

WELCOME

The Paragraph Four Report® is dedicated to mining, tracking, and analyzing Paragraph Four activity as it affects pharmaceutical products, generic and branded companies, and the industry. The Report is a publication of Parry Ashford Inc., Tampa, FL. More details, information, searchable databases and analysis can be found on-line at ParagraphFour.com.

PARAGRAPHFOUR.COM: 15 YEARS! SOMEONE HAS TO CELEBRATE!

While the January Quarterly Note is usually reserved for a year-end review, I decided to start with something more personal: the 15 Year Anniversary of ParagraphFour.com. While the research started in 2003, the site launched on a cold January day in 2004. While I remember the drizzle outside, I kind of forget the exact day the site was launched on the “world wide web.”

Before the research started, I had been working for years in the pharmaceutical industry, both as a market researcher and attorney. Much of my work became dedicated to the “end of brand, beginning of generic” product life cycle, and I had the good fortune to work for both brand and generic companies. All of the time and dedication led me to believe that Paragraph IV research was not only possible but also could be really useful and time-saving.

Starting out, it was not so clear. Though it is hard to imagine in 2019, internet access to most federal courts was limited back then. This meant spending hours going to New Jersey, New York, and Delaware and poring through volumes of dusty case dockets to compile the initial data set. I was used to this kind of work, since I have been diving into court dockets since I was 16 years old and spent plenty of time trying cases in federal courts when I practiced law.

Our industry has a strong focus on “good science” so, importantly, I wanted the research to be like our industry: **providing accurate, reliable and honest data.** However, even with this mission in mind, there were a few obstacles that help guide what ParagraphFour.com provides.

The most obvious obstacle is that ANDA’s are confidential. So, as the public does not have access to ANDA’s, a researcher is left with the next best thing: the Paragraph IV cases filed in federal courts. The PIV cases will tell us the things we really want to know: who filed the ANDA, how many filers are present, and what patents are at-risk for the brand. Analysis of the court proceeding also helps provide guidance as to when the generic market may emerge.



However, this is the point where we can separate research from conjecture. In order to fulfill the mission of providing accurate, reliable, and honest data, I had to acknowledge the limitations this type of data provides and keep ParagraphFour.com contained with research, not conjecture.

For example, to delve into further parts of court cases and their dockets is to open up haphazard research and introduce bias. For example, in a public court docket, Paragraph IV cases are special as **many documents are sealed.** Often, if you click on a critical document in a docket that might provide case or product insight, you often get the message “You do not have permission to view this file.” Finding out more is often not possible.

Moreover, if not sealed, **many court documents are redacted** which leaves the viewer with a black line and nothing more, like this: “the keys to health and happiness are ████████████████████.”

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Now, we can always guess what the redacted portion may contain, but in order to provide accurate, reliable and honest data, there must be a simple tenet: **no guessing**.

Not only are researchers denied access to many court documents, but they are also denied access to company documents, witnesses, and experts. So, the only thing left to review would be a few documents and live court testimony. While this is one way to research PIV cases or evaluate a legal argument, this, unfortunately, introduces **research bias** as two people can read documents and hear testimony yet arrive at two entirely different conclusions.

Because of the research limitations and bias, I have always kept the research to just that -- research. While opinion, conjecture, and prediction have their places, they are just not research. Research is reliable and void of bias, the primary reasons why so many pharmaceutical companies, legal and investment professionals, academia, supply chain, formulators and others rely on ParagraphFour.com.

Starting with a reliable data set, our subscribers perform a multitude of different tasks including things as simple as tracking a molecule and analyzing the emergence of a future market to creating complex timing and life-cycle models and econometric analysis. Some even evaluate the strength of PIV cases but, importantly, they use their own experience, perceptions, and culture to evaluate risk.

Over the 15 years, we have amassed a great deal of data, reports, and statistical analysis and track all PIV activity from start-to-finish. At present, ParagraphFour.com contains data for over 800 products and 4,000 cases. We have also been tracking Inter Partes Review proceedings affecting PIV products (over 500 of them) and aBLA cases.

Over these 15 years, of course, we have seen the PIV Market change. Like any industry, the pharmaceutical business and the PIV Market within it have seen many changes and has been through several ebbs and flows.

Over the past few years, the industry -- for both brands and generics -- has been going through an ebb, hallmarked by downward price pressure. This has been brought on by a few factors, including, more ANDA's filed, more ANDA's approved, and more PIV Market entrants which has led

to consolidation and some re-thinking on how to best proceed.

Having been in this industry for close to 25 years, I know enough that whenever there is an ebb, there is a recalibration, which will lead to future flows. (And, yes, the picture below is 15 years old (but I am keeping it!)) Frankly, it is true for just about every industry, and the PIV Market is no exception: in 2018, the number of products receiving their first PIV case increased from last year and many PIV products have fewer than 4 ANDA filers, suggesting ANDA filers are adjusting their filing strategies.

Thank you to all of our subscribers. Many of you have been with us all 15 years. It can be humbling that you have the confidence in the research which some deemed 15 years ago to be impossible and has enabled me to pursue a unique career path that I truly love. Thank you

ABOUT THE EDITOR



Gregory Glass is the Editor of The Paragraph Four Report.

Mr. Glass earned an MBA from the Fuqua School of Business at Duke University. For twenty plus years, he has worked in the pharmaceutical industry in a variety of capacities

including market research, legal, managed care sales, and product strategy and has authored many papers.

He also is a graduate of Vanderbilt Law School and practiced in both state and federal courts.

more information at
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PUBLICATIONS

Parry Ashford Inc.
100 S. Ashley Drive
Suite 600
Tampa, FL 33602
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