DNA-based patents: an empirical analysis

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The perception of rising litigation rates is driving the push for patent reform.

The Patent Reform Act of 2007 (S.1145, H.R.1908) was introduced in the US Congress in April 2007, and it includes major patent reform measures, which if enacted may have a considerable impact on the country's patent system. Among the controversial reforms included in the proposed legislation is the initiation of post-grant opposition proceedings[1]. Some reform measures contained in S.1145 are controversial because they will affect dissimilar industries differently. For example, in younger industries such as biotechnology where patents are among the primary, if not only, assets, there is fear that a new post-grant opposition proceeding would call into question a patent's validity. This uncertainty would likely discourage future investment by venture capitalists who help support the industry and, in turn, may hinder future innovation and successful commercialization[2,3]. While rising energy costs, a melt-down in the financial sector and a slowing economy have temporarily diverted the attention of the House and Senate, the American Academy for the Advancement of Science indicates in its Research and Development Report for fiscal year 2009 that patent reform is considered to be a vital issue for "competitiveness and innovation," and Congress expects to continue to discuss patent reform[4]. The bill now remains in the Senate. Moreover, at least one of the Presidential candidates, Sen. Barack Obama, considers patent reform to be an important issue and has discussed his position on the reform of the current patent system[5].

One reason advocates of S.1145 justify the need for reform is because they are convinced that the rate of litigation is rising[6]. The perception of rising rates of litigation derives from three reports warning of dire consequences if industry is unable to innovate and successfully commercialize new products[7–9]. Costs associated with litigation are thought to hamper innovation and successful commercialization because they may divert resources away from innovative activities. And there are costs associated with the strategies followed by companies to protect them from the risk of litigation. Such strategies may include defensive patenting by enlarging a firm's portfolio of patents to influence settlement terms or foregoing otherwise valuable research because of the risk of litigation[10].

Although there is anecdotal evidence supporting the perception that the rate of litigation is rising, there is little empirical evidence supporting this[7–9]. And what evidence there is seems to point in a different direction. For example, Lanjouw and Schankerman[11] point out that growth in patent litigation, particularly over the 1990s, encouraged the perception that research companies are burdened by growing enforcement costs. They argued that at that time, the growth in patenting was comparable to the growth in litigation, with the rate of suit filings remaining about constant over two decades[11].

Because some of the reform measures contained in S.1145 are controversial and because there is little objective empirical data supporting the notion that litigation rates are rising, we undertook a small empirical study of DNA-based litigated patents to determine whether or not rates of litigation on DNA-based patents are actually increasing.

Methods

We collected data on lawsuits from the LitAlert database, which contains records for patent lawsuits filed in the 94 US District Courts and reported to the Commissioner of the US Patent and Trademark Office (USPTO), and is updated weekly. In addition, records for thousands of lawsuits filed since the early 1970s that have not been reported in the *Official Gazette* are included in this database. We collected data on lawsuits, rather than patents, to avoid over-counting because one lawsuit may involve multiple patents. We collected the data on lawsuits on April 18, 2008.

To collect the data, we used a slightly modified version of the algorithm that had

Table 1 Litigated cases by patent issue date on DNA-based patents in the biotechnology industry

Date	Number of cases	Total patents issued	Rate
1982	2	72	0.027778
1983	2	86	0.023256
1984	4	105	0.038095
1985	3	96	0.03125
1986	1	134	0.007463
1987	3	219	0.013699
1988	11	280	0.039286
1989	11	373	0.029491
1990	3	375	0.008
1991	5	491	0.010183
1992	1	597	0.001675
1993	16	783	0.020434
1994	38	819	0.046398
1995	6	955	0.006283
1996	21	1,588	0.013224
1997	24	2,556	0.00939
1998	14	3,788	0.003696
1999	12	4,106	0.002923
2000	14	3,827	0.003658
2001	7	4,463	0.001568
2002	6	3,872	0.00155
2003	5	3,536	0.001414
2004	1	3,055	0.000327
2005	1	2,772	0.000361
Total	211		

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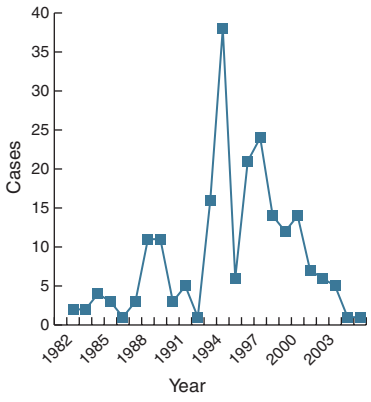

Figure 1 The number of lawsuits involving DNA-based patents occurring in each year between 1982 and 2005.

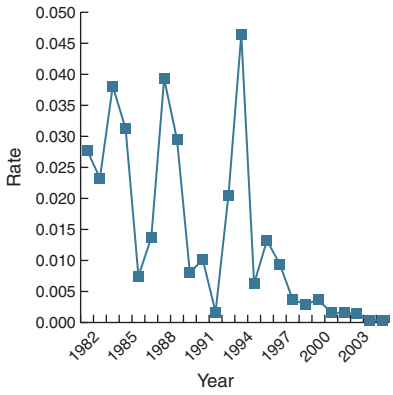

Figure 2 The rate of cases involving DNA-based patents to total number of DNA-based issued patents between 1982 and 2005.

been used to develop the DNA Patent database (http://dnapatents.georgetown.edu/), a publicly available database containing all DNA-based issued patents since 1971 and all DNA-based patent applications since 2001. Our search employed the same algorithm as that used to develop the DNA database with one small modification. The algorithm used to develop the DNA database searches patent 536/subclasses 22 through 23.1 (nucleic acids, genes, etc., but not peptides or proteins) and subclasses 24 and 25 (various nucleic acids, variants, and related methods). LitAlert does not allow searching subclasses. So in LitAlert we searched all of class 536. Therefore, we searched the LitAlert database for US Patent classes 047 (plant husbandry), 119 (animal husbandry), 260 (organic chemistry), 426 (food), 435 (molecular biology and microbiology), 514 (drug, bio-affecting and body treating compositions), class 536 and class 800 (multicellular organisms). And, within these classes we searched for one or more of the following terms in their claims: Antisense, cDNA, centromere, deoxyoligonucleotide, deoxyribonucleic, deoxyribonucleotide, DNA (with or without following letters, such as DNAs), exon, gene or genes (exact match only), genetic, genome, genomic, genotype, haplotype, intron, mtDNA (with or without following letters such as mtDNAs)-exact case match only, nucleic, nucleotide, oligonucleotide, oligodeoxynucleotide, oligoribonucleotide, plasmid, polymorphism, polynucleotide, polyribonucleotide, ribonucleotide, ribonucleic, recombinant DNA (exact match for case and words only), RNA (all upper case only, with or without following letters such as RNAs), mRNA (exact case match only, with or without following letters such as mRNAs), rRNA (exact case match only, with or without following letters such as rRNAs), siRNA (exact case match only, with or without following letters such as siRNAs), snRNA (exact case match only, with or without following letters such as snRNAs), tRNA (exact case match only, with or without following letters such as tRNAs), ribonucleoprotein, hnRNP (exact case match only, with or without following letters such as hnRNPs), snRNP (exact case match only, with or without following letters such as snRNPs) or SNP (exact case match only, with or without following letters such as SNPs).

Because we searched all of class 536 and in order to validate that the cases we identified involved DNA based patents, we cross-referenced the patent numbers involved in the cases we identified to the DNA Patent Database and discarded the case if the patent was not listed in the DNA Patent Database. We then eliminated duplicate cases. (When a subsequent action is taken, LitAlert adds another record instead of updating existing record.)

Six patents were not in the DNA database, and as they were not defined as DNA-based patents, we discarded from our dataset the cases associated with them. We also eliminated one case because LitAlert did not include the date when the case was filed. We then cross-referenced the patents we identified to the USPTO database to obtain issue dates for the patents (LitAlert does not include issue dates of patents). We collected the patent issue dates on April 22–23, 2008.

Because we were only concerned with litigation associated with DNA-based patents, we used the DNA Patent database (rather then the USPTO database) to ascertain the total number of issued patents by year. We collected the data on the total numbers of issued DNA-based patents on April 23, 2008.

We copied and pasted the data we obtained from LitAlert, the DNA Patent and the USPTO databases to eliminate as much as possible the risk of error in building our database. Our dataset contained 211 litigated cases on DNA-based patents issued between 1982 and 2005.

We define litigation rate as the number of cases filed divided by the total number of DNA patents issued in a year. We used Fisher's Exact Test, a 2-tailed test at the 95% confidence level to test for significance.

Results

We did not find any lawsuits for patents issued in 2006, 2007 or 2008. This is not surprising because we calculated the mean time in our dataset between patent issue date and a lawsuit being filed for the patents we studied to be 56.17 months. In **Table 1** and **Figure 1** we show lawsuits by patent issue date on DNA-based patents in the biotechnology industry. For instance, in 1982 a total of 72 patents were issued. Of these 72 patents, there were two lawsuits, which may or may not have involved other patents. Comparing by issue dates allows for the calculation of a true rate of litigation. Moreover, the great majority of lawsuits had a complaint filed with no further action taken. Only 48 of the total cases (211) during the time period studied (23%) had some further action taken on the case. This could mean, for example, the case was settled, there was a jury verdict, summary judgment, or the case was dismissed. For the remaining cases, a complaint was filed with no further action taken.

Additionally, the rate of litigation in the genetic and genomic sector studied has decreased in recent years (**Fig. 2**). Between 2000 and 2005, the rate of patent litigation for the patent classifications studied dropped significantly from 14/3,827 to 1/2,772 ($P < 0.0006$).

Discussion and conclusions

The empirical analysis we undertook shows that the overall number of litigated cases for the classifications studied is declining for the indicated time periods. There are, however, limitations to this study. First, there is considerable lag time between the filing of a lawsuit in a district court and this information being reported to and entered into the LitAlert database used in this study. In addition, these findings are limited to the patent classifications studied. The results of this study cannot be extended to draw conclusions regarding overall litigation rates or litigation rates in other patent classifications.

Notwithstanding these limitations, the results of this small study should call into question whether the perception of rising litigation rates is valid for some industries and whether this argument can continue to be used to justify patent reform without additional research. Our results point to the need for additional empirical research before reform initiatives are implemented. This is important when passage of such legislation may be accompanied by introducing uncertainty as to patent validity, which may in turn discourage investment in younger industries and ultimately stifle innovation and commercialization.

Moreover, future empirical studies should take into account that various industry sectors are different and have different business models. It is possible that empirical data may yield different results for different industry sectors. It is time to step back and reflect upon the adequacy of current evidence to support those reform measures that have the potential to adversely impact commercialization in some industry sectors.

COMPETING INTERESTS STATEMENT
The authors declare competing financial interests: details accompany the full-text HTML version of the paper at http://www.nature.com/naturebiotechnology/

1. Patent Reform Act of 2007 (H.R.1908 and S.1145). Passed by the US House of Representatives on 7 September 2007.
2. *Biotechnology Industry Organization's Position on Patent Reform Measures* (http://bio.org/ip/domestic/postgrant.pdf).
3. Anonymous. *Nat. Biotechnol.* **25**, 1187 (2007).
4. Heath, E. & Karaoglanova, L. *Political and Policy Context for the FY 2009 Budget*. in AAAS Report XXXIII Research and Development (2008).
5. *Barack Obama: Connecting and Empowering All Americans through Technology and Innovation*. (http://www.BarackObama.com).
6. The 101th Congress Senate Judiciary Committee's Report on The Patent Reform Act of 2007 (http://patentsmatter.com/issue/legislation.php/).
7. Federal Trade Commission. *To Promote Innovation: the Proper Balance of Competition and Patent Law and Policy* (2003) (http://www.ftc.gov/os/2003/10/innovationrpt.pdf).
8. Committee on Information Property Rights in the Knowledge-Based Economy. *A Patent System for the 21st Century* (National Academies Press, Washington, DC, 2004).
9. Committee on Intellectual Property Rights in Genomic and Protein Research and Innovation. *Reaping the Benefits of Genomic and Proteomic Research: Intellectual Property Rights, Innovation, and Public Health* (National Academies Press, Washington, DC, 2006).
10. Azher, A.I. *U. Pa. J. Intl. Econ. L.* **25**, 383 (2004).
11. Lanjouw, J. & Schankerman, M. in *Patents in the Knowledge-Based Economy* 145–179 (The National Academies Press, Washington, DC, 2003).