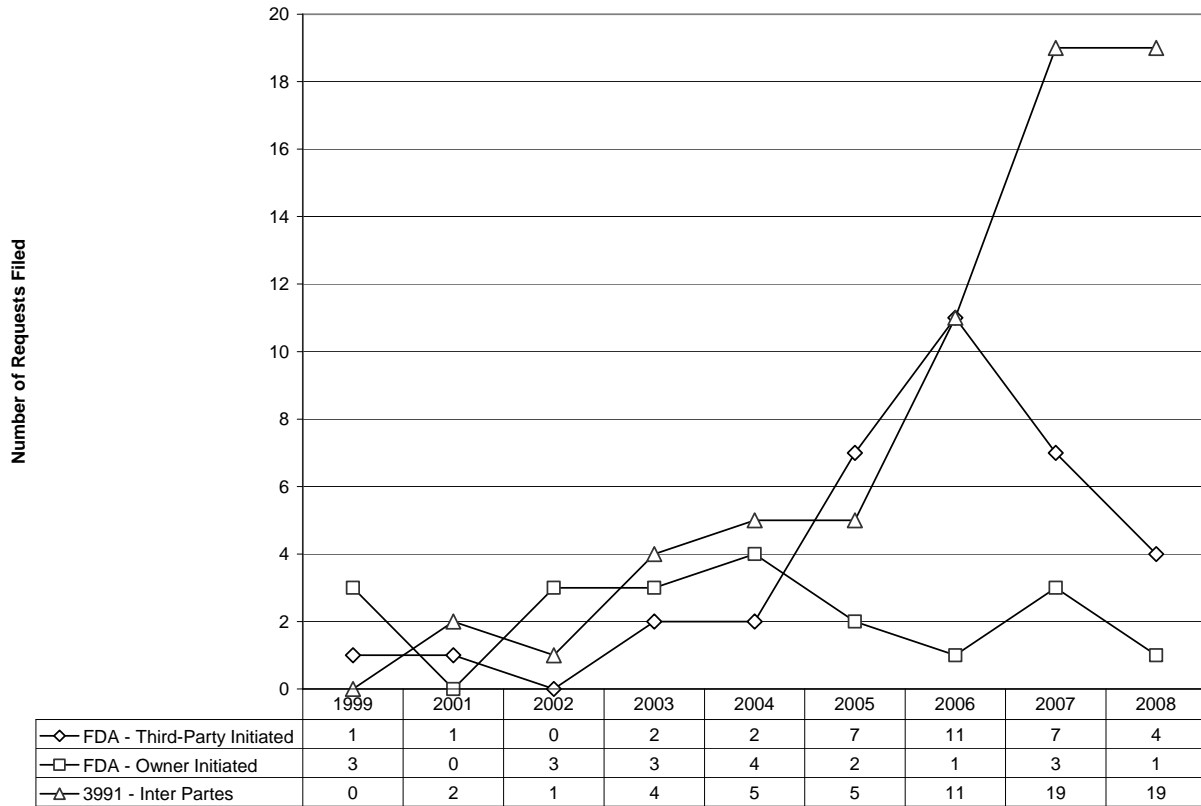
compared with only a third of the time in most owner initiated proceedings. Likewise, petitions were filed 20% to 75% of the time as compared with 15% of most owner initiated proceedings. In about half of the reexaminations, a NIRC had already issued, as well as a Right of Appeal, signifying the number that will likely be (or have already been) heard by the Board.

Figure 5: Inter Partes Proceedings in Top Classes of AU 3991 Subset



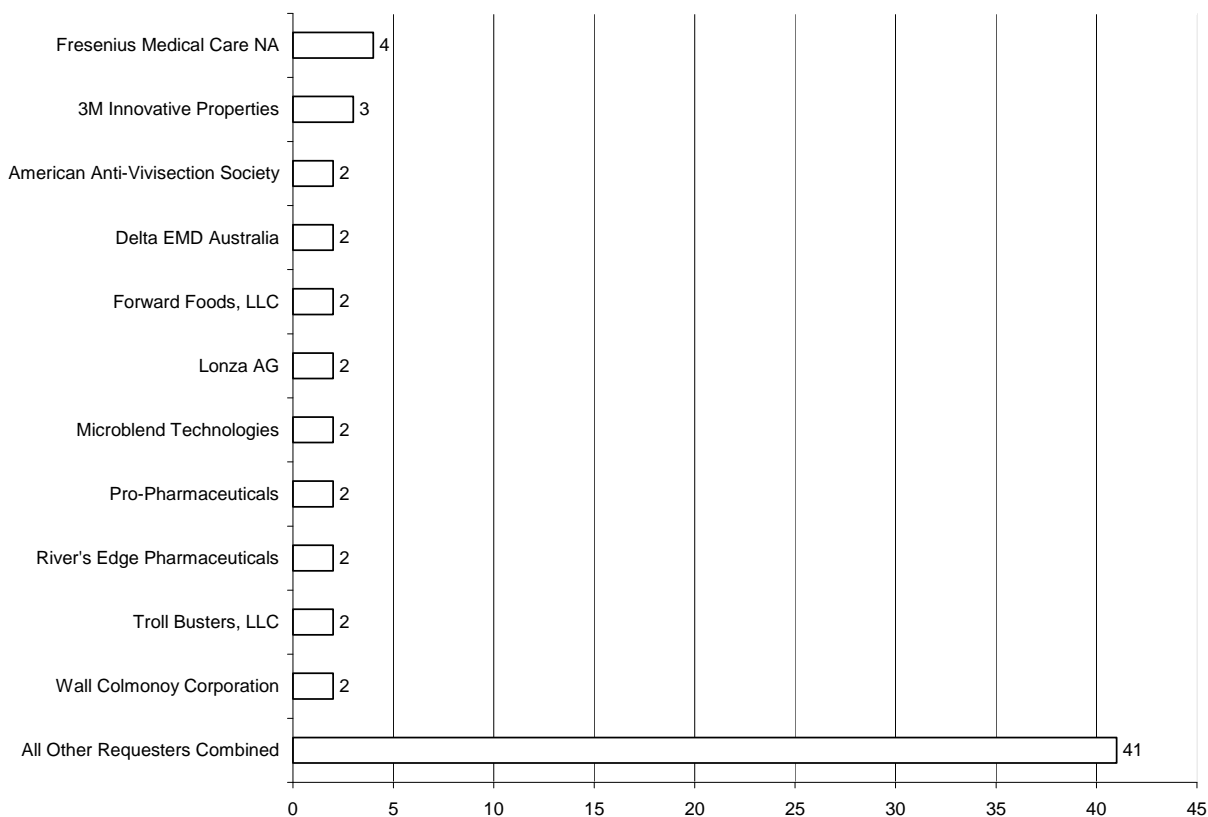
Requests for *inter partes* reexamination in the AU 3991 subset have shown a steady increase over the past decade, with a sharp incline beginning in 2006 and continuing on to the present, as shown in Figure 6. This trend was mirrored by third-party reexaminations on patents associated with FDA approved products until 2007 until filings in this category declined sharply and have proceeded to trend downwards in 2008. Trends in this area will continue to be monitored.

Figure 6: Requests for AU 3991 Inter Partes Compared with FDA Approved Product Patents for 1999-2009



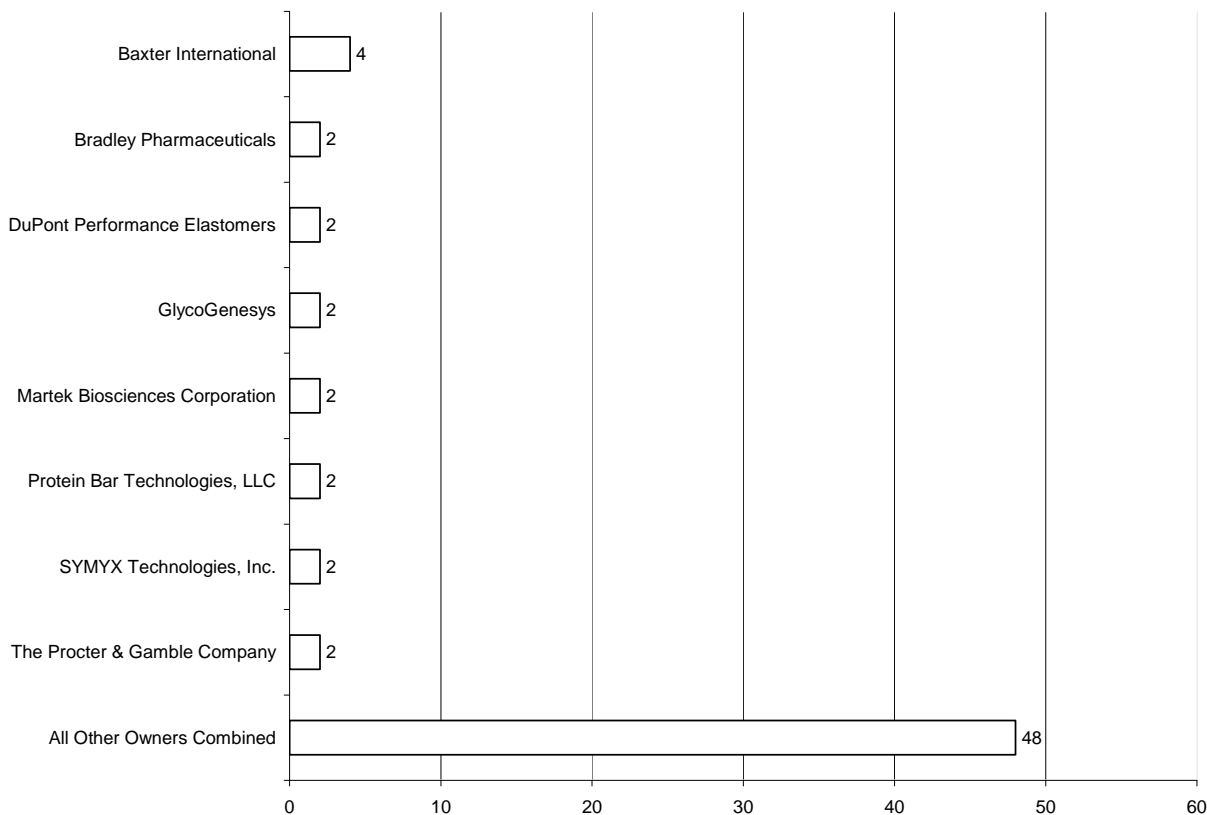
As part of this survey, the top requesters of, and patent owners associated with, these *inter partes* proceedings over the 1999-2009 period were investigated. Figure 7 illustrates that the top two requesters were Fresenius Medical Care North America (with 4 *inter partes* requests filed against Baxter International in June of 2008) and 3M Innovative Properties Company (with 2 *inter partes* requests filed against patents owned by DuPont Performance Elastomers and one against Inverness Medical Switzerland GMBH).

Figure 7: Top Requesters of AU 3991 Subset of Inter Partes Reexaminations 1999-2009



Baxter International was the top patent owner targeted by these requests for its inventions in liquid purification and separation (*e.g.*, methods and apparatus for kidney dialysis) followed by an eight-way tie for second: Bradley Pharmaceuticals (antimicrobials for the treatment of dermatological disorders), DuPont Performance Elastomers (process aid for melt processable polymers), GlycoGenesys (methods for enhancing the effectiveness of cancer therapies and controlling angiogenesis), Martek Biosciences Corporation (infant formula supplements), Protein Bar Technologies (high protein foodstuff), SYMYX Technologies (methods and apparatus for screening catalysts in a parallel fixed-bed reactor), The Procter & Gamble Company (packaging system to provide fresh packed coffee), and Rohm & Haas Company (paint manufacturing system).

Figure 8: Top Patent Owners of 3991 Subset of Inter Partes Reexaminations 1999-2009



VI. *Ex Parte* Requests Filed in 2002 (Baseline)

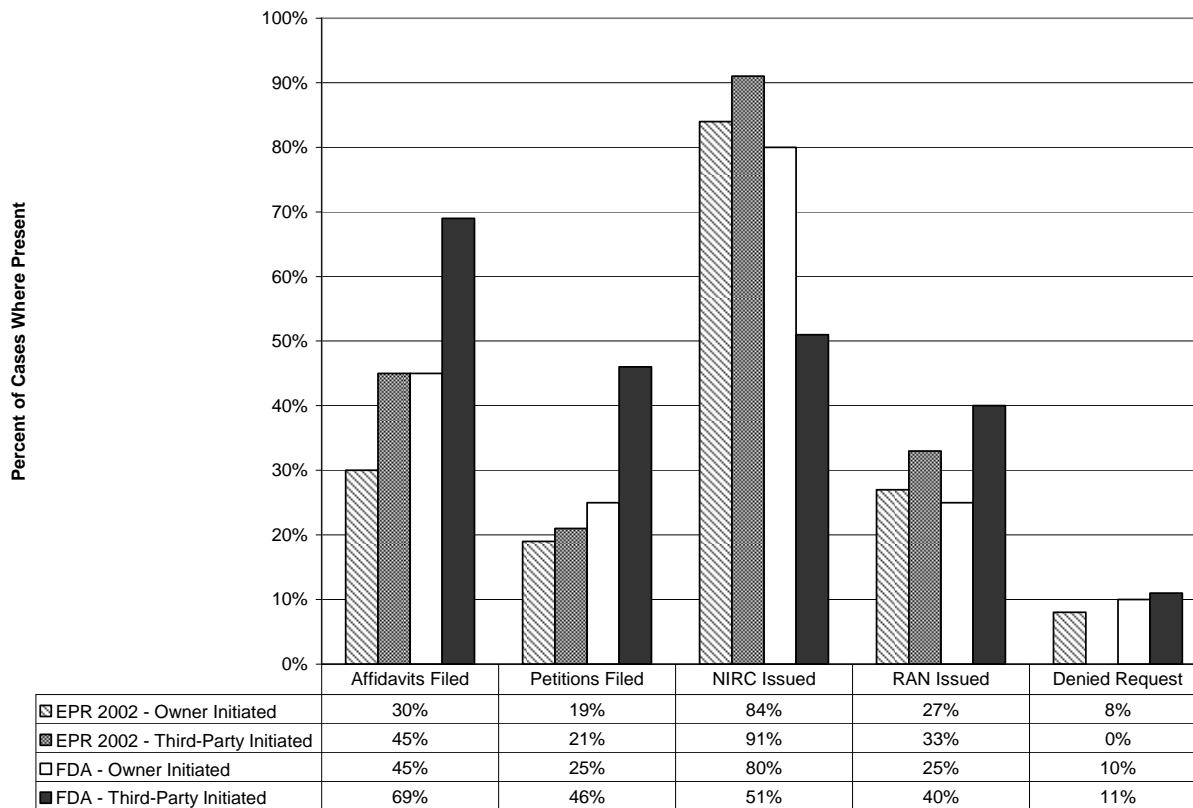
All 70 *ex parte* reexamination proceedings in the disciplinary subset filed in 2002 were chosen to provide a baseline of the reexamination process. Proceedings filed in 2002 have had sufficient time to reach the end of their pendency. Reexaminations can terminate upon abandonment, issuance of a NIRC, or Right of Appeal. Following a Board decision or resolution of the outstanding issues, a NIRC may (again) issue. As illustrated by the high percentage of NIRCs disposed for this class (87 %) one may assume that these represent complete reexamination proceedings (*e.g.*, through most office actions, responses, and notice of appeal).

Table 2: Summary of *Ex Parte* Requests Filed in 2002 (Events)

Ex Parte Requests Filed in 2002 (3991)	Affidavits Filed	Petitions Filed	EOT Request	Examiner Interview	NIRC Issued	RAN Issued	Total
Owner Initiated	30% (11)	19% (7)	27% (10)	41% (15)	84% (31)	27% (10)	37
Third-Party Initiated	45% (15)	21% (7)	39% (13)	48% (16)	91% (30)	33% (11)	33
Total (Combined)	37% (26)	20% (14)	33% (23)	44% (31)	87% (61)	30% (21)	70

For sake of comparison, the various events in the sample of 70 *ex parte* reexaminations were compared to those for patents associated with FDA approved products.

Figure 9: Comparison of FDA Product Associated Patent and General Ex Parte AU 3991 Subset from 2002



Interestingly, in the subset of 70 *ex parte* reexaminations filed in 2002, a NIRC issued 84 % of the time in owner initiated reexaminations, as compared to 91 % of the time in third party initiated reexaminations. For owner initiated reexaminations of patents linked to FDA approved products this number was similar (80 %), as opposed to third party initiated reexaminations where the number was substantially lower (51 %).

VII. A Statistical Snapshot of Typical Legal Issues Involved in *Ex Parte* Reexamination Proceedings

To obtain a more comprehensive idea of the legal issues involved in reexamination practice, a single year, 2008, was closely reviewed. The year 2008 was chosen due to its proximity in time, as well as the fact that it represents reexamination practice post-KSR. 83 *ex parte* requests for reexamination were filed in 2008 in the AU 3991 subset. The 3 *ex parte* requests related to patents which correlated with FDA approved products were excluded. Each of the remaining 80 *ex parte* requests was closely reviewed regarding the following factors:

- (A) Substantial New Questions of Patentability: How many SNQs were raised, and were those SNQs based on old art or new art;

(B) Grounds of Rejection: What grounds of rejection were adopted by the Examiner in the first office action;

(C) Size of Requests and Office Actions: How many pages were the requests as filed and how many pages were in the resulting office actions;

(D) Type of External Evidence Presented: How many proceedings submitted external evidence and what is the nature of the evidence submitted;

(E) Presence of Concurrent Litigation: What percentage of proceedings were concurrently involved in litigation;

(F) Submission of Petitions and Request for Extensions of Time: What percentage of proceedings submitted requests for extensions of time and other petitions.

A. Substantial New Questions of Patentability

In every request for reexamination, the requestor must provide one or more substantial new questions of patentability (SNQs). U.S.C. § 304. The number of SNQs in a single request for reexamination can vary greatly from a single SNQ to dozens of SNQs. As exemplified in Table 3, the number of SNQs in a typical *ex parte* reexamination request correlates with the source of the request for reexamination:

Table 3: # SNQs per Request for Reexamination in Ex Parte Requests Filed in 2008

Source of Request for Reexamination	# of Requests for Reexamination	Mean # of SNQs	Median # of SNQs	Range of # of SNQs
Owner initiated	15	4.7	2	1-22
Third-party	65	5.9	4	1-35

As is somewhat expected, the average and median number of SNQs in a request for reexamination originating from a third-party is higher (mean and median) relative to those originating from owner initiated requests for reexamination. It is also interesting to note that while the numbers of SNQs can be relatively high (30+), the average (mean) number of SNQs is less than 6.

An SNQ can be based on a previously cited document, i.e., "old art" or a document that was considered during prosecution, if the old art is presented in a new light or in a different way that escaped review during earlier examination. Alternatively, an SNQ can be based on a newly cited document, i.e., "new art" or a document that was not in front of the Examiner during prosecution. During reexamination proceedings, the characterization of art as either "old" or "new" generally occurs in the Examiner's order granting the request for reexamination. It is in the Examiner's order where it is acknowledged that art previously cited, considered, or applied during the prosecution of the patented application is now being reconsidered and why. For example, if the art has been previously cited, the Examiner may explain that it was cited by the

applicant but not applied in a rejection, that it is now being used in combination with a new reference, or that it is being reviewed in a "new light."

As summarized in Table 4 below, whether new art is submitted in a request for reexamination is strongly correlated with whether the request is filed by the patent owner or a third party requestor.

Table 4: SNQs Containing "Old Art" or "New Art" in Ex Parte Requests Filed in 2008

Source of Request for Reexamination	At Least One Piece of "New Art" Cited
Owner initiated	87% (13/15)
Third-party	23% (50/65)

Generally, patent owners are more likely to submit new art when filing a request, and do not resubmit old art to the Examiner. 87 % of owner initiated requests presented at least one piece of new art as opposed to only 23 % of third-party initiated requests. Stated differently, 13 % of owner initiated requests presented only previously cited reference, compared with 77 % of third-party initiated proceedings. This reliance on old art by third parties is consistent with the presumption that third parties would use old art with new *KSR* analysis in reexamination practice.

B. Grounds for Rejection

Grounds for rejections in a reexamination can be based on novelty (35 U.S.C. § 102), obviousness (35 U.S.C. § 101), and double patenting using patents and printed publications. Original grounds of rejections cannot be based on documents other than patents and printed publications, such as public use or for-sale documents, and cannot be based on lack of utility (35 U.S.C. § 101), insufficiency of disclosure (35 U.S.C. § 112), or conduct issues. The relative frequency of § 102, § 103 and double patenting rejections are presented below in Figure 10.

Figure 10: Grounds of Rejection in Ex Parte Reexaminations Filed in 2008

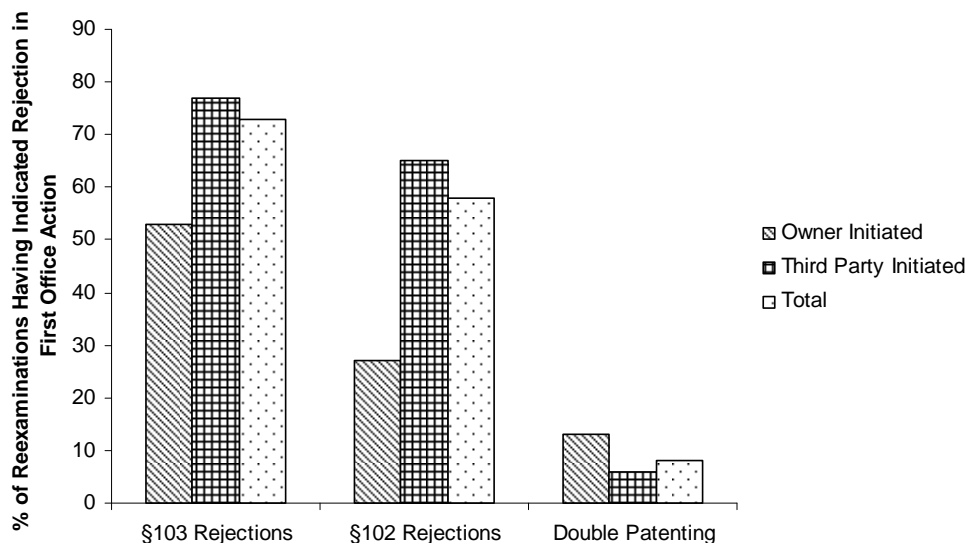


Figure 10 shows that for office actions resulting from owner initiated requests, § 103 rejections were the most common rejections (53 %), followed by § 102 rejections (27 %) and double patenting rejections (13 %).⁵ Office actions resulting from third-party initiated requests had a high percentage of § 103 rejections (77 %), but also had a high percentage of § 102 rejections (65 %). This data suggests that owner initiated reexaminations are more likely to raise questions of obviousness, whereas third party initiated reexaminations are more likely to raise questions of obviousness and novelty. Interestingly, owner initiated reexaminations were more than twice as likely to raise issues of double patenting relative to third party initiated reexaminations, 13 % to 6 %, respectively.

C. Size of Requests and Office Actions for Ex Parte Reexaminations in 2008

In general, a tremendous amount of time and cost is required for the preparation of requests for reexaminations, preparation of office actions, in addition to defending patents undergoing reexaminations. To gain an objective understanding as to the amount of paperwork prepared and submitted in a typical reexamination proceeding, the length (in total number of papers) of each request for reexaminations and the resulting first office action was determined. The results are summarized in Table 5.

⁵ These figures do not include analysis of requests for reexaminations that have been ordered, but for which no first office action has issued. It is noted that multiple rejections based on § 102, § 103 and/or double patenting rejections can be present in the same office action. Additionally, on at least one occasion, a rejection based on U.S.C. § 112 was issued in a first office action based on a preliminary amendment which was filed before the first office action.

Table 5: Size of Requests and First Office Actions

	Size of Request (# pages)			Size of First Office Action* (# pages)		
	Median	Mean	Range	Median	Mean	Range
Owner initiated	14	18.4	5-62	15	14.8	9- 20
Third party initiated	33	55.2	11-616	18	18.9	5-43

* The figures exclude first office actions that had not yet been issued when this information was collected on December 15, 2009.

As would be expected, the size of the request for reexamination is much larger when prepared by a third party initiator relative to an owner initiator. Surprisingly, even though third party originated requests are larger in size, the office action resulting from third party requests are generally not significantly larger than the office actions resulting from owner initiated requests.

D. Type of External Evidence Presented in *Ex Parte* Reexaminations in 2008

Affidavits, declarations and other external evidence can be submitted in response to an office action in an *ex parte* reexamination proceeding. Generally, these submissions fall into two categories: Declarations Under 37 CFR § 1.131 (Rule 131 Affidavits) to establish earlier invention of the subject matter, and Declarations Under 37 CFR § 1.132 (Rule 132 Affidavits) to present other external evidence to traverse a rejection. By reviewing the random subset of 80 *ex parte* reexaminations in 2008, a general idea can be established as to the frequency by which external evidence is used, and the purposes of such evidence. In this survey it was found that in 26 % (4 out of 15) of owner-initiated reexaminations, a Rule 131 and/or 132 Affidavit was submitted. In third party initiated reexaminations, 51 % (33 out of 65) of the time a Rule 131 and/or 132 Affidavit was submitted.

Thirty-seven (37) proceedings (4 owner initiated and 33 third party initiated) were reviewed at a very high level, to determine what type of Affidavit was submitted. The results are presented in Table 6:

Table 6: Use of Affidavits in *Ex Parte* Reexaminations in 2008⁶

Ex Parte Requests Filed in 2008	Total # Submitting Declarations	Rule 131 Affidavits	Rule 132 Affidavits
Owner Initiated	4	13% (2/15)	20% (3/15)
Third-Party Initiated	33	14% (9/65)	43% (28/65)
Grand Total	37	13% (11/80)	39% (31/80)

⁶ Table 6 reflects the number of reexaminations in which a Declaration was submitted. It does not reflect the total number of Declarations submitted, and therefore no statistics are presented to indicate the number of Declarations submitted for each reexamination proceeding.

A substantially higher number (>100% increase) of Rule 132 Affidavits are submitted in third party initiated reexaminations, relative to owner initiated reexaminations. However, this number may be misleading due to the small sample size of the owner initiated proceedings.

The 37 proceedings in which an Affidavit was submitted were reviewed to determine the most frequent secondary considerations of non-obviousness (*e.g.*, commercial success, long felt need, unexpected results, and licensing) the Rule 132 Affidavit was directed to. The results are provided in Table 7:

Table 7: Secondary Consideration Affidavits in Response to § 103 Rejections

Ex Parte Requests Filed in 2008	Commercial Success	Long Felt Need	Unexpected Results	Praise of Others	Copying/Licensing	Total
Owner Initiated	25% (1/4)	25% (1/4)	50% (2/4)		25% (1/4)	4
Third-Party Initiated	17% (5/29)	17% (5/29)	48% (14/29)	14% (4/29)	10% (3/29)	29
Grand Total	18% (6/33)	18% (6/33)	48% (16/33)	12% (4/33)	12% (4/33)	33

This evidence suggests that a broad spectrum of secondary considerations are submitted for consideration by the Examiner. The most common secondary consideration argued is unexpected results, in both owner initiated and third-party initiated proceedings.

(E) Presence of Concurrent Litigation:

Patent owners are required to inform the Patent Office of the presence of concurrent litigation of patents involved in reexamination proceedings. Additionally, the Examiners in Group AU 3991 periodically perform an independent search to determine if a patent involved in a reexamination proceeding is concurrently involved in litigation.

Concurrent litigation was found to be present in only 13 % (2 out of 15) of owner initiated reexamination proceedings, and 35 % (23 out of 65) of third party initiated reexaminations proceedings. Thus, concurrent litigation occurs more frequently in third party initiated proceedings than in owner initiated proceedings, but in neither instance is there concurrent litigation in a majority of reexamination proceedings. Further analysis is needed to determine whether litigation occurs after a reexamination proceeding has terminated, or at a later stage of an reexamination proceeding.

(F) Submission of Petitions and Request for Extensions of Time:

Various petitions can be filed during reexamination. The patent office designates two types of petitions in the PAIR system: (1) extensions of time, and (2) all other petitions *e.g.* petitions to suspend the rules. The subset of year 2008 *ex parte* reexaminations was reviewed to determine the frequency with which each of these two types of petitions were submitted. The results are presented in Table 8.

Table 8: Frequency of Petitions Filed in Ex Parte Reexaminations

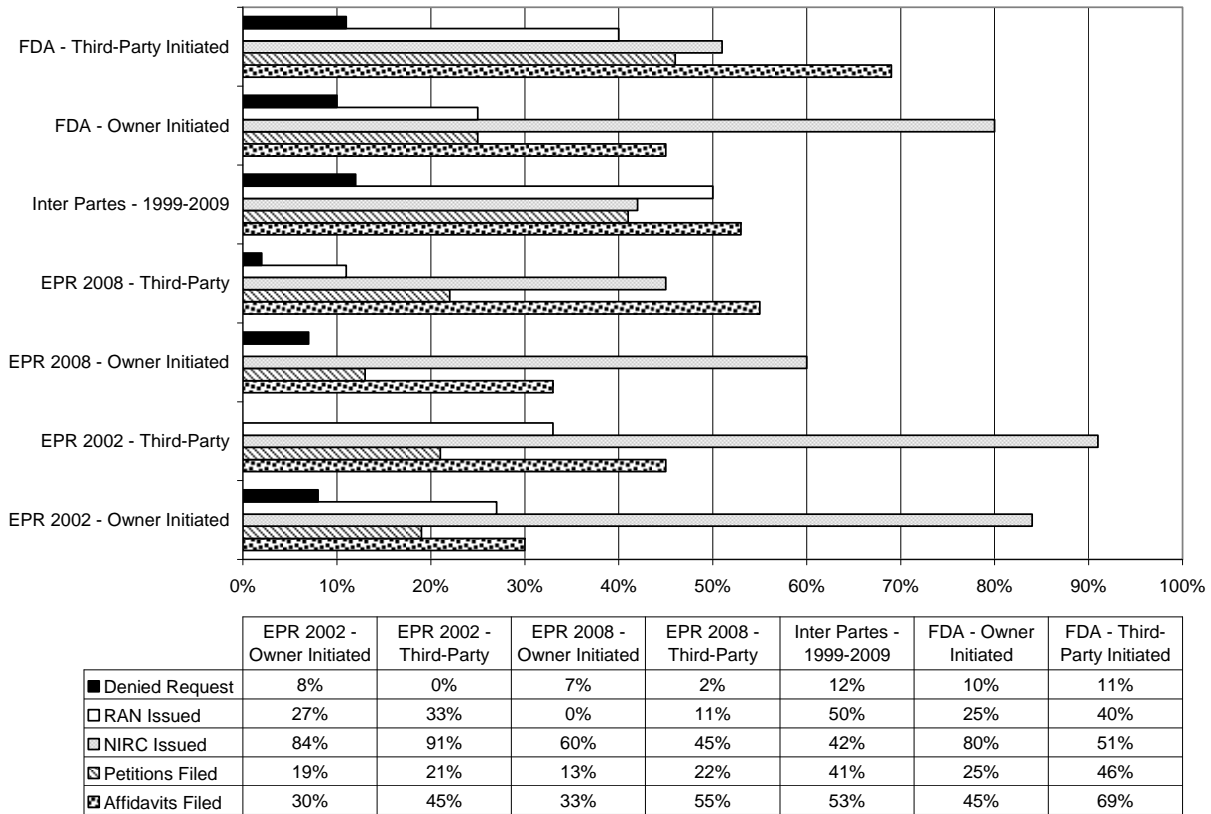
	Petitions for Extension of Time	All Other Petitions
Owner Initiated	27% (4/15)	13% (2/15)
Third Party Initiated	42% (27/65)	22% (14/65)

37 CFR § 1.550 recites that *ex parte* reexaminations will be extended only for sufficient cause. In spite of this requirement, extensions of time are commonly requested, e.g., in 42% of reexaminations requested by third parties. Further analysis is required to determine what percentage of requests for extensions of time are granted.

VIII. Comparisons of EPR, IPR and FDA Approved Product Reexaminations

A comparison of EPR (Sections VI and VII), IPR (Section V) and FDA approved product-associated reexaminations (Section IV) is provided to demonstrate differing trends in Figure 11:

Figure 11: Comparison of the Various Ex Parte, Inter Partes, and FDA Approved Product-Associated Reexaminations



IX. Concluding Observations for AU 3991

- In the context of ANDA challenges for FDA approved drugs, it appears that competitors rarely use reexamination to challenge a patent listed in the Orange Book (only 6.4 % of the time).
- Forty percent (40 %) of the time there is a concurrent litigation in reexaminations of patents associated with an FDA approved product.
- There was a pronounced rise in third-party initiated reexaminations of patents linked to FDA approved products, starting in 2005, indicating an increased awareness in the use of reexamination in lieu of, or concurrently with, district court litigation.
- Not surprisingly, the average number of SNQs in a request for reexamination originating from a third party appears to be higher relative to those originating from owner initiated requests for reexaminations.
- In the snapshot of 2008 *ex parte* requests, it appears that most of the time third parties submit SNQs based solely on old art, as compared to patent owners (87 % vs 23 %, respectively).
- For office actions resulting from owner initiated requests, § 103 rejections were the most common rejections (53 %). The data suggests that owner initiated reexaminations are more likely to raise questions of obviousness.
- Office actions resulting from third-party initiated requests had a high percentage of § 103 rejections (77 %) and § 102 rejections (65 %). It appears that third party initiated reexaminations are more likely to raise questions of obviousness and novelty.
- Owner initiated reexaminations are more than twice as likely to raise issues of double patenting relative to third party initiated reexaminations (13 % to 6 %, respectively). We conjecture that these numbers are significantly higher than seen in AUs 3992 and 3993.
- Not surprisingly, it appears that in both owner initiated and third-party initiated reexaminations, the most common secondary consideration for which a Rule 132 Declaration is submitted is "unexpected results."
- Extensions of time for one month are frequently requested (in 42% of reexaminations). However, it is within the discretion of the SPRE to grant or deny same, and her decision is not appealable.

Appendix A

Disciplinary Subset of 66 Biological, Pharma, and Chemical Classes

<u>Class</u>	<u>AU</u>	<u>Description</u>
420	3991	Alloys or metallic compositions
502	3991	Catalyst, solid sorbent, or support therefor: product or process of making
422	3991	Chemical apparatus and process disinfecting, deodorizing, preserving, or sterilizing
260	3991	Chemistry of carbon compounds
585	3991	Chemistry of hydrocarbon compounds
423	3991	Chemistry of inorganic compounds
436	3991	Chemistry: analytical and immunological testing
204	3991	Chemistry: electrical and wave energy
429	3991	Chemistry: electrical current producing apparatus, product, and process
71	3991	Chemistry: fertilizers
518	3991	Chemistry: fischer-tropsch processes; or purification or recovery of products thereof
435	3991	Chemistry: molecular biology and microbiology
530	3991	Chemistry: natural resins or derivatives; peptides or proteins; lignins or reaction products
23	3991	Chemistry: physical processes
209	3991	Classifying, separating, and assorting solids
134	3991	Cleaning and liquid contact with solids
510	3991	Cleaning compositions for solid surfaces, auxiliary compositions therefor
516	3991	Colloid systems and wetting agents; subcombinations thereof; processes of
506	3991	Combinatorial chemistry technology: method, library, apparatus
106	3991	Compositions: coating or plastic
202	3991	Distillation: apparatus
203	3991	Distillation: processes, separatory
201	3991	Distillation: processes, thermolytic
424	3991	Drug, bio-affecting and body treating compositions
514	3991	Drug, bio-affecting and body treating compositions
205	3991	Electrolysis: processes, compositions used therein, and methods of preparing
426	3991	Food or edible material: processes, compositions, and products
44	3991	Fuel and related compositions
210	3991	Liquid purification or separation
208	3991	Mineral oils: processes and products
800	3991	Multicellular living organisms and unmodified parts thereof and related processes
977	3991	Nanotechnology
532	3991	Organic compounds -- part of the class 532-570 series
534	3991	Organic compounds -- part of the class 532-570 series
536	3991	Organic compounds -- part of the class 532-570 series
540	3991	Organic compounds -- part of the class 532-570 series
544	3991	Organic compounds -- part of the class 532-570 series
546	3991	Organic compounds -- part of the class 532-570 series
548	3991	Organic compounds -- part of the class 532-570 series
549	3991	Organic compounds -- part of the class 532-570 series
552	3991	Organic compounds -- part of the class 532-570 series
554	3991	Organic compounds -- part of the class 532-570 series
556	3991	Organic compounds -- part of the class 532-570 series
558	3991	Organic compounds -- part of the class 532-570 series
560	3991	Organic compounds -- part of the class 532-570 series
562	3991	Organic compounds -- part of the class 532-570 series
564	3991	Organic compounds -- part of the class 532-570 series
568	3991	Organic compounds -- part of the class 532-570 series

570	3991	Organic compounds -- part of the class 532-570 series
987	3991	Organic compounds containing a bi, sb, as, or p atom or a metal atom of the 6th to 8th
930	3991	Peptide or protein sequence
512	3991	Perfume compositions
504	3991	Plant protecting and regulating compositions
419	3991	Powder metallurgy processes
430	3991	Radiation imagery chemistry: process, composition, or product thereof
117	3991	Single-crystal, oriented-crystal, and epitaxy growth processes; non-coating apparatus
241	3991	Solid material comminution or disintegration
520	3991	Synthetic resins or natural rubbers -- part of the class 520 series
521	3991	Synthetic resins or natural rubbers -- part of the class 520 series
522	3991	Synthetic resins or natural rubbers -- part of the class 520 series
523	3991	Synthetic resins or natural rubbers -- part of the class 520 series
524	3991	Synthetic resins or natural rubbers -- part of the class 520 series
525	3991	Synthetic resins or natural rubbers -- part of the class 520 series
526	3991	Synthetic resins or natural rubbers -- part of the class 520 series
527	3991	Synthetic resins or natural rubbers -- part of the class 520 series
528	3991	Synthetic resins or natural rubbers -- part of the class 520 series

Appendix B

1. Index of Reexaminations Associated with FDA Approved Products

<i>Product</i>	<i>Reexaminations</i>	<i>Total</i>
RISPERDAL CONSTA	90/007,587; 90/007,907; 90/008,093; 90/008,151; 90/008,212; 90/008,216	6
VIAGRA	90/006,617; 90/006,886; 90/007,110; 90/007,478; 90/007,614	5
ATRIPLA	90/008,549; 90/008,550; 90/008,555; 90/008,556	4
TRUVADA	90/008,549; 90/008,550; 90/008,555; 90/008,556	4
VIREAD	90/008,549; 90/008,550; 90/008,555; 90/008,556	4
CADUET	90/007,209; 90/008,727; 90/009,048	3
FAZACLO ODT	90/007,684; 90/008,133; 95/000,160	3
FLUXID	90/007,684; 90/008,133; 95/000,160	3
INOMAX	90/008,894; 90/009,319; 90/010,354	3
KEMSTRO	90/007,684; 90/008,133; 95/000,160	3
LIPITOR	90/007,209; 90/008,727; 90/009,048	3
NIRAVAM	90/007,684; 90/008,133; 95/000,160	3
ORAPRED ODT	90/007,684; 90/008,133; 95/000,160	3
REGLAN ODT	90/007,684; 90/008,133; 95/000,160	3
FACTIVE	90/006,498; 90/006,499	2
FELBATOL	90/007,991; 90/007,992	2
FERTINEX	90/005,521; 90/005,940	2
GONAL-F	90/005,521; 90/005,940	2
GONAL-F RFF	90/005,521; 90/005,940	2
GONAL-F RFF PEN	90/005,521; 90/005,940	2
METRODIN	90/005,521; 90/005,940	2
VELCADE	90/008,475; 90/008,476	2
VIVITROL	90/007,587; 90/008,093	2
ABILIFY	90/007,167	1
AMBIEN CR	95/000,282	1
APIDRA	90/006,928	1
APIDRA SOLOSTAR	90/006,928	1
BYSTOLIC	90/008,356	1
CLARINEX	90/006,820	1
CLIMARA PRO	90/006,899	1
DITROPAN XL	90/007,772	1
DUREZOL	90/006,548	1
FOCALIN	90/007,177	1
FOCALIN XR	90/007,177	1
GLUCOTROL XL	90/006,268	1
HALFLYTELY	90/010,319	1
IXEMPRA KIT	90/007,605	1
LAMISIL	90/007,982	1
LIPIDIL	90/005,586	1
MUCINEX	90/007,514	1
MUCINEX D	90/007,514	1
MUCINEX DM	90/007,514	1

NAMENDA	90/007,176	1
OLUX E	90/008,230	1
SOLODYN	90/009,180	1
SPORANOX	90/007,801	1
TACLONEX	95/000,153	1
TACLONEX SCALP	95/000,153	1
TARGRETIN	90/005,296	1
TRICOR	90/005,586	1
TRICOR (MICRONIZED)	90/005,586	1
VERDESO	90/008,230	1
VISIPAQUE 270	90/005,305	1
VISIPAQUE 320	90/005,305	1
ZEGERID	90/007,686	1

2. FDA Products Associated with Orange Book Patents Undergoing Reexamination

<i>Product</i>	<i>Patent</i>	<i>Reexamination</i>
ABILIFY	5,006,528	90/007,167
AMBIEN CR	6,514,531	95/000,282
APIDRA	6,221,633	90/006,928
APIDRA SOLOSTAR	6,221,633	90/006,928
ATRIPLA	5,922,695	90/008,555
	5,935,946	90/008,556
	5,977,089	90/008,550
	6,043,230	90/008,549
BYSTOLIC	6,545,040	90/008,356
CADUET	4,681,893	90/008,727
		90/009,048
	5,969,156	90/007,209
CLARINEX	6,514,520	90/006,820
CLIMARA PRO	5,393,529	90/006,899
DITROPAN XL	6,919,092	90/007,772
DUREZOL	6,114,319	90/006,548
FACTIVE	5,776,944	90/006,498
	5,962,468	90/006,499
FAZACLO ODT	6,024,981	90/007,684
		90/008,133
	6,221,392	95/000,160
FELBATOL	4,978,680	90/007,991
	5,082,861	90/007,992
FERTINEX	5,767,067	90/005,521
		90/005,940
FLUXID	6,024,981	90/007,684
		90/008,133
	6,221,392	95/000,160
FOCALIN	6,355,656	90/007,177

FOCALIN XR	6,355,656	90/007,177
GLUCOTROL XL	5,591,454	90/006,268
GONAL-F	5,767,067	90/005,521
		90/005,940
GONAL-F RFF	5,767,067	90/005,521
		90/005,940
GONAL-F RFF PEN	5,767,067	90/005,521
		90/005,940
HALFLYTELY	7,291,324	90/010,319
INOMAX	5,485,827	90/009,319
		90/010,354
	5,873,359	90/008,894
IXEMPRA KIT	6,670,384	90/007,605
KEMSTRO	6,024,981	90/007,684
		90/008,133
	6,221,392	95/000,160
LAMISIL	6,005,001	90/007,982
LIPIDIL	4,895,726	90/005,586
LIPITOR	4,681,893	90/008,727
		90/009,048
	5,969,156	90/007,209
METRODIN	5,767,067	90/005,521
		90/005,940
MUCINEX	6,372,252	90/007,514
MUCINEX D	6,372,252	90/007,514
MUCINEX DM	6,372,252	90/007,514
NAMENDA	5,061,703	90/007,176
NIRAVAM	6,024,981	90/007,684
		90/008,133
	6,221,392	95/000,160
OLUX E	7,029,659	90/008,230
ORAPRED ODT	6,024,981	90/007,684
		90/008,133
	6,221,392	95/000,160
REGLAN ODT	6,024,981	90/007,684
		90/008,133
	6,221,392	95/000,160
RISPERDAL CONSTA	5,688,801	90/007,907
		90/008,093
		90/008,216
		90/007,587
		90/008,212
		90/008,151
SOLODYN	5,908,838	90/009,180
SPORANOX	5,707,975	90/007,801
TACLONEX	6,753,013	95/000,153
TACLONEX SCALP	6,753,013	95/000,153
TARGRETIN	5,780,676	90/005,296

TRICOR	4,895,726	90/005,586
TRICOR (MICRONIZED)	4,895,726	90/005,586
TRUVADA	5,922,695	90/008,555
	5,935,946	90/008,556
	5,977,089	90/008,550
	6,043,230	90/008,549
VELCADE	6,747,150	90/008,476
	7,119,080	90/008,475
VERDESO	7,029,659	90/008,230
VIAGRA	6,469,012	90/006,617
		90/006,886
		90/007,110
		90/007,478
		90/007,614
VIREAD	5,922,695	90/008,555
	5,935,946	90/008,556
	5,977,089	90/008,550
	6,043,230	90/008,549
VISIPAQUE 270	5,366,722	90/005,305
VISIPAQUE 320	5,366,722	90/005,305
VIVITROL	5,792,477	90/008,093
	6,110,503	90/007,587
ZEGERID	6,699,885	90/007,686

3. FDA Products Associated with Reexaminations Sorted by Initiator

<i>Owner Initiated</i>	<i>Third-Party Initiated</i>
ABILIFY	AMBIEN CR
APIDRA	ATRIPLA
APIDRA SOLOSTAR	CADUET
BYSTOLIC	FAZACLO ODT
CLARINEX	FELBATOL
CLIMARA PRO	FERTINEX
DITROPAN XL	FLUXID
DUREZOL	GONAL-F
FACTIVE	GONAL-F RFF
FERTINEX	GONAL-F RFF PEN
FOCALIN	INOMAX
FOCALIN XR	KEMSTRO
GLUCOTROL XL	LAMISIL
GONAL-F	LIPITOR
GONAL-F RFF	METRODIN
GONAL-F RFF PEN	MUCINEX
HALFLYTELY	MUCINEX D
IXEMPRA KIT	MUCINEX DM
LIPIDIL	NIRAVAM

METRODIN	ORAPRED ODT
NAMENDA	REGLAN ODT
OLUX E	RISPERDAL CONSTA
TRICOR	SOLODYN
TRICOR (MICRONIZED)	SPORANOX
VELCADE	TACLONEX
VERDESO	TACLONEX SCALP
VISIPAQUE 270	TARGRETIN
VISIPAQUE 320	TRUVADA
	VIAGRA
	VIREAD
	VIVITROL
	ZEGERID
Total: 28 Products Associated	Total: 32 Products Associated

4. Patents Associated with Civil Litigation, Reexaminations, and FDA Approved Products

<i>Patent</i>	<i>Litigation</i>	<i>Reexamination</i>	<i>Product Name</i>
4,681,893	1:03CV00209 PFIZER INC., ET AL v. RANBAXY LABORATORIES, ET AL 02/21/2003 D.DEL.	90/008,727	CADUET LIPITOR
		90/009,048	CADUET LIPITOR
	1:03CV00259 PFIZER INC, ET AL v. RANBAXY LABORATORIES, ET AL 03/07/2003 D.DEL.	90/008,727	CADUET LIPITOR
		90/009,048	CADUET LIPITOR
	1:03CV00375 PFIZER INC., ET AL v. RANBAXY LABORATORIES, ET AL 04/11/2003 D.DEL.	90/008,727	CADUET LIPITOR
		90/009,048	CADUET LIPITOR
	1:07CV00138 PFIZER INC. ET AL v. RANBAXY LABORATORIES LIMITED ET AL 03/09/2007 D.DEL.	90/008,727	CADUET LIPITOR
		90/009,048	CADUET LIPITOR
	1:08CV00162 PFIZER INC. ET AL v. RANBAXY LABORATORIES LIMITED ET AL 03/24/2008 D.DEL.	90/008,727	CADUET LIPITOR
		90/009,048	CADUET LIPITOR
	3:03CV00792 PFIZER INC., ET AL v. RANBAXY LABORATORIES, ET AL 02/21/2003 D.N.J.	90/008,727	CADUET LIPITOR
		90/009,048	CADUET LIPITOR
	3:07CV01191 PFIZER INC. ET AL v. RANBAXY LABORATORIES LIMITED ET AL 03/09/2007 D.N.J.	90/008,727	CADUET LIPITOR
		90/009,048	CADUET LIPITOR
4,895,726	2:03CV00809 ABBOTT LABORATORIES, ET AL v. PAR PHARMACEUTICAL 02/24/2003 D.N.J.	90/005,586	LIPIDIL
			TRICOR
			TRICOR (MICRONIZED)

4,978,680	No Litigation Found Current January 5, 2010	90/007,991	FELBATOL	
5,006,528	1:07CV00236 OTSUKA PHARMACEUTICAL CO., LTD. v. SYNTHON HOLDING BV ET AL 03/28/2007 M.D.N.C.	90/007,167	ABILIFY	
	3:07CV01000 OTSUKA PHARMACEUTICAL CO., LTD. v. SANDOZ, INC. 03/02/2007 D.N.J.	90/007,167	ABILIFY	
	3:07CV01110 OTSUKA PHARMACEUTICAL CO., LTD. v. TEVA PHARMACEUTICALS USA, INC. ET AL 03/09/2007 D.N.J.	90/007,167	ABILIFY	
	3:07CV01267 OTSUKA PHARMACEUTICAL CO., LTD. v. BARR LABORATORIES, INC. ET AL 03/16/2007 D.N.J.	90/007,167	ABILIFY	
	3:07CV01346 OTSUKA PHARMACEUTICAL CO., LTD. v. APOTEX CORP. ET AL 03/23/2007 D.N.J.	90/007,167	ABILIFY	
	3:07CV01516 OTSUKA PHARMACEUTICAL CO., LTD. v. SUN PHARMACEUTICAL INDUSTRIES LTD. 04/02/2007 D.N.J.	90/007,167	ABILIFY	
	3:07CV02919 OTSUKA PHARMACEUTICAL CO., LTD. v. TEVA PHARMACEUTICALS USA, INC. ET AL 06/22/2007 D.N.J.	90/007,167	ABILIFY	
	3:07CV04112 OTSUKA PHARMACEUTICAL CO., LTD. v. SYNTHON HOLDING BV ET AL 08/23/2007 D.N.J.	90/007,167	ABILIFY	
	3:08CV01583 OTSUKA PHARMACEUTICAL CO., LTD. v. TEVA PHARMACEUTICALS USA, INC. ET AL 03/31/2008 D.N.J.	90/007,167	ABILIFY	
	3:08CV02675 OTSUKA PHARMACEUTICAL CO., LTD. v. ZYDUS PHARMACEUTICALS USA, INC. ET AL 05/30/2008 D.N.J.	90/007,167	ABILIFY	
	3:08CV04958 OTSUKA PHARMACEUTICAL CO., LTD. v. APOTEX CORP. ET AL 10/06/2008 D.N.J.	90/007,167	ABILIFY	
	3:09CV05531 OTSUKA PHARMACEUTICAL CO., LTD. v. TEVA PHARMACEUTICALS USA, INC. ET AL 10/29/2009	90/007,167	ABILIFY	
	5,061,703	1:08CV00022 FOREST LABORATORIES INC. ET AL v. BARR LABORATORIES INC. ET AL 01/10/2008 D.DEL.	90/007,176	NAMENDA
		1:08CV00052 FOREST LABORATORIES INC. ET AL v. DR. REDDY'S LABORATORIES INC. ET AL 01/25/2008 D.DEL.	90/007,176	NAMENDA
	1:08CV000FOREST LABORATORIES INC. ET AL v. COBALT LABORATORIES INC. ET	90/007,176	NAMENDA	

	AL 01/10/2008 D.DEL. 1:08CV00291 FOREST LABORATORIES INC. ET AL v. ORGENUS PHARMA INC. 05/16/2008 D.DEL.	90/007,176	NAMENDA
5,082,861	No Litigation Found Current January 5, 2010	90/007,992	FELBATOL
5,366,722	No Litigation Found Current January 5, 2010	90/005,305	VISIPAQUE 270 VISIPAQUE 320
5,393,529	No Litigation Found Current January 5, 2010	90/006,899	CLIMARA PRO
5,485,827	No Litigation Found Current January 5, 2010	90/009,319	INOMAX
		90/010,354	INOMAX
5,591,454	9:03CV80216 PFIZER, INC., ET AL v. ANDRX PHARMACEUTICAL, ET AL 03/20/2003 S.D.FLA.	90/006,268	GLUCOTROL XL
	9:03CV80289 PFIZER INC., ET AL v. ANDRX PHARMACEUTICAL, ET AL 04/11/2003 S.D.FLA.	90/006,268	GLUCOTROL XL
5,688,801	No Litigation Found Current January 5, 2010	90/007,907	RISPERDAL CONSTA
5,707,975	No Litigation Found Current January 5, 2010	90/007,801	SPORANOX
5,767,067	1:04CV10305 SERONO, INC., ET AL v. INDUSTRIA PHARMACEUTICALS, INC. 02/13/2004 D.MASS.	90/005,521	FERTINEX
			GONAL-F
			GONAL-F RFF
			GONAL-F RFF PEN
			METRODIN
		90/005,940	FERTINEX
			GONAL-F
			GONAL-F RFF
			GONAL-F RFF PEN
			METRODIN
5,776,944	No Litigation Found Current January 5, 2010	90/006,498	FACTIVE
5,780,676	No Litigation Found Current January 5, 2010	90/005,296	TARGETIN
5,792,477	No Litigation Found Current January 5, 2010	90/008,093	RISPERDAL CONSTA VIVITROL
5,873,359	No Litigation Found Current January 5, 2010	90/008,894	INOMAX
5,908,838	1:09CV00033 MEDICIS PHARMACEUTICAL CORPORATION v. MYLAN INC. ET AL 01/13/2009 D.DEL.	90/009,180	SOLODYN
	1:09CV00435 MEDICIS PHARMACEUTICAL CORPORATION v. RANBAXY INC. ET AL 06/11/2009 D.DEL.	90/009,180	SOLODYN
	1:09CV03464 MEDICIS PHARMACEUTICAL CORPORATION v. BARR LABORATORIES ET AL 12/28/2009 D.MD.	90/009,180	SOLODYN
	3:08CV00253 IMPAX LABORATORIES, INC. v. MEDICS PHARMACEUTICAL CORP 01/15/2008 N.D.CAL.	90/009,180	SOLODYN
5,922,695	No Litigation Found Current January 5, 2010	90/008,555	ATRIPLA TRUVADA VIREAD
5,935,946	No Litigation Found Current January 5, 2010	90/008,556	ATRIPLA

			TRUVADA
			VIREAD
5,962,468	No Litigation Found Current January 5, 2010	90/006,499	FACTIVE
5,965,168	No Litigation Found Current January 5, 2010	90/008,216	RISPERDAL CONSTA
5,969,156	1:04CV00223 PFIZER INC., ET AL v. AMUDHAN 04/12/2004 D.DEL.	90/007,209	CADUET LIPITOR
	1:04CV00280 PFIZER INC., ET AL v. ADIRONDACK COMPANY 05/04/2004 D.DEL.	90/007,209	CADUET LIPITOR
	1:04CV00281 PFIZER INC., ET AL v. KOLI, ET AL 05/04/2004 D.DEL.	90/007,209	CADUET LIPITOR
	1:04CV00282 PFIZER INC., ET AL v. SARANATH, ET AL 05/04/2004 D.DEL.	90/007,209	CADUET LIPITOR
	1:04CV00283 PFIZER INC., ET AL v. SINGH, ET AL 05/04/2004 D.DEL.	90/007,209	CADUET LIPITOR
	1:04CV01212 PFIZER INC., ET AL v. INTL-PHARMACY CORP., ET AL 09/02/2004 D.DEL.	90/007,209	CADUET LIPITOR
	1:04CV01213 PFIZER INC., ET AL v. FITZSIMONS 09/02/2004 D.DEL.	90/007,209	CADUET LIPITOR
	1:04CV01216 PFIZER INC., ET AL v. LUKE AMORESANO, ET AL 09/02/2004 D.DEL.	90/007,209	CADUET LIPITOR
	1:04CV01217 PFIZER INC., ET AL v. SARODE 09/02/2004 D.DEL.	90/007,209	CADUET LIPITOR
	1:04CV01219 PFIZER INC., ET AL v. JAYANTI NAGAR 09/02/2004 D.DEL.	90/007,209	CADUET LIPITOR
	1:04CV01222 PFIZER INC., ET AL v. BECKER 09/02/2004 D.DEL.	90/007,209	CADUET LIPITOR
	1:04CV01223 PFIZER INC., ET AL v. BECKER, ET AL 09/02/2004 D.DEL.	90/007,209	CADUET LIPITOR
	1:04CV01224 PFIZER INC., ET AL v. GENERIC LIPITOR, ET AL 09/02/2004 D.DEL.	90/007,209	CADUET LIPITOR
	1:04CV01225 PFIZER INC., ET AL v. GDL ACCESS 09/02/2004 D.DEL.	90/007,209	CADUET LIPITOR
	1:09CV00079 PFIZER INC. ET AL v. MYLAN INC. ET AL 06/15/2009 N.D.W.VA.	90/007,209	CADUET LIPITOR
	1:09CV00441 PFIZER INC. ET AL v. MYLAN INC. ET AL 06/15/2009 D.DEL.	90/007,209	CADUET LIPITOR
	1:09CV00889 PFIZER INC. ET AL v. MYLAN INC. ET AL 11/23/2009 D.DEL.	90/007,209	CADUET LIPITOR
	1:09CV00924 PFIZER INC. ET AL v. KREMERS URBAN LLC ET AL 12/03/2009 D.DEL.	90/007,209	CADUET LIPITOR
	1:09CV00943 PFIZER INC. ET AL v. DR. REDDY'S LABORATORIES LTD. ET AL 12/08/2009 D.DEL.	90/007,209	CADUET LIPITOR
	1:09CV02457 SANDOZ INC. v. PFIZER, INC. ET AL 10/16/2009 D.COLO.	90/007,209	CADUET LIPITOR
	3:04CV00741 PFIZER INC ET AL v. DOMAINS BY PROXY INC ET AL	90/007,209	CADUET LIPITOR

	05/04/2004 D.CONN.		
5,977,089	No Litigation Found Current January 5, 2010	90/008,550	ATRIPLA TRUVADA VIREAD
6,005,001	No Litigation Found Current January 5, 2010	90/007,982	LAMISIL
6,024,981	0:03CV02477 CIMA LABS INC, ET AL v. KV PHARMACEUTICAL CO, ET AL 03/17/2003 D.MINN.	90/007,684	FAZACLO ODT FLUXID KEMSTRO NIRAVAM ORAPRED ODT REGLAN ODT
		90/008,133	FAZACLO ODT FLUXID KEMSTRO NIRAVAM ORAPRED ODT REGLAN ODT
	1:08CV00531 CIMA LABS INC. ET AL v. BARR LABORATORIES INC. ET AL 08/21/2008 D.DEL.	90/007,684	FAZACLO ODT FLUXID KEMSTRO NIRAVAM ORAPRED ODT REGLAN ODT
		90/008,133	FAZACLO ODT FLUXID KEMSTRO NIRAVAM ORAPRED ODT REGLAN ODT
	1:08CV00886 CIMA LABS INC. ET AL v. NOVEL LABORATORIES INC. 11/25/2008 D.DEL.	90/007,684	FAZACLO ODT FLUXID KEMSTRO NIRAVAM ORAPRED ODT REGLAN ODT
		90/008,133	FAZACLO ODT FLUXID KEMSTRO NIRAVAM ORAPRED ODT REGLAN ODT
	1:09CV00349 CIMA LABS INC. ET AL v. BARR LABORATORIES INC. ET AL 05/15/2009 D.DEL.	90/007,684	FAZACLO ODT FLUXID KEMSTRO NIRAVAM ORAPRED ODT REGLAN ODT Total
		90/008,133	FAZACLO ODT FLUXID KEMSTRO NIRAVAM ORAPRED ODT

			REGLAN ODT	
	2:06CV01970 CIMA LABS INC. v. KALI LABORATORIES INC. 04/28/2006 D.N.J.	90/007,684	FAZACLO ODT	
			FLUXID	
			KEMSTRO	
			NIRAVAM	
			ORAPRED ODT	
		REGLAN ODT	90/008,133	FAZACLO ODT
		FLUXID		
		KEMSTRO		
		NIRAVAM		
		ORAPRED ODT		
	REGLAN ODT	90/007,684	FAZACLO ODT	
	FLUXID			
	KEMSTRO			
	NIRAVAM			
	ORAPRED ODT			
	REGLAN ODT	90/008,133	FAZACLO ODT	
	FLUXID			
	KEMSTRO			
	NIRAVAM			
	ORAPRED ODT			
	REGLAN ODT	90/007,684	FAZACLO ODT	
	FLUXID			
	KEMSTRO			
	NIRAVAM			
	ORAPRED ODT			
	REGLAN ODT	90/008,133	FAZACLO ODT	
	FLUXID			
	KEMSTRO			
	NIRAVAM			
	ORAPRED ODT			
	REGLAN ODT		FAZACLO ODT	
6,043,230	No Litigation Found Current January 5, 2010	90/008,549	ATRIPLA	
			TRUVADA	
			VIREAD	
6,110,503	No Litigation Found Current January 5, 2010	90/007,587	RISPERDAL	
			CONSTA	
			VIVITROL	
6,110,921	No Litigation Found Current January 5, 2010	90/008,212	RISPERDAL	
			CONSTA	
6,114,319	No Litigation Found Current January 5, 2010	90/006,548	DUREZOL	
6,221,392	1:08CV00531 CIMA LABS INC. ET AL v. BARR LABORATORIES INC. ET AL 08/21/2008 D.DEL.	95/000,160	FAZACLO ODT	
			FLUXID	
			KEMSTRO	
			NIRAVAM	
			ORAPRED ODT	
	REGLAN ODT	95/000,160	FAZACLO ODT	
	1:08CV00886 CIMA LABS INC. ET AL v. NOVEL LABORATORIES INC. 11/25/2008		FLUXID	

	D.DEL.		KEMSTRO NIRAVAM ORAPRED ODT REGLAN ODT
	1:09CV00349 CIMA LABS INC. ET AL v. BARR LABORATORIES INC. ET AL 05/15/2009 D.DEL.	95/000,160	FAZACLO ODT FLUXID KEMSTRO NIRAVAM ORAPRED ODT REGLAN ODT
	2:06CV01999 SCHWARZ PHARMA, INC. ET AL v. PAR PHARMACEUTICAL COMPANIES, INC. ET AL 04/28/2006 D.N.J.	95/000,160	FAZACLO ODT FLUXID KEMSTRO NIRAVAM ORAPRED ODT REGLAN ODT
	2:07CV00893 CIMA LABS, INC. ET AL v. ACTAVIS GROUP HF ET AL 02/23/2007 D.N.J.	95/000,160	FAZACLO ODT FLUXID KEMSTRO NIRAVAM ORAPRED ODT REGLAN ODT
6,221,633	No Litigation Found Current January 5, 2010	90/006,928	APIDRA APIDRA SOLOSTAR
6,355,656	2:07CV05552 CELGENE CORPORATION ET AL v. BARR LABORATORIES, INC. ET AL 11/16/2007 D.N.J.	90/007,177	FOCALIN FOCALIN XR
	3:06CV06154 CELGENE CORPORATION ET AL v. TEVA PHARMACEUTICALS USA, INC. 12/21/2006 D.N.J.	90/007,177	FOCALIN FOCALIN XR
	3:07CV05367 CELGENE CORPORATION ET AL v. ACTAVIS SOUTH ATLANTIC LLC ET AL 11/08/2007 D.N.J.	90/007,177	FOCALIN FOCALIN XR
	3:07CV05552 CELGENE CORPORATION ET AL v. BARR LABORATORIES, INC. ET AL 11/16/2007 D.N.J.	90/007,177	FOCALIN FOCALIN XR
6,368,632	No Litigation Found Current January 5, 2010	90/008,151	RISPERDAL CONSTA
6,372,252	0:09CV60609 RECKITT BENCKISER INC. v. WATSON LABORATORIES, INC. - FLORIDA ET AL 04/24/2009 S.D.FLA.	90/007,514	MUCINEX MUCINEX D MUCINEX DM
	0:09CV60852 RECKITT BENCKISER INC. v. WATSON LABORATORIES, INC. - FLORIDA ET AL 06/05/2009 S.D.FLA.	90/007,514	MUCINEX MUCINEX D MUCINEX DM
	0:09CV61986 RECKITT BENCKISER INC. v. WATSON LABORATORIES, INC.- FLORIDA ET AL 12/17/2009 S.D.FLA.	90/007,514	MUCINEX MUCINEX D MUCINEX DM
	1:07CV00993 ADAMS RESPIRATORY THERAPEUTICS, INC. ET AL v. PERRIGO COMPANY ET AL 10/02/2007 W.D.MICH.	90/007,514	MUCINEX MUCINEX D MUCINEX DM
	1:08CV00014 ADAMS RESPIRATORY THERAPEUTICS, INC. ET AL v. PERRIGO COMPANY ET AL 01/07/2008 W.D.MICH.	90/007,514	MUCINEX MUCINEX D MUCINEX DM

	1:09CV03933 RECKITT BENCKISER INC. v. WALTSON LABORATORIES, INC.- FLORIDA ET AL 04/20/2009 S.D.N.Y.	90/007,514	MUCINEX MUCINEX D MUCINEX DM
	1:09CV04455 RECKITT BENCKISER, INC. v. WATSON LABORATORIES, INC.- FLORIDA 05/08/2009 S.D.N.Y.	90/007,514	MUCINEX MUCINEX D MUCINEX DM
	2:06CV04418 ADAMS RESPIRATORY THERAPEUTICS, INC. v. PHARMACEUTICAL HOLDINGS CORP. ET AL 10/04/2006 E.D.PA.	90/007,514	MUCINEX MUCINEX D MUCINEX DM
	2:06CV04700 ADAMS RESPIRATORY THERAPEUTICS, INC. v. PHARMACEUTICAL HOLDINGS CORP. ET AL 10/02/2006 D.N.J.	90/007,514	MUCINEX MUCINEX D MUCINEX DM
	2:06CV05485 ADAMS RESPIRATORY THERAPEUTICS, INC. v. PHARMACEUTICAL HOLDINGS CORP. ET AL 12/15/2006 E.D.PA.	90/007,514	MUCINEX MUCINEX D MUCINEX DM
	2:07CV04619 ADAMS RESPIRATORY THERAPEUTICS, INC. ET AL v. PERRIGO COMPANY ET AL 09/27/2007 D.N.J.	90/007,514	MUCINEX MUCINEX D MUCINEX DM
	6,469,012	1:03CV00888 PFIZER INC., ET AL v. BAYER AG, ET AL 09/22/2003 D.DEL.	90/006,617
90/006,886			VIAGRA
90/007,110			VIAGRA
90/007,478			VIAGRA
90/007,614			VIAGRA
6,514,520	No Litigation Found Current January 5, 2010	90/006,820	CLARINEX
6,514,531	1:07CV00086 IN RE SANOFI-AVENTIS U.S. LLC 02/05/2007 M.D.N.C.	95/000,282	AMBIEN CR
	2:07CV00443 SANOFI-AVENTIS ET AL v. WATSON PHARMACEUTICALS, INC. ET AL 01/26/2007 D.N.J.	95/000,282	AMBIEN CR
	2:07CV01605 SANOFI-AVENTIS ET AL v. BARR LABORATORIES, INC. 04/05/2007 D.N.J.	95/000,282	AMBIEN CR
	2:07CV02250 SANOFI-AVENTIS ET AL v. MUTUAL PHARMACEUTICAL COMPANY, INC. ET AL 05/11/2007 D.N.J.	95/000,282	AMBIEN CR
	2:08CV01190 SANOFI-AVENTIS ET AL v. SANDOZ INC. 03/07/2008 D.N.J.	95/000,282	AMBIEN CR
	5:08CV00160 SANOFI-AVENTIS v. SYNTHON HOLDING BV, ET AL 03/27/2008 E.D.N.C.	95/000,282	AMBIEN CR
6,545,040	No Litigation Found Current January 5, 2010	90/008,356	BYSTOLIC
6,670,384	No Litigation Found Current January 5, 2010	90/007,605	IXEMPRA KIT
6,699,885	1:07CV00551 SANTARUS INC. ET AL v. PAR PHARMACEUTICAL INC. 09/13/2007 D.DEL.	90/007,686	ZEGERID
	1:07CV00827 SANTARUS INC. ET AL v. PAR PHARMACEUTICAL INC. 12/20/2007 D.DEL.	90/007,686	ZEGERID
6,747,150	No Litigation Found Current January 5, 2010	90/008,476	VELCADE
6,753,013	No Litigation Found Current January 5, 2010	95/000,153	TACLONEX
			TACLONEX

			SCALP
6,919,092	No Litigation Found Current January 5, 2010	90/007,772	DITROPAN XL
7,029,659	No Litigation Found Current January 5, 2010	90/008,230	OLUX E
			VERDESO
7,119,080	No Litigation Found Current January 5, 2010	90/008,475	VELCADE
7,291,324	No Litigation Found Current January 5, 2010	90/010,319	HALFLYTELY