

Biotechnology Innovation Report 2005

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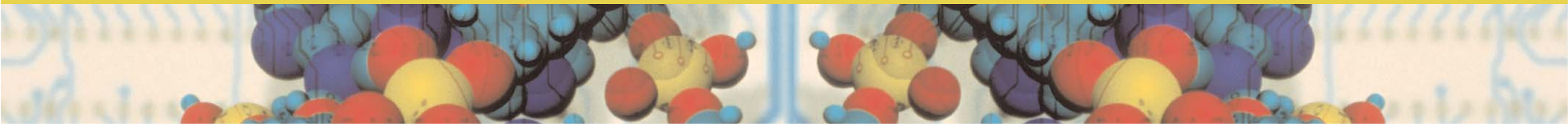
Focus



Finnegan, Henderson, Farabow, Garrett & Dunner, LLP

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June 2005



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[COMMITTEE PRINT]

109TH CONGRESS
1ST SESSION

H. R. _____

To amend title 35, United States Code, relating to the procurement, enforcement, and validity of patents.

IN THE HOUSE OF REPRESENTATIVES

M. _____ introduced the following bill; which was referred to the Committee on _____

A BILL

To amend title 35, United States Code, relating to the procurement, enforcement, and validity of patents.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

4 (a) **SHORT TITLE.**—This Act may be cited as the
5 “Patent Act of 2005”.

6 (b) **TABLE OF CONTENTS.**—The table of contents of
7 this Act is as follows:

- Sec. 1. Short title; table of contents.
- Sec. 2. Reference to title 35, United States Code.

Welcome from Thomas H. Jenkins

Finnegan Henderson’s Biotechnology/Pharmaceutical
Practice Group Leader



We are pleased to bring you this second edition of our
Biotechnology Innovation Report.

The recent introduction by the House subcommittee on
intellectual property of potentially sweeping draft patent
legislation (see the first page, left) underscores continued
active debate about reform of the U.S. patent system.
Debate remains especially marked with respect to the
biotechnology and pharmaceutical industries.

We continue to believe that discussions about law and policy can only benefit
from the availability of salient empirical evidence. To this end, as debate
ensues and consensus emerges, we hope that this Report will contribute to
the continued evolution of a patent system that functions as a powerful
vehicle for progress in science and technology.

Your comments and suggestions are most welcome.

Sincerely,
Thomas H. Jenkins
tom.jenkins@finnegan.com

From the Editor

Arie M. Michelsohn, Ph.D., Finnegan, Henderson, Farabow, Garrett & Dunner, LLP



We were encouraged by the positive feedback we received on last year's Report to continue our studies of patenting and patent litigation in the biotechnology and pharmaceutical industries. The baseline data we presented last year has been updated, and several new experiments have been performed. We have, for example, added queries of U.S. published patent applications to our queries of issued U.S. patents. We have also conducted a study of individual district court patent cases decided between 2000 and

2004, prompted by feedback we received on our presentation last year of data on individual patent cases decided by the U.S. Court of Appeals for the Federal Circuit (we have included a study of those this year as well). In Chapter 3, we are particularly pleased to provide this year an analysis by Finnegan Henderson partner Kenneth J. Meyers of major developments at the U.S. Patent and Trademark Office (USPTO or PTO) during 2004.

In view of our efforts to extend last year's studies and hone in on some of the details, we have subtitled this year's Report "Focus." As with last year's Report, we have tried throughout this year's edition to be clear about what we did, and what we got. We recognize that there are many limitations on possible interpretations of the data, given our sample sizes and the veracity of our methods. These limitations notwithstanding, we do hope that the various stakeholders in the biotechnology and pharmaceutical industries will scrutinize the data to productive ends.

We greatly appreciate, and sincerely welcome, your comments and suggestions.

Arie M. Michelsohn, Ph.D.
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The Finnegan Henderson Biotechnology Innovation Report 2005

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Section I: Patenting Trends

Chapter 1

Subject Matter Trends

Chapter 2

Ownership Trends

Chapter 3

2004 at the USPTO

Charles E. Van Horn

Finnegan, Henderson, Farabow, Garrett & Dunner, LLP



Our study of patenting trends has followed up and expanded upon the two questions we asked last year: what is being patented, and by whom. Chapter 1 focuses on the first question, while Chapter 2 addresses the second. In Chapter 3, we shift focus to the USPTO and present an overview of major developments at the agency in 2004.

Data from searches both of issued patents and published patent applications suggest a modestly declining trend with respect to many of the parameters we measured. Ownership trends have maintained their course. The USPTO has commented, and acted, upon several substantive and procedural issues.

More on these and other topics in the pages that follow, along with this year's list of the Top 20 *nucleic acid* and *kinase* patent holders, as well as updated patent holdings over time for the Top 10 biotechs by market cap.

We look forward to your comments.

Charles E. Van Horn

charles.vanhorn@finnegan.com

Our Metrics: “Patent Share” and “Published Application Share”

As with last year’s Report, we compared patenting trends in the biotechnology and pharmaceutical industries relative to other industries. To do so, we employed metrics that normalize the number of patents or published patent applications containing particular search terms to the total number of issued patents or published applications, respectively. For issued patent data, we measured “patent share,” in patents per thousand (PPT), defined as the number of patents in a particular year containing a particular search term, divided by the total number of patents issued that year, times 1000. Similarly, for published patent application data, we measured “application share,” in published applications per thousand (PAPT). Normalization using this procedure for the generic search term “background” yielded the expectedly flat, stippled curves shown in Figures 1-1A and 1-1B, for issued patents and published patent applications, respectively.

Issued Patents Decline, Published Applications Are Up

Figure 1-1C, which plots the last year of the total patent and published application data in Figures 1-1A and 1-1B, illustrates that, in terms of absolute numbers, issued patents decreased by 3.0% in 2004 relative to 2003, while published patent applications increased by 13.2% during the same period. The decrease in the total number of issued patents is notable as the only decrease during this entire period (see Figure 1-1A). The steep rise we observed in the number of published applications between 2001¹ and 2002 likely represents a transition period during which publication increased dramatically as different categories of previously-filed applications (provisional, foreign-filed, and regular utility) became ripe for publication.

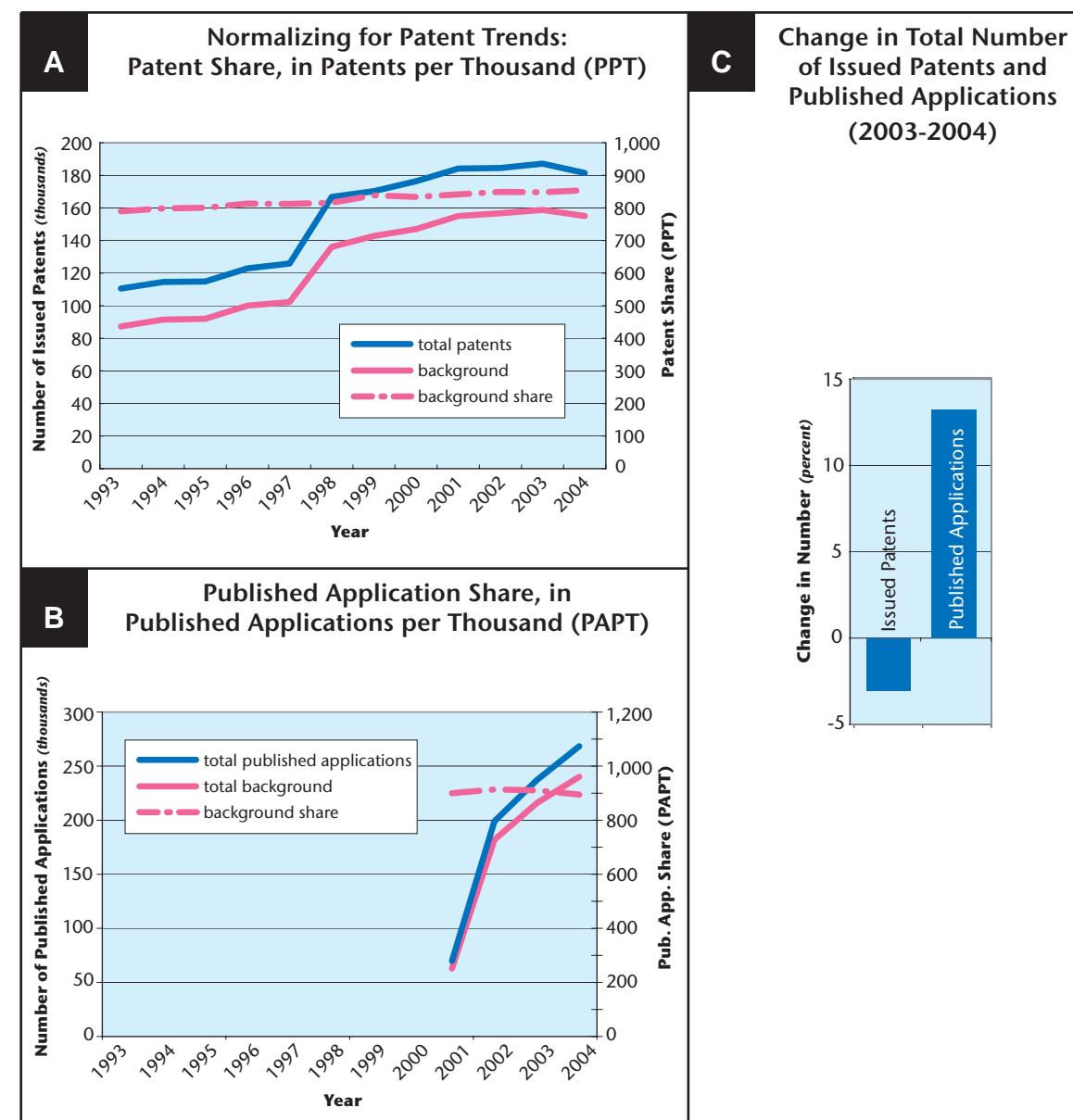


Fig 1-1 Raw Numbers and Share

A: The solid curves are plotted on the left scale and show the total number of patents as a function of year of issue (blue curve) and the number of patents containing the search term *background* as a function of year of issue (pink curve), from 2003 through 2004. The dashed pink curve is plotted on the right scale and shows the patent share (measured in patents per thousand) of patents containing the search term *background* as a function of the year of issue. **B:** Same as A, but for published patent applications. The dashed (pink) curve shows published application share (measured in published applications per thousand) for the period 2001 through 2004, where 2001 values are normalized to 12 months. **C:** Percent change from 2003 to 2004 in number of issued patents and published applications are compared.

¹ The data in Figure 1-1B are normalized to 12 months from March 15, 2001, the earliest date in the PTO’s published application database.

Biotech and Pharmaceutical Share Shows Modest Decline

Figure 1-2A plots patent share, in patents per thousand, for each indicated search term in the specifications of issued U.S. patents each year from 1993 through 2004. The plateau in biotech and pharmaceutical patenting, following a steep rise in the late 1990s, discussed in last year's Report, can be seen in the context of continued growth between 2003 and 2004 in *semiconductor* and *Internet* patent share, as those terms continue to pervade all industries, not just biotechnology and pharmaceuticals. As shown in Figure 1-2C, *nucleic acid* and *pharmaceutical* patent share (as measured in specifications) declined, while the patent share of each of the other search terms increased. The decline was generally modest, except relative to search terms like *nanotechnology*, which showed substantial growth from an albeit still low patent share (0.58 PPT in 2004) for an early-stage technology. The decline in *nucleic acid* and *pharmaceutical* patent share also contrasted with continued log-phase increase in *Internet* patent share.

A similar message regarding the decline in biotech and pharmaceutical share relative to other industries is obtained from searches of published U.S. applications, although the data are more difficult to interpret in view of the transition period previously discussed. Figure 1-2B plots published application share for each of the indicated search terms in each year from 2001 (normalized to 12 months) through 2004. As discussed, the total number of published applications increased considerably from 2001 (normalized) to 2002 (Figure 1-1B). Figure 1-2B shows the share of that increasing total application pool containing search terms representative of various industries. *Nucleic acid* and *pharmaceutical* applications showed a sharp increase in share from 2001 to 2003. However, from 2003 to 2004 this trend was reversed (Figure 1-2D). Consistent with the increase in *nanotechnology* patent share observed from 2003 to 2004, published application share has increased as well; although, as with patent share, the 2004 application share of *nanotechnology* patents was still low, at 1.38 PPT. Interestingly, *Internet* application share declined slightly.

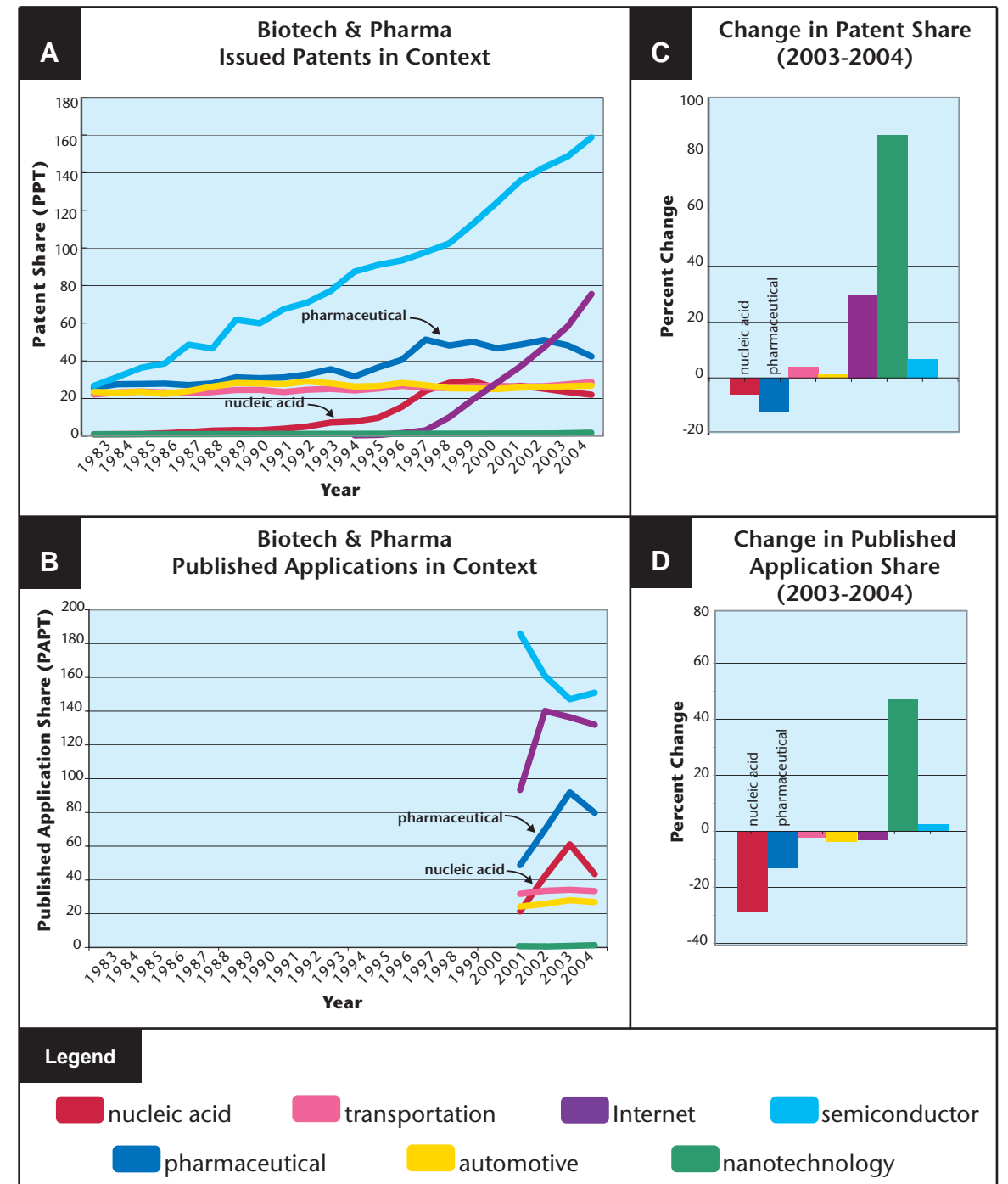


Fig 1-2 Biotech and Pharmaceutical Search Terms in Context

A: Patent share for each indicated search term in the specifications of issued patents is plotted as a function of year, from 1983-2004. **B:** Same as A, but for published applications from 2001 through 2004, with the 2001 values normalized to 12 months. **C:** Percent change in patent share from 2003 to 2004 is plotted from the data in A. **D:** Same as C, but for published application share using the data in B.

The Decline in Biotech and Pharmaceutical Share, in Focus

As discussed with respect to Figure 1-1C, the total number of issued patents fell in 2004 by about 3% relative to 2003. As shown in Figure 1-3A (left side), the number of issued *nucleic acid* patents (as measured by appearance of the term in patent specifications) fell nearly three-fold, representing a decline in *nucleic acid* patent share of about 6%. We noted a similar trend for *pharmaceutical* patents. The decrease in *nucleic acid* and *pharmaceutical* patent share was comparable to the decrease in patent share seen using a variety of search terms both in the specifications and claims. Results for several such search terms are shown in Figure 1-3B. As shown in Figure 1-3B, in both the specifications and claims of issued patents, we observed a modest decrease in patent share of between about 1% (for *nucleic acid* in the claims) and 13% (for *pharmaceutical* in the specification and claims) for each of the search terms tested, i.e., *amino acid*, *antibody*, *nucleic acid*, *peptide*, *pharmaceutical*, and *protein*.

The results for published applications likewise showed a decline in both absolute numbers and share for biotech and pharmaceutical search terms, although, as discussed, these data show considerable volatility. As discussed with respect to Figure 1-1C, the total number of published applications increased by about 13% in 2004 relative to 2003. As shown in Figure 1-3A (right side), in contrast, the number of published applications containing the search term *nucleic acid* in the specification decreased by nearly 20%, representing a decline in patent share of 28%. Other biotech search terms yielded similar results. We note that the share of *pharmaceutical* published applications stayed closer to baseline, especially as measured in the claims.

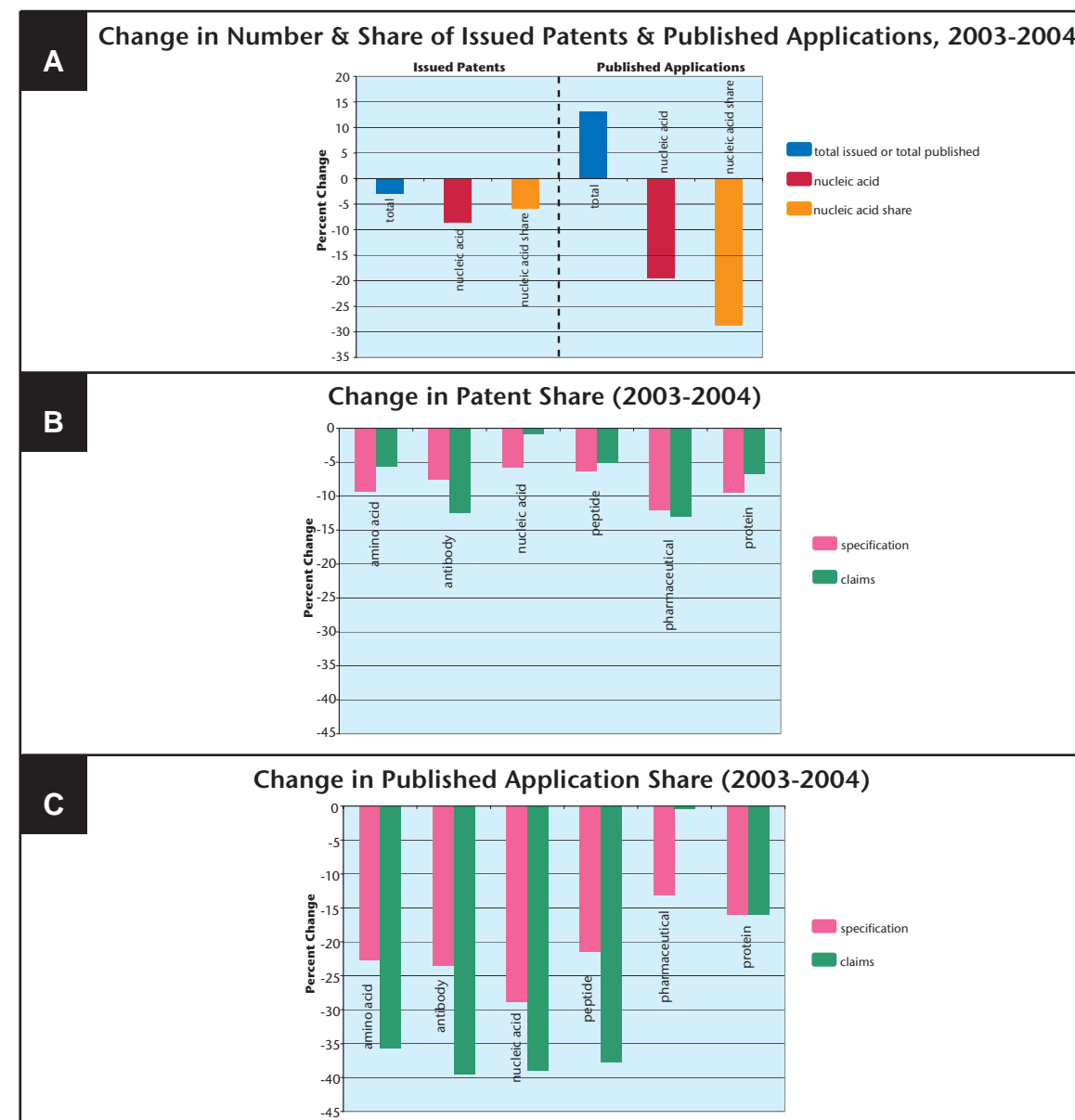


Fig 1-3 Biotech and Pharmaceutical Search Terms

A: Percent change in number of patents or in patent share. Data for issued U.S. patents are plotted on the left side; data for published U.S. patent applications are plotted on the right. **B:** Change in patent share from 2003 to 2004 for each of the indicated search terms in the specifications (pink) and claims (green) in issued U.S. patents is plotted. **C:** Same as B, but for published applications.

Patenting Trends in Diagnostics & Research Tools

As with last year's Report, we queried the USPTO database for issued patents claiming methods of detecting, methods of screening, and kits, by measuring the patent share of *method* claims that were also *detect* or *screen* claims, as well as the patent share of *kit* claims. To select for biotech-related and pharmaceutical-related patents, we limited our searches to patents claiming such methods or kits in the claims that also contained either *nucleic acid* (as an index of biotech patents) or *pharmaceutical* (as an index of pharmaceutical patents) in the specification. The results of our queries are shown in Figures 1-4A (tracked over the period 1993 through 2004; *nucleic acid* searches in solid lines, *pharmaceutical* searches in stippled lines) and 1-4C (showing the percent change from 2003 to 2004; *nucleic acid* searches on left, *pharmaceutical* searches on right). It appears that diagnostic and research-tool claims have remained near 2003 levels for 2004, showing a slight or modest decline for all *nucleic acid* searches and *screen* and *kit* claims for *pharmaceutical* searches, and a slight increase in *detect* claims in our *pharmaceutical* search.

Comparable searches were likewise performed in the USPTO published applications database from 2001 (normalized to 12 months) through 2004. Results of these queries are shown in Figures 1-4B (showing data from 2001 through 2004; *nucleic acid* searches in solid lines, *pharmaceutical* searches in stippled lines) and 1-4D (showing the percent change from 2003 to 2004; *nucleic acid* searches on left, *pharmaceutical* searches on right). *Detect* claims showed the greatest volatility.

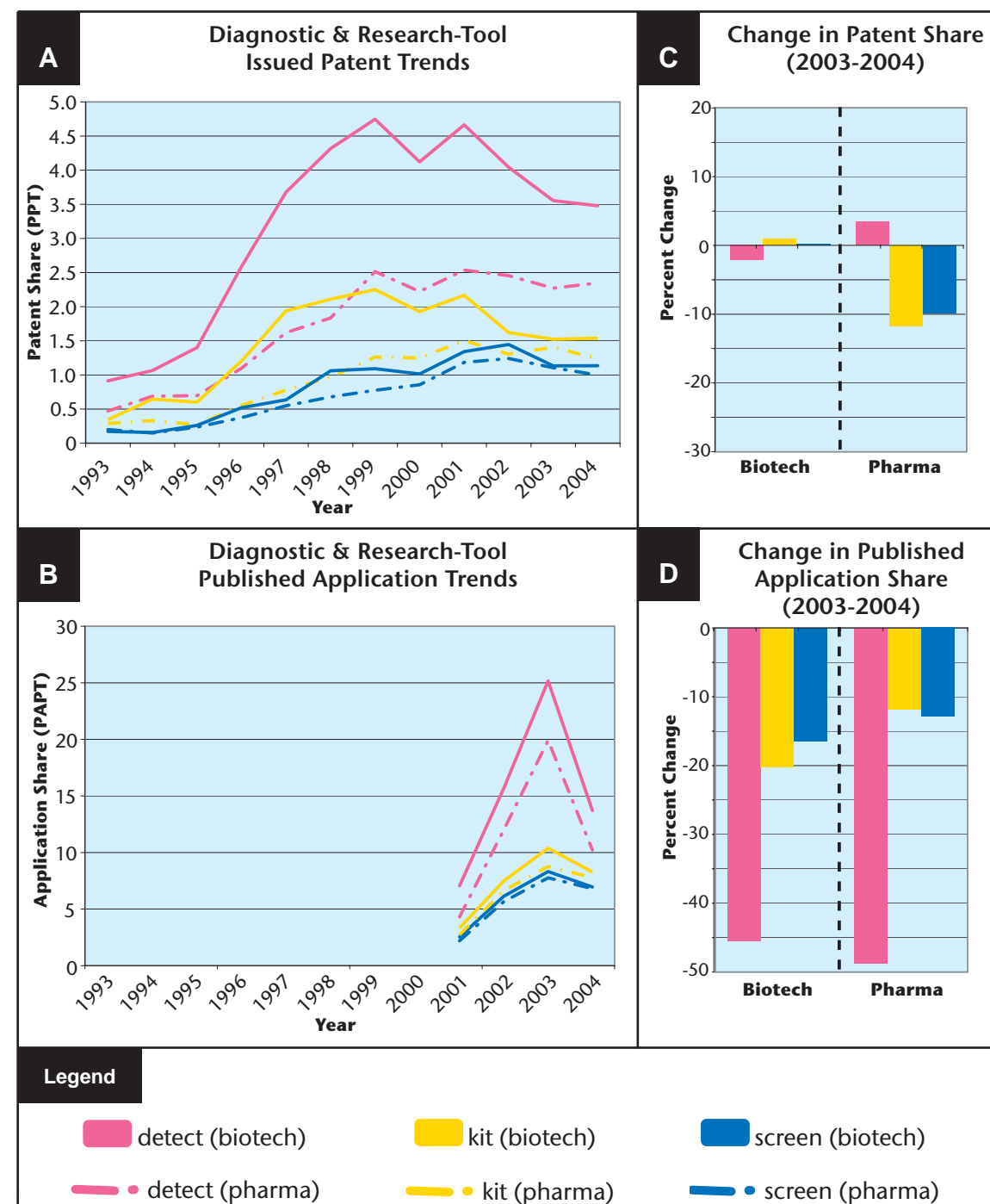


Fig 1-4 Patent Share for Diagnostics and Research-Tool Patent Claims

A and B plot patent and application share, respectively, for the period 1993-2004, while C and D plot the change in patent and application share, respectively, from 2003 to 2004, for each of the searches indicated. Queries are explained in the text.

Patenting Trends in the “New Biology”

We continued to track patenting trends in such technologies as functional genomics, stem cells, and novel drug delivery methods, by measuring the claim share of patents and published applications containing search terms indicative of such technologies. Results of our queries using the search terms we employed last year are provided in Figure 1-5. Data for additional terms, both in claims and specifications, are provided in Figure 1-7.

Figure 1-5A updates last year’s graph of patent share over time for the search terms *protease*, *probe*, *kinase*, *transgenic*, *drug delivery*, and *stem cell*. All of the terms showed a decrease in patent share between 2003 and 2004 (Figure 1-5C). Figures 1-5B and 1-5D show corresponding data for published applications. As with the trend we observed for issued patents, all of the search terms we tested in the claims of published applications showed a decline in share between 2003 and 2004. Claims to (*nucleic acid* or *nucleotide*) *probes* showed particular volatility.

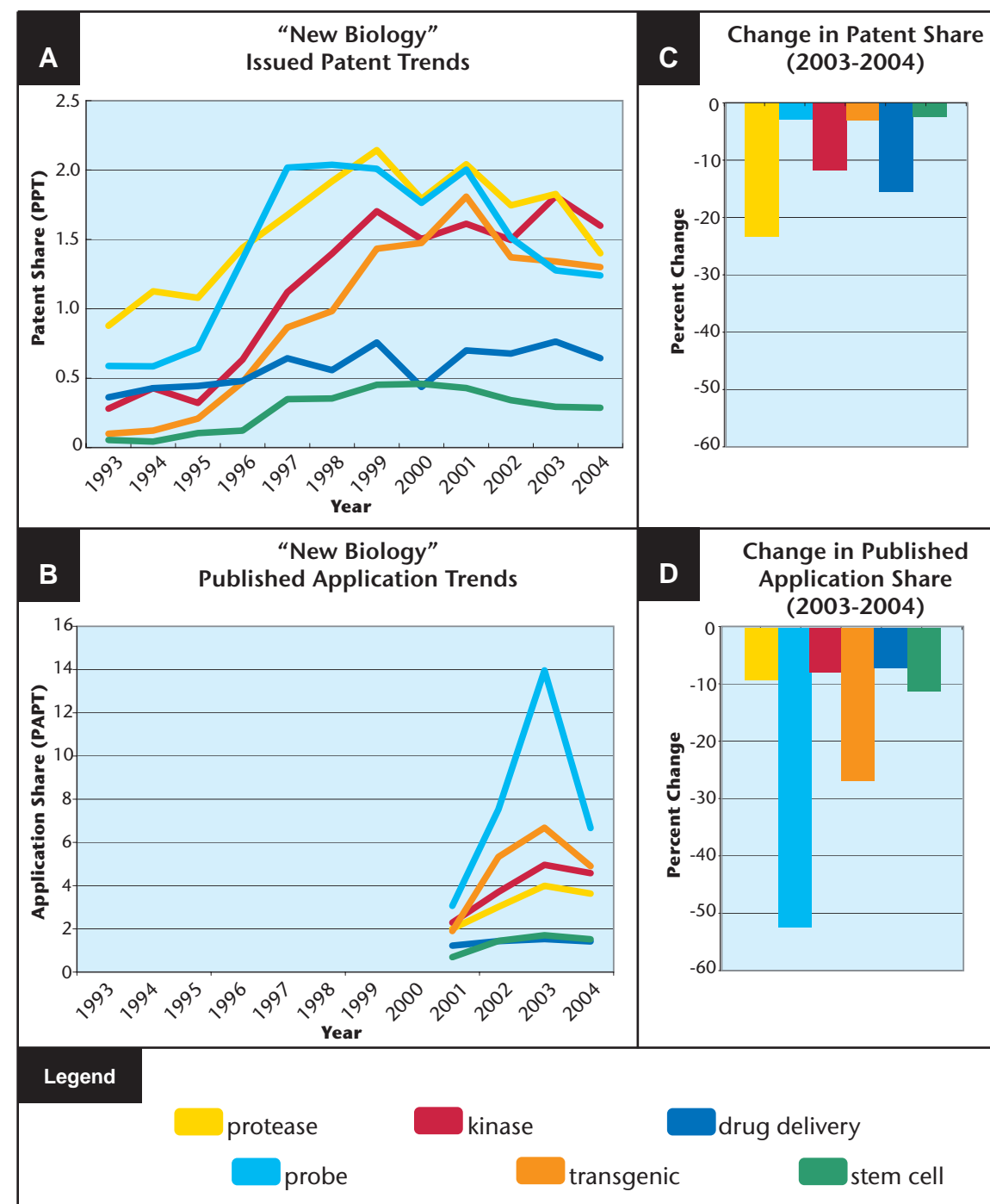


Fig 1-5 “New Biology” Claim Share in Issued Patents and Published Applications

A: Patent share for each indicated search term as a function of year, for the period 1993 through 2004. B: Published application share for each indicated search term as a function of year, for the period 2001 (normalized to 12 months) through 2004. C: Change in patent share for each indicated search term from 2003 to 2004. D: Same as C, but for published application share, using the data in B.

Patenting Trends in Therapeutic Areas

We likewise updated our searches of claims containing terms indicative of five therapeutic areas: cancer, heart disease, the brain/nervous system, arthritis, and HIV.¹ Results are presented in Figure 1-6.

As shown in Figure 1-6A, the general decline since 2002 that has characterized the trend in issued patents with respect to terms used as indices for four of the five therapeutic areas tested (cancer, the brain/nervous system, arthritis, and HIV) has continued into 2004. As shown in Figure 1-6C, two of those areas (HIV and arthritis) showed a double-digit decline in patent share from 2003 to 2004. Interestingly, the share of heart disease terms decreased by nearly 20% from 2003 to 2004, following the steady rise since 1999 that we noted last year.

We likewise observed a modest decline in published application share over the past year for three of the five therapeutic area claim terms tested (Figure 1-6D). Cancer terms showed particular volatility (Figure 1-6B). Heart disease terms showed a modest increase from 2003 to 2004 following steady growth since 2001, suggesting that the share of these terms in issued patents may rebound in the future.

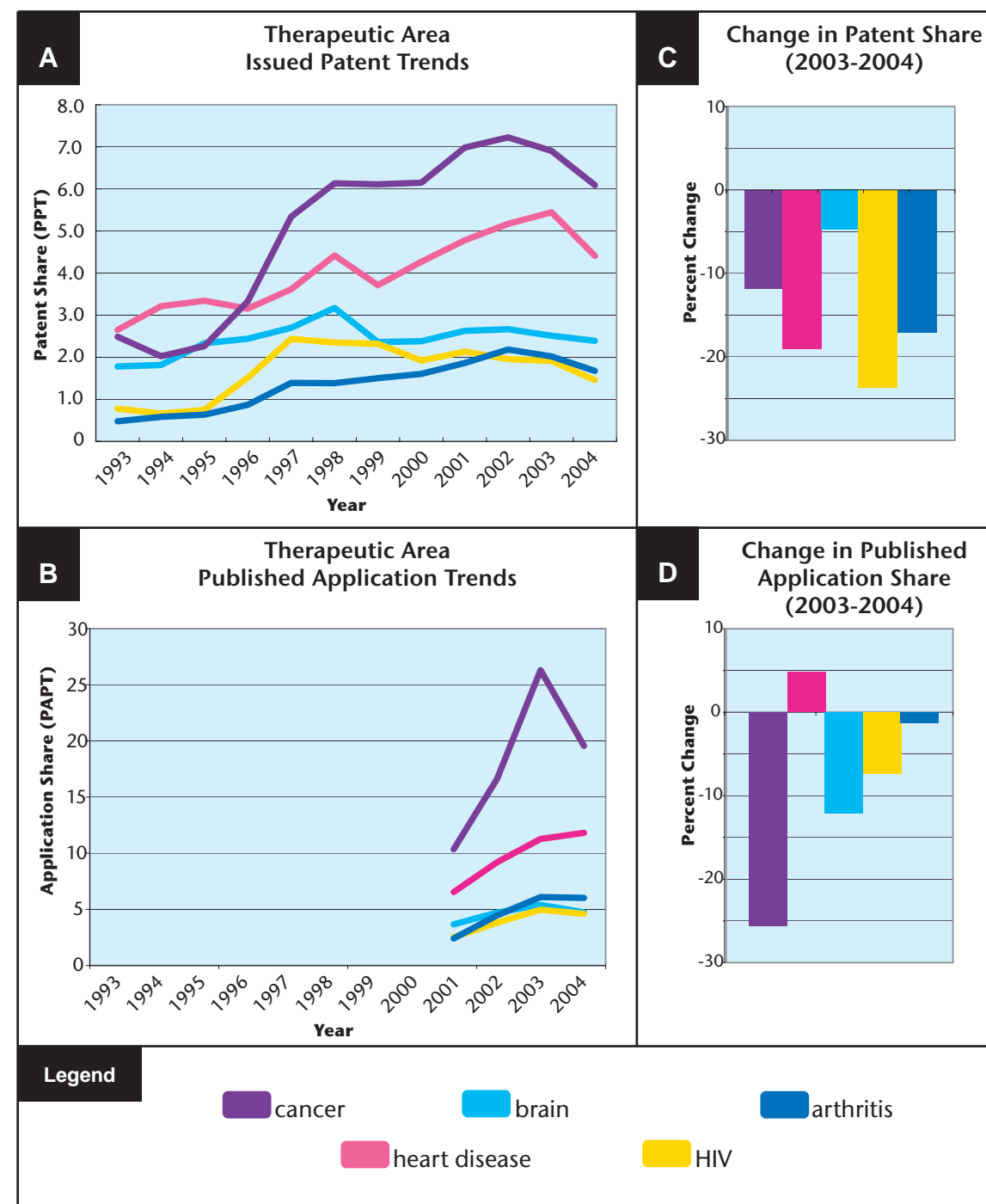


Fig 1-6 “New Biology” Claim Share in Issued Patents and Published Applications
 A: Patent share for each indicated therapeutic area term (see note 1, previous page) as a function of year, for the period 1993 through 2004. B: Published application share for each indicated therapeutic area term as a function of year, for the period 2001 (normalized to 12 months) through 2004. C: Percent change in patent share from 2003 to 2004 using the data in A. D: Same as C, but for published application share, using the data in B.

¹ The search terms were: cancer: *oncogene, tumor, oncogenesis, angiogenesis*; heart disease: *cardiovascular, atherosclerosis, cardiac*; brain: *neural, neuron, neuronal*; HIV: *immunodeficiency, HIV*; and arthritis: *rheumatoid, rheumatism, arthritis, arthritic*.

The Decline in Biotech and Pharmaceutical Patenting: A Composite View

The modest downward trend that we observed with respect to the various biotechnology-related and pharmaceutical-related search terms tested, as discussed throughout this Chapter, is further underscored by the data presented in Figure 1-7 on the following pages. In Figure 1-7, we provide the 2004 share and the change in share from 2003 to 2004 for each of the indicated search terms in the specifications (1-7A and 1-7C) and claims (1-7B and 1-7D) of both issued patents (1-7A and 1-7B) and published applications (1-7C and 1-7D). The search terms presented include those in each of the previous figures, as well as several others. Search terms showing an increase in patent share from 2003 to 2004 are shaded blue; search terms showing a decline are shaded pink.

As shown in Figures 1-7A-D, the majority of search terms showed an across-the-board decline in share from 2003 to 2004, both in their appearance in specifications and claims, both in issued patents and in published applications. Notable by contrast with all the other terms tested was the increase both in patent and application share for the search string (*RNA interference* or *RNAi*) both in specifications and claims. However, the patent and application share for (*RNA interference* or *RNAi*) is still relatively low and is thus volatile to even small changes in absolute number of patents or published applications. We note, nonetheless, that the increase in 2004 share for (*RNA interference* or *RNAi*) appears underscored by the disparity between the relatively large application share (3.66) compared to the patent share (0.26) in specifications containing this term in 2004. The disparity is likewise evident in the claims (0.51 application share *vs.* 0.02 patent share).

USPTO Issued Patents Search Term in Specification	PPT 2004	Change in Patent Share (2003-2004)
RNA interference or RNAi	0.26	125%
transgenic	10.85	8%
gene therapy	7.79	-1%
stem cell	2.94	-1%
polymerase chain reaction	12.31	-3%
kinase	14.81	-4%
nucleotide	22.10	-4%
hybridoma	6.47	-5%
nucleic acid	22.03	-6%
peptide	29.56	-6%
brain terms***	15.30	-7%
antibody	26.75	-8%
genomic	16.12	-8%
monoclonal	18.24	-9%
growth factor	10.66	-9%
amino acid	31.39	-9%
protein	50.65	-9%
protease	14.27	-10%
cancer terms****	33.21	-11%
drug delivery	8.63	-11%
reverse transcriptase	6.57	-12%
pharmaceutical	42.33	-12%
HIV or immunodeficiency	9.66	-16%
arthritis terms**	11.44	-17%
heart disease terms*****	25.19	-17%
catheter or stent	15.53	-18%

Fig 1-7 Share Changes for a Compendium of Biotech and Pharmaceutical Search Terms

B

USPTO Issued Patents Search Term in Claims	PPT 2004	Change in Patent Share (2003-2004)
RNA interference or RNAi	0.02	55%
hybridoma	0.56	10%
gene therapy	0.15	7%
monoclonal	1.72	5%
growth factor	1.37	3%
stem cell	0.29	0%
nucleic acid	9.18	-1%
transgenic	1.30	-3%
brain terms***	2.39	-5%
peptide	5.26	-5%
amino acid	11.38	-6%
protein	13.64	-6%
kinase	1.60	-12%
cancer terms****	6.09	-12%
antibody	4.61	-12%
polymerase chain reaction	0.68	-13%
pharmaceutical	13.32	-13%
nucleotide	5.45	-14%
drug delivery	0.64	-16%
arthritis terms**	1.68	-17%
heart disease terms*****	4.41	-19%
HIV or immunodeficiency	1.23	-20%
catheter or stent	6.17	-20%
protease	1.40	-23%
genomic	0.64	-30%
reverse transcriptase	0.29	-40%

C

USPTO Published Applications Search Term in Specifications	PPT 2004	Change in Application Share (2003-2004)
RNA interference or RNAi	3.66	70%
kinase	30.12	30%
catheter or stent	25.26	-2%
heart disease terms*****	47.04	-6%
pharmaceutical	79.78	-13%
brain terms***	29.03	-13%
protein	92.67	-15%
cancer terms****	64.86	-17%
peptide	56.59	-22%
amino acid	58.68	-23%
antibody	52.22	-24%
reverse transcriptase	15.64	-25%
arthritis terms**	24.69	-25%
nucleic acid	43.48	-29%
monoclonal	36.08	-30%
protease	26.63	-30%
drug delivery	19.63	-30%
nucleotide	41.32	-31%
growth factor	23.87	-31%
HIV or immunodeficiency	21.01	-33%
transgenic	22.32	-35%
genomic	31.27	-36%
polymerase chain reaction	25.64	-37%
gene therapy	17.09	-42%
hybridoma	13.27	-48%
stem cell	8.27	-53%

D

USPTO Published Applications Search Term in Claims	PPT 2004	Change in Application Share (2003-2004)
RNA interference or RNAi	0.51	62%
catheter or stent	9.80	8%
heart disease terms*****	11.80	5%
pharmaceutical	34.85	-1%
gene therapy	1.21	-1%
arthritis terms**	6.02	-1%
HIV or immunodeficiency	3.74	-7%
drug delivery	1.42	-7%
kinase	4.58	-8%
protease	3.63	-9%
stem cell	1.52	-11%
growth factor	4.02	-12%
brain terms***	4.74	-12%
protein	32.78	-15%
reverse transcriptase	1.21	-15%
hybridoma	1.74	-19%
polymerase chain reaction	2.41	-22%
cancer terms****	19.56	-26%
transgenic	4.90	-27%
amino acid	23.46	-36%
genomic	2.65	-37%
peptide	14.62	-38%
nucleic acid	22.56	-39%
antibody	19.05	-40%
nucleotide	14.50	-45%
monoclonal	6.71	-57%

Fig 1-7 Share Changes for a Compendium of Biotech and Pharmaceutical Search Terms

2004 patent share (7A and C) and published application share (7B and D) and the change in share from 2003 to 2004, for each of the indicated search terms in the specifications (7A and C) and claims (7B and D) are provided. Increases in share are shaded blue; decreases are shaded pink. Composite terms: **arthritis or rheumatology or rheumatoid or arthritic or rheumatism; ***neuron or neural or neuronal; ****cancer or oncogene or tumor or oncogenesis or angiogenesis; *****heart disease or cardiovascular or atherosclerosis or cardiac.

Trends in Ownership

How We Sampled Assignee Data

Ownership trends discussed in last year's Report have been updated. From independent searches in the USPTO patent database, we sampled data on patents containing the search term *nucleic acid* in the specifications of U.S. patents issued in 2004. In particular, we sampled all the patents containing the search term that appeared in the database during the last three weeks of each quarter of 2004—a total of 12 weeks of patents sampled. For each sampled patent, we ascertained the assignee and then binned the assignees into four categories: (1) Private Sector, (2) University/Institute, (3) Government, and (4) Collaborations (representing joint assignees consisting of any combination of the first three categories).¹ We combined these data with the data obtained previously.

Results

Figure 2-1 provides a three-dimensional view of the ownership distribution for *nucleic acid* patents for each of four years tested—1993, 1998, 2003, and 2004. We note that the shift from university/institute ownership towards the private sector discussed in last year's Report appears to have been nearly maintained in 2004 (Figure 2-1, green and blue bars). We observed a slight further decrease in university/institute ownership, in favor of an apparently concomitant increase in joint “collaboration” (red bars) and government (yellow bars) ownership. These trends in patent ownership are likewise evident when one measures the percent ownership among the Top 10 owners of *nucleic acid* patents, as shown in Figure 2-2 (page 23).

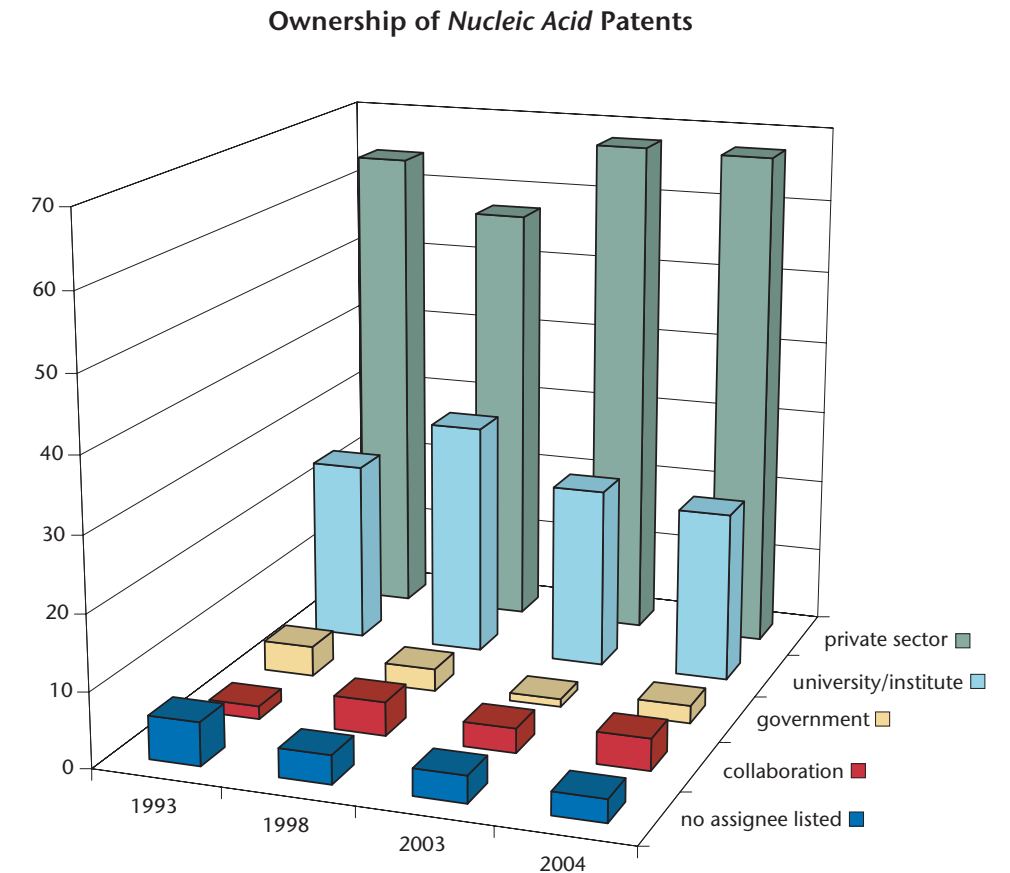


Fig 2-1 Types of Assignee in Nucleic Acid Patents over Time

Assignee data were compiled by searching for *nucleic acid* patents in each of the indicated years and examining the individual search results, as described in the text.

¹ For a small number of patents in each sample, no assignee could be ascertained, as shown in Figure 2-1.

Assignee Type Among Top 10 Nucleic Acid Patent Holders

For each *nucleic acid* patent sampled for assignee data as previously described, we counted the number of patents belonging to each assignee and rank-ordered them from highest to lowest number of patents assigned. We then chose the top 25, and for each of those assignees, conducted separate queries for the term *nucleic acid* in combination with that assignee (for example, we conducted the query *nucleic acid* in the specification + *Genentech* as assignee in 2004, because our review of our 2004 sample placed Genentech in the top 25 patent holders for that year). This allowed us to produce a Top 20 list of *nucleic acid* patent holders in 2004 (page 25) that ranks patentees by decreasing number of assigned *nucleic acid* patents. Ownership distribution among the top 10 from our list parallel the overall trend discussed with respect to Figure 2-1, as shown in Figure 2-2. Our Top 20 list is shown in Figure 2-3 (page 25) We note that to tabulate assignee names, we used the entity name listed on the face of each patent, even if the patent subsequently changed ownership as a result of a merger, acquisition, or sale.

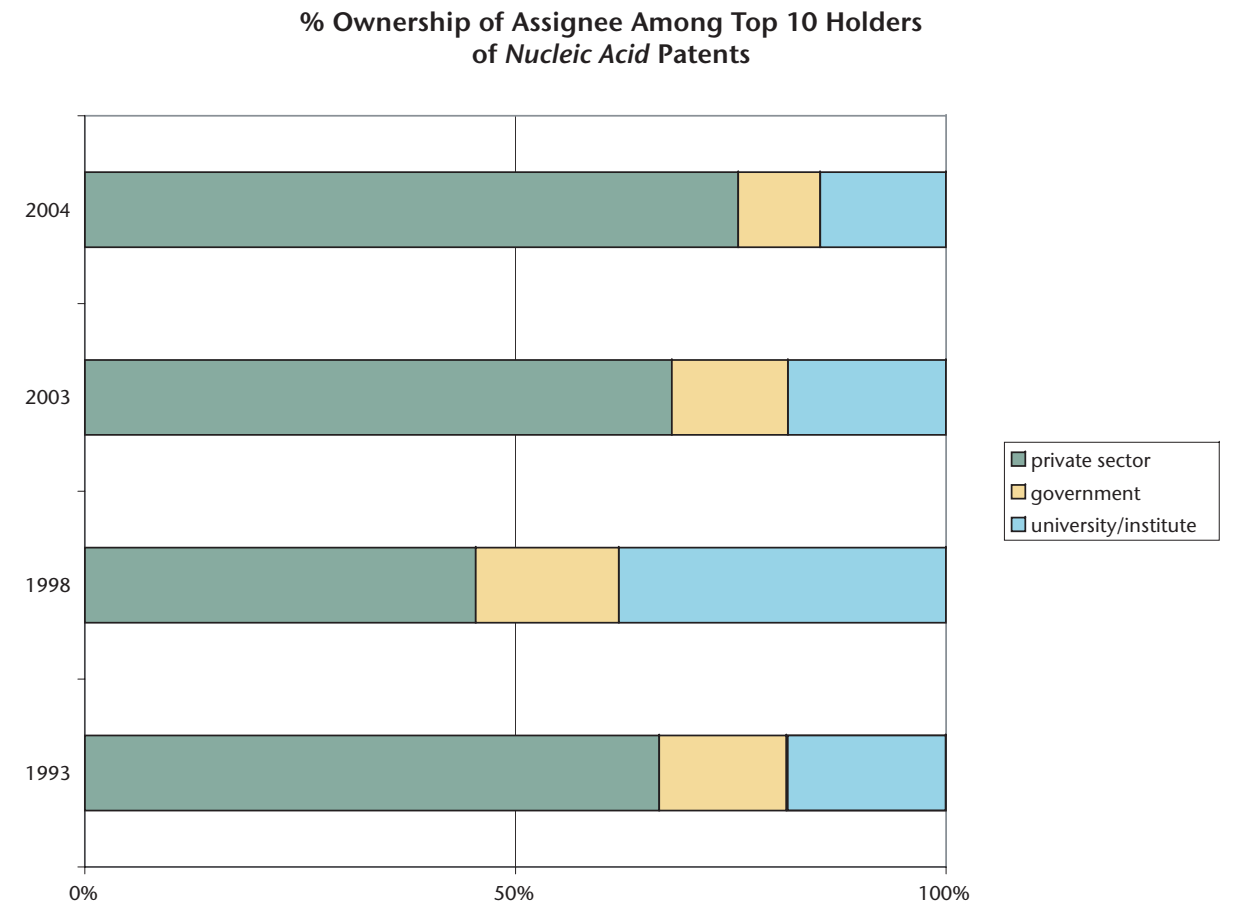


Fig 2-2 Assignee Type Among the Top 10 Nucleic Acid Patent Holders

The percentage of *nucleic acid* patents held by private sector, government, and university/institute assignees was ascertained, as described in the text.

Nucleic Acid Patent Holders: The Top 20

We ascertained the Top 20 assignees of *nucleic acid* patents in 2004 (based on the entities listed on the face of the patents examined) as described in the text accompanying Figure 2-2. We have marked private sector assignees in green, university/institute assignees in blue, and government (the U.S., in particular) in yellow. The trends discussed with respect to Figures 2-1 and 2-2 are generally apparent in Figure 2-3 as well. The University of California and the U.S. government have maintained their positions at the top of the list.

Top 20 Patent Holders of *Nucleic Acid* Patents

2003		2004	
University of California	(118)	University of California	(132)
USA	(87)	USA	(94)
Human Genome Sciences	(82)	Applera	(78)
ISIS Pharmaceuticals	(65)	Genentech	(55)
Applera	(54)	ISIS Pharmaceuticals	(54)
Genentech	(54)	Human Genome Sciences	(46)
Millennium Pharmaceuticals	(48)	Millennium Pharmaceuticals	(42)
E.I. duPont	(48)	University of Texas	(41)
Affymetrix	(45)	E.I. duPont	(37)
Corixa	(42)	Pioneer Hi-Bred	(36)
Pioneer Hi-Bred	(41)	Affymetrix	(33)
University of Texas	(41)	Bayer	(29)
Caliper Technologies	(35)	Columbia University	(27)
Immunex	(35)	Johns Hopkins	(27)
SmithKline Beecham	(33)	Pharmacia	(25)
Monsanto	(31)	Agilent	(24)
Columbia University	(28)	Fuji Photo	(23)
Cornell University	(27)	SmithKline Beecham	(22)
Genencor International	(25)	Harvard	(21)
California Institute of Technology	(23)	California Institute of Technology	(19)

■ private sector
■ government
■ university/institute

Fig 2-3 The Top 20 *Nucleic Acid* Patent Assignees

Methods for obtaining the results shown are described in the text. The number of patents issued to each assignee during each year surveyed is provided in parentheses.

Kinase Patent Holders: The Top 20

We likewise updated for 2004 our search for the Top 20 owners of *kinase* patents. We sampled ownership of *kinase* patents identically to our sampling of *nucleic acid* patents (including using the assignee listed on the face of the patents surveyed), substituting *kinase* for the search term. The University of California was once again near the top of the list. We note an apparent increase in 2004 in the relative number of *kinase* patents owned by entities in agricultural biotechnology.

Top 20 Patent Holders of *Kinase* Patents

2003	2004
Human Genome Sciences (78)	Pioneer Hi-Bred International (112)
University of California (71)	University of California (72)
Bristol-Myers Squibb (50)	Genentech (48)
Genentech (47)	USA (47)
Pioneer Hi-Bred International (41)	Human Genome Sciences (41)
USA (38)	Applera (38)
Millennium Pharmaceuticals (37)	Pfizer (37)
Aventis (35)	Bristol-Myers Squibb (36)
Immunex (34)	Lexicon Genetics (32)
Pfizer (28)	Millennium Pharmaceuticals (30)
Merck & Co. (28)	Stine Seed Farm (29)
Applera (27)	University of Texas (29)
SmithKline Beecham (27)	Wyeth (25)
Corixa (24)	Johns Hopkins (25)
University of Texas (23)	Pharmacia & Upjohn (24)
Pharmacia & Upjohn (21)	Mertec (21)
Lexicon Genetics (20)	Boehringer Ingelheim (20)
Cytokinetics (20)	Schering (19)
Novartis (16)	Bayer (15)
Rigel Pharmaceuticals (16)	Diversa (14)

■ private sector
 ■ government
 ■ university/institute

Fig 2-4 The Top 20 *Kinase* Patent Assignees

Methods for obtaining the results shown are described in the text. The number of patents issued to each assignee during each year surveyed is provided in parentheses.

Patent Share of the Top 10 by Market Cap

We assessed the patent holdings of the ten largest biotech companies by market cap for 2004, as identified by multiplying values for shares outstanding and price per share listed in *The Wall Street Journal* on October 31, 2004. We queried the USPTO database as a function of time for each of the ten company names as assignee and converted raw numbers to patent share. Plots of patent share for each company are provided in Figure 2-5. We note that the ratio of companies with declining patent share to those with increasing patent share was about 2:1, consistent with the overall decline in biotech patent share previously discussed.

Patent Share of the Top 10 Biotech Companies by Market Cap

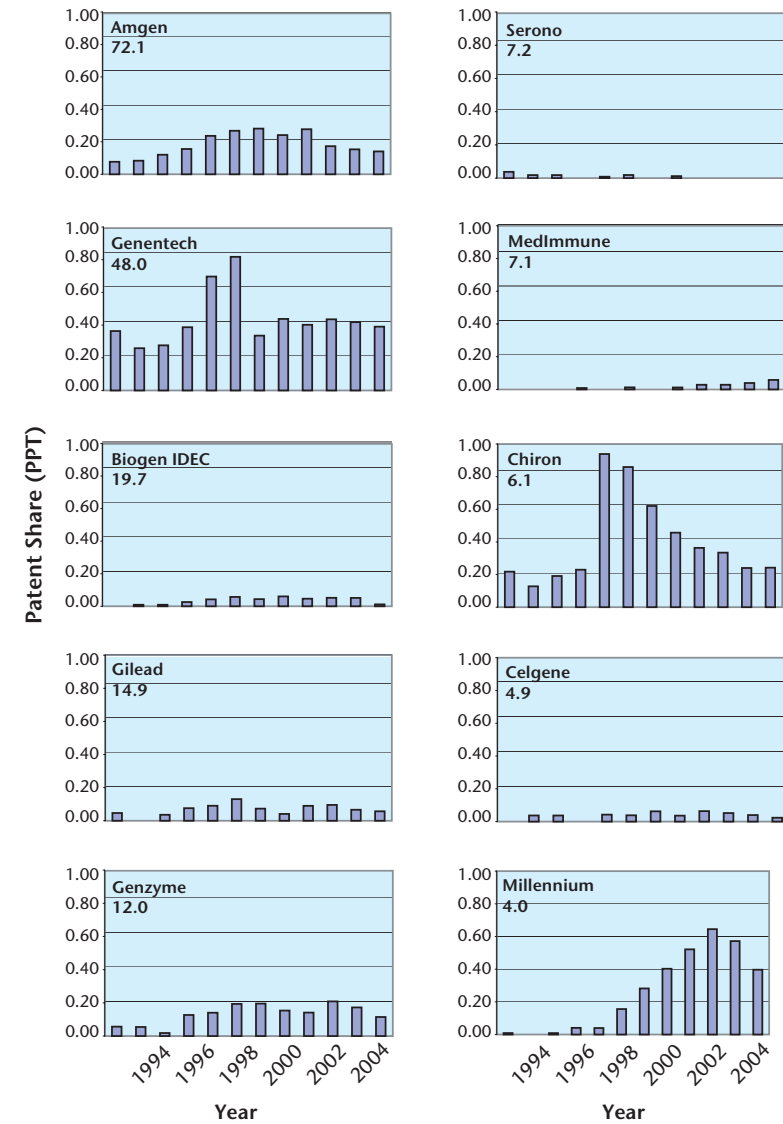


Fig 2-5 Patent Share by Year for the Ten Largest Biotech Companies by Market Cap
 Patent share per year was calculated from the number of patents issued each year to each of the Top 10 biotech companies by market cap, identified as described in the text. Market cap values are in \$Billion.

Chapter 3

2004 at the USPTO

By Kenneth J. Meyers

Introduction

Over the past twenty years, patent practice before the PTO has been characterized by change. It is useful to examine the reasons for change, how the changes have affected practice before the PTO, and what the practitioner must do to adapt to these changes. Here we consider the changes that have occurred at the PTO in 2004, in their respective historical contexts.

PTO Statistics¹

Identifiable trends in practice before the PTO are the result of filings by applicants in the PTO and disposal of pending cases by the PTO. Overall application filings continued to increase between 2000 and 2004 from 311,807 to 376,810, increasing the PTO's workload. Patent application disposals also increased during the period, but the pendency time of the average patent application also increased from 25.0 to 27.6 months.

The effects of the increased workload are not uniform throughout the PTO. The average pendency in 2004 from filing to a first action on the merits was just over one year (14 months) in the semiconductor, electrical, and optical system art (TC2800), but almost three years (33.3 months) in the computer, architecture, software, and information security arts (TC2100). In biotechnology and pharmaceutical arts, average pendency from filing to first PTO action was 19.2 months.

Without increased hiring, responding to attrition, and changes to examination processing or examination efficiencies, the PTO has estimated that the number of months it would take to reach first action on the merits in the business methods arts (Art Unit 3620) could reach almost nine years. Nevertheless, the PTO has shown that allocation of its resources and management of those resources can reduce pendency times, as evidenced by a decline in pending *ex parte* appeals during the same time period.

¹ See presentation of Peggy Focarino, USPTO Deputy Commissioner for Patent Operations, January 27, 2005.

Overcoming § 103(a) Rejections Using the Cooperative Research & Technology Enhancement Act of 2004 – “CREATE”

The “Cooperative Research and Technology Enhancement (CREATE) Act of 2004” responds to the 1997 *Oddzon* decision of the Court of Appeals for the Federal Circuit. *Oddzon Prods., Inc. v. Just Toys, Inc.*, 122 F.3d 1396, 43 U.S.P.Q.2d 1641 (Fed. Cir. 1997). The legislation ameliorates the effects of the decision permitting the patenting of inventions that result from collaborative or “team research” in circumstances not permitted under prior law. Enactment of the CREATE Act provides collaborative researchers affiliated with multiple organizations a statutory “safe harbor” similar to the one available under the 1984 Amendments to the patent law to researchers employed by a single organization or who have established certain types of legal relationships.

In *Oddzon*, the Federal Circuit found that in the case of an invention that involved researchers from more than one organization, the sharing of confidential information by members of a research team could render an invention obvious within the meaning of § 103, and therefore unpatentable, if the researchers did not have an obligation to assign their rights to the invention to a single entity in advance of making the invention. The court wrote:

The statutory language provides a clear statement that subject matter that qualifies as prior art under subsection (f) or (g) cannot be combined with other prior art to render a claimed invention obvious and hence unpatentable when the relevant prior art is commonly owned with the claimed invention at the time the invention was made. While the statute does not expressly state . . . that § 102(f) creates a type of prior art for purposes of § 103, nonetheless that conclusion is inescapable; the language that states that § 102(f) subject matter is not prior art under limited circumstances clearly implies that it is prior art otherwise.

Oddzon, 122 F.3d at 1403.

The decision created a situation where an otherwise patentable invention may be rendered nonpatentable on the basis of confidential information routinely exchanged between research partners. Thus, parties who entered into a clearly defined and structured research relationship, but who did not elect to define a common ownership interest in or a common assignment of inventions jointly developed, could unwittingly create an obstacle to patent protection by simply exchanging *secret* information among themselves. Under the court's interpretation of § 103(c), there was no requirement that the patent-disqualifying information be publicly disclosed or commonly known.

In enacting the "Cooperative Research and Technology Enhancement (CREATE) Act of 2004," subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of section 102 of Title 35, and a claimed invention, shall be deemed to be owned by the same person, or subject to an obligation of assignment to the same person, where specific conditions are satisfied. The CREATE Act eliminates the use of certain information and prior art in obviousness determinations in the circumstances addressed in the legislation.

The CREATE Act amends the patent laws to provide that subject matter developed by another person shall be treated as owned by the same person or subject to an obligation of assignment to the same person for purposes of determining obviousness if three conditions are met. First, the claimed invention was made by or on behalf of parties to a joint research agreement that was in effect on or before the date the claimed invention was made. Second, the claimed invention was made as a result of activities undertaken within the scope of the joint research agreement. Third, the application for patent for the claimed invention discloses or is amended to disclose the names of the parties to the joint research agreement.

The revised standard permits one party to a joint research agreement, who owns an invention, to claim the benefit of 35 U.S.C. § 103(c) without requiring the potentially disqualifying subject matter and the invention be owned by a single entity or subject to an obligation of common assignment. The revised standard requires the invention be made after the date of an eligible joint research agreement. Section 3 of the CREATE Act provides that its amendments shall apply to any patent (including any reissue patent) *granted* on or after December 10, 2004.

35 U.S.C. § 103(c)(3) defines a "joint research agreement" as a written contract, grant, or cooperative agreement entered into by two or more persons or entities for the performance of experimental, developmental,

or research work in the field of the claimed invention. The agreement must have been in effect on or before the date the claimed invention (under examination or reexamination) was made to meet all of the requirements of the definition.

In practice, once an examiner has established a *prima facie* case of obviousness under 35 U.S.C. § 103(a), the burden of overcoming the rejection by invoking the "safe harbor" 35 U.S.C. § 103(c) as amended by the CREATE Act is on the applicant. To overcome a rejection under 35 U.S.C. § 103(a) based upon subject matter (whether a patent document, publication, or other evidence), which qualifies as prior art under only one or more of 35 U.S.C. § 102(e), (f), or (g) via the CREATE Act, the applicant must provide a statement to the effect that the prior art and the claimed invention were made by or on the behalf of parties to a joint research agreement within the meaning of 35 U.S.C. § 103(c)(3), and that the claimed invention was made as a result of activities undertaken within the scope of the joint research agreement.

In addition to providing a statement, the applicant must also: (1) amend the specification to disclose the names of the parties to the joint research agreement, and (2) either amend the specification to either set forth the date the joint research agreement was executed and a concise statement of the field of the claimed invention, or specify where (i.e., by reel and frame number) this information is recorded in the assignment records of the PTO.

The specification may disclose or be amended to disclose the names of the parties to a joint research agreement. Rule 1.71(g). This amendment to the specification will not be treated as new matter.

A joint research agreement can be amended to be in compliance with 35 U.S.C. § 103(c) as amended by the CREATE Act. The date the amended joint research agreement was executed is the date the joint research agreement was executed for purposes of 35 U.S.C. § 103(c)(2)(A) and is the date that must be provided to comply with Rule 1.17(g).

Rule 1.71(g)(3) provides that if a patent does not include the names of the parties to the joint research agreement, an amendment to include the names of the parties to the joint research agreement will not be effective unless the patent is corrected by a certificate of correction. It is unnecessary to file a reissue application or request for reexamination of the patent to submit the amendment and other information necessary to take advantage of 35 U.S.C. § 103(c) as amended by the CREATE Act. *See* H.R. Rep. No. 108-425, at 9 ("The omission of the names of parties to the agreement is not an error that would justify commencement of a reissue or reexamination proceeding.").

Double Patenting

The effect of the CREATE Act on the applicant is that the application or patent and subject matter disqualified under 35 U.S.C. § 103(c) as amended by the Act will be treated as commonly owned for purposes of double-patenting analysis. The PTO may require a terminal disclaimer in accordance with Rule 1.321(d) when double patenting is determined to exist for two or more claimed inventions for any application for which the applicant takes advantage of the “safe harbor” provision in 35 U.S.C. § 103(c) as amended by the Act.

The PTO proposed a new Rule governing double-patenting rejections. New Rule 1.109(a) provides as follows:

§ 1.109 Double patenting.

(a) A double patenting rejection will be made in an application or patent under reexamination if the application or patent under reexamination claims an invention that is not patentably distinct from an invention claimed in a commonly owned patent. This double patenting rejection will be made regardless of whether the application or patent under reexamination and the commonly owned patent have the same or a different inventive entity. A judicially created double patenting rejection may be obviated by filing a terminal disclaimer in accordance with Sec. 1.321(c).

This new Rule replaces old Rule 1.130(b). The new Rule is intended to contain the provisions of Rule 1.130(b), with a few changes for clarity. 70 Fed. Reg. at 1820.

Part (b) of Rule 1.109 applies to double-patenting rejections following an applicant’s reliance on the safe harbor provision of § 103 provided by the CREATE Act. It provides:

(b) A double patenting rejection will be made in an application or patent under reexamination if the application or patent under reexamination claims an invention that is not patentably distinct from an invention claimed in a non-commonly owned patent by or on behalf of parties

to a joint research agreement in which the inventions claimed in the application or patent under reexamination and in the other patent were made as a result of activities undertaken within the scope of the joint research agreement. This double patenting rejection will be made regardless of whether the application or patent under reexamination and the non-commonly owned patent have the same or a different inventive entity. This double patenting rejection may be obviated by filing a terminal disclaimer in accordance with § 1.321(d).

Thus, Rule 1.109(b) provides that this double-patenting rejection will be made regardless of whether the application or patent and the noncommonly owned patent have the same or a different inventive entity, and whether or not the application and patent are, in fact, commonly owned. The application or patent and the subject matter disqualified under 35 U.S.C. § 103(c) as amended by the CREATE Act will be treated as commonly owned for purposes of double-patenting analysis. Rule 1.109(b) also provides that a double-patenting rejection may be obviated by filing a terminal disclaimer in accordance with Rule 1.321(d).

One of the differences between part (a) and part (b) of new Rule 1.109 is that part (b) provides for a terminal disclaimer under Rule 1.321(d), which is a new Rule requiring among other things that:

(d) A terminal disclaimer, when filed in a patent application (rejected application) or in a reexamination proceeding (rejected patent) to obviate a double patenting rejection based upon a patent (disqualified patent) or application (disqualified application) that is not commonly owned but was disqualified under 35 U.S.C. 103(c) as resulting from activities undertaken within the scope of a joint research agreement, must:

* * *

(4) Include a provision that the owner of the rejected application or patent and the owner of the disqualified patent or application *each*:

- (i) Waive the right to separately enforce and the right to separately license the rejected application or patent and the disqualified patent or application;
- (ii) Agree that the rejected application or patent and the disqualified patent or application shall be enforceable only for and during such period that the rejected patent or application and the disqualified patent or application are not separately enforced and are not separately licensed; and
- (iii) Agree that such waiver and agreement shall be binding upon the owner of the rejected application or patent, its successors, or assigns, and the owner of the disqualified patent or application, its successors, or assigns.

Rule 1.321(d) specifically requires that a terminal disclaimer must comply with the provisions of Rules 1.321(d)(2) through (b)(4). The terminal disclaimer must be signed by the applicant in accordance with Rule 1.321(b)(1) if filed in a patent application, or be signed by the patentee in accordance with Rule 1.321(a)(1) if filed in a reexamination proceeding. The terminal disclaimer must also be signed by the patentee or by the applicant, or an attorney or agent of record, of the disqualified patent or application. The terminal disclaimer must also include a provision that the owner of the rejected application or patent and the owner of the disqualified patent or application each: (1) waive the right to separately enforce and license the rejected application or patent and the disqualified patent or application; (2) agree that the rejected application or patent and the disqualified patent or application shall be enforceable during the period that the rejected patent or application and the disqualified patent or application are not separately enforced and are not separately licensed; and (3) agree that such waiver and agreement shall be binding upon the owner of the rejected application or patent, its successors, or assigns, and the owner of the disqualified patent or application, its successors, or assigns.

The PTO's proposed rules to implement the amendments to 35 U.S.C. § 103(c) are presently the subject of public commentary and can be found at 70 Fed. Reg. 1818, Jan. 11, 2005.

In order to take advantage of the new safe harbor offered by the CREATE Act, joint research partners need to make sure that they properly prepare their joint research agreements.

Requirements for Information Under Rule 1.105

There is a noticeable trend in the PTO's increased use of Rule 1.105 dealing with requirements for information. The inherent authority of the PTO to require applicants to reply to requirements for information under 35 U.S.C. §§ 131 and 132 was made explicit in Rule 1.105(a)(1) to encourage its use by PTO employees so that the PTO can perform the best quality examination possible. The authority is not intended to be used by examiners without a reasonable basis, but to address legitimate concerns that may arise during the examination of an application or consideration of some matter.

The Rule states, in part:

§ 1.105 Requirements for information.

(a)(1) In the course of examining or treating a matter in a pending or abandoned application filed under 35 U.S.C. 111 or 371 (including a reissue application), in a patent, or in a reexamination proceeding, the examiner or other PTO employee may require the submission, from individuals identified under § 1.56(c), or any assignee, of such information as may be reasonably necessary to properly examine or treat the matter

Where an assignee has asserted its right to prosecute the application, specific requests may also be applied to the assignee.

Requirements for factual information known to applicant may be made in any appropriate manner—for example, a requirement for factual information; interrogatories in the form of specific questions seeking applicant's factual knowledge; or stipulations as to facts with which the applicant may agree or disagree.

Any reply to a requirement for information that states either that the information required to be submitted is unknown to or is not readily available to the party or parties from which it was requested may be accepted as a complete reply. A reply, or a failure to reply, to a requirement for information may result in abandonment of the application.

It is incumbent upon patent applicants to bring “material” information to the attention of the PTO, whether required by the PTO or voluntarily submitted. It matters not whether the “material” information can be classified as a trade secret, or as proprietary material, or whether it is subject to a protective order. The obligation is the same; it must be disclosed if “material to patentability” as defined in 37 C.F.R. § 1.56(b). The same duty rests upon a patent owner under 37 C.F.R. § 1.555 whose patent is undergoing reexamination.

In some circumstances, it may be possible to submit the information in such a manner that legitimate trade secrets or proprietary information will not be disclosed, e.g., by appropriate deletions of nonmaterial portions of the information. This should be done only where there will be no loss of information material to patentability under 37 C.F.R. §§ 1.56 or 1.555.

Thus, situations arise in which it becomes necessary, or desirable, for parties to proceedings relating to pending patent applications or reexamination proceedings to submit to the PTO trade secret, proprietary, and/or protective order materials. While one submitting materials to the PTO in relation to a pending patent application or reexamination proceedings must generally assume that such materials will be made of record in the file and be made public, the PTO is mindful of the difficulties this sometimes imposes and, thus, has provided MPEP § 724.

Information that is considered by the party submitting the same to be either trade secret material or proprietary material, and any material subject to a protective order, must be clearly labeled as such and be filed in a sealed, clearly labeled envelope or container. A petition under 37 C.F.R. § 1.59 and fee therefor (37 C.F.R. § 1.17(h)) to expunge the information, if found *not* to be important to a reasonable examiner in deciding whether to allow the application to issue as a patent, should accompany the envelope or container.

Prior to publication, an original application is not open to the public under 35 U.S.C. § 122(a). After the application has been published under 35 U.S.C. § 122(b)(1), copies of the file wrapper of the pending application are available to any member of the public who has filed a request under 37 C.F.R. §§ 1.14(a)(1)(ii) or (a)(1)(iii).

If the application file and contents are available to the public pursuant to 37 C.F.R. §§ 1.11 or 1.14, any materials submitted under MPEP § 724.02 will only be released to the public with any other application papers if no petition to expunge (37 C.F.R. § 1.59) was filed prior to the mailing of a notice of allowability or notice of abandonment, or if a petition to expunge was filed and the petition was denied.

If any portion or all of the submitted information is found important to a reasonable examiner in deciding whether to allow the application to issue as a patent, the petition to expunge will be denied and the information will become a part of the file history and scanned, if the application is an Image File Wrapper (IFW) application, which upon issuance of the application as a patent would become available to the public. If any portion or all of the submitted information is found *not* to be important to a reasonable examiner in deciding whether to allow the application to issue as a patent, the petition to expunge will be granted and the information expunged.

The types of materials or information contemplated for submission under MPEP § 724.02 include information “material to patentability,” but do not include information favorable to patentability. Neither 37 C.F.R. §§ 1.56 nor 1.555 require the disclosure of information favorable to patentability, e.g., evidence of commercial success of the invention (see 42 Fed. Reg. 5590). If any trade secret, proprietary, and/or protective order materials are submitted in amendments, arguments in favor of patentability, or affidavits, they will be made of record in the file and will not be given any special status.

Ex Parte Appeals in the PTO

The Director of the U.S. Patent and Trademark Office at a March 4, 2005, “town meeting” on patent reform in Chicago unveiled a three-part initiative to improve the agency’s processes for handling patent applications. The town meetings followed two studies by the National Academies of Science and the FTC that addressed common patent concerns, including cost, complexity, and unpredictability in patent procurement and enforcement, and called for reform. The planned reforms are to the PTO’s internal operations and may lead to some new trends.

One change is a preappeal-brief conference. The PTO will convene a conference of three examiners—the examiner assigned to the application, that examiner’s supervisor, and a senior examiner—who will review the file to decide whether to maintain the PTO position, or instead to allow the patent or reopen the application for further prosecution. Applicants will be required to request the conference in writing, identifying the rejections that they intend to challenge, and the reasons for those challenges.

Interferences in the PTO

The genesis of the Board of Patent Appeals and Interferences in its present form dates back to 1985 when the patent laws were changed and new PTO rules were promulgated, which allowed the Board to address patentability issues, as well as the conventional priority issues, in an interference proceeding. This expanded the jurisdiction of the Board, and the expanded jurisdiction was accompanied by an expansion in the complexity of interference proceedings.

This led to reform in 1998 when the Board created the Trial Section composed of a limited number of administrative patent judges whose principal duties were to manage and decide interference proceedings. Most of the APJ’s had limited or no involvement in *ex parte* appeals. At the same time, the Trial Section streamlined interference practice under a Standing Order that supplemented the existing Rules of Practice as they related to interference proceedings.

The year 2003 saw further reform to interference practice. The Trial Section managed interferences during the early stages and then handed the interference off to other members of the Board to decide the case.

Rules further revising the practice before the Board of Patent Appeals and Interferences (hereinafter “2004 Rules”) were published in the Federal Register on August 12, 2004 (69 Fed. Reg. 49960) and in the Official Gazette on September 7, 2005 (1286 O.G. 21). The 2004 Rules became effective on September 13, 2004.

The goals of the 2004 Rules were to better align rule expectations and practice, clarify points of confusion in the rules, provide flexibility to customize each case, and provide a test bed for cancellation procedures. A key change brought about by the 2004 Rules is to give the Board more control over the issues raised in an interference.

The Board has indicated that an interference has a limited purpose, determining who is the first inventor or as it is often called, “priority of invention.” The 2004 Rules seek to efficiently determine priority of invention. An interference exists if the subject matter of a claim of one party would, if prior art, have anticipated or rendered obvious the subject matter of a claim of the opposing party and vice versa. Rule 41.203.

Nevertheless, in order to properly resolve priority of invention, it may be necessary to consider patentability over the prior art of (1) the subject matter of the count, and (2) some claims corresponding to the count. But the PTO has also indicated that an interference is not a statutory procedure having as its principal objective cancellation of a patent. However, as a consequence of a determination of priority in an interference, claims in a patent may end up being cancelled.

One way the Board will control interferences is to consider threshold substantive motions at an early stage. Threshold substantive motions are those which, in effect, raise a standing-like issue. There are some issues not affecting the patentability of the claims of an involved patent which, if resolved against the applicant, tend to establish that an applicant should not be involved in an interference with the patent. Following are issues that can be raised in threshold substantive motions.

35 U.S.C. § 135(b)

If an applicant has not complied with the one-year time bar under 35 U.S.C. § 135(b) for copying the claims of a patent, then the applicant is not entitled to a patent and the patentee should not be subject to an interference. Accordingly, under the 1984 Rules, the Trial Section adopted a practice of treating a substantive motion for judgment based on an alleged failure to comply with § 135(b) as a threshold issue. The Trial Section practice is recodified in the 2004 Rules. Granting the motion ends the interference.

Interference-in-fact

In order for the Director to be of the opinion that an interference exists, at least one claim of an application and one claim of a patent must be claiming the same patentable invention, i.e., there must be interference-in-fact. The Trial Section uses a “two-way” test to determine the existence of interference-in-fact. The subject matter of the involved claim of the application, presumed to be prior art, must anticipate or render obvious the subject matter of the involved claims of the patent. Likewise, the subject matter of the involved claim of the patent, presumed to be prior art, must anticipate or render obvious the subject matter of the involved application. If there is no interference-in-fact, then there is no need for an interference. A determination of no interference-in-fact raised in a threshold substantive motion may result in termination of the interference and authorizes the examiner to issue a patent to the applicant.

Failure to comply with the written description requirement of 35 U.S.C. § 112

An applicant may convince an examiner that it has presented a claim that interferes with a patent, and that the applicant has support for the claim in its application. In fact, the applicant may not have complied with the written description requirement. As a result, it is not appropriate to continue the interference. A written description issue can be raised in a threshold substantive motion, which may terminate the interference if it is decided against the applicant.

Raising and deciding threshold issues at an early stage of an interference may limit the applicant's ability to seek cancellation of a patent if the issue is decided adverse to the applicant. This could reduce the complexity, cost, and pendency of applications vs. patent interferences.

Post-Grant Opposition

Congress has incrementally added to the range of proceedings under the PTO's jurisdiction under which third parties can provoke PTO review of issued patents. It introduced *ex parte* reexamination in 1980, under which a third party could petition for reexamination of the patent. In 1984, section 135 of the Patent Act was amended to allow issues of patentability, as well as priority, to be included in interference proceedings. In 1999, the American Inventors' Protection Act (AIPA) created *inter partes* examination, whereby the third party could participate in the reexamination proceeding and appeal to the Board of Patent Appeals and Interferences. The AIPA's *inter partes* reexamination practice was expanded in 2002 to afford third parties the right to appeal to the U.S. Court of Appeals for the Federal Circuit.

Although, through these amendments, the PTO's role in helping the efficacy of the patent system after patent issuance has grown, none of these procedures alone, or collectively, have proven sufficient to optimize the PTO's post-grant capability. Although a patentability challenge can be raised on all grounds in interferences, interference proceedings only lead to challenges of patents when a pending application raises a priority issue as to a recently issued patent. Further, a third party may file a protest in a reissue proceeding; however, that is rare, and the third party has very limited participation. Apart from interferences and a reissue protest, a third party may challenge the patentability of patent claims in the PTO only on certain prior art references, namely, patents or printed publications via reexamination. In addition, except in interferences, a third party cannot conduct discovery and develop evidence necessary to challenge patentability, nor can the third party challenge patent owner evidence by cross-examination.

Potential challengers have regarded *ex parte* reexamination as an insufficient mechanism because, after the proceeding has begun, the third party's participation is limited to one reply, and then, only if the patent owner files a preexamination statement. As a result, *ex parte* reexamination has not been utilized by third parties to the degree anticipated.

The *inter partes* reexamination procedure established in 1999 was intended to address this defect; however, limitations on that process have led to it being rarely used. In particular, a challenger in an *inter partes* proceeding is bound by its result by way of estoppel, including in

subsequent litigation. However, the lack of such procedural mechanisms as discovery and cross-examination that would be available in litigation seem to be reasons why challengers have been unwilling to invoke *inter partes* reexamination and risk its estoppel effect. The most significant deficiencies of the *inter partes* reexamination system have been identified as follows.

- It is not possible to use the procedure to review patentability issues that are most commonly encountered in biotechnology patents and applications; namely, compliance with 35 U.S.C. §§ 101 and 112, first paragraph. Issues of compliance with the written description and enablement provisions of 35 U.S.C. § 112, first paragraph, and the utility requirement of § 101 frequently are significant inquiries affecting the validity of many biotechnology patents and patent applications. Not permitting these grounds to be raised in a post-grant review procedure renders the system far inferior as an alternative to litigation in a federal court.
- The law imposes a “statutory estoppel” that makes the procedure unattractive as an alternative to litigation in a federal court. 35 U.S.C. § 315(c) prohibits a requestor from raising in a federal court any issues of validity that “could have been raised” at the time of the request for reexamination in view of art known to the requestor. This broad estoppel attaches by the mere filing of a request for *inter partes* reexamination.
- The *inter partes* reexamination system does not permit third parties to use certain evidentiary procedures that would ensure that the procedure is sufficiently rigorous. For example, it is not possible to cross-examine expert witnesses used in the proceeding or direct questions to the opposing party.
- Finally, the system cannot be used to review issues of validity involving patents issued on applications filed

before November 29, 1999. This limitation, in particular, has rendered the system of marginal value to many companies in the biotechnology industry, in part because there still remains a significant number of biotechnology patent applications pending before the PTO that were filed before this date.

These limitations in the *inter partes* reexamination system—ostensibly established in 1999 to provide a more robust alternative to *ex parte* reexamination—have made the procedure of marginal value to the public. Over the past five years, the PTO has received approximately 1,600,000 applications and issued approximately 900,000 patents.¹ Yet the total requests for *inter partes* reexamination during the nearly five years for which the procedure has been available is a mere 46.² It has not been an effective alternative to expensive, unpredictable, and protracted litigation in the federal courts. As such, the *inter partes* reexamination procedure has not met expectations.

In an attempt to address these deficiencies in the current system, a post-grant review proposal was published on the PTO web site in April 2003 as part of its 21st Century Strategic Plan.³ It proposed a review model different from reexamination—namely, a contested case presided over by a panel of administrative patent judges, which, upon the challenger’s presenting sufficient grounds to believe that patent claims are unpatentable, would include closely directed discovery and cross-examination. The proceeding would be designed to be concluded within a year and would provide for challenges based on all grounds of unpatentability, but not inequitable conduct. It would be available to all challengers for a year after a patent issues and thereafter to those threatened with infringement litigation.

¹ U.S. PATENT AND TRADEMARK OFFICE PERFORMANCE AND ACCOUNTABILITY REPORT FISCAL YEAR 2003. <http://www.uspto.gov/web/offices/com/annual/2003/index.html>.

² These *inter partes* reexamination requests included 29 patents from mechanical technologies, 8 in electrical arts, 7 in chemical arts, and 2 in biotechnology.

³ See Action Papers and Implementation Plans as of April 2, 2003, Post-Grant Review of Patent Claims, located at <http://www.uspto.gov/web/offices/com/strat21/action/sr2.html>.

The PTO identified the following problems that a post-grant opposition must avoid. Such a system:

- must *not* be a system that allows for the harassment of inventors and patent owners. The PTO intends to have a rigorous standard for allowing full proceedings and sanctions for frivolous filings. Inventors should not be faced with relitigating issues that there has been an opportunity to air thoroughly before the PTO.
- must *not* be a Japanese or European-style opposition system, both of which have been criticized as being wide, open-ended, and indeterminate procedures for the parties involved. The PTO expects to have tightly controlled time frames. It also expects that the proceeding will have definite scope and duration.

A number of parameters have been suggested for any post-grant review procedure. These include: scope, estoppel, preliminary showing to initiate procedure, time limits to initiate proceeding, applicable to all patents, limited additional evidentiary procedures, prohibit inequitable conduct challenges based on actions of parties during post-grant proceedings, and authority to delegate certain issues for resolution.

Litigation is very expensive. The American Intellectual Property Law Association (AIPLA) conducts an Economic Survey of its membership every two years to collect data on a number of aspects of the practice of intellectual property law. According to the most recent Economic Survey, the average cost of patent litigation, including the costs of discovery, ranges between \$500,000 and \$3,995,000 per party, depending on the amount at risk. A post-grant opposition proceeding in the PTO is a proposed low-cost, speedy alternative to such litigation. At the present time, the patent community at large has not coalesced around the particulars of one proposal.

New PTO Initiatives

In addition to the preappeal-brief conference, the Director of the Patent and Trademark Office proposed two other reforms.

One component of the PTO's planned improvements is to "clean up" the backlog of pending *ex parte* patent reexamination cases. By the end of 2005, the PTO expects to have completed one-half, or 600, of the 1,200 reexamination prosecutions that have been pending for two or more years. The PTO will accomplish this goal by instituting a new panel review process, similar to the preappeal-brief conference, to consider each reexamination action on its merits. The panel, made up of senior and supervisory examiners as well as a reexamination specialist, will produce a "second office action" in each case that will be a final ruling on the merits. By bringing the three examiners together for one group evaluation, the PTO hopes to speed up the process.

Finally, to better assist the examining corps and improve the reliability of the patent search, the PTO will develop a "search template" for each of more than 600 classes of patents in the PTO system. The PTO hopes to produce the first templates for public comment by July 2005. A search grid on which the search template will be based is already available in the business method patent Class 705.

Conclusion

Each one of these trends in PTO practice presents new and continuing challenges in the practice of patent law. Patent practitioners need to develop new strategies for enabling their clients to take advantage of these trends while avoiding the pitfalls.

Section II: Patent Litigation Trends

Chapter 4

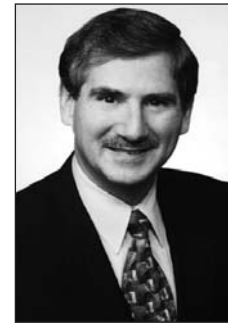
District Court Litigation

Chapter 5

Appellate Litigation

Charles E. Lipsey

Finnegan, Henderson, Farabow, Garrett & Dunner, LLP



Last year, we measured the number of reported district and appellate court decisions containing the term *patent* in combination with a variety of biotechnology and pharmaceutical search terms, as well as terms representative of other industries. The relatively small number of litigated patent cases, however, gave rise to somewhat noisy data. For appellate cases, we used the sharper lens of looking at individual cases, but the data were for a single year only.

This year we have focused on individual district court decisions as well as appellate decisions. We have gathered historical data for district court cases going back to 2000. Interestingly, in each year 2000 through 2003 the patentee lost in the district court by a margin of about two to one, while in 2004 patentees won about twice as often as in the previous four years. Win rates in district courts gathered from this year's and last year's appellate data were consistent with the low win rates observed in the district court data through 2003. The Federal Circuit in 2004 affirmed a greater percentage of wins than losses, however, thus evening the patentee's odds. Low numbers continue to limit interpretation of the data, but we will watch the trends closely. We have also tabulated various additional case parameters this year, as explained in the coming pages.

We welcome your input.

Charles E. Lipsey

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Chapter 4

District Court Litigation

In last year's Report, we presented a series of graphs that traced the appearance of biotechnology and pharmaceutical search terms, as well as search terms representative of other industries, in reported patent decisions by U.S. district courts and the U.S. Court of Appeals for the Federal Circuit.¹ We have updated some of these data, particularly for federal court litigation generally, in Figure 4-1. As shown in Figure 4-1A, appearance of the search term *patent* in the Westlaw® ALLFEDS database continues to rise gradually, at a relatively constant rate.² A similar trend is observed using the search query (*patent + pharmaceutical*). As shown in Figure 4-1B, in which the data are normalized to appearance of the term *patent*, the rise in appearance of the term *pharmaceutical* parallels the rise in appearance of the term *Internet*. One also observes a modest rise in appearance of biotechnology-related search terms, with appearance of biotech search terms roughly on par with the appearance of the search term *semiconductor*. This year, we have extended our study of district court cases by focusing on individual decisions. Our results are presented below, followed by a Table of Cases that summarizes the data collected for each case studied.

District Court Biotech and Pharmaceutical Patent Cases, 2000-2004

Methodology

We queried the Westlaw® ALLFEDS database for each year from 2000 through 2004 using the search string *patent + (pharmaceutical or nucleic acid or nucleotide or protein or amino acid or peptide or antibody)*. For each set of hits, we eliminated non-district court cases (including appellate decisions; we discuss those in Chapter 5). We then selected biotech and pharmaceutical patent cases, which we defined as cases concerning patent infringement, validity, or enforceability for products or processes involving small molecules, biomolecules, cells, or organisms as therapeutics, diagnostics, reagents, antibiotics, vitamins, or vaccines, in medicine, animal health, agriculture, or industrial biotechnology. Medical devices

¹ The Federal Circuit has appellate jurisdiction over all patent cases except cases where a patent issue arises only from a counterclaim. Interestingly, the *Xechem* case decided by the Federal Circuit in 2004 bears on the question of when a state court may decide issues of patent inventorship; see the text, below.

² We note that the rise from 2002-2003 as measured this year was about 10% higher relative to values published in last year's Report, possibly reflecting a lag in the appearance of some records in the ALLFEDS database that extended beyond the time at which we performed our searches this year, in the first quarter of 2005.

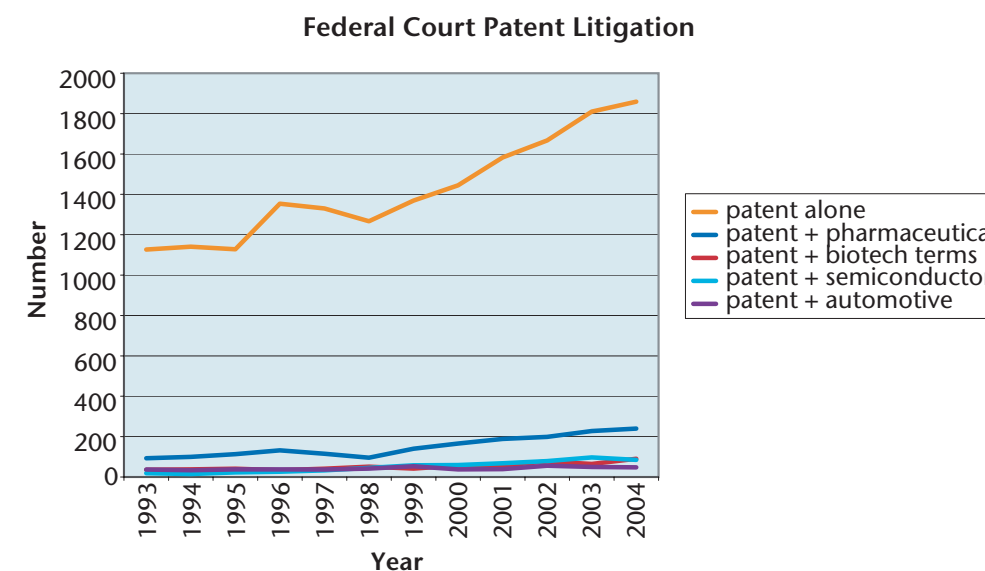


Fig 4-1A Relative Number of Reported Federal Court Patent Decisions

The Westlaw® ALLFEDS database was queried with the search term *patent* alone and the search term *patent* in combination with *pharmaceutical*, biotech terms (*nucleic acid, nucleotide, amino acid, peptide, protein, antibody*), *semiconductor*, or *automotive*, as a function of time. Absolute numbers of decisions are plotted for each query as a function of year.

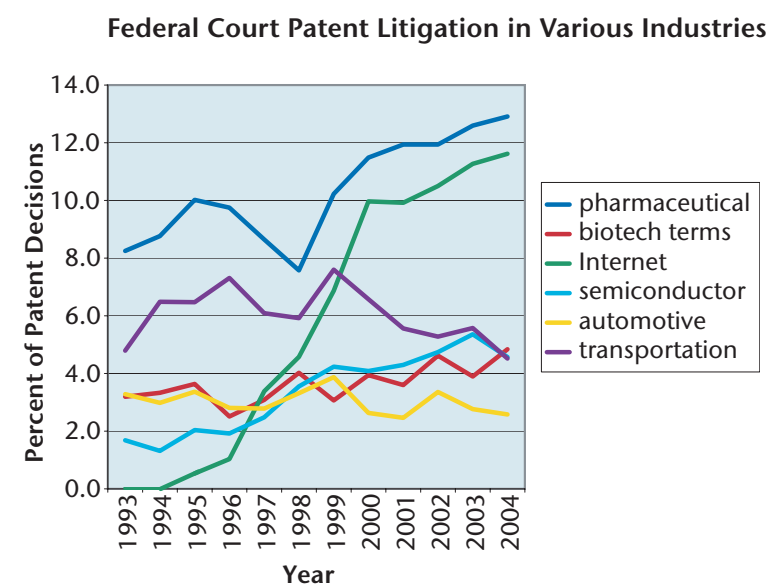


Fig 4-1B Relative Number of Reported Federal Court Patent Decisions Containing Various Search Terms

The Westlaw® ALLFEDS database was queried with the search term *patent* in combination with *pharmaceutical*, biotech terms (*nucleic acid, nucleotide, amino acid, peptide, protein, antibody*), *Internet, semiconductor*, or *automotive*, and *transportation* as a function of time, and the results were normalized to the total number of *patent* decisions per year shown in Figure 4-1A.

were not included. We then selected our set of “final” decisions by eliminating all decisions on such issues as discovery, evidence, or jurisdiction, and including only those decisions in which the court ruled on infringement, validity, and/or unenforceability, even if not final for purposes of appeal, and even if the court had not yet ruled on all three issues. We scored as patentee “wins” those cases in which the court held at least one claim infringed unless that claim was held invalid or the patent was held unenforceable. Similarly, we included decisions in which the court held at least one claim valid, unless that claim was held invalid or the patent held unenforceable, and so forth. A patentee “loss” was defined as any decision in which the court held all claims of a patent invalid and/or not infringed, or held all patents at issue unenforceable.

Results

Number of “Final” Decisions

The number of “final” decisions included in our set of cases for study for each year queried, as derived from our searches as described above, is provided in Table 1. Our total sample for all five years examined consisted of 78 decisions.

Table 1 - Search Results

Year	Total ALLFEDS Search Hits	District Court Cases	Biotech and Pharmaceutical Decisions	“Final” Biotech & Pharmaceutical Decisions
2000	203	162	46	8
2001	238	185	47	17
2002	253	198	85	21
2003	257	186	58	16
2004	298	178	81	17

We note that the number of biotech and pharmaceutical decisions appears to have increased overall, both in number and share of total district court decisions, during the period 2000 through 2004.¹

However, the number of “final” decisions selected has not changed appreciably since 2001. The data may suggest an increasing inventory of biotech and pharmaceutical patent cases yet to be finally decided.

¹ We note that the 2004 values may underestimate the number of decisions, due to a possible lag period in the addition of records to the ALLFEDS database (see note 2, page 50).

Win Rates

Using the “win” criteria described above, we counted the number of “final” decisions in each year from 2000 through 2004 that were “won” by the patentee, and converted raw numbers to percent of total cases for each year. Our results are shown in Table 2.

Table 2 - ‘Final’ Decisions Classified as ‘Wins’ by the Patentee

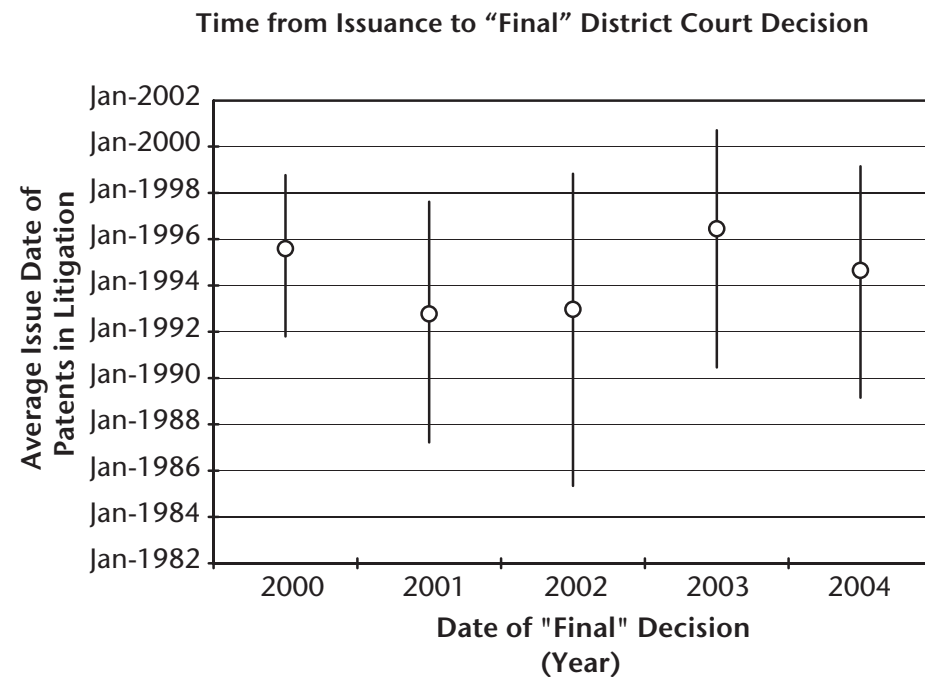
Year	Total # of “Final” Decisions	Patentee Wins (#)	Patentee Wins (%)
2000	8	2	25%
2001	17	6	35%
2002	21	3	14%
2003	16	5	31%
2004	17	12	71%

We note that between 2000 and 2003 the percent of cases won by the patentee remained below 50% for each year, and that, by contrast, the patentee “won” 71% (12/17) of the “final” decisions examined in 2004, more than twice as often as in each of the previous four years. Overall, the patentee “won” in $28/78 = 37\%$ of the “final” decisions examined, using our criteria.

Average Patent Number

To assess the average time from patent issuance until “final” decision, we noted the patent number of each patent at issue in each case in our sample each year. We then calculated, for each year, the “average patent number” at issue that year and correlated the average number obtained, as well as one standard deviation in each direction of the mean, to the issue date of each patent number. The data are presented in Figure 4-2.

We note the considerable overlap in the data, which show an average patent number that hovers around the mid-1990s throughout the five-year period studied, for “final” decisions rendered between 2000 and 2004. This corresponds to an average lag from patent issuance to “final” decision of approximately five to nine years.



Technologies Litigated

Of the 78 “final” decisions in our total sample for all years examined, 30 (38%) concerned biomolecules (e.g., DNA, proteins, antibodies, screening assays, cells, organisms) and thus were classified as biotechnology cases. We classified 48 cases (62%) as pharmaceutical cases, involving small molecule drugs or antibiotics. A further breakdown of the cases by major technology litigated is presented in Table 3 below:

Table 3 - Technologies Litigated

Biotechnology Cases		Pharmaceutical Cases	
Recombinant Proteins	6	Brain	12
Antibodies	6	Cardiovascular	8
Recombinant Seeds and Plants	6	Pain Relief	6
Recombinant Reagents	4	GI	6
Screening Assays	2	Antibiotics	3
Veterinary Vaccines	2	Eye Disease	2
Biochemically Purified Proteins	1	Bone Disease	2
Stem Cells	1	Cancer	2
Transgenic Animals	1	Ob/Gyn	2
		Anesthesia	1
		Immunosuppression	1
		Infectious Disease	1
		Dermatology	1

Fig 4-2 Average Patent Number for District Court Biotech and Pharmaceutical Patent Cases

Average patent number (circles) +/- standard deviation of the mean (lines) for “final” decisions was determined for each year from 2000 through 2004, as described in the text.

Patent Decisions, by Jurisdiction

We counted the number of “final” decisions rendered by each court represented in our sample. Courts deciding more than 5 cases during the period sampled (2000 through 2004) included the following:

Table 4 - District Courts Deciding the Most Patent Cases, 2000-2004

D. Del.	10
N.D. Ill.	10
D. Mass.	10
D.N.J.	10
S.D.N.Y.	8

We also classified each case by disposition. Of the 78 cases in our sample, 35 (45%) were rendered on summary judgment; and 38 (49%) were decided after trial to the bench. We only counted 5 jury trials (6%), of which one was decided on JMOL. One case in our sample, *Pfizer v. Dr. Reddy's Labs*, was decided on a motion to dismiss.

Table of Cases

For the reader's convenience, we have provided below in tabular form a compendium of the data we collected for all of the district court decisions in our sample, 2000 through 2004. For each year, the table lists first those cases classified as biotechnology cases, followed by those cases classified as pharmaceutical cases.

**Table of Cases
2000 District Court Biotechnology & Pharmaceutical Patent Decisions**

Case/Cite	Technology	Patent(s)-in-Suit	Decision			Plee Win or Loss
			Tribunal	Disposition	Result	
Biotech Cases						
Biogen, Inc. v. Amgen Inc., 115 F. Supp. 2d 139	General use plasmid vector	4,874,702	D. Mass.	SJ	Not infringed	L
Biogen, Inc. v. Berlex Laboratories, Inc., 113 F. Supp. 2d 77	DNA construct for expression of human interferon	4,966,843; 5,376,567; 5,795,779	D. Mass.	SJ	Not infringed	L
Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp., 106 F. Supp. 2d 696 and 106 F. Supp. 2d 667	Method of growing and isolating swine infertility and respiratory syndrome virus (classical vaccine)	5,476,778	D.N.J.	Bench	No inequitable conduct	W
Conopco Inc. v. Wamer-Lambert Co., 2000 WL 33310847, 58 U.S.P.Q.2d 1344	Immunoassays for pregnancy testing	5,622,871; 5,602,040; 5,656,503	D.N.J.	SJ	Not infringed	L
Elan Pharm., Inc. v. Mayo Foundation for Medical Educ. and Research, 175 F. Supp. 2d 1209	Transgenic animal (rodent) for Alzheimer's research	5,612,486; 5,850,003	N.D. Cal.	SJ	Invalid	L
Pharmaceutical Cases						
Apotex Corp. v. Merck & Co., 2000 WL 656670 and 2000 WL 97582	Method of making antihypertension drug (enalpril sodium)	5,573,780; 5,690,962	N.D. Ill.	Bench	Infringed, but invalid	L
Biovail Corp. Int'l v. Andrx Pharmaceuticals, Inc., 158 F. Supp. 2d 1318	Pharmaceutical product (Diltiazem composition) for treating heart disease (ANDA)	5,529,791	S.D. Fla.	Bench	Not infringed	L
Zeneca Ltd. v. Pharmachemie B.V., 2000 WL 34335805	Pharmaceutical product (tamoxifen)(treatment of breast cancer) (ANDA)	4,536,516	D. Mass.	Jury	Valid and enforceable	W

Table of Cases 2001 District Court Biotechnology & Pharmaceutical Patent Decisions

Case/Cite	Technology	Patent(s)-in-Suit	Decision			P'ee Win or Loss
			Tribunal	Disposition	Result	
Biotech Cases						
Abbott Laboratories v. Dey, L.P., 2001 WL 558142	Lung surfactant composition (classical biochemistry)	4,338,301; 4,397,839	N.D. Ill.	SJ	Not infringed	L
Angen, Inc. v. Hoechst Marion Roussel, Inc., 126 F. Supp. 2d 69, 57 U.S.P.Q.2d 1449	Recombinant erythropoietin and method of making it	5,547,933; 5,618,698; 5,621,080; 5,756,349; 5,955,422	D. Mass.	Bench	Valid and infringed (product claims)	W*
Boehringer Ingelheim Vetmedica, Inc. v. Schering Plough Corp., 166 F. Supp. 2d 19	Method of growing and isolating wine infertility and respiratory syndrome virus (classical vaccine)	5,476,778	D.N.J.	Jury and JMOL	Valid and infringed (motion for JMOL denied)	W*
Edberg v. CPI--The Alternative Supplier, Inc., 156 F. Supp. 2d 190	Industrial biotechnology product for testing water for E. coli	4,925,789; 5,429,933; 5,780,259	D. Conn.	SJ	Not infringed	L
Invitrogen Corp. v. Biocrest Manufacturing, L.P., 2001 WL 34456772	Process for producing transformable E. coli cells	4,981,797	W.D. Tex.	SJ	Not infringed (as to most cells produced)	L
Monsanto Co. v. Hartkamp, 2001 WL 34079482	Recombinant herbicidal cotton and soybean genes	5,352,605	E.D. Okla.	Bench	Valid and infringed	W
Monsanto Co. v. Traniham, 156 F. Supp. 2d 855	Recombinant herbicidal cotton and soybean genes	5,352,605	W.D. Tenn.	SJ	Infringed	W
Nexell Therapeutics, Inc. v. AmCell Corp., 143 F. Supp. 2d 407	Monoclonal antibodies and a highly purified suspension of human stem cells	4,714,680; 4,965,204	D. Del.	SJ	Not infringed	L
Plant Genetic Systems v. DeKalb Genetics Corp., 175 F. Supp. 2d 246	Herbicide-resistant food plant cell	5,561,236	D. Conn.	Bench	Invalid (cell claims) and not infringed (plant/seed)	L
Pharmaceutical Cases						
Abbott Laboratories v. Torpharm, Inc., 156 F. Supp. 2d 738	Pharmaceutical product (valproate/valproic acid) for treating seizures) (ANDA)	4,988,731; 5,212,326	N.D. Ill.	SJ	Valid, enforceable, and infringed	W

* indicates that the "W" characterization is conservative. In other words, we are erring on the side of counting the case as a win for the patentee.

Case/Cite	Technology	Patent(s)-in-Suit	Decision			P'ee Win or Loss
			Tribunal	Disposition	Result	
Bio-Technology General Corp. v. Duramed Pharmaceuticals, Inc., 174 F. Supp. 2d 229	Method of treating with contraceptive pill (ANDA)	RE 35,724 (from 4,921,843)	D.N.J.	SJ	Not infringed	L
Board of Educ. v. American Bioscience, Inc., 2001 WL 34104924	Pharmaceutical product (taxol derivatives) for chemotherapy (ANDA)	5,780,653	N.D. Fla.	Bench	Unenforceable for inequitable conduct	L
Eli Lilly & Co. v. Zenith Goldline Pharmaceuticals, Inc., 2001 WL 1397304	Pharmaceutical product (nizatidine) for treating acid reflux (ANDA)	4,375,547	S.D. Ind.	Bench	Valid and infringed	W
In re '639 Patent Litigation, 154 F. Supp. 2d 157	Pharmaceutical product (nabumetone) for treatment of inflammation (ANDA)	4,420,639	D. Mass.	Bench	Invalid and unenforceable	L
In re Omeprazole Patent Litigation, 2001 WL 585534	Pharmaceutical product (nizatidine) for treating acid reflux (ANDA)	4,636,499	S.D.N.Y.	SJ	Not infringed	L
Minnesota Mining and Mfg. Co. v. Barr Laboratories, Inc., 139 F. Supp. 2d 1109	Pharmaceutical product (flecainide acetate) for treatment of heart disease (arrhythmia) and method of making it (ANDA)	4,650,873; 4,642,384	D. Minn.	SJ	Not infringed	L
Warner-Lambert Co. v. Apotex Corp., 2001 WL 1104618	Method of treating neurodegenerative diseases using gabapentin (ANDA)	5,084,479	N.D. Ill.	SJ	Not infringed	L

* indicates that the "W" characterization is conservative. In other words, we are erring on the side of counting the case as a win for the patentee.

Table of Cases 2002 District Court Biotechnology & Pharmaceutical Patent Decisions

Case/Cite	Technology	Patent(s)-in-Suit	Decision			P'ee Win or Loss
			Tribunal	Disposition	Result	
Biotech Cases						
Abbott Laboratories v. Syntro Research Inc., 2002 WL 32068939	Immunoassays for pregnancy testing	5,073,484; 5,654,162	S.D. Cal.	Jury and JMOL	JMOL denied	L
Columbia University v. Roche Diagnostics GmbH, 272 F. Supp. 2d 90	Method of making erythropoietin	4,399,216; 4,634,665; 5,179,017	D. Mass.	Bench	Certain '216 patent claims valid, enforceable, and infringed	W
Monsanto Co. v. Bayer Bioscience, N.V., 264 F. Supp. 2d 852	Plant cell containing chimeric gene that is an insecticidal <i>Bacillus thuringiensis</i> polypeptide toxin	5,254,799; 5,545,565; 5,767,372; 6,107,546	E.D. Mo.	Bench	Unenforceable for inequitable conduct	L
Morphosys AG v. Cambridge Antibody Technology Ltd., 193 F. Supp. 2d 125	Method of obtaining antibodies to specific human self antigens (HuCAL library)	5,885,793	D.D.C.	SJ	Not infringed	L
Pharmaceutical Cases						
Abbott Laboratories v. Baxter Pharmaceutical Products, Inc., 2002 WL 449007	Inhalation anesthetic pharmaceutical product (sevoflurane) (ANDA)	5,990,176	N.D. Ill.	SJ	Not infringed	L
Abbott Laboratories v. Novopharm Ltd., 2002 WL 433584	Pharmaceutical product (comronized fenofibrate) for treating high cholesterol (ANDA)	Current patent	N.D. Ill.	SJ	Not infringed	L
Allergan, Inc. v. Alcon Laboratories, Inc., 200 F. Supp. 2d 1219, 63 U.S.P.Q.2d 1427	Method of treating glaucoma (brimonidine) (ANDA)	6,194,415; 6,248,741	C.D. Cal.	SJ	Not infringed	L
Astra Aktiebolag v. Andrx Pharmaceuticals, Inc., 222 F. Supp. 2d 423	Pharmaceutical product (omeprazole) for treatment of acid reflux (ANDA)	4,786,505; 4,853,230; 5,093,342	S.D.N.Y.	Bench	'505 and '230 valid and infringed	W
In re Buspirone Patent Litigation, 185 F. Supp. 2d 340	Method of treating anxiety using buspirone (ANDA)	4,182,763; 6,150,365	S.D.N.Y.	SJ	Not infringed	L
Elian Corp., PLC v. Andrx Pharmaceuticals, Inc., 272 F. Supp. 2d 1325	Pharmaceutical product (naproxen sodium) for treatment of inflammation (ANDA)	5,637,320	S.D. Fla.	Bench	Infringed	L

Case/Cite	Technology	Patent(s)-in-Suit	Decision			P'ee Win or Loss
			Tribunal	Disposition	Result	
Geneva Pharmaceuticals, Inc. v. GlaxoSmithKline PLC., 213 F. Supp. 2d 597 and 189 F. Supp. 2d 377	Pharmaceutical product (clavulanic acid + penicillin) used as an antibiotic (ANDA)	4,525,352; 4,529,720; 4,560,552; 6,218,380	E.D. Va.	Bench	Invalid	L
Glaxo Wellcome, Inc. v. Andrx Pharmaceuticals, Inc., 190 F. Supp. 2d 1354	Pharmaceutical product (bupropion hydrochloride) for treatment of depression (ANDA)	5,427,798	S.D. Fla.	SJ	Not infringed	L
Glaxo Wellcome, Inc. v. Eon Labs Mfg., Inc., 2002 WL 1874830	Pharmaceutical product (bupropion hydrochloride) for treatment of depression (ANDA)	RE 33,994; 5,427,798	S.D.N.Y.	Bench	Invalid	L
Glaxo Wellcome, Inc. v. Impax Laboratories, Inc., 220 F. Supp. 2d 1089	Pharmaceutical product (bupropion hydrochloride) for treatment of depression (ANDA)	4,523,798	N.D. Cal.	SJ	Not infringed	L
Knoll Pharmaceutical Co., v. Teva Pharmaceuticals USA, Inc., 2002 WL 31050138	Analgesic pharmaceutical product (combination of hydrocodone and ibuprofen) (ANDA)	4,587,252	N.D. Ill.	SJ	Invalid	L
McNeil-PPC, Inc. v. L. Perrigo Co., 207 F. Supp. 2d 356, 63 U.S.P.Q.2d 1493	Method of treating gastrointestinal disorders using loperamide-simethicone combination drug (ANDA)	5,248,505; 5,612,054; 5,679,376; 5,716,641	E.D. Pa.	Bench	Invalid	L
Merck & Co. v. TEVA Pharmaceuticals USA, Inc., 228 F. Supp. 2d 480	Method of treating osteoporosis by administering 4-amino-1-hydroxybutane-1,1-biphosphonic acid (ANDA)	4,621,077	D. Del.	Bench	Valid and infringed	W
Organon, Inc. v. Teva Pharmaceuticals, Inc., 244 F. Supp. 2d 370	Pharmaceutical product (mirtazapine with a selective serotonin reuptake inhibitor ("SSRI")) for treating depression (ANDA)	4,062,848	D.N.J.	SJ	No induced infringement	L
Pfizer v. Dr. Reddy's, 2002 WL 31833744, 67 U.S.P.Q.2d 1525	Pharmaceutical product (amlodipine) for treating heart conditions (ANDA)	4,572,909	D.N.J.	Bench	Dismissed	L
Schering Corp. v. Geneva Pharmaceuticals, Inc., 275 F. Supp. 2d 534, 64 U.S.P.Q.2d 1032	Pharmaceutical product (loratadine) for treating allergies (ANDA)	4,659,716; 4,282,233	D.N.J.	SJ	Invalid	L
SmithKline Beecham Corp. v. Excel Pharmaceuticals Inc., 214 F. Supp. 2d 581, 64 U.S.P.Q.2d 1132	Pharmaceutical product (bupropion hydrochloride) for treatment of depression (ANDA)	4,523,798	E.D. Va.	SJ	Not infringed	L

Table of Cases
2003 District Court Biotechnology & Pharmaceutical Patent Decisions

Case/Cite	Technology	Patent(s)-in-Suit	Decision			P'ee Win or Loss
			Tribunal	Disposition	Result	
Biotech Cases						
Amgen, Inc. v. Hoechst Marion Rousssel, Inc., 287 F. Supp. 2d 126	Isolated erythropoietin glycoprotein	5,621,080	D. Mass.	Bench	Reaffirmed infringement post-Festo	W
Aventis Croscience N.V. v. Pioneer Hi-Bred International, Inc., 269 F. Supp. 2d 644	Genetic transformation vectors that allow the expression of an insecticidal endotoxin in certain hybrids of corn	5,254,799; 5,545,565; 5,767,372; 6,107,546	M.D.N.C.	SJ	Unenforceable, invalid, and not infringed	L
Bayer AG v. Hoesey Pharmaceuticals, Inc., 2003 WL 22953187	Cellular assays for determining whether a substance is an inhibitor or activator of a protein	4,980,281; 5,266,464; 5,688,655; 5,877,007	D. Del.	Bench	Unenforceable for inequitable conduct	L
Goldenberg v. Cytogen, Inc., 2003 WL 22454399	Method of detecting and localizing tumors using intracellular marker substances	4,460,559; 4,444,744	D.N.J.	SJ	Not infringed	L
Pieczeniak v. Dyax Corp., 2003 WL 1562239	Linear DNA molecules	4,359,535; 4,528,266; 5,866,363	D. Mass.	SJ	Not infringed	L
University of Michigan v. Bristol-Myers Squibb Co., 301 F. Supp. 2d 633	Protein for regulation of immune response	5,434,131; 5,844,095; 5,851,795; 5,885,579; 5,988,510; 5,977,318; 5,885,796	E.D. Mich.	Bench	Inventorship correct	W
University of Rochester v. G.D. Searle & Co., 249 F. Supp. 2d 216, 175 Ed. Law Rep. 539, 68 U.S.P.Q.2d 1424	Method for selecting compound that will inhibit pain by inhibiting activity of PGHS-2 gene product	6,048,850	W.D.N.Y.	SJ	Invalid	L
Pharmaceutical Cases						
Alcon Laboratories, Inc. v. Allergan, Inc., 256 F. Supp. 2d 1080, 67 U.S.P.Q.2d 1178	Method of treating the optic nerve with brimonidine tartrate (ANDA)	6,194,415; 6,248,741; 5,856,329; 6,465,464 B2	C.D. Cal.	SJ	Not infringed	L
AsiraZeneca AB v. Mutual Pharmaceutical Co., 2003 WL 22794868	Pharmaceutical product (felodipine formulations) for use in extended release drugs (ANDA)	4,803,081	E.D. Pa.	Bench	Valid and infringed	W
Bristol-Myers Squibb Co. v. Teva Pharmaceuticals USA, Inc., 288 F. Supp. 2d 562	Pharmaceutical product (fosinopril sodium) for treating hypertension (ANDA)	5,006,344	S.D.N.Y.	Bench	Not infringed	L

Case/Cite	Technology	Patent(s)-in-Suit	Decision			P'ee Win or Loss
			Tribunal	Disposition	Result	
Glaxo Group Ltd. v. Apotex, Inc., 268 F. Supp. 2d 1013	Pharmaceutical product (highly pure, substantially amorphous cefuroxime axetil) used as broad spectrum antibiotic and process of making (ANDA)	4,562,181; 4,820,833	N.D. Ill.	Bench	Valid and infringed	W
ICN Pharmaceuticals, Inc. v. Geneva Pharmaceuticals Technology Corp., 272 F. Supp. 2d 1028	Method of treating hepatitis C using ribavirin (ANDA)	5,767,097; 6,063,772; 6,150,337	C.D. Cal.	SJ	Not infringed	L
Merck & Co. v. Teva Pharmaceuticals USA, Inc., 288 F. Supp. 2d 601	Method for treating osteoporosis using alendronate sodium (ANDA)	5,994,329	D. Del.	Bench	Valid, enforceable, and infringed	W
Novartis Pharmaceuticals Corp. v. Abbott Laboratories, 294 F. Supp. 2d 557	Pharmaceutical product (cyclosporine formulation) used to prevent organ rejection (ANDA)	6,007,840	D. Del.	Jury	Granted JMOL of no infringement	L
SmithKline Beecham Corp. v. Apotex Corp., 247 F. Supp. 2d 1011	Pharmaceutical product (crystalline paroxetine hydrochloride hemihydrate) for treating depression (ANDA)	4,721,723	N.D. Ill.	Bench	Not infringed	L
Warner Lambert Co. v. Purepac Pharmaceutical Co., 2003 WL 21698310, 68 U.S.P.Q.2d 1686	Method for treating neurodegenerative disorders with gabapentin (ANDA)	5,084,479	D.N.J.	SJ	Not infringed	L

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Case/Cite	Technology	Patent(s)-in-Suit	Tribunal	Disposition	Result	P'ee Win or Loss
Biotech Cases						
Amgen v. Hoechst Marion Roussel, 339 F. Supp. 2d 202	Recombinant erythropoietin alpha and methods for making	5,955,422; 5,621,080; 5,618,698; 5,756,349	D. Mass.	Bench (on remand for post-Festo analysis of rebuttal of PHE)	Valid and infringed	W
Inveness Medical v. Acon Labs, 323 F. Supp. 2d 227	Immunoassay testing device for pregnancy and ovulation	6,485,982	D. Mass.	SJ	Infringement	W
Monsanto v. Scruggs, 2004 WL 1535690	Recombinant herbicidal soybean genes	5,352,605; 5,164,316; 5,196,525; 5,322,938	N.D. Miss.	SJ	Infringed	W
Novo Nordisk v. Bio-Technology General, 2004 WL 1739720	Method of making biosynthetic ripe human growth hormone (hGH)	5,632,352	D. Del.	Bench	Invalid and unenforceable	L
Pharmastem Therapeutics v. ViaCell, 2004 WL 2127192 (D. Del. 2004)	Cryopreserved hematopoietic stem cell compositions and methods of treatment	5,004,681; 5,192,553	D. Del.	Jury ('553; 681) JMOL ('553) New trial ('681)	'553 (method) infringed; 681 (product) new trial	W
Pharmaceutical Cases						
Abbott Labs v. Torpharm, 309 F. Supp. 2d 1043	Pharmaceutical product (valproate/valproic acid) for treating seizures (ANDA)	4,988,731; 5,212,326	N.D. Ill.	Bench	Infringed (on remand after affirmation of validity)	W
Alza Corp. v. Mylan Labs, 310 F. Supp. 2d 610	Method of treatment to stop smoking by transdermal administration of fentanyl (ANDA)	4,588,580	D. Vt.	Bench	Valid and infringed	W
Bristol-Myers Squibb v. Andrx Pharm., 337 F. Supp. 2d 475	Pharmaceutical product (fosinopril sodium) for treating hypertension (ANDA)	5,006,344	S.D. Fla.	Bench	Valid but not infringed	L
Glaxo Group v. Teva, 2004 WL 1875017	Method of treating nausea using ondansetron (ANDA)	4,753,789; 5,578,628	D. Del.	Bench	Valid and infringed	W
Impax Labs v. Aventis, 333 F. Supp. 2d 265	Method of treating ALS using riluzole (ANDA)	5,527,814	D. Del.	Bench	Valid, enforceable, and infringed	W

Case/Cite	Technology	Patent(s)-in-Suit	Tribunal	Disposition	Result	P'ee Win or Loss
Lilly v. Teva, 2004 WL 1724632	Method of treating PMS using fluoxetine (ANDA)	4,971,998	S.D. Ind.	Bench	Valid, enforceable, and infringed	W
In re Omeprazole Patent Litigation, 2004 WL 1171254	Pharmaceutical product (omeprazole) for treatment of acid reflux (ANDA)	6,013,281	S.D.N.Y.	Bench	Infringed but invalid	L
Ortho-McNeil Pharm v. Mylan Labs, 348 F. Supp. 2d 713	Pharmaceutical product (levofloxacin) used as an antibiotic (ANDA)	5,053,407	N.D. W. Va.	Bench	Valid and infringed	W
Purdue Pharma v. Endo Pharm, 2004 WL 26523	Pharmaceutical product (oxycodone analgesic) used for pain relief (ANDA)	5,549,912; 5,508,042; 5,656,295	S.D.N.Y.	Bench	Unenforceable for inequitable conduct	L
Purdue Pharma L.P. v. Teva Pharmaceuticals USA, Inc., 2004 WL 1444883	Pharmaceutical product (oxycodone) used for pain relief (ANDA)	5,549,912; 5,508,042; 5,656,295	S.D.N.Y.	SJ	Not infringed	L
Tristrata Technology v. ICN Pharm, 2004 WL 856595	Hydroquinone composition used for treating skin (ANDA)	5,561,157; 5,665,776	D. Del.	Jury	Valid and infringed	W
Warner-Lambert v. Teva, 2004 WL 1498162	Pharmaceutical product (quinapril hydrochloride) to treat hypertension (ANDA)	4,743,450	D.N.J.	Bench	Valid	W

Biotech and Pharmaceutical Patent Cases at the Federal Circuit, 2004

We examined for 2004, as we did for 2003, individual patent cases decided by the U.S. Court of Appeals for the Federal Circuit in the areas of biotechnology and pharmaceuticals. We have tabulated affirmance ratios, win rates, and other parameters, and present our results below. A Table of Cases is provided at the end of the chapter summarizing the information collected.

Methodology

We searched the Westlaw® CTAF database for all cases decided in 2004 that contained the word *patent* in combination with any of *pharmaceutical*, *nucleic acid*, *nucleotide*, *amino acid*, *peptide*, *protein*, or *antibody*. Of the 47 search results obtained, we selected cases that impacted patent eligibility, infringement, validity, or enforceability for products or processes involving small molecules, biomolecules, cells, or organisms as therapeutics, diagnostics, reagents, antibiotics, vitamins, or vaccines, in medicine, animal health, agriculture, or industrial biotechnology. Medical devices were not included. Using this selection procedure, we obtained 26 cases for study. For each case, we noted (1) the technology and claims at issue; (2) the nature of the dispute; (3) the parties involved; (4) the tribunal, disposition, and result below; (5) the result on appeal; and (6) the major legal issue(s) decided.

Results

To calculate affirmance ratios, we sometimes had to evaluate the effect of mixed results. We counted as affirmances those instances in which the prevailing party did not switch on appeal (patentee to accused party, or vice versa; USPTO to patent applicant, or vice versa, and so forth) with respect to the patentability, infringement, validity, or enforceability of a U.S. patent or patent application (as notated in the Table of Cases at the end of this chapter), even if the prevailing party lost on some issues. In

view of the small number of cases in the sample, we have not evaluated the statistical significance of the data, if any. The data are intended for longer-term study.

Of the 26 cases in our sample, 17 were affirmed on appeal, for an affirmance ratio of 65% (2003 = 65%). Of the 26 cases, the decision below was rendered by a district court in 22 of them; in four instances, the decision below occurred in the USPTO. All four USPTO decisions were affirmed, continuing the 100% affirmance rate for such biotechnology and pharmaceutical decisions in 2003. Removing the USPTO cases from the affirmance ratio (using only the 22 district court cases) lowers the affirmance ratio to $13/22 = 59\%$ (2003 = 59%). The affirmance ratio for cases on summary judgment was $4/11 = 36\%$ (2003 = 50%); for cases tried to the bench, $6/7 = 86\%$ (2003 = 60%); and the court agreed with the jury's verdict in two out of the three occasions (2003 = 75%). The one case appealed after a grant of JMOL was affirmed (last year's one such case was reversed). Of the 22 district court cases, 20 involved patent enforcement, while two involved inventorship challenges. It is perhaps interesting that in enforcement cases before district courts, about three times as many results below were in favor of the defendant (i.e., the patentee lost) than in the patentee's favor (in 2003 there were about twice as many losses for the patentee).¹ The patentee fared comparatively better on appeal, with a win rate of $11/20 = 55\%$ (2003 = 62%).

Major therapeutic areas in which decisions were rendered included pain (5 cases), cancer (5 cases), hypertension (3 cases), depression (3 cases), immunosuppression (3 cases), and agricultural biotechnology (2 cases).² For the 26 cases in our sample, we calculated an average patent number of 5,363,323 +/- 543,706, translating to a date of November 8, 1994 (i.e., about 10 years from issuance to final decision) with a standard deviation of about 5 years.

¹ One 2004 case, *Noelle v. Lederman*, was an interference proceeding at the PTO between a patent applicant and a patentee; as an alternative procedural venue that may be used in some circumstances to challenge issued patents, we have characterized the prevailing party as a winning patentee (see the Table of Cases).

² We did not include *Monsanto v. McFarlane*, 363 F.3d 1336 (Fed. Cir. 2004), on our list, since in that case the defendant, McFarlane, did not raise infringement or validity issues on appeal (the case concerned contract damages and patent misuse).

Case Highlights: Excerpts from Biotech and Pharmaceutical Patent Decisions of the Federal Circuit, 2004

We provide below excerpts from ten Federal Circuit opinions in our 2004 sample, as representative of the various technologies and issues considered by the Court in the past year. We give some context for each excerpt, including the technology involved and the posture of the case as presented for resolution, and then we let the Court speak for itself. For general readability, we have provided case citations under short case names and do not provide pinpoint cites. We have also omitted most internal citations.

The first four opinions in our review contain discussions about written description:

In re Wallach

378 F.3d 1330

Partial Amino Acid Sequence Does Not Describe Complete Protein

Panel: Judges Mayer, Lourie (author), and Gajarsa

Wallach and colleagues isolated two proteins from urine that selectively inhibit the cytotoxic effects of tumor necrosis factor (TNF), named “TNFI and TNFII.” They filed a patent application disclosing a partial amino acid sequence of TNFII, along with molecular weight data for the complete protein. At issue were claims to isolate DNA molecules that encode the complete protein. The PTO Board of Patent Appeals and Interferences affirmed the examiner’s rejection of the claims on written description grounds. On appeal, the applicants argued that the PTO had effectively conceded that their claims were adequately described, because the applicant’s specification was identical to that of another application claiming a partial TNFII sequence that was previously allowed. The Federal Circuit noted the difference in claims between the two applications, and affirmed the Board’s decision:

Appellants did not claim the nucleic acid molecules that encode the simple protein sequence that they disclosed. Rather, they claimed the nucleic acids encoding a protein for which they provided only a partial sequence. Appellants

concede that it is now known that urinary TBP-II has a sequence of 185-192 amino acids. Without the approximately 95% of the amino acid sequence that Appellants did not disclose, we cannot say that the DNA molecules claimed in the ‘129 application have been described. As the MPEP [Manual for Patent Examining Procedure] explains, “disclosure of a partial structure without additional characterization of the product may not be sufficient to evidence possession of the claimed invention.” MPEP § 2163.II.A.3.a.i. The Board’s decision was thus consistent with its guidance in the MPEP. Here, Appellants disclosed a partial structure and possibly sufficient additional characterization of the TBP-II protein to satisfy the PTO that they were in possession of the claimed subject matter in their ‘443 application, but that additional characterization contributes little, if anything, to the description of the DNA molecules claimed in the ‘129 application.

Chiron v. Genentech

363 F.3d 1247

Panel: Judges Rader (author), Archer, and Bryson (concurring)

Chiron asserted its patent, claiming chimeric and humanized HER2 antibodies, against Genentech’s product, Herceptin®. After a jury trial, the United States District Court for the Eastern District of California entered judgment in favor of Genentech that all claims of Chiron’s asserted patent are invalid as anticipated, because none of the asserted claims are entitled to priority to a series of applications filed in 1984, 1985, and 1986. Finding that Chiron did not adequately describe chimeric antibodies in the 1984 application, nor enable them in the 1985 and 1986 applications, the Federal Circuit affirmed:

The written description requirement prevents applicants from using the amendment process to update their disclosures (claims or specifications) during their pendency before the patent office. Otherwise applicants could add new matter to their disclosures and date them back to their original filing date, thus defeating an accurate accounting of the priority of invention. . . .

Priority is always a vital issue in patent prosecution procedures—often determining entitlement to an invention. In 1967, this court’s predecessor began to enforce priority as a component of the 35 U.S.C. 112, first paragraph, written description requirement. *In re Ruschig*, 54 C.C.P.A. 1551, 379 F.2d 990 (1967). In the context of a new claim added “[a]bout a year after the present application was filed,” the Ruschig court sought to determine “whether [the new] claim 13 is supported by the disclosure of appellants’ application.” *Id.* at 991. As later explained, “[t]he function of the description requirement is to ensure that the inventor had possession, as of the filing date of the application relied on, of the specific subject matter later claimed by him.” *In re Wertheim*, 541 F.2d 257, 262 (CCPA 1976). In this case, the Chiron scientists, by definition, could not have possession of, and disclose, the subject matter of chimeric antibodies that did not even exist at the time of the 1984 application. Thus, axiomatically, Chiron cannot satisfy the written description requirement for the new matter appearing in the ‘561 patent, namely chimeric antibodies

Turning next to the 1985 and 1986 applications, this court examines compliance with the enablement requirement. For these applications, the jury was entitled to determine as a matter of fact that chimeric antibodies were not future technology, but were nascent technology requiring a “specific and useful teaching.” This question, in turn, depends on evidence that undue experimentation would be required to make and use the chimeric antibodies claimed by the ‘561 patent. Of course, undue experimentation “is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations.”

Evidence presented to the jury showed that creation of genetically engineered antibodies, such as chimeric antibodies, required significant experimentation in 1985 and 1986 because those antibodies were unpredictable at that early stage of development. The record also shows that only a few laboratories contained the necessary equipment to make these new antibodies—another indication of the excessive experimentation necessary to make

and use that technology at that time. The 1985 and 1986 applications provide no disclosure of either how to make and use chimeric antibodies or working examples of chimeric antibodies within the scope of the ‘561 patent’s claims.

Noelle v. Lederman

355 F.3d 1343

Disclosure of Mouse Antigen Does Not Describe Human Antigen

Panel: Judges Clevenger, Bryson, and Garjarsa (author)

The PTO declared an interference between a patent issued to Lederman and an application filed by Noelle. Both the patent and the application claimed humanized¹ monoclonal antibodies against CD40 antigen. Noelle’s application also contained claims to CD40 mouse antibodies. Lederman’s patent disclosed examples of humanized antibodies, while Noelle’s priority application disclosed examples of mouse antibodies and methods for making humanized antibodies. The PTO Board of Patent Appeals and Interferences found Noelle’s humanized antibody claims to be inadequately described by Noelle’s priority application and, accordingly, denied Noelle’s humanized antibody claims the benefit of Noelle’s priority filing date. Without the benefit of its early filing date, Noelle conceded that his claims were anticipated by the prior art, including prior art by Lederman. The Interference rules next required the PTO to determine whether Noelle’s mouse claims and Lederman’s humanized antibody claims were directed to the same patentable invention (i.e., whether there was an interference-in-fact). The Board found no interference-in-fact, on the ground that one of ordinary skill in the art “lacked a reasonable expectation of success of obtaining Lederman’s claimed ‘human’ subject matter when provided with Noelle’s ‘mouse’ subject matter and using the screening techniques cited by Noelle.” The Federal Circuit affirmed:

¹ Claims to chimeric antibodies were also at issue. As they were treated similarly by the Court, we have for simplicity omitted discussion of them.

As to written description:

[B]ased on our past precedent, as long as an applicant has disclosed a “fully characterized antigen,” either by its structure, formula, chemical name, or physical properties, or by depositing the protein in a public depository, the applicant can then claim an antibody by its binding affinity to that described antigen.

Noelle did not provide sufficient support for the claims to the human CD40CR antibody in his ‘480 application because Noelle failed to disclose the structural elements of human CD40CR antibody or antigen in his earlier ‘799 application. Noelle argues that because antibodies are defined by their binding affinity to antigens, not their physical structure, he sufficiently described human CD40CR antibody by stating that it binds to human CD40CR antigen. . . . This argument fails, however, because Noelle did not sufficiently describe the human CD40CR antigen at the time of the filing of the ‘799 patent application. In fact, Noelle only described the mouse antigen when he claimed the mouse, human, and genus forms of CD40CR antibodies by citing to the ATCC number of the hybridoma secreting the mouse CD40CR antibody. If Noelle had sufficiently described the human form of CD40CR antigen, he could have claimed its antibody by simply stating its binding affinity for the “fully characterized” antigen. Noelle did not describe human CD40CR antigen. Therefore, Noelle attempted to define an unknown by its binding affinity to another unknown. As a result, Noelle’s claims to human forms of CD40CR antibody found in his ‘480 application cannot gain the benefit of the earlier filing date of his ‘799 patent application.

As to interference-in-fact:

After examining the record as a whole, we conclude there was substantial evidence to support the Board’s decision. The Board’s decision was reasonable in that, given the state of the art in the early 1990s as described by the expert witnesses, a person of ordinary skill in the art would not have had a reasonable likelihood of success in isolating human CD40CR antigen given mouse CD40CR antigen.

University of Rochester v. G.D. Searle & Co., Inc.

358 F.3d 916

Method of Screening, Without More, Does Not Describe Compounds Screened

Panel: Judges Lourie (author), Bryson, and Dyk

The University of Rochester asserted its claimed methods “for selectively inhibiting [COX-2] activity in a human host, comprising administering a non-steroidal compound that selectively inhibits activity of the [COX-2] gene product” The Panel noted the district court’s findings that, *inter alia*,

[A]lthough all of the claims require the use of a “non-steroidal compound that selectively inhibits activity of the [COX-2] gene,” the ‘850 patent neither discloses any such compound nor provides any suggestion as to how such a compound could be made or otherwise obtained other than by trial-and-error research.

On summary judgment, the district court invalidated the University’s claims for lack of written description. The Federal Circuit affirmed:

While it is true that this court and its predecessor have repeatedly held that claimed subject matter “need not be described in haec verba” in the specification to satisfy the written description requirement, it is also true that the requirement must still be met in some way so as to “describe the claimed invention so that one skilled in the art can recognize what is claimed.” . . .

A description of an anti-inflammatory steroid, *i.e.*, a steroid (a generic structural term) described even in terms of its function of lessening inflammation of tissues fails to distinguish any steroid from others having the same activity or function. A description of what a material does, rather than of what it is, usually does not suffice. The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described

In the case of DNA, the four nucleotides include the bases adenine, thymine, cytosine, and guanine; RNA also includes adenine, cytosine, and guanine, but contains the base uracil in place of thymine. Adenine on one strand of DNA binds, or “hybridizes,” to thymine on the other; in RNA, adenine binds to uracil; and in either DNA or RNA, cytosine binds to guanine. Given the sequence of a single strand of DNA or RNA, it may therefore have become a routine matter to envision the precise sequence of a “complementary” strand that will bind to it. Therefore, disclosure of a DNA sequence might support a claim to the complementary molecules that can hybridize to it.

The same is not necessarily true in the chemical arts more generally. Even with the three-dimensional structures of enzymes such as COX-1 and COX-2 in hand, it may even now not be within the ordinary skill in the art to predict what compounds might bind to and inhibit them, let alone have been within the purview of one of ordinary skill in the art in the 1993-1995 period in which the applications that led to the ‘850 patent were filed. Rochester and its experts do not offer any persuasive evidence to the contrary.

Another method-of-screening case was decided by the Court in 2004, which turned on an issue of claim construction rather than written description:

Housey Pharmaceuticals v. Astrazeneca

366 F.3d 1348

Broad Construction of “Inhibitor or Activator” Invalidates Screening Claims

Panel: Judges Mayer, Newman (dissenting), and Clevenger (author)

Housey asserted the following claim against several pharmaceutical companies:

A method of determining whether a substance is *an inhibitor or activator of a protein* whose production by a cell evokes a responsive change in a phenotypic

characteristic other than the level of said protein in said cell per se, which comprises: (1) providing a first cell line which produces said protein and exhibits said phenotypic response to the protein; (b) providing a second cell line which produces the protein at a lower level than the first cell line, or does not produce[] the protein at all, and which exhibits said phenotypic response to the protein to a lesser degree or not at all; (c) incubating the substance with the first and second cell lines; and (d) comparing the phenotypic response of the first cell line to the substance with the phenotypic response of the second cell line to the substance.

The patented method is essentially an assay to determine whether a substance is an inhibitor or activator of a particular protein (called a “protein of interest” or “POI”) in a cell. The method employs two cell lines and compares the effect the tested substance has on the phenotypic response to the POI in each cell line.

The district court construed the phrase “inhibitor or activator of a protein” to include substances that operate indirectly to inhibit or activate, not just those that bind directly to the protein. Based on this broad construction, Housey stipulated that its patents-in-suit were invalid and not infringed. Housey appealed the district court’s claim construction. The Federal Circuit affirmed:

Housey’s principal argument on appeal with respect to the construction of “inhibitor or activator of a protein” is the same one that was rejected by the district court: Housey argues that this limitation is “properly construed to mean substances that interact with, *i.e.*, bind to, the POI in order to exert their inhibiting or activating effect on the cellular functioning of the POI.” We do not agree that, as used in the ‘281 patent, an “inhibitor or activator of a protein” is limited to substances that achieve their effect on the biological activity of the POI through a particular reaction mechanism, namely binding to the POI. A substance need only have “a greater effect on the phenotype of cells that express the protein of interest at a higher level than one the phenotype of cells that express the protein of interest at a lower level or not at all” to be an “inhibitor or activator of a protein,”

and an inhibitor or activator of a POI may alter the biological activity of the POI through a direct POI-binding mechanism or an indirect pathway-binding mechanism. The word “bind” or “binding” appears nowhere in the ‘281 patent in conjunction with an “inhibitor or activator of a protein.”

In dissent, Judge Newman asserted that the majority’s approach to claim construction was based upon “confusing recent pronouncements” of the Court that exalt dictionary definitions over technical context. She argued that the majority had reinforced the recently created dominance of general definitions, and further contended that terms in patent claims should be understood in the technical and scientific context of the specification and should be presumed to have their technical meaning, not a general meaning.

Claim construction was also the main issue in several of the Court’s pharmaceutical cases in 2004, including the following:

Novartis v. Eon Labs

363 F.3d 1306

“Hydrosol” Formation Inside the Body Does Not Infringe Novartis’s Claims

Panel: Judges Clevenger (dissenting), Dyk (author), and Prost

This lawsuit concerned Novartis’s patent claims directed to “hydrosol” formulations of the immunosuppressant cyclosporin. Eon Labs manufactures capsules containing cyclosporin dissolved in ethanol, which Novartis conceded does not constitute a “hydrosol.” However, Novartis contended that when an Eon capsule is ingested, an infringing hydrosol is formed in the user’s stomach. The district court construed “hydrosol” to only include synthetic pharmaceutical preparations in solid particle form, and accordingly found on summary judgment that Eon does not infringe. The Federal Circuit affirmed:

In light of the specification and prosecution history, we conclude that the narrower definition of “hydrosol” applies; that is, the term “hydrosol” is limited to a medicinal

preparation consisting of a dispersion of solid particles in a liquid colloidal solution prepared outside the body. While none of the statements in the intrinsic record is an explicit disclaimer of subject matter sufficient to vary the scope of the claim from its ordinary meaning, these statements are helpful in guiding us to choose between competing dictionary definitions of a claim term .

Judge Clevenger dissented, arguing that because the patentee (as noted by the majority) did not make an explicit disclaimer of the ordinary meaning of “hydrosols,” “under our precedent Novartis would appear to be correct in its understanding of the disputed term.”

Agricultural biotechnology was also considered by the Federal Circuit in 2004:

Monsanto v. Bayer Bioscience

363 F.3d 1235

Insecticidal Plant Patents Given Another Chance

Panel: Judges Newman, Bryson (author), and Prost

Bayer’s patents directed to insecticidal plant genes and plants containing them were challenged by Monsanto in a declaratory judgment action. The Eastern Missouri district court granted summary judgment to Monsanto finding the patents unenforceable due to inequitable conduct, based on Bayer’s failure to disclose certain test results to the examiner; invalid as not enabled, based on the state of the art as previously characterized by the Federal Circuit in an earlier plant patent case involving a different patent and different parties; and not infringed, based on a narrow claim construction. The Federal Circuit reversed and remanded:

As to inequitable conduct:

In determining that the omitted test results were “contrary to the positive test results Bayer experienced with other species,” the district court necessarily discounted the affidavit in which Mr. Jansens explained the nature of those test results and their relationship to the conclusions set forth in his PTO declaration. In so doing, the court erred. On summary

judgment, “[t]he evidence of the nonmovant is to be believed, and all justifiable inferences are to be drawn in his favor.” . . . The district court, however, resolved the central dispute over the omitted test results in favor of Monsanto, a decision that required the court to reject the explanation provided in Mr. Jansens’ affidavit. If the court were to credit Mr. Jansens’ affidavit, it could find that the test results withheld from the PTO were not negative and that Mr. Jansens’ statement to the PTO that he knew of no contrary results was true. Thus, there is a factual dispute about the truth of the PTO declaration that should not have been resolved on summary judgment.

As to enablement:

In order to determine whether the specifications of the ‘546 and ‘372 patents enable the transformation of monocots through the use of *Agrobacterium*, the district court must consult those specifications, which differ significantly from the specification of the patent at issue in the *Plant Genetic Systems* case. Bayer does not dispute that the parties in *Plant Genetic Systems* fully litigated the issue of whether one of ordinary skill in the art in 1986 would be able to transform a monocot using *Agrobacterium*. For that reason, if Monsanto succeeds in showing by clear and convincing evidence that the specifications of the ‘546 and ‘372 patents do not teach one of ordinary skill how to transform a monocot with a gene for a Bt toxin, Bayer would be precluded by *Plant Genetic Systems* from arguing that one of skill in the art in 1986 would already have known how to perform such a transformation. Thus, collateral estoppel may bear on the enablement issue, but only if the district court concludes that the specifications of the ‘546 and ‘372 patents themselves do not teach the transformation of monocots.

In order to determine whether the claims of the ‘799 patent must be construed to be limited to dicots, the court must consult the intrinsic evidence relating to the ‘799 patent, which was not at issue in the *Plant Genetic Systems* case. It is not enough for the court simply to rely on the conclusion of the court in *Plant Genetic Systems* that the prosecution history of the

patent in that case and the corresponding extrinsic evidence support a narrow construction of the term “susceptible to transformation by *Agrobacterium*,” because similar terms can have different meanings in different patents depending on the specifics of each patent.

As to infringement:

Because the claims define “Bt2” in terms of the molecular weight and amino acid sequence of the claimed toxin, and because neither the specifications of the patents at issue nor their prosecution histories suggest that the term must be limited to a toxin derived from a particular source, the district court erred in its claim construction. The grant of summary judgment of noninfringement based on that claim construction was therefore erroneous. Accordingly, we reverse the district court’s judgment on the claims affected by the “Bt2” claim construction issue, and we remand the case for further proceedings

The Court granted a victory for Pfizer in 2004, when it released a district court’s decision regarding patent term expansion:

Pfizer v. Dr. Reddy’s Labs

359 F.3d 1361

Patent Term Extension Applies to Other Salts of Pfizer’s Approved Drug

Panel: Chief Judge Mayer, Judges Newman (author), and Lourie

Dr. Reddy’s Labs filed a paper NDA seeking to market a generic version of Pfizer’s dihydropyridine drug, Norvasc®. In response, Pfizer asserted its patent directed to certain dihydropyridine compounds and their acid addition salts, useful in the treatment of hypertension. Norvasc®, for which Pfizer had obtained federal registration, is a dihydropyridine besylate salt, whereas Reddy’s proposed generic contained the maleate salt form. Pfizer applied to the Patent Office requesting term extension for its asserted patent, and identified Norvasc® as the product for which regulatory approval had been obtained. Pfizer further identified

Norvasc® as “amlodipine [a dihydropyridine] besylate.” Dr. Reddy’s argued to the district court that the patent term extension applies only to the besylate salt, not to the maleate form that Dr. Reddy’s intended to sell, and the district court agreed with Dr. Reddy’s. The Federal Circuit reversed:

We conclude that the active ingredient is amlodipine, and that it is the same whether administered as the besylate salt or the maleate salt. The statutory definition of “drug product” is met by amlodipine and its salts. Dr. Reddy’s is proposing to market the “drug product,” as defined in 35 U.S.C. § 256(f), for the same approved uses. The statute foresaw variation in the salt or ester of an active ingredient, and guarded against the very loophole now urged. See 35 U.S.C. § 156(f); 21 U.S.C. § 355(j)(5)(D)(i) and (v). As several amici curiae point out, the Hatch-Waxman Act established a balance whereby the patent term extension is offset by facilitating generic entry when the extended term expires, yet preserving the innovation incentive. Whether or not this bargain achieved “perfect symmetry”—Dr. Reddy’s argues that it was not intended to do so, but was designed to favor the generics—the text of the statute shows that it was not intended to be defeated by simply changing the salt. None of the aspects offered to the district court or on this appeal suggests a statutory intent to provide the generic producer with access to the pioneer’s approved uses and data while barring extension of patent coverage of the drug product whose approvals and data are provided. To the contrary, as we have discussed, the Hatch-Waxman Act foresaw and averted the potential loophole of a change in the salt of the active ingredient.

Whether an offer to enter a licensing agreement constitutes an on-sale bar to patenting was a question answered by the Federal Circuit in 2004.

Elan Corporation v. Andrx Pharmaceuticals

366 F.3d 1336

Proposal for License Does Not Constitute an On-Sale Bar

Panel: Judges Michel, Lourie (author), and Dyk

In the 1980s, Elan began development of a controlled-release naproxen formulation for once-daily administration in the treatment. In 1987, Elan’s Executive Vice President for Business Planning and Commercial Development wrote a letter to Lederle Laboratories as well as other pharmaceutical companies, proposing a licensing structure for a partnership with Elan in the marketing of a controlled-release naproxen. In 1991, Elan filed a patent application directed to naproxen formulation for once-daily oral administration, which eventually issued in 1997. In 1998, Andrx submitted an ANDA seeking approval to market a generic naproxen. Elan sued for infringement under the Hatch-Waxman Act. The district court held, *inter alia*, that Elan’s patent was invalid over the licensing proposal to Lederle as on sale more than one year before the patent’s effective filing date. The Federal Circuit reversed:

An offer to enter into a license under a patent for future sale of the invention covered by the patent when and if it has been developed, which is what the Lederle letter was, is not an offer to sell the patented invention that constitutes an on-sale bar. The letter to Lederle is clear on its face that Elan was not offering to sell naproxen tablets to Lederle, but rather granting a license under the patent and offering Lederle the opportunity to become its partner in the clinical testing and eventual marketing of such tablets at some indefinite point in the future. Although no particular language is required to be present in order for an offer of a license to constitute an offer for sale of the licensed product, a communication that fails to constitute a definite offer to sell the product and to include material terms is not an “offer” in the contract sense The letter to Lederle lacked any mention of quantities, time of delivery, place of delivery, or product specifications beyond the general statement that the potential product would be a 500 mg

once-daily tablet containing naproxen. Moreover, the dollar amounts recited in the fourth paragraph of the letter to Lederle are clearly not price terms for the sale of tables but rather the amount that Elan was requesting to form and continue a partnership with Lederle. Indeed, the letter quickly explicitly refers to the total as “licensing fee.”

The inventorship dispute from which our final case arose concerned a research collaboration and licensing agreement between a biopharmaceutical company and a state university. It was dismissed by the district court on Eleventh Amendment grounds.

Xechem International v. The University of Texas M.D. Anderson Cancer Center

382 F.3d 1324

Eleventh Amendment Bars Suit Against University of Texas

Panel: Judges Newman (author), Gajarsa, and Linn

Xechem entered into a research collaboration agreement, and later a patent and technology license agreement, with the University of Texas. The purpose of the agreements was to develop and market a new pharmaceutical formulation of the cancer drug paclitaxel. A successful formulation was eventually developed. Xechem prepared a patent application naming Xechem and University of Texas scientists as joint inventors. After the University objected to the inventorship designation, the Xechem scientist wrote to the University, “I recognize [the University scientist] as the sole inventor of the above-referenced patent application.” Two patents eventually issued to the University based on this collaboration and were licensed to Xechem exclusively. The University prosecuted both patents, and Xechem agreed to pay the costs of prosecution. Both patents name a University of Texas scientist as the sole inventor. The University eventually terminated the license agreement to Xechem based on allegations of Xechem’s insolvency, and informed Xechem that its use of the claimed technology was patent infringement. Xechem filed suit in federal court, alleging tort and contract claims, and also seeking a correction of inventorship to add the Xechem scientists, and a declaration of noninfringement. The district court dismissed the case on Eleventh Amendment grounds. The Panel affirmed:

In *Seminole Tribe* [§ 517 U.S. 44 (1996)] the Court discussed the congressional power to abrogate state immunity by federal statute, and reaffirmed that the Commerce Clause is not a source of such power. In *Parden* [377 U.S. 184 (1964)] the Court had relied on the Commerce Clause to hold that when a state voluntarily enters into federally regulated activity—in *Parden*, operating a railroad—the state is deemed to have consented to federal jurisdiction arising from that activity, in that case an action under the Federal Employers’ Liability Act. In overruling *Parden*’s constructive waiver, the Court stressed in *College Savings* [527 U.S. 666 (1999)] that a state’s waiver of Eleventh Amendment rights cannot be imposed or implied based on a state’s entry into commerce, but must be founded on a “clear declaration” by the state of its intent to submit to federal jurisdiction. [*College Savings*, 527 U.S. at 675.] Such a declaration was not made by the University in entering into its various relationships and contracts with Xechem.

Table of Cases
2004 Federal Circuit Biotechnology & Pharmaceutical Patent Decisions

Case/Cite	Technology	U.S. Patent No.	Tribunal	Decision Below		Decision on Appeal	
Biotech Cases - Infringement Decisions							
Chiron v. Genentech 363 F.3d 1247	Biopharm treatment method, chimeric and humanized monoclonal antibodies for breast cancer	6,054,561	E.D. Cal.	Jury	L Invalid	L Affirmed	+
Goldenberg v. CytoGen 373 F.3d 1158	Biopharm, diagnostic & therapeutic antibodies to detect and treat tumors	4,460,659	N.J.	SJ	L Not infringed	W Remand on DOE	-
Housey Pharms v. Astrazeneca 366 F.3d 1348	Biotech, methods of screening for protein inhibitors and activators	4,980,281; 5,266,464; 5,688,655; 5,877,007	Del.	Bench	L Invalid and not infringed	L Invalid and not infringed	+
Metabolite Labs v. Lab Corp of America 370 F.3d 1354	Biotech, method of detecting vitamin deficiencies in blood	4,940,658	Colo.	Jury	W Valid and contributorily infringing	W Affirmed	+
Monsanto v. Bayer Bioscience 363 F.3d 1235	Bioag, genetically engineered insecticide resistant plants	5,545,565; 5,767,372; 6,107,546; 5,254,799	E.D. Mo.	SJ	L Not infringed, invalid and unenforceable	W Remand on each issue	-
Mycogen Plant Science v. Monsanto 91 Fed. Appx. 666	Bioag, recombinant insecticide gene expressed in plants	5,380,831	S.D. Cal.	SJ	L Invalid	L Affirmed	+
Univ of Rochester v. G.D. Searle 358 F.3d 916	Pharm, cyclooxygenase inhibitors (non-steroidal anti-inflammatory)	6,048,850	W.D.N.Y.	SJ	L Invalid	L Affirmed	+

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PTO - Interference Decisions							
Noelle v. Lederman 355 F.3d 1343	Biopharm, human monoclonal antibodies for CD40CR	5,474,771	BPAI	Final Judgment	W - no interference between application and challenged patent	Affirmed	+
PTO - Ex Parte Appeals							
<i>In re</i> Crish 393 F.3d 1253	Biotech, DNA promoter (nucleic acid)	N/A	BPAI	Final Judgment	Not Patentable (Anticipated)	Affirmed	+
<i>In re</i> Ngai 367 F.3d 1336	Biotech, amplification and normalization of RNA	N/A	BPAI	Final Judgment	Not Patentable (Anticipated)	Affirmed	+
<i>In re</i> Wallach 378 F.3d 1330	Biotech, nucleic acid encoding TNF binding proteins	N/A	BPAI	Final Judgment	Not Patentable (No written description)	Affirmed	+
PTO - Invention Disputes							
Lilly v. Aradigm 376 F.3d 1352	Biopharm, aerosolized delivery for insulin analog	5,888,477	S.D. Ind.	Jury	Lilly	Aradigm	-

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Case/Cite	Technology	U.S. Patent No.	Decision Below			Decision on Appeal	
			Tribunal	Disposition	Result	Result	Affirmed (+)/ Reversed (-)
PHARMA - ANDA Decisions							
Alza Corp. v. Mylan Labs 391 F.3d 1365	Pharm treatment method, transdermal skin patch, fentanyl (narcotic) (ANDA)	4,588,580	Vt.	Bench	W Valid and infringed	W Affirmed	+
Astrazeneca v. Mutual Pharm. 384 F.3d 1333	Pharm, extended release felodipine tablets (anti-hypertensive) (ANDA)	4,803,081	E.D. Pa.	SJ	W Valid and infringed	L Valid but not infringed	-
Bristol-Myers Squibb v. Pharmachemie 361 F.3d 1343	Pharm, platinum coordination compounds (cancer) (ANDA)	4,657,927	N.J.	SJ	W Valid and infringed	Invalid and not infringed	-
Elan v. Andrx Pharm 366 F.3d 1336	Pharm, naproxen (non-steroidal anti-inflammatory) (ANDA)	5,637,320	S.D. Fla.	Bench	L Invalid	W Valid, remand for infringement	-
Glaxo Group v. Apotex	Pharm, cefuroxime axetil (antibiotic) (ANDA)	4,562,181; 4,820,833	N.D. Ill.	Bench	W Valid and willfully infringed	W Valid and infringed, (but not willful)	+
Glaxo Wellcome v. Impax Labs 356 F.3d 1348	Pharm, sustained release formulation, bupropion (antidepressant) (ANDA)	5,427,798 (claims bupropion with HPMC)	N.D. Cal.	SJ	L Not infringed	L Not infringed	+
Knoll Pharm v. Teva 367 F.3d 1381	Pharm, hydrocodone and ibuprofen combo for pain (ANDA)	4,587,252	N.D. Ill.	SJ	L Invalid	W Remand	-
Pfizer v. Dr. Reddy's Labs 359 F.3d 1361	Pharm, amlodipine (anti-hypertensive) (ANDA)	4,572,909	N.J.	Bench	L No patent term extension	W Patent term extension	-
Schwarz Pharma v. Warner-Lambert 95 Fed. Appx. 994	Pharm, moexipril (anti-hypertensive) (ANDA)	4,743,450	N.J.	SJ	L Not infringed	W Remand	-
SmithKline Beecham v. Apotex 365 F.3d 1306	Pharm, paroxetine (anti-depressant) (ANDA)	4,721,723	N.D. Ill.	Bench	L Invalid	L Affirmed	+

Case/Cite	Technology	U.S. Patent No.	Decision Below			Decision on Appeal	
			Tribunal	Disposition	Result	Result	Affirmed (+)/ Reversed (-)
PHARMA - ANDA Decisions							
SmithKline Beecham v. Excel Pharm	Pharm, sustained release formulation, bupropion (antidepressant) (ANDA)	5,427,798 (claims bupropion with HPMC)	E.D. Va.	SJ	L Not infringed	W Remand on DOE	-
PHARMA - Non-ANDA Decisions							
Novartis v. Abbott Labs 375 F.3d 1328	Pharm, cyclosporin (immunosuppressant)	6,007,840	Del.	JMOL	L Not infringed	L Affirmed	+
Novartis v. Eon Labs 363 F.3d 1306	Pharm, cyclosporin (immunosuppressant)	5,389,382	Del.	SJ	L No contributory infringement	L Affirmed	+
PHARMA - Inventorship Disputes							
Xechem v. Univ. of Texas 382 F.3d 1324	Pharm, new formulations of paclitaxel to increase solubility (cancer)	5,877,205; 6,107,333	S.D. Tex.	Bench	Univ. of Texas (dismissed on 11th amendment grounds)	Univ. of Texas, affirmed	+

Concluding Remarks

The number of issued biotechnology and pharmaceutical patents, as well as their share of the issued patent space, appears to be modestly declining. The number and share of published applications is down for 2004; the patent share of 7 of the top 10 biotech companies is down as well; and, by the PTO's account, the number of applications filed in Technology Center 1600 was down 1.2% last year. Possible explanations for what appears to be an across-the-board decline in patenting activity include a greater focus by companies on what to patent; a backlog in the PTO's inventory of unexamined applications (although this does not explain a drop in applications filed); and the challenges biotech and pharmaceutical patent applicants confront in meeting patent eligibility requirements.

Patentees also confront challenges in enforcing issued patents. Between 2000 and 2003, patentees tended to lose in the district courts by a margin of about two to one. Patentees fared considerably better in 2004. Because the number of final decisions studied is low, however, long-term data collection is necessary in order to determine the significance, if any, of this result. It will be interesting to see if the three-to-one loss ratio below that we observed for patentees in our appellate sample this year will decrease as the 2004 decisions make their way to the Federal Circuit. In any event, patentees ultimately fared about even on appeal last year, as the Federal Circuit in 2004 reversed more losses than wins.

The patent ownership distribution between the private sector and academic institutions that we measured last year, representing an apparent shift since the late 1990s towards the private sector, appears to have been maintained through 2004. We also observed a modest increase in the number of issued patents with joint assignees, suggesting that collaborations are on the rise. It will be interesting to see to what extent the CREATE Act affects the appearance of jointly-owned patents in the future.

We look forward to continued debate over patent policy reform and a continued focus on empirical measures of the patent system.