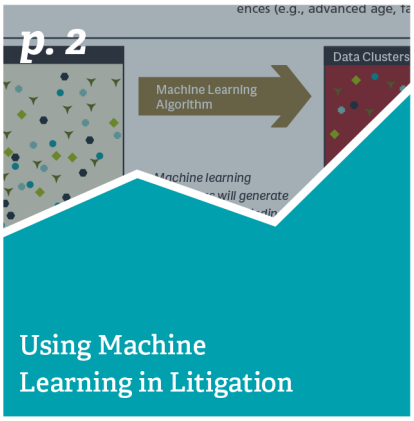
ANALYSIS GROUP ECONOMIC, FINANCIAL and STRATEGY CONSULTANTS

FORUM

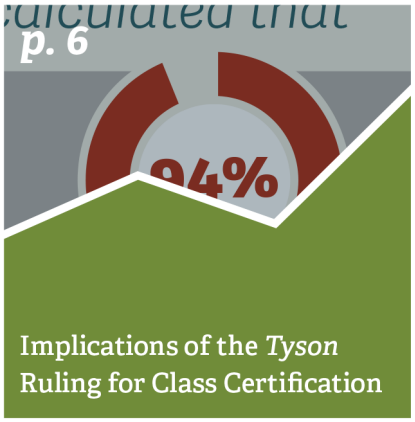
Spring 2017

A look at the events and analyses shaping our work



Using Machine Learning in Litigation

Q&A with Austan Goolsbee



Implications of the *Tyson* Ruling for Class Certification

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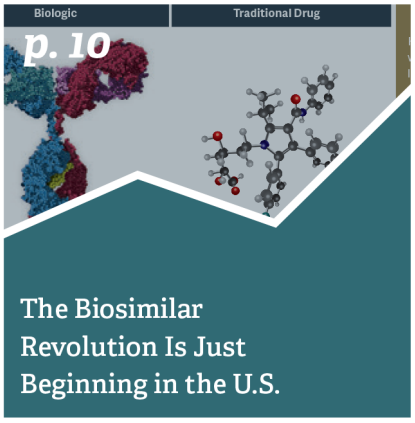
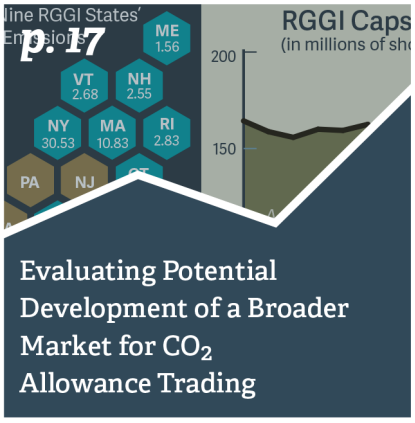


The Biosimilar Revolution Is Just Beginning in the U.S.

Affiliate Spotlight: Oliver Hart

Will Expanded EEO-1 Data Collection Yield New Insights into Discrimination?

Affiliate Roundtable: Privacy and Data Security



Evaluating Potential Development of a Broader Market for CO_2 Allowance Trading

From Our CEO

This issue of *Forum* demonstrates the broad scope and deep impact of Analysis Group's ongoing work on behalf of our clients. We continue to use leading-edge methodologies and analysis to tackle issues across virtually every sector in the landscape of economic and litigation consulting.

Our teams are exploring new applications for machine learning and big data in different types of litigation support. Exciting developments in other evolving areas include examining the bases of competition for biosimilar products introduced in the pharmaceutical market; clarifying key privacy and data security issues in the online world; analyzing the impact of new regulatory requirements in the area of labor and employment; and providing analytical insights into new frameworks for clean energy. We also strengthened our relationships with groundbreaking thinkers in the field of economics.

Our firm continues to grow – in size, geographic reach, depth of expertise, and scope of our extensive network of affiliates. We also recently modified our firm leadership. While continuing as CEO, I am now also Chairman of Analysis Group's Board of Directors. Pierre Cremieux is now President, and Bruce Stangle, formerly Chairman and Co-founder, continues as Co-founder.

We remain committed to our distinctive, collaborative culture, which provides the underpinning for the success of our firm and our clients.

MARTHA S. SAMUELSON,
CEO AND CHAIRMAN

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Using Machine Learning in Litigation

A proliferation of data is requiring analyses beyond the limits of familiar tools such as spreadsheets and statistical software.

LISA B. PINHEIRO
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ADAPTED FROM "MACHINE-LEARNING ALGORITHMS CAN HELP HEALTH CARE LITIGATION," BY LISA B. PINHEIRO, JIMMY ROYER, NICK DADSON, AND PAUL E. GREENBERG, PUBLISHED ON *LAW360.COM*, JUNE 8, 2016; AND "PRACTICAL USES FOR MACHINE LEARNING IN HEALTH CARE CASES," BY MIHRAN YENIKOMSHIAN, LISA B. PINHEIRO, JIMMY ROYER, AND PAUL E. GREENBERG, PUBLISHED ON *LAW360.COM*, SEPTEMBER 22, 2016.

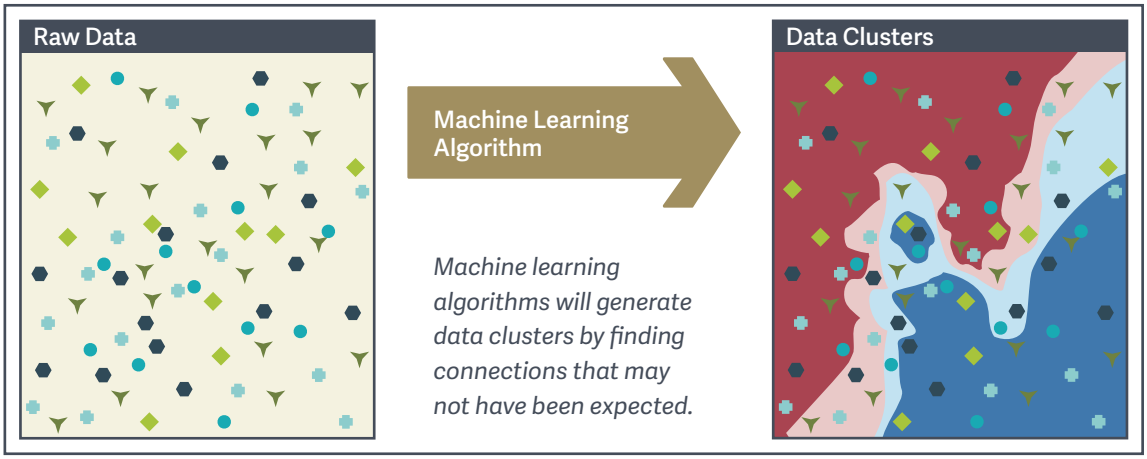
In health care, the advent of electronic medical records, the marked decline in DNA sequencing costs, and the introduction of industry reporting requirements such as the Sunshine Act have ballooned the volume of available data. In retail, advances in payment technology allow point-of-sale devices to capture millions of individual transactions, resulting in much larger data sets along with increased security risks. Indeed, in almost any business, the volume of unstructured information contained in electronic documents and communications such as email and instant messaging is now enormous. In a litigation context, this proliferation of data can be daunting.

Enter machine learning. Machine learning uses algorithms to detect complex and unforeseen relationships in high-dimensional data (i.e., where there is an abundance of different types of variables, whether involving numbers or unstructured data contained in text or visual images).

These new techniques can be harnessed to help attorneys improve legal strategies, conduct informed fact discovery, provide testifying experts with the most complete set of relevant information, and prepare analyses at a previously unseen level of granularity.

Here are a few examples of how attorneys can leverage machine learning:

Crafting a legal strategy. Machine learning can be applied during the discovery phase of litigation to quickly find relevant information in large quantities of data. Consider a dispute over alleged off-label promotion of prescription drugs. Conventional analyses might serve as a blunt instrument, grouping together all patients with a particular condition (e.g., lung cancer). Machine learning methods, on the other hand, can identify similarities among patients based on a wider and deeper range of variables or characteristics. *(See figure.)* Such clustering could reveal clinical differences (e.g.,



Machine learning algorithms will generate data clusters by finding connections that may not have been expected.

advanced age, failure of other cancer therapies, genetic markers) among groups of patients that might explain use of the drug independent of any promotion. Uncovering these types of patterns at an early stage can be beneficial to attorneys as they contemplate the theory of the case.

Accessing information in unstructured communications. Unlike conventional statistical methods, machine learning algorithms can be "taught" to recognize the importance of particular word and phrase combinations or other characteristics within documents such as published articles, patent claims, medical notes, regulatory filings, and emails. These characteristics can be associated with specified outcomes, and then used to improve predictions or support an argument.

In patent infringement cases, for example, machine learning can be used to sort through reams of filings using natural language processing capabilities to reveal features common to desired outcomes. This information can be combined with other data to approximate the patent office processes leading to final judgments. Such predictions can help the parties decide whether to negotiate a settlement or engage in costly litigation.

Mining data more efficiently to strengthen arguments. Machine learning can make use of the vast amounts of data in a company's possession to conduct more sophisticated analyses that support testimony or provide counterfactual scenarios. Information that might once have been discarded as impractical or irrelevant for expert modeling purposes can be mined for use in discovery or economic analysis.

For example, a discrimination case may be proven or refuted on the basis of unstructured data in the form of email and voicemail communications. Conventional methods can be cumbersome, taking up valuable time and staff resources to sift through physical records. With a natural language processing algorithm based on machine learning, search efficacy can be enhanced while reducing the time and effort required.

How to Employ a Machine Learning Approach

Of course, as was the case with other new technologies that have been introduced to the courtroom (e.g., fingerprints, DNA evidence), testifying experts' reliance on machine learning might invite initial skepticism. When using such a methodology, the expert will need to rigorously validate the chosen model and evaluate whether results are meaningful and sufficiently accurate (e.g., a model that accurately predicts an outcome 90 percent of the time but has a high false positive rate might not be appropriate). Testifying experts using these methods will also need to educate and convince the court of the validity of these less familiar models.

If appropriate care is taken, widespread adoption of machine learning may prove to be a significant advantage in the increasingly complex and technical world of litigation. ■

New ABA Working Group to Explore Guiding Principles for Data Science Testifiers

Analysis Group is pleased to announce the formation of a new working group within the American Bar Association (ABA) Section of Science & Technology Law's Big Data Committee, led by Vice President Mihran Yenikomshian. The ABA describes this new initiative as follows:

The Big Data Committee has created a new working group devoted to the use of data scientists as expert witnesses. Data science is a broad and actively changing "big data" topic with many ill-defined roles compounded by ever-changing standards and evolving technologies. This places this topic squarely in the purview of the Big Data Committee. Accordingly, the Big Data Committee will work to explore standards and existing efforts that will help refine and guide these experts in their roles as testifying witnesses. The Big Data Committee will also collaborate with the Expert Witness Committee of the Section of Litigation and plan a CLE webinar.

Q&A with Affiliate Austan Goolsbee

Analysis Group affiliate Austan Goolsbee recently shared his thoughts on innovation, competition, and commercial litigation. Dr. Goolsbee is the Robert P. Gwinn Professor of Economics at The University of Chicago Booth School of Business. He has held several key roles in government, including Chairman of the Council of Economic Advisers during the Obama Administration and as a member of the President's Cabinet.[1]

AUSTAN GOOLSBEE

ROBERT P. GWINN PROFESSOR OF ECONOMICS, THE UNIVERSITY OF CHICAGO BOOTH SCHOOL OF BUSINESS

There is much public debate about how we can increase growth in America – cutting taxes, eliminating regulations, focusing on science and technology, and so on. What's your opinion?

Dr. Goolsbee: I think two main worldviews are being debated among economists (and among political leaders, too) about the question of where growth and innovation come from. One view is that they come from the absence of government. If you cut taxes and get the government out of the way, we will grow. Now, for sure, you can damage an economy by over-taxing and over-regulating. For example, I once did some empirical research looking back on how taxes would have affected the spread of broadband technology in broadband's early days. This research showed how taxes could produce enough surplus that suppliers in many smaller markets would be unable to cover their fixed costs and would delay the diffusion of broadband. It also showed that the inefficiency costs from those taxes were orders of magnitude larger than in other industries.

That said, the absence-of-government proponents still have to puzzle over the fact that some of the most innovative, highest-productivity places in the country, and in fact, the world – places like Silicon Valley or Manhattan – do not have either low taxes or low regulation. In the alternative worldview, growth comes from a private sector that relies on human capital, scientific research, economic infrastructure, and a series of other things where some investment and coordinating function from government is actually quite important. I would say I lean more to this view. But the debate will probably continue for quite some time.

1 Dr. Goolsbee is also a strategic partner to 32 Advisors, where he leads their Economic Advisory practice.

What role does immigration play in innovative capacity for U.S. businesses?

Dr. Goolsbee: The current administration has focused on limiting immigration. I think it's a mistake. The data show that immigrants are much more likely to start companies, and they make up a disproportionate share of our engineering and technology talent. The share of foreign-born inventors and patent holders has risen dramatically over the last 20 years. Keeping out skilled and ambitious immigrants, coupled with cutting science funding and reducing financial aid to encourage native-born students to get more education, makes a pretty bleak triumvirate in my opinion.

The trade implications of an "America First" policy are front and center. What might be the implications for competition or intellectual property law?

Dr. Goolsbee: The antitrust laws are designed to protect competition, and ultimately that means asking whether consumers are better or worse off because of the way that competition has unfolded in a particular market, and of course that market may include foreign competitors. If enforcement actions keep the end goal in mind, I am not too worried. But if enforcement becomes politicized – that is, if the interests of particular firms are put ahead of consumers, whether foreign entities are present or not – then I worry that competition will get distorted and it's the American people who will suffer.

In terms of intellectual property, efforts have been underway for at least the past decade to further harmonize the USPTO [U.S. Patent and Trademark Office] and the U.S. Copyright Office with their foreign counterparts, or with international organizations such as WIPO [World Intellectual Property Organization]. Regardless of any border concerns, intangible assets travel easily. Our policies need to acknowledge that.

"[A]ntitrust laws are designed to protect competition... But if enforcement becomes politicized – that is, if the interests of particular firms are put ahead of consumers, whether foreign entities are present or not – then I worry that competition will get distorted and it's the American people who will suffer."

You have some experience serving as an expert in litigation matters. Can commercial litigation be good for us?

Dr. Goolsbee: That's a funny way of putting it, perhaps. For sure, it's critical to have an enforceable system of law that allows disputes to get resolved in a predictable way. I have had the chance to work on some really interesting matters – some that have had broader implications for precedent or for policy. It strikes me that the higher the stakes, the more vested the parties are in trying to get the right answer. It's an adversarial process, but that creates almost a form of peer review for the experts. Like in academia, that kind of situation forces a high standard of evidence and makes the facts essential. ■

Implications of the *Tyson* Ruling for Class Certification

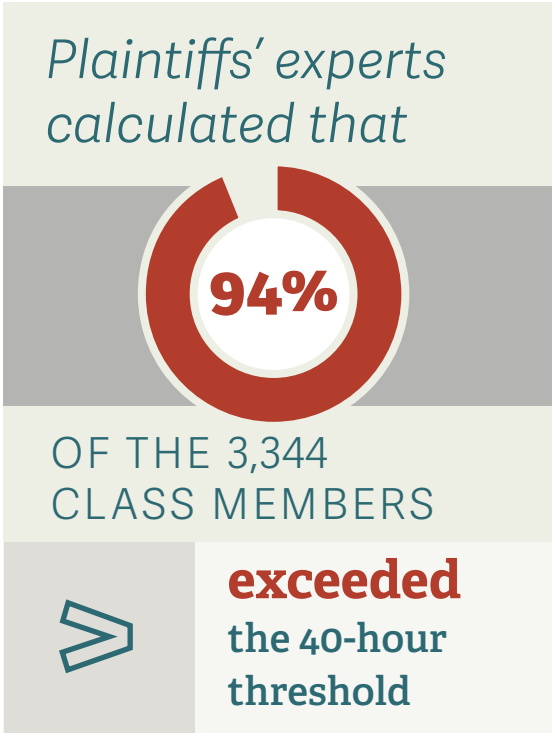
The U.S. Supreme Court's decision in *Tyson Foods Inc. v. Bouaphakeo et al.* addressed the use of statistical techniques to satisfy questions for class certification. Although its origins are in labor law, the case has broader implications for methods and evidence in class certification in antitrust matters.

AARON YEATER
MANAGING PRINCIPAL

MARK J. LEWIS
VICE PRESIDENT

ADAPTED FROM "DONNING AND DOFFING DAMAGES: TYSON TAKEAWAYS FOR ANTITRUST," BY AARON YEATER AND MARK J. LEWIS, PUBLISHED ON *LAW360.COM*, MAY 12, 2016.

The putative class comprised employees of Tyson Foods working in a pork processing plant who were required to wear protective gear while performing their jobs. The employees claimed that, even though they were hourly workers, many of them were not fully compensated for the time it took to "don and doff" the gear during their workday. The employees sought certification as a class, claiming the activity was essential to their jobs and that the time spent changing meant that they were owed overtime compensation of 1.5 times their hourly wages under the 1938 Fair Labor Standards Act (FLSA).



Tyson argued that the class should not be certified, as individual inquiry would be needed to determine what gear was necessary, how long it took each employee to change, and whether that additional time pushed the employee's total weekly work time above the 40 hours required for overtime. However, Tyson did not maintain records of the time individual employees took to don and doff the gear.

Based on a review of 744 videotaped employee observations, plaintiffs' experts calculated the average time spent donning and doffing. They then applied the average to individual timekeeping records to determine whether total work time, including time required for donning and doffing, exceeded 40 hours a week. Using this method, the experts found that, of the 3,344 class members, 212 never exceeded the 40-hour threshold. They calculated damages of $6.7 million, which could be distributed to the remaining class members. However, a jury reduced the class damages to $2.9 million.

Issues Before the Court and Findings

Tyson petitioned the Supreme Court on whether the putative class could rely on a statistical sample for determination of

class-wide liability, as opposed to individual records. The court's majority found this argument to be too broad, recognizing that sampling is often the only practical means of providing information in the absence of other data. They concluded that if one individual plaintiff could rely on evidence from a representative sample to establish under-compensation, then the class could do the same.

Tyson also questioned to what extent the court must have a method available to avoid compensating class members who were not injured. The jury's reasoning behind its decision to reduce damages was unclear – they either found the estimates of donning and doffing time by the plaintiffs' expert unreliable, or reduced those estimates to exclude some of the estimated donning and doffing time that the jury concluded did not need to be compensated (specifically around meal breaks).

In his concurring opinion, Chief Justice John Roberts opined that this uncertainty might make it difficult for the district court to avoid compensating uninjured class members, since the court would have to "reverse-engineer" the estimated uncompensated time from the lump sum awarded by the jury.

Implications

Our survey of recent class certification decisions suggests that while this case has been regularly cited, it has not yet led to a shift in class certification. Nonetheless, it is worth asking whether *Tyson* will allow future courts to tighten or weaken standards for class certification. On the one hand, *Tyson* supports the use of samples and surveys of data by putative classes to address the Rule 23 predominance standard, especially where more "complete" data may be unavailable. On the other hand, litigants may find that courts will scrutinize damages methods even more closely at the class certification stage to ensure that they provide the finders of fact with sufficient information to distinguish the injured from the uninjured. ■

Martha Samuelson Recognized as One of *Global Competition Review*'s Women in Antitrust

Martha Samuelson has been recognized as one of 10 economists on *Global Competition Review*'s (GCR's) distinguished list of Women in Antitrust 2016. The list is part of a broader GCR profile of women considered among the top private practitioners, enforcers, in-house counsel, economists, and academics in antitrust, and recognizes those who have been at the forefront of competition law and made groundbreaking contributions to the competition landscape.

Q&A with Affiliate David Dranove

Earlier this year, Analysis Group welcomed Dr. David Dranove as an Academic Affiliate to the firm.

DAVID DRANOVE

WALTER J. MCNERNEY DISTINGUISHED PROFESSOR OF HEALTH INDUSTRY MANAGEMENT; PROFESSOR OF MANAGEMENT AND STRATEGY, KELLOGG SCHOOL OF MANAGEMENT, NORTHWESTERN UNIVERSITY

Dr. Dranove, the Walter J. McNerney Professor of Health Industry Management and a professor of management and strategy at Northwestern University's Kellogg School of Management, is widely recognized for his research, especially in its application to competitive analysis in the field of health care. Dr. Dranove recently provided testimony in challenges to proposed health care mergers brought by the U.S. Federal Trade Commission and the U.S. Department of Justice. (*See sidebar.*)

What areas of research are you most known for, and what strand of research are you most proud of?

Dr. Dranove: My general areas of expertise are industrial organization and competitive strategy. Within these subfields, I'm known principally as a researcher who studies health care markets, and particularly provider markets (i.e., physicians, hospitals, etc.). I've authored or coauthored dozens of articles and books in this area. I've also written extensively about the economics of business strategy, and have authored a textbook on that topic. I am most proud of my work on provider competition. My early studies challenged the conventional wisdom that competition among providers "didn't work," and my recent work sheds more light on provider/insurer negotiations.

You've talked about "bending the cost curve" in health care. How much success have we had in bending the cost curve, what has held us back, and what are the prospects going forward?

Dr. Dranove: That's a complicated question. I teach a 10-week course on this and still don't have all the answers. Partly, the premise is wrong. Technological change is partly to blame for rising costs, but we would be unwise to sacrifice life-enhancing innovations on the altar of cost containment. That said, we don't do a particularly good job of "producing" health care services, and we often make poor choices about what services to purchase and where to purchase them from. There are too many opportunities for improvement to answer here, but I will note that big data, modern IT, and social media hold many opportunities for promoting prevention, consumerism, and improved provider incentives. We have known about the problems plaguing health care systems for

decades; we may finally have the wherewithal to do something about it.

You have testified in a number of interesting cases. How is testifying different than the academic work that you do, and what do you enjoy about testifying as an expert?

Dr. Dranove: As a business school professor, I have always been eager to have an impact on the real world. Testifying is thrilling because you get to put your own research ideas on display before an important non-academic audience. But, precisely because it is a non-academic audience, one must find a way to simplify often complex ideas without sacrificing intellectual rigor, and one must be careful when dealing with the kinds of ambiguities that are part and parcel of academic research, but which can be landmines in the courtroom. ■

RECENT TESTIMONY

Analyzing Competitive Impact in Anthem/Cigna and St. Luke's

Dr. Dranove recently served as the testifying economist in two notable regulatory matters:

Dr. Dranove testified (and was supported by an Analysis Group team) on behalf of the U.S. Department of Justice (DOJ), which sought to block the proposed merger of Anthem and Cigna, the largest announced merger in the history of the health insurance industry *(U.S. et al. v. Anthem Inc. et al.)*. Citing Dr. Dranove's testimony, Judge Amy Berman Jackson of the federal district court for the District of Columbia ruled that the proposed merger would violate federal antitrust laws, likely resulting in higher prices, decreased competition, diminished innovation, and fewer health insurance choices for consumers. The ruling was upheld by the U.S. Court of Appeals for the D.C. Circuit, and Anthem subsequently abandoned its plans to merge with Cigna. As the DOJ's primary expert witness, Dr. Dranove testified on market definition, the impact on market concentration, competitive effects including the loss of innovation, the impact on medical costs, and entry.

In *Saint Alphonsus Medical Center - Nampa et al. v. St. Luke's Health System Ltd.*, the Idaho Office of the Attorney General and the Federal Trade Commission (FTC) contested St. Luke's acquisition of Saltzer Medical Group – the largest independent, physician-owned, multispecialty group in Idaho – alleging that the acquisition would substantially lessen competition for health care services, in violation of federal and state antitrust law. Dr. Dranove testified on behalf of the FTC, and concluded that Nampa was a separate geographic market from Boise when it came to primary care, and that post-merger, the result would be a highly concentrated primary care market in Nampa. U.S. District Judge B. Lynn Winmill agreed and ordered St. Luke's to unwind the acquisition.

The Biosimilar Revolution Is Just Beginning in the U.S.

The age of biologics is upon us. These medicines are "grown" biologically, rather than manufactured chemically.

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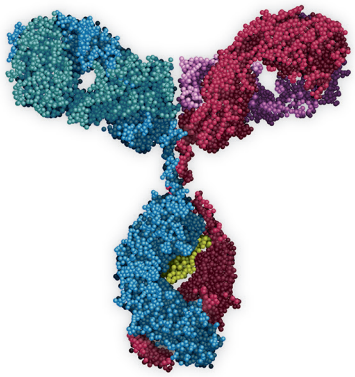
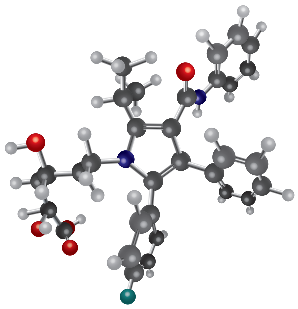
ADAPTED FROM "CAN THE LIFE SCIENCES INDUSTRY BANK ON BIOSIMILARS?" BY PAUL E. GREENBERG, TAMAR SISITSKY, AND RICHARD A. MORTIMER, PUBLISHED ON *LAW360.COM*, APRIL 13, 2016; AND "THE POTENTIAL FOR LITIGATION IN NEW ERA OF BIOSIMILARS," BY CHRISTIAN FROIS, RICHARD A. MORTIMER, AND ALAN G. WHITE, PUBLISHED ON *LAW360.COM*, SEPTEMBER 20, 2016.

Biologic	Traditional Drug
	
Herceptin (breast cancer) molecular weight = 185,000 daltons	**Lipitor (hypercholesterolemia)** molecular weight = 559 daltons

High-molecular-weight biologics like Herceptin are more complex than traditional, small-molecule chemical drugs like Lipitor. This complexity increases the costs, challenges, and risks of developing and manufacturing biosimilars.

In terms of total U.S. revenue, 7 of the top 10 drugs in 2015 were biologics, including such blockbusters as Humira, Enbrel, Rituxan, and Herceptin. Biosimilars are drugs approved by the Food and Drug Administration (FDA) upon demonstrating similarity to a branded biologic. They are akin to generic drugs, which are approved based on demonstrating equivalence to a branded small-molecule drug. While entry of biosimilars to the U.S. market is still in its infancy, their potential for widespread introduction represents one of the most significant events to impact the drug industry in decades, with many top-selling biologic drugs expected to be affected over the next few years. The impact of biosimilars on the competitive landscape is also likely to include an evolving mix of related litigation.

The Biologics Price Competition and Innovation Act (BPCIA) of 2009 paved the way for biosimilar entry, and the FDA Biosimilar Product Development Program currently includes more than 50 biosimilars, referencing more than 15 different innovative biologics. To date, five of those biosimilars have been approved:

1. Zarxio (brand reference product Neupogen) in March 2015
2. Inflectra (brand reference product Remicade) in April 2016
3. Erelzi (brand reference product Enbrel) in August 2016
4. Amjevita (brand reference product Humira) in September 2016
5. Renflexis (brand reference product Remicade) in April 2017

The global market for biologic drugs has been forecast to exceed $390 billion annually by 2020, and some analysts predict substantial cost savings after more biosimilars are approved and introduced, as was the case with the introduction of generics.

Greater Complexity and Unique Regulations Lead to Economic Challenges

Indeed, one goal of the BPCIA was to achieve substantial cost savings, resembling those realized from the widespread adoption of generics. However, the development and approval processes for biosimilars, which are large-molecule biologics, are very different from those for generics, which are small-molecule chemical drugs. One reason for the difference from generics is that biologic drugs are substantially more complex than small-molecule drugs, as they are derived from living organisms. *(See figure.)*

Such complexity has the potential to introduce more variability into the development and production of biosimilars, as compared with generics. This reality is reflected in current FDA approval requirements. For example, the FDA requires costly Phase III trials to approve a biosimilar. Once approved, manufacturers must use distinct brand-like names for their biosimilars. In addition, approved biosimilars are currently not considered "equivalent" to the originator by the FDA. Taken together, these differences can greatly increase the costs and risks associated with developing, producing, and marketing biosimilars.

In fact, these high costs are likely to limit entry to a relatively small number of competitors, in contrast to the experience with small-molecule generics. And the uptake of any approved products may well be tempered, as they are unlikely to benefit from state substitution laws and payer mechanisms that would encourage switching between the innovator and the biosimilar.

Consequently, biosimilar competition may share more features with traditional brand-brand drug competition than with brand-generic competition. Indeed, the limited experience of biosimilar entries to date reveals penetration rates that are much more modest than for generics, coupled with substantially smaller price discounts. *(See table.)*

As a result of all these factors, we expect biosimilar adoption to be more gradual than has been seen with the rapid shift to generics for many small-molecule drugs.

An Evolving Landscape

These economic considerations will figure prominently in manufacturers' decisions and damages disputes in litigation involving biosimilars and their innovator counterparts. And, litigation in this context is likely to be wide-ranging – from patent disputes and antitrust allegations that have characterized generic entry, to product safety lawsuits and allegations of improper or misleading promotion. Understanding how competition will play out as additional biosimilars are introduced to the U.S. marketplace will be key to assessing damages correctly in these cases. ■

Comparison of U.S. Biosimilar and Generic Drug Average Share of Sales and Price Discount (Six Months After Launch)

	Share of sales vs. originator	Price discount vs. originator*
Generic Drug Average	≥75%	≥40%
Zarxio (biosimilar Neupogen)	~10%	15%
Granix (quasi-biosimilar Neupogen)	5–10%	~11–23%

* Public price (e.g., WAC), not including contracted discounts/rebates

Source: Generic drug average: Berndt et al., *Health Affairs*, 26, no. 3 (2007); Grabowski et al., *Journal of Medical Economics* (2016). Zarxio and Granix: Publicly available data.

Affiliate Spotlight: Oliver Hart

Renowned economist and longtime Analysis Group Academic Affiliate Professor Oliver Hart is honored with the Nobel Prize.

Currently the Andrew E. Furer Professor of Economics at Harvard University, Professor Hart is a leading expert in contract theory, the theory of the firm, corporate finance, and corporate governance. He is affiliated with the Program on Corporate Governance at Harvard Law School's John M. Olin Center for Law, Economics, and Business, and is a past president of the American Law and Economics Association.

"[Dr. Hart's] findings on incomplete contracts have shed new light on the ownership and control of businesses and have had a vast impact on several fields of economics, as well as political science and law."

In 2016, Professor Hart received one of the most prestigious awards in the field of economics – the Sveriges Riksbank Prize in Economic Sciences in Memory of Alfred Nobel given by the Royal Swedish Academy of Sciences. He and his co-winner, Dr. Bengt Holmström, the Paul A. Samuelson Professor of Economics at the Massachusetts Institute of Technology, were honored for their contributions to contract theory.

According to the Royal Swedish Academy of Sciences, "The new theoretical tools created by [Dr.] Hart and [Dr.] Holmström are valuable to the understanding of real-life contracts and institutions, as well as potential pitfalls in contract design. … [Dr. Hart's] findings on incomplete contracts have shed new light on the ownership and control of businesses and have had a vast impact on several fields of economics, as well as political science and law."

Professor Hart's research centers on the roles that ownership structure and contractual arrangements play in the governance and boundaries of corporations. He also researches bankruptcy proceedings and bankruptcy reform, with a focus on how to mitigate wasteful conflicts of interest that can arise among different claimant groups. Professor Hart has consulted and provided expert testimony on tax disputes in which he has evaluated the business purpose and economic substance of special purpose entities. In other matters, he has provided guidance on damages and the broader economic consequences associated with breaches of contract.

Professor Hart's book, *Firms, Contracts, and Financial Structure,* is a leading reference in the field. He is a Fellow of the Econometric Society, the American Academy of Arts and Sciences, the British Academy, and the American Finance Association, and a member of the National Academy of Sciences. ■

Will Expanded EEO-1 Data Collection Yield New Insights into Discrimination?

Proposed changes to the U.S. Equal Employment Opportunity Commission (EEOC) employer information report (EEO-1) may impact employer reporting requirements for 63 million employees and substantially increase the risk of wage discrimination class actions.

SHANNON N. SEITZ
VICE PRESIDENT

LAURA O'LAUGHLIN
MANAGER

ADAPTED FROM "WILL EXPANDED EEO-1 DATA COLLECTION YIELD NEW INSIGHTS?" BY SHANNON N. SEITZ AND LAURA O'LAUGHLIN, PUBLISHED ON *LAW360.COM*, SEPTEMBER 7, 2016.

Employers with 100 or more employees already report data on race, ethnicity, and sex within 10 job categories. Under changes proposed by the EEOC and Department of Labor, in the future they will also be required to submit information on employee earnings and hours worked. The EEOC intends to use these data to try to identify significant differences in pay between employee groups within a firm or when comparing employee pay across firms, such as differences between men and women.

Even though data from an expanded EEO-1 could expose companies to litigation risk, the EEO-1, by itself, may be insufficiently informative for detecting discrimination in practice. In a simple world, if two otherwise identical groups of men and women, for example, are in the same job but paid different wages, the difference in wages would be interpreted as a measure of discrimination. In reality, many individual and firm-specific factors may account for differences in wages.

The expanded EEO-1 will not capture data on labor market experience, work interruptions, education, or other factors that may determine wages. If these are not identified and accounted for, differences in wages between groups such as men and women may be incorrectly attributed to discrimination.

Despite these omissions, observers expect that the EEO-1 will be used by employees in future equal-pay lawsuits. However, future employment class actions alleging wage discrimination should not rely exclusively on the EEO-1. Instead, the data may serve as a starting point for more in-depth investigations of alleged discrimination.

Nevertheless, employers should use the time before the changes go into effect in 2018 to thoroughly evaluate current and historical data to determine whether the EEOC is likely to identify pay disparities. Since the EEOC will also compare company pay practices to industry and/or regional peers, employers may want to compare their internal data to a subsample of the Current Population Survey, used by the U.S. Census Bureau to collect labor force statistics. ■

Affiliate Roundtable: Privacy and Data Security

The collection, storage, use, and disclosure of consumer data are hot topics in the legal, regulatory, and legislative communities.

ADAPTED FROM "PRIVACY AND CYBERSECURITY: THE CORPORATE PERSPECTIVE," A Q&A WITH RANDAL S. MILCH; "THE IMPACT OF DATA BREACHES AND HACKING," A Q&A WITH MICHAEL SIEGEL; AND "IS BIG DATA A TRUE SOURCE OF MARKET POWER?" A Q&A WITH CATHERINE E. TUCKER; ALL PUBLISHED ON ANALYSISGROUP.COM.

In addition to the types of data that may be particularly sensitive and/or targeted by hackers (e.g., credit card information, health data), many organizations collect consumer data to better understand and connect with customers (e.g., demographic information, consumer preferences). However, the collection and use of data sets the stage for unauthorized individuals to access information through cyberattacks and misuse that data to harm both the entities that legitimately collect data and their customers. In this Q&A, affiliates Randal S. Milch, Michael Siegel, and Catherine E. Tucker offer corporate and academic perspectives on data breaches, related litigation, and big data as a potential source of market power.

What are the most pressing issues on the minds of company boards and executives with respect to privacy and data security?

Professor Siegel: Based on my research, most of the questions we are getting from board members are related to what is an appropriate cybersecurity framework. Cybersecurity is a mostly non-regulated field in which there are many issues to be discussed, including risk, compliance, security, and best practices. Most organizations have made building a culture around security a major priority. Many are using the NIST [National Institute of Standards and Technology] Cybersecurity Framework as an overall guide for understanding cyber-readiness. But there is always a question of how much to spend and where to allocate resources.

Mr. Milch: Directors and management certainly recognize the risk as a general matter. In highly regulated industries, the regulators are driving investment. All studies continue to confirm that the first and most productive step to cyber health is good cyber hygiene. So investment in cybersecurity makes sense, but I suspect that there is very uneven investment currently.

How can companies minimize their exposure to the potential disclosure of sensitive data through a breach?

Professor Siegel: First and foremost, cyber-security is about people, process, and technology. The largest emphasis is on people

MICHAEL SIEGEL
Principal Research Scientist, MIT Sloan School of Management

RANDAL S. MILCH
Distinguished Fellow at the New York University School of Law Center on Law and Security

because most breaches – some say as much as 90 percent – have been aided and abetted, knowingly or unknowingly, by insiders in the organization.

Is the exposure clear?

Mr. Milch: The degree of exposure is not clear. Companies must first determine what their cyber risk is; for many organizations, the risk will be relatively small. For those with greater risk, careful planning is essential. Cyber insurance is cheaper if you have a good post-breach plan; in fact, some insurance rates depend more on post-breach planning than prevention abilities. Determining exposure in an actual or potential privacy or data breach matter is a key step that will inform potential settlements and spending on litigation. Also critical is thinking through how the firm can maintain, provide, and analyze information that would be responsive to subpoenas or discovery requests.

How is the world of big data affecting data breach class action lawsuits?

Professor Tucker: The explosion of digital data has been matched by an increase in related litigation, including data breaches, alleged privacy intrusions, and many other things that can happen when companies collect detailed data about an individual customer. However, what I think is interesting is that parallel to this increase is the opportunity to get more information about how the consequences of these different data breaches or privacy issues vary so much across individuals. For example, in my research I have shown that while many users of social networking sites can respond negatively to intrusive use of their data in advertising, there is a subset of users who appreciate the personalization of their advertising and respond positively to it. In addition, it is not clear that the effects of a privacy intrusion or a data breach are going to be constant across time or instance. My research indicates that people's privacy preferences evolve over time, and change considerably between the ages of 18 and 30. We have also observed that, although people can be protective of their data, for a small financial incentive they are willing to behave differently. All of these inconsistencies and idiosyncrasies are important when thinking through the implications of class certification cases related to data breaches and privacy.

Can big data be a source of market power?

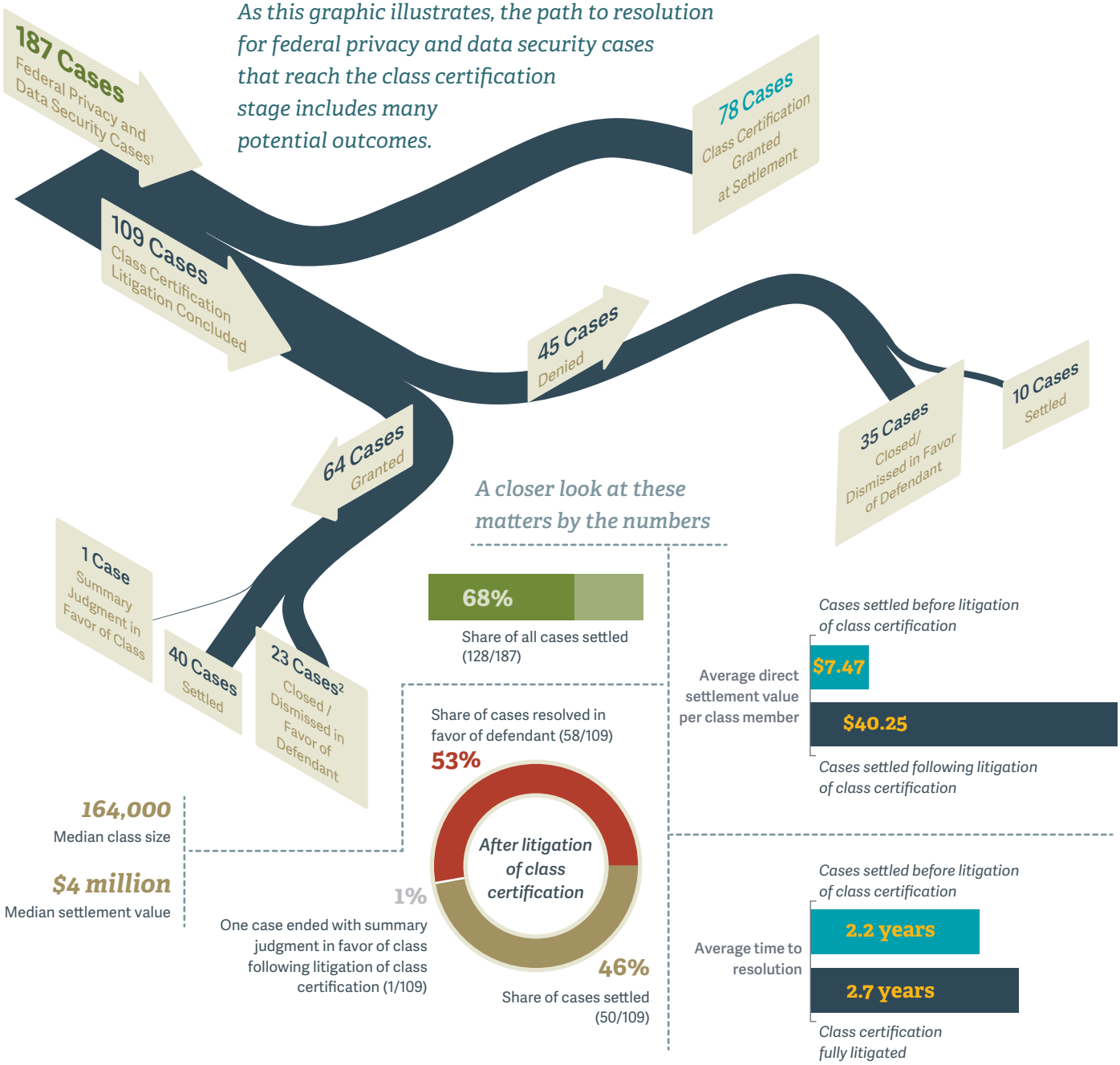
Professor Tucker: Although policymakers often make this argument, this contrasts with standard strategic managerial models of what can confer market power. We analyzed whether or not big data meets the four traditional criteria for being a barrier to entry or a source of sustainable competitive advantage (inimitability, rarity, value, and non-substitutability). At least at the moment, the kind of big data that most digital firms have access to doesn't make the cut. Big data's advantages are relatively easily to mimic, and by itself big data is often not that valuable. Instead, competitive advantage stems from having the right personnel with the right training to make sense of the swaths of data. ■

CATHERINE E. TUCKER
Sloan Distinguished Professor of Management; Professor of Marketing, MIT Sloan School of Management

To read the full Q&As on Privacy and Data Security with Mr. Milch, Professor Siegel, and Professor Tucker, visit www.analysisgroup.com/privacy

Resolution of Federal Privacy & Data Security Cases: 1999–2016

As this graphic illustrates, the path to resolution for federal privacy and data security cases that reach the class certification stage includes many potential outcomes.



For more information about this research, contact Managing Principal Aaron Yeater or Principal David Sosa.

Notes

1 Excludes pending cases and cases that were closed or dismissed before the conclusion of class certification litigation.

2 Of these, 12 were dismissed following a motion to dismiss, 10 had a summary judgment or a jury verdict in favor of the defendant, and one was closed administratively.

Sources

Cases in which court decisions granted or denied class certification were identified from the LexisNexis U.S. Federal and State Cases database. Cases in which class certification was granted at settlement were identified from the Lexis Jury Verdicts & Settlements database. Additional research was conducted via *Law360* and *Bloomberg Law*. Includes cases filed between January 1, 1999, and December 31, 2016.

Evaluating Potential Development of a Broader Market for CO_2 Allowance Trading

Around the U.S., states are considering or developing policies, on their own or in cooperation with neighboring states, to control carbon dioxide (CO_2) pollution from power plants, which is a major source of greenhouse gas emissions.

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Since 2009, nine northeastern states (Connecticut, Delaware, Maine, Maryland, Massachusetts, New Hampshire, New York, Rhode Island, and Vermont)[1] have cooperated voluntarily to participate in the Regional Greenhouse Gas Initiative (RGGI). This is the first multi-state carbon-trading program formed in the country to limit CO_2 emissions. Through a mass-based approach to program design, RGGI has exceeded its original goals for reducing the region's release of CO_2 into the atmosphere by millions of tons. *(See figure.)* The lessons learned from the RGGI program's successes and challenges may be useful for other states seeking to make similar gains.

Over the years, teams from Analysis Group (including Senior Advisor Susan F. Tierney, Principal Paul J. Hibbard, Vice President Andrea Okie, Manager Pavel Darling, and Senior Analyst Ellery Berk) have conducted extensive research on programs and policies for controlling greenhouse gas emissions from the power sector. Analysis Group's 2016 report – the third in a series of RGGI studies, and authored by Dr. Tierney, Mr. Hibbard, and Ms. Berk – is titled *RGGI and CO_2 Emissions Trading Under the Clean Power Plan: Options for Trading Among Generating Units in RGGI and Other States.*

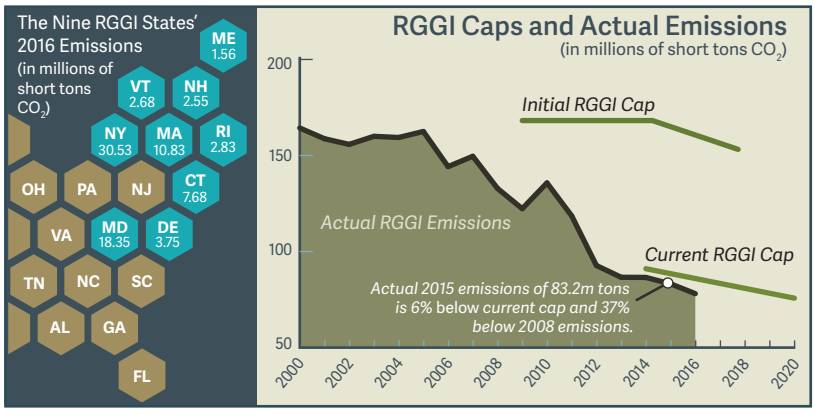
The Analysis Group report examines RGGI's potential for participating in an expanded market for CO_2 emission allowance trading, as well as whether and how RGGI's guidelines could be revised to ensure compliance with the Clean Power Plan, the regulatory framework adopted by the U.S. Environmental Protection Agency in 2015. Pointing to RGGI's successes in designing and operating a liquid, efficient market for trading emissions allowances for the past seven years, the report explains how lessons from this experience are relevant for other states exploring ways to meet their own compliance obligations or state goals for reducing CO_2 emissions.

Specifically, the report emphasizes the many features of the RGGI program design that produce long-run efficiencies and cost savings for states, including allowing power plants to participate in a broad, regional allowance-trading market, and enabling states to determine the manner in which CO_2 allowances enter the market, such as by auction with proceeds available for use for a variety of public purposes and policy goals.

Analysis Group's report on the feasibility and economic impact of these markets could provide a starting point for expanding efforts to address CO_2 emissions into new regions in the coming years. ■

1 New Jersey was part of the original group forming RGGI, but left the program in 2011.

SOURCES: acadiacenter.org, *Regional Greenhouse Gas Initiative Status Report: Part I: Measuring Success*, July 2016; rggi-coats.org/eats/rggi/



Recent Litigation

Below is a representative sampling of the complex matters in which Analysis Group has recently worked with top law firms, Fortune 500 companies, health care organizations, and government agencies worldwide.

Uruguay Prevails in Cigarette Packaging Arbitration Dispute with Philip Morris International

A World Bank tribunal rejected Philip Morris's challenge to Uruguay's cigarette packaging regulations, ruling that the regulations were reasonable exercises of the country's sovereign right to protect public health. In this landmark case, the value of Philip Morris's intangible assets was at issue under a bilateral investment treaty between the Government of Uruguay and the Government of Switzerland. Arbitration was conducted under the International Centre for Settlement of Investment Disputes (ICSID). With assistance from Vice President Federico Temerlin and Manager Mark Berberian, Managing Principal Jeffrey Cohen testified about valuation and economic damages, and submitted two expert reports on behalf of Uruguay. As part of its ruling, the arbitration panel also rejected Philip Morris's claim that its investment in Uruguay had been expropriated, and ordered Philip Morris to pay Uruguay's arbitration costs and fees.

Daiichi Sankyo Awarded over $500 Million in Arbitration

A Singapore International Arbitration Centre panel awarded Daiichi Sankyo, a Japanese pharmaceutical firm, the rupee-denominated equivalent of approximately US$525 million in connection with an arbitration related to Daiichi Sankyo's 2008 investment in Indian generic pharmaceutical firm Ranbaxy. The damages award, which includes attorneys' fees and expenses, pre-award interest, and reimbursement of arbitration costs, relates to the former owners of Ranbaxy fraudulently concealing and misrepresenting U.S. Food and Drug Administration and Department of Justice investigations into Ranbaxy at the time of Daiichi Sankyo's investment. An Analysis Group team led by Managing Principal Richard Starfield and including CEO and Chairman Martha Samuelson, Managing Principal Crystal Pike, and Vice President Ted Davis, supported academic affiliate Dr. Ray Ball of The University of Chicago Booth School of Business in assessing economic damages to Daiichi Sankyo stemming from the fraudulent concealment.

For more examples of Analysis Group's recent casework, visit our website:

www.analysisgroup.com/insights/

ITC Invalidates Trademark in Victory for Analysis Group Client New Balance

In a victory for a broad group of apparel companies, including Analysis Group client New Balance, the U.S. International Trade Commission (ITC) invalidated one of the trademarks for Converse's Chuck Taylor All Stars shoe, ruling that not all parts of the sneaker are protected by trademark. Analysis Group affiliate Peter Golder, Professor of Marketing at the Tuck School of Business at Dartmouth College, was retained as a marketing expert by New Balance. Supported by an Analysis Group team led by Managing Principal Aaron Yeater, Professor Golder analyzed the marketing efforts by Converse to assess whether those efforts indicated that the at-issue design elements were "source identifying" as required under U.S. trademark law. Professor Golder offered two expert reports and testified in an ITC hearing. In an effort to protect the trademarked designs for its Chuck Taylors, Converse had sought to block importation of certain products. An exclusion order from the ITC would have enabled Converse to pursue broad relief against products it alleged violated its trademark designs. The scope of such a potential ruling had concerned many apparel companies, including New Balance, which argued that the trademarks were too broad and would encompass both unbranded products imported from overseas and well-known brands with a long history of offering sneakers with similar at-issue design elements.

Class Certification Denied in Favor of Analysis Group Client CBSI

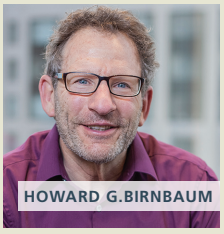
In the matter of *Lightbourne v. CBS Interactive, et al.*, a judge in the U.S. District Court for the Central District of California denied class certification in a case brought by student-athletes against CBS Interactive Inc. (CBSI) and other defendants. The plaintiff alleged that CBSI had used student-athletes' names, images, and likenesses without their consent; asked the court to certify a nationwide class of current and former student-athletes; and sought statutory damages under California's right of publicity statute. CBSI retained Analysis Group affiliate Catherine E. Tucker, the Sloan Distinguished Professor of Management and Professor of Marketing at the MIT Sloan School of Management. Professor Tucker, supported by an Analysis Group team led by Managing Principal Aaron Yeater and including CEO and Chairman Martha Samuelson and Vice President Emily Cotton, provided expert analysis that demonstrated several dimensions on which the proposed class would not meet the requirements for class certification. Professor Tucker also analyzed whether members of the proposed class were injured by the conduct, and whether class-wide inquiry could demonstrate injury and damages. Judge Josephine L. Staton denied certification in its entirety, concluding that class certification was improper in part because CBSI had shown that "[t]his case presents a slew of individual questions and affirmative defenses that would need to be litigated for each image and student-athlete" that "clearly predominate over the common issues present in this action."

Bausch + Lomb, Senju Prevail in PTAB Ruling

The U.S. Patent and Trademark Office's Patent Trial and Appeal Board (PTAB) ruled that patents held by Analysis Group clients Bausch + Lomb, Inc., and Senju Pharmaceutical Co., Ltd., were valid. Three generic drugmakers had challenged the validity of patents on the drug Prolensa, a non-steroidal anti-inflammatory drug used to treat inflammation and pain associated with cataract surgery, on obviousness grounds. Patent owners have had particular difficulty demonstrating commercial success, which requires an assessment of the marketplace success of the patent-practicing product and a showing of a sufficient causal nexus between the marketplace success of the patented product and the claimed advantages of the patent. Managing Principal John Jarosz and Manager F. Michael Nolan led an Analysis Group team that examined issues related to the absolute and relative marketplace success of Prolensa on behalf of Bausch + Lomb and Senju, as well as the connection between that success and the claims of the two challenged patents. The PTAB ruling credited Mr. Jarosz's expert testimony and analysis, finding that Prolensa has enjoyed substantial commercial success and that petitioners had not shown that the patents were invalid as obvious. ■

NEW BOOK EDITED BY ANALYSIS GROUP

Decision Making in a World of Comparative Effectiveness Research


HOWARD G.BIRNBAUM

PAUL E.GREENBERG

Five years ago, Analysis Group edited a special issue of the journal *PharmacoEconomics* that focused on comparative effectiveness research (CER), which at the time was a relatively new area in health outcomes research. The issue focused on the emerging approaches for using observational data in real-world settings to yield new insights. Since then, the proliferation of CER research has considered the effectiveness of comparative evidence from many data sources, including electronic medical records, administrative claims, patient surveys, and clinical trials. Accordingly, the focus of CER work has shifted to the practitioners who are tasked with making critical decisions based on this evidence.

Decision Making in a World of Comparative Effectiveness Research, a new book edited by Howard G. Birnbaum and Paul E. Greenberg, is a guide for real-world CER analysis and interpretation for use by decision makers. The chapters are authored by senior industry executives, key opinion leaders, accomplished researchers, and leading life sciences attorneys. The book is intended for decision makers who wish to make the best use of CER in today's landscape of big data and enhanced methodology. Published in May 2017, the book also features a number of other Analysis Group coauthors, including Nick Dadson, Christian Frois, Patrick Lefebvre, Genia Long, Cinzia Metallo, Dave Nellesen, Crystal Pike, Lisa Pinheiro, Jimmy Royer, James Signorovitch, Sean Tiggelaar, Francis Vekeman, and Jipan Xie. ■

Highlights from Our Pro Bono Work

Analysis Group regularly provides pro bono economics consulting to a variety of nonprofit organizations.

Our pro bono efforts encompass diverse matters in social innovation, legal assistance, health care, and other areas. We work with nonprofit, governmental, and private organizations, both domestically and in other countries, that are targeting traditionally underserved locales and populations. Our pro bono efforts are driven by our people, at all levels of the firm, who take the initiative to pursue socially beneficial work for organizations that may not be able to commit the level of resources needed on their own. Our recent pro bono projects include the following:

- Assisting Harvard Medical School faculty by applying machine learning techniques to the tuberculosis genome to predict drug resistance. The ultimate goal of this project is to allow clinicians to provide individualized treatment tailored to each patient's specific condition.

- Continuing a long-term partnership with GHESKIO (Haitian Group for the Study for Kaposi's Sarcoma and Opportunistic Infections) on a range of issues associated with HIV and TB treatment in urban slums in Haiti. Our work includes analytical support to develop best practices, participation in research published in leading medical journals such as the *Journal of Acquired Immune Deficiency Syndrome* and *PLOS ONE*, and research supported by grants from the U.S. National Institute of Health. Topics we have studied include evaluating the most cost-effective approach to HIV treatment, using behavioral economics to improve retention in care and outcomes, documenting the impact of sexual assault on victims, and analyzing statistical methods used to measure mortality from HIV.

- Helping the Massachusetts Housing and Shelter Alliance (MHSA) determine the cost savings resulting from moving homeless individuals with high utilization of emergency services into permanent housing. We also worked with MHSA on a successful grant application to study the health impacts of social services.

- Teaming with Partners in Health to conduct studies of two hospitals' construction and operation in Haiti and Rwanda, respectively, detailing economic impacts on the local economies.

- Working with Massachusetts General Hospital and Harvard University to quantify the parental out-of-pocket medical costs associated with raising a child with Down syndrome. The resulting research was published in the *American Journal of Medical Genetics*, and was reported on by WCVB News and the Fox 25 news station in Boston.

- Collaborating with the Massachusetts Alliance for Complex Care (MACC) to evaluate a program to provide a higher level of care for children born with complex medical needs (e.g., autism, epilepsy, muscular dystrophy). The Analysis Group team is analyzing patient data to assist the clinical team in developing real-time clinical improvements, identifying changes in quality of life and health care satisfaction, and examining the cost-effectiveness of this prospective study. ■

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MIT Sloan School of Management

For a list of our academic affiliates and experts, visit our website.
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Analysis Group is one of the largest private economics consulting firms, with approximately 750 professionals across 13 offices in North America, Europe, and Asia. Since 1981, we have provided expertise in economics, finance, health care analytics, and strategy to top law firms, Fortune Global 500 companies, and government agencies worldwide. Our internal experts, together with our network of affiliated experts from academia, industry, and government, offer our clients exceptional breadth and depth of expertise.

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